
by

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A thesis submitted in conformity with the requirements for the degree of SJD
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University of Toronto

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2012

Abstract

In 2000, Jordan signed the Agreement on Trade-related Aspects of Intellectual Property Rights (the TRIPS Agreement) and a free trade agreement with the US (USJFTA). Both commitments have required Jordan to comply with various obligations, including full compliance with the minimum standards for the protection of intellectual property rights (IPRs) under the TRIPS Agreement and TRIPS-Plus IP standards set out under the terms of the USJFTA. Enticed by views that strong IP protection would create prosperity in the Kingdom by promoting technological innovation and inducing transfer and dissemination of technology to Jordanians, Jordan implemented the provisions of TRIPS and the USJFTA to the letter. However, Jordan focused little attention on important “TRIPS flexibilities”. In particular, Jordan has qualified parallel importation and limited the grounds of compulsory licenses. In addition, Jordan provides pharmaceutical testing data with data exclusivity.

This thesis focuses on the Jordanian experience in the pharmaceutical sector. It argues that strong patent protection has not been conducive to the promotion of technological innovation and the transfer and dissemination of technology. Moreover, this protection has resulted in adverse outcomes such as increased drug prices,
unavailability of essential medicines in some public hospitals for serious diseases, and a
dwindling local pharmaceutical industry, in part, as a consequence of its inability to
access advanced, patented technology on reasonable commercial terms.

The thesis also investigates the legitimacy of establishing certain grounds of
compulsory licensing by Jordan, even in light of the TRIPS-Plus obligations under the
USJFTA. It advocates that such grounds contribute to the promotion of technical
innovation, lead to the transfer of advanced technology, and above all improve access to
affordable medicines. Finally, the thesis explores Jordan’s obligations to protect
pharmaceutical testing data under TRIPS and USFTA arguing that neither of these two
instruments requires data exclusivity as claimed by Pharmaceutical Research and
Manufacturers of America (PhRMA) and some developed countries.
DEDICATION

Dedicated with love and respect

to my parents, Fatima and Abdel kareem Abuelghanam

and


Rest in peace.
ACKNOWLEDGMENT

I am indebted to many people for their support and involvement through the process of writing my doctoral dissertation. I would like to thank my first and best distinguished teachers: my parents, Fatima and Abdel kareem Abuelghanam. Thank you for raising me to become what I am, thank you for your flowing unconditional love, thank you for your relentless and exhaustless support and for believing that I could do it. A big thank you to my beloved entire family: brothers – alive and deceased, sisters, nieces, and nephews. I am especially in gratitude to my brother Prof. Khaled Abuelghanam (1960-1999) who was a great example and aspiration to me. Khaled I did it, and I promise you I will continue working relentlessly to make your dreams come true. I pray you rest in peace. To my sister Fatima, thank you for all the prayers and to my sister-in law, Debbie, thank you for everything, not least of all your editorial support.

I am grateful to a dream team of scholars who guided my research and writing process from the very beginning; I have been blessed since the very start. To my supervisor, Ariel Katz, thank you so much for investing your time and energy in me. You were always there when I needed you. Thank you for your patience in going through my arguments with me, often for hours. Thank you for encouraging me always. I am so grateful to Michael Trebilcock for his efforts well beyond the call of duty. Thank you very much for all the insightful discussions, great ideas, direction, and guidance. Without all of your support, care, persistence, supervision, and splendid revisions, I would never have been able to complete my dissertation and earn my doctorate. You have demonstrated confidence in me in my ups and downs; I am indebted for you as long as I live. I also want to thank Jillian kohler for her valuable contributions.

I sincerely thank several faculty of the Law School for their help, support, and encouragement. I am especially thankful to Trudo Lemmens for his support, insightful conversations, and for introducing me to the Canadian Institutes for Health Research Health Law, Ethics, and Policy Program. I also extend my thanks to Colleen Flood for her continuous encouragement and confidence. Big thank you goes to Mariana Mota
Prado, Mohammed Fadel, Jutta Brunnée, David Dyzenhaus, David Schneiderman, and Benjamin Alarie.

I could not embark on this project without the financial support I received from the University of Jordan. I am also thankful and grateful to the Graduate Program at the Faculty of Law and the Canadian Institutes for Health Research Health Law, Ethics, and Policy Program for their very generous financial support without which I would never have been able to complete my dissertation. Julia Hall and Melissa Casco, without you this entire journey and the past three years would have been considerably much more difficult; you both are credits to the programs you work for. Your generous, prompt, and genuine assistance along the way has been splendid and breathtaking, above and far beyond the call of duty and truly appreciated.

Last, though certainly not least, I would like to recognize the assistance and contributions I received from many friends and colleagues who have been invaluable resources, readers, and partners in countless stimulating discussions. I single out Amar Bhatia, Patricia Ferreira, Emily Satterthwaite, Gail Henderson, Howard Kislowicz, Richard Arthur Haigh, Ubaka Ogbogu, Cathleen Powell, Zoe Sinel, Ahmed Saleh, Rommel Salvador, Kimberley Petrie, Umut Özsu, Michael Fakhri, and Mohannad Al-Durgham. From Jordan, I am grateful to the honorable Senator Prof. Khaled Al-karaki (former chief of the Royal Court, past President of the University of Jordan, and minister for several times). I extend my gratitude to the following distinguished people from the University of Jordan: Professor Adel Tweissi, President, vice-president Prof. Basheer Al-Zoubi, vice-president Prof. Dia-Eddin Arafà, Professor Ghazi Abu-Orabi: Dean of the Faculty of Law, His Excellency Minister of Legal Affairs Dr. Ibrahim Al-Jazy, His Excellency Commissioner Dr. Fayyad Qudah, former Dean Prof. Kamel El-Said, Dr. Khaldoun Said Qtaishat, Dr. Basem Melhem, Dr. Nofan Ajarmeh, Maisa Amairha, Amal El-Degs, and Enas Dababneh.

Finally -

ان الحمد والنعمة لك والملك لا شريك لك -

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Thesis Introduction

In April 2000, Jordan became the 136th member of the World Trade Organization (WTO), following an accession process which required it to comply with various obligations. Among those obligations was full compliance with the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS, or the Agreement), which sets minimum standards for the protection of intellectual property rights (IPRs). Six months later, Jordan signed a free trade agreement with the US (USJFTA), which obliged it to adopt intellectual property (IP) standards that go beyond those of TRIPS. Believing that becoming a member of the WTO and a party to an FTA with the U.S. would lead the Kingdom to greater prosperity, Jordan implemented the provisions of TRIPS and the FTA to the letter. For example, it allowed patents for pharmaceutical products (not only for the processes of manufacturing them), extended the term of patent protection from 16 to 20 years, restricted the grounds of compulsory licenses, and, for the first time, granted market exclusivity for drug companies that register new drugs with the Jordan Food and Drug Administration (JFDA). At the same time, lured by the prospect of opening new markets for its exports, and enticed by protectionists’ propaganda that the strongest protection of IP rights will promote technological innovation and increase the transfer and dissemination of technology to Jordanians, Jordan gave very little attention to the so-called “TRIPS flexibilities”: that is, the availability and scope of certain legal and policy measures as to substantive standards of protection and mechanisms of enforcement of IPRs and their implementation in Jordanian law.

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In this thesis, I focus on the Jordanian experience in the pharmaceutical sector and argue that the implementation and enforcement of strong patent protection, including limitations on the utilization of available flexibilities, have not been conducive to the promotion of technological innovation and to the transfer and dissemination of technology. Moreover, implementing TRIPS and the FTA resulted in serious adverse outcomes, such as increasing drug prices, unavailability in some public hospitals of essential medicines for serious diseases – for example, Cancer, Diabetes and cardiovascular-related health complications - and a dwindling local pharmaceutical industry that is unable to access advanced, patented technology on reasonable commercial terms. As such, this thesis could be read as yet another indictment of globalization, or criticizing its current form. However, I hope to make the case that despite many of its flaws, TRIPS provides the necessary legal means and policy tools for

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mitigating some of the harmful social and economic implications arising from its implementation. Moreover, I will show that most of these measures are available for Jordan despite the additional limitations imposed by the USJFTA. In short, I argue that the TRIPS Agreement should be taken seriously. While Jordan undoubtedly has taken its obligations seriously, it is time for it to assert its flexibilities as least as vigorously to ensure that the Agreement’s promise to promote technological innovation and technology transfer and dissemination will be fulfilled.

**Thesis Structure**

In order to develop the argument advanced by this thesis, I proceed in four chapters with the following common themes running throughout: obligations under the TRIPS Agreement, the implications of these obligations for access to medicine in developing countries and other socioeconomic costs, the availability of policy safeguards and their legitimate use under the international and bilateral rules to address these implications, and the implementation and enforcement of the obligations in, and the utilization of the various safeguards by, Jordan.

The thesis opens with Chapter One, “Grafting” Intellectual Property onto Trade and the Evolution of Pharmaceutical Patents in Developing Countries: Ongoing Debates”. This chapter provides a historical account of how pharmaceutical patents have evolved over time. The Chapter emphasizes how shifting the locus of debates on the international regulation of IPRs from the World Intellectual Property Organization (WIPO) to the General Agreement on Tariffs and Trade (GATT), and subsequently, to the WTO was influenced by developed countries’ demands to extend pharmaceutical patent protection to developing countries as well as for the goal of limiting utilization of measures such as compulsory licenses. The Chapter reviews the ongoing debates between developed and developing countries whether enforcing the TRIPS-mandated standards of patent protection will reliably result in increased investment in R&D activities, innovation, and inflows of technology and foreign direct investment (FDI) in pharmaceutical sectors of developing countries. It also highlights the safeguards available to WTO members that seek to mitigate the anticipated negative effects of implementing strong patent rights. Furthermore, the chapter identifies the relevant safeguards
(compulsory licenses, parallel importation, and protection of pharmaceutical test data) and then reviews the different arguments about the availability, scope, extent of, and/or limits on their utilization by developing countries. It also reviews the implications for the above of: The Doha Declaration on TRIPS and Public Health (the Declaration), the 2003 Decision of the WTO General Council, and the Decision of December 6, 2005 to amend the Agreement.

Chapter Two, “Extending Patent Protection to Pharmaceuticals in Jordan: Costs or A Potential Significance for Development?” investigates whether Jordan stands to gain from extending patent protection to pharmaceutical products. I show that eleven years of implementing and enforcing strong patent rights has neither led to more investment in R&D activities and innovation by the local pharmaceutical sector nor to meaningful technology transfer. I further argue that this is not an unexpected result: for a local pharmaceutical sector to respond to the incentives provided by patent protection, the state of development of local innovative capabilities matters. To measure such capabilities, the chapter draws upon the concept of the National Innovation System (NIS) developed in the industrial management literature, and shows that in light of the state of the Jordanian NIS (as well as other reasons), strong patent protection in Jordan is unlikely to lead to an increase in local innovation or technology transfer. I will show that while some of these reasons are peculiar to the Jordanian context, others are intrinsic to the institution of patents.

In this chapter I demonstrate that the local technical capabilities and financial capacities of the various elements of the Jordanian NIS, private and public, to undertake innovative R&D activities are modest and limited. These shortcomings are aggravated by a lack of cooperation, coordination, and integration between private firms, on the one hand, and public research institutions, centers, and universities, on the other hand. As to the patent institution itself, the chapter explores whether it has been theoretically, empirically, or historically established that strong patent protection is a prerequisite (or not) for promoting innovation and encouraging technology transfer and Foreign Direct

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6 NIS refers to a framework embracing the following primary elements: the structure and capabilities of companies in an industry, the related scientific and technological infrastructure in a country, and the establishment of a coherent and supportive government policy for the industry concerned, that determines the capacity of the country concerned in building and attracting advanced and knowledge-intensive technology.
Investment (FDI). In particular, I investigate the effectiveness, in the context of Jordan, of particular three mediums of technology transfer: data and information contained in patent documents, licenses, and FDI.

Chapter Two concludes that the regime of strong patent protection has failed, at least thus far, in fulfilling the promised dynamic socioeconomic benefits (increased R&D, innovation, and technology transfer). These benefits are supposed to constitute the *win* expression of an “equation” where potential consequences to consumer welfare, in the form of considerable static costs associated with reforming the regime, represent the other side of the equation. These costs are extensively discussed in the literature and may include all or many of the following. First, prices of patented medicines have increased. Second, higher royalty rates for licensing-in necessary technology are likely to be experienced. Third, costs of replacing or adapting infrastructure installed to undertake imitation activities will be considerable. And, fourth, administrative costs sustained in order to implement and enforce the new regime are substantial. Although significant, these socioeconomic costs may be mitigated by utilization of safeguards available under the TRIPS Agreement. Such safeguards are especially designed to address the above implications. But, unfortunately, wherever developing countries have implemented or invoked these safeguards, developed countries have challenged their right do so.

Chapter Three, “From TRIPS to the USJFTA, Limiting the Limited: Eroding Flexibilities and Misinformed Implementation in Jordan” establishes the availability and legitimacy of compulsory licensing as a valid measure under the TRIPS Agreement and the USJFTA that can mitigate some of the anticipated socioeconomic costs associated with patent protection. In addition to the grounds for granting a compulsory license specifically mentioned by the TRIPS Agreement, the chapter discusses the availability of other grounds, such as non-working of patented inventions, unavailability of a medicine on reasonable prices and quantities, and outright refusal to license (refusal to deal) and a general “public interest” ground.

Although compulsory licensing and parallel importation may lead to the production and/or importation of more affordable medicines, access to medicines may be

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7 These grounds are: public non-commercial use, national emergency or other circumstances of extreme urgency, and to remedy practices determined to be anti-competitive.
frustrated by an uninformed implementation of the obligation to protect pharmaceutical test data against unfair commercial use required under Article 39.3 of the TRIPS Agreement. Jordan decided to implement this requirement by affording originators an exclusive proprietary right in the use of their data: Data Exclusivity. Chapter Four, “Pharmaceutical Regulatory Data Protection between TRIPS and USJFTA: Any Sense in Jordan’s Implementation?” analyzes the obligations under Article 39.3. In this chapter, I challenge the view that Article 39.3 mandates data exclusivity. Based on textual analysis in accordance with the rules on treaty interpretation, and based on the history of the Article’s negotiation, I conclude that Jordan is only under an obligation to protect testing data against unfair commercial use; this obligation does not entail data exclusivity. I further argue that, even if the TRIPS Agreement mandates data exclusivity, it does not require the breadth of the regime that Jordan has adopted. More specifically, I show that the obligations under the TRIPS Agreement apply only if the data in question satisfy the following requirements. First, the data must relate to a product containing a chemical entity that is novel (new). Second, the data must be required by the regulatory agency and must lead to the authorization of the product for the marketing approval of which the data were submitted. Third, the data must be confidential and kept secret. And, fourth, the data must require a considerable effort to generate.

Finally, in the specific case of Jordan, the chapter investigates the obligations to protect test data under the USJFTA. This agreement contains obligations beyond the forgoing mentioned requirements under the TRIPS Agreement: require the protection of data related to new uses of old chemical entities and data submitted to health authorities of third countries. Although these obligations may entail serious implications of the kinds mentioned earlier for public health in Jordan, I argue that they do not transform the more benign obligation to protect test data against unfair commercial use into an obligation of the strictest sort - data exclusivity.

**Methodology**

Developed and developing countries disagree on many issues related to the obligations to implement and enforce strong IPRs under the TRIPS Agreement in the field of pharmaceuticals. The disagreements particularly relate to the following: the
outcome and effects of the obligation to make patents available for pharmaceutical inventions, the obligation to protect pharmaceutical test data against unfair commercial use, and the right of developing countries to adopt and invoke certain legal measures that they consider effective in mitigating the negative effects, particularly to public health, which stem from enforcing patent rights therein. One the one hand, developing countries have questioned the causal relationship between strong IPRs and increased technological innovation in and technology transfer to their pharmaceutical sector. They argue that such protection might indeed slow the process of their development. Therefore, they advocate their right to invoke measures such as compulsory licenses on various grounds. On the other hand, developed countries maintain that adopting such measures under certain circumstances such as non-working, refusal to deal, and high drug prices, is either illegal (under the TRIPS Agreement and with regard to Jordan, under the USJFTA as well) or ineffective. This thesis provides a legal analysis of the merits of these two positions by investigating them in the context of Jordan as a case study.

Case study is a research mechanism that focuses on a specific case (an individual, an organization, a community, or a country) in contrast to a research methodology based primarily on collecting and analyzing data from a large set of cases. The case study methodology often involves the use of various methods to explore a question within the context of the case. In this study, I will draw on the analyses, results, conclusions, and recommendations of qualitative and quantitative research, studies, and reports developed in particular non-juridical social sciences such as Industrial management, Economics (including Political Economy), and Public Policy. Reference to these fields is necessary to evaluate the potency of strong patent protection in delivering its claimed benefits, the likely socioeconomic costs of such protection, and the viability and effectiveness of certain policy measures in mitigating the burden of such costs. In addition, I have interviewed various stakeholders from the Jordanian pharmaceutical sector to gain first-hand information and reflections on how the new law has been perceived, evaluated, and reacted to by actors on the ground in Jordan. The interviewees included officials from eight local pharmaceutical manufacturers, the Jordanian Association of Manufacturers of Pharmaceuticals and Medical Appliances (JAPM), the Patent Office and two other

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departments of the Ministry of Industry and Trade, and the Jordan Food and Drug Administration (JFDA). I also interviewed personnel from the King Hussein Center for Cancer, the Head of the Professional Association of Pharmacists, and the Director General of the Drug Importer’s Association (an association of local representatives of pharmaceutical MNCs).

The evidence available from cross-country, sector-specific econometric studies, and Nomothetic\(^9\) Research in general, on the effects on the levels of technological innovation in, and technology transfer to, developing countries that enforce strong patent rights is ambiguous and inconclusive at best. This type of research often ignores contextual factors and local details and does not take them into consideration; it mainly focuses on the variables of interest.\(^{10}\) Hence, the omission of such details and factors may raise questions as to the validity of econometric studies investigating the impact of enhanced patent rights in developing countries. This probabilistic observation might hold since “[knowledge] of local details is required not just to identify exogenous costs, but also to determine whether outcomes are economically efficient”\(^{11}\).

Consequently, this means that the underlying assumptions underpinning the TRIPS Agreement rules on patents, which call for robust protection of pharmaceutical patents, have not been conclusively established in a developing country context and remain debatable even in the context of developed states. In part, the inconclusiveness of the evidence derived from this type of studies is due to the multiplicity and complexity of factors involved in, and important for, the innovative capacity of a given market, including its ability to respond to patent-provided incentives. This reality, therefore, supports studying this topic through the case study method, which is argued to be most appropriate for studying complex social situations or interventions, where multiple variables exist.\(^{12}\)

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\(^9\) Nomothetic research refers to methods of research that use groups of subjects to investigate a few variables. The aim of this research is to generate probabilistic generalization through the use of statistics. See Jane JF. Gilgun, “A Case for Case Studies in Social Work Research” (1994) 39 Social Work 371 at 372.

\(^10\) Ibid.


The case study method “has been tried and found to be a direct and satisfying way of adding to experience and improving understanding”.\(^\text{13}\) Moreover, unlike empirical methods such as econometric research, it is “particularly useful when we do not wish to or are unable to screen out the influence of ‘external’ variables but when we wish to examine their effect on the phenomenon we are investigating”.\(^\text{14}\) Case studies can be used to test a theory or hypothesis. This is particularly relevant when the aim is to analyze a “single exception that shows the hypothesis to be false”.\(^\text{15}\) Therefore, the legal analysis and conclusions with regard to the obligations of the TRIPS Agreement on the protection of pharmaceuticals in Jordan, their potential impact, and the available legal means to mitigate the social and economic costs of such obligations, should represent not only a source of generalization based on a finding of commonalities, but also a tool to identify peculiarities where no such generalization can be made. In that regard, this thesis questions the adequacy of the approach of creating legal norms equally applicable to all (one-size-fits-all) in ignorance of the importance of the context and localities of where such norms apply.

**Selection of the Case: Why Jordan?**

My decision to select Jordan as the case for this study was influenced by several factors and attributes. First, Jordan is an upper middle income developing country with a population composed disproportionately of youth where significant segments are highly educated. It also hosts a number of relatively advanced generics manufacturers. These two elements would make Jordan a suitable context to investigate the forgoing disagreements over the impact of strong patent rights, as required under the TRIPS Agreement, on innovation in developing countries. The combination of educated youth and the availability of pharmaceutical industrial capacity should serve as a good environment to test the influence of patent rights on levels of local R&D and innovation. Second, over time, Jordan has experienced both strong and relaxed protection and


\(^{14}\) See de Vaus, supra note 8 at 232.

\(^{15}\) See supra, note 13.
enforcement of pharmaceutical patents. This background provides a natural experiment as to how enhanced patent rights may produce positive effects in a particular development stage. Third, following accession to the WTO and under the USJFTA, Jordan committed itself to so-called “TRIPS-Plus” IP standards. It has been ten years since these standards were adopted and began being enforced. Therefore, if enforcing strong pharmaceutical patent rights is conducive to the objectives declared under Article 7 of the TRIPS Agreement, then Jordan should realize these objectives; if not, this will call into question the viability of achieving these goals through such protection in developing countries. Finally, Jordan repealed pharmaceutical product patents in 1986. Between 1986 and the end of 2000 the local industry grew substantially. This period of lax protection provides an opportunity to compare the effects this period has had on the development of the local pharmaceutical sector with those of strong patent rights, effective since 2000, in the context of a single country.

Limitations

The primary limitation of this study relates to the use of the case study research approach. Critics of this method argue that case studies, although they provide a profound understanding of a single case, they lack external validity. That is, case studies provide “no basis for generalizing to wider population beyond that case”.16 Applied to this thesis, this would mean that its findings are not necessarily applicable to other developing countries since they may exhibit different contextual factors and localities. For instance, if we assume for the sake of argument that this study found that compulsory licenses are effective in inducing patentees to voluntarily license their patents, then it could be argued that this outcome may not be the same in a developing country lacking a manufacturing capacity in pharmaceuticals that is similar to that which exists in Jordan. This criticism is raised because a case study “is often thought of as a constituent member of a target population. And since single members poorly represent whole populations, the case study is seen to be a poor basis for generalization”.17 It should be emphasized that since it is not

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16 See de Vaus, supra note 8 at 237.
based primarily on empirical investigation, this study does not strive to make empirical generalizations. However, the thesis seeks to provide a legal framework for analyzing how strong patent rights function in developing countries: by testing it in the context of Jordan. The concluding chapter offers some observations with regard to particular findings of the thesis and to their potential generalizability to other developing countries exhibiting similar endowments.
CHAPTER ONE

“Grafting” Intellectual Property onto Trade and the Evolution of Pharmaceutical Patents in Developing Countries: Ongoing Debates

1. Introduction

The Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement, the Agreement, or TRIPS) obliges developing countries to extend patent protection to pharmaceutical inventions.¹ The Agreement also imposes certain substantive and procedural conditions that member countries must follow before issuing a compulsory license.² And it requires countries to protect against unfair commercial use and disclosure data submitted by drug companies that register new drugs with their national health regulators.³ These obligations provoked intense debates before and after the conclusion of the Agreement in 1994.⁴ The debates touched upon every aspect of the patent system, and frequently questioned the very foundation of it. Participants in these debates included scholars from many disciplines, including economists, historians,⁵ and - of course – jurists.

¹ See Article 27.1 of the TRIPS Agreements which, in part, stipulates that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” See infra note 4.
² See Article 31 of the TRIPS Agreement, infra note 4.
³ See Article 39.3 of the TRIPS Agreement, infra note 4
Notwithstanding the multiplicity of participants, diversity of views, and the conflicting nature of the arguments advanced, a review of the debates addressing the extension of pharmaceutical patent protection to developing countries reveals that they have focused mainly on three issues. First, the protection of pharmaceutical inventions by patents under the Paris Convention in both developed and developing countries, the reasons for the latter consenting to the General Agreement on Tariffs and Trade (GATT) as the forum to negotiate Intellectual Property Rights (IPRs), and the reasons developing countries agreed to the minimum standards of patent protection under the TRIPS Agreement. Second, a considerable part of the debates and literature focuses on a cost/benefit analysis of implementing pharmaceutical product patent protection in developing countries. This class of literature encompasses economic and political economy analyses as well as focusing on the potential costs/benefits of the extent and scope of protection provided, including under various scenarios of using particular safeguards such as compulsory licenses and parallel importation. Third, a legal policy analysis of the scope and extent of the minimum standards for the protection of pharmaceuticals required by developing countries in order for them to fulfill their obligations under the TRIPS Agreement. This question has led many scholars to articulate how best developing countries can implement such obligations given that they clearly have a comparative advantage in lax patent protection. The literature on legal policy emphasizes the so called “TRIPS Flexibilities” as the means to mitigate the perceived disadvantages to developing countries from enforcing a stringent pharmaceutical patent regime, including obligations related to the protection of undisclosed pharmaceutical regulatory data. Although the protection of regulatory data demanded by Article 39.3 of the TRIPS Agreement is not dependant on the existence of patent protection, a meaningful use of certain flexibilities such as compulsory licensing and parallel importation of pharmaceuticals may be jeopardized by data protection. Recently, this issue has attracted considerable attention and there is a growing body of

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6 See, for example, Abbott, “First World”, infra note 39; Sykes, infra note 53; Sell, infra note 45; and see Nogués, infra note 46.
8 See, for example, De Carvalho, infra note 252; Correa, “Protection of Data”, infra note 253; Reichman, “Undisclosed”, infra note 253; and see Fellmeth, infra note 253.
literature on the scope and extent of the obligations under Article 39.3 that members of the World Trade Organization (WTO) must provide to test data.

However, debates with regard to determining what implications might be associated with the extension of strong patent protection to developing countries mainly occur within a welfare framework, whether static or dynamic. Opponents of strong patent protection argue that the static losses are large and imminent, while dynamic benefits, if any, are marginal and would not offset the anticipated static losses.9 Advocates of strong patent rights disagree. They claim that dynamic gains would be substantial, mainly through enhancing innovation in the long run and fostering technology transfer through Foreign Direct Investment (FDI) and technology licensing.10 There are, therefore, debates as to the proper scope - protectable subject matter – duration, and extent of protection.

I will examine the existing literature that has dealt with these debates to the extent pertinent to the subject of this study: the relevance of the international and bilateral rules on patent protection for the pharmaceutical sector in Jordan, as a small, upper middle income developing country. The literature reviewed does not provide a full evaluation of the competing arguments. Rather, it is intended to establish a framework for this study. More specifically, I intend to show that the above debates are not settled although it has been more than sixteen years since the TRIPS Agreement was signed in 1994. In that regard, this chapter shows that the underlying assumptions underpinning the TRIPS Agreement rules on patents have not been conclusively established in a developing country context and remain debatable even in the context of developed states. Therefore, this chapter will illustrate why it is important to study this topic in the context of Jordan as the case of this thesis.


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9 See, for example, Trebilcock and Howse, infra note 65 at 401; Nogués, “Social Costs”, infra note 127; Nogués, “Notes”, infra note 128; Chin & Grossman, infra note 136; and see Li, infra note 132
10 See Diwan & Rodrik, infra note 67; Grabowski, infra note 67; Sherwood (multiple references), infra note 67; Leaffer, infra note 67; and see Rapp & Rozek, infra note 67.
From its inception, the Patents regime has been controversial. Scholars have disagreed even over the nature of the patent regime itself. Some perceive the regime as constituting a form of monopoly that is considered injurious to trade.\textsuperscript{11} This concern is reflected in one of the very first codes to recognize patents,\textsuperscript{12} the Statute of Monopolies.\textsuperscript{13} The Statute’s goal was to enjoin all forms of monopolies. Patents for new inventions were excepted, so long as they were not “contrary to the Law, nor mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or generally inconvenient”.\textsuperscript{14}

A wave of laws emerged during the subsequent centuries and by the end of the Nineteenth Century a number of European countries and the United States had adopted statutory patent regimes.\textsuperscript{15} By the time these laws were enacted, the nature of the inventor’s “right”, and the legal or economic philosophy underlying a public policy to establish and maintain a patent system were hotly debated issues.\textsuperscript{16} Penrose identified four general arguments advanced by advocates during that time as a basis for the system: “natural property rights”, “reward for rendered services”, “disclosure of secrets”, and “innovation encouragement”.\textsuperscript{17} The former two arguments are based on “individual justice” and the latter two are concerned with “economic policy”. Opponents of the patent

\textsuperscript{11} See Edith T. Penrose, \textit{The Economics of the International Patent System}, (Baltimore: Johns Hopkins Press, 1951) at 19-40.

\textsuperscript{12} Although a reference here is made to the Statute of Monopolies of England of 1623, a well-developed patent system was in place in the fifteenth century in Venice where monopoly privileges were granted during the sixteenth and seventeenth centuries in the western and central parts of Europe. See Fritz Machlup & Edith Penrose, “The Patent Controversy in the Nineteenth Century” (1950) 10(1) The Journal of Economic History 1 at 3.

\textsuperscript{13} For example, while France passed its first patent statute in 1791, the American Patents Act was enacted by Congress in 1793. More countries followed suit during the subsequent decades, including: Austria in 1810, Russia in 1815, Belgium in 1826, Sweden 1834, as well as some other European countries. See see Fritz Machlup, An Economic Review of the Patent System, the Subcommittee on Patents, Trademarks, and Copyright of the Senate Committee on the Judiciary, 85TH CONG., 2nd SESS, (Washington: United States Government Printing Office, 1958), at 19-43.

\textsuperscript{14} See Machlup & Penrose, supra note 5.

\textsuperscript{15} See Machlup & Penrose, supra note 12.

\textsuperscript{16} This movement started in England during the period 1827-1872 and in Germany around the same time. Ibid.

\textsuperscript{17} See Penrose, supra note 11 at 19-40; and see Fritz Machlup, An Economic Review of the Patent System, the Subcommittee on Patents, Trademarks, and Copyright of the Senate Committee on the Judiciary, 85TH CONG., 2nd SESS, (Washington: United States Government Printing Office, 1958), at 19-43.
system raised serious objections about the validity of these arguments as a sound basis of the legal nature or the economic effectiveness of the inventor’s right.\textsuperscript{18}

Nevertheless, the Paris Convention (the Convention) was concluded in 1883 and after a strong opposition movement against the patent institution during the second half of the nineteenth century.\textsuperscript{19} The Convention was considered a landmark in the history of patent protection as the start of the international phase of the regulation of the grant and maintenance of patents with effect in harmonization of the national rules of the contracting states on these issues as one of its main objectives.\textsuperscript{20}

The conclusion of the Convention was not an absolute triumph for those supporting the patent system. As we shall later see, most of the objections raised by opponents of the system were taken into consideration at the time of drafting the rules of the Convention. Therefore, as adopted in its final version in 1883 the Convention is considered to have struck a delicate balance between the interests of inventors and those of the general public. To balance these two sets of interests the Convention encompasses rules that are flexible enough\textsuperscript{21} for its contracting states to address their various developmental needs, policies, and objectives.\textsuperscript{22} In particular, the Convention left to its members the full discretion to decide upon matters such as the duration of patent protection and, more importantly, the technological fields and inventions that countries might protect by patents. Exercising this freedom, most members of the Convention excluded pharmaceutical product inventions from patent protection, but not process inventions. The German Association of Chemical Industry explained the justification for protecting process inventions but not product inventions as follows:

the same chemical product can be obtained by different processes and methods and even starting from initially different materials and components. Hence, there is social value in patenting a new process, as it rewards the innovator without preventing further innovation. There is negative social value in patenting a
specific product, as this would exclude all other from producing it, even through different processes.23

2.1. Pharmaceutical Patents from the Paris Convention’s Legislative Flexibility to the Rigidity of the TRIPS Agreement

The framers of the Paris Convention sought to facilitate the acquisition of patents for inventions in the various contracting states. Reciprocally, the Convention gives its members a full discretion to pursue the legislative policy they deem appropriate in determining how to protect industrial property, including patents.24 This freedom extends to the adoption of legal measures of substantive law with regard to issues such as defining patentable inventions and determining patentability criteria and deciding on patentable subject matters, period of protection, grant and maintenance of exclusive rights, and exceptions to and restrictions on their use.25

This freedom made it possible for many countries to exclude from patent protection certain sectors of vital importance for their social and economic welfare. Most of the world’s countries, including those with membership in the Paris Union,26 have excluded inventions in the pharmaceutical sector from patents protection, particularly product, but not process patents. When patents were made available in this sector, they would be granted for a short duration, for example, 7 years,27 or made subject to involuntary use through compulsory licensing (foreign patents in particular).28 This

26 Article 1 (1) of the Convention states that “[the] countries to which this Convention applies constitute a Union for the protection of industrial property.” Although the convention does not define the word “Union”, it has been observed that the establishment of a union means the creation of a legal personality (entity) under international law with administrative organs to conduct its mission. These administrative subordinates are the Assembly, the Executive Committee, and the International Bureau of WIPO (World Intellectual Property Organization. See Leaffer, International Treaties, infra note 29.
27 This was the case under the 1970 Indian Patent Act; see the Act of 1970, infra.
28 For a review of various aspects of the Canadian experience with patent protection of pharmaceuticals, see Donald G. McFetridge, “Intellectual Property, Technology Diffusion, and Growth in the Canadian
freedom was not absolute. Member countries had to be in compliance with certain substantive legal principles and obligations against discriminatory or arbitrary exercise of such freedoms. Namely, countries are required to comply with the doctrine of National Treatment and recognize a Right of Priority for patent applicants.

National treatment, as contained in Articles 2 and 3 of the Convention, means that each member state of the Union must apply to the nationals (or those assimilated to nationals), natural and legal alike, of other member states the same treatment a country provides to its own nationals or residents. The doctrine of National treatment guaranteed inventors of other contracting states not only protection in foreign jurisdictions, but also protection against discrimination with regard to the availability and enforcement of legal protection to their respective inventions.

Right of priority is provided for in Article 4. In essence, the Priority right enabled inventors to acquire patent protection for their inventions in several countries (provided such protection is available to nationals in the first place) without being required to make simultaneous applications in their home country and the various foreign countries. The Priority right functions by stipulating that a previous application should not render inventions obvious in subsequent foreign applications if the subsequent application(s) is/are submitted within 12 months calculated from the date of the first application.

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31 Ibid.

During the 1960s and 1970s, the number of developing state members of the Paris Union increased significantly. Compared to three members in 1900, the number of developing member states of the Conventions was 44 in 1973. By 1987, the number grew to 60 members. These new members were critical of a number of aspects of the Convention, especially the role played by the Convention’s rules in facilitating the transfer of advanced technologies by their proprietors to developing countries. They also complained that almost all patents granted by their national offices were obtained by foreigners and that these patents were not worked, by actually producing their products through the establishment of manufacturing plants, within their territories. Intuitively, this led them to conclude that patent owners were using their exclusive rights to protect export markets but not to transfer their advanced, patent-protected technology. Given their growing membership in the Union, developing countries could block proposals to make rules on issues such as compulsory licenses more stringent, which developed countries kept calling for but ultimately failed to accomplish by means of amending the Convention.

By and large, both developing and developed countries criticized the Paris Convention on different grounds and in pursuit of different goals. Developing countries sought to address their misgivings about the contribution of the patent system in transferring advanced technology, which they considered necessary for their industrial
and economic development.\textsuperscript{40} Pursuing this objective, they called for a revision of the Convention to provide for more liberal compulsory licensing provisions.\textsuperscript{41} In 1975, the United Nations Conference on Trade and Development (UNCTAD) called for a conference to revise the Convention,\textsuperscript{42} initiating a process for this revision during the 1980s. This process has not led to any amendment of the Convention, however, and the provisions of the Convention today remain unchanged as they were last revised and amended in 1967 (the Stockholm Act).\textsuperscript{43}

On their part, developed countries, the United States in particular, condemned the Convention for its levels of patent protection, which they perceived as lax. They argued that the Convention gives its members a broad legislative freedom. For example, the Convention allows members to provide compulsory licensing of patents in cases of insufficient or non-working of a patented invention locally. So far as patents are concerned, developed countries criticized the Convention on several grounds. First, it does not adequately address the subject matter of technologies. Second, it does not set a minimum patent term. Third, it does not expressly provide for the payment of full compensation for compulsory licenses. And fourth, it is too permissive with respect to the granting of compulsory licenses as well as lacking established standards for national enforcement and cannot, in any event, be considered to provide a meaningful dispute

\textsuperscript{40} See United Nations Conference on Trade and Development (UNCTAD), \textit{The International Patent System as an Instrument of Policy for National Development}, (TD/B/C.6/AC.2/3 Geneva, 1975). In this report, the organization concluded that “[the] available evidence suggests that the international patent system is not, in its present form, proving to be of benefit to the developing countries and that it is having a negative effect on their development” at 2; Michael Blakeney, “The International Protection of Industrial Property: From the Paris Convention to the TRIPS Agreement” (2003) WIPO Document WIPO/IP/CAI/1/03/2, at 7; Jerome H. Reichmann, “Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection” (1989) 22 Vanderbilt Journal of Transnational Law 747 at 764-766.


\textsuperscript{42} See United Nations Conference on Trade and Development (UNCTAD), “Major Issues Arising from the Transfer of Technology to Developing Countries” (1975b) TD/B/AC.11/10/Rev.2 United Nations publications, Report by the UNCTAD Secretariat.

\textsuperscript{43} See Blakeney, supra Note 40; Peter Drahos, “Developing Countries and International Intellectual Property Standards-Setting” (2002) 5 Journal of World Intellectual Property 765[Developing Countries].
settlement mechanism, although it provides for recourse to the International Court of Justice (ICJ) in disputes between member states.44

Due to the above-mentioned objections, developed countries, the United States in particular, sought and was thus successful in including Intellectual Property (IP) as a negotiation item on the Agenda of the GATT’s Uruguay Round of negotiations.45 Protection of pharmaceutical patents was a central cause and driver for this move. According to Nogués, institutional regulatory changes in the US pharmaceutical field resulted in greater competition from generic medicines and limited the effective life of patents. First, the Food and Drug Administration (FDA) introduced stricter regulations requiring sponsors of new medicinal product submissions to provide evidence proving not only that the sponsored medicines are safe, but also that they are efficacious and of a quality for human use.46 Second, almost all the States eliminated anti-substitution laws, which prohibit a pharmacist from dispensing a drug product other than the specific drug identified by trade name in the prescription. This waiver of elimination has led to more replacement of brand drugs by generics. And third, the enactment of the Drug Price Competition and Patent Term Restoration Act (the so-called Hatch-Waxman Act)47 facilitated the early introduction of competition from generics.48 These developments led

44 There are, at least, two problems concerning the settlement of disputes over obligations under the Paris Convention by referral to the ICJ. First, although parties to the Paris convention may refer disputes to the ICJ, such a referral may only take place with regard to members who, at the time of accession to the Convention, did not opt out of the court jurisdiction over such disputes. This option is available to members in accordance with Article 28 of the Convention. The second problem has to do with enforcement of the court’s judgments. The enforcement of such judgments, according to the United Nations Charter, comes about by one of two means: voluntary cooperation of the concerned member state or through referral to the Security Council. According to Abbott, “[it] seems unlikely that the United Nations Security Council would act to enforce an ICJ judgment protecting intellectual property rights.” See Abbott, “First World”, supra note 39 at 703; David Hartridge & Arvind Subramanian, “Intellectual Property Rights: The Issues in GATT” 22 Vanderbilt Journal of Transnational Law 893; Kenneth Dam, “The Growing Importance of International Protection of Intellectual Property” (1987) 21 International Lawyer 627; U.S. Framework Proposal to GATT Concerning Intellectual Property Rights, 4 Int’l Trade Rep. (BNA) 1371 (Nov. 4, 1987).
46 See Julio Nogués, “Patents and Pharmaceutical Drugs: Understanding the Pressure on Developing Countries” (1990) 24(6) Journal of World Trade 81 [Understanding the Pressure].
48 See Nogués, supra note 46.
to a decline in the profits from Research and Development (R&D) experienced by branded pharmaceutical manufacturers.

To make up for these losses, the US pharmaceutical industry lobbied for and convinced the federal government to advocate extending patent protection of pharmaceuticals to developing countries since their markets were gaining in importance. For example, after the launch of the Uruguay Round of trade negotiations in March 1987, Mossinghoff, then president of the US Pharmaceutical Manufacturers Association (PMA), stated that the association was working with the Congress to have it pass “the intellectual property revisions of the Omnibus Trade bill that would strengthen the hand of the U.S. Government in urging all of our trading partners to respect our rights in inventions”.

By the early 1980s, both developed and developing countries realized the need to revise the international patent protection system as regulated under the Paris Convention, which is administered by the World Intellectual Property Organization (WIPO). The two sides, however, had different views with regard to the most appropriate forum for negotiating revisions. Developed countries insisted that WIPO was not the suitable forum, accusing the organization of functional and structural weaknesses. They advanced, instead, the GATT as the right forum for hosting the negotiations, since it did not suffer from the same weaknesses attributed to WIPO. Developing countries vehemently opposed the idea of negotiating IP issues in general, patents in particular, under GATT. They argued that WIPO is the appropriate multilateral forum to address subject matters related to IP. Despite their opposition, the IP matter was put on the table at Punta del Esta in Uruguay, and on April 15, 1994 the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations was signed in Marrakech declaring the conclusion of the Round. The Act contains several agreements, including

52 See World Trade Organization (WTO), Understanding the WTO, at 19, online: WTO Homepage <http://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf> (date accessed: November 02, 2010).
the Agreement Establishing the World Trade Organization (WTO) and the TRIPS Agreement.

Conventional wisdom holds, as will be seen below, that developing countries are likely to suffer a welfare loss by accepting the TRIPS Agreement’s standards on patent protection, particularly when extending protection to pharmaceuticals. Therefore, it is necessary to explore why developing countries “agreed” to the TRIPS Agreement. In other words, what convinced the southern countries to change their hostile reaction to the idea when it was first proposed as part of the negotiation agenda at the Uruguay Round?\textsuperscript{53} According to Bhagwati the following reasons explain why. First, since they sought concessions from developed nations on areas such as agriculture and textiles, developing countries believed that businesses in industrialized nations were not going to endorse a package without them accepting the TRIPS Agreement. Second, they sought avoiding US unilateral trade measures for not providing protection for American IP. And third, some developing countries accepted the Agreement based on the expectation that IP protection would attract foreign investment in and facilitate technology transfer to their territories.\textsuperscript{54}

Others, however, argue that scrutiny of the developments preceding the conclusion of the Agreement suggests otherwise. They firmly insist that there was an element of coercion in securing the consent of developing countries,\textsuperscript{55} and not the opening of the western markets for their textile products.\textsuperscript{56} Drahos and Braithwaite’s detailed research of the Uruguay negotiations of the TRIPS Agreement offers a convincing answer as to why and how developing countries consented to such stringent obligations and terms. According to Drahos & Braithwaite and based on what they call

\textsuperscript{54} Ibid.
\textsuperscript{55} See Susan K. Sell, “TRIPS and the Access to Medicines Campaign” (2002) 20 Wisconsin International Law Journal 481 [Medicines Campaign]; Drahos argued that “in the case of TRIPS a basic and well established causal mechanism operated coercion. States coerce other states”. He also adds that “[the] intellectual property story is one of coercion, but it is economic rather military in kind. The US used a sophisticated process of trade threats and retaliation to coerce some states into complying with its intellectual property objectives”. See Drahos, “Global Property”, supra note 45 at 16.
“Democratizing Intellectual Property”, three main factors contributed to securing this consent. First, there was no real and effective representation for most developing countries during the negotiations on TRIPS - most of them, for instance, were not invited to participate in the important meetings where proposals were developed. Second, most delegates representing developing countries lacked a full understanding of the social and economic implications of the proposed standards of protection for their public health, standards such as the extension of product patent coverage to pharmaceuticals, 20-year duration of protection, and restrictions on exceptions to patentees’ exclusive rights. Third, the unilateral approach adopted by the US to target opposition to the TRIPS from certain developing countries constituted coercion. For example, the initiation of unilateral trade retaliation under Section 301 of the trade act and the notorious 301 Watch and Priority-Watch Lists, and the threat of aid suspension or the withdrawal of benefits under the Generalized System of Preferences were all forms of coercion used to compel developing countries to sign the TRIPS Agreement.

Despite the above-mentioned views indicating that developing countries perceived the standards under the TRIPS Agreements as injurious to their interests, some scholars have claimed that developing countries would stand to benefit in the long term from providing for pharmaceutical patent protection. I will review these would-be advantages and how they might materialize in the next section. This review will be followed by a critique of this line of argument.

3. The TRIPS Agreement and Pharmaceuticals Patent Protection: Any Benefits for Developing Countries?

From a legal perspective, debates over protection of patents in developing countries almost always constitute a reiteration of those articulated in the context of the 19th Century controversy. Accusations such as “immoral”, “unjust”, and the

57 See Drahos with Braithwaite, supra note 49 at 187-97.
58 Ibid.
59 Ibid. at 85-92.
60 See Machlup and Penrose, supra note 12.
contemporary deployment of the term “piracy”, “free-riding” in economics parlance, are commonly used to describe imitation activities and the lack of pharmaceuticals product patent protection in developing countries. Such axioms were mobilized as part of the movement to eliminate not only the claimed lack of protection, but also to constrict the use of legislative policy tools such as compulsory licenses.

Oddi asserts that natural law-based arguments were used by industrialists in developed countries to convince their governments of the necessity to extend patent protection to developing countries. According to these arguments, imitation of any patented invention is an act of “piracy” or “theft”, thus immoral. This would be the case regardless of where this act is conducted and whether the imitated invention is protected by a patent in the country of imitation or even if such protection is not available due to a lack of positive law. Being so characterized, all acts of imitation should be outlawed by providing for patent protection in developing countries. Trebilcock and Howse, for example, question this natural right view, arguing that it is difficult to conceive of a natural right that is limited in time. They then add that the issue is one of remuneration to be paid to inventors for their efforts in developing the patented inventions, which requires that the level of protection afforded inventors be “balanced against other social interests.” This means it makes sense for developing countries to enhance patent protection when there is a comparative advantage for them in doing so: producing advanced knowledge. This issue may vary among fields and countries. Given that developing countries are not producers of technical knowledge, but rather consumers of innovative technology, it is reasonable for them to prefer a lenient regime of patent protection since such lax rules facilitate acts of imitation, thus maximizing consumer welfare.

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61 See Sykes, supra note 53 at 50.
66 Ibid. at 399-400.
Despite this sound argument, it has been claimed that strong patent protection in developing countries is conducive to positive dynamic welfare outcomes.\textsuperscript{67} It is argued that patent protection will increase welfare by: enhancing incentives for more R&D activities, leading to more useful inventions; encouraging Multinational Corporations (MNCs) to transfer their advanced technology to developing countries through FDI and licensing contracts; and enhancing access to the most innovative medicines, as well as improving efficiency in resource allocation by shifting them from imitation to innovation.

3.1. Patent Protection, Pharmaceutical Innovation, and Developing Countries

Rapp and Rozek\textsuperscript{68} contend that developing countries should make patent protection available for inventions in all fields of technology in order to provide the necessary incentives to stimulate innovation.\textsuperscript{69} The logic of this argument is that economic efficiency requires government intervention to support innovative and creative activities. This support, in the form of patents, provides private innovators with the proper incentives as they can anticipate capturing a substantial part of the value of their innovation. Patents function as an incentive, since they enable inventors to exclude others from emulating new innovations without their consent. By securing a private return for inventors, patents stimulate inventive and creative activity, which is a necessary input for technological change. Therefore, economic growth and development objectives are served through patent protection.\textsuperscript{70}


\textsuperscript{68} See Rapp and Rozek, ibid.

\textsuperscript{69} For an in-depth discussion on innovation in a patent law context, see Chapter Two.

In the case of pharmaceuticals, the R&D inducement role of patents is claimed to be of peculiar importance due to two characteristics. First, initial pharmaceutical R&D is associated with high sunk costs incurred prior to actual marketing of drugs to which both “the costs of failures and the opportunity cost of funds during the R&D process” are accounted for. Second, once developed and tested for human consumption, pharmaceuticals are known for their low marginal cost of production. Low marginal production cost coupled with no R&D expenses enables imitators to compete with innovators by providing relatively low-priced drugs. These low-priced, imitation drugs inevitably exert a downward pressure on prices risking the non-recovery of R&D costs by the innovative pharmaceutical firms. Therefore, without a patent that guarantees exclusive rights in pharmaceuticals for a period long enough to prevent an immediate market entry and thus competition from imitation, the private sector would not make the necessary investments in pharmaceutical R&D.

This argument may be valid in a developed country context. In such countries there exist at least two prerequisites for innovation: good R&D infrastructure and sufficient capital to develop and commercialize inventions resulting from R&D activities. However, the validity of the argument that a strong patent protection system inherently

71 See Sykes, supra note 53 at 60-1.  
73 Ibid. Kettler.  
plays a positive role in inducing R&D activities in a developing country context has been contested on multiple grounds, including that “patents are not a relevant factor or effective in stimulating R&D and bringing new products to market”.  

Braga and Fink argue that developing countries, particularly small and poor ones, do not have the infrastructure necessary to conduct such activities in the first place. That is, they lack skilled personnel, advanced modern laboratories and equipment, as well as adequate financial resources. Furthermore, The British Commission on Intellectual Property Rights (IPR Commission) observed that R&D activities conducted in developing countries are of a modest and basic nature. In developing countries, most R&D activities and projects are undertaken by academic and public institutions and the findings are not systematically transferred to the private sector for further development and application.

Correa and many others argue that extending strong patent protection to developing countries, in particular recognition of broad patents, may not produce the claimed positive effects on innovation because inventive and creative activities in developing countries are mainly made up of incremental developments based on existing technologies rather than novel additions to the state of the art. The holding of this type

76 See the WHO, ibid. at 22.  
79 Ibid. at 60.  
80 Correa used the phrase “intellectual property rights”. This phrase encompasses patents as one of the categories of intellectual property rights encompassed under part two of the TRIPS Agreement. See Article 1.2 of the TRIPS Agreement, supra note 4.  
of patents by a firm may deter others from trying to invent near the area covered by the broad patent, fearing infringement and costly litigation. The outcome of such patents is even worse, as argued by Mazzoleni & Nelson, when competitors are “deterred from themselves undertaking any of the wide variety of follow-on inventive work that improves, or variegates, on an initial invention”.\(^{82}\) In addition, the weak innovation systems in most developing countries are unlikely to be suddenly transformed as a result of introducing strong patent protection. Technological capacity building, by its nature, is a cumulative process which requires time in upgrading not only the scientific base, but also the education systems in these countries.\(^{83}\)

A recent study conducted by Kyle and McGahan confirms that strong patent protection alone is not enough for inducing further R&D in developing countries. The study analyzed data from over 180 countries to investigate the relationship between investments in the development of new pharmaceuticals and the introduction of patent protection. The study found that R&D spending does not increase after the introduction of patents in developing countries. However, patent protection was associated with and followed by more R&D efforts when adopted in high income countries. Contrary to arguments made by proponents of enhanced patent protection, the study concluded that making the provision of patent protection available in developing countries was not “sufficient to induce R&D for diseases that have no significant potential market in high-income countries” (diseases affecting developing nations), by either the pharmaceutical companies in developing countries or those operating in the industrialized members of the WTO.\(^{84}\)

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A different argument for the R&D inducement function of patents is advanced by Rapp and Rozek. They implicitly claim that patent protection for pharmaceuticals in developing countries would lead to an increase in the share of R&D activities conducted there by innovative pharmaceutical firms based in developed countries. Their claim is based on statistical figures about the percentage of R&D expenditures spent abroad by US firms that indicates, according to them, an increasing share of such expenditures by countries improving IP protection.85

Canada is one of the countries cited by Rapp and Rozek as receiving an increased share of the R&D expenditures after improving its patent protection.86 According to the relevant percentages presented in Table 6 of their study, Canada’s share of the US pharmaceutical company R&D expenditures abroad was 5.8%, 6.1%, and 7.6% in 1977, 1982, and 1987, respectively.87 In fact, the Canadian example supports a case against their argument. The reason is that during the period from 1967 through 1987 Canada actually weakened88 patent protection for pharmaceuticals by relying heavily on compulsory licensing as a policy mechanism to make medicines affordable to its citizens.89 In discussing the patent policy shift in 1969, Professor Cohen argued:

[the] result was the implementation of a more effective compulsory licensing regime. In 1969, the Canadian Parliament asked the Commissioner of Patents to approve compulsory licenses for drug patents under most circumstances…. Once granted a compulsory license, the licensee is obliged to pay a small royalty to the holder of the patent.90

Since the legislative history of the Canadian patent protection reveals that Canada did not tighten the regulation of compulsory licensing within its patent system until the end of 1987, by means of passing Bill C-22,91 the increasing share received by Canada of the

85 See Rapp and Rozek (1990), supra note 67 at 87-8.
86 Ibid.
87 Ibid. table 6 at 89.
88 Advocates of strong patent protection argue that compulsory licensing weakens the level of protection afforded to patents as they deprive innovators from recouping their R&D expenses.
90 Cohen, supra note 28 at 7 (emphasis mine).
91 According to Cohen, the Bill did not pass but after a “much heated debate and political maneuvering” on the side of the government. In addition, the government committed itself to the opposition by a pledge to
US Pharmaceutical R&D expenditures spent abroad cannot be attributed to strengthening patent protection.

Rapp and Rozek’s argument that the level of patent protection in a given country impacts the decision of US pharmaceutical firms to conduct R&D activities in that country is shared by Mansfield. In a survey of 100 American firms representing six industries, including pharmaceuticals, Mansfield asked executives of the sample firms to provide information about the influence of IP protection on their decision making to invest directly in R&D facilities, among other things, in certain foreign countries. The responses revealed that 80% of the surveyed firms said IP protection is important. Pharmaceuticals firms, relative to those from other industries, had “the largest percentage of firms regarding intellectual property protection as important”.

Mansfield extended the results of this study to include firms from Germany and Japan focusing on chemicals, pharmaceuticals, electrical equipment, and machinery. The findings of the second study were similar to those of the 1994 study with about 80% of the firms claiming the importance of IP protection (patents of course). Further, in both studies the surveyed firms were asked to evaluate whether the IP systems in 16 countries, mainly composed of developing countries, were perceived as too weak for them to conduct R&D activities in these countries. The surveyed firms perceived those systems were weak. The findings of Mansfield’s two studies suggest that R&D activities conducted by foreign firms in developing countries, thus innovation, would not increase as long as they maintain weak patent systems. Therefore, they need to strengthen protection for patents.

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create a governmental institution to monitor prices for patented medicines; indeed, the Patented Medicines Prices Review Board (PMPRB) was established in 1987. See Cohen, supra note 28 at 9.


93 Ibid. at 2.


95 These countries are: Argentina, Brazil, Chile, Hong Kong, India, Indonesia, Japan, Mexico, Nigeria, Philippines, Singapore, Republic of Korea, Spain, Thailand, Venezuela and Taiwan, and China.
However, the methodology in both of Mansfield’s studies has been criticized as being “very subjective”. Their findings are based on the personal perceptions of the surveyed personnel of the participating firms. Given the publicity of discourses and rhetoric about the IP protection associated with the Uruguay Round as well as the direct involvement of the Pharmaceutical Research and Manufacturers of America (PhRMA) in the negotiations, the subjectivity of the methodology makes the findings less reliable. In addition, UNCTAD has argued that empirical research carried out to analyze the impact of strong IP systems (patents in particular) suffered from “methodological difficulties”. That is, for example, when different criteria are used by similar researchers to rank the strength of developing countries’ IP systems.

The findings of Mansfield’s studies were further questioned by Paul Heald. He observed that the results of these studies may not be generalized to all classes of IPRs, including patents. Particularly, the findings of both studies show that the surveyed firms indicted that the level of IP protection in a given country principally impacts their decision to establish R&D activities there, but not their decisions, for instance, to build a production plant or to establish a manufacturing joint venture with a local firm. Accordingly, the responses of the surveyed firms and the findings of Mansfield’s studies are pertinent to and about the protection of trade secrets, which is very important to protect R&D results against industrial espionage, disclosure, or spillover to competitors. Generalizing the studies’ results to patent protection is further criticized since they did not ask the surveyed firms about the separate relevance of each type of IPRs; rather, the inquiry was about IPRs as a block of rights. Moreover, protecting research results by keeping them secret, which belongs to the realm of trade secrets and contract law, is the opposite of what patent law is all about: the full disclosure of research results by filing a patent application.

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99 Ibid.
The R&D argument in support of patent protection was strongly challenged by the findings of Scherer and Weisburst who analyzed the impact of Italy’s introduction of product patent protection in 1978. They concluded that the regime change had little or no impact on the trend of adjusted R&D expenditures, nor on the introduction of new chemical entities during the decade following 1978. Scherer emphasized these findings given, in his opinion, the fact that the Italian generic pharmaceutical industry at the time was a “vibrant generic industry”.

Challu, in his study of the impact of this Italian legal regime change, confirmed the findings of Scherer and Weisburst. He concluded that neither multinationals nor domestic pharmaceutical firms provided the anticipated increase in R&D expenditures as a response to introducing patent protection.

Another line of argument is that pharmaceutical patents will lead to more innovation due to increased incentives to innovators - located mainly in industrialized countries – from the extra revenues brought about by extending patent protection to developing economies. This argument is based on estimates of potentially “forgone” revenues as a result of weak patent protection in developing countries. According to Trebilcock and Howse these estimates assume that “a quantity of original products would be consumed equal to that of the imitation now being purchased”. The estimates of foregone revenues likely are exaggerated, however, since, as Trebilcock and Howse persuasively argue, patented products are priced much higher than generic versions,

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103 See Trebilcock and Howse, supra note 65 at 400.

104 For a typical example, see Robert M. Feinberg & Donald J. Rousslang, “The Economic Effects of Intellectual Property Right Infringement” (1990) 63 (1) Journal of Business 79 at 82 (they observe the following “[we] assume that the infringing output is a perfect substitute for the genuine article in the eyes of consumers”).

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which presumably suggests that patented products experience a decline in demand and thus fewer units are sold.  

Abbott also has argued against the soundness of a tangible impact on innovation incentives due to increase in revenues flowing from developing countries. He relies on several grounds in support of his argument. First, MNCs are not dependent, when formulating their R&D budgets, on the possible additional revenue derived due to patent protection in developing countries. Second, it is questionable that these companies would be insufficiently funded due to lack of patent-generated revenues derived from the markets of developing countries. Third, diseases peculiar to developing countries hold minimal, if any, weight in research projects of these firms whose main focus are diseases affecting industrialized countries.

Finally, Lacetera and Orsenigo studied the effect of the interaction between “policy regimes”, including patent protection regimes, and “technological regimes”, particularly the pharmaceutical industry. Specifically, they analyzed how this interplay contributed to the innovative performance of pharmaceutical industries in several European countries and the US. They observed that providing for process patents only, but not for product patents, facilitated the industrial lead by the German pharmaceutical firms during the first phase of development. They explain that the unavailability of product patents did not inflect a negative impact on the development of German firms since the scientific and technological knowledge, as an input in R&D, was not limited by process patents. They further suggest that given these limitations, innovation could be hindered rather than advanced by providing for product patents. In other words, the lack

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105 Ibid.
108 Lacetera & Orsenigo identified three phases of development for the innovative pharmaceutical industry. First, the initial stages and industry development “epoch” (1850-before World War II); second, the pharmaceuticals’ golden age period of industry development, following World War II until mid 1970s; and third, the era of molecule biology and cost containment, which runs from mid 1970s through the present time.
of product patents, among other factors, contributed to the creation of both formal and informal markets for technology, providing an incentive to develop alternative processes, me-too drugs, inventing around, and getting licenses from other companies, which became the main research activities. Lacetera and Orsenigo added that non-restriction of knowledge trading and dissemination, made available to an extent by the absence of product patents, facilitated these activities.

In addition, they concluded that patents are a component of a larger body of regulations where there is no direct correlation between innovation progress and a particular regulation per se. Lacetera and Orsenigo eloquently argued that patents alone “are not enough to promote innovation in contexts where innovation capabilities are low or missing altogether ... In other words, patents magnify the incentives to innovate but do not create them in the absence of competencies to make innovation possible in the first place”. They caution that if strong competencies to innovate are missing, “strong incentives”, in the form of patents, “might be ineffective and even dangerous”.

3.2. Patent Protection in Developing Countries and Technology Transfer: International Licensing and FDI

Scholars in support of strong patent protection have argued that owners of foreign technology would not transfer their advanced technology, through either arms-length licensing or direct investment, if developing countries lack adequate levels of patent protection. Owners of technology, it is claimed, are unwilling to transfer leading-edge

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109 According to Lacetera & Orsenigo, these factors included: 1) a rigor in the examination process that leads to the patenting of only actually novel processes, which mandated defining the scope of claims precisely. 2) Mandating a precision of claims avoided broad patent grants, which would have blocked entire fields. 3) These two factors led to have the granted patents being more secure and less prone to litigation compared to their English or American counterparts, which saved the German firms litigation costs and vulnerability of invalidation and infringement. And, 4) “the German system allowed the industry – not simply individual monopolists – to grow and to construct such competencies, also exploiting the ample possibilities of infringing British patents”. Ibid. at 12.

110 See Lacetera & Orsenigo, supra note 107 at 26 (emphasis mine).

111 Ibid.

technology because they fear losing their “property” to local competitors if patent and trade secret protection is entirely missing or lax: that is, less stringent than the minimum standards provided for under TRIPS. Therefore, for developing countries to attract advanced foreign technology and investment, they should enhance protection for IP, particularly patents.113 In turn, strengthening protection afforded to patents contributes to transferring technology since technology owners would be confident in concluding licensing contracts114 and/or conducting FDI.

Maskus argues that the opposite view, however, is equally possible, if not more compelling.115 He conducted a detailed survey of the limited empirical analysis of the effects of strengthening patent protection on technology transfer to developing countries via licenses. He concluded that strong patents in *small and poor developing* countries may result in their markets becoming monopolized by exporting patentees and that strong patents “could also permit firms to choose not to license their closely held technologies except in cross-licensing or patent-pooling arrangements”.116

In an earlier study, Maskus attempted to estimate the static and dynamic welfare implications of the then proposed TRIPS Agreement. He analyzed the potential effects of enhanced IPRs in encouraging the transfer of technology, the diffusion of technical knowledge, and the expansion of FDI. He asserted that whether strong IP protection is available in a given country is of minimal weight in firms’ decisions as to the choice of

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114 See Rapp and Pozek, supra note 67 at 85-6.
115 Studies have shown a declining trend in concluded licenses which not only transfer patented technology, but also the necessary “Know-How” for the application and performance of the licensed technology. In particular, such decline has been observed in technical fields with technology developing at a quick pace. See Nagesh Kumar, “Technology Generation and Technology Transfer in the World Economy: Recent Trends and Implications for Developing Countries” (1998) 3 Science Technology Society 266. In addition, Correa observed that following the introduction of enhanced pharmaceutical patent protection in some South American countries (Andean countries, in particular), MNCs started to close down their manufacturing plants in that country, leading to a decrease in FDI. See Carlos M. Correa, “Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?” (Presentation at The TRIPS Conference: A Law and Economics Conference, Duke Law School, April 4 - 6, 2003), online: Duke Law School website <http://www.law.duke.edu/trips/webcast.html> (date accessed and downloaded: October 25, 2010) [Technology Transfer].
operating in a market by licensing or FDI. Other factors are weighted more heavily, such as the capability of the host market to absorb and exploit the concerned technology, the real cost of transferring the technology involved, and the conventional determents for technology transfer such as the cost of other input factors, including transportation and the stability of the hosting country’s political and economic regimes.117

Correa similarly concluded that factors other than the level of patent protection may carry much more weight in MNCs decision-making calculus when they opt to invest in foreign markets.118 Such factors may include the availability of technical skills and market size and structure.119 In addition to the considerations mentioned by Correa, UNCTAD adds “per capita Gross Domestic Product (GDP), level of corporate taxation, trade balance …and political stability”.120

Besides the fact that empirical evidence on the impact of strengthening patent protection on FDI is anecdotal, an account of past investment activities of MNCs in the pharmaceutical sectors of some developing countries does not support this argument. Relative to other sectors, the pharmaceutical sectors in both Brazil and Turkey received greater flows of FDI after the two countries had abolished pharmaceutical product patents.121 By the same token, despite the unavailability of pharmaceutical product patents in Egypt during the 1970s and 1980s, FDI in the Egyptian pharmaceutical sector grew.122

The IPR Commission, which included renowned authorities in the field of intellectual property rights and developing countries Barton, as chair, and Correa, considered the influence of strong IPRs on the flow of FDI. After extensive research, the

119 Correa, ibid. at 28.
120 See UNCTAD, *Fostering Technology*, supra note 97 at 45.
121 See Correa, *Policy Options*, supra note 118.
Commission concluded, *inter alia*, that “[the] evidence that foreign investment is positively associated with IP protection in most developing countries is lacking”\(^{123}\).

Based on the preceding discussion and from a small, upper middle income developing country perspective, the following two conclusions can be made with regard to the impact of strengthening pharmaceutical patents on the rate of innovation, technology transfer, and FDI. First, it is highly unlikely that providing for strong patents in developing countries will enhance domestic innovation. This inference is supported by previous experiences of other nations, where minimal positive effects on the rate of indigenous innovative activities were realized after introducing strong pharmaceutical patents. The lack of strong domestic technical, industrial, educational, financial, and other pertinent capacities also supports this finding.\(^{124}\) Second, given the lack of evidence that strong patent protection, by itself, encourages FDI and technology transfer to large developing countries, one cannot see why the case would be different for small developing countries.

It may be claimed, however, that even if enforcing strong patent protection does not enhance domestic innovative activities, such enforcement is beneficial for the development of new and innovative drugs developed elsewhere. And, without providing for enhanced patent protection, pharmaceutical MNCs might not market their new products in developing countries. In addition, enhanced patent protection may make imitators in developing countries shift resources inefficiently allocated for developing

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\(^{123}\) See IPR Commission, supra note 78 at 24. Describing the commission’s extensive work, John Barton, Commission Chair, said:

> [we] first met on 8-9 May 2001, and have held seven meetings since. All or some of us have visited Brazil, China, India, Kenya, and South Africa, and we have consulted with public sector officials, the private sector and NGOs in London, Brussels, Geneva, and Washington. We visited the Pfizer research facility in Sandwich. A list of the main institutions we have consulted appears at the end of the report. We have commissioned seventeen working papers and held eight workshops in London on various aspects of intellectual property. And we held a large conference in London on 21-22 February 2002 to ensure that we could hear questions and concerns from many perspectives. We regard these sessions as important parts of our work in their own right. They brought together a range of individuals with a view to facilitating dialogue and exploring the scope for moving some of the issues forward.

See the preface of the Commission’s report.

\(^{124}\) According to Teece, these other capacities include services such as marketing, competitive manufacturing, and after-sales support, which are often obtained from complementary assets. See David J. Teece, “Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing and Public Policy” (1986) 15(6) Research Policy 285 at 288.
imitative capacity and activities to fund inventive activities with the probability of developing innovative products and processes. This would, in general, benefit both developing and developed countries by eradicating disincentives to innovation created by the chance to free-ride on the efforts and innovations of others.\footnote{See Adelman & Baldia, supra note 62 at 510; and see G. Mossinghoff & T. Bombelles, “The Importance of Intellectual Property to American Research-Intensive Pharmaceutical Industry” (1996) 31 Columbia Journal of World Business 38 at 45.}

On the issue of a linkage between patent protection in developing countries and an increase in R&D in industrialized countries that is of a level and scale such as to result in the development of such new, innovative drugs, reliable evidence establishing such a link is missing. Even if such a linkage is assumed, there is no guarantee that health sectors and patients in developing countries would benefit significantly from the new drugs. This skepticism is because such research is unlikely to focus on the health needs of developing countries. If such research does focus on their needs and successfully develop new drugs, they would be patent-protected, unaffordable, and, thus, inaccessible by most of the poor patients in developing countries. Despite these observations, I will next review the conclusion of some studies that have examined the overall welfare implications of extending strong IPRs regimes, patents in particular, to developing countries. The objective of this review is to uncover whether there has been any evidence that strong patent protection in developing countries would make the world better-off despite the negative effects that these countries may experience.

3.3. Patent Protection in Developing Countries and Aggregate Welfare Implications

The mandate of Article 27.1 of the TRIPS Agreement eliminated most of the flexibility allowed under the Paris Convention to its contracting states such as permitting them to exclude from patent protection sectors where they enjoyed a comparative advantage in imitation. Specifically, WTO members must make patent protection available in all fields of technology, even in those fields where such protection may prove disadvantageous to them. In addition, Article 33 stipulates a 20-year patent term counted
from the filing date; hence, depriving countries from providing for a shorter term when it would be considered optimal given their stage of economic development.126

Providing strong protection for pharmaceutical patents undoubtedly affects the social and economic welfare in developing countries. What remains debatable, however, are the scope and the extent of the social and welfare effects. In the words of Velasquez and Boulet, the negative effects of strong patent protection include significant costs to developing countries, including the increased prices of drugs, the cost of replacing or adapting the “existing infrastructures set up for the development of imitations of patented products” and the administrative costs of implementing and enforcing the Agreement.127

Several studies128 have analyzed the potential impact on developing countries’ social and economic welfare of implementing the minimum standards mandated under the TRIPS Agreement. In India, for example, where one of the most advanced pharmaceutical industries in the developing “South” has been thriving, Chaudhuri et al. estimated that Indian consumers stand to suffer a “substantial welfare loss”. Their analysis indicates that the negative impact of protecting patents in India is not only limited to the affordability of medicines, but also to their availability.129 In 1994, Subramanian observed that prices of medicines in Indonesia, where both pharmaceutical manufacturing processes and products were patentable, were 20% to 760% higher than prices of the corresponding medicines in India, which only protected pharmaceutical manufacturing processes. Given the profit-maximizing behavior of patentees based on “what the market can bear”, he anticipated that had product patents been available in

126 See Trebilcock and Howse, supra note 65 at 401.
India, prices would have been 10 fold those reported in Indonesia.\textsuperscript{130} Watal arrived at similar findings. She anticipated the likely increase in pharmaceutical prices associated with the introduction of product patents for 22 drugs could be in the range of 26\% to 242\%.\textsuperscript{131}

Xuan Li recently carried out a comparative study to analyze how China’s patents system, which has protected pharmaceutical product patents since 1993, influenced the development of the country’s indigenous pharmaceutical industry. Compared to India, where product patents were only made available in 2005, the study concluded that China experienced lower levels of drug accessibility and affordability. In addition, the study found India far ahead of China in terms of pharmaceuticals-related R&D investments and patent filings. Li attributed the lagging state of the Chinese pharmaceutical industry to the stifling effect of product patents and recommended that governments in developing countries make maximum use of the flexibilities and safeguards available under the TRIPS Agreement.\textsuperscript{132}

One important implication of the Li’s study follows from the conclusion that India experienced dynamic development gains by only providing patent protection for pharmaceutical manufacturing processes, but not for products. This conclusion implies that the lack of product patent protection in India facilitated the application of foreign technology by Indian manufacturers. This is similar to Germany’s experience before 1967 where only process patents were afforded to pharmaceutical inventions.\textsuperscript{133} It seems that this level of protection facilitates the local industry’s quest for acquiring or transferring the necessary technology, which in turn leads to expansion in production.\textsuperscript{134}

\textsuperscript{130} See Subramanian, ibid. at 9-10.


\textsuperscript{133} See Boldrin & Levine, supra note 23 at 245.

\textsuperscript{134} Imitation as a process of learning improves the capacity of manufacturers to absorb technology developed by others. The OECD (Organization for Economic Co-Operation and Development) defines capacity as “the ability of firms to learn and use the technology developed elsewhere through a process that involves substantial investments, particularly of an intangible nature”. See OECD, Technology and the Economy: The Key Relationships, (Paris: OECD, 1992) at 17. In addition, following the initial phase of absorptive capacity building, a lax regime of patent protection enabled the firms in these countries to improve their productivity and “to adapt product, process and organizational technologies already developed elsewhere to local conditions”, a process that Mytelka calls “catching-up” which depends upon
Large scale production leads to more profits and provides the necessary capital to finance R&D activities. In contrast, Li’s study demonstrates that product patents have not resulted in technological and economic dynamic benefits for China in terms of increased levels of investment in R&D or number of patent filings.\textsuperscript{135} That developing countries were likely to suffer welfare losses once they implement the mandate of the TRIPS Agreement was argued by several renowned economic theorists before the Agreement was concluded in 1994.\textsuperscript{136}

In a seminal study, Deardorff analyzed the implications of mandating strong patent protection in developing countries. He argued that extending such protection will benefit inventors located in developed nations at the expense of poor consumers in developing countries. Deardorff, therefore, recommended a complete exemption from the obligation to provide for patent protection for certain countries in the South. He also marinated that such exemption may, in the aggregate, maximize the world’s welfare.\textsuperscript{137} Specifically, he based his argument on three factors. First, the extra revenues accruing from extending patent protection to poor countries are unlikely to be significant enough to incentivize more innovation by patentees in industrialized countries. Second, even if these extra revenues induced innovation, losses suffered because of banning imitation in developing countries would be far more substantial. Third, this extension is likely to cause a reduction in global allocative efficiency since resources in developing countries

\textsuperscript{135} See Xuan, supra note 132 at 1375-6.
\textsuperscript{137} See Deardorff, ibid.
will be withdrawn from imitation, in which they have a comparative advantage, and extended to innovation where they have only a nominal comparative advantage.\textsuperscript{138}

The work of Deardorff confirmed the observations of a model developed by his precursors, Chin and Grossman.\textsuperscript{139} They concluded that the South will be worse off as a consequence of implementing strong IPRs and demonstrated that it may be in the interest of developing countries to provide no patent protection at all. They suggested that extending patent protection to developing countries would enhance global welfare only if it resulted in “substantial innovations”.\textsuperscript{140} According to Deardorff’s analysis, innovations of such a scale are unlikely as a result of extra revenues collected because of patent protection in developing countries.

Despite all indications about the negative effects of strong patent protection in developing countries, they have committed themselves to the minimum standards of IPRs protection under the TRIPS Agreement. They, subsequently, had to implement the Agreement’s minimum standards in their national laws. Thus, they had to undertake the arduous task of reforming their patent regimes to enact the necessary legal rules on product patents during what Reichman calls “a complicated set of transitional arrangements”.\textsuperscript{141} The transitional phase for higher standards of patent protection proved to be very difficult for many developing countries. This is particularly true in the pharmaceutical sector where patent protection was either weak or non-existent prior to the TRIPS Agreement. Rooted in this weakness were strong established domestic interests, namely generic manufacturers, which had legitimately profited from imitation, and the consuming public, which had enjoyed access to low-priced medicines. Together, these two interests brought pressure to bear on governments in developing countries against enhanced patent protection.\textsuperscript{142}

\textsuperscript{138} Ibid.
\textsuperscript{139} Chin & Grossman, supra note 136.
\textsuperscript{140} Ibid. at 23-4.
As the case against strong patent protection in the pharmaceutical sector was developing during the transitional period, developing countries sought to minimize the negative effects of the new standards which they committed themselves to under the TRIPS Agreement. Many developing countries believed that limiting patentees’ exclusive rights through use of the so-called “TRIPS flexibilities” and safeguards would provide the necessary antidote for these drawbacks.143

4. TRIPS Flexibilities: Wrestling over Implementation

The TRIPS Agreement contains certain flexibilities that are available not only to industrial countries, but to developing countries as well. However, some of the provisions regulating these measures are ambiguous (called by some scholars a constructive ambiguity).144 This ambiguity has led to serious difficulties for developing countries wishing to implement and utilize such flexibilities and sometimes such implementation was contentious.145 Contentions and challenges have been much less about what these flexibilities are, rather they have been about the scope and extent of the available ones.

Correa, appealing to Articles 7 and 8 and from a developmental perspective, argues that the TRIPS Agreement leaves “considerable room” for national laws to address two broad issues. The first relates to the definitions of many legal concepts used in Article 27 of the Agreement; for example, invention, novelty, inventive step, and ordre public. The second concerns parallel importation (Article 6, Exhaustion of rights) and exceptions to the patentee’s exclusive rights.146 Besides Compulsory licenses (Article 31, Other Uses), Correa identifies several specific exceptions under Article 30 (Limited Exceptions);147 for example, an Experimental Exception, the “Bolar” Provision,148 and

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143 Ibid. at 106.
144 This phrase is commonly used to explain the reason behind ambiguous language used in many provisions of the WTO agreements; a strategy for successful negotiations by providing a text that can be dynamic in application and through interpretation. As to the use of the phrase in the TRIPS Agreement see Carvalho for a description of what he calls a “dynamic diminution of the TRIPS Agreement” as a means to provide dynamic construction to the meaning of many provisions of the agreement, such as Articles 6 and 27, through decisions adopted by the WTO Dispute Settlement Body, see Nuno Pires de Carvalho, The TRIPS Regime of Patent Rights, (London/ The Hague/New York: Kluwer Law International, 2003) at 27.
145 See Watal, “Legislative Strategies”, supra note 142 at 106.
146 See Correa, Policy Options, supra note 118 at 49-93.
147 Ibid.
the Prior Use Exception.\footnote{149} The next section briefly addresses the arguments for and against specific issues related to two of these measures that are very critical in securing access to pharmaceutical products before patent expiration: compulsory licenses and parallel importation.

4.1. Compulsory Licenses under Article 31 (Other Uses) and Developing Countries

Article 31 of the TRIPS Agreement makes explicit reference to grounds on which member countries may issue compulsory licenses, provided that they are in compliance with certain conditions specified therein. These grounds are: (1) emergency and extreme urgency, (2) anti-competitive practices, (3) public non-commercial use, and (4) dependent patents. That these grounds constitute a basis for issuing compulsory licenses is not a disputed legal matter among WTO members and legal scholars. However, they disagree on whether grounds other than these may serve as a basis for granting compulsory licenses. The debates are mainly focused on two particular grounds. The first ground is insufficient or non-working of patents within the territory of a patent-granting country. The second relates to grounds reflective of the public interest such as high prices of medicines and a refusal to license a patent to a local enterprise offering reasonable remuneration in exchange for the requested license. It should be noticed that in support of their argument, those involved in these debates rely on Paragraphs 4 & 5 of the Preamble.

\footnote{149} The “Bolar Provision”, also referred to as the “regulatory exception”, is an exception to the patentee exclusive rights to use and make a patented invention. This exception allows manufacturers of generic medicines to use a patented product in order to obtain marketing approval, from the health authorities responsible for the grant of such approval, before the expiry of the relevant patent and without consent of the right holder. The establishment by national legislations of a Bolar-like provision was upheld by a WTO Dispute Ruling as legitimate under the TRIPS Agreement. See WTO Panel report, \textit{Canada – Patent Protection of Pharmaceutical Products}, WTO Document WT/DS114/R, adopted by the Dispute Settlement Body (the “DSB”) on 7 April 2000. For a discussion of this provision and other exceptions, see Carlos M. Correa, “The International Dimension of the Research Exception” (2004), online: The American Association for the Advancement of Science \texttt{<http://sippi.aaas.org/Pubs/Correa International%20Exception.pdf> } (date accessed: October 20, 2010) [Research Exception]; for a criticism of this Ruling, see Robert Howse, “The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times” (2000) 3(4) The Journal of World Intellectual Property 493; see also UNCTAD- ICTSD, \textit{The Research and Experimentation Exceptions in Patent Law: Jurisdictional Variations and the WIPO Development Agenda}, UNCTAD- ICTSD Project on IPRs and Sustainable Development, Policy Brief Number 7. March 2010, (authored by Evans Misati & Kiyoshi Adachi), online: UNCTAD \texttt{<http://www.unctad.org/en/docs/htdocs/prs_in20102_en.pdf> } (date accessed: October 20, 2010).

\footnote{149} See Correa, “Research Exception”, ibid. at 88.
to the TRIPS Agreement,\textsuperscript{150} Article 2(1), which by reference incorporated Article 5 of the Paris Convention\textsuperscript{151} in the TRIPS Agreement,\textsuperscript{152} Article 7 (Objectives),\textsuperscript{153} and Article 8 (Principles).\textsuperscript{154}

\textbf{4.1.1. Non-Working, Refusal to License, and Compulsory Licensing}

Carvalho claims that compulsory licenses cannot be granted on the basis of insufficient or no local working\textsuperscript{155} of a patented invention, or due to patentees refusing to license their patents. His claim is based on the following arguments: compulsory licenses have a “harmful” impact on both patentees and issuing countries, they are exceptions that should be limited, and they deny patentees their fundamental right to “say no”. He argues that compulsory licenses issued on such grounds are injurious to granting-countries, since such licenses hinder the establishment of research-based industries. Carvalho adds that the latter factor is relatively important with respect to easily copied innovations such as those of pharmaceuticals.\textsuperscript{156} As to his specific objection to issuing compulsory licenses for a lack of local working of patents, he contends it violates Article 27.1 of the TRIPS Agreement,\textsuperscript{46} Paragraph 4 of the Preamble reads “[recognizing] the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives”; Paragraph 5 reads “Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base”. See the TRIPS Agreement, supra note 4.

\textsuperscript{150} Paragraph 4 of the Preamble reads “[recognizing] the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives”; Paragraph 5 reads “Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base”. See the TRIPS Agreement, supra note 4.

\textsuperscript{151} The relevant part of Article 5 (5A(2)) reads “‘[each] country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work’”.

\textsuperscript{152} Article 2.1 of the Agreement reads “In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967)”.

\textsuperscript{153} Article 7 of the Agreement reads “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.

\textsuperscript{154} Article 8 of the Agreement reads:

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

\textsuperscript{155} The phrases “non-working”, “failure to work”, and “lack of local working” are used to mean the same thing.

\textsuperscript{156} See de Carvalho, supra note 144 at 231.
Agreement, which implies that such licenses may not be granted based on this ground. Subramanian\textsuperscript{157} and Braga\textsuperscript{158} seem to be in support of this argument. In relation to the ground of refusal to license, Carvalho maintains that it may not qualify as a ground for issuing compulsory licenses. He thinks if licenses are granted on this basis, they would amount to an “outright impairment of the patent right itself” and, hence, would be in contradiction with the essential objectives of the TRIPS Agreement.\textsuperscript{159}

Correa disagrees with the above argument. He maintains that pursuant to the Preamble and Articles 7 and 8 of the TRIPS Agreement technology transfer is one of the Agreement’s objectives. In some conditions, this objective may be achieved through compulsory licensing, particularly when there is a lack of local working of patents, including as a result of a denial of voluntary licensing.\textsuperscript{160} With regard to this ground, Correa argues that the “like treatment” stipulated by the non-discrimination clause of Article 27.1 is meant to address the manner with which countries treat infringing products, whether imported or locally produced. He adds that this is not the case in establishing non-working as a ground for compulsory licensing. Correa emphasizes that his argument is supported by an interpretation of what exactly is meant by “patent rights” mentioned in Article 27 in light of the nature of such rights as delineated under Article 28.1 of the Agreement. Article 28.1 requires members of the WTO to grant patentees the right to “exclude” others from using, selling, etc., which are negative rights.\textsuperscript{161} In addition, the Agreement does not enjoin members from establishing grounds other than those mentioned in the Agreement, including non-working and “in order to protect the environment or for reasons of ‘public interest’”.\textsuperscript{162}

Champ and Attaran argued for the right of WTO members to grant compulsory licenses on the ground of insufficient or no local working. In their opinion, this is an

\begin{footnotesize}
\begin{enumerate}
\item[\textsuperscript{157}] Arvind Subramanian, “Intellectual Property Post-Seattle: Challenges for India as User and Creator” (1999) Paper presented at the workshop on South Asia and the WTO, New Delhi December 20-21,1999, Footnote 9 at 9 [Post-Seattle]. Subramanian stated that “[the] only ground on which compulsory licenses cannot be granted is non-working of the patent locally”.
\item[\textsuperscript{159}] Ibid. at 232.
\item[\textsuperscript{160}] See Correa, \textit{Policy Options}, supra note 118 at 91.
\item[\textsuperscript{162}] Ibid. at 313.
\end{enumerate}
\end{footnotesize}
established ground under the TRIPS Agreement based on several justifications, including the following. First, the negotiation history of the TRIPS Agreement indicates that local working was proposed as a “permissible exception to patent rights” to accommodate the conflicting positions of the United States, in trying to bar any remedy for non-working, and that of developing countries, which were seeking to make local working a mandatory obligation for every patent. Second, providing for the ground of non-working would not violate the non-discrimination clause of Article 27.1, since it is a general rule that ought to be read in conjunction with the specific provisions of Articles 31 and 30 of the Agreement. Third, pursuant to Article 5(A)2 of the Paris Convention, as incorporated into the TRIPS Agreement by Article 2, non-working is considered an abuse of patent rights (understood in the historical application of the article to mean failure to manufacture), thus subject to a remedial issuance of compulsory licensing. In line with Champ and Attaran’s argument, Halewood also argues for granting compulsory licenses based on the ground of non-working pursuant to Article 5(A) 2 of the Paris Convention.

Furthermore, Thomas Cottier maintains that WTO members are free to establish grounds of compulsory licenses as long as the members issuing such licenses comply with the relevant substantive and procedural conditions of Article 31 of the TRIPS Agreement. According to Cottier, Article 31 was drafted in its final version because

[developing] countries and Canada argued in favor of an obligation to work the patent domestically (i.e., excluding importation even on normal commercial terms). Exporting countries argued that importation should fully satisfy the

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164 Ibid.

165 Ibid. at 387; this interpretation of Article 5 of the Paris Convention has been adopted by Bodenhausen (a leading authority in matters related to the Convention); see Bodenhausen, supra note 30 at 70.


167 Cottier was the chief Swiss negotiator for TRIPs, dispute settlement, and subsidies during the Uruguay Round. He was Chairman and member of several GATT and WTO panels. See Thomas Cottier, “The Agreement on Trade-Related Aspects of Intellectual Property Rights” in Patrick F. J. Macrory, Arthur E. Appleton, & Michael G. Plummer, eds., The World Trade Organization: Legal, Economic and Political Analysis (New York, USA: Springer, c2005) 1043.
requirement of exploitation or working as economies of scale would not permit local “working” in the territory of every WTO Member.\footnote{168}{Ibid. at 1092.}

Finally, post-TRIPS legislative practices of some WTO members substantiated the preceding arguments with regard to the legitimacy of establishing non-working as a compulsory licensing ground under the TRIPS Agreement. In particular, there are countries that have implemented non-working of patents in their law as a legal ground of compulsory licensing.\footnote{169}{In 2001, Oxfam International conducted a review (draft) of comparative law. At the time of the review, the review found that the law and regulation of the following countries contain working requirements. Indonesia and Cuba (provisions like those in the Brazil law); Ghana, Ireland, South Africa, Sudan and Zimbabwe (based on former United Kingdom laws); Greece and Lesotho (compulsory licensing linked to local working); Turkey, Spain and Portugal (certificate of working required); and Sweden, Norway, Finland and Iceland (local working tied to reciprocity). The review also lists India, Israel, Zaire, Thailand, Pakistan, and Liberia. See Oxfam, \textit{Local Working Requirements and the TRIPS Agreement: Using Patent Law as a Means of Ensuring Affordable Access to Essential Medicines. A Case Study from the U.S.-Brazil Dispute}, (draft) (2001), online: Foundation for International Environmental Law and Development, Archive <http://www.field.org.uk/fielstwta.pdf>, cited in Carlos M. Correa, “The TRIPS Agreement and Developing countries” in Patrick F. J. Macrory, Arthur E. Appleton, & Michael G. Plummer, \textit{The World Trade Organization: Legal, Economic and Political Analysis} (New York, USA: Springer, c2005) 419 at 443 [TRIPS Agreement].}

For instance, the Brazilian 1996 Industrial Property Law (Law No. 9,274 of 14 May 1996 (effective May 1997)) established local working as a mandatory requirement. The law specifies that for a patent to be considered worked, the subject matter of such a patent shall be produced within Brazil.\footnote{170}{The inclusion of a local working requirement in Brazilian law was due to a pressure from local health-related interests; See Cohen, supra note 28.}


On the issue of refusal of patentees to license their patents voluntarily, several knowledgeable commentators have argued that this behavior may constitute a ground for an application for compulsory licensing.\footnote{172}{See, for example, Jerome H. Reichmann, “Compulsory Licensing of Patented Inventions: Comparing United States Law and Practice with Options under the TRIPS Agreement” (2006) (Paper presented to the AALS Mid-Year Workshop on Intellectual Property, Vancouver, Canada, June 14-16, 2006). Reichmann observed that “[i]nternational law clearly allows states to treat both excessive prices and refusals to deal as actionable abuses under the Paris Convention and the TRIPS Agreement”; see also Gianna Julian-Arnold, “International Compulsory Licensing: The Rationales and the Reality” (1993) 33 IDEA 349 at 349–55;}
alternative legal measures to guarantee the local working of patents without risking a violation of the non-discrimination clause of Article 27.1, Watal argues for enacting refusal to deal as a statutory ground of compulsory licenses, since such a ground “is not prohibited under Article 31”. Therefore, she encourages developing countries to include this ground in their law. 173 Musungu and Cecilia maintain that if a patentee refuses to license its patented invention, although approached by a local applicant offering a commercially reasonable contract, such a refusal may constitute a ground to make an application for a compulsory license. In support of their argument, they refer to the Patent Law of the People’s Republic of China. 174 In addition, Correa cites the Patent Law of Argentina, which authorizes the grant of a compulsory license as a remedy for a refusal to license. 175

In summary, the above-discussed literature makes the case that Article 31 of the TRIPS Agreement does not limit WTO member countries’ legislative freedom to establish grounds in their national laws that they deem reasonably necessary to trigger the submission of applications for the grant of compulsory licenses. If issued, the grant of such licenses must be in conformity with the procedural and substantive conditions of Article 31 of the TRIPS Agreement. In particular, there is a strong legal argument for establishing the grounds of non-working, refusal to deal, and high prices, which are consistent with the rules of the TRIPS Agreement. In addition, granting compulsory licenses on the particular ground of non-working most likely would not constitute a violation of the non-discrimination clause of Article 27.1.


173 See Watal, “Legislative Strategies, supra note 142 at 111.
4.2. Exhaustion of Patent Rights, Parallel Importation, and Developing Countries

In the context of patents, “Exhaustion of Rights”, or “First sale” as it is called in the US, means that once a patentee releases, or authorizes others (an assignee or a licensee) to release, into the stream of commerce goods embodying its patented invention, a patentee exhausts its rights over the goods. Consequently, control over so dispensed of goods is transferred to the buyer. The underlying philosophy of the doctrine is that extending control of right holders beyond the point of the first sale, where an economic return has accrued to them, means a grant of perpetual control over the goods embodying their inventions. Perpetual control, in turn, means stifling the free movement of goods and services that is crucial for all market-based economies. Therefore, no restrictions shall be imposed on the purchaser’s freedom to use or dispose of legitimately obtained goods.

Although it seems a simple concept at first glance, exhaustion of IP rights was one of the most difficult subjects during the negotiations of the TRIPS Agreement. Yet, the outcome is ambiguously reflected in Article 6 of the Agreement: “[for] the purposes of dispute settlement under this Agreement …nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights”. Negotiations on this issue focused on three designations of exhaustion. The first is national exhaustion, which means that patent rights are exhausted with the first authorized sale only within the territory of a patent-granting country. The second is international exhaustion. Under this doctrine, patent rights are exhausted with the first authorized sale of patented goods anywhere in the world. The third is regional exhaustion, where patent rights would be exhausted with the first authorized sale of patented goods in the market of any member of a regional market or its equivalent. This doctrine has been adopted by the European Union. During negotiations, some WTO members, including the United States and Switzerland, supported adopting a rule of national exhaustion. Others, developing

177 Ibid.
178 See Article 6 of the TRIPS Agreement, supra note 4 (emphasis mine)
countries, Australia, and New Zealand, advocated either an international exhaustion rule or allowing members the discretion to decide without any regulation of the issue under the TRIPS Agreement. Next, I will review the legal and economic debates on the international exhaustion of patent rights.

4.2.1. The Legal Arguments

International exhaustion of patent rights occurs once goods embodying a patented invention are placed in the market by, or with the consent of, the patentee anywhere in the world. Carvalho argues that this occurs only when such goods are accordingly disposed of by, or with the consent of, right holders for an importation of such goods by third persons to be considered as parallel. He adds that based on the doctrine of territoriality of patent protection, there is no exhaustion of rights when goods are first sold in a country where either the corresponding patent is invalid or nonexistent. Accordingly, any importation of such goods into a third country would constitute an infringement of the patentee’s exclusive right to import. This line of logic implies that if the law of a given WTO member permits the importation into its market of any such goods, the member would be in violation of Article 28 of the Agreement. The same would also apply to any importation of goods manufactured under a compulsory license, since they would be put into trade channels against the patentee’s will.

Correa advocates that a first sale with the consent of a right holder triggers the exhaustion of the patentee’s exclusive rights notwithstanding the legal status of the patent where the first sale takes place. In support of his argument, Correa cites the European Court of Justice’s confirmation of an interpretation of the Treaty of Rome in Merck vs Stephar. In this case, the court maintained that there was no patent protection for a product in the country of export was not a sufficient ground to ban the importation by third parties of the same product into a country where it is protected by a valid patent.

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180 Ibid.
181 See Carvalho, supra note 144 at 102-8.
182 Ibid. at 99.
183 See Correa, Policy Options, supra note 118 at 88.
Moreover, Correa seems to support the view that a first sale of goods produced under compulsory licenses may exhaust patent rights. In his opinion, the entitlement of the patentee to remuneration is served by the first sale of the goods “with the consent of the owner, a licensee or any other authorized person”. 184

According to Abbott, Articles 6 and 31(f) of the TRIPS Agreement are a textual basis for international exhaustion of patent rights that is triggered by the sale of goods produced under a compulsory license. 185 To support his argument, he articulates the following two grounds. First, since Article 6 of the TRIPS Agreement excludes the issue of exhaustion from being a subject of dispute settlement and that exhaustion “is not a specifically defined term”, it could be concluded that each member country is free to opt for the definition it reasonably deems appropriate. The second ground is based on the text of Paragraph (f) of Article 31. This Article requires that the authorization of a compulsory license “shall be…predominantly for the supply of the domestic market of the Member authorizing such use”. A corollary of this wording would be that the residual goods, the non-predominant percentage of the goods, may be imported by a third party without the consent of the right holder, although under different legal means that may include parallel importation. 186

4.2.2. The Economic Arguments

The preponderance of economic literature on international exhaustion and whether parallel importation of patented pharmaceuticals in developing countries should be allowed focuses on analyzing the socioeconomic implications of this policy measure. The approach followed is a cost/benefit analysis. Costs that developing countries may sustain if they follow a legal policy permissive of parallel trade in medicines may range

184 Ibid. at 87 (emphasis mine). The quote is not the wording that Correa used in support of his argument for the legitimacy of international exhaustion under the TRIPS Agreement. The quote is a provision of Article 34(d) of Decision 344 of 1993 of the Andean countries’ “Common Regime on Industrial Property”.
186 Ibid.
from higher drug prices, relative to the possible prices absent parallel trade, to a complete suspension of introduction of new medicines in their markets by drug originators. 187

According to Malueg and Schwartz, a restriction on parallel trade between developed and developing countries would enhance the social welfare in the latter and globally. The logic underlying their view is one that espouses price discrimination in international trade. 188 In other words, a ban on parallel trade, would allow right holders to “selectively lower prices” in developing countries. If parallel trade is permitted, low-priced products would be re-exported to developed countries. Once they realize that low-priced products are diverted to high-priced markets, right holders would follow uniform pricing, assumed to be higher for developing countries, to protect their rich markets. Malueg and Schwartz, therefore, suggest that rules permissive of parallel importation may reduce global economic welfare, 189 since they lead to international price unification, making products less affordable to consumers in the developing South. 190

Scherer and Watal empirically examined the validity of the argument that pharmaceutical MNCs would maintain lower price levels for their HIV/AIDS products in developing countries if they could keep the markets for their products segmented. They analyzed data representing sales, sales revenues, and quantities sold of about 15 AIDS’ Anti-retroviral medicines over five years in 18 low or middle-income countries. 191 Out of 465 cases, prices in the panel countries were higher than those in the US in 98 cases, in some instances substantially. 192 Scherer and Watal offered five possible explanations for the apparent lack of correlation between product prices and per capita income.

188 In a patent context, a product is price-discriminated when the same product is placed in two different markets by the same right holder or with its authorization where its price in one of the markets is lower than that in the other.
189 See Malueg and Schwartz; supra note 187 at 184-192.
190 Ibid. at 193.
191 These countries are Argentina, Brazil, Central America, Chile, Colombia, the Dominican Republic, Ecuador, French West Africa, India, Indonesia, Malaysia, Mexico, Peru, the Philippines, South Africa, Thailand, Uruguay, and Venezuela.
First, multinational drug companies may find it more profitable selling only to the “affluent minority” in developing countries. Second, demand functions facing drug companies in real pharmaceutical markets may not reflect a straight-line demand curve as theoretically predicted.\(^{193}\) Third, low-priced drugs may be diverted from the markets of developing countries to those of developed ones, causing substantial profit reduction if so priced. Fourth, stringent price control regulation in many affluent markets may keep prices for medicine lower than in developing countries. And, fifth, MNCs may fear that if they sell their drugs in developing countries for lower prices, such prices may be used as benchmarks by health regulators in developed countries.\(^{194}\) Based on their analysis and these possible explanations, Scherer and Watal recommended that parallel importation “should be allowed” in developing countries under certain conditions to mitigate “the adverse consequences from multinational drug providers’ niche-pricing strategies”.\(^{195}\)

Although supported by sound legal, economic, and trade arguments, the utilization of the above-discussed policy measures by developing countries has proven difficult, often contentious. For example, Brazil’s legitimate codification of non-working of patents as a compulsory licensing ground for preventing abuses of patent rights provoked the American government to request the opening of consultations with the Dispute Settlement Body claiming that the Brazilian local working measure violates Articles 27 and 28 of the TRIPS Agreement.\(^{196}\) Subsequently, the two countries settled this dispute. In the settlement, Brazil agreed that “in the event it deems necessary to apply Article 68 to grant compulsory license on patents held by the U.S. companies, to hold

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\(^{193}\) A straight-line demand curve depicts the relation between the price elasticity and the demand curve when there is a constant change in price elasticity on the demand curve with constant slope. Since they suggest in their study that pharmaceutical companies target the affluent segments of developing countries’ population, demand on the drugs produced by these companies may be inelastic. In other words, demand may not decrease in response to and following a price increase. This may be explained by the value that the affluent people in developing countries associated to the drugs vended by these companies, and to their purchasing power, which makes them demand the product regardless of an increase in prices.

\(^{194}\) See Scherer and Watal, supra note 192 at 44-48.

\(^{195}\) Ibid. at 49.

prior talks on the matter”. However, the disputed provision of the Brazilian patent law remains unchanged.

Another example on these conflicts is the lawsuit brought by 39 pharmaceutical companies against the government of South Africa in 1998. The case challenged the conformity with the TRIPS Agreement and the Constitutionality of specific provisions of the South African Medicines and Related Substances Control Amendment Act, which would authorize the South African Minister of Health, inter alia, to issue compulsory licenses for manufacturing or importing affordable medicines. Following intense international pressure, particularly from International NGOs (Non-Governmental Organizations), the claimant companies ultimately dropped the case on April 19, 2001.

4.3. Pharmaceutical Patents and Public Health: the Doha Declaration “a Change in the Wind”

Disputes over the use of flexibilities and support by vigorous campaigns organized by international NGOs199 emboldened developing countries to initiate discussions on the above issues in the WTO Council for TRIPS. During these discussions, developing countries insisted that the Council should address the issue of their rights to enact and invoke the policy tools allowed under the TRIPS Agreement. They also demanded this matter be considered before the launch of a new round of trade negotiations in Doha.200 Since the measures, compulsory licenses and parallel importation, contested in the two disputes mentioned earlier would have been invoked in

199 See IPR Commission, supra note 123 at 165.
the fight against the HIV/AIDS pandemic, those who challenged this legitimate use were morally exposed to the public as they were perceived to be trading life for profit.201

In addition, after the 9/11 terrorist attacks, massive bioterrorist attacks were feared, particularly in the US and Canada. This incident has led to demands of urgent access to Cipro (an antibiotic used in treating different types of bacterial infections, and it may be used to prevent or slow anthrax after exposure). At the time, Cipro was still protected by patent. The United States, however, threatened to issue a compulsory license for manufacturing and stockpiling the drug notwithstanding the willingness of the patentee, Bayer Corporation, to provide the necessary quantities.202 The American action was preceded by a similar move by the Canadian authorities. The Canadian Health Ministry “commissioned” a local drug company to make generic copies of Bayer’s ciprofloxacin (effectively, issuing a compulsory license). As a result, Bayer donated a large quantity to the Canadians and promised more in case of an emergency.203

Before the Cipro episode, the American government had opposed the demands of developing countries with regard to the disputed measures. This stand changed after this incident. According to Correa, the “Cipro event” brought pressure to bear on the US, which ultimately led to its consent to the proposed agenda for discussion in the Council for TRIPS on “Public Health and the TRIPS” before the Doha Round of trade negotiations.204


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These efforts and events subsequently developed into three “episodes” on the impact of the TRIPS Agreement on public health in developing countries. First, in 2001, WTO ministers adopted a separate declaration on this matter in Doha, Qatar, The Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration, or the Declaration). Second, WTO members decided to waive the obligations under certain provisions of Article 31 of the TRIPS Agreement in August of 2003. And third, the WTO General Council decided to amend the TRIPS Agreement in September 2005. Although I will analyze and critique these three sequences in detail in Chapter Three, they are briefly reviewed next.

4.3.1. The Doha Declaration on TRIPS and Public Health

The Doha Declaration addressed many issues of particular importance for developing countries. It explicitly affirmed the right of developing countries to implement in their legislation the various inherent flexibilities of the TRIPS Agreement. In that regard, the Declaration proclaimed that the Agreement “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all”. Many commentators considered the Declaration an important step in the struggle of developing countries to secure access to affordable medicines.

Vandoren accurately observed that the Declaration elucidated the relationship between the TRIPS Agreement and policies related to public health. For Correa, the Declaration provided developing countries with the legal certainty they were seeking, since it affirmed that the Agreement was not concluded solely to protect the interests of patentees, but that it is also capable of accommodating the national policies of developing countries in sectors critical to their social and economic development, particularly public

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206 See Paragraph 4 of the Doha Declaration, ibid.
208 See Vandoren, ibid.
health. The Declaration also emphasized that the objectives of the Agreement should be considered and weighed against the overall public interest of society. Furthermore, Abbott concluded that Paragraph 4 of the Declaration represents the most significant accomplishment of the Declaration, potentially since it constitutes a decision of WTO members, based on both its “operative language” (drafted in an agreement format), and because the paragraph was adopted unanimously.

Further, the Declaration clarified that Article 31 of the Agreement does not restrict the rights of WTO members to establish grounds of compulsory licenses. It also confirmed their rights to decide on their own policy on the exhaustion of IP rights and authorization of parallel importation. With regard to compulsory licenses, Paragraph 5 of the Declaration clarified in detail the availability of such measures under the Agreement. Therefore, the paragraph confirmed the rights of developing countries to

209 Professor Correa maintains that this certainty stems from the Declaration being a strong political statement and a Ministerial Decision with legal effects on both members and institutions of the WTO. He further explains that

[it] is implicit within the Doha Declaration that differentiation in patent rules may be necessary to protect public health. The singling out of public health, and in particular pharmaceuticals (Paragraphs 6 and 7), as an issue needing special attention in TRIPS implementation constitutes recognition that public health-related patents deserve to be treated differently from other patents (emphasis mine).

See Correa, “Doha Declaration, supra note 204 at 42.

210 This point is particularly important, in light of the widely criticized view adopted by the WTO Panel in the Canada Patent Protection Case (see WTO, Report of the Panel in Canada – Patent Protection of Pharmaceutical Products, supra note 148), for future interpretation of the Agreement’s provisions. In that case and by considering the meaning of the expression “limited” in Article 30 of the TRIPS Agreement, the panel found that a provision in the Canadian Patent Act (Section 55.2(2)), which authorized manufacturers of patented products availing themselves of a regulatory exception to produce and stockpile the products during a certain period before a patent expiry (see Paragraph 7.7. of the decision) constitutes an exception that is not limited, thus violating Article 30 of the Agreement (Paragraphs 7.36 and 8.1(1)). The interpretation of the relevant TRIPS’ Article adopted by the panel indicated that it was exclusively concerned with the interests of right holders and ignored those of society as enshrined in the objectives behind enacting the disputed exception. That is, as Trebilcock and Howse put it, “…the panel was only interested in how much the right holder might lose, not in how much society might gain”. (See Trebilcock and Howse, supra note 65 at 418; and see Howse, supra note 148). Given the Doha Declaration, ignoring the interests of the public might well be indefensible when dealing with exceptions to patent rights. This reading is provided for in Paragraph 5(a) of the Declaration, the relevant part of which reads “…each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles” (for more details on this point, see Abbott, “Doha Declaration”, supra note 185 at 493).

211 See Abbott, “Doha Declaration”, supra note 185 at 491.

212 Ibid.


214 Ibid.
enact in their national legislation, without fearing legal challenges by developed countries, grounds such as non-working of patents locally, refusal to license on reasonable commercial terms, and unreasonably high drug prices.  

Despite its far-reaching importance, the Declaration left unresolved the so-called Paragraph (f) problem. Article 31(f) of the TRIPS Agreement bans the issuance of compulsory licenses for the exclusive purpose of exportation; production under such licenses shall be predominantly for the supply of the market of the issuing country. Consequently, developing countries with insufficient or no pharmaceutical manufacturing capacity would be unable to make effective use of compulsory licenses, since they lack local manufacturing capacities to work such licenses locally. Therefore, importation would be the only mechanism left for them to obtain the necessary drugs and from sources other than originators. On the other hand, if the medicines they need are also protected by patents in potential exporting countries, this would require issuing a compulsory license by a foreign country in order to manufacture such medicines by third persons. But, as explained above, Article 31(f) does not permit issuing such licenses for the exclusive purpose of exportation. Paragraph 6 of the Declaration mandated the Council for TRIPS to find an “expeditious solution” to this problem.

4.3.2. A Solution for Paragraph 6: the 2003 Decision of the WTO General Council

The mandate to the Council for TRIPS to find an expeditious solution to the problem of difficulties faced by countries without pharmaceutical manufacturing capacity

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216 See Bryan, supra note 213 at 212.
217 See Bryan, supra note 213 at 214; and see Abbott, “Doha Declaration”, supra note 185 at 497-501.
218 The legal side of the problem was then perceived to stem from both Article 31(f) of TRIPS and the coming to an end in 2005 of the transitional allowed to developing countries that, at the time the TRIPS was signed in 1994, did not provide for pharmaceutical product patent protection to fully comply with the TRIPS standards by 2005.
219 Paragraph 6 of the Declaration reads:

[we] recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

See Doha Declaration, supra note 205.
in making effective use of compulsory licenses was debated by negotiators\textsuperscript{220} and extensively analyzed by scholars\textsuperscript{221}. Debates in the Council focused on the substantive elements of the solution to identify the most suitable legal means to implement the mandate of Paragraph 6. By and large, three broad sets of issues were debated: the scope of diseases to be covered, the eligible countries (whether as importers or as exporters), and the identification of provisions of the TRIPS Agreement as a potential solution to tackle this problem\textsuperscript{222}. The Council, subsequently, has considered the following four proposals:

- [an] authoritative interpretation of TRIPS Article 30, authorizing third parties to make, sell and export pharmaceutical products without the consent of the patent holder;
- An amendment of TRIPS Article 31, authorizing exports of medicines produced under a compulsory licence to a country with insufficient manufacturing capacities;
- A dispute settlement moratorium with regard to the non-respect of the export restriction under Article 31(f); or
- A waiver with regard to the export restriction under Article 31(f)\textsuperscript{223,224}.

Two years after Doha, WTO members adopted a Decision\textsuperscript{225} (the Decision) on the implementation of Paragraph 6 of the Declaration, which is confined to the provisions


\textsuperscript{222} Abbott, “Medicines Decision”, supra note 102 at 327.

\textsuperscript{223} Bourgeois & Burns, ibid. at 835.

\textsuperscript{224} For a full discussion of these proposals regarding Articles 30, 31 and the moratorium proposal, including legal grounds as a basis for the solution, see Correa, “Doha Declaration”, supra note 204; and see Abbott, “Compulsory Licensing”, supra note 221.

of Article 31 of the TRIPS Agreement. The Decision contains two waivers. The first waived the limitation imposed by Article 31 (f) on exportation of production under compulsory licensing. It stipulates that countries may issue compulsory licenses for export purposes, according to certain conditions and procedures specified in the Decision, to members with no or insufficient pharmaceutical manufacturing capacity. The second waived the requirement of remunerating right holders, required under Paragraph (h) of Article 31, in the importing country if a compulsory license is issued by that country. However, the Decision is a provisional measure until replaced by an agreement among WTO members to amend the TRIPS Agreement.

The Decision was met with diverse reactions. Some considered the mechanism established by the Decision a success. Others, however, deemed it bureaucratically cumbersome and impractical. Furthermore, the Decision was criticized as containing many ambiguous concepts and criteria for eligibility – for example, how a developing country could be determined to lack sufficient industrial capacity in pharmaceuticals.

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226 See Mercurio, supra note 214 at 229.
227 See WTO, supra note 225.
228 Ibid. Paragraph 2.
229 Ibid.
230 Ibid. Paragraph 3 of the Decision.
231 Paragraph 11 of the Decision reads: “[t]his] Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision”.
233 Abbott embraced the different reactions made by various involved stakeholders when he stated “The leadership of the WTO hailed the Decision as evidence that the organization could deal effectively with important issues of social concern. However, the reaction among a broad cross-section of stakeholders was more tempered. Nongovernmental organizations (NGOs) concerned about access to medicines were disappointed by the complexity of the arrangement, arguing that it would be unworkable in practice. Similar misgivings were expressed by developing country producers of generic pharmaceuticals. Spokespersons for the group of pharmaceutical companies that engage in substantial research and development …said they welcomed the Decision as finally resolving an open issue, but these companies later lobbied actively in Canada to restrict implementing legislation. The developing countries that had led the negotiations expressed satisfaction with the result, but others harbored doubts. The United States accepted the Decision as a problematic compromise, but has since sought to limit its scope of application”.
235 See Abbott and Reichman, supra note 202 at 939.
Despite implementation by the European Community, Canada, Norway and others, the mechanism has attracted trenchant criticism. It has been utilized only once, by Canada. In this country, it was reported that the Canadian company to whom the license was issued declared its intention not to repeat the experience due to the bureaucratic and administrative complications and constraints involved on both the national and WTO levels. The issuance of a CL to a local pharmaceutical manufacturer to export medicines to developing and least-developing countries for humanitarian purposes requires undergoing multi-step process as stipulated under the relevant Canadian legislation, “Use of Patents for International Humanitarian Purposes to Address Public Health Problems”, (CAMR) which added a new section to the Patent Act (Section P-4) and was passed to implement the WTO’s 2003 decision. Besides prior negotiations to obtain a voluntary license from the right holder on reasonable terms and conditions, the Act stipulates that the Canadian producer identifies a would-be importer from (a developing country) and specify the needed quantities. The Act also limits the duration of such licenses for only two years, renewable under certain circumstances and conditions. Notwithstanding the above misgivings, the WTO transformed the Decision to a proposed permanent amendment to the TRIPS Agreement in 2005.

236 See Bill C-9, An Act to amend the Canadian Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa), of May 2004.
240 See the testimony of Richard Elliott (Executive Director, Canadian HIV/AIDS Legal Network) before the Canadian Standing Senate Committee on Banking, Trade and Commerce during its session to review Bill S-232 that was held on October 22, 2009.
243 For a critique of the CAMR regime, see Jillian Clare Kohler et al., “Canada’s Access to Medicines Regime: Promise or Failure of Humanitarian Effort?” (2010) 5(3) Health Policy 40.
4.3.3. Amending the TRIPS Agreement: The Decision of December 6, 2005

On December 6th of 2005, the WTO General Council decided to amend the TRIPS Agreement. The amendment consists of a waiver, Article 31bis, an Annex on the terms and conditions for the application of the waiver, and an Appendix providing basic guidance on the issue of assessment of pharmaceutical manufacturing capabilities of potential importing members. Although the deadline for the amendment to become effective is December 1, 2007, the amendment is not yet in force. The 2007 deadline was extended on December 17, 2009 for a second time, and the new deadline is 31 December 2011. By May 24, 2011, in addition to the EU, only 33 WTO members have ratified the Amendment.

The mechanism established by the Amendment, however, has been declared ineffective, and has failed to make affordable medicines more accessible for the needy populations in developing countries. Calls have already been made to consider a better alternative. The issue was placed on the Agenda of the WTO Council for TRIPS meeting held on October 27, 2010. In that meeting, inputs about alternative solutions to the waiver mechanism were contributed by the UN Organizations participating in the meeting such as the UNCTAD, WHO, and WIPO.

5. The Mandate of Article 39.3: Protection of Pharmaceutical Regulatory Data

244 For the text of the Decision, see WTO, Amendment of the TRIPS Agreement, WTO Document WT/L/641 dated December 8, 2005, online: WTO Homepage <http://www.wto.int/english/tratop_e/trips_e/wtl641_e.htm> (date accessed: November 02, 2010).
246 Ibid.
While compulsory licenses, their legitimate grounds, and parallel importation attracted most of the attention as the means for enhanced access to affordable medicines in the South, using these legal instruments might become a “paper boat”, useless for getting the medicines to those who need them. This will occur if entrepreneurs providing these drugs are not able to have them registered with national health authorities. Pharmaceuticals are strictly regulated; before a medicine, whether original or generic, can be placed on the market, it must be registered with drug regulators. Health regulators may register new drugs if their sponsors provide the necessary evidence of safety and efficacy of such drugs. The safety and effectiveness proof, regarding original medicines, is provided by submitting data developed by conducting extensive testing, pre-clinical and clinical, on a substance before undergoing a marketing authorization process.

Since, generally, drugs manufactured under compulsory licenses or imported from third markets are generic copies, constituting bioequivalent of their original counterparts, the safety and efficacy of these drugs can be established by submitting bioequivalence studies. These studies establish that a generic and its branded counterpart are bioequivalent, attesting that the two drugs are identical or very similar in their chemical composition and rate and extent of absorption when administered to humans. Once it is established that a generic medicine is the bioequivalent of an original drug, the safety and effectiveness of the former could be demonstrated by reliance on the testing data of the latter. The legitimacy of such referencing and reliance has become a contentious issue after the conclusion of the TRIPS Agreement. More specifically, Article 39.3 of the Agreement obligates WTO members to protect such data against unfair commercial use and disclosure. In this regard, if the drafters of the TRIPS Agreement intended to outlaw reliance by health authorities on originators’ data, policy measures such as compulsory licenses and parallel importation are seriously frustrated as flexibilities vital for making patented medicines affordable.

249 The word bioequivalence “refers to the speed and absorption by the body of the pharmaceutical, the active principle or its therapeutic fraction.” See Jean-Yves Videau, “Generic Drugs: The Hidden Issues of Quality and Costs” (2000) 14 WHO Drug Information 77 at 79, online: WHO Homepage <http://apps.who.int/medicinedocs/pdf/h1463e/h1463e.pdf> (date accessed: July 4, 2010); two products are regarded as being bioequivalent “if they are pharmaceutical equivalents or alternatives and if their bioavailabilities (i.e. the rate and extent of their absorption into the body and transfer to the site of action) after administration in the same molar dose are similar to such a degree that their effects, with respect to both efficacy and safety, will be essentially the same”) ibid. at Para. 31.
In addition, if it is implemented as demanded by certain WTO members, in the form of data exclusivity, the mandate under Article 39.3 itself will become detrimental to the availability of affordable medicines. Further, since the obligation of data protection is not dependent on the existence of a valid patent, such interpretation makes this obligation a far-reaching tool, capable of preventing competition in a pool of drugs that is much larger than that comprised of patented medicines. In other words, even when an original drug is off-patent, manufacturers of competing generic drugs may not be able to place their products in the market for the entire duration of data protection. Recently, this issue has elicited considerable attention and there is a growing body of literature on the nature, scope and extent of this obligation.

5.1. The Nature of the Obligation to Protect Regulatory Data under Article 39.3

There are persistent disagreements as to the nature of the obligation to protect testing data against “unfair commercial use” under Article 39.3.250 Some contend that this obligation can only be fulfilled by providing sponsors251 of applications for marketing authorization of new drugs with the exclusive right over the use of their testing data. This means that drug regulators should prevent third persons who do not have the permission of data proprietor from relying on such data to register a generic medicinal product.252

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250 Article 39.3 reads:

[members], when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use (emphasis mine).

See Article 39.3 of the TRIPS Agreement, supra note 4.

251 The words “sponsors”, “originators of the data”, “developers of the data”, or the like are used to mean the same: entity which submitted the Data to the regulatory authorities first in order to register a sponsored drug. Normally, this entity would be the company owning the drug, an assignee, or a voluntary licensee.

Many, however, reject this claim. They argue that the obligation under Article 39.3 does not mandate the creation of a *sui generis* proprietary right in testing data. Rather, this obligation can be discharged by protecting the testing data as *undisclosed information* and *under the general rules of protection against unfair competition*.253 Moreover, this line of argument maintains that interpreting the obligation to protect testing data against unfair commercial use to mean a requirement of data exclusivity is contrary to the negotiating history of Article 39.3, violates Article 31 of the Vienna Convention on the rules of treaty interpretation, violates Article 1.1 of the TRIPS Agreement, and constitutes “imposing unbargained-for trade concessions under a discredited ‘TRIPS-plus approach’”254 on developing members of the WTO. They also add that this interpretation “has no legal foundation whatsoever” in the TRIPS Agreement.255
5.2. Does Reliance by Health Authorities Constitute an Unfair Commercial Use of Test Data?

The other contentious issue with regard to protecting the testing data against unfair commercial use has to do with the scope of this protection. In particular, there are disagreements as to whether this obligation encompasses reliance by national health authorities on the originator’s data to authorize a subsequent generic version. Some developed countries claim that it does arguing, inter alia, that a regulatory reliance on originators’ data is an act of unfair commercial use covered by the provisions of Article 39.3.

Supporters of this reading of the obligations under Article 39.3 advance their view based on the following arguments. First, it is contended that the generation of testing data requires the commitment of extensive resources, making it very expensive, lengthy, and thus commercially risky. Reliance on the data to market a competing product saves a competitor the cost of developing its own data; hence, such reliance provides second entrants to the market with a considerable commercial advantage over originators by free riding on the efforts of originators. This reliance, it is claimed, intrinsically constitutes an act of “dishonesty” despite the fact that no acts of fraud or deceptions are involved. Second, testing data are developed for the single purpose of obtaining a marketing authorization of a sponsored drug, which is the only conceivable commercial use of the data. Therefore, reliance on the data by national health authorities to authorize a competing generic version represents an unfair commercial use.

Well-respected scholars on the topic reject this line of logic. Correa, for example, argues that the clear intention of negotiators was to protect testing data as undisclosed information (trade secrets) against dishonest commercial and industrial practices perpetrated by competitors and in the context of unfair competition law. Unfair competition does not include acts of governments, health regulators in the case of


257 See, for example, PhRMA 2010, supra note 252; and see Carvalho, supra not 252.
pharmaceuticals, since they do not compete with originators when they rely on their data.\textsuperscript{258} Accordingly, the mere fact that an advantage accrues to a competitor as a result of regulatory reliance does not render regulators’ reliance an unfair commercial use. Thus, claiming that reliance constitutes unfair commercial use is not based on a characterization of the act of reliance itself as intrinsically dishonest commercial behavior.

Moreover, given that the TRIPS Agreement does not specify reliance on originators’ data as an act of unfair competition, the issue of whether WTO members consider such a practice as unfair conduct is a matter left to their domestic law, provided that the legislation is in conformity with the Agreement.\textsuperscript{259} A considerable number of WTO members have asserted that they understand their obligations under Article 39.3 not to require protecting testing data beyond preserving their confidentiality by the competent national agency.\textsuperscript{260}

On the characterization of reliance by the regulator as a commercial use of testing data, it is persuasively argued that although reliance on the data leads to a new market entry, which represents a commercial result, such an outcome does not render a legitimate sovereign practice, as such, a commercial use.\textsuperscript{261} For a particular activity to


\textsuperscript{259} See Correa, ibid.


\textsuperscript{261} See Carlos M., Correa, Protecting Test Data for Pharmaceutical and Agrochemical Products Under Free Trade Agreements, UNCTAD-ICTSD Dialogue on Moving the Pro-Development IP Agenda Forward: Preserving Public Goods in Health, Education and Learning (Bellagio, 29 November – 3 December 2004) at 5, online: iprsonline.org
constitute commercial conduct, it must be carried out by an entity actually engaging in commercial activities. Governments, generally, are not entities engaged in commerce, particularly with regard to states’ legitimate regulatory functions such as marketing approval of medicinal products.  

State practice following the conclusion of the TRIPS Agreement supports the argument against data exclusivity. Many WTO members have provided pharmaceutical testing data with protection as confidential information against unfair competition, but have not afforded them exclusivity. In addition, it has been the practice to explicitly provide for data exclusivity in bilateral agreements concluded by the US which has been advocating that Article 39.3 of the TRIPS Agreement requires exclusivity; most of these agreements involved other WTO members. If Article 39.3 clearly meant exclusivity, there would have been no need to reiterate the same obligations in these bilateral covenants.


See, for example, the US-Australia, the US-Morocco, the US-Sultanate of Oman Free Trade Agreements, online: USTR Homepage <http://www.ustr.gov/trade-agreements/free-trade-agreements> (date accessed: November 03, 2010).
6. Concluding Remarks

The discussion in this chapter clearly indicates that whether developing countries benefited, or may in the future, from extending patent protection to pharmaceutical inventions remains obscure. In addition, PhRMA and developed countries in support of its interests have been questioning, often challenging, the scope and extent of developing countries’ rights under the TRIPS Agreement to enact and to invoke safeguard measures such as compulsory licenses and parallel importation. These issues remain contentious. Indeed, on May 18, 2011, on behalf of the African Group and the Development Agenda Group and in respect of a work program on patents and health, the South African Delegation to WIPO submitted a proposal to the organization’s Standing Committee on the Law of Patents.\(^{265}\) The proposal states that the sponsoring groups “are of the view that the patent system should be consistent with fundamental public policy priorities, and in particular the promotion and protection of public health”. They further emphasize that

[in] order to protect public health, the flexibilities and safeguards contained and allowed by the TRIPS Agreement would need to be incorporated in the national legislation. There is equally the need to ensure that international commitments, including regional and bilateral arrangements, do not restrict these flexibilities and safeguards. Moreover, these safeguards and flexibilities have to be workable in practice, particularly with respect to ensuring access to medicine.\(^{266}\)

Debates on the obligations of developing countries to extend patent protection to pharmaceutical inventions under the TRIPS Agreement also persist in scholarly works, as illustrated by the studies discussed in this chapter. For the most part, the analysis in these studies focuses on legal and economic policy, particularly the benefits from, and impacts of, implementing such obligations, as well as the most appropriate legal means to mitigate their likely impacts. However, the following observations about the reviewed studies can be made.


\(^{266}\) Ibid.
First, most of the literature has analyzed the protection of pharmaceutical patents in developing countries on a uniform basis. In other words, the analysis assumes that all developing countries are at the same development stage, but they are not. In addition, the legal and policy measures proposed to overcome the likely economic and social impacts of patent protection of pharmaceutical products are also recommended indistinctively, without taking into account the influence and impact that the context and localities may have on the efficacy of these measures in certain economies – for example, size of the economy or the availability of industrial capacity. Again, there is an underlying assumption that these mechanisms would work in all affected developing countries. This assumption has proven erroneous.

The incorrectness of a “one-size-fits-all” approach in the regulation of IPRs was indeed realized by WTO members, and thus identified by Paragraph 6 of the Doha Declaration, which acknowledged that the application of uniform rules and/or standards may result in varying outcomes in different countries. By the same token, a measure conducive to redressing abuses of patent rights in a given jurisdiction may not be equally appropriate in another. Focusing on Jordan as the case of this thesis will illustrate how such elements of the new patent system apply and work with regard to pharmaceuticals and in the context of one particular WTO member.

Second, the literature is mainly theoretical and the available empirical studies are cross-country or focusing on developing countries with large economies and advanced pharmaceutical industries and capacities such as China, India, and Brazil. In other words, the available empirical analysis on the actual impact of strong patent protection in the aftermath of the TRIPS Agreement is generally concerned with developing countries as a group, but not in a small, middle-income developing country setting. In addition, since it was only in 2005 that the transitional period for full compliance with the Agreement elapsed, an examination of the actual impact of implementing the Agreement’s obligations has not been feasible. That is, enforcement of these obligations by certain countries has not been long enough for a meaningful evaluation of their impact on those countries and, by extension, to similar developing countries. This thesis will help fill this gap as it has been almost 12 years since Jordan implemented the protection of pharmaceutical patents.
Third, the focus on large developing countries is also found in studies concerning the policy measures available to correct abuses of patent rights. By and large, if compulsory licenses and/or parallel importation work for Brazil and India, this does not necessarily mean that they will for Jordan or other similar economies. There are numerous asymmetries among developing countries, which may lead to different results when utilizing a given measure in different countries. This thesis analyzes whether the TRIPS Agreement’s flexibilities are as effective in Jordan as has often been claimed.

Fourth, the analysis in this thesis provides, from an upper middle income developing country perspective, a new examination of the impact not only of patent protection, but also of pharmaceutical testing data when an exclusivity provision is enforced. In addition, this thesis highlights the interplay between patents and data protection and the potential detrimental consequences for access to medicines as a result of this interaction. This emphasis should particularly clarify the influence that data protection may have on utilizing legal measures such as compulsory licensing and parallel importation. The inclusion in the analysis of this influence on access to essential medicines should improve our understanding of the true impact of the TRIPS Agreement. This is particularly important due to the following three factors. First, an analysis of the effects of the Agreement’s obligations in developing countries is incomplete without studying the impact of data protection. Second, data protection is not dependent on patents and relatively easy to obtain with the successful registration of a new drug. Third, in small, upper middle income countries such as Jordan, data protection has been resorted to as a monopolization mechanism alternative to patents when drugs might not be patentable, off-patent, or right holders opt not to patent, hence, thwarting the objectives of both the patent and data protection regimes.

Finally, as the case of this thesis, Jordan may provide valuable insights in the debate over extending patent protection for pharmaceuticals to developing countries and for multiple reasons. Jordan hosts a viable pharmaceutical industry that provides low-cost medicines not only to a considerable part of the domestic market, but also to over 60 export markets around the world. In addition, Jordan signed a free trade agreement with the United States (USJFTA) which, with regard to pharmaceuticals, mandated protection standards that are beyond those of the TRIPS Agreement. Therefore, the developmental
status of the industry after almost 12 years of stringent patent protection should be indicative of the true impact of such protection in developing countries, at least in those with conditions similar Jordan’s. If enhanced patent protection is conducive to positive outcomes, then such advantages would most likely materialize in Jordan. Whether strong patent protection in Jordan has been conducive to positive outcomes such as the promotion of technological innovation and the transfer of advanced technology will be examined in the next chapter.
CHAPTER TWO

Extending Patent Protection to Pharmaceuticals in Jordan: Costs or Potential Significance for Development?

1. Introduction

The 1999 Patents Law of Jordan introduced many changes to the national patent regime. The law, for example, extended patent protection to encompass pharmaceutical products on which patents could not be obtained since 1986. Article 36(b) of the law, other than rules on patent protection generally, contains the rules pertinent to the protection of pharmaceuticals. The article, in part, reads “[after] the enforceability date of this law, it shall be permissible to file patent applications for registering inventions involving the protection of final products for chemicals relating to pharmaceuticals or medicines or foodstuffs”.1 This article implements the mandate of Article 27 of the TRIPS Agreement, which requires Jordan to make patent protection available “for any invention… in all fields of technology”.2

The objectives underlying all articles of TRIPS, including Article 27, are reflected in Article 7 of the Agreement which reads:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.3

It is clear that the institution of a patent regime to regulate the issuance of patents and the subsequent protection and enforcement of exclusive rights derived thereof is not

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3 See Article 7, ibid.
an ultimate goal in and of itself. Rather, the patent institution is a mere mechanism that
should contribute to the economic development and growth of the concerned country. 4
Therefore, Article 7 came to codify the underlying policy objectives of the system sought
by the drafters of the TRIPS Agreement. 5 The emphasis on the objectives of intellectual
property (IP) protection generally and patents in particular reflects a compromise reached
during the Uruguay Trade Negotiations. 6 The compromise was reached in order to
reconcile the conflicting interests of two negotiating blocks, developed and developing
countries, over the scope and extent of patent protection.

On the one hand, developing countries were opposed to enhancing patent
protection by setting a minimum patent life (extent or length). They also opposed
restricting their discretion to issue compulsory licenses on patented inventions or to
extend patent protection to encompass subject matters like pharmaceuticals and food
stuff, which traditionally countries could exclude from patent protection under the Paris
Convention (scope or width of protection). Several arguments were advanced for their
stand. Most important was the argument that the preponderance of patents harvested in
developing countries were granted to foreigners and that most of them were not locally
worked. 7 Accordingly, the argument continues, patents became a means to protect export
markets in developing countries. In addition, instituting a stringent patent regime that is
robustly enforced would retard their imitation activities, perceived as necessary for the

4 See Edith Penrose, “International Patenting and the Less-Developed Countries” (1973) 83 The Economic
Journal 768.
5 See Carlos M Correa, “The TRIPS Agreement and Developing Countries” in Patrick F. J. Macrory,
Arthur E. Appleton, & Michael G. Plummer, eds., The World Trade Organization: Legal, Economic and
Political Analysis, (New York, USA: Springer Science, c2005) 419 at 437. A similar explanation, as to how
the objectives of the Agreement were formulated, is mentioned by Abbott with regard to Article 30. He
notes that “Article 30 of the TRIPS Agreement was adopted as a compromise solution following the
inability of negotiators during the Uruguay Round to agree on a list of exceptions to patent holder rights
that might be recognized by Members”. See Frederick M. Abbott, “Compulsory Licensing for Public
Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health” Quaker
<http://www.quno.org/geneva/pdf/economic/Occasional/Compulsory-Licensing.pdf> (date accessed:
December 15, 2010).
6 See Correa, ibid.
7 See Constantine V. Vaitsos, “The Revision of the International Patent System: Legal Considerations for a
Third World Position” (1976) 4(2) World Development 85 at 88 and 91-3; and also see Pedro Roffe,
transfer of needed foreign technology and for the development of needed local skills, which in turn contribute to their economic and social development and growth.⁸

For economic, political, social, and cultural reasons, developed countries, on the other hand, rejected this logic and advanced their case for an enhanced patent regime. They argued that patent protection is necessary to provide effective incentives for technological innovation and that imitation activity of Southern firms (firms located in developing countries) diminishes this incentive. In turn, the logic goes, the economic well-being of the South would be advanced by strengthening patent protection, which should lead to more innovation, but not through imitation. In addition, it was added that financial and technical capital is an important input factor for the development ambitions of the South. Foreign Direct Investment (FDI) and International Technology Transfer (ITT) are two important means to induce capital flows from developed to developing countries.⁹ If they are not assured the security of their Intellectual property rights (IPRs), owners of advanced technology, however, may not transfer it by either of these two means. Owners’ reluctance to transfer their technology would thus frustrate the achievement of the developmental objectives of Southern countries.

As mentioned above, Article 7 constitutes a reflection and representation of the claimed link between patents protection as part of the IPRs regulated by the Agreement and the means conducive to development such as innovation and technology transfer through licensing and FDI. This chapter investigates one question: whether protecting pharmaceutical patents in Jordan supports the argument that such a protection is conducive to the forgoing development benefits; or whether this experience further calls into question the extent to which this link is established in a developing country context.

To investigate the question raised in this chapter, I proceed as follows. Section Two will explore the relationship between enhanced patent protection and pharmaceutical innovation and the role of this protection in fostering economic growth and development in Jordan. Therefore, the section provides an overview and assessment of the national innovation system (NIS) in pharmaceuticals. The concept of NIS refers to a framework.

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⁹ See, for example, Richard Rapp & Richard Rozek, “Benefits and Costs of Intellectual Property Protection in Developing Countries” (1990) 24 Journal of World Trade 75; also see the discussion on these two points below.
embracing the following primary elements: the structure and capabilities of companies in
an industry, the related scientific and technological infrastructure in a country, and the
establishment of a coherent and supportive government policy for the industry concerned,
that determines the capacity of the country concerned in building and attracting advanced
and knowledge-intensive technology.\(^{10}\) The appraisal of the NIS helps clarify the extent
to which enhanced patent protection may influence levels of domestic innovation and,
thus, economic development and growth in Jordan. This assessment is important since the
overwhelming evidence available to date indicates that if enhanced patent protection is
advantageous to the South, its benefits are principally dependant on the developmental
stage and status of a particular industry in the country concerned as well as on the size of
its economy.

Section Three investigates the impact of the 1999 patents reform on technology
transfer *vis-à-vis* international licensing and FDI. Section Four explores the likely
implications for the availability and accessibility of medicine in Jordan. Finally,
concluding remarks are provided in Section Five. This chapter concludes that the strong
patent protection afforded pharmaceutical since the year 2000 has neither led to more
investment in R&D activities and innovation by the local pharmaceutical sector nor to
meaningful technology transfer.

**2. Patent Protection, R&D and Innovation, and the Jordanian Pharmaceutical Sector**

2.1. A Critique of the Incentive Theory

The underlying economic theory of the patent protection regime holds that if
inventors or developers of new innovative ideas, products, and/or processes are not
compensated for the full social value of their intellectual output, there would be sub-
optimal investment in research and development (R&D) activities. These activities are
very expensive to undertake and risky. However and given their “non-rival” nature, new
inventions may be copied by competitors with relative ease and at low cost once

developed and introduced to the public. Without a legal means that guarantees to researchers and inventors their entitlement to the exclusive exploitation of the fruits of their R&D, committing the necessary resources becomes a risky enterprise. The patent regime steps in and provides this assurance, thus, addressing a market failure, leading to the allocation of sufficient resources to economically and socially desirable innovative activities.11

It should be emphasized here that the patent regime is not designed only to advance the well-being of researchers and inventors. Rather, its focus is on the users of the innovative output and ensuring that more inventions are available to them, which arguably requires the granting of proprietary rights in the form of patents. The essence of the economic theory underlying the patent system is captured in the wording of the US Constitution, which states that the granting of IPRs is to “promote the Progress of Science and useful Arts.” The functionality of this theory as depicted in this constitutional phrase was explained by the US Supreme Court, although in the context of copyright law, in the landmark case: Mazer v. Stein (1954). The court in that case said:

[the] economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in "Science and useful Arts." Sacrificial days devoted to such creative activities deserve rewards commensurate with the services rendered.12

At the center of this logic is the free-rider problem.13 That is, innovators will be much less likely to invest in a particular activity if a third party (the free rider) can appropriate, capture, or partake in a significant share of the economic return of the innovation in question without incurring any development costs.14 To avoid this, a private property right should be conferred upon the inventor or the creator of innovative products and/or processes. Hence, participation in the benefits derived from the inventive work by

14 Ibid.
any private person in society must be with the consent of the creator and for the consideration it demands. The price paid should compensate the creator and reward it for its work and, hence, spur creativity. Patents, which act to limit activities of imitation and competition, create a quasi-rent for innovators and, therefore, stimulate creative activities.15

Besides assuming that a society has the R&D capacities – for example, skilled researchers, laboratories equipped with the necessary apparatus, needed fiscal resources to invest in R&D and other inventive activities - which enables entrepreneurs to respond to the claimed patent-generated incentive, the incentive or reward economic theory of the patent regime is based on several other assumptions. The first is that there is a need for more inventions than would be created by a society absent incentives provided by patents.16 Be it that a society needs more inventions (since there will always be problems for which solutions are demanded), the second assumption is based on the premise that temporary private exclusive proprietary rights represent the best incentives to bring about such inventions.17 This theory is further criticized on the basis that the relation among patent protection, R&D, and innovation is not often linear.18

Indeed, even absent patent protection, society would still undertake R&D activities, formulate inventive ideas, and develop new and innovative products and services. An example would be the many inventions produced by academic researchers because of knowledge curiosity or serendipity.19 Therefore, the true benefits of the patent system as an innovation catalyst would be limited to those inventions which might have not been discovered without the incentive provided by patent protection. Whether the preceding economic rationalization of the incentive function would, or even could, be of a relevance to the Jordanian pharmaceutical sector or whether the patent-induced

17 Ibid.
18 See the discussion below on the assumed linear relation among these elements.
incentive operates therein as it does in a developed country context, will be the subject matter of this Section.

2.2. Patent Protection, R&D, and Innovation

2.2.1. Innovation as a Concept

Innovation as a concept is neither defined in the TRIPS Agreement nor in the patent laws of most countries. Rather, the focus of these instruments is on defining the legal requirements that a patentable invention must satisfy: that is, an invention must be novel, involve an inventive step, and capable of industrial application.\(^20\) The term “innovation”, however, is frequently used in the literature to define the process of developing new inventions to new products. For Freeman, an invention is an idea, a sketch, or a model for developing a new product, equipment, process, or a system, or for improving already developed ones. Innovation in the economic sense occurs only when the first commercial transaction involving the new or improved product, equipment, process, or system takes place.\(^21\)

Based on the substantiality of the technical knowledge contributed by the new product, equipment, process, or system, innovation is categorized as “discrete” or “cumulative”.\(^22\) A discrete innovation is independent of and not based on previous innovations,\(^23\) that is a product, process, service or system which has no previous foundation in the mass of technical knowledge (previous inventions). In real life, however, most new scientific and technical knowledge and creations are extensions built on and added to a collective pool of scientific discoveries and innovative products, processes, or systems that are in the public domain and which we already know.\(^24\)

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\(^{20}\) See Article 27 of the TRIPS Agreement, supra note 2.


\(^{24}\) Ibid.
type of innovation is called cumulative innovation: based on many small advances to the present state of our technical knowledge or incremental developments.\textsuperscript{25}

That most innovations are increments means that they would have not been originated without “[utilizing] current technology in the current market to strengthen current competencies”.\textsuperscript{26} Therefore, such incremental advancements “[generate] value by accumulative effect and by creating versatility”\textsuperscript{27} perceived to constitute a functional process. Accordingly, technologists and behavioral scientists view innovation as “a sequence of activities involving the acquisition, transfer and utilization of information”.\textsuperscript{28}

As a process, innovation may involve the combination of knowledge and resources to “produce new knowledge, some of which then spills over into the research community and thereby facilitates the creation of still more knowledge”.\textsuperscript{29} Central to this line of thinking of innovation as a process that is dynamic and path-dependent is the conflict between technical knowledge dissemination and the promotion of innovation through incentives like patents. Given that most innovation is incremental, based on sequential and complementary small steps, this means that limited patent protection (scope of protected subject matter and duration thereof) is conducive to a faster pace of innovation.\textsuperscript{30} Based on this view of the relation and interplay between a weaker patent regime and the flow of incremental innovative creations, scholars like Bessen and Maskin argue “that imitation promotes innovation and that strong patents inhibit it”.\textsuperscript{31}

Imitation, conceived of as constituting an integral element of innovation as a process, facilitates firms’ capacity building and helps them to “master and implement the design and production of goods and services that are new to them, irrespective of whether

\begin{itemize}
  \item \textsuperscript{25} Ibid.
  \item \textsuperscript{26} See Rogerio C. Caliaa \textit{et al.}, “Innovation Networks: From Technological Development to Business Model Reconfiguration” (2007) 27(8) Technovation 426 at 427.
  \item \textsuperscript{27} Ibid.
  \item \textsuperscript{28} See William J. Abernathy & Kim B. Clark, “Innovation: Mapping the Winds of Creative Destruction” (1985) 14 (1) Research Policy 3 at 3 (citing multiple references) (emphasis mine).
\end{itemize}
or not they are new to their competitors – domestic or foreign”.32 Such a function highlights the importance of learning through application, namely, the ability to develop the necessary capabilities of problem solving, “learning to learn”, which, in turn, enables firms to improve their productivity and “to adapt product, process and organizational technologies already developed elsewhere to local conditions”.33 This process of “catching-up”, as described by Mytelka, depends upon “deepening production capabilities, thereby ensuring that clones [and] copies are, at the least, of similar quality and yet initially competitive because they are cheaper”.34

Therefore, innovation as a concept in this study is understood to represent a process that is dynamic and pervasive; a process that is inclusive of development considerations, including contributions obtainable through imitation to acquire tacit technical knowledge35 and operational information. In a developing country context, it was observed, conceptualization to encompass imitation is relevant since the partly tacit nature of knowledge and its characteristics of partial private appropriability makes imitation, as well as innovation, a creative process, which involves search, which is not wholly distinct from the search for ‘new’ developments, and which is economically expensive – sometimes even more expensive than the original innovation ... this applies to both patented and non-patented innovations.36 [Citations omitted]

The close link between imitation and innovation is best indicated when the latter is understood as an accumulative learning process that involves “ingenuity, scientific and


33 See Lynn K. Mytelka, Competition, Innovation and Competitiveness in Developing Countries, (Paris, France: Development Centre, Organisation for Economic Co-operation and Development, c1999) at 18 [Innovation and Competitiveness].


35 Tacit technical knowledge is used here to mean “technical know-how”. In other words, it refers to the technical information necessary to effectively operationalize a technology. This kind of information is inexplicit, although parts of it may be converted to explicit forms such as instructions, manuals of operations. However, this kind of knowledge is often uncodified. In this sense, tacit knowledge, according to Collins, means “knowledge or abilities that can be passed between scientists by personal contact but cannot be, or have not been, set out or passed on in formulae, diagrams, or verbal descriptions and instructions for action”; see H.M. Collins, “Tacit Knowledge, Trust and the Q of Sapphire” (2001) 31 Social Studies of Science 71 at 72.

36 See Dosi, “Microeconomic Effects”, supra note 29 at 1140.
technological skills, abilities to use specialized knowledge for problem solving, managerial abilities, and organizational effectiveness and flexibility – all of which influence production costs, market competitiveness, and hence the evolution of the industry”. The contribution of imitation to the accumulation of technical knowledge, skills and expertise may explain the evolution of industrialization in many developing countries despite the dearth and low levels of R&D conducted by public or private institutions therein. Hence, innovation is not limited to the outcome of the linear process, which begins with basic research, and further refined by applied research through the introduction of new products and services, as depicted by the economic analysis of the underlying economic justifications of patents as incentives for innovation. Rather, innovation is a process that, besides that linearity, incorporates other means of learning such as problem solving and the actual application of technical knowledge and improvements achieved in other countries or sectors.

Based on the above conceptualization of innovation, this study argues that the rules of the TRIPS Agreement on the protection of patents do not operate to enhance innovation in Jordan in the way they may in developed countries. This study goes further and argues that these rules might be even injurious to local innovative activity since they frustrate the ability of local manufacturers to build their technical capacity through imitation. In order to investigate the merits of this argument, we shall next explore the reasons as to why enhanced patent protection alone may not lead to more R&D activities in the pharmaceutical sector in Jordan.

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38 Ibid.
40 It should be mentioned here that the issue as to whether strong patent rights enhance innovation remains debatable even in developed countries (for discussion on this issue, see subsection 2.2.4, “Enhanced Patent Protection and the level of R&D” below.
2.2.2. Would Product Patents in Jordan be Conducive to More Pharmaceutical R&D?

Standard economic IP theory, as reviewed above, tends to assume that technical change (innovation) is a linear process that progressively evolves in a discrete unidirectional manner through independent steps. According to this conception, the innovation process begins by the undertaking of basic research through the introduction of a new market input: be it a product, a process, a system, or development of an existing product, process, or system. Therefore, relative to the emphasis placed on other factors and steps in the innovation process, the linearity view puts a significant emphasis on research, as one step in the innovation process. This understanding implies that there is a progressive correlation between the levels of research undertaken and those of innovation: as research increases, so does innovation.

The preceding logic has left a considerable impact on the formulation of patent policy, leading it to focus mainly on providing an incentive for conducting more research, which “eventually will lead” to the development of new innovations. Accordingly, the nexus between patents and innovation exists since the former incentivizes more research, which represents a critical informational (basic research) and technical (applied research) input of innovation. In order to test whether enhancing patent protection in Jordan results in more pharmaceutical R&D undertakings, it is crucial that the assumption underlying the incentive theory of patents be examined in the framework of the Jordanian NIS as it pertains to and affects the pharmaceutical sector. In other words, the composition of the NIS as well as the nature and scale of inventive activities

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42 Ibid.
44 Contrasted to basic research, Dasgupta defines applied research as “activity whose informational output is an input in the production of commodities”.) See Dasgupta, “Welfare Economics”, ibid.
performed by its various constituents will be determinative of whether patents may constitute an incentive for these various elements.

2.2.3. The Jordanian National Innovation System & Pharmaceutical R&D

NIS is a system constituted “by elements and relationships which interact in the production, diffusion and use of new, and economically useful, knowledge and that national system encompasses elements and relationships, either located within or rooted inside the border of a nation state”.45 These national elements are primarily made up, first, of government policies. Such policies need to be formulated in a manner that matches the scientific and technological infrastructure of a given state, which represents the second element of NIS. Such a matching between policies and available infrastructure is critical in order for a country to make the most out of its various assets in light of this infrastructure. The third element of NIS rests on the structure and capabilities of the firms in an industry, which interact with and, ideally, would benefit from the state of the previous two elements.46 Given the multiplicity and complexity of factors which shape these three elements of NIS, the next part of this work will explore these factors. “Sketching” the various elements of NIS and the relevant factors impacting their performance will help explain why the incentive to conduct more R&D, assumed to be provided by patents, may not function in the Jordanian context in the same way it may in an industrialized country context.

2.2.3.1. The Structure and Capabilities of the Local Pharmaceutical Industry

The local Jordanian pharmaceutical industry evolved over a period of 45 years with the establishment of the first factory (Arab Drug Manufacturing Company (ADM))

46 See Nelson, supra note 42 at 287; for a discussion on various aspects and different methodological approaches to the study of NIS, see Lundvall, Ibid; Christopher Freeman, Technology Policy and Economic Performance: Lessons from Japan, (London: Pinter, 1987); Michael Porter, The Competitive Advantage of Nations, (New York: Free Press, 1990); and see Abdelgafar, supra note 37 at 54-5.
in 1962, with support from the government.\textsuperscript{47} A rapidly growing population during the 1960s and 1970s as well as a significant general price rise in the early and late 1970s led to an increasing demand for inexpensive drugs.\textsuperscript{48} To meet this pressing need, three more companies were established during the 1970s: Dar Al Dawa Development and Investment Co. (DAD), Hikma Pharmaceuticals, and Jordanian Pharmaceutical Manufacturing Medical Equipment Co. Ltd. (JPM).\textsuperscript{49} Furthermore, while four more companies entered the market in the subsequent decade, the number of new entrants during the 1990s was eight corporations; bringing the total number of manufacturing companies in the sector to 17 by the end of the last century. However, subsequent to the accession of Jordan to the WTO in 2000, the total number of local manufacturing companies declined to 14 by 2011. This decline has been caused by mergers and acquisitions among the local companies.\textsuperscript{50}

The initial industrial drug production of the four companies incorporated before the 1980s involved activities such as dosage formulation and packaging of imported synthesized molecules and materials. In parallel, these firms were distributing in the local market finished, imported consumer drugs (branded and generics).\textsuperscript{51} In 1978, one of these companies, Hikma Pharmaceuticals, built a plant specializing in the production of Penicillin and its formulations, while another factory specialized in manufacturing Cephalosporins, a subgroup of antibiotics.\textsuperscript{52}


\textsuperscript{48} Jordan experienced two major influxes of population caused by massive immigration of Palestinians as a direct consequence of two wars in 1948 and 1967.

\textsuperscript{49} See Rahahieh, supra note 47.


\textsuperscript{51} See Rahahleh, supra note 47.

Specialization characterized the activities of most of the companies joining the pharmaceutical manufacturing industry during the 1980s. The focus on specialized activities was led by the Arab Center for Pharmaceuticals and Chemicals (ACPC) whose two factories were making Gelatin capsules and general medicaments. As their technical knowledge and expertise was developing, by means of previous manufacturing experience, during the late 1980s and the 1990s the companies started to focus on the quality and portfolio of their production and expanded their reach to export markets. For example, they started to provide the local and export markets with a wide range of pharmaceuticals, including: Antibiotics, Anti-ulcerants, Hormones, Anti-AIDS, Anti-Cancer drugs, Biotechnology-based drugs, and herbal treatments. Furthermore, the companies developed their production and technical capabilities by expanding their manufacturing to a new array of products: dosages forms such as Injectables and transdermal Patches.

The majority of medicines manufactured by most of Jordan’s pharmaceutical companies consist of Branded Generics (generics marketed under their own brand). Branded Generics represent 95 per cent of the industry’s production and the remaining 5 per cent is production under licensing agreements. Licensors are from various parts of the world and, for example, include: Aventis, Chanelle, Fujisawa, Mundipharma, Novartis, Organon, Pfizer, Roche, and Takeda. While 35 per cent of the local industry’s production is supplied to the local market, the preponderance of production is exported. The exported pharmaceuticals are sold in 66 markets, including the USA and the EU. However, Saudi Arabia, other Gulf countries, Iraq, Algeria, and Libya are the major importers. This export-oriented strategy led the industry to become Jordan’s second largest exporter after garment manufacturing. In 2006, pharmaceutical products

53 See Export and Finance Bank, ibid.
56 See Ministry of Planning, ibid. at 70-2.
comprised approximately 11% of Jordan’s exports: $500m. In that year, export of drugs grew approximately 20% over 2005.57

The forgoing background clearly indicates that the industry has been focusing on fortifying its production capabilities and capacities. This capacity building would have been difficult had these firms been prevented from imitating technology developed elsewhere. As a result of reforming the patent law in 1999, this practice is no longer available to them. Therefore, in order for these firms to maintain production of new products, they need to obtain the necessary licenses from patented technology owners or develop their own innovative products through R&D. Whether the local pharmaceutical sector has, or has not, such a R&D capacity will be examined next.

2.2.3.2. The Local Industry and Indigenous R&D

The in-house R&D conducted by the local pharmaceutical industry is of a modest nature and scale. Most of the local firms established and still maintain R&D units. The main role of these units is to facilitate and complement the principal business of these firms: production of generic medicines.58 These units have been designed to undertake research in three areas, namely, formulation and stability studies, bio-equivalence studies,59 and, in a later stage, process development.60 The local firms developed their capacities in these areas in order to reverse-engineer and thus understand advanced technology developed elsewhere in the world, diversify their products portfolio, and to

58 See Ministry of Planning, supra note 55.
60 For example, a sector report prepared by the Export and Finance Bank stated that Hikma Pharmaceuticals’ Research & Development Center has its own analytical research laboratory run by chemists and technicians who work together with R&D teams to undertake, inter alia, “method development and testing on behalf of other subsidiaries”. See Export and Finance Bank, supra not 52 at 7.
develop alternative manufacturing processes to produce new drugs without infringing on those of patentees.  

However, the research activities of the local firms were not directed to synthesizing new molecules and, in turn, the development of innovative products. As a result, the skilled workforce of these firms lacks the capacity for undertaking this kind of research. Besides this business model, several other reasons might explain why local firms have neglected to design R&D projects with a potential to develop new and innovative medicinal products. 62 The first, and maybe the most important, reason is the lack of finance for the high cost of innovative research. As to the finance issue, it has been reported that the rate of investment in R&D by the local firms in Jordan does not exceed 0.1 per cent of sales, 63 while the corresponding percentage invested by research-based, innovative pharmaceutical firms may reach up to 19 per cent.64

In order to better reflect on the minimal influence that the limited local spending on R&D may have on indigenous innovation, it is necessary to consider it in the context of the reported estimations about the cost of new drug development. R&D in pharmaceuticals, although the methodologies of calculation are contested,65 is known for its high costs. This factor is attributed to the intensity of research required66 and duration for development. For example, it is estimated that it may take a pharmaceutical firm from

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61 This was the case after amending the Patents Law in 1986 where pharmaceutical inventions became protectable only by process patents, but not product patents.

62 Although the bulk of their research is directed to the three areas mentioned earlier, there has been some activity to conduct genuine research. For example, one of the local firms, ABM, has obtained a few patents for its inventions. But, most of these patents are not exploited, according to one of the company’s senior management officials, since the firm lacks the capacity, capability and the necessary financial resources to invest in the development of these inventions into innovative products. (Interview with the author, Amman, Jordan, August 2009).


64 See Congress of the United States of America, ibid. at 9 (footnote 19, citing figures published by the pharmaceutical industry itself).


8-12 years to turn a potential chemical compound into a medicinal product that is distributable in health trading channels. The out-of-pocket cost sustained by drug innovators per approved new product has been estimated in the range of $400 million. This estimation is claimed to double, hovering around $800 million, when cost of capital and unsuccessful R&D projects are included in the calculations.\(^{67}\) Simply put, without access to the necessary capital, neither individually nor collectively can the local pharmaceutical firms afford to make such sums available, let alone investing them in R&D. According to Al-Saied, the “combined paid capital of all Jordanian manufacturers did not exceed JD129 million (US$184 million) in 2005”\(^{68}\).

Obviously, the finance and cost data presented indicate that the local firms’ in-house R&D is highly unlikely to be conducive to the development of new and innovative medicinal products. However, it might be argued that although the local firms may not do so by themselves, they still can do so in cooperation and partnership with other institutions in the society such as public and non-for-profit organizations (NGOs), for example, public laboratories and universities. This would lead us to the second reason as to why the state of indigenous R&D may not result in innovative products: namely, the weak state of R&D activities of public institutions like public research centers and laboratories and other public organizations such as universities as well as the lack of linkages and cooperation between these entities and the private sector.

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\(^{68}\) See Hamed and Mohammed El-Said, supra note 54 at 457 (citing a correspondence with Hanan Shoul, the executive director of JAPM). However, when the capital of firms not members in the JAPM is included in the calculus, the value reaches up to $400 million. See Ministry of Planning and International Cooperation, supra note 59 at 71.
2.2.3.3. Indigenous R&D in the Public Sector’s Institutions

The ability of the local pharmaceutical industry to respond to the incentive claimed to be provided by patent protection will depend, to a great extent, on the level and extent of support the industry may derive from the various other constituents of the NIS, which, of course, include public research centers and departments as well as universities. Together with the private sector these elements constitute the national scientific infrastructure upon which all parties can build. However, the state, sophistication, propensity, and level of the research performed in and by these other elements of the NIS in Jordan are all detrimental to the level of support that the private sector may derive thereof.

Notwithstanding the availability of a relatively considerable network of public research centers and labs operated by skilled personnel and backed by a supportive government policy, R&D activities performed by these organizations, unfortunately, are relatively immature.69 The same is also true in regard to scientific research conducted by the 29 universities which embrace 9 pharmacy schools,70 other faculties, and specialized centers and units.71 This weakness may be attributed to various reasons that have been identified by analysts. These reasons include: lack of adequate funding and scarcity of specialized research centers; inadequate management in research design, quality, and standardizations; a lack of integration with the private sector; and finally, a lack of trust among personnel within and among these institutions to design, form, and work on research projects.72

Activities of R&D in the public sector, excluding universities, are managed under a public organization called the Higher Council for Science and Technology (HCST). The HCST was established in 1987 as a structure responsible for the planning, coordinating, and managing of scientific and technological activities as well as their finance and promotion in Jordan. Among the several affiliated research center and units, there is only one unit that focuses on pharmaceuticals: the Pharmaceuticals Research Unit (PRU). The unit has the following facilities: analytical facilities; clinical facility; and product safety research laboratory. However, bioequivalence studies represent the principal activity of the unit. Its total annual budget in 2006 was 1.3 million JD (Jordan Denier) ($1.836 million), where the share of R&D was 5.9% only, salaries 15.9%, and laboratory equipment 78.1%.

Universities are among the three major recipients of the limited and small public funds channelled to support R&D in the country. In 2006, for example, the annual total value of total funding provided to universities was $4.5 million, which is inclusive of funds for undertaking research activities. Basic research, similar to many academic institutions around the world, is the main focus of Jordanian universities, besides education and development of human resources. Indeed, these institutions host a number of centers and laboratories that contribute to scientific research and innovation.

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73 The following activities represent the main duties performed by the Council:
1) Ratifying the general policy of science and technology in the Kingdom, defining its priorities, and drawing up the related programs and plans as well as following up on their implementation and evaluation. 2) Drawing up the strategies suitable for the development of scientific and technological potential in the Kingdom and providing the scientific environment suitable for this purpose. 3) Supporting the institutions and units of scientific and technological research and providing the necessary funding for the support of scientific and technological research as well as scientific and technological services and activities in the kingdom. 4) Participating in the supply and training of manpower and technical potential for scientific and technological research institutions. 5) Representing the Kingdom before Arab, regional and international institutions and bodies concerned with science and technology. 6) Undertaking scientific and technological cooperation and concluding agreements related to scientific and technological research in collaboration with local, Arab, regional and international organizations. 7) The Council may establish affiliated specialized centers of scientific and technological research. See the Council’s Homepage at <http://www.hcst.gov.jo/>; also see Higher Council for Science and Technology (HCST), Science & Technology and Innovation Profile of Jordan, (report submitted to: Evaluation of Scientific and Technological Capabilities in Mediterranean Countries (ESTIME)) no date available, online, ESTIME, Jordan <http://www.estime.ird.fr/IMG/pdf/Final_report_Jordan_IM_RA.pdf> (date accessed: December 29, 2010).

74 See Higher Council for Science and Technology, ibid. at 16.
75 Ibid.
76 The other two main supported research entities are, first, the Higher Council for Science and Technology, and second, the National Center for Agricultural Research and Technology Transfer. See Ministry of Planning and International Cooperation, supra note 69 at 4.
77 See Abdelgafar, supra note 37 at 118.
of distinguished academics with high levels of education, skills, and experience. The credibility of their educational and scientific base is attested to by the strength of the knowledge base of their new graduates both at the graduate and post graduate levels and by scholarly papers published in peer-reviewed journals. However, publication within the Jordanian universities is motivated by reasons related mainly to promotion within the academic hierarchy, social recognition, and self-esteem.

Although basic research and scholarly publications derived therefrom are critical to the development of a country’s scientific infrastructure base, having the mentioned motivations as an incentive to undertake research projects was criticized as being a very narrow approach to research. It was argued that such an approach is limited as it is basically individually-driven without institutional planning, design, and coordination of research priorities and projects. As a result, this approach is associated with a lack of cooperation and exchange of expertise, information, and research results not only among different institutions, but also among various scientists within the same entity; this, in turn, means that the preponderance of publications are not based on or derived from projects coordinated to work on the development of a particular technology that is responsive to societal needs and market necessities.

78 See Higher Council for Science and Technology, supra note 73.
79 According to the Jordan Investment Board (a government institution entrusted to work with the private sector to promote Jordan as a unique and friendly business environment and the marketing of the country for its diverse investment opportunities) there are 500 pharmacists graduating every year from nine pharmacy colleges. The total number of Jordanian pharmacists exceeds 10 thousand, where 60-70% of which is employed by the local market. And, it was estimated that 1.7 thousand Jordanians graduate in paramedical sciences every year. See Jordan Investment Board, online <http://www.jordaninvestment.com/BusinessandInvestment/tabid/64/language/en-US/Default.aspx> (date accessed: January 1, 2011).
80 For example, see the number of papers published by a relatively recently established research unit in the Pharmacy Faculty, University of Jordan: Drug Design and Discovery Unit. Papers reporting the results of research performed by the unit appears in a well respected, with high international impact factor journals such as the Journal of Medicinal Chemistry, online: University of Jordan, Faculty of Pharmacy <http://pharmacy.ju.edu.jo/Pages/QuickLinks/DDUmore.aspx> (date accessed: January 1, 2011).
81 Al Arab Al Yawm, a national newspaper, cited professor Anwar Battikhi (the head of Jordan’s Association of Scientific Research) and Nabil Shawaqfeh (then vice president of the University of Jordan), to have blamed the infancy of R&D within academic institutions on the lack of coordination between these institutions and the private sector, teaching loads, social recognition, faculty financial problems, and many others. See Al Arab Al Yawm Newspaper, Universities cost the treasury billions of Dinars annually as a result of weak scientific research, (Amman: Al Arab Al Yawm, March 12, 2007), online: Al Arab Al Yawm <http://alarabalyawm.batelco.jo/pages.php?news_id=6707> (date accessed: January 2, 2011) [original in Arabic, translation mine].
82 Ibid.
The reality of scientific research conducted in academic institutions and public research centers has led to a second critique: namely, a relative weakness of these institutions in developing applied science and technology. Besides emphasis on basic research and scholarly publications, the following two factors may be identified as major causes of this weakness.

First: Marginalized Applied Research

The majority of the local scientific and technical human infrastructure is found in academic institutions where there is a “heavy emphasis on low-level rudimentary science and the production of papers.” Applied research, in such an environment, tends to lack priority and is consequently marginalized. This situation is aggravated by the problem of scarcity of necessary financial resources to fund applied research projects as well as making essential lab and field equipments and advanced technology available, which are often very expensive and unaffordable. As was mentioned earlier, universities are among the main recipients of public funding that is channeled to R&D ($4.5 million in 2006) yet the vast majority of this funding goes to cover salaries. For example, out of its 78 millions JD budget ($110 millions) the University of Jordan (the most advanced among national universities) spends around 75.9% to cover salaries; however, only 6.8% of the budget is spent to finance R&D activities.

Given their fiscal situation, public universities tend to be understaffed, from an applied research perspective. In turn, this leads to the available faculty being overwhelmed with the ever growing number of students, teaching four courses a term, at the minimum, where the average number of students enrolled in each course ranges between 50-80 students. In addition, universities have a chronic problem of not being able to retain their scientific and technical personnel since academic positions in Jordan are not among the well-paid professions. For example, the monthly salary paid to a

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83 See Abdelgafar, supra note 37 at 119.
84 Ibid.
85 See Higher Council for Science and Technology, supra note 73 at 17.
newly appointed assistant professor does not exceed $1500. This situation, indeed, results in a problem of national brain drain to other countries in the region, mainly the gulf countries, as well as to countries in the developed west such as the USA and Canada, where individual researchers hope to have their personal and professional needs fulfilled.\textsuperscript{87}

\textit{Second: Lack of Linkage and Integration}

The second factor contributing to the weakness of applied research in universities and affiliated research centers is a linkage problem. This problem includes a lack of coordination, cooperation, integration, and even communication within and among these various organizations. This problem exists at all levels: between researchers and scientists within the same individual university or center, among researchers in different universities, between universities and other public research centers, and between universities and industry.\textsuperscript{88}

The dominance of the individualistic approach to and the lack of institutionalized planning, design and execution of research projects results, to a considerable extent, in cooperation among researchers within and among universities being affected by researcher personalities and preferences.\textsuperscript{89} Within universities, individual faculty work independently on projects of their own choice, and oftentimes without team work or documentation of steps taken and progress made to make them accessible to other faculty who might share the same research interests or working on a similar project. In addition, results obtained from such research are kept secret until publication time even to the hosting institution. This is again a negative consequence of not having established

\textsuperscript{87} Indeed, the Arab Human Development Report of 2003 stated that emigration of highly qualified Arabs to the West is perhaps among the most serious factors undermining knowledge acquisition in Arab countries. ‘The Arab brain drain constitutes a form of reverse development aid, they note, since receiving countries clearly benefit from Arab investments in training and educating their citizens. More significant, however, is the lost potential contribution of the emigrants to their countries of origin’. See UNDP 2003, Ibid. at 145.


institutional relationships among researchers that revolve around research projects not persons.\(^90\)

The personal and individual characterization of research projects has become the norm at the institutional level. This is the case despite the fact that all public universities fall under the general supervision of the Ministry of Higher Education and Scientific Research and despite a web of cooperation understandings and memoranda intended to facilitate the exchange of research inputs and outputs among these institutions.\(^91\) Given these organizational arrangements, the problem of universities acting as stand-alone institutions lies with practice, implementation, and – maybe – culture.\(^92\) Two factors may explain these shortcomings according to Abdelgafar, who identified a similar situation in the context of Egypt. The first factor is a matter of research teams seeking credit if projects are to be successful,\(^93\) or avoiding criticism if projects fail. Second, weak procedures for tracking progress and implementation of research projects in most of these institutions forestall their abilities “to ensure that a collaborative project is pursued to the end”\(^94\).


\(^{93}\) This may be a byproduct of two reasons. First, research teams may fear, if they share their work with teams/researchers from other institutions, that inventions developed by their research are patented by would-be co-institutions/researchers. Second, this fear, in turn, is partially caused by the lack of a disciplined and clear institutional framework for a robust documentation of research projects and contributions of the different participants.

\(^{94}\) See Abdelgafar, supra note 37 at 122.
Finally, a significant linkage and cooperation between universities (public research centers as well) and industry has been nonexistent. This missing connection originates from and is due to multiple considerations on the part of both sides. On the one hand, the policy and efforts of the local industry have been focused on enhancing production capacities and not on the discovery and development of new and innovative products. Therefore, the industry was not able to come to the universities and other public research centers with clearly formulated joint research projects. In addition, approaching these institutions by the industry for cooperation in R&D projects would have necessitated that the latter finance potential joint projects. But, as explained earlier, the financial situation of the local manufacturers has limited their ability to reach out to these research institutions. To a lesser extent, the industry also perceives pharmacy departments as public institutions devoted to academic research and publications, which are inefficient and not capable of applied research. Such discernment may have added to the industry’s hesitation not to risk its scarce capital in mutual projects with universities.

On the universities’ side, their research policy lacked a vision of a role for the industry as a partner in planning, designing, and implementing R&D projects. In fact, as explained above, universities did not have an established institutional relationship framework to coordinate its own projects, let alone cooperating with the private sector. Nevertheless, there were some isolated individually-driven incidents of faculty in pharmacy departments being approached by investors in the sector or vice versa. According to Anwar Battikhi, however, these incidents were acrimoniously questioned, being either driven by personal gains and benefits or involving the utilization of the

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96 See MOP, supra note 88.
98 See Al-kasby, supra note 89; also see Al-Bakhit, supra note 91.
99 See MOP, supra note 88.
100 Ibid.
public scientific infrastructure and resources for a private gain, which constitutes illegal conduct under Jordanian law. Accusations of this kind would not have been made had an institutional discipline been established to regulate, or even foster, cooperation between the universities and the private sector. This state of discord between the two sides may be generally attributed, in part, to national universities not trusting the local industry.

The Jordanian NIS’s state of affairs portrayed above persisted even in the years after the country’s reform of its patents law in 1999 and the two subsequent amendments in 2001 and 2007. The persistent weakness is best illustrated by the World Competitiveness Report (the Report), which provides an evaluation covering several elements of Jordan’s NIS, including all of the shortcomings discussed earlier. According to the Report, out of 75 participating countries the overall rank of Jordan’s expenditures on R&D is 55. In addition, cooperation among the industry cluster agents, private companies, universities, private laboratories, and public research organizations, ranked 50. Moreover, Jordan ranked last out of 65 participants for patents granted to Jordanian nationals by the US Patent Office.

To sum up, R&D activity performed in the Jordanian economy is weak. Several factors have contributed to that status, including the following, in particular: a lack of finance resources and specialized research centers devoted to innovative pharmaceutical-

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101 For a criticism of this particular issue, see comments attributed to Professor Anwar Battikhi about his own experience on this issue, see Al Arab Al Yawm, supra note 81.
102 Using public resources for personal gains is against the Jordanian Law and considered a criminal conduct) see Article 176 of the Jordanian Criminal Law as amended No. 16 for the year 1960 (Official Gazette of November 5, 1960, No. 1487 page 374.
103 It might be argued here that the absence of patent protection exacerbates the issue of trust. It does so since researchers would file for a patent and thus preserve their rights from being freely exploited by private entrepreneurs. This line of argument has some merit, but it does not address most situations that might give rise to trust concerns under a joint research projects setting. For example, even if patent protection were available, this may not stop a malicious project partner from abandoning participation in the joint project and continue its own to collect a patent and later on harvest all profits if a would-be developed product meets with success. In such a situation, it is contract law that provides security to the partners not the patent law.
104 The World Competitiveness Report is a yearly report published by the World Economic Forum and which constitutes an index that “measures the set of institutions, policies, and factors that set the sustainable current and medium-term levels of economic prosperity”. See the World Economic Forum, Reports, online (date accessed: January 3, 2011).
related research, a focus on basic research and marginalized applied research in academic institutions and associated research centers, and an acute lack of linkage among the NIS’s various constituents.

Thus, under these circumstances even if it is \textit{arguendo} assumed that there is causality between patents and R&D, where the former constitutes \textit{a priori} incentives for the latter with positive outcomes on the level of indigenous innovation, the NIS has been too weak for it to respond to that incentive. The assumed incentive is not absolute, and how it interacts with the development state of a given country is still ambiguous. In other words, would the patent–provided incentive work in a developing country context the same way it might do in a developed country? Or, conventionally, could it be the case that the causality mentioned above actually operates the other way around: as the level of and expenditures on R&D increase, a need to enhance patent protection emerges from within the economy. Therefore, the relationship between enhancing patent protection and the level of R&D will be addressed next.

\textit{2.2.4. Enhanced Patent Protection and the level of R&D}

That scientific research and development is an “ultimate source of economic advance”\textsuperscript{106} is conventional wisdom. Yet, as I will explain below, it is not conclusively settled whether particular policies are the optimal means to increase scientific research in a society. This debate is particularly true in the context of patent policy and the impact of patent protection on the level of research conducted. Nevertheless, scholars agree that there is \textit{a connection} between patents and R&D, but they disagree as to whether such a connection is a positive one as advocates claim.\textsuperscript{107} This debate is also present with regard to extending enhanced patent protection to developing countries.

\textsuperscript{106} See Freeman, supra note 21 at 5.

For proponents of this extension, the positive link between strengthened patent protection and R&D rests in the incentives patent provides to inventors and investors to undertake and finance research. This line of argument contends that there is a progressively increasing relationship between R&D and innovation which is fueled and catalyzed by patents.\(^{108}\) On the other side, critics of the patent system challenge this claim, advancing their own counterarguments. They maintain, for example, that such a link has not been established by theory nor has it been proved by empirical investigations.\(^{109}\)

Although undertaken in a developed country context, many studies have attempted to investigate the influence of the scope and extent of patent protection on the level of R&D. Some studies concluded that strong and broad patent rights lead to a duplication of R&D efforts and expenditures.\(^{110}\) This duplication happens when competitors simultaneously undertake research on identical or similar projects in order to win a patent (so-called patent race), given that the winner would collect all benefits derived from a potentially patentable invention. This excessive duplication of R&D leads to a socially inefficient allocation of resources that could have been saved absent patents. The excessive duplication effect of patent protection extends even to research conducted after a patent grant, when competitors invest their resources trying to invent around a patented technology.\(^{111}\)

In addition, contrary to the R&D incentive theory of patents, it has been argued that strong patents, especially when based on broad claims, may discourage R&D.\(^{112}\) The holding of this type of patents by a firm may deter others from trying to invent near the area covered by the broad patent, fearing infringement and costly litigation. The outcome


\(^{109}\) See, for example, De Almeida, infra note 117 at 214; Mowery & Rosenberg, infra note 117 at 15; Boldrin & Levine, infra Note 97; and see Noguès, infra note 129 at 89.


\(^{111}\) See, for example, Mazzoleni & Nelson, supra note 108.

\(^{112}\) Ibid.
of such patents is even worse, as argued by Mazzoleni & Nelson, when competitors are “deterred from themselves undertaking any of the wide variety of follow-on inventive work that improves, or variegates, on an initial invention”.  

Moreover, the findings of a growing number of empirical studies conducted over the last 40 years in various parts of the developed North have increasingly pointed in the direction of calling into question the importance of the claimed positive link between strong patents and R&D in the field of pharmaceuticals. These studies have sought to determine the importance of patents to firms doing industrial R&D. Ironically, the studies have come to the convergent conclusion that firms in most industries reported that patents were neither effective nor necessary for enabling them to appropriate returns from their R&D. Rather, as reported by Levin et al., the surveyed firms adapted the following common mechanisms: “lead time, secrecy, learning advantages, and sales and service effort”. Thus, it has been argued that factors like the probability of success, size of market, demand, and purchasing power of potential consumers would drive firms to invest in R&D regardless of patent protection.

113 Ibid.
115 Commenting on the importance of alternative means, such as lead time, secrecy, learning advantages, and sales and service effort, for the appropriability of returns from innovation; Levin et al. asserted that “The survey confirmed that these other means of appropriation are typically more important than the patent system”; see Levin et al., ibid. at 816.
116 Ibid.
117 For instance, De Almeida concluded that “in a wide variety of industries, investments in R&D are made by firms for maintaining their technological leadership and market position and they would do so regardless of the availability of patent protection”, see Paulo R. De Almeida, “The Political Economy of Intellectual Property Protection: Technological Protectionism and Transfer of Revenue among Nations” (1995) 10 (2/3)
In some of these studies, however, pharmaceuticals were said to represent an exception, implying that patent protection matters most for R&D in this field. For instance, based on data obtained about 48 innovative products, Mansfield et al. estimated that 90 per cent of the innovative products covered in the study would not have been commercially introduced into markets had it not been for patent protection.118 In another study and based on information obtained from 100 US firms randomly selected from twelve industries, Mansfield sought to obtain estimates on the proportion of inventions developed or commercially introduced during the 1981-83 period, which would not have been developed or commercially introduced without the availability of patent protection. He reported that “patent protection was judged to be essential for the development or introduction of 30 percent or more of the inventions in only two industries - pharmaceuticals and chemicals”.119

These studies, though, suffered from the limitation, among others,120 that they were concerned with one particular group of innovators: large, established firms. This group has, as Mazzoleni and Nelson put it, an “established presence in their product markets and thus having access to the complementary assets needed to commercialize the end-product of their innovative efforts”.121 But patents may not have the same incentive effects on firms that lack these capabilities and resources to develop and commercialize

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118 See Edwin Mansfield, Mark Schwartz & Samuel Wagner, “Imitation Costs and Patents: An Empirical Study” (1981) 91 The Economic Journal 907. The authors also found that the commercial introduction of approximately 20 per cent of chemical, electronic, and machinery products would not have taken place without patent protection. Also, see Mansfield, “Patents and Innovation”, supra note 66.

119 See Mansfield, “Patents and Innovation”, supra note 66 at 174. Mansfield combined the individual firms’ estimations to create an industry-wide estimation. In relation to industries other than pharmaceuticals and chemicals the results were “(petroleum, machinery, and fabricated metal products), patent protection was estimated to be essential for the development and introduction of about 10-20 per cent of their inventions. In the remaining seven industries (electrical equipment, office equipment, motor vehicles, instruments, primary metals, rubber, and textiles), patent protection was estimated to be of much more limited importance in this regard. Indeed, in office equipment, motor vehicles, rubber, and textiles, the firms were unanimous in reporting that patent protection was not essential for the development or introduction of any of their inventions during this period.

120 For a discussion on the various limitation of these studies, see Section 3.1, “Patent Protection, Pharmaceutical Innovation, and Developing Countries” of Chapter Two of this thesis.

121 Mazzoleni & Nelson, supra note 108 at 276.
the end-product of their innovative efforts, which is the case of most pharmaceutical firms in developing countries like Jordan.

In addition, these studies do not explain why activities of R&D have been carried out by institutions where patents are not the potential objective or simply when they are unobtainable. To illustrate, the studies do not explain why public organizations such as universities and other research-based NGOs conduct R&D when patenting as an incentive is not an element in their decision-making calculus to undertake a specific project. Furthermore, assuming that we agree with their conclusion that patents are most essential to pharmaceuticals, why would industries in other sectors follow rules suitable only for pharmaceuticals? Alternatively, why would we design the patent system to satisfy the pharmaceutical industry’s requirements and ignore those of other industries?

Moreover, again with regard to the sample of firms surveyed, they were already enjoying an advanced technical capacity and classified as innovative entities with high stakes in the patent institution. Accordingly, it makes sense that they would attribute a great deal of significance to patent protection; it also makes sense that they were strongly in favor of enhanced patent protection in the pharmaceutical field.

Also, the timing of the Mansfield et al. study and that of the Mansfield (1986) might argue against attaching too much weight to their findings. Both studies were carried out around the time when debates about the inclusion of the issue of IPRs in the GATT’s Negotiations Agenda were ongoing. Since the US pharmaceutical industry

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122 In relation to the U.S.A, the observation applies to the time preceding the enactment of the University and Small Business Patent Procedures Act, so called “Bayh-Dole Act” (35 U.S.C. § 200). However, for a critical criticism of the role of the Act in promoting innovation, see Mazzoleni & Nelson, supra note 108 at 277-8.

123 Following an explanation of the ease with which pharmaceutical inventions can be copied from their patents documents specifications, Macdonald stated that “[t]he pharmaceutical industry has done much to ensure that the patent system meets its own requirements, basically the requirements of large companies, operating with highly codified information”. See Stuart Macdonald, “Exploring the Hidden Costs of Patents”, (2001) (Quaker United Nations Office – Geneva, Occasional Paper 4) at 6, online: Quaker United Nations Office <http://www.quno.org/geneva/pdf/economic/Occassional/Costs-of-Patents.pdf> (date accessed: January 15, 2011).

124 See Mansfield et al., Supra note 118.

125 See Mansfield, “Patents and Innovation”, supra note 66.

had been deeply involved, nationally and internationally, in advocating reform of the international patent regime, the outcome of these studies should be handled with caution. Finally, these studies do not address the fact that several developed countries, such as Italy, Spain, France, and even Switzerland, built strong pharmaceutical industries that are research-based even when a patent-driven incentive to invest in R&D was entirely missing in these countries.

Therefore, it seems that there is no conclusive evidence to support the argument that strong patents constitute a prerequisite for undertaking R&D and increasing expenditures thereon, leading, hence, to more innovation in pharmaceuticals. Evidence is increasingly emerging in support of this indication. For instance, in the United States and notwithstanding the introduction of stringent administrative procedures for and regulation of pharmaceuticals (safety and efficacy) during the period 1938-1962, which practically curtailed the period of effective patent protection as a result of time spent in obtaining marketing approvals, Nogués observed that pharmaceutical R&D activities and expenditures continued to increase during that period. In addition, in spite of complaints about a lack of adequate international patent protection, the typical minimum of 10 per cent invested by firms in this industry increased to approximately 16 per cent in 1988.

Evenson reported similar observations with regard to Japan. A survey covering 2,390 corporate researchers indicated that relative to competition and academic or technical interest, patents were less important when it came to assessment of R&D decisions.

Furthermore, historically-oriented studies further substantiate the argument against the patent-R&D link, particularly when the experiences of many of today’s industrialized countries are considered. According to Boldrin & Levine, several developed countries historically provided protection only to process patents of


Ibid.

See Boldrin & Levine, Infra Note 131.


pharmaceuticals, but introduced product patents relatively recently.\textsuperscript{131} Protection of pharmaceutical product patents in France, for example, was not fully enjoyed until the late 1970s.\textsuperscript{132} Spain is another example where a flourishing pharmaceutical industry developed without making product patents protection available until 1986, and, according to Boldrin & Levine, that protection was implemented “as a consequence of the country’s entrance to the EEC”.\textsuperscript{133} With regard to Switzerland (a country hosting some of the world’s leading global pharmaceutical companies like Roche), Schiff found no evidence that the country suffered a lack of R&D caused by an absence of patent law in the mid-nineteenth and early twentieth centuries; to the contrary, the chemical industries, including pharmaceuticals, thrived.\textsuperscript{134} The Swiss industry continued its growth notwithstanding the fact that it was not until 1977 that the country introduced pharmaceutical product patents.\textsuperscript{135} Schiff argues that the lack of patent protection even helped the development of domestic industries since it allowed unrestricted importation and transfer of technology from other countries.\textsuperscript{136}

Italy is another remarkable example where R&D was not hindered by the lack of patent protection. On the contrary, pharmaceutical R&D and industry flourished before reforms to the patent law in 1978 to provide for such protection. Scherer and Weisburst analyzed the impact of that reform. They concluded that the regime change had little or no impact on the trend of adjusted R&D expenditures, or on the introduction of new chemical entities during the decade following 1978.\textsuperscript{137} Challu, in his study of the impact

\begin{footnotesize}
\begin{enumerate}
  \item According to Boldrin & Levine, the theorem justifying the patent of processes of manufacturing of pharmaceuticals and chemicals but not final products, as argued by the German Association of Chemical Industry in a memorandum to the Reichstag (reference omitted), is “the same chemical product can be obtained by different processes and methods and even starting from initially different materials and components. Hence, there is social value in patenting a new process, as it rewards the innovator without preventing further innovation. There is negative social value in patenting a specific product, as this would exclude all other from producing it, even through different processes.” See Michele K. Boldrin & David K. Levine, \textit{Against Intellectual Monopoly}, (New York: Cambridge University Press, 2008) at 216.
  \item Ibid.
  \item Ibid.
  \item See Boldrin & Levine, Supra Note 131.
  \item See Schiff, supra note 134.
  \item It should be mentioned that Scherer emphasized his findings given, in his opinion, the fact that the Italian generic pharmaceutical industry at the time was a “vibrant generic industry”; an industry that flourished without patent protection. See F.M. Scherer & Sandy Weisburst, “Economic Effects of
\end{enumerate}
\end{footnotesize}

It seems that a correlation between R&D expenditures and patent protection does exist, but ironically the causality goes the other way around (reverse causality). Namely, it seems that as levels of R&D activities and expenditures increase, countries tend to strengthen their patent protection. Bessen and Meurer examined five types of evidence on links between property, patents, innovation and economic growth. These five types of evidence derived from:

- economic history, especially from the Industrial Revolution;
- cross-country econometric studies;
- evidence from ‘natural economic experiments,’ observing the impact of discrete changes in patent law;
- evidence about the effect of imitation; and

Based on their analysis of evidence from these segments, they conclude that “the empirical economic evidence strongly rejects simplistic arguments that patents universally spur innovation and economic growth”.\footnote{140See Bessen and Meurer, “Patents Perform”, ibid. at 21.} On the cross-country analysis and with regard to the correlation between patents protection and R&D, they observed that “simple casual observations about the correlation between US or Western technology and patent systems can be misleading”. They also maintain that if patents have any effect on
economic growth, it would be, at best, weak, indirect, tentative, and contingent on several factors, including the state of economic development.141

Innovation, including R&D as a necessary input therein, involves multiple factors and depends on an extremely complex economic environment, where patent protection may only represent one element.142 This complex multiplicity of factors makes it, as correctly argued by Jaffe, extremely difficult to single out the specific impacts of changes made to patent protection on innovation even in the context of the U.S. patent regime.143 He maintains this view since “despite the significance of the policy changes and the wide availability of detailed data relating to patenting, robust conclusions regarding the empirical consequences for technological innovation of changes in patent policy are few”144.

The findings of the numerous studies presented above (and many others) emphasize the difficulty one faces in trying to accommodate patent theory (the incentive element, in particular) with history and empirical evidence. Indeed, it is this kind of inability to unambiguously attest to the premise of the patent institution which convinced Machlup fifty-some years ago to maintain that:

[if] we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.145

Nevertheless, and despite the ambiguity of the claimed link between patent protection and R&D and innovation in the context of a developed country, I will next explore what insight the situation in Jordan might provide to address this unanswered question.

141 The following factors, for instance, were also mentioned: details of the patent system, the relevant technology and/or industry. Ibid. at 11-12.
143 Ibid.
144 Ibid. at 531-2.
2.2.4.1. Enhanced Patent Protection and the Level of R&D in Jordan

Given the historical and empirical evidence indicating that the claimed correlation between changes of the patent policy to strengthen protection and the levels of R&D and technological innovation is, at best, weak, one would think that the difficulty of establishing this link in the case of developing countries should not be different, if not more evident. This would be the case since the little evidence available on this matter tends to be derived from developed countries. Despite that, supporters of enhancing patent protection in Jordan, as a developing country signatory to the TRIPS Agreement, claim that such protection will result in more R&D in the local pharmaceutical sector. Still further, it has been claimed that the stronger (relative to that mandated under TRIPS) patent protection enforced in Jordan in order to implement its obligations under the United States – Jordan Free Trade Agreement (USJFTA) has led to the establishment of an innovative domestic industry!

Consider, for instance, the following statement by the United States Trade Representative (USTR): “Since enactment of the FTA, the Jordanian drug industry has begun to develop its own innovative medicines. This is an example of how strong intellectual property protection can bring substantial benefits to developing countries”.\textsuperscript{146} This statement was echoed by the International Intellectual Property Institute (IIPI). In a document presented to a conference in Amman, Jordan, the IIPI, arguing against critics of enhanced patent protection and its negative effects on the local pharmaceutical industry and access to medicine, alleged that “Jordan is … benefiting from stronger intellectual property rights through an increase in pharmaceutical research and development investment”.\textsuperscript{147}

These two statements are riddled with flaws and inaccuracies. First, they try to indicate a direct causality between strengthening patent protection and a claimed increase


in indigenous research as well as the development of innovative drugs. Again, the historical and empirical evidence does not support such a strong link. Instead, a reverse causality may be indicated.\textsuperscript{148} Second, they allege that the local industry increased its R&D investment subsequent to reforming the Patents Law in 2000. The data presented earlier on the R&D activities and expenditures, by means of discussing the NIS in Jordan, contradict such a claim. In fact, some firms stated that the new legal regime will force them to cut spending on R&D. They argue that in order to invest in R&D activities, they need adequate and stable financial resources. Manufacturing generics provides the rates of profits necessary to sustain R&D units and their activities. This has been facilitated by lax protection, which the new strong patent protection will undercut.\textsuperscript{149}

Third, they claim that the industry “has begun to develop its own innovative medicines”. This claim is implausible in light of the average time required to develop an innovative drug,\textsuperscript{150} how could it be possible to evaluate what the industry was doing and conclude that its activities were going to yield innovative drugs given that, at the time of

\textsuperscript{148} See Bessen and Meurer, “Patents Perform”, supra note 139 at 21.

\textsuperscript{149} Several interviews conducted by the author with many of the local firms (Amman, Jordan -from July 12, 2009 to September 8, 2009). Similar observations were also reported by Hamed & Mohammed EL-Said, supra note 54. The importance of cash flow for Generics manufacturers is captured by a statement made by Jack Kay (president of the Canadian Drug Manufacturers Association) when he testified before the Senate Standing Committee on Banking, Trade and Commerce (27:112; 20/1/93). Commenting on the role of compulsory licensing in securing a cash flow that was said as necessary for the development of the Canadian generic industry from imitation to innovation, that:

\[ \text{[it] is important not to lose track of the fact that, under compulsory licensing, what the government envisaged back in 1969 was that the generic industry would grow and mature from being copycats to being innovators. We are now at that stage where the two major companies, Novapharm and Apotex, are undertaking innovative research. We have new products which are under development for the treatment of cancer and AIDS but we require continued cash flow which was guaranteed to us under bill C-22, which stated that there would be no negative change until 1996, to bring these products to fruition.}\]

\textsuperscript{150} Studies show that in the 1970s the average time required to develop a drug was 11.6 years. Development time, however, has since been on the increase, and it was reported that in 1994 the average time needed to develop a new drug was 14.8 years. These figures, however, correspond to the situation in developed countries. See, for example, U.S. Library of Congress, Congressional Research Service, \textit{Prescription Drug User Fee Act of 1992: Effects on Bringing New Drugs To Market}, (CRS Report 97-838 E, by David J. Cantor, Washington, 1997) at 4, online: University of Maryland, School of Law <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/97-838_E.pdf> (date accessed: January 10, 2011), (citing PhRMA, (1996), \textit{INDUSTRY PROFILE}, at 16). The estimated time required in the context of an innovative country (developed one) may not apply to a developing country setting. Thus, it may be fair to assume that the average time needed, in a developing country, would be longer.
the statement, it was only three years since the law became effective. And, fourth, such statements seek to suggest that the Jordanian case can be generalized and applied to other developing countries, which may exhibit different circumstances and market endowments.

The 1999 Patents Law, as amended in 2001 to implement the USJFTA, is not the first experience for Jordan in protecting pharmaceutical product patents. In fact, such a protection was available in Jordan when many of today’s developed countries denied it; namely, the period which lasted from 1953, when the Jordanian Patents and Design Law151 was enacted, until 1986. In 1986, the Patents and Design Law was amended for the single purpose of abolishing product patent protection of inventions related to food, drugs, and chemicals.152

Before the 1986 amendment, the only three local companies153 then manufacturing in Jordan undertook almost no R&D.154 Their business mainly focused on two activities: importation and distribution of final drugs and medicines to the local market as well as the formulation and packaging of imported ingredients.155 As well, there were no public institutions specializing in pharmaceuticals-related R&D, and it was not until 1986 that the first pharmacy faculty (established in 1980) started to provide the local market with graduates. As a result, stringent protection was not going to transform the NIS, under the described conditions, to an innovative environment.

However, the situation changed following the 1986 repeal of pharmaceutical product patents. Positive shifts were evident in both the number of new entrants and the level of R&D conducted by local firms. Between 1986 and 1999, 15 new pharmaceutical manufacturing firms were established. From almost no R&D activity before 1986, most firms established research units, and began to undertake research, although modest, in three areas: formulation and stability studies, bio-equivalence studies,156 and, at a later

153 These companies are: the Arab Pharmaceutical Manufacturers (APM), Dar Al-Dawa (DAD), and Hikma Pharmaceuticals.
154 See the discussion above on NIS and the level of local R&D activities.
156 See Ministry of Planning and International Cooperation, supra note 59.
stage, process development. Therefore, while 33 years of enhanced protection had no effect on the state of R&D conducted by the industry, 14 years of lax protection had made a more positive impact.

Moreover, the inference made based on this brief historical review of the interaction between the strength of patent protection and the level of R&D activity finds support in a statistical comparison between the number of patents issued to Jordanian nationals or residents by selected foreign patent offices, the US Patent and Trademark Office (USPTO) and the EU Patent Office (EUP), as well as by that of Jordan before and after 1999. The outcome of the comparison actually negates the alleged causality between enhanced protection and higher levels of R&D. In 1997, 1998 and 1999 the numbers of patents granted by the USPTO to applicants residing in Jordan were 4, 3 and 1 respectively. However, the number of patents granted during almost a decade of enhanced patent protection is still almost the same. According to the statistics of the USPTO, Jordanians were granted one patent only in 2006 and two patents in 2007, however, the corresponding number in 2008 is “zero”. Also, out of 54,699 thousand patents granted by the EPO in 2007, only two were obtained by Jordanian residents.

157 See Export and Finance Bank, supra note 60.

158 The lax protection bore fruit as it enabled the local firms to enhance their productivity and trade earnings. In 2000, the value of exported pharmaceutical products reached $110 million JD, treble the $35 million JD achieved by the industry in 1991. In the year 2000, the pharmaceutical industry accounted for 10.3% of total Jordanian exports, representing the second largest exporting industry after potash, compared to 5.8% in 1991. In addition, Jordanian drugs are exported to more than 60 markets around the world. See Export and Finance Bank, supra note 60; also see Ministry of Planning and International Cooperation, supra note 59.

159 Given that these two offices represent the largest two markets in the world for pharmaceuticals and in which firms hope to market their innovative products, the number of issued patents by these offices (the U.S. Office, in particular) are used to measure the innovative activity in different countries. For a case as to the importance of statistics about patents collected in these markets as a viable measure to meter innovation, see Freeman, supra note 21.


161 Ibid.


In relation to the Jordanian Patent Office, the picture is even bleaker. The available data indicate a deteriorating situation. Whereas in 2000 the number of applications submitted by Jordanian scientists and researchers was 71, the number dropped to 21 and 25 in 2002 and 2003 respectively. In addition, the number of patents granted to Jordanian nationals is also declining. Compared to 12 patents in 2000, nationals won only four patents in 2004. Based on the above statistics, strong patent protection prevailing in Jordan since 2000, clearly, has not so far stimulated R&D in the pharmaceutical sector. Local firms are dependent on the production of existing drugs and compounds, which involves little molecular synthesis and manipulation. These activities are the primary target that is mainly undercut by the new patent regime adopted under the TRIPS Agreement and, with respect to Jordan, the USJFTA. This outcome has negative impacts on domestic R&D capabilities, to the extent that such imitative activities contribute to building human and institutional capacities needed to advance and augment local R&D in the medium and long run.

Yet, it might be argued that although patent protection may not lead to more local R&D activity, thus innovation, it will contribute to the incentives provided to innovators located in other parts of the world. Consequently, the logic goes, the global overall rates of newly discovered, innovative medicines would increase as a result of the incentives from protection in Jordan. This added incentive effect occurs since granting patents in Jordan enables innovators to appropriate a larger share of the social value of their innovations, which in turn, increases the incentive to innovate. Along these lines, Jordan stands to benefit from having these medicines developed, even if they are developed

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164 For full statistical details about patents applications and grants, see the Website of the Jordanian Ministry of Industry and Trade at: <http://www.mit.gov.jo/portals/0/tabid/571/%D8%A7%D9%84%D8%A7%D8%AD%D8%B5%D8%A7%D8%A6%D9%8A%D8%A7%D8%AA.aspx>.

165 Since 1992 through 2008 the USPTO granted 12 drugs-related patents to inventors who mentioned Jordan in their applications as their country of residence. Six of these patents were granted in the period from 1992 through 1999, while the other six issued during the period starting in 2000 until 2008. Among these patents, five were product patents; see US patents 5,122,366; 5,607,971; 6,242,444; 7,084,144; and 7,176,206. Out the five patents three were granted after 2000; these are patents- 6,242,444 and 7,084,144- both claiming compounds for the treatment of erectile dysfunction and 7,176,206 claiming compounds usefull as active ingredients in pharmaceutical compositions, as an antibiotic. In contrast, the remaining seven patents claimed process inventions: see US patents: 5,574,154; 5,646,131; 5,665,775; 5,827,544; 6,187,333; 6,380,175; and 6,555,126. It is a fair inference based on these numbers as a means to measure innovative activities that the R&D activity in the Jordanian Pharmaceutical sector after the new Patents Law was enacted has not changed relative to that prevailing prior to its passage.
elsewhere. The merits of such an argument in light of the domestic realities of Jordan will be analyzed in the next section.

2.2.4.2. Strong Patent Protection in Jordan and Global Pharmaceutical R&D

The overall value of the medicine market in Jordan is insubstantial if considered in a global context. This is true with regard to innovative drugs, which are mainly imported from foreign manufacturers. For example, the entire pharmaceutical market was valued at $350 million in 2008, compared to $778.3 billion worldwide market in the same year (of which North America alone comprises $304.1 billion). This sum includes expenditures on patented and generics, imported and locally produced. Locally manufactured generics represent about 45 per cent of this value. This means that the added incentive provided to the global pharmaceutical industry remains trivial, and may be next to nil no matter how substantial the share an innovative drug might acquire.

It might, then, be argued that notwithstanding its triviality, the incentive derived from protection provided in Jordan and other developing countries may be substantial in the aggregate. This scenario has not escaped economic analysis. Indeed, research by prominent scholars in economics such as Chin and Grossman, Deardorff, Helpman, and Maskus addresses exactly the point stressed by this kind of

168 Ibid.
argument. For instance, in 1990, Chin and Grossman\textsuperscript{173} developed a model to study the incentives that motivate a government in the South (developing countries) to protect the IPRs of Northern firms and the subsequent implications for both welfare in the North and the efficiency of the world equilibrium. They concluded that the South will be worse off when implementing strong IPRs protection, and demonstrated that it may be in the interest of developing countries to provide no patent protection at all.\textsuperscript{174}

Deardorff, by examining the operation of the incentive theory in a developing country context where a would-be patent protection is as stringent as that mandated by the TRIPS Agreement,\textsuperscript{175} recommended a complete exemption from any obligation to provide for patent protection for certain countries in the South. He maintained that the world’s welfare, in the aggregate, may be maximized as a result of such exemption.\textsuperscript{176} The unappreciable degree of added incentive that protection of patents in developing countries may contribute to the global incentive to innovate constituted the principal justification of his conclusion. He argued, first, that the \textit{extra revenue accruing from extending patent protection to poor countries is not likely to be significant enough to incentivize more innovation by patentees in the industrialized countries}. Second, even if the extra revenue may induce innovation, the losses suffered by outlawing imitation in developing countries are far more substantial. Third, a reduction in the global allocative efficiency is expected by extending patent protection since resources in developing countries will be withdrawn from imitation, in which they have a comparative advantage, and extended to innovation where they have no comparative advantage.\textsuperscript{177} Chin and Grossman\textsuperscript{178} suggested that if there was any possibility of enhancing global welfare as a result of extending patent protection to developing countries, this would be only in the case of “substantial innovations”.\textsuperscript{179} According to Deardorff’s analysis, innovations of

\begin{flushleft}
\textsuperscript{173} See Chain & Grossman, supra note 169.
\textsuperscript{174} Ibid.
\textsuperscript{175} Deardorff, “Welfare Effects”, supra note 170.
\textsuperscript{176} Ibid.
\textsuperscript{177} Ibid.
\textsuperscript{179} Ibid. at 23-4.
\end{flushleft}
such a scale are unlikely as a result of extra revenues collected because of patent protection in developing countries.

Obviously, Jordan may stand to benefit, as may the rest of the world, from more global innovation and from the development of new and substantially innovative drugs. However, the following two observations are relevant. First, it is not a certain outcome that overall global R&D will increase in developed countries as a result of making patent protection in developing countries congruent with the TRIPS mandate, or even TRIPS-Plus in the case of Jordan. The reason for this skepticism is that, even if patents promote innovation, their marginal contribution diminishes beyond a certain point. Second, assuming arguendo that this is true, the issue then remains as to how much of a share, if any, people in developing countries may enjoy in the additionally invented drugs. In other words, it is highly likely that such drugs would either end up being unavailable or unaffordable (thus inaccessible) by health sectors and patients in developing countries, or because research by pharmaceutical MNCs may not address their health and medicinal needs.

Notwithstanding the uncertainty about the actual impact on local pharmaceutical R&D as a result of enhancing patent protection, Jordan may still gain on other “fronts”. That is, the preceding analysis has focused on examining the influence patent protection might have in a closed economy environment; but Jordan may still gain from patent reform in an open market setting. Particularly, again as declared in the TRIPS Agreement itself, gains may be in the form of advanced technology transfer and/or inducing MNCs to invest in the local pharmaceutical sector or in other sectors. The next section will study this dimension of the overall equation.

3. Has Stronger Patent Protection Increased Technology Transfer to Jordan through Licensing and Foreign Direct Investment?

Besides the R&D inducement justification explored in the forgoing discussion, the compromise contained in Article 7 of the TRIPS Agreement, which was concluded between developed and developing countries during the Uruguay Round of Trade Negotiations (hereinafter “UR”) to “sell” the agreement to the latter, embraces another
component. Namely, strong IPRs, patents protection of course, should contribute, inter alia, to the transfer and dissemination of technology. Therefore, according to the WTO (World Trade Organization), “developing countries, in particular, see technology transfer as part of the bargain in which they have agreed to protect intellectual property rights”.

Accordingly, the relationship between the level of patent protection and the means of International Technology Transfer (hereinafter ITT) such as licensing and FDI constitutes a central issue in the overall calculation of the socioeconomic costs and benefits of patent protection. The relevance of this relationship acquires a special importance with regard to finding an answer to the following question: to what extent enhancing patent protection in a developing country will induce or convince technology owners, mainly located in developed countries, to transfer their advanced technical knowledge to that country?

Addressing this question prompts another set of important and relevant questions.Namely, is the level of patent protection in a potential recipient country factored in by technology owners when they consider transferring their technology? If yes, and relative to the influence of other factors, say the overall economic environment, what is the weight that might be given to patent protection in the said calculus? Furthermore, what would constitute an optimal level of protection that is considered strong enough to induce ITT, but at the same time is not disadvantageous, or may be injurious, to other factors conducive to economic development in the would-be recipient country? Restrictions on imitation and on reverse-engineering as mechanisms to expand access to affordable medicines would represent one example of such adverse effects.

In fact, no conclusive, evidence-based answers to the foregoing questions were available at the time of signing the TRIPS Agreement in 1994. Nor, almost 16 years later, does the world today have a clear-cut and confident answer as to whether there is a

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181 Consider, for example, the following comment made by Maskus about the unrealistic nature of claims made by the U.S. and the EU that stronger and more globally harmonized IPR (Intellectual Property Right) systems lead to trade expansion as they reduce the cost of trade: “[but] how could they [U.S. and EU] know this? There was no systematic evidence on this point-not even good economic theory”. See Keith E. Maskus, “The WIPO Development Agenda: a Cautionary Note” in Neil Weinstock Netanel, ed., The Development Agenda: Global Intellectual Property and Developing Countries (New York: Oxford University Press, 2009) 163 at 164 [Development Agenda].
positive causal relationship between strengthening patent protection and the various means of ITT. This section attempts to provide a Jordanian perspective seeking to understand the claimed link. It will do so by providing an analysis of the interaction between strong patent protection enforced in Jordan, which even goes beyond what is required under TRIPS, and ITT thereto through licensing and FDI. I will first articulate what ITT, as a concept, means in this study, as well as an account for the various mechanisms through which advanced technology might be transferred to developing countries.

3.1. International Technology Transfer: Meaning and Means

3.1.1. Technology Transfer Defined

Although the phrase “Technology Transfer”, or other versions of it like “Transfer and Dissemination of Technology”, is mentioned four times in the TRIPS Agreement, the agreement does not define the phrase nor indicates what it might comprise. Although it has been incorporated in many other multilateral agreements, there is unfortunately no universally accepted standard definition of what Technology Transfer (TT) means. Rather, the concept has been defined by various entities and scholars. The articulated definitions are not uniform; discrepancies exist since varying emphasis is placed by the

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182 The WIPO Development Agenda instructed under cluster C and as detailed by agenda item 25 mandate the undertaking, among others, empirical studies to understand the link, if any, between strong patent protection and ITT.


184 For example, Technology Transfer clauses are found in other WTO agreements, including the Agreement on the Application of Sanitary and Phytosanitary Measures, and the Agreement on Technical Barriers to Trade.


186 For example, see UNCTAD, infra note188; Grace, infra note 189; and see Maskus, Technology Transfer, infra note 192.
different definitions on the means used in transferring the technology and/or on the outcome of TT.\footnote{This might include absorbing the transferred information and utilizing them in R&D projects to build on and advance the involved information, develop human resources and technical skills, and apply the information to expand local production.}

For example, Article 1.2 of Chapter One of the Draft Code on the regulation of TT defines it as the “transfer of systematic knowledge for the manufacture of a product, for the application of a process or for the rendering of a service and does not extend to the transactions involving the mere sale or mere lease of goods”.\footnote{See United Nations Conference on Trade and Development, Draft International Code of Conduct on the Transfer of Technology, as at the close of the sixth session of the Conference on 5 June 1985, UN Doc. TD/CODE TOT/47 (1985).} This definition thus excludes from the concept any technology transferred indirectly and through trade in goods or services. Therefore, a technology is considered transferred only if the knowledge, skills, expertise, and/or know-how underlying such a technology (but not a matter embodying it like a product) is/are the subject matter of a transaction between two parties regardless of their nature – private or public.

The Code’s definition, according to Grace, focuses on TT as a “process of sharing knowledge, skills, expertise and know-how”.\footnote{See Cheri Grace, Leveraging the Private Health Sector for Public Health Objectives, (A Briefing Paper for DFID [Department for International Development, in the UK] on technology transfer in the pharmaceuticals sector, (London: DFID Health Systems Resource Centre, September 2004)) at 7, online: DFID <http://www.dfidhealthrc.org/publications/atm/Grace.pdf> (date accessed and downloaded: January 15, 2011).} Such a process, added Grace, covers four categories of technical knowledge:

- Technoware, including physical objects and equipment;
- Humanware, including skills and human aspects of technology management and learning;
- Infoware, including designs, blueprints, and document-embodied knowledge on information and technology;
- Orgaware, including organisational knowledge needed to operate a given technology.\footnote{Ibid.}

However, as far as pharmaceuticals are concerned, she perceives TT to mean “the dissemination of knowledge and expertise in the pharmaceutical sector from developed country organisations to organisations in developing countries”.\footnote{Ibid. at 5.}

In line with the view of TT as a process, Maskus emphasizes the objectives underlying TT which to him means “any process by which one party gains access to a
second party’s information and successfully learns and absorbs it into his production”.192 According to this conceptualization, a technology is considered transferred if, following cross-border exchange, the transferee successfully learns and becomes capable of applying the technical knowledge into its production. In other words, TT involves the dissemination and effective diffusion of the technology, including the provision of know-how and technical expertise necessary for effective utilization of the technology. For purposes of this thesis, Maskus’ definition of TT will be embraced as long as the transfer process occurs through commercial mechanisms, since they are claimed to be sensitive to and affected by the level of patent protection in a would-be recipient country.

3.1.2. Mechanisms of International Transfer of Technology

Technology may be transferred among countries through a multitude of channels. Based on the common factor utilized or followed by a classification, these means are grouped in different classes. Seen as an economic activity, Maskus classifies the various channels of TT into two groups: market-based and non-market-based.193 While he considers trade in goods and services, FDI, licensing, joint ventures, and cross-border movement of personnel as market mechanisms; he perceives the following as non-market based: imitation, departure of employees, information contained in patent applications and test data, and temporary migration.194

The same mechanisms are also classified based on the legal means utilized to transfer the concerned technology: as contractual and non-contractual. Whereas licensing, joint ventures, and cross-border movement of personnel are examples of the former, FDI, imitation, and information contained in patent applications are mostly grouped under the latter (non-contractual). Yet, a third categorization divides these means as direct (e.g. FDI

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193 Maskus also refers to those channels that derive from market transactions as “formal” while those that do not involve such transactions are described as “informal”; ibid. at 10.
194 Ibid. at 10-13.
and licensing) and indirect (e.g. trade in goods and services, imitation, departure of employees, and temporary migration).  

Here, the analysis of the claimed link between the level of patent protection and TT in the context of Jordan will be limited to three of the above mentioned means only. These are data and information contained in patent applications, licensing, and FDI. These mechanisms are chosen for three reasons. First, the selected modes of transfer are considered representative of the various modes. For example, licensing is considered a market-based mechanism that is contractual and transfers technology in a direct mode from the licensor (the owner) to the licensee. In addition, licensing may lead to non-market-based TT, such as spillovers and departure of employees.

Second, if the level of patents protection affects TT, it should be observed most through the means chosen for analysis herein. To explain, consider for example the difficulty that one would encounter in singling out the influence of patents on TT through what Maskus calls “temporary immigration”; which includes TT through: “migration of students, scientists, and managerial and technical personnel to universities, laboratories, and conferences located mainly in the developed economies”. Third, the three modes emphasized in this chapter are the means that are driven by commercial considerations, in light of the legal and economic environment in host countries, and without direct inducement or brokering from governments or NGOs (Non-government Organizations).

3.2. Specifications in Patent Applications and TT

Since inventors applying for patents are required to make full disclosure of their inventions, which must be in a manner sufficiently clear and complete for the inventions to be performed by a person skilled in the relevant art, it is argued that patent applications submitted by foreign inventors constitute a form of TT and dissemination. Details and

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196 The challenge faced by developing countries which try to have a foreign technology transferred via this mechanism, according to Maskus, is “to encourage its expatriate students and professionals to return home and undertake local scientific, educational, and business development”. Often, unfortunately, these people do not return resulting in a reverse TT. See Maskus, Technology Transfer, supra note 192 at 13.
specifications contained in the applications are considered technical information serving a diffusion function, thus, making them accessible for everyone, including local rivals. Such information, it is added, would have not been disclosed but for patent applications (the social contract theory of patents). Therefore, local enterprises of R&D can study these applications and the associated information, absorb the underlying technology, and build on it (advance it or invent around) to develop their own innovative products and processes.

Although such logic might be true in a developed country context where both advanced technical expertise and R&D capabilities exist, its relevance as a medium for the transfer of technology to a developing country such as Jordan is considerably qualified. This limitation stems from and is based on several reasons and factors, which may be legal, economic, or relate to the overall innovative environment.

First, the disclosure of an invention, even in a full and complete manner, does not mean a transfer of technology. Consider, for example, the text of Article 8.1 of the Jordanian Patents Law which reads:

> [a patent] application shall be submitted to the Registrar with the detailed description of the invention. The description shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person having ordinary skill in the art while stating the best mode for carrying out the invention known to him on the application date or the priority date.

The italicized part of this article stipulates that disclosure extends only to the information known to the inventor at the time of application. This means that the important actual know-how necessary to reduce an invention to a product or perform it as a manufacturing

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201 See the Patents of Invention Law No.32 of 1999, as published in the Official Gazette No. 4423, April 4, 2000(emphasis mine).
process is usually not included in the patent application and remains secret. Furthermore, the disclosure requirement extends to the information pertinent to the invention only, but not those of other relevant inventions either applied for separately or kept as secrets. Since many technologies involve multiple inventions and secret know-how and experience obtained through actual production, which is retained by engineers and technicians, it becomes much more difficult for a local rival to utilize such information in its production as envisaged by Maskus’ above definition of TT.202

Second, in light of the importance of experimentation and actual production experiences in the development of actual technical know-how, the information disclosed in patent applications may be of little relevance for effective TT to take place. That would be the case since the vast majority of patented inventions is not exploited in developing countries, including Jordan of course.203 This inference is reasonable because it is widely recognized that patent applications are documents drafted by legal counsel where technical information is disclosed only to the extent necessary to obtain a patent.204

Moreover, patent-conveyed information has been criticized as a source of technical information and diffusion not only in developing countries, but also in developed countries as well. For example, it has been reported that scientists and technologists are generally unaware of technical knowledge contained in patent “literature”. Also, technical information contained in patent documents are associated with access issues. On the accessibility matter, for anyone wishing to find out if particular technical information exists in one or several patent documents, one has to overcome, according to Smith, the following three obstacles: “the enormous number of patent documents; the fact that many of them will be in a language that the searcher of the information does not understand; and the effort of locating and the cost of obtaining copies of the desired patent documents”.205

202 See Pedro Roffe, supra note 7.
203 See Vaitsos, supra note 7 at 88 and 91-3; also see Roffe, supra note 7.
204 According to Macdonald “the information the patent system has accumulated is less a contribution to innovation than an obstacle to innovation. It becomes the responsibility of the patent attorney to help his clients avoid such obstacles”. He then observes the influence of the protective legal aspect of patenting even in deciding future research projects: “[corporate] patent attorneys have started scrutinizing their companies’ patent portfolios and have become more reluctant to give R&D managers the go-ahead on a new idea or business for fear of duplicating a patented product”. See Macdonald, supra note 123 at 14 (citing: Perry N., “The Surprising New Power of Patents” (1986) The Fortune 73 at 80).
205 See Smith, supra note 198 at 75.
However, it might be argued that pharmaceuticals are different since inventions in this industry are readily codified. In other words, pharmaceutical inventions are based on chemical or biological entities (molecules, and genes or proteins in the case of biologics) or processes used to make or retrieve such products; therefore, patent specifications provide a precise description of their subject matters. In turn, local rivals can easily obtain these precise specifications and use them. Again, it is assumed that local manufacturers in developing countries possess the necessary R&D infrastructure, skills, and expertise to reduce such information into medicinal products, which is not always the case. In addition, if such information is provided in patent applications, this means they can be acquired from foreign patent filings, at least with regard to foreign applications. That is, such information could be obtained for nominal fees by subscribing to journals of foreign patent offices where such specifications are published, or relevant data located on the internet,206 thus saving the local economy the static and dynamic socioeconomic costs associated with patent grants.

Nevertheless, despite the uncertainty about how viable a medium for TT patent documents are, enhanced local protection of patents may still represent a necessity to have advanced technology transferred via other means. Patent protection may be needed as a legal framework which functions to provide security against risks that might be associated with transferring advanced technology through contractual mediums such as licenses.

3.3. TT through Licensing

3.3.1. The Theoretical Basis

The influence that a level of patent protection in a given country may have on the decision of owners to transfer their technology is, at best, ambiguous. In a paper commissioned by WIPO to review existing empirical literature on the relation between levels of protection afforded IPRs by developing countries and ITT, Arora concluded that “there remain a number of important gaps concerning the role of IPRs in international

technology transfer, particularly in developing countries and countries with economies in transition”. In particular, Arora observes ambivalence in the literature as to how enhanced patent protection may affect the mode of transferring advanced technologies, whether such transfer is to affiliates of owners or to unrelated licensees in developing countries.

A growing number of studies have analyzed whether proprietors positively respond to patent protection in developing countries by licensing their technology or increasing its “quantity” and/or “quality”. Theoretically, Arora articulates a link that is assumed to exist between patent protection and licenses as a mode of TT. He maintains that protection provides the necessary legal framework in order to make technology licensing secured and meaningful, making it possible to formulate complex commercial transactions to transfer “tacit knowledge”. He explains that TT involves not only the transfer of technology codified in patents, but also valuable non-codified, tacit knowledge necessary to “activate” the patented part. Thus, specifically designed contracts to transfer such tacit information by means of technical support and training services become inevitable. It is practically impossible to draft such economically efficient contracts in light of information asymmetries and difficulties associated with implementation and monitoring; but, so the argument goes, patents make it possible to bundle the provision of training and technical services along with the patented technology.

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208 Ibid. at 47.

However, the level of protection afforded to patents is only one of the numerous factors that might influence technology owners to undertake ITT through licensing. Important factors may encompass: the local investment environment of the host country, the state of competition, available skills and expertise of labor market and its efficiency, regulatory and governance policies, and market openness.\textsuperscript{210} In addition, it is argued that the level of imitative capacity of local institutions in a host country may dictate the mode of TT. For example, studies have shown that the stronger such a capacity is the less attractive licensing becomes, which shifts the mode of TT towards FDI. Hence, the level of patent protection becomes relevant only if proprietors of technology prefer licensing.\textsuperscript{211}

Further, on the supply side, firms’ endowments such as size, scale of business, and complementary commercial capabilities may have an influence on how the level of patent protection impacts a firm’s decision to transfer its technology through licensing. For example, Arora and Ceccagnoli conclude that while stronger protection results in increasing propensity to patent, as did several other studies,\textsuperscript{212} it does not, however, increase the propensity to license by large technology owners (defined as firms with specialized complementary assets to commercialize proprietary technology), who prefer to invest their technology through FDI.\textsuperscript{213} The implication of this finding is that in a sector like pharmaceuticals, where the preponderance of technology is either developed

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\textsuperscript{210} See Maskus, “Using”, ibid. at 222.

\textsuperscript{211} See, for example, Carlos A. Braga & Carsten Fink, “The Relationship Between Intellectual Property Rights and Foreign Direct Investment” (1998) 9 Duke Journal of Comparative & International Law 163; also see Thitima Puttitanun, “Intellectual Property Rights and Multinational Firms’ Modes of Entry” (2002), Unpublished Manuscript, Department of Economics, University of Colorado, online: University of Colorado <http://www.colorado.edu/econ/CEA/papers02/wp02-14/wp02-14.pdf> (date accessed and downloaded: January 20, 2011). Puttitanun conducted an empirical study on how MNCs respond to changes in a country’s patent regime n the mode of entry to the market of that country. He concluded that “…strong IPR impacts positively on FDI more than on licensing. This internalization incentive is reduced in high R&D industries where imitation may become more difficult”.


by large firms or exclusively licensed or assigned to them, technology may not be transferred through licensing. Instead, these firms may favor exploiting their technology directly through FDI under a stronger patent regime. Consequently, by enhancing its patent protection, Jordan may not obtain technology from these firms through licensing. Nor may the country have the technology transferred through FDI, as will be seen in the next section, mainly due to the small size of its economy as well as other factors.²¹⁴

Yet, the relationship between the extent of patent protection and the level of licensing or the quality of licensed technology is a complex one. Licensing decisions depend on and are affected by interactions among various local factors.²¹⁵ For example, although the high costs associated with licensing, due to information asymmetries, would fall in a stronger patent protection environment with increased rates of rents for licensors, such an environment may reduce the number of new innovative products as a result of market power.²¹⁶ This reduction could potentially lead to negative impacts on the rate and number of licenses granted by innovating firms.²¹⁷

3.3.2. Empirical Evidence

Empirically, several studies have investigated whether strengthening patent protection in developing countries has positive effects on licensing rates. But, these studies have not reached convergent conclusions. Some found a positive relation;

²¹⁴ According to Braga and Fink, for a MNC to invest in a foreign market directly, two conditions must be met. First, the foreign market represents and offers location advantages, compared, say, to exportation. Location advantages are attributed to factors such as high transportation costs and tariffs, low input prices, access to distribution networks, and local regulatory environments. Second, it is more profitable for the MNC, when undertaking FDI compared to licensing, to independent entities located in a foreign market. This choice would be followed to avoid transactions costs associated with licensing, to control production inputs, and/or to preserve quality.) See Braga and Fink, supra note 211 at 170.


²¹⁶ Discussing the theoretical ambiguity of the impact of strong patent protection on the level of concluded licenses between innovative Northern licensor and potential Southern licensee, Yang and Maskus observed that “[o]n the one hand, stronger IPRs reduce imitation risk faced by the licensor, reduce licensing cost, and increase the licensor's rent share. These effects increase economic returns to the licensor and raise her incentives to innovate and license. On the other hand, the licensor has more monopoly power due to tighter protection and her incentive to innovate and license is correspondingly reduced” (emphasis mine). Ibid. at 58.

²¹⁷ Ibid.
Smith, Yang and Maskus, and Puttitanun are examples of these studies. However, two observations about their findings are worth a brief mention here.

First, they are cross-country studies relying on some form of index, where the levels of IPRs protection in various countries of the world are quantified. The two most frequently used indexes are those developed by Park and Ginarte and by Rapp and Rozek. These indexes have been criticized on various grounds, including methodological difficulties. For example, the indexes follow different criteria to develop acceptable means for ranking countries based on the strength of their IPR protection. That means, depending on the index followed, that the level of protection in a given country may vary. Therefore, the different results of similar cross-country studies, or their accuracy, may be influenced by index choice. Further, these indices were said to be based on the level of protection as indicated in the national laws but not the actual level of enforcement of the laws; and when it comes to using them by “regression-based studies, their use is additionally problematic if they are used, as is frequently the case, as cardinal variables, since the indices are ordinal”. Moreover, for differences among countries regarding criteria like coverage, protection duration, and enforcement,
the minimum standards of the TRIPS agreements substantially abridged these differences.\textsuperscript{227}

The second observation about the findings of the mentioned empirical studies, except that by Yang and Maskus, has to do with the measure utilized to study a possible link between the levels of patent protection and licensing. They used measures such as revenues generated from technology transferred intra-firm. In this context, the use of such a measure is problematic for at least two reasons. First, increases in royalty flows from foreign affiliates (which assumes some form of FDI is taking place) may be a direct result of higher prices charged by technology proprietors because of stronger market power ensuing from enhancing patent protection and not necessarily due to higher quantity or quality of technology transferred. Second, given that their conclusions are based on royalty flows from foreign affiliates, including those from parent-subsidiary relationships, these economic flows may be driven by reasons such as taxes and “Transfer Pricing”, but may not be as a consequence of an increase in the levels of TT.\textsuperscript{228}

Contrary to the findings of the preceding studies, no significant or measurable link between strengthening patent protection and international technology licensing has been found by many other empirical studies. In a cross-sectional study of industrial and developing countries, Fink estimated econometrically the impacts of different IPR regimes on the individual modes of TT, including foreign production and licensing, by U.S. and German firms in various manufacturing industries, including chemical products. The study found, \textit{inter alia}, a very weak link between the level of patent protection and the level of licensing concluded by German firms.\textsuperscript{229}


Studies such as that conducted by Fosfuri did not observe a correlation between stronger patent protection, as measured by the Ginarte and Park index, and the level of licensing in chemicals to unaffiliated foreign firms located in 75 countries.\textsuperscript{230} The same was reported by Bascavusoglu and Mariapluvia. They investigated whether patent protection had an influence on French technology owners to license and concluded that “patent protection in low-income countries seems to be not significant (or not pertinent)”.\textsuperscript{231} To repeat, it is obvious thus far that an answer as to whether, how, and to what extent the level of patent protection in developing countries such as Jordan impacts the propensity of owners to license their technology to unaffiliated firms located therein remains a matter on which the available evidence is ambiguous at best.

Therefore, it becomes relevant to find out whether strong patent protection is associated with TT through licensing in an individual country, sector specific setting: the pharmaceutical sector in Jordan. In Jordan, a strong patent regime has been implemented since 2000, and the country hosts an active non-innovative manufacturing industry consisting of several potential licensees of advanced technology. This, in principle, means that for this industry to produce patented drugs, it needs to obtain licenses from technology owners.

Despite claims to the contrary,\textsuperscript{232} a review of the level of licenses obtained by the local pharmaceutical industry following the implementation of the strong patent regime


\textsuperscript{232} Ryan, a scholar of the George Washington University and who was contracted by USAID to help the Jordanian government in drafting the 1999 patents law, claimed “[b]y 2004, a quarter of Hikma sales owed to its license relationships with European, Japanese, and Korean firms. Before IP reforms some leading American and European innovator firms say that as a matter of principle they refused to license to Jordanian firms. Post-reform, several companies distribute for European and American companies”. However, in a different document and by means of responding to a study conducted by OXFAM where a lack of FDI in and licensing to the Jordanian pharmaceutical sector was reported (mentioned above), Ryan contradicted himself stating that “the paucity of pharmaceutical manufacturing investment owes to the nature of the product—high-value but small and inexpensive to ship, which means that drug companies are not in general big global manufacturing investors. Second, Jordan is a small pharmaceutical market in a region riddled with pharmaceutical import barriers, so there is little business reason to invest in manufacturing capacity in the country”. See, respectively, Michael Ryan, “Seeking Health Competitiveness, Embracing Free Trade with the United States: Pharmaceuticals, Intellectual Property
in 2000 reveals, relative to licenses granted before that year, that a measurable influence of the regime change cannot be established. This lack of impact finds supportive indications, for example, in the ratio of under-licensing production to the overall local drug production, which remains insignificant. It is reported that less than 3 per cent of the total local drug production is manufactured under licenses. In addition, this percentage covers not only production under licenses concluded after 2000, but also includes contracts established before the advent of the new regime. In other words, this is an indication that the “quantity” of licenses granted to local pharmaceutical firms before and after the new patents regime remains stable. On this point, a senior manager at one of the few successful local licensees commented that:

[we] have several licensing agreements but most of them go back to before 1999 and those signed after 1999 had nothing to do with the FTA itself [as a reference to the level of patent protection]. It is our firm’s long standing policy to sign such strategic agreements whenever possible and beneficial. The FTA did not lead to any licensing agreements because it was a one-sided agreement. They told us that the FTA will be good for us, that it will lead to more innovation, joint ventures, licensing and R&D. It led to none of the above because stronger IP protection was never the problem. The problem itself was lack of resources, lack of sufficient R&D, lack of human skills and lack of infrastructure that are all necessary for innovation.

The situation with regard to the “quality” of licensed technology is no different. License agreements signed with local firms do not involve the transfer of advanced technology and know-how. Most of these licenses authorize local licensees only to distribute manufactured products of foreign licensors. If any form of manufacturing and development is allowed, it extends to packaging but not to synthesis of molecules and the


See Ministry of Planning and International Cooperation: Competitiveness Team, supra note 55 at 63.

See Hamed & Mohammed EL-Said, supra note 54 at 455.

This description of the firm was used by Hamed & Mohammed EL-Said, ibid.

Ibid.
manufacturing of medicinal products. Following field interviews with Jordanian pharmaceutical firms, OXFAM International reported that:

existing licensing agreements transfer little know-how to local manufacturers, and often are only distribution agreements. In interviews, many producers noted that licensing agreements are merely for the packaging of life-style drugs, including Cialis, an erectile-dysfunction medicine. Licensing agreements for synthesis or manufacturing are nearly non-existent. [Citation omitted]

In summary, evidence on a link between the level of patent protection and the level of TT through licensing is at best ambiguous. This inference is valid regarding both theoretical and empirical studies. Accordingly, a set of agendas adopted by the World Intellectual Property Organization (WIPO) in 2007 (so-called “Development Agenda”) called for an empirical examination of this relationship as well as investigating the lack of ITT to developing countries, although most developing countries have implemented a robust patent protection in accordance with minimum standards under the TRIPS Agreement. Central to the Agenda is the influence that enhanced patent protection may have on TT. Unlike the organization’s view of “IP as power tool of development” and approach to IPRs protection, WIPO’s Development Agenda, however, ties “IP-related policies and initiatives necessary to promote the transfer and dissemination of technology” with taking “appropriate measures to enable developing countries to fully understand and benefit from …flexibilities provided for in international agreements”.

238 Ibid.

[to] explore IP-related policies and initiatives necessary to promote the transfer and dissemination of technology, to the benefit of developing countries and to take appropriate measures to enable developing countries to fully understand and benefit from different provisions, pertaining to flexibilities provided for in international agreements, as appropriate.

Item 26 focuses on the role to be played by developed countries in transferring technology to developing countries. The item “[encourages] Member States, especially developed countries, to urge their research
It is evident that advanced technology has not been finding its way to the local pharmaceutical industry in Jordan through licenses. In addition, an appreciable change has neither been seen in the quality nor in the quantity of licensed technology as a consequence of reforming the patent regime in 2000. However, strong patent protection may still lead to advanced technology transfers through means other than licensing. In particular, this protection may induce MNCs, owners of technology, to invest their technology in the Jordanian market directly.

3.4. FDI as a Means of Technology Transfer to Jordan

Besides constituting a possible viable medium for the transfer and dissemination of technology, FDI is argued to bring about economic growth and consumer welfare.\(^{241}\) In particular, as far as TT is concerned, FDI-generated benefits include technology spillovers and enhanced productivity through, \textit{inter alia}, the formation and development of technical, skillful, and trained indigenous human labor capital.\(^{242}\) Enhancing IPR protection is said to constitute a prerequisite for inward FDI flows in technology intensive industries such as pharmaceuticals.\(^{243}\)

In light of potential disadvantageous outcomes to consumer welfare in developing countries as a result of implementing strong patent protection to pharmaceuticals, Helpman maintains that such welfare losses (especially in terms of trade)\(^{244}\) may be offset if enhancing patent protection leads to FDI.\(^{245}\) In this subsection, the relation between patent protection and FDI will be analyzed before a consideration of a potential role for FDI as a means of TT. The logic of this order of analysis is that it is \textit{a priori} and scientific institutions to enhance cooperation and exchange with research and development institutions in developing countries, especially LDCs”.\(^{246}\)

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\(^{242}\) Ibid.

\(^{243}\) See Mansfield, “1994”, infra note 262; Lee and Mansfield, infra note264; also see Richard C. Levin et al., supra note 114.

\(^{244}\) Higher drug prices, increased rates of licensing fees, costs in the form of lost employment opportunities, and capital transfer are some examples of such losses.

necessary to have FDI taking place before engaging in a determination of the effectiveness (or not) of this economic activity in transferring advanced technology to developing countries. In other words, we need to first determine whether enhancing patent protection increases inflows of FDI to developing countries.

3.4.1. Patent Protection and FDI

As an economic activity conducted by firms abroad, FDI is explained in the context of the well-known Ownership-location-internalization Theory (OLI) which links the decisions of firms to transform themselves into transnational corporations (TNCs) to the ownership of knowledge-based assets such as a new technology or know-how. In a weak patent protection environment, due to ownership advantages, it is argued that foreign technology owners stand to sustain additional costs in order to protect their technical assets if transferred to foreign markets. The additional costs might be suffered since technology owners would need further measures, relative to those needed under strong protection, to prevent imitation of their proprietary assets by, say, potential licensees.

Because of such additional costs and in order to keep their competitive ownership advantages vis-à-vis competitors in foreign markets, owners prefer to internalize their proprietary assets by investing them directly in foreign markets. But a potential market should offer locational advantages to make it more profitable for a firm to locate its business therein rather than having its products exported, or license their production to a

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247 See the discussion above about the transaction costs associated with licensing where an environment of weak protection prevails.

248 Although, relative to the size of the overall pool of technical knowledge, the protection-eligible share of intellectual outputs is small and given that there are other means for technology proprietors to invest these outputs, it is argued that the ownership of intellectual assets has two implications to the interplay between patent protection and FDI. First, there is a likelihood of engaging in FDI by firms active in the creation of such proprietary intellectual assets; and, second, the decisions of these firms to indigenize their ownership advantages are influenced by the level and policy of protection available in foreign markets. See Braga and Fink, supra note 211 at 170-71.
local entrepreneur. Locational advantages may embrace those stemming from multiple factors such as “high transportation costs and tariffs, low input prices, access to distribution networks, and local regulatory environments”.250

It is argued that the impact of both the level of patents protection and policy is relevant to firms’ decisions to invest abroad and this effect is pertinent to the three elements of the OLI theory individually.251 On the Ownership element, those who develop and own technology are likely to engage in FDI; thus, decisions to invest their technical property in a foreign market would be impacted by the level of patent protection therein.252 With regard to the location “axis” of the theory, the level of patent protection is conceived of as a location advantage.253 Namely, it is assumed that there are different levels of patent protection in various markets as a consequence of the territorial nature of IPR regulation. This claimed advantage and its influence on FDI, however, is substantially offset by the TRIPS Agreement whose mandated minimum standards effectively abridge most of the differences among WTO members’ national law, hence, making them highly harmonized.

The forgoing normative argument in support of a positive link between strong patent protection and levels of FDI inflows is disputed on several grounds. First, it is argued that enhanced patent protection may not lead to more FDI. Since the OLI thesis suggests that weak patent protection increases transaction costs leading firms to internalize their proprietary technology through FDI, robust patent regimes may conversely lead firms to externalize the investment of their intellectual assets by licensing them to unaffiliated licensees.254 This dynamic suggests an inverse relation between patent protection and FDI inflows, where higher levels of the former may lead to negative effects on the latter.255

250 Ibid.
251 See Dunning, supra note 246.
252 See Braga and Fink, supra note 211.
253 Ibid.
254 Yang and Maskus found that in a strong patent protection environment, licensing is more likely to take place rather than FDI) see Yang and Maskus, supra note 215; a similar finding was also reported by Joanne E. Oxley, “Institutional Environment and the Mechanisms of Governance: the Impact of Intellectual Property Protection on the Structure of Inter-firm Alliances” (1999) 38 (3) Journal of Economic Behavior and Organization 283.
255 Arguing for a case of a positive relationship between higher levels of patent protection and TT through licensing, Maskus explains the dynamics of this relation in the following way: “[as] IPRs improve,
Second, the market power of innovative MNCs is bound to increase because of introducing enhanced patent protection, which limits competition from imitation. This market power could, instead of increasing FDI, make MNCs disinvest their assets in foreign markets since the driver for internalization of the intellectual assets (fear of losing them to imitators) is eliminated by patent protection; thus, switching to exports becomes a better business model for serving foreign markets. This was, for instance, how some pharmaceutical MNCs reacted to reforms of patent regimes in some South American Countries, the Andean countries, to introduce pharmaceutical patents. According to Correa, MNCs have begun to close down manufacturing plants after the reforms and, instead, serve these markets through importation. Therefore, the claim of a link between enhanced patent protection and FDI rests upon an unsettled theoretical foundation.

Further, although criticized on grounds related to methodology and on limitations regarding generalization of results, empirical evidence reported by survey studies indicates that there are many nuances in the relationship between levels of patent protection and FDI. In other words, at a time of globalizing not only industrial production of consumer goods, but also the various inputs of industrial production such as R&D, higher levels of protection have varying impacts on the different elements of the production process. This means that if there is a positive impact of a given level of patent protection on FDI, this impact would influence the composition of FDI, but not in its entirety.


256 See Maskus and Penubarti, supra note 212 at 227-9, 244.
258 The following critiques, for example, were voiced. It was argued that the surveys are based on the subjective perception of the interviewed executives of potential competitors (imitators), which may not necessarily reflect business realities. Another ground for criticism, with regard to the Lee and Mansfield index, is that their sample selection “is biased towards countries that have at least some technological capabilities and in which international disputes over IPRs are common”. See Braga and Fink, supra note 211 at 177.
259 See infra notes 262, 263, and 264.
261 Ibid.
For example, while IP executives in American companies operating in six industries, including pharmaceuticals, indicated that local levels of IPRs protection matter most for locating their R&D activities in a given foreign market, they associated much less impact to protection on their decisions to locate their sales and distribution outlets abroad. Similar results were reported for German and Japanese firms. In addition, the results of the abovementioned two surveys were applied in a cross-country regression analysis against a compiled index of IPRs protection in sixteen selected newly industrialized and developing countries. The analysis pointed to varying influence of patent protection on different stages of the production process and depending on a country’s score on the said index.

Moreover, it has been argued that firms have engaged in FDI, particularly with regard to establishing production plants, for reasons related to competition with rivals’ products in low-protection-level markets. This means that even in the absence of patent protection, innovating firms keep investing in foreign markets for commercial interests and to protect their market shares, particularly in large developing markets where they fear that competing products from developed countries would be exported thereto.

It seems that the historical practices of MNCs support this line of logic. For example, despite being accused of maintaining patent regimes that were described as weak, developing countries such as Brazil, Argentina, Turkey, and Egypt represented an investment destination for pharmaceutical MNCs before the conclusion of the TRIPS Agreement in 1994.

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266 Ibid.

Unlike the above-mentioned countries, Jordan provided strong patent protection to pharmaceutical inventions until 1986. Still, this protection was not enough to induce pharmaceutical MNCs to invest directly in the local pharmaceutical sector. This reluctance has been the case since the inception of the industry in the early 1960s. FDI is missing from the entire spectrum of production stages: from R&D to the establishment of manufacturing plants. Accordingly, patented medicinal products have been mostly made available, although expensive and often unaffordable, through importation. Moreover, the lack of FDI in the sector has been persistent regardless of the various levels of protection enforced throughout the different periods, including that since 2000 where TRIPS-Plus measures (“dictated” in the USJFTA for the protection of pharmaceutical patents) have been implemented.268

That FDI has been missing from the local pharmaceutical sector seems to indicate that, relative to the influence of the level of patent protection, MNCs’ decisions to invest abroad are predominantly influenced by factors related to the overall economic environment in and the size of a given market or economy. In addition to these factors, the nature of the pharmaceutical product itself has been claimed to represent another factor that explains why MNCs are not investing their technology in the local pharmaceutical sector directly: being “high-value but small and inexpensive to ship” 269

Combined, these factors explain why Jordan has not been a destination for investment by pharmaceutical MNCs despite the implementation of strong patent protection, according to Ryan.270 Given that pharmaceutical FDI is entirely missing in Jordan, it is not feasible, therefore, to investigate its role in having advanced technology transferred to the local pharmaceutical sector.


269 See Ryan, supra note 232 and accompanying text.

270 Ibid.
4- Implications for Medicine Availability and Accessibility

The preceding sections have established that strong patent protection in Jordan has failed to lead to the dynamic socioeconomic benefits, claimed by advocates to ensue from such protection. These benefits were supposed to constitute the win side of an “equation”. The loss side would have involved potential consequences to consumer welfare in the form of considerable static costs associated with reforming the patent regime. These costs are extensively discussed in the literature and may include the following:271 first, prices of patented medicines would increase. In the case of off-patent drugs, such increase in prices may result from testing data protection preventing generic competition. Second, higher royalty rates would likely be experienced for licensing the necessary technology, when any licenses were available in the first place. Third, the costs of replacing or adapting infrastructure installed for the development of imitations of patented products would be considerable. And fourth, substantial administrative cost would arguably be sustained in order to implement and enforce the new regime.272

The effects of patent protection on royalty rates and costs incurred as a result of implementing and enforcing the new patent system in Jordan will not be subject to further discussion for the following reasons. As I have explained in Section 3 above, enforcing


272 The administrative costs would result from the following: larger number of patent applications submitted to the national patent office and patents granted thereof. These applications involve procedures and activities that need administrative infrastructure such as offices and office equipment and supplies. They also require laboratories furnished with up-to-date technology to examine submitted applications for patentability requirements, skilled personnel, and legal expenses to draft laws and regulations.
enhanced patent rights since 2000 has not led to the conclusion of more licensing contracts by local pharmaceutical firms. Also, with regard to the terms of granted licenses, local licensees have kept them secret. Therefore, if strong patent rights have led licensors to raise their royalties, the necessary data for an accurate assessment of increases in royalty rates are thus far too difficult to obtain. Nevertheless, the inability of the local industry to conclude more licenses demonstrates, arguably, another type of cost: that is, preventing the industry from acquiring, using, and learning from new patented technologies not worked locally. Before the year 2000, the industry could legally accomplish these activities through imitation. In addition, the lack of positive change in licensing activity may cause an avoidable deadweight loss when products under licenses are more affordable and associated with higher access rates, compared to the prices of brand medicines.

On the issue of administrative costs, the author has not been able to locate the necessary systematic, disaggregated data on the costs sustained by the Jordanian government as a result of implementing and enforcing the new Patents Law and the provisions on testing data protection. This has been the case despite efforts made by the author to obtain such data directly from the national governmental institutions entrusted with enforcing the new rules during a visit to Jordan in 2009. In light of this reality, the discussion in this section is limited to the effects of patent and data protection on access to medicines, as a result of increasing prices, and to the costs of replacing or adapting infrastructure installed for the production of generics by the local industry.

4.1. Increasing Prices and Implications for Access to Medicines

The effects of enhanced patent and testing data protection in Jordan are consistent with the results of several studies that have investigated the impact of the new multilateral IP system on prices of medicines in developing countries.273 Increased prices

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of medicines were reported immediately following the implementation of the new Patents Law in 2000. There is some evidence that links this price increase with the new rules on patent and testing data; however, investigating the validity of this link, although consistent with the predictions about extending such protection to developing countries, is beyond the scope of this thesis.274

According to a study by OXFAM, medicine prices in Jordan experienced an increase of at least 20% by 2006.275 The increase was not limited to patented drugs, but also was seen in prices of off-patent medicines, arguably, as a result of pharmaceutical testing data protection.276 Prices of medicines across 179 therapeutic classes increased. One of the major factors contributing to this price increase was a lack of competition from generics attributed to the new IP rules in the country. Since at the time of the OXFAM study (2007) only 5 patented new medicines entered the Jordanian market, the study attributed its estimates of the costs of preventing competition from generics only to the protection afforded to testing data. According to OXFAM, “the Jordanian government and consumers could have saved between $6.3m and $22.04m” on drug expenditures between 2002 and 2006. The estimates cover savings on 81 medicines protected with data exclusivity as the only form of protection available during the studied period. The estimates represent “between 13.7 per cent and 47.9 per cent of the cumulative cost of new medicines with no generic equivalent on the Jordanian market, or between 1.2 per cent and 4.4 per cent of total pharmaceuticals spending”.277

These price increases have made it difficult for a considerable part of the Jordanian population to access essential treatments. Health officials at the Jordan University Hospital, a main public health provider, have stated that “a large number of poor Jordanians admitted for hospitalization refuse to be admitted partly because of high

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274 There are multiple factors with impact on the prices of new medicines. Besides a lack of competition from generics because of patent and testing data protection, the following may be responsible for changes in medicine prices: economies of scale and their influence on procurement negotiations and transactions, currencies exchange rates and fluctuations, and inflation.

275 See Oxfam, supra note 237.

276 For an extensive discussion on this issue, see Chapter Four.

277 See Oxfam, supra note 237 at 13-14.
costs of medicines”. In addition, officials at another public health provider, Royal Army Services Hospital, have voiced their concern over the health complications of decreasing rates of medicine consumption by poor patients. The officials have observed that “poor patients take less tablets each day, week or month than they should…because they no longer can afford the high costs of full medication”. Still worse than this accessibility problem, critical, live-saving drugs are not even available in some hospitals. For instance, national media has documented frequent complaints about regular unavailability, particularly in public hospitals, of imported medicines for the treatment of chronic diseases such as cancer, diabetes, asthma, high cholesterol, and cardiovascular diseases.

The regular unavailability of the above examples of medicines may be linked to the new IP regime to which studies have attributed the escalating prices of new drugs. Officials at the Ministry of Health state that their figures showed that 25 per cent of the ministry’s budget was spent to buy medicines in 2006. 2009 figures indicated even a higher percentage: 30 per cent. This increasing expenditure on drugs has impacted the ability of the Ministry of Health to pay drug wholesalers and stores (mainly importers), which may compromise Jordan’s health programs. A serious illustration of this potential was an incident in 2008 during which medicine suppliers stopped providing public hospitals with medicines as a mechanism to force the government to pay them. The lack of alternative cheaper generic drugs, much of which used to be supplied by the local industry, has contributed to the unavailability of drugs in the public health sector. El-Said cited a high ranked official at the Jordanian Joined Procurement Department stating that:

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278 See El-Said, supra note 54 at 462.
279 Ibid.
280 For example, in a report in the Jordan Times Newspaper (a daily national newspaper published in English) patients at Jerash Public Hospital were quoted as complaining that medicines such as “Daonil” and “Glucophage” used to treat diabetic patients and “Zocor” and “Lipitor” used for high cholesterol patients are missing regularly. See J. Irshaidat, “Patients Complain of Medicine Shortages in Jerash” Jordan Times (24–25 February 2006) 3, cited in Hamed and Mohammed El-Said, supra note 224 at 465.
281 See OXFAM, supra note 237 at 19 (citing Dr Salah Mawajdeh, Head of JFDA at the time (2006)).
282 See the Introduction of this thesis.
Before 1999 we used to produce everything, now we cannot produce patented drugs anymore. We can only produce drugs that either come out of patent protection, or out of five year data protection. Sometimes we even have to wait much longer in the case of new use or new indication protection.284

The new IP rules are partially responsible for the unavailability of medicines in the public sector leading to reduced generic competition. These rules target the domestic pharmaceutical sector limiting its ability to manufacture cheaper generic drugs for local consumption and for export.

4.2. Impact on the Local Pharmaceutical Industry

The new rules on patent and testing data protection have exerted a negative effect on the local pharmaceutical industry’s capacity to continue its supply of affordable generics not only to the local market, but also to export markets. The rules have meant that local manufacturers have to wait between 5 to 20 years before they can produce their generic versions of new medicines. For instance, under the rules of testing data protection, local manufacturers must wait from 5 to 8 years to register a generic copy of a newly registered medicine with JFDA.285 The industry has thus suffered heavy costs and its share of the local market has been shrinking. On the export side, recent statistics portray a dark picture of a declining trend.286

Preventing local firms from obtaining marketing authorizations for generic copies of new drugs until after the expiry of patent or data protection has taken its toll on their competitiveness. With dwindling production volumes and diversification, because of a

284 See El-Saied, supra note 54.
285 JFDA provides originators of new medicines with three years of data exclusivity if their products are registered for a new medical use. The implication of this extra period of protection is that data exclusivity over such products can be extended to 8 years. See Chapter Four for an extensive discussion on the protection of testing data under the Jordan law and the implications of such protection for access to medicines and the local industry in Jordan.
286 Data exclusivity negatively impacts exportation by the local generic manufacturers. It prevents them from obtaining a Free Sale Certificate (a certificate endorsing that a product is authorized for marketing in the country issuing the certificate) necessary to get their products approved in third markets. During the first eight months of 2009, a decline of 11.4 per cent in exports was suffered by the industry. This trend has not stopped in 2010. According to a monthly statistical report and compared to exports during the first quarter of 2009, export of pharmaceutical decreased by 3 per cent during the first quarter of 2010. See Central Bank of Jordan, Recent Monetary & Economic Developments in Jordan, (May 2011) at 41, online, CBJ Homepage <http://www.cbj.gov.jo/uploads/monthly_english.pdf> (date accessed: July 04, 2011).
lack of economies of scope and shift of demands to newer products, revenues from old products have been decreasing since 2001. In addition, the lack of economies of scope caused by preventing firms from marketing new drugs has raised the cost of production of their traditional production lines, making it difficult for these firms to sustain their manufacturing facilities. To survive the new reality, some local firms closed down or merged with others. For example, the Arab Pharmaceutical Manufacturing Company (APMC) was created by a merger between two companies in 2003, Arab Pharmaceutical Manufacturing (APHA) and Advanced Pharmaceutical Industries (ADPH). In the same year, the Jordanian Pharmaceutical Manufacturing Company (JPHM) was formed by the merger of two companies, Al Razi Pharmaceutical Industries Company and Jordanian Pharmaceutical Manufacturing Medical Equipment Co. Ltd. These developments will have serious implications for the welfare of citizenry in Jordan and have negative impacts on the country’s social and economic development.

4. Concluding Remarks

With regard to pharmaceuticals, the analysis presented in this chapter indicates that the protection and enforcement of strong patent rights in Jordan have not been conducive to its objectives as declared in Article 7 of the TRIPS Agreement: to contribute to the promotion of technological innovation and to the transfer and dissemination of technology. In the near future, it remains doubtful that such strong patent rights will achieve these objectives. We have seen that innovation may not increase to an appreciable level as a result of introducing strong patent rights and for a host of reasons. While some of these reasons are peculiar to the Jordanian context, others are intrinsic to the patent institution itself.

First, the local capabilities and capacities of the NIS to undertake R&D activities are modest. This state of affairs prevails not only in the private sector, but in the public sector as well, including educational organizations and research centers. Second, R&D is

expensive and needs substantial financial resources to make the necessary advanced technical equipments and human resources available in order for effective research projects to be undertaken. Fiscal resources are not available on a scale required to sustain research undertakings of innovative drugs. Third, these weaknesses of the individual elements of the NIS are aggravated because cooperation, coordination, and integration among these various elements are basically missing.

As to the reasons related to the patent institution itself, the following were observed. First, it has not been theoretically established that strong patent protection is a prerequisite for promoting innovation. In fact, evidence on the claimed positive link between enhanced patent protection and increased levels of pharmaceutical R&D, considered as an input for innovation, is at best ambiguous. This link has proven negative with adverse impact on subsequent innovation, particularly when broad patents are granted. Further ambiguity over the actual impact of levels of patent protection on rates of R&D has been revealed by empirical evidence and historically-oriented studies and analysis.

The lack of impact on local innovation is evident by the following indicators. First, the number of patents obtained by local inventors either locally or internationally remains similar to those claimed before reforming the regime. Second, expenditures on R&D have not increased. Third, various indicators of the performance of the NIS, including R&D activities and expenditure have been reported as weak by the World Competitiveness Report. In fact, strong patent protection has had a negative impact on innovation since it particularly restricts imitation activities, necessary for learning and fundamental to incremental technological developments.

The outcome is not much different in regard to the second principal objective intended by requiring developing countries to implement the minimum standards mandated in the TRIPs Agreement and as argued by advocates of stronger protection: the transfer and dissemination of advanced technology. In Jordan, the implementation and enforcement of high and unprecedented levels of protection afforded to pharmaceutical patents have failed to contribute to the transfer and dissemination of advanced technology to the local pharmaceutical sector. This failure is attributed to shortcomings peculiar to the function of the various means of TT in the Jordanian context.
The means of TT are categorized into several typologies. Of the different classes, three methods are considered representative. These are: data and information contained in patent documents, licenses, and FDI. Data provided in patent applications fall short of being the relevant medium for transferring technology to Jordan for the following reasons. Inventions disclosed in patent documents do not translate into transferred technology since the obligation to disclose extends only to the data known to the applicant at the time of application. This means the actual know-how necessary to reduce an invention to an applied technology is retained and remains secret. In addition, although the level of disclosed information may be adequate to perform the invention by a person skilled in the art in a developed country context, such a level of disclosure may not be so in a developing country such as Jordan. This inference is due to the technological development levels of the country, where the technical knowledge of the skilled person test requires more disclosure to perform the invention.

The same applies also to TT through licensing. It is not yet clear either theoretically or empirically how technology owners would respond to higher levels of patent protection in developing countries, including Jordan. In other words, the effect of higher protection levels on the propensity to license advanced technology remains ambiguous at best. While stronger patent protection may provide a legal framework to make it possible to formulate complex commercial transactions to transfer “tacit knowledge”, strong protection enhances the competitiveness of patentees and provides them with security against competition; shielded by this protection, technology proprietors may instead opt for exporting their patented products.

Moreover, among an array of factors that influence decisions to license technology internationally, patent protection represents only one element. These factors may include: the local investment environment of the host country, the state of competition, available skills and expertise of labor market and its efficiency, regulatory and governance polices, and market openness. They also extend to levels of imitative capacity of local competitors and to licensors’ endowments such as size, scale of business, and complementary commercial capabilities. Therefore, we have seen that some Jordanian pharmaceutical firms obtained licenses even before reforming the patent
regime. This regime, however, has not thus far led to an appreciable change in the “quantity” or the “quality” of licensed technology.

Finally, the prospect of transferring advanced foreign technology through FDI is yet less positive. Similar to that of licensing, the available evidence on the claimed positive link between enhancing patent protection and FDI is ambiguous, if not negative, as reported by several studies. Neither strong nor lax patent protection in Jordan has succeeded in convincing pharmaceuticals MNCs to invest directly their technology through production in Jordan. Instead, they have always supplied their patented drugs to the local market through exportation. Therefore, TT to the local pharmaceutical sector via FDI has been entirely missing.

The inference from all the above is that a regime of strong patent protection has failed to lead to the promised dynamic socioeconomic benefits. These benefits were supposed to constitute the win side of an “equation” where potential consequences to consumer welfare, in the form of considerable static costs associated with reforming the regime, represent the other side. These costs may include the following: first, increasing prices of patented medicines; there are reports of at least 20% price increases in Jordan since enforcement of the new patent regime. Second, higher royalty rates are likely to be experienced for licensing necessary technology. Third, the costs of replacing or adapting infrastructure installed for the development of imitations of patented products will be considerable. And fourth, the substantial administrative cost that is arguably sustained in order to implement and enforce the new regime.

Jordan seems to lose on both sides of the above-mentioned equation. This outcome should have convinced a rational Jordanian policy maker to take every legal means and measure available in order to mitigate and limit a burdensome impact on the welfare of Jordanian consumers. Compulsory licenses and parallel importation are two examples of the most referred-to measures. How much use, if any, Jordan has made of these and similar measures will be explored in the subsequent chapter.

288 See Section Four above for a discussion on these costs in the context of Jordan.
289 See Oxfam, supra note 237.
290 See Sub-section 4.2 above for a discussion on this issue in the context of Jordan.
291 See supra note 272.
CHAPTER THREE

TRIPS and the USJFTA Limiting the Limited: Eroding Flexibilities and Misinformed Implementation in Jordan

1. Introduction

As demonstrated in the previous chapter, strengthening the standards for patent protection has not enhanced local innovative activities of pharmaceuticals in Jordan, nor, by itself, has it persuaded the domestic manufacturers to invest more resources in R&D. In addition, the new legal environment has failed to convince and hence encourage MNCs either to invest directly in the local manufacturing sector or to enhance the “quality” or “quantity” of concluded voluntary licenses with Jordanian pharmaceutical firms, thus enabling the latter to obtain the former’s advanced technology for the development and manufacturing of pharmaceuticals. While none of the above-mentioned advantages, claimed to accrue for countries providing strong patent protection, have been enjoyed in Jordan - at least up to now - most of the anticipated drawbacks have either already been experienced or are likely to be felt in the near future. Given its own

1 For a detailed discussion on this issue see Chapters One and Two.
2 Studies have shown a considerable increase in drug prices in Jordan. See, for example, Oxfam International, “All Costs, no Benefits: How TRIPS-plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines”, (Oxfam Briefing Paper, March 2007) at 15, online: OXFAM (date accessed and downloaded: April 15, 2010); also see Hamed EL-said & Mohammed EL-Said, “TRIPS-Plus Implications for Access to Medicines in Developing Countries: Lessons from Jordan–United States Free Trade Agreement” (2007) 10(6) The Journal of World Intellectual Property 438. In addition, some national firms closed down or merged with others. For example, the Arab Pharmaceutical Manufacturing Company (APMC) was created by a merger between two companies the Arab Pharmaceutical Manufacturing (APHA) and Advanced Pharmaceutical Industries (ADPH) in 2003. In the same year, the Jordanian Pharmaceutical Manufacturing Company (JPHM) was formed out when two companies, Al Razi Pharmaceutical Industries Company and Jordanian Pharmaceutical Manufacturing Medical Equipment Co. Ltd., merged. See Global Investment House, Jordan Pharmaceutical Sector: The Healing Touch of Dead Sea, 2007 at 10, online: Golbal invistment (date accessed: April 15, 2010).
3 Since studies estimate that the average time spent on the development of a new pharmaceutical product from inception to market is around a decade, most patent applications filed following the 1999 Patents Law becoming effective may have not been developed in marketable products that are suitable for human medicinal use. See Joseph A DiMasi, Ronald W. Hansen & Henry Grabowski, “The Price of Innovation: New Estimates of Drug Development Costs” (2003) 22 Journal of Health Economics 151 at 166
and other developing countries’ previous experiences with enhanced patent protection, such a reality should have been predictable at the time the Jordanian government enacted the current Patents Law. Thus, one would think it reasonable to incorporate into the law as many measures as possible to address such anticipated drawbacks.

Jordan’s current Patents Law was enacted to implement the minimum standards for the protection of patents required under the TRIPS Agreement\(^4\) in order for Jordan to accede to the WTO. In anticipation that the regime they were about to construct could disadvantage developing countries, Uruguay Round negotiators insisted on keeping those measures that were necessary to maintain legal flexibilities for member countries. The aim was mainly to prevent a total curtailment of all means vital for securing access to affordable and life-saving medicines by the poor in developing countries. The Secretariat of the World Intellectual Property Organization (WIPO) has identified four groups of legal measures in the agreement considered as flexibilities afforded to WTO member countries: flexibilities as to the method of implementing TRIPS obligations, as to the substantive standards of protection, as to the mechanisms of enforcement, and as to areas not covered by the Agreement.\(^5\) This chapter is primarily concerned with those flexibilities related to substantive standards of patent protection to the extent that their availability, or not, impacts public health in Jordan as a developing country.

Contrary to the prediction made earlier that it would have been reasonable for the Jordanian government to adopt a permissive policy utilizing a broad range of such measures in the Patents Law, the statute has, in fact, implemented fewer measures than could be predicted. Jordan completely waived its rights to an additional transitional period available for developing countries who are required to extend product patent protection to areas of technology not previously protected (pharmaceuticals) in their

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territories on the general date of the application of TRIPS. Jordan also considerably limited the use of most flexibilities related to the substantive standards of patent protection afforded to WTO members under the TRIPS Agreement.

On the one hand, while the TRIPS Agreement left its signatories the full freedom, provided certain conditions were met, to determine and specify in their national legislation the circumstances that may lead to the issuance of compulsory licenses (hereinafter CLs), the Patents Law limited these grounds to a particular few. According to Article 22 of the Law, the following are the “exclusive” grounds on which the minister may issue CLs on patented inventions: in emergencies, as a corrective measure against anti-competitive practices conducted by right holders, for public non-commercial use, if the patentee fails to work its patent within a specific period of time, or to export medicines to countries devastated by epidemics or other serious public health problems.

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6 In accordance with Paragraphs 2 and 4 of Article 65 of the TRIPS Agreement and as a developing country not providing patent protection for pharmaceuticals at the time when the agreement was concluded in 1994, Jordan was entitled to delay the implementation of its obligations related to product patent protection of pharmaceuticals until 2005. Yet, the Jordanian Patents Law was fully enforced in late 1999, making product patents available to all pharmaceutical inventions. Paragraph 4 of Article 65 reads:

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

See the TRIPS Agreement, supra note 4.

7 The preponderance of these conditions is procedural safeguards that licenses-issuing members should preserve before, during, and/or until the termination of licenses. For particulars on these conditions, see below.

8 Article 2 of the law states that whenever the word minister is used, it shall be considered to refer to the Minister of Industry and Trade. The Article partially reads:

[the] following terms and expressions wherever mentioned in this law shall have the meanings assigned against them unless the context requires otherwise:

[...]

The Minister: The Minister of Trade & Industry.


9 This ground was added by the Amending Law No. 28 for the year 2007. The law added this ground to implement the WTO Decision of 30 August 2003 adopted for implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

10 Article 22 of the Patents Law reads:
On the other hand, parallel importation of products embodying patented inventions was effectively banned.\textsuperscript{11} In principle, Article 37 (A) of the Law considered importation of patented products placed in third markets by the patentee or with his consent legal.\textsuperscript{12} However, the second paragraph of the same article made any such importation conditioned upon patentee’s consent.\textsuperscript{13}

\begin{quote}
[the] Minister may grant a license to use a patent to third parties without obtaining the patentee’s consent in any of the following cases exclusively:

A. If the use of the patent by the state authorities or licensed third parties is a necessity for national defense or emergency or for noncommercial public good provided that the patentee is notified as soon as it becomes possible.

B

1. If the patentee doesn’t exploit it or exploits it insufficiently before the elapse of 4 years as of the application date or 3 years as of the granting date, the period to be applied is the one that elapses later. However, the Minister may grant the patentee an additional grace period if he deems that reasons beyond the control of the patentee have prevented exploitation.

2. For the purposes of item (1) of this paragraph, and without prejudice to the provisions of the related International Conventions, the importation of the subject goods of the patent to the kingdom shall be deemed utilization of the patent.

C. If the patentee exercises his rights in such a way as to prevent others from competing fairly.
\end{quote}

See Article 22 of the Patents Law, ibid.

\textsuperscript{11} Entitled “the Patentee Rights”, Article 21 of the law in part reads:

A. A patent shall grant its owner the following rights:

1. Where the subject of the patent is a product, the right to prevent any person who hasn’t obtained the owner’s authorization from making, exploiting, using, offering for sale, selling or importing that product (emphasis mine).

2. Where the subject of the patent is an industrial process, the rights to prevent any person who hasn’t obtained the owner’s authorization from using the process or the product directly made by the process, or offering for sale, or selling or importing the product.

See Article 21 of the Patents Law, supra note 8.

\textsuperscript{12} Article 37 (A) reads:

A. The provisions of this law shall not prevent any person from importing any materials or goods from a third party if that party enjoys the legal protection of the same patent protected in the Kingdom and if that importation is lawful, complies with the principles of commercial competition and fairly takes into account the economic value of the protected patent.

See Article 37 of the Patents Law, supra note 8.

\textsuperscript{13} Paragraph (B) of Article 37 of the Law, which was added as an amendment to the article in 2001, reads:

B. In spite of the inclusions of paragraph (A) of this article and without prejudice to the provisions of the related International conventions, importation of any goods covered by patent of invention from a licensee shall be banned if the licensing contract prohibits him from exporting to the kingdom, provided that the patent owner notify in writing the Customs Administration and the Registrar in this respect. The Registrar shall, at the expense of the patent owner, publish this notification in at least one of Local daily gazettes; and the applicable legislations shall apply to this case.

See Article 37 of the Patents Law, supra note 8 (original in Arabic, translation is mine, since the English version of the law, that is available from WIPO’s database of national laws, is not accurate).
importation by, or from, licensees. This paragraph, therefore, constitutes \textit{de facto} ban on parallel importation, preventing the importation of more affordable drugs. Such conditionality has been enacted despite a prevailing near consensus\textsuperscript{14} that the TRIPS Agreement does not require such a restriction and indeed Article 6 leaves this issue to each country’s discretion. This stipulation even includes 

Except for its commitment to protect pharmaceutical regulatory data against “unfair commercial use” for five years\textsuperscript{15} and conceding its entitlement for an additional five-year transitional period to implement the pharmaceuticals-related legal standards and commitments, the Protocol of Accession to the WTO\textsuperscript{16} indicates that the Jordanian government did not relinquish any other measure recognized as legal flexibility under the TRIPS Agreement. Thus, the price required from Jordan to join the multilateral trade forum did not embrace prohibiting parallel importation or confining CL to the above-mentioned limited grounds. Nor did it include the many other TRIPS-plus measures stipulated under the Patents Law. However, while negotiations to join the WTO were under way, the Jordanian government was engaged in a parallel process. Namely, the government was negotiating a Bilateral Trade Area Agreement with the United States (the USJFTA). Matters related to IPRs were among the central issues addressed by the negotiations, and were subsequently regulated under Article 4 of the Agreement\textsuperscript{17}.

Indeed, Article 4 of the USJFTA contains provisions that oblige Jordan to surrender several TRIPS-preserved safeguards and to adopt far stricter standards of patent protection. For example, the agreement broadens the scope of patentable subject-matters


\textsuperscript{15} For a detailed analysis and discussion of Pharmaceutical Regulatory Data protection in Jordan in accordance with the pertinent rules under both the TRIPS and the USJFTA Agreements, see Chapter Four.


to include, in addition to business methods and computer programs,\textsuperscript{18} plants and animals. Furthermore, the USJFTA limits the scope of exclusion of subject matters that might be legitimately excluded from patent protection under the TRIPS Agreement;\textsuperscript{19} hence, Jordan can exclude an invention from patenting only if it “is necessary to protect \textit{ordre public} or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment”.\textsuperscript{20} Jordan may also exclude from patentability “diagnostic, therapeutic, and surgical methods for the treatment of humans or animals”, but not human, animal, or plant as such.\textsuperscript{21} This means the USJFTA expands protectable subject matters since it demands its parties make patents available for inventions for which the TRIPS Agreement explicitly permits WTO members to deny patentability.\textsuperscript{22} And as mentioned above, after the USJFTA, Jordan amended its law to qualify the concept of international exhaustion of patent rights in the Patents Law. Effectively, the amendment resulted in banning parallel importation of patented medicines since it gave patentees the right to prevent non-consensual importation of their patented medicines. Thus, the law, in effect, extended right holders’ power to block any parallel importation of medicines legitimately placed on third markets by the patentee itself or by others with its consent into the Jordanian market by third persons.\textsuperscript{23}

This chapter seeks to analyze the extent to which Jordan’s discretion to implement these various flexibilities in its relevant domestic legislation has been confined. With regard to Jordan’s right to implement the measures discussed in this chapter, the analysis will focus on the provisions of the TRIPS Agreement. The analysis first identifies and considers the flexibilities available under the TRIPS Agreement. Then, it considers the

\textsuperscript{18} See Paragraph 5 of, Memorandum of Understanding on Issues Related to the Protection of Intellectual Property Rights under the Agreement between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, 24 October 2000, clarifying that “Jordan shall take all steps necessary to clarify that the exclusion from patent protection of “mathematical methods” in Article 4(B) of Jordan’s Patent Law does not include such “methods” as business methods or computer-related inventions.” online: USTR Homepage <http://www.ustr.gov/sites/default/files/uploads/agreements/fta/jordan/asset_upload_file120_8462.pdf> (date accessed: June 21, 2010).

\textsuperscript{19} Besides these excludable under the USJFTA, according to Article 27 of the TRIPS Agreement, Jordan has the discretion not to protect the following by patents: plants, animals, essentially biological processes for the production of plants or animals. See supra note 6 art. 27.

\textsuperscript{20} See the USJFTA, supra note 17 art. 4.18(a).

\textsuperscript{21} Ibid. art. 4.18(b).

\textsuperscript{22} See TRIPS Agreement, supra note 4 art. 27. (2&3).

\textsuperscript{23} See Article 21 of the Patents Law, supra note 11.
scope-limiting effects of certain provisions of the USJFTA on the availability of these measures. With respect to this latter point, a comparison with the relevant US statutes and case law will be conducted to determine how the provisions of the USJFTA related to these flexibilities are understood and thus enforced by its parties. The comparison should help to cast some certainty on the interpretation of these provisions; specifically, how interpreting these provisions would determine the scope and extent of the measures legitimately implementable by Jordan in accordance with the USJFTA.24 Whenever relevant, I will also refer to subsequent FTAs with provisions on the same issues.25

I argue in this chapter that Jordan, as a small, upper middle income developing country, has experienced and will continue to suffer negative impacts as a result of not enacting in its pertinent legislation many of these measures. Contrary to claims calling for a limited utilization of measures such as CLs, on certain grounds, and parallel importation in patent law, I argue that it is the inclusion in, rather than the removal from, patent law of like measures that brings about the desired objectives a country might strive for through a patent regime. However, such measures may become counterproductive if enacted for and based on grounds that are not reasonably founded and when invoked and used expansively.26 Yet, the advantages of these measures are critical to the social and economic development of Jordan and may include: enhancing the availability of, facilitating accessibility to, and augmenting the affordability of essential and life-saving medicines; increasing the rate of concluded licensing contracts; facilitating technology transfer; and improving the industrial and technological development of Jordan.

Given, undeniably, the disadvantageous size of its economy, Jordan should comprehensively make use of limitations on, and exceptions to, patent rights such as CLs. Grounds for the grant of CLs, such as failure or insufficient working of patented inventions as well as advancing the public interest (a refusal to license and high drug

24 See Section 4.3 below.
25 A considerable number of FTA Agreements were concluded by the American government after the USJFTA was signed in 2001. According to the USTR website, this number is 13 agreements. See the USTR website: <http://www.ustr.gov/trade-agreements/free-trade-agreements> (date accessed: September 13, 2010).
26 A compulsory licensing regime, for example, should be designed to execute a policy conducive to enhancing better access to affordable medicines. However, if the regime is enforced in such a way to respond to minor incidents of price increases, for instance, or being invoked with unreasonable frequency, it might become counterproductive. It might retard local innovation and deter foreign innovators from investing therein.
prices are examples of such interest), would constitute effective measures to combat abuses of exclusive rights by foreign and national patentees. Accordingly, in this chapter I will focus on these particular grounds. More precisely, I seek to determine whether Jordan can still enact all or any of them in its law; and, whether such enactment, provided it confirms to multilateral and bilateral obligations, is a viable choice and why.

Therefore, the next section will review the evolution of CL. The review begins by investigating what prompted the Union of the Paris Convention for the Protection of Industrial Property27 (the Paris Convention) to establish CL. It will examine how the law and judiciary of particular members of the Convention implemented and enforced its provisions on CL: in part, under statutory grounds. In addition, the section will take into account the extensive regulation of this matter under Article 31 of the TRIPS Agreement.

Section Three explores the non-working of patents as a ground of CL. I review the meaning of this ground and situations in which a patent might be considered not worked, as understood under the Paris Convention and comparative law. This section further examines the ability of WTO members to provide for this particular ground in light of the controversial non-discrimination clause in Article 27 of TRIPS Agreement. The analysis focuses on whether the TRIPS Agreement restricts the freedom of its members with regard to this ground. I then turn to examine the USJFTA’s provisions on this subject matter. Given the restrictive wording of Article 4.20 (c) of the USJFTA28 and considering that the non-working ground may constitute a legal basis to grant CLs under

28 Article 4.20 reads:
[neither] Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances:
(a) to remedy a practice determined after judicial or administrative process to be anti-competitive;
(b) in cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or
(c) on the ground of failure to meet working requirements, provided that importation shall constitute working.
Where the law of a Party allows for such use pursuant to sub-paragraphs (a), (b) or (c), the Party shall respect the provisions of Article 31 of TRIPS and Article 5A(4) of the Paris Convention (emphasis in original).

See Article 4.20 of the USJFTA, supra note 17.
certain US Acts (the US being a party to the USJFTA and bound by its rules), I investigate whether it is legally possible for Jordan to implement this particular ground.

However, in light of the ambiguity surrounding the non-working of patents as a ground of CL, Section Four examines the concept of the “Public Interest” as a safe legal “harbor” on the basis of which CLs may be granted. Accordingly, the analysis is limited to the context of public health as the principal determinant of whether a given situation or a circumstance might lead to a finding of the public interest and thus granting a CL on a particular patented invention. In addition, conditions and circumstances such as “a refusal to deal” (when a patentee refuses to license its patented invention to third persons on reasonable terms)\(^{29}\) and high drug prices (considered to constitute a *per se* public interest) are two circumstances that will be closely explored in the section. Similar to Section Three, the analysis will be supported by illustrations from comparative law and jurisprudence as well as other bilateral accords such as FTAs concluded by the US government with other countries. Section Five evaluates the likely pros and cons of establishing the discussed situations as legal bases for granting CLs in order to provide Jordanian citizens with better access to necessary medicines. Section Six concludes this chapter.

2. The Evolution of Compulsory Licensing

International, regional, and bilateral agreements for the protection of patent rights have always pushed for stronger patent protection, including introducing new measures or tightening old ones. This trend has been increasingly encroaching upon countries’ freedom (developing countries in particular) to design their national patent system as a tool to advance economic and technological development as they deem appropriate. For example, what might be considered patentable is no longer a matter left for the national

policy of countries. Following the conclusion of the TRIPS Agreement, it has become mandatory that patents be made available for all fields of technology regardless of what impacts such protection might have on national interests. In addition, several bilateral agreements mandate extending patent protection to subject matters that were not conventionally protected by patents such as business methods and computer software as well as animals and plants. CL has been a primary target at the center of this “freedom-eroding” trend.

2.1. Compulsory Licensing under the Paris Convention

Although deliberations that preceded the conclusion of the Paris Convention in 1883 strongly considered making it integral to the treaty, it was not until Article 5 of the Convention was revised at the Hague Conference in 1925 that compulsory licensing was first introduced in the text of the Convention. At that conference, two new provisions were added to Article 5. The first of these is Paragraph 2 which reads “…each contracting country shall have the right to take the necessary legislative measures to prevent the abuses which might result from the exclusive rights conferred by the patent, for example, failure to work”. The second is Paragraph 3 which states “[these] measures

30 See Article 27 of the TRIPS Agreement.
31 See, for example, Article 4 of the USJFTA, supra note 17; Article 15.9 of the US-Morocco FTA, and Article 15.10(4). With regard to banning parallel importation, see Article 15:8 (1)(b) of the US-Oman FTA and Article 16:9 of the U.S-Columbia FTA. The texts of the mentioned agreements are available online, USTR Homepage http://www.ustr.gov/trade-agreements/free-trade-agreements (date accessed: August 15, 2010).

1. The introduction by the patentee into the country where the patent has been granted of objects manufactured in any of the States of the Union shall not entail forfeiture.
2. Nevertheless, each contracting country shall have the right to take the necessary legislative measures to prevent the abuses, which might result from the exclusive rights conferred by the patent, for example, failure to work.
3. These measures shall not provide for forfeiture of the patent unless the grant of compulsory licenses is insufficient to prevent such abuses.
4. In any case, the patent may not be subjected to such measures before the expiration of at least three years from the date of grant or if the patentee proves the existence of legitimate excuses (emphasis mine) (as quoted in Ladas, supra note 32 at 527).
shall not provide for forfeiture of the patent *unless the grant of compulsory licenses is insufficient to prevent such abuses*. The measure was advanced as a corrective remedy in lieu of forfeiture, which was the only remedy hitherto enforced against patentees failing to work their patents in a patent-granting country.35

At that time, CL was perceived as a relief from forfeiture. The new rule delays forfeiture until after the grant of a CL and the failure of this measure to correct the non-working abuse. It was argued that replacing forfeiture, a stringent punishment, with CLs to “prevent the abuses” of exclusive patent rights, “for example, failure to work”, led to achieving two important goals. First, forfeiture may not be resorted to as an initial remedy; it is only allowed after an issuance of a CL fails to remedy the abuse concerned. Yet, neither forfeiture nor CL may be issued before the elapse of three years from the date of patent grant or four years counted from the application date for a patented invention. The second goal relates to the nature of the act of non-working itself. It was argued that the Hague Reform shifted the focus from failure to work as such being an illegal act entailing forfeiture to being an act that constitutes abuse of exclusive patent rights (just like any other abuse). Such a shift, as Ladas understood it, meant that:

…the patentee’s failure to work the patent becomes actionable if it amounts to an abuse, which could depend on such ancillary factors as the willingness of the patentee to grant licenses on reasonable terms and the extent to which the market for the patented article was adequately supplied.37

34 Ibid. paras. 2 & 3 (emphasis mine).
35 Before the Paris Convention entered into force, most industrial countries of the 19th century provided for forfeiture of patents not only as a remedy for failure to work, but also for the mere act of importing the patented product into a country. Members of the Paris Union, by signing the Paris Convention, undertook an obligation that “introduction by the patentee into the country where the patent has been granted of objects manufactured in any of the States of the Union shall not entail forfeiture”. See Paragraph 1 of Article 5 of the Paris Convention as adopted in Paris 1883, cited in Ladas, supra note 32 at 527.
36 The phrase “for example, failure to work” was inserted in the text during discussions because the Canadian Delegation to the Hague Conference insisted on making clear in the text that failure to work a patented invention is such an act considered as a *per se* abuse of the patentee’s exercise of its exclusive rights. See Ladas, supra note 32 at 528 (citing authorities).
In light of the subsequent practices of member countries, the above interpretation of the Hague Reform was not considered a substantial change, as portrayed above, for most members of the Paris Union. Almost all industrialized members considered the mere fact that a patented invention was not being worked as *prima facie* proof of abuse. This view was, seemingly, accepted by Bodenhausen, an eminent authority on the Paris Convention who was associated with the international organization overseeing the administration of the Convention: WIPO. In fact, the integration into the Convention of CL as a remedy for non-working was seen as a clear legitimization for using the mechanism by countries to correct a wide range of abuses, including non-working; and it “[stimulated] the adoption of a [CL] system in the patent laws of most countries which theretofore had no such provision”. In these countries, CL was adopted not only to remedy non-working and other abuses such as anti-competitive practices, but also to address other situations not associated with abuses of patent rights such as refusal to deal and high prices.

Countries have found in CL a suitable mechanism to respond to and control the power of right holders over patented inventions in situations where no rights have been abused. Thus, it has been used to address a range of issues and for various reasons, supposedly conducive to and supportive of the “public interest”. National emergencies, government use, and/or the broad concept of the “public interest” itself were all categorized as legal grounds for granting CLs since they were considered to be in the public interest. In addition to these grounds, many countries considered it *per se* in the public interest to compulsorily license pharmaceutical innovations as a means to secure

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38 Until early 1990, the vast majority of the world’s countries mandated local working of patented inventions as an obligation of the patentee. Indeed, they provided that a patentee’s failure to work constitutes a *prima facie* “abuse” of its exclusive rights. See Paul Champ & Amir Attaran, “Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute” (2002) 27 The Yale Journal of International Law 365 at 372. Also see Ladas, supra note 32 at 528-29, citing examples which show that the laws of most industrialized countries considered failure to work *prima facie* evidence of abuse.

39 Ibid.

40 See Bodenhausen, supra note 33 at 71.

41 See Reichman and Hasenzahl, *Historical Perspective*, supra note 37.

42 See Ladas, supra note 32 at 530.


44 Unlike the situation under the TRIPS Agreement, members of the Paris Convention could exclude particular fields of technology from patent protection altogether. Pharmaceutical (medicinal in general) and food products were the most commonly excluded fields by many members. It was reported that at the time
their nation’s access to patented medicinal products. Despite arguments to the contrary, it should be mentioned that member states considered the limitations under Paragraphs 3 and 4 of Article 5 applicable only to licenses issued in cases of abuse of rights, but not when licenses were granted on other grounds such as the public interest.

In spite of the aforementioned reform to liberalize the Convention’s rules pertaining to members’ discretion to institute CLs, it was still perceived that the consecutive revision conferences brought pressure to bear on this discretion. Thus, the various conditions and procedures enacted under Article 5 since the London Conference of Revision in 1934 (the first to take place after integrating CL in the Convention) were perceived as limiting members’ freedom to grant CLs, particularly in developing countries where the preponderance of patented inventions were not worked. One such

the TRIPS Agreement was concluded in 1994 some forty countries did not provide for either pharmaceutical product patents or process patents or both. See General Agreement on Tariffs and Trade (GATT), Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, GATT Document MTN.GNG/NG11/W/24, Note prepared by the International Bureau of WIPO, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, of 5 May 1988, online: WTO Homepage (GATT Documents) <http://www.wto.org/gatt_docs/English/SULPDF/92040090.pdf>(date accessed: August 15, 2010).

45 It has been observed that the condition that countries should not compulsorily license a patented invention on grounds based on a finding of abuse of rights before the elapse of three years from the grant date or four years from the application date is equally applicable to non-abuse grounds. See Reichman and Hasenzahl, Historical Perspective, supra note 37 at 11.

46 Article 5(4) of the Paris Convention as added at the Hague revision reads “In any case, the patent may not be subjected to such measures before the expiration of at least three years from the date of grant or if the patentee proves the existence of legitimate excuses” (emphasis mine). See Ladas, supra note 32.

47 At the end of the Lisbon Revision Conference, states decided to limit the application of the limitations on the freedom of members under Article 5(4) to abuses of failure to work or insufficient working only. Indeed, the following was then added at the beginning of Paragraph 4’s text “An application for a compulsory license may not be made on the ground of failure to work or insufficient working” (emphasis mine). See Ladas, supra note 32 at 535-36.

48 It was reported at the time of the Lisbon revision of the Paris Convention that around 15 members, the majority of whom were developed countries, “reserved the right in case of public interest to grant a compulsory license at any time” even before the period in Paragraph 4 elapses. The following countries were among the reported, Belgium, Canada, Denmark, Finland, France, Germany, Israel, Japan, Norway, The Netherlands, Rhodesia, Romania, South Africa, Sweden, and Yugoslavia. See Ladas, supra note 32 at 534-5, citing the International Bureau clarifying the applicability of the said limits under Article 5(4) to instances of licensing not involving abuses, at 534-35.

49 According to Vaitos, “[practically] all patents granted in developing countries are never worked in their territories. As such, patent protection is not only divorced from innovative but also from investment activity, and can block the use of technology to directly work the patented processes or products. Some investment activity, though, takes place in forward-linked operations that contain imported products that are covered in one way or another by patents.” He then concluded that the reasons behind holding patents without working them by foreign innovators, as represented in MNCs, in developing countries are: “(a) They are used to preserve import markets in developing countries for the patent holders. […] (b) Patents are used to exclude competitors, including other transnational enterprises, from investing in productive
condition was that two years had to pass following the grant of a CL before a patent could be subject to forfeiture arising from failure to work.\textsuperscript{50} In addition, the waiting periods stipulated under Article 5(4) meant that issuing a license to remedy a non-working abuse of patents could take as long as seven years from the date of patent application.\textsuperscript{51} Furthermore, patentees could avoid having their non-worked patents being compulsorily licensed if they advanced “legitimate reasons”\textsuperscript{52} for their inaction. According to Bodenhausen, matters related to legal, economic, and/or technical reasons with regard to exploiting a patented invention could constitute legitimate reasons.\textsuperscript{53}

Therefore, two opposing views prevailed regarding rules on CLs under the Paris Convention. For some, the rules were considered liberal and countries placed patented inventions under non-voluntary production for relatively any ground.\textsuperscript{54} However, for developing countries and international organizations such as the United Nations Conference on Trade and Development (UNCTAD), the international patent system, including rules on compulsory licensing,

\ldots is not, in its present form [1975], proving to be of benefit to the developing countries and that it is instead having a negative effect on their development. [and] \ldots patent laws and practices of developing countries, following international standards, have legalized an anomalous situation which had come to act as a reverse system of preferences granted to foreign patent holders in the markets of developing countries.\textsuperscript{55}

Dissatisfaction with the Convention’s rules on CLs of both developed and developing countries led to a protracted conference for the revision of the Convention activities in developing countries and from using them as bases for exporting to the rest of the world”. See Constantine V. Vaitos, “The Revision of the International Patent System: Legal Considerations for a Third World Position” (1976) 4(2) World Development 85 at 88 and 91-3.

\textsuperscript{50} Ibid. This criticism is directed at the condition inserted during the London Conference mandating that forfeiture of patents shall not be provided for by members “unless the grant of compulsory licenses is insufficient to prevent such abuses”. See Ladas, supra note 32 at 535-36.

\textsuperscript{51} See Vaitos, supra note 49

\textsuperscript{52} In 1956 at the Lisbon revision, members agreed that an application for a compulsory license should be refused “if the patentee justifies his inaction by legitimate reasons.” See the text of Article 5(4) Paris Convention, supra note 27.

\textsuperscript{53} See Bodenhausen, supra note 33 at 73.

\textsuperscript{54} See generally Jerome H. Reichman, “Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection” (1989) 22 Vanderbilt Journal of Transnational Law 747 [Opportunities and Risks]; and see also Reichman and Hasenzahl, Historical Perspective, supra note 37 at 12.

\textsuperscript{55} See United Nations Conference on Trade and Development (UNCTAD), Major Issues Arising from the Transfer of Technology to Developing Countries, (19975b) TD/B/AC.11/10/Rev.2 United Nations publications, Report by the UNCTAD Secretariat at 2 & 28.
initiated in 1979. Unfortunately, the member states could not bridge the gap separating their different views and negotiations ultimately collapsed in 1985 without any progress on the revision. The failure of the conference was blamed on the ideological differences between the two groups of members regarding the patent system generally and the rules on CLs in particular. Especially provocative, as perceived at the time by developed countries, were proposals advanced by developing countries to enhance their powers to impose CLs. Such developments were “instrumental in the decision to remove efforts to reform international industrial property law from the exclusive jurisdiction of WIPO and to bring them within the legislative and judicial jurisdiction of the GATT and its successor institution, the WTO.”

2.2. Compulsory Licensing under the WTO TRIPS Agreement

The protection of IPRs was one of the subjects for negotiation listed in the Ministerial Declaration which launched the GATT Uruguay Round of Trade negotiations at Punta del Este (Uruguay) in 1986. With regard to IP, this Round led to the conclusion of the TRIPS Agreement. Negotiations, of course, had to determine the rules governing the various contentious issues related to CLs of patented inventions. Overcoming demands by, and contentions with, developing countries on liberalizing rules on non-voluntary licenses that prevailed during the last revision conference of the Paris Convention was, in part, the underlying goal behind developed countries’ action to shift the discussions on international IP issues from WIPO to the GATT. These same contentions, however, had to be faced by delegates to the TRIPS negotiations during the Uruguay Round. Disagreements persisted throughout negotiations and were difficult to

57 Ibid.
58 For an account of arguments against these proposals, see Chapter One.
59 See Reichman and Hasenzahl, Historical Perspective, supra note 37 at 13-4.
60 See Gervais, Drafting History, supra note 14 at 11.
reconcile; the provisions on compulsory licensing spawned some of the most intense negotiations of the agreement.62

Nevertheless, the TRIPS Agreement was concluded in 1994 with Article 31 containing the provisions governing “Other Use Without Authorization of the Right Holder”,63 which represented a “compromise” reached by negotiators on the issue of CLs.64 Although the Agreement does not refer to the notion of “compulsory” or “non-voluntary” licenses, it is widely recognized that the phrase “other use” in the title of Article 31 refers to compulsory licensing, distinguishing it from uses allowed under Article 30.65 CLs, as understood under the TRIPS Agreement, are “other” exceptions to the exclusive “Rights Conferred”66 by patents, which are detailed under Article 28. They include preventing third parties from the acts of making, using, offering for sale, selling, or importing (subject to the provisions of Article 6)67 a patented product without consent from its proprietor.68 The patentee also has the rights to assign the patent, or transfer it by succession, and to conclude licensing contracts.69

Unlike the simple and less intrusive regime under the Paris Convention, CLs are governed by a comprehensive framework developed under Article 31 of the TRIPS Agreement as well as the provisions of Article 5 of the Paris Convention which was

62 Watal observed that “[some] of the most intensely negotiated provisions of TRIPs were those set out in Article 31 on the limitations that could be set by the State on the other use of patents without the authorization of the right-holder”. See Jayashree Watal, “The TRIPS Agreement and Developing Countries Strong, Weak or Balanced Protection?” (1998) 1 (2) the Journal of World Intellectual Property 281 at 296 [Balanced Protection].
63 See the TRIPS Agreement, supra note 4 art. 31.
65 See footnote 7 to article 31 of the TRIPS Agreement, supra note 4.
66 Article 30 is entitled “Exceptions to Rights Conferred”; and it reads “[members] may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”. Ibid.
67 Article 6 embraces the provisions on the regulation of IP rights’ “Exhaustion”. Ibid. at art. 6.
68 Ibid. at art. 28.1.
69 Ibid. at art. 28.2.
incorporated into TRIPS by virtue of Article 2(1). Article 31 elaborates a detailed set of substantive and procedural conditions constituting minimum standards required of all WTO members whose respective domestic legislation allows for compulsory licensing of patented inventions, making the two mentioned articles the primary authorities on this matter.

These mandated conditions specified the following: that applications for licenses should be evaluated on a case by case basis;\(^71\) that applicants should first seek to obtain voluntary licenses from the right holders on reasonable commercial terms and conditions; and that such efforts failed to culminate in a voluntary license within a reasonable period of time.\(^72\) However, the prior negotiations requirement may be waived in cases of “national emergencies” or “other circumstances of extreme urgency” and “in cases of public noncommercial” use.\(^73\) Also, the authorization to use the patented invention should be nonexclusive,\(^74\) non-assignable,\(^75\) and predominantly for the domestic market.\(^76\) In addition, right holders shall receive adequate remuneration “taking into account the economic value of the authorization”.\(^77\) The license should also terminate, or

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\(^{70}\) Article 2.1 reads: “[in] respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967)”. Ibid. art. 2.

\(^{71}\) Paragraph (a) of Article 31 reads “authorization of such use shall be considered on its individual merits”. See the TRIPS Agreement, supra note 4 art. 31.

\(^{72}\) The relevant part of Paragraph (b) reads “such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time”. Ibid.

\(^{73}\) However, right holders are entitled to be notified that their patents are being licensed without their consent. Accordingly, the second part of Paragraph 2 reads:

[The wireless version of the text]

\(^{74}\) Ibid. para. 2.

\(^{75}\) Ibid. para. (d).

\(^{76}\) This limitation does not apply if a license is assigned “with that part of the enterprise or goodwill which enjoys such use”; ibid. para. (e).

\(^{76}\) Ibid. para. (f).

\(^{77}\) Paragraph (h) reads “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization,” ibid. at para. (h).
be terminated, “if and when the circumstances that led to it cease to exist and are unlikely to recur”. 78

Finally, decisions regarding the legal validity of issued licenses as well as “any decision relating to the remuneration provided” in respect of such authorizations “shall be subject to judicial review or other independent review by a distinct higher authority” in the country authorizing the use. 79 However, notwithstanding its detailed regulation of non-voluntary licenses, Article 31 contains no restriction on WTO members’ freedom to determine the grounds upon which CLs may be granted, following the approach adopted by the Paris Convention in regard to this matter. 80

Along with the above-mentioned set of conditions and requirements, Article 31 speaks of certain illustrations that may establish bases for issuing licenses. The grounds mentioned include: 1) emergency and other circumstances of extreme urgency, 2) practices judicially-determined to constitute anti-competitive undertakings, 81 3) public non-commercial use, and 4) dependent patents (patents that cannot be exploited without infringing upon other patents). 82

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78 The Agreement requires that a decision to terminate an authorization to use a patented invention without the consent of the right holder is “subject to adequate protection of the legitimate interests of the persons so authorized”, ibid. at para. (g).
79 Ibid. paras. (i) & (j).
80 Commenting on the scope of Article 31 Cottier stated “[t]his provision, for the first time in international law, contains a detailed list of substantive and procedural conditions for compulsory licensing, yet leaves the motives for compulsory licensing to Members”. See Cottier, supra note 61. In addition, this freedom was confirmed in Paragraph 5(b) of the Doha Declaration on the TRIPS Agreement and Public Health, See Doha Declaration, WTO document WT/MIN(01)/DEC/W2, of 14 November 2001.
81 On this particular ground, the drafters of the TRIPS Agreement decided to waive two (contained in Paragraphs b & f) of the eleven conditions applicable to compulsory licenses and ameliorating the strictness of a third one (Paragraph (h) regarding adequate remuneration). Members authorizing the use of patented inventions on the basis of a finding of right holders’ conduct of an anti-competitive practice are free to grant non-exclusive licenses and free to export products produced under compulsory licenses. With regard to compensation in such cases, the Agreement states that “[the] need to correct anti-competitive practices may be taken into account in determining the amount of remuneration…” see Doha Declaration, ibid. para. (k).
82 With regard to dependant patents, the agreement stipulates the following additional conditions:
   (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
   (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
   (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

See Doha Declaration, ibid. para. (l).
TRIPS’ various stakeholders agree that these grounds constitute a legal basis to issue non-voluntary licenses. However, they disagree as to whether grounds other than those mentioned in Article 31 may serve as a basis to grant CLs. Disagreement is generally focused on two grounds. These include the insufficient or non-working of a patented invention within the territory of a patent-granting country and other situations representing the “public interest”. Granting involuntary licensing on the basis of certain circumstances considered necessary to advance the public interest was legally developed by countries in conformity with the provisions of Article 5 of the Paris Convention (discussed earlier). These situations include grounds such as a refusal to license a patent to a willing local enterprise on reasonable commercial terms, including an equitable consideration in exchange for the requested license, and high drug prices in the case of public health.

In light of the so-called non-discrimination clause in Article 27.1 of the TRIPS Agreement which reads “patents shall be available and patent rights enjoyable without discrimination as to …whether products are imported or locally produced”, some contend that this clause repeals the pre-existing right of member countries to recognize failure to locally work a patent as an abuse of the exclusive right that is legally redressable through issuing a CL. In any case, they add that it is a violation of the said clause when a member’s law establishes such situation as a ground for the grant of a CL in order to force local working. Many commentators, however, disagree. They maintain that instituting non-working as an abuse of patent rights remains a legitimate option and in conformity with the rules under the TRIPS Agreement for the following reasons. First, it is valid under Article 5 of the Paris Convention (incorporated in TRIPS by Article 2.1). Second, reading the non-discrimination clause of Article 27.1 together with other articles

83 Ibid. art. 27.1.

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and provisions of the agreement negates the “repeal effect claim”. And third, such a reading is further supported by the objectives and principles of the TRIPS Agreement.

Given the polarization of views on these issues, it is not surprising that legal disputes over these measures have arisen. Legal challenges were brought against South Africa and Brazil concerning provisions in their domestic legislation allowing CLs when certain situations arise. The first incident involved a lawsuit brought by 39 pharmaceutical companies against the South African government in 1997. The claimants contested the conformity with the TRIPS Agreement and the constitutionality of specific provisions of the South African Medicines and Related Substances Control Amendment Act. The contested provisions would have authorized the South African Minister of Health, inter alia, to issue CLs to import generic copies of patented HIV/AIDS-related medications to provide to its HIV/AIDS-infected patients at affordable prices.

The second legal challenge concerned a request by the Government of the United States on 8 June 2000 for the opening of a consultation with the Dispute Settlement Body on particular provisions in Article 68 of Brazil’s 1996 Industrial Property Law (Law No. 9,279 of 14 May 1996) which imposed a “local working” requirement on all patented inventions. The disputed law stipulated that a patented invention would be subject to compulsory licensing if an invention was not “worked” within the territory of Brazil. The

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85 It is argued that the rules contained in Articles 30 and 31, read together with the general principles of Article 8 of the TRIPS Agreement, limit the application of the non-discrimination clause. In addition, this limitation becomes clearer when Article 5(A)(2) of the Paris Convention is read “in the operation” of these TRIPS articles. Under Article 5(A)(2) Paris, failure to work was considered an abuse of rights although importation of patented products is allowed. In other words, the concomitant existence of importation and an obligation to work locally is not new to international patent law. See Halewood, infra.


87 See Section 15C of the South African Medicines and Related Substances Control Act (No. 101 of 1965), as inserted by Article 10 of the Medicines and Related Substances Control Amendment Act (No. 90 of 1997).

United States claimed that this local working measure violated Brazil’s obligations under the TRIPS Agreement, Articles 27 and 28, in particular.89

These two incidents provoked global criticism, since they, arguably, would have enjoined the two governments (and by implication, the rest of WTO developing members) from resorting to CLs to make low-cost and affordable drugs available to their citizens, depriving patients afflicted with HIV/AIDS and other serious illnesses in developing countries from having access to necessary medicines.90 Both incidents were terminated by either withdrawal91 or settlement through mutual agreement,92 and the disputed measures were left intact without any changes. Moreover, these incidents contributed to placing on the agenda of the WTO’s Council on TRIPS the issue of challenges to members’ rights to implement flexibilities afforded to them under the TRIPS Agreement (particularly compulsory licensing and the legitimate grounds thereof as long as public health is concerned). This ultimately led to the adoption of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health in 2001.93

2.3. The Doha Declaration on TRIPS and Public Health: Importance of Compulsory Licensing Recognized

2.3.1. The Doha Declaration

90 A march to the US consulate to protest the complaint against Brazil was organized by a global meeting for non-governmental organizations (NGOs) in Brazil. Similar demonstrations also voiced anger against the US action in other major Brazilian cities. In addition, a widespread NGO signature campaign involving organizations like Oxfam and Doctors without Borders publicized and called the public’s attention to the complaint. See Robert C. Bird & Daniel R. Cahoy, “The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach” (2008) 45 (2) American Business Law Journal 283 at 312-3, citing multiple references.
92 On June 25, 2001, the US Trade Representative withdrew the WTO complaint against Brazil and Brazil agreed, privately and voluntarily, to provide the US government with advance notice of compulsory licenses authorized pursuant to article 68 of its law. See the United States Trade Representative (USTR), “Special 301” Report, (2000) USTR Reports and Publications, Watch List, online: USTR Homepage<http://hongkong.usconsulate.gov/uploads/images/6EH6KGM-c0kwU0CSnXhA/usinfo_301_00-special.pdf> (date accessed: August 15, 2010).
93 See the Doha Declaration, supra note 80.
At the Fourth WTO Ministerial Conference in Doha a special Declaration on the TRIPS Agreement and Public Health was adopted on November 14, 2001 (the Declaration).\(^94\) The Declaration addressed many issues of importance to developing countries. Namely, it contained an explicit confirmation of their rights to utilize the flexibilities inherent in TRIPS and clarified that the Agreement’s rules “can and should be interpreted and implemented in a manner supportive of WTO members’ rights to protect public health and, in particular, to promote access to medicines for all”.\(^95\)

Although it did not add to the substantive rights and obligations under the TRIPS Agreement, the Declaration is considered an important step in the struggle to secure access to affordable medicines, since it “attempts to clarify the flexibility already embodied in the TRIPS provisions”.\(^96\) Further, the Declaration provided developing countries with the certainty\(^97\) they were seeking as to their right to avail themselves of the flexibilities under TRIPS. It also confirmed that the Agreement was not concluded solely to protect the interests of patentees (based mainly in developed countries), but that the Agreement was also able to accommodate the national policies of developing countries in sectors critical to their social and economic development, such as public health.\(^98\)

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\(^{94}\) Ibid.

\(^{95}\) See Paragraph 4 of the Doha Declaration, ibid.


\(^{97}\) Correa maintains that given its status as a strong political statement and being a Ministerial Decision with legal effects on both members and institutions of the WTO, the Declaration provided legal certainty to developing countries availing themselves of measures to secure access to health-related products such as pharmaceuticals without being dragged into legal disputes or being intimidated by actions of the kind. He further explains that

[it] is implicit within the Doha Declaration that differentiation in patent rules may be necessary to protect public health. The singling out of public health, and in particular pharmaceuticals (Paragraphs 6 and 7), as an issue needing special attention in TRIPS implementation constitutes recognition that public health-related patents deserve to be treated differently from other patents (emphasis mine).


\(^{98}\) See Vandoren, ibid.
Abbott, in his “Lighting a Dark Corner at the WTO”, provides a detailed background and analysis of events leading up to Doha as well as the contributions and roles of the various WTO members and NGOs influencing the adoption of the Declaration. Besides considering it an “unequivocal statement regarding the right of Members to grant compulsory licenses”,\(^9\) he concluded that the most significant accomplishment of the Declaration is Paragraph 4.\(^{10}\) The significance of Paragraph 4 mainly lies in its potential for constituting a WTO decision which is based on its “operative language” (as the paragraph was drafted in an agreement format), and the fact that it was adopted unanimously.\(^{11}\)

Moreover, an important achievement embodied in Paragraph 4 is the strategic placement of the second provision of the paragraph. The provision reads “In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”\(^{12}\) Given that the mentioned provision was preceded by an “agreement” that addresses public health and mandates that the TRIPS Agreement “should be interpreted and implemented in a manner supportive of WTO Members’ rights to protect public health and, in particular, to promote access to medicines for all”\(^{13}\) indicates that the referenced flexibilities enjoy exceptional status with respect to access to medicines.

Throughout the debates on the TRIPS Agreement and public health, compulsory licensing was a central issue. In Paragraph 5, the Declaration addressed two contentious, CL-related matters. On the one hand, it affirmed that there were no restrictions on members’ freedom to establish situations as grounds for CLs,\(^{14}\) including non-working of patents and grounds for the advancement of the public interest such as a refusal to deal and/or unreasonably high drug prices.\(^{15}\) On the other hand, the Declaration corrected the inaccurate notion that in order for WTO members to license compulsorily a

\(^{10}\) Ibid.
\(^{11}\) Ibid.
\(^{12}\) See the Doha Declaration, supra note 80 at para. 4 (emphasis mine).
\(^{13}\) Ibid. (emphasis mine).
\(^{14}\) Paragraph 5(b) reads “[each] Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”. See Doha Declaration, supra note 80.
pharmaceutical product in accordance with Article 31 of TRIPS, they must “proclaim a full-fledged national emergency”. The Declaration recognized that “[each] Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency”. 

In addition to its far reaching importance in clarifying the ambiguities of some TRIPS’ provisions, the Declaration pointed to the inability of many WTO members “with insufficient or no manufacturing capacities in the pharmaceutical sector” to avail themselves of compulsory licensing. In other words, issuing a CL on a patented invention does not help those countries. This is because they cannot manufacture the licensed product due to the developmental state of their local industry, nor can they import it from the markets of other WTO members where the product would be under patent protection and available from the patentee only. In the latter case, the third party member would be required to justify issuing a license and even then might not be able to export the required quantities to the country in need as a result of Article 31(f) of the TRIPS Agreement, where it is mandated that production under a CL shall be predominantly for the supply of the domestic market of the license-issuing country. Thus, Paragraph 6 of the Declaration instructed the WTO Council for TRIPS to find an expeditious solution to this problem and to report to the WTO General Council before the end of 2002.

2.3.2. The 2003 Decision of the WTO General Council: A Solution for Paragraph 6

The mandate given to the Council for TRIPS, to find expeditious solutions to the difficulties that would face certain WTO members in making effective use of CLs in the public health sector, was debated in the Council and was extensively analyzed by

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106 See Reichman and Hasenzahl, Historical Perspective, supra note 37 at 16.
107 See Paragraph 5 (c) of the Doha Declaration, supra note 80. Note that developing countries demanded this clarification since it was perceived that a general paragraph broadly recognizing their right to utilize policy measures under TRIPS would not clear up the uncertainty associated with past experiences when attempts were made to utilize measures such as compulsory licenses and parallel importations. See Bryan C. Mercurio, “TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World” (2004) 8(2) Marquette Intellectual Property Law Review 211 at 225.
108 See Paragraph 6 of the Declaration, supra note 94.
many scholars. The Council for TRIPS’ debates focused on substantive elements of the solution as well as identification of the most suitable legal means to fulfill the mandate of Paragraph 6 of the Declaration. By and large, the following three broad sets of issues were debated: 1) the scope of diseases to be covered by the solution, 2) the eligible countries to use the solution whether as importers or exporters, and 3) the TRIPS provisions that might constitute a potential legal solution to the problem. The following proposals were then discussed:

- an authoritative interpretation of TRIPS Article 30, authorizing third parties to make, sell and export pharmaceutical products without the consent of the patent holder;
- an amendment of TRIPS Article 31, authorizing exports of medicines produced under a compulsory licence to a country with insufficient manufacturing capacities;
- a dispute settlement moratorium with regard to the non-respect of the export restriction under Article 31(f); or
- a waiver with regard to the export restriction under Article 31(f).

Ultimately, two years after Doha, WTO members reached a consensus as to the mandate of Paragraph 6. They adopted the Decision of August 2003. The Decision contains two waivers regarding two of the conditions required under Article 31 of the TRIPS Agreement. The first negates the condition under Paragraph (f) of Article 31, whereby countries may issue CLs to export, according to certain conditions and

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112 See Bourgeois and Burns, supra note 221.
113 For a full discussion of these proposals regarding Articles 30, 31 and the moratorium proposal, including legal grounds against their use as potential solutions, see Correa, “Implications”, supra note 97; Abbott, “Compulsory Licensing”, supra note 64.
114 See Mercurio, supra note 221 at 229.
procedures specified in the decision,\textsuperscript{116} to third members with no or insufficient pharmaceutical manufacturing capacity.\textsuperscript{117} The second waives the requirement to compensate patentees for use of their patented inventions as regulated under Paragraph (h) of the same article. This waiver applies to CLs issued by importing members only; remuneration should be paid by licensees in exporting members.\textsuperscript{118} In addition, the Decision is a provisional waiver awaiting replacement by an agreement among WTO members to amend the TRIPS Agreement.\textsuperscript{119}

The Decision was met with diverse reactions. Some considered it a success; others, however, deemed its mechanism both impractical\textsuperscript{120} and bureaucratically cumbersome.\textsuperscript{121} Furthermore, the Decision was criticized as containing many ambiguous concepts and criteria for eligibility - for example, how and against what criteria a developing country could be determined to lack an industrial capacity in pharmaceuticals or an insufficiency thereof was left vague.\textsuperscript{122} Notwithstanding its implementation by

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\item\textsuperscript{116} Ibid. Paragraph 2.
\item\textsuperscript{117} Ibid.
\item\textsuperscript{118} Ibid. Paragraph 3 of the Decision.
\item\textsuperscript{119} Paragraph 11 of the Decision reads “[this] Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision”. Ibid. para. 11.
\item\textsuperscript{120} Abbott embraced the different reactions made by various involved stakeholders when he stated: [the] leadership of the WTO hailed the Decision as evidence that the organization could deal effectively with important issues of social concern. However, the reaction among a broad cross-section of stakeholders was more tempered. Nongovernmental organizations (NGOs) concerned about access to medicines were disappointed by the complexity of the arrangement, arguing that it would be unworkable in practice. Similar misgivings were expressed by developing country producers of generic pharmaceuticals. Spokespersons for the group of pharmaceutical companies that engage in substantial research and development (commonly known as Pharma) said they welcomed the Decision as finally resolving an open issue, but these companies later lobbied actively in Canada to restrict implementing legislation. The developing countries that had led the negotiations expressed satisfaction with the result, but others harbored doubts. The United States accepted the Decision as a problematic compromise, but has since sought to limit its scope of application.
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several developed countries, including the European Community, Canada, and Norway, the mechanism has attracted trenchant criticism. Such criticism has pointed to the fact that since its adoption, the mechanism was utilized only once, by Canada. It was reported that the company to whom the license was issued had already declared its intention not to repeat the experience, blaming it on the administrative complications involved both on the national and WTO levels. As a result, many have been calling for amendments to the pertinent regulations to make them less onerous, with particular emphasis on the list of permissible drugs. Despite criticism, the 2003 Decision became the basis of a proposed amendment to the TRIPS Agreement in 2005.

2.3.3. *Amending the TRIPS Agreement: The Decision of December 6, 2005*

On December 6, 2005 the WTO General Council decided to amend the TRIPS Agreement. The amendment adopted the above-mentioned waiver as a permanent measure regarding the difficulties caused by Article 31(f) of the TRIPS Agreement. The amendment consists of a waiver, Article 31bis, an annex on the terms and conditions for the application of the waiver, and an appendix providing basic guidance on the assessment of pharmaceutical manufacturing capabilities of potential importing members. The amendment is not yet in force, and on December 17, 2009 the deadline for its

124 See Bill C-9, An Act to amend the Canadian Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa), of May 2004.
125 Regulations of 20 December 1996, No. 1162, as amended by Royal Decree of 14 May 2004 (see WTO Document: IP/C/W/427 dated 17 September 2004 which contains a copy of new three provisions to the mentioned regulations, namely 107 through 109).
126 See testimony of Richard Elliott (Executive Director, Canadian HIV/AIDS Legal Network) before the Canadian Standing Senate Committee on Banking, Trade and Commerce during its session to review Bill S-232 that was held on October 22, 2009.
ratification was extended until 31 December 2011.\footnote{See WTO, Decision of the General Council for the WTO, *Amendment of the TRIPS Agreement – Second Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, WTO document WT/L/785 of 17 December 2009.} Two-thirds of WTO members must formally accept the amendment in order for it to become effective; however, in addition to the EU, only 30 WTO members had ratified the amendment by October 28, 2010.\footnote{See WTO, *Members Accepting Amendment of the TRIPS Agreement*, online: WTO Homepage <http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> (date accessed: October 28, 2010).}

Although the TRIPS Agreement tightened the requirements and conditions of granting CLS, it left for its signatories the discretion with regard to the circumstances and situations that they may establish as grounds of CLs. However, a “web” of Free Trade Agreements (FTAs) have been targeting, and thus encroaching on, the freedom of some WTO members to resort to this and other of TRIPS’ inherent flexibilities.

By these FTAs, the United States,\footnote{The United States has signed over 14 FTA agreements with developing countries, where four of which are Arab states Jordan, Morocco, Bahrain, and Oman; see Office of the United States Trade Representative/Free Trade Agreements at <http://www.ustr.gov/trade-agreements/free-trade-agreements> (date accessed: October 10, 2010).} the European Union,\footnote{The European Union signed more than thirty agreements with developing countries, many of which are located in the Middle East and North Africa Region (MENA) (including Jordan, Syria, Egypt, Turkey, and Israel). See the European Commission, online: <http://ec.europa.eu/trade/creating-opportunities/bilateral-relations/> (date accessed: September 20, 2010).} and, to a lesser extent, Japan,\footnote{For example, Japan concluded a bilateral agreement with Mexico, which contains a provision for the regulation of Intellectual Property Rights: Article 73 of the Agreement. The text of the Agreement is available online at: <http://www.mofa.go.jp/region/latin/mexico/agreement/index.html> (date accessed: September 10, 2010); see also Article 96 of Chapter 10 - entitled Intellectual Property – of Japan’s Bilateral Agreement with the Republic of Singapore, available online: <http://www.mofa.go.jp/region/asia-paci/singapore/jsepa-1.pdf> (date accessed: September 10, 2010).} have stamped out most of these flexibilities for many developing countries.\footnote{For example, these agreements, commonly, extend the scope of patentable subject matters to plants and animals, require patent term extension, limit or eliminate compulsory licensing all together on grounds other than those mentioned under the TRIPS Agreement.} Jordan has signed trade agreements with the US and the EU. However, the USJFTA has whittled away most of the legislative discretion (flexibilities) preserved in the TRIPS Agreement. To illustrate: the USJFTA mandates that Jordan shall protect health regulatory data related to second uses of old chemical entities against unfair commercial use and disclosure for three years;\footnote{Footnote 10 to Article 4(22) of the USJFTA reads “[i]t is understood that protection for ‘new chemical entities’ shall also include protection for new uses for old chemical entities for a period of three year” (emphasis mine), see the USJFTA Agreement, supra note 17.} shall not exclude business methods and
computer software from patentability;\textsuperscript{137} shall make available an extension of the patent term for pharmaceuticals-related inventions;\textsuperscript{138} and shall restrict circumstances for the authorization of CLs to include remedying anti-competitive practices, authorizing public non-commercial use, and/or responding to “national emergency or other circumstances of extreme urgency”.\textsuperscript{139}

2.4. Grounds for Compulsory Licenses Identified

The TRIPS Agreement, as the Doha Declaration confirms, does not restrict the substantive right of WTO Members to determine grounds for the issuance of CLs.\textsuperscript{140} Accordingly, a country may authorize the use of a given patent without the consent of its owner on grounds other than those explicitly mentioned in Article 31 such as emergency and extreme urgency, anti-competitive practices, public non-commercial use, and dependent patents. In addition, non-voluntary licenses may be issued not only to counteract abuses of the exclusive rights by patentees, but also to address general, broad objectives such as promoting the public interest in a given invention or even a particular field.\textsuperscript{141} Therefore, WTO member countries have the flexibility to “orchestrate” their

\textsuperscript{137} Paragraph 5 of the Memorandum of Understanding on Issues Related to the Protection of Intellectual Property Rights Under the Agreement between the United States and Jordan on the Establishment of a Free Trade Area (the Memorandum) reads: “Jordan shall take all steps necessary to clarify that the exclusion from patent protection of ‘mathematical methods’ in Article 4(B) of Jordan’s Patent Law does not include such ‘methods’ as business methods or computer-related inventions”, see Memorandum of Understanding, supra note 18; also available online at: <http://www.ustr.gov/sites/default/files/uploads/agreements/fta/jordan/asset_upload_file120_8462.pdf> (date accessed: September 20, 2010).

\textsuperscript{138} See Article 4(23) of the USJFTA, supra note 17.

\textsuperscript{139} See Article 4(20), ibid.

\textsuperscript{140} The only exception to this freedom is the Agreement’s mandate with regard to “semi-conductor technology”, where compulsory licenses may be authorized only for public non-commercial use and to correct anti-competitive practices.

\textsuperscript{141} When such a policy is pursued to promote the public interest in public health, this certainly is not in contradiction with Article 27.1 of the agreement. For example, the US provides preferential treatment to pharmaceutical inventions by making a patent term extension available in this field but not in others. In addition, both France and Belgium amended their laws to permit the grant of compulsory licensing on pharmaceutical patents relying on Articles 30 and 8 of the TRIPS Agreement. On the Belgian Law, see Overwalle & Zimmeren, infra note 463, and on the French law, see infra note 462.
compulsory licensing system in accordance with their needs and goals as long as it does not contradict the provisions of the TRIPS Agreement.\textsuperscript{142}

Exclusive patents rights are not absolute. Accordingly, and principally for public policy objectives, countries may establish in their respective laws exceptions to these rights and authorize the use of patented inventions without their proprietors’ consent. Over time, countries have established various statutory grounds for the issuance of non-voluntary licenses.\textsuperscript{143} Although it contains the most comprehensive legal framework ever to regulate such licenses, the TRIPS Agreement did not adopt an exhaustive list of legal grounds for the authorization of CLs. Further, it did not attempt to enumerate specific potential abuses of rights against which licenses might be authorized.\textsuperscript{144} This is the case since the delegates of different countries to the Uruguay Round of negotiations have failed to form a consensus about limitations on patentees’ exclusive rights, particularly non-confinement of compulsory licensing to specific, predefined grounds or abuses.\textsuperscript{145}

For developing countries, compulsory licensing has over time acquired a central importance in their negotiating position in the different multilateral fora of international patent regulation. During the late 1970s and early 1980s and through the negotiations to revise the Paris Convention under the auspices of WIPO, developing countries called for a change to the multilateral rules governing compulsory licensing. Perceiving the rules on CL as overly stringent, developing countries called for their modification in order to


\textsuperscript{143} See Reichman and Hasenzahl, \textit{Historical Perspective}, supra note 37.

\textsuperscript{144} For example, on the ground of failure to work a patent as an abuse of exclusive rights, Article 5 (4) of the Paris Convention restricts the discretion of its members in authorizing a compulsory use of a patented invention before the expiration of a period of four years from the date of filing of the patent application or three years from the date of patent grant to remedy the abusive non-working. Article 5A(2) of the Paris Convention reads: “[each] country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work”. Paragraph 4 of the same Article reads: “(4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license”. See Paris Convention for the Protection of Industrial Property, supra note 27.

facilitate the transfer of advanced technology to their economies. Developed countries firmly opposed this demand. Contentions over this issue, ultimately, led to the collapse of negotiations to revise the Paris Convention.\(^\text{146}\) This dissension between developed and developing countries was also present during the GATT’s Uruguay Round where developing countries stood their ground in rejecting all proposals that attempted to limit their power to grant CLs.\(^\text{147}\)

After the conclusion of the TRIPS Agreement, developing countries\(^\text{148}\) had to honor their obligations under the Agreement. Thus, they had to make patent protection of pharmaceuticals available not only for process inventions, but also for product inventions. In addition, they had to render their patent laws compliant with the minimum substantive standards prescribed in, among others, Article 27.1 of the Agreement. Believing that the language of Article 31 of the Agreement contains no restraint on their rights to provide for statutory ground to issue CLs, developing countries attempted to exercise their discretion with regard to this matter. Therefore, countries such as Brazil, Argentina, India, South Africa, Taiwan, and Indonesia decided to establish in their relevant law CL grounds, including abusive non-working of patents. Such grounds were commonly found in the legislation of most developed countries throughout the 20th century.\(^\text{149}\) “Ventures” of this kind were faced with fierce political pressure from developed countries in addition to attempts of legal challenge in the WTO Multilateral Dispute Settlement System.\(^\text{150}\) Based on the national practices of member countries, the

\(^{146}\) See Vaitos, supra note 49.


\(^{148}\) The advent of the TRIPS Agreement required not only developing countries to change their patent laws’ underlying public policy with regard to pharmaceutical patent protection, but also developed countries like Canada were under pressure to carry out major changes to its policies.


\(^{150}\) See WTO, Brazil - Measures Affecting Patent Protection, WTO document WT/DS199/1 of 8 June 2000; also the Association of Innovative Pharmaceutical Companies in tandem with its 39 members filed a legal case challenging the South African medicines law which, inter alia, would have authorized the Health Minister to issue non-voluntary licenses to import certain medicines. Furthermore, in May 2000 the United States initiated a complaint against Argentina in accordance with the WTO rules on disputes as contained in the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU). The US
following grounds were identified as legitimate for authorizing the use of patents without the consent of their proprietors: refusal to license, non-working and inadequate supply, public interest, anti-competitive practices, governmental use, dependent patents, and CLs for medicine.\textsuperscript{151}

In summary, the compulsory licensing measure was introduced into the Paris Convention and its adoption was encouraged by industrial interests as a “salvation” from forfeiture of non-worked patents. Therefore, the Paris Union\textsuperscript{152} particularly envisaged this measure as a remedy for non-working of patents, which to date may be considered a \textit{per se} abuse of patent rights under the Paris Convention in and of itself and by reference under the TRIPS Agreement. Over time the measure was used to correct other abuses of rights, including the utilization of patent rights to effectuate anti-competitive practices. Furthermore, members of the Paris Union expanded the actionable situations with compulsory licensing to embrace situations not constituting an abuse, but rather which would enhance the public interest; for example, refusal to license and high prices. As to the particular case of non-voluntary licensing of patented pharmaceutical inventions, several members of the Convention have considered it a special case justified on the basis of protecting public health.

\textsuperscript{152} Article 1 (1) of the Convention states “[the] countries to which this Convention applies constitute a Union for the protection of industrial property.” However, the Convention does not define the word “Union”. It has been observed that the establishment of a union meant the creation of a legal personality (entity) under international law with administrative organs to conduct its mission. These administrative subordinates are the assembly, the Executive Committee, and the International Bureau of WIPO (World Intellectual Property Organization. See Marshall A. Leaffer, \textit{International Treaties on Intellectual Property}, 2d ed. (Washington: The Bureau of National Affairs, Inc., 1997) at 17.
3. Is Jordan’s Decision to Exclude Non-working as a Basis for Compulsory Licensing Rational?

3.1. Overview

Jordan’s Patents Law has confined the statutory grounds for the issuance of CLs to those illustrative limited grounds mentioned in Article 31 of the TRIPS Agreement, and has considerably restricted the conditions that may legally lead to establish others. The primary target of this restriction is the ground of non-working. According to Article 22 of the Patents Law, the Minister may grant a license to use a patent to third parties without obtaining the patentee’s consent in any of the following cases exclusively:

B. 1. If the patentee does not exploit it or exploits it insufficiently before the elapse of 4 years as of the application date or 3 years as of the granting date, the period to be applied is the one that elapses later. However, the Minister may grant the patentee an additional grace period if he deems that reasons beyond the control of the patentee have prevented exploitation.

2. For the purposes of item (1) of this paragraph, and without prejudice to the provisions of the related International Conventions, the importation of the subject goods of the patent to the kingdom shall be deemed utilization of the patent.\(^\text{153}\)

These provisions have liberalized the concept of local working from a robust one entailing the full performance of the patented invention within the territory of Jordan to a mere requirement to make patented products available through importation, thus compromising a developmental objective behind the patent grant.

The objectives underlying the patent system go beyond the mere encouragement of scientific inventions.\(^\text{154}\) Scientific invention constitutes only one of the means that

\(^{153}\) See Patents Law No. 32 for the year 1999, Official Gazette No. 4389 of November 1, 1999 (emphasis mine).

\(^{154}\) This understanding equally applies to the patent system of the United States. Although some, based on the Patents Act, argue that patentees are not required to work their inventions, the Supreme Court in *Kewanee Oil Co. v. Bicron Corp*, 416 U.S. 470, (1974) at 480-81 stated that the objectives of the constitution to “promote the Progress of Science and useful Arts”, by means of the patent system, are served by working granted patents. According to the court, the objective to “promote the Progress of Science and useful Arts” sought by Congress from granting patent protection to patentees is that “The productive effort thereby fostered will have a positive effect on society through the introduction of new
leads to the realization of the objectives of the patent system: industrial and economic
development.155 These objectives, including the dissemination of technical knowledge, may
not be accomplished by the mere conclusion of inventions in the abstract, by providing
descriptive details in patent documents about the invention only to the extent necessary
to secure patent protection, or by the placement of products embodying the patented
invention in the local market for consumption by customers. Often, the objectives are only attainable when the patented inventions are put into actual application
through industrial manufacturing within the territory of the patent-granting country by, or
with (or without) the consent of, right holders.156

The very requirements of patentability imply that the industrial application aspect
of patented inventions is a cornerstone of the patent system. In other words, being new
and novel is not enough for an invention to be considered patentable; it also has to have
properties for industrial application. In addition, local working of patented inventions was
historically (with regard to the United Kingdom even until after the conclusion of the
TRIPS Agreement)157 perceived as a mandatory obligation of the patentee in most of
today’s industrialized WTO members. Commenting on the importance of this particular
point, Gontijo maintained that:

"patents] were granted to develop the exploitation of natural resources and increase the numbers of skilled workers and engineers; the aim was to establish
new industries, or new technologies for those already existing. In the United
States, a law from 1886 determined that the patents of foreign inventors had to be
exploited on US territory. This rule also applied in England, France and Germany.158

products and processes of manufacture into the economy, and the emanations by way of increased
employment and better lives for our citizens.”). 155
According to Bodenhausen, abuses of patent rights “may exist in cases where the owner of the patent,
although working the patent in the country concerned, refuses to grant licenses on reasonable terms and thereby hampers industrial development,” (emphasis mine). See Bodenhausen, supra note 33 at 71.
156 The actual application through manufacturing by the patentee itself rests in labor training, skills
development, technology transfer, and Industrial capacity building generally. The same is also true when the patented technology is used by a local licensee. In this latter case, the patentee needs to disclose to the licensee all the tacit knowledge necessary to reduce the invention to consumer products or to introduce patented industrial processes to its production. For more discussion on the importance of actual application of technology for local technical capacity-building and development, see Chapter Two.
157 This was the case under the terms of Section 48(3) of the U.K Patent Act, 1977, until it was modified in
1999 by means of The Patents and Trade Marks Regulations of 1999, effective from 29 July 1999, a copy
of the act is available online: World Intellectual Property Organization (WIPO)
158 See Gontijo, supra note 149.
The industrialization role of patents was particularly emphasized by the Canadian Court of the Exchequer in *De Frees v. Dominion Auto Accessories Ltd*. The court held that

…the under the Patent Act patents are granted for new inventions, not only to encourage inventions, but also to make sure that there be attained without undue delay a working of the invention on a commercial scale within Canada adequate and reasonable under the particular circumstances.\(^{159}\)

Accordingly, CL has since 1925 been the legal corrective measure to address patentees’ failure to fulfill their obligation in working patented inventions locally to accomplish the developmental objectives of the patent system. Unfortunately, the Jordanian Patents Law lacks this critical safeguard.

Although the law was initially enacted to fulfill the minimum legal standards of patents protection under the TRIPS Agreement, it seems that limitations on establishing the ground of failure to work locally were imposed by the USJFTA Agreement, more specifically Article 4(20).\(^{160}\) The language used in this article reiterates the conventional rule that the use of a patented invention shall not be permitted without the right holder’s authorization. The article also specified limited circumstances as the only legally establishable situations as legitimate exceptions to that rule. This stipulation marked an unprecedented,\(^{161}\) serious departure from the approach adopted in multilateral treaties that have regulated involuntary licenses of patents. It further constitutes a severe

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\(^{159}\) See *De Frees v. Dominion Auto Accessories Ltd.*, [1967] at 51, 1 Ex. C.R. 46, 51 C.P.R. 42, 33 Fox Pat. C. 137 (emphasis mine).

\(^{160}\) Article 4(20) of the agreement reads:

\[\text{[neither] Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances:}\]

\((a)\)…;

\((b)\)…; or

\((c)\) on the ground of failure to meet working requirements, provided that importation shall constitute working.

Where the law of a Party allows for such use pursuant to sub-paragraphs (a), (b) or (c), the Party shall respect the provisions of Article 31 of *TRIPS* and Article 5A(4) of the *Paris Convention*.

\(^{161}\) Until the time of its entry into force, the USJFTA was the first bilateral agreement to restrict the issuance of compulsory licenses so severely. Before concluding the USJFTA agreement, principally, three main instruments have addressed this matter, namely: the Paris Convention, the NAFTA Agreement, and the TRIPS Agreement. All three instruments left the establishment of grounds for granting compulsory licenses to the national legislator of member countries.
limitation on the ability of its parties to address several forms of abusive conduct of patentees as in the case of non-working, and in cases not related to an act of default on the part of the right holder such as the public interest in preserving public health. Both the Paris Convention and the TRIPS Agreement have refrained from limiting the freedom of their members to decide upon CLs’ grounds. They also did not attempt to limit such grounds to a set of exhaustive, predefined circumstances as is the case under the USJFTA. While the TRIPS Agreement only requires members to abide by certain conditions and procedures articulated under Article 31, the Paris Convention contained much less stringent requirements. On the abuse of non-working of patents, the Convention requires that a license may not be applied for except after three years from the date of the patent grant. Such a requirement, however, is not applicable to other abuses of rights or even to other grounds.

Nevertheless, in the above-mentioned article, the USJFTA recognizes non-working of patents as an abuse that is redressable through authorization of involuntary licensing. The second part of the article, however, qualifies this authority, stipulating that importation should constitute working. This limitation deprives Jordan from requiring local working of patents as traditionally understood and applied under the Paris Convention and the TRIPS Agreement. In other words, working of patented inventions under the USJFTA may no longer mean the actual application and manufacturing locally. Instead, it means a “commercial working”; patentees can discharge the working obligation entirely through importation without, consequently, being obliged even to undertake the so-called “nominal working”. It should be mentioned that until

162 For example, the Convention contains no mandate that the party requesting a compulsory license negotiate a voluntary license from the patentee. Also, production under compulsory licenses could be exported in its entirety. This option is not available under the TRIPS Agreement as a result of Article 31(f).
163 This interpretation was authoritatively conformed to the House of Lords in the Famous Park-Davis case in Great Britain. In this case, the court held that the waiting time stipulated in Paragraph A(4) of Article 5 of the Convention applies only to licenses granted on an act of default of the patentee, an abuse of right. See Parke-Davis Co. v. Comptroller of Patents, Designs and Trade Marks, [1954] 71 R.P.C. 169 (C.A.); also see Ladas, supra note 32 at 532-34. In 1995, the same conclusion was reached by the German Federal Supreme Court in XZR 26/92 of 5 December 1995 (an excerpt from the case can be examined at: Case No. XZR 26/92 of 5 December 1995, in IIC (1997) 28 (2)). See Straus, supra note 84 at 204, footnote 188; see also Watal, “Balanced Protection”, supra note 62 at 297.
164 This issue is controversial under the TRIPS Agreement because of the provisions of Article 27.1.
165 Nominal working occurs when a patentee offers to license his patent under reasonable terms to a potential licensee who then would undertake the actual industrial working of the invention. See Ladas, supra note 32 at 426.
approximately the early 1990s, before the conclusion of the TRIPS Agreement, working of patents through importation was rejected as an acceptable medium of fulfilling working obligations by many countries. In fact, many of these countries considered importation of patented products an abuse of patent rights under the provisions of Article 5 of the Paris Convention.\textsuperscript{166}

To appreciate fully the extent and scope of the potential impairment that might have been inflicted on Jordan as a result of this commitment, we need to find out whether providing for the ground of insufficient or non-working is available under the TRIPS Agreement. To serve this quest, it would be more convenient to explore first what the “working” of a patented invention means and when it might be considered worked. This clarification, thus, will assist in better comprehending when an invention is not worked and what might constitute a “failure to work” in the context of patent law. Since a lack of working may be caused by legitimate reasons, a clarification of what is considered an abusive non-working would also highlight the importance of maintaining such a ground in the patent law.

\textsuperscript{166} According to Paragraphs b & c of Section 37 of the 1949 UK Patents Act, an invention would be subject to an involuntary license if the local working of such an invention is prevented or hindered by importation or when a demand for a patented article is being met to a substantial extent by importation. See the Patents Act of 1949, online: WIPO Homepage<http://www.wipo.int/wipolex/en/text.jsp?file_id=127261> (date accessed: August 15, 2010). Under the Patents Act of 1977 and its amendments, the same rule remains applicable with regard to an invention whose proprietor is not a WTO proprietor. The relevant part of Article 48(B) of the act reads:

[in] the case of an application made under section 48 above in respect of a patent whose proprietor is not a WTO proprietor, the relevant grounds are –

(b) where the patented invention is a product, that a demand for the product in the United Kingdom –

(ii) is being met to a substantial extent by importation from a country which is not a member State.

See the Patents Act of 1977, online: WIPO Homepage<http://www.wipo.int/wipolex/en/text.jsp?file_id=127257> (date accessed: August 15, 2010). Also see also Section 65 (2)(b) of the Canadian Patent Act, R.S.C. 152, c.203, which reads:

[the] exclusive rights under a patent shall be deemed to have been abused in any of the following circumstances:

(b) if the working of the invention within Canada on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by the patentee or persons claiming under him, by persons directly or indirectly purchasing from him or by other persons against whom the patentee is not taking or has not taken any proceedings for infringement.
Therefore, the aforementioned issues as regulated under the Paris Convention and as implemented by selected comparative jurisprudence shall be explored first. The Convention represents a relevant point of reference since it is the first multilateral instrument to regulate the protection of patents, and it still constitutes a source of rights for and obligations of WTO members as it is incorporated by reference in the TRIPS Agreement as provided for in Article 2 thereof. In particular, this incorporation encompassed Article 5 of the Convention, which allows the granting of involuntary licenses on non-worked patents. Accordingly, the Article maintains its authority under the TRIPS Agreement. Last but not least, reference to the Paris Convention is made since the last provision of Article 4(20) of the USJFTA Agreement referred its parties to the pertinent provisions of the Paris Convention and to those of the TRIPS Agreement on CLs.

3.2. From the Paris Convention to the TRIPS Agreement: No Change in the Concept of Local Working

The concept of patent “working” as a legal obligation of the patentee is not defined in the Paris Convention. This is also the case for the TRIPS Agreement. In both instruments, the drafters omitted the definition to avoid frustrating the freedom of member countries to adopt a definition most suited to their needs. Thus, what constitutes a working of a patented invention is a matter left for the national legislature to decide in accordance with a member’s public policy on protection of patents. Consequently, working as a legal obligation of the patentee has never been a uniform concept and has varied across different legal jurisdictions.

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167 Given that Canada maintained a robust compulsory licensing regime which lasted for a long period of time, illustrative examples on comparative law and jurisprudence are mainly derived from this experience. In particular, reference to the Canadian experience will focus on the issue of patentees’ obligation to work their inventions and when such an obligation might be considered not to have been fulfilled, making a patented invention subject to correction by compulsory licensing.

168 The relevant provision of the USJFTA reads “[where] the law of a Party allows for such use [compulsory licensing] pursuant to sub-paragraphs (a), (b) or (c) [of the USJFTA Article], the Party shall respect the provisions of Article 31 of TRIPS and Article 5A(4) of the Paris Convention”. See the USJFTA, supra note 17.

169 See Ladas, supra note 32 at 425.
In some countries, it sufficed that the patentee offers its patent for licensing on reasonable terms to any interested person: “nominal working”. This offer would be considered “working” if made through either a publication by patentees of their intention to license their inventions in relevant trade or official publications, or if an offer is made directly to a particular person, provided a proof of such action is recorded with the national regulatory authorities. For most countries, however, the working obligation is satisfied only if a patented product or a part thereof is produced or assembled, or if a patented process is applied, in the country concerned. In other words, the patented product is actually manufactured or the patented process is put into industrial use. In some countries, this requirement is enforceable only if commercially viable.

Although the legislation of the countries which opted for actual working has not elaborated a set of concise requirements that should be satisfied before a patent may be deemed worked, national courts and administrative bodies such as the Patents Commissioner in Canada (hereinafter the Commissioner) or the Patents Comptroller in Great Britain have assumed this task. These entities served this role, since they often had to address the question as to when a patent is not being worked before adjudicating cases involving infringements of patents, where non-working was often a defense, and/or deciding upon applications requesting the compulsory license of patented inventions claimed not to be worked by their proprietors.

In countries where the relevant legislation specified failure to work as a patent abuse qualifying for granting a CL by the competent authorities upon application by a private person or a public entity, the Commissioner or courts had to decide on whether the patented invention in question had been worked by its proprietor. For example,

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170 See supra note 165 and accompanying text; this is the case under Section 46 of the UK 1977 Patents Act.
171 See Ladas, supra note 32 at 426.
173 For example, Article 64 of Brazilian Law stipulates local working.
174 This was the case under Canadian Patents Act, see supra note 166; British Patents Act of 1977, see supra note 166; and Indian Patents Act of 1970, as amended by the Patents Act No. 15 of 2006, infra note 206.
175 For example, see Section 65 of Canadian Act, ibid.
176 The Patents Registrar in Canada is called “Patents Commissioner”.
177 See Reichman and Hasenzahl, Historical Perspective, supra note 37.
Section 65 of the 1985 Canadian Patent Act makes it possible for the Attorney General of Canada or any interested person to apply to the Commissioner asking for relief from an abuse of a patented invention that is not being worked by the right holder at the time of application. Applicants seeking CLs of non-worked patents have often relied upon this section. In many instances, decisions on such applications were disputed before courts where it was often ruled that a patented invention is considered worked in Canada if manufactured therein on a “commercial scale” that is commensurate with the domestic market demand. Such a determination was made on a case by case basis. However, Canada repealed the mandatory local working of patents in 1993.

A definition of what constitutes failure to work has been articulated in several rulings. By and large, the case law developed under Section 65 adopted a four-factor

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178 See Patent Act of Canada, R.S.C. 1985, c.P-4, §65(1). In part, Section 65 states “(1) [the] Attorney General of Canada or any person interested may, at any time after the expiry of three years from the date of the grant of a patent, apply to the Commissioner alleging in the case of that patent that there has been an abuse of the exclusive rights thereunder and asking for relief under this act; (2) the Exclusive rights shall be deemed to have been abused in any of the following circumstances: (a) if the patented invention, being one capable of being worked within Canada, is not being worked within Canada on a commercial scale, and no satisfactory reason can be given for that non-working”. The provisions of this section are similar to those of section 37(2) of the British Patent Act of 1947, before it was amended in 1999. Section 37(2), in the relevant part, reads “(a) that the patented invention, being capable of being commercially worked in the United Kingdom, is not being commercially worked therein or is not being so worked to the fullest extent that is reasonably practicable”. See Ladas, supra note 32 at 428, citing Section 37(2) of the law. The corresponding section under the 1977 Patents Act is Section 48. The local working requirement is retained in the present Act as Section 48B (1)(a) with wording that matches that of Section 37(2) (a) cited above. It reads “where the patented invention is capable of being commercially worked in the United Kingdom that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable”. See (Patents and Trade Marks (WTO) Regulations 1999 (SI 1999/1899) (in force 29 July 1999)), available online at, the Intellectual Property Office of the United Kingdom: http://www.ipo.gov.uk/p-legislation.htm.

179 Ibid.


181 According to the Economic Council of Canada (1971), 53 applications for compulsory licenses under Section 65 of the patent law were made between 1935 and 1970. Of these applications 11 had been granted licenses, 9 had been declined, 32 had been withdrawn, and one was pending. Throughout the following two decades, 70s and 80s, 43 applications have sought compulsory licenses based on failure to work under Section 65. 6 applications of the mentioned 43 have led to the grant of compulsory licenses, 6 were turned down, while 25 applications have been officially withdrawn or abandoned by their applicants. Of particular importance is the outcome of applications in both epochs where the highest number of applications had been withdrawn. In both periods the percentage of withdrawn applications had been as high as 60 per cent of all applications. Such outcome confirms what many have argued about the true value of compulsory licenses provisions based on nonworking; that is, there provisions contribute to the conclusion of more voluntary licenses rather than the grant of compulsory licenses. Thus, they help accomplish the working of patents within the territory of the granting country, which is a critical objective of patent policy. See Donald G. McFetridge, “Intellectual Property, Technology Diffusion, and Growth in the Canadian
test to be followed by the Commissioner when deciding on applications involving an allegation of abusive non-working. These factors, as considered by the court in *Rodi & Wienenberger A.G. v. Metalliflex Ltd.*, are: first, the nature of the invention; second, the amount of time required to establish a plant in Canada to work the patent; third, the time elapsed since the grant of the patent; and fourth, the size of the market for the patented good in Canada. Canadian courts and/or the Commissioner of patents have had to consider these factors not only in order to assess whether a given patentee has failed to adequately work its patent on a commercial scale, but also to determine whether such a lack or insufficient working has constituted an abuse and thus would be amenable to sanction by a CL. In addition, courts have often concluded that the mere existence of products embodying the patented invention on the Canadian market by either *importation* or illegal conduct of others does not constitute working in the legal sense of fulfilling the patentee’s obligation to work its patent.

Furthermore, Canadian patent law has established *prima facie* assumption of abuse by the patentee of its exclusive rights whenever it is found to have failed to work
its patented invention. This assumed abuse may not be negated by an exploitation that falls short of a full working of the patented invention. In other words, a nominal working such as the establishment of a plant to assemble different parts of a patented product may not constitute a working that satisfies the legal requirements of the law since it does not constitute a working on a commercial scale, unless otherwise justified on reasonable grounds.

In order to preclude a determination of abuse of their exclusive rights, patentees had to justify the non-exploitation of their patents, which had to be vindicated on reasonable grounds. There was no limit as to what might have constituted a reasonable ground; it could have been, but was not limited to, technical reasons, economic factors, and/or a lack of persons interested in obtaining a voluntary license. As mentioned before, however, the existence of products embodying the patented invention by either importation or illegal conduct of others (infringements) was not considered to constitute a reasonable defense for non-working in order to discharge a patentee of its working obligation.

Although the Canadian regime of compulsory licensing was criticized as discouraging innovative activity, a review of the four-factor test, which must be followed before a license could be granted, proves that the regime was meant to address abusive conducts of patentees. The regime was established to restore the balance

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188 Section 65(2) of the Patent Act read: “[the] exclusive rights under a patent shall be deemed to have been abused in any of the following: (a) if the patented invention, being one capable of being worked within Canada, is not being worked within Canada on a commercial scale, and no satisfactory reason can be given for that non-working”. It should be noted that Paragraphs (a) and (b) of Section 65 were repealed in 1993 by the Patent Act Amendment Act, S.C. 1993, c.2, §5. Paragraph (b) of Section 65 had to do with importation as a separate abuse of patent rights the effect of which is the prevention of working a patent on a commercial scale within Canada.
189 Ibid.
190 A lack of local market and demand for a patented product in Canada was considered a justification not to enforce the working requirement. See Jerome H. Reichman & Catherine Hasenzahl, Non-Voluntary Licensing of Patented Inventions: The Canadian Experience, UNCTAD-ICTSD Project on IPRs and Sustainable Development, (Draft, 2002) at 15-18, online: IPRsonline.org Homepage (date accessed: August 15, 2010) [Canadian Experience].
191 For example, a patentees can protect their patents from being compulsory licensed by registering them with the relevant national authorities to be licensed to any interested party.
192 A clear example would be an infringer illegally working a patented invention. The same may apply to a licensee exploiting a patent beyond the terms of the license.
envisaged in the patent law: the balance between the interests of the patentee and those of the public in general. Thus, when evaluating an application to compulsory license, the Commissioner would have to consider, not only the interests of the general public in the relevant national industry, but also those of the patentee.

The fact that the Commissioner was under the obligation to consider the interests of the patentee indicates that the objective was not, indeed, to arbitrarily require the working of every patent.\(^{195}\) For example, the test mandated that the Commissioner investigate the “size of the market for the patented good in Canada.” In other words, a CL would not be issued if there was a lack of evidence demonstrating the existence of a market in Canada for the patented product concerned, and that the size of such a market justified the costs of working the patent therein. Moreover, any such evaluation would weigh the potentially positive industrial benefits against the overall public interest, including the accessibility and affordability of the patented product. This factor was always considered notwithstanding the fact that the working requirement reflected the country’s explicit industrial policy to stimulate local manufacturing of patented products.\(^{196}\)

The above-discussed application of the working provision was developed under Article 5 of the Paris Convention. The Article provides that “the patentee shall remain bound to work his patent.”\(^{197}\) This Article was incorporated by reference into the TRIPS Agreement.\(^{198}\) Accordingly, an application of the working requirement, as developed under this article, is equally applicable under the TRIPS Agreement. In other words, WTO members enjoy the full discretion to adopt a definition of the working concept that may require actual production and application of the patented invention locally.

However, it is contended that the so-called non-discrimination clause in Article 27.1 of the TRIPS Agreement repeals the pre-existing right of member countries to institute failure to work locally as an abuse by patentees of their exclusive rights that is

\(^{195}\) This proves, unlike what critics claim, that the local working provision was not intended to force the exploitation of every single issued patent. Instead, the aim was to work inventions whose exploitation is reasonably practicable and economically viable.


\(^{197}\) See Ladas, supra note 32 at 516.

\(^{198}\) See Article 2 of the TRIPS Agreement, supra note 4.
legally redressable through compulsory licensing.\textsuperscript{199} And, in any case, it is added that establishing such a situation as a ground for CLs, to force local working, constitutes a violation of this clause.\textsuperscript{200} In essence, this line of argument contends that the non-discrimination clause restricts members’ freedom to implementing the working obligation, confining it to “commercial working”, where a patentee can discharge of this obligation through importation.

Many, however, disagree and argue that this right is preserved for WTO members and was not revoked by Article 27.1.\textsuperscript{201} Instituting non-working as an abuse of patent rights remains a legitimate option that is in conformity with the rules of the TRIPS Agreement since it is legitimate under Article 5 of the Paris Convention. They add that a reading of Article 27.1 of TRIPS together with other articles of the Agreement (Articles 8, 30, and 31) and of the Paris Convention (Article 5) negates the “repeal effect claim”.\textsuperscript{202} It is further argued that what the clause requires countries to do is to treat \textit{infringing articles}, whether imported or locally produced,\textsuperscript{203} equally, which the objectives and principles of the TRIPS Agreement support.\textsuperscript{204} Notwithstanding disagreements on this issue, local working of a patented invention is a requirement under the law of leading WTO members, including: Brazil,\textsuperscript{205} India,\textsuperscript{206} Argentina,\textsuperscript{207} and even the United States;

\textsuperscript{199} The Clause reads “patents shall be available and patent rights enjoyable without discrimination as to ... whether products are imported or locally produced”. Ibid. art. 27.1.
\textsuperscript{200} See, for example, Straus, supra note 84; Adelman & Baldia, supra note 84 at 517; and Watal, “Balanced Protection”, supra note 62. Commenting on the legal impact of the Non-Discrimination Clause of Article 27.1, Watal maintained that “[this] sub-clause was meant to rule out the forcing of local manufacture or ‘working’ of patents through compulsory licences”.
\textsuperscript{201} See supra notes 85 and 86.
\textsuperscript{202} See supra note 85 and accompanying text.
\textsuperscript{203} See infra.
\textsuperscript{204} See, for example, multiple references, supra note 86.
\textsuperscript{205} See Article 68 of Law No. 9.279; for more details on the Brazilian Law, see supra note 86.
\textsuperscript{206} Under Chapter XVI, titled “Working of Patents, Compulsory Licences, Licences of Right and Revocation”, an interesting example is provided by Section 83 of the Indian Patents Act which contains the pertinent rules on the provision of patents’ working. The Section prescribes the following:
83. Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely:
(a) that patents are granted to encourage inventions and \textit{to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay};
(b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article[...](emphasis mine).

the University and Small Business Patent Procedures Act is one such example from the US law.208

This US example is particularly troubling given the restrictive limitation on establishing specific grounds under Article 4(20) of the USJFTA, including failure to work, by which the US is bound. The US act mandates patented products developed with federal research funds be “available to the public on reasonable terms.” Commenting on the meaning of the cited clause before an National Institutes of Health of the US Department of Health & Human Services’ (NIH) Public Hearing, Jerome Reichman testified that:

…the availability of a nonvoluntary license for abuse or on public interest grounds in the United States depends primarily on specialized enabling statutes or on specialized clauses incorporated into specific statutes. [Footnote omitted]

The Bayh-Dole Act’s requirement that patented products be made available “to the public on reasonable terms” is one of the clearest examples of such a specialized enabling clause. It may be compared with a Canadian statute that authorized compulsory licenses for acts of abuse, which occur, inter alia, “if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms.”209 [Footnote omitted][Italics in original]

This “enabling clause” contains two requirements. First, for an invention to be made available to the public, it must be worked. Second, worked inventions of the kind specified in the Act should be available “on reasonable terms”. If either of these two provisions is not satisfied, the patented invention in question may become subject to

207 Article 43 of Argentinean Patents Law provides that if the invention has not been fully utilized after three years since the grant of the patent, and if no genuine or effective preparations have been made for the exploitation, such as making, hiring, selling, or otherwise disposing of the product, of the invention, any person may apply for the competent authority seeking an authorization to use the invention without the permission of the owner thereof. See Argentinean Patents, Utility Models, Law No. 24.481 as amended by Law No. 24.572 of 1995 (entered into force: October 23, 1995), an English translation of the law, online: Japanese Patent Office Homepage <http://www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/pdf/argentine_e/e_tokkyo.pdf> (date accessed: August 15, 2010).

208 See, for example, the University and Small Business Patent Procedures Act 18 USC §§200, 201(f), 203(1)(a), so-called Bayh-Dole Act. This law mandates that patented products resulting from research funded by the Federal Government of the US be “available to the public on reasonable terms.”

compulsory licensing. However, neither of the two mentioned scenarios is among the exclusive grounds of CLs under the USJFTA article mentioned earlier.

Accordingly, this US example constitutes either a violation of the USJFTA, or an understanding, and thus interpretation, of the pertinent provisions of the agreement by the United States. If it is the latter, then Jordan is legitimately entitled to establish grounds beyond those mentioned under Article 4(20) of the USJFTA, including insufficient or failure to work or other grounds based on the public interest mentioned in Reichman’s testimony (cited earlier). Furthermore, the Bayh-Dole Act is not an isolated instance. As I will discuss in the following section, decisions from as high in the US judicial hierarchy as the Supreme Court have ruled that injunctive relief may not be available to a patentee in a patent infringement case, even though the patent concerned is valid and an infringement is established. This was the position taken in the well known eBay, Inc. v. MercExchange, L.L.C. and several subsequent cases by lower courts. As correctly argued by many, these cases essentially represent a de facto compulsory licensing of the patented inventions in question, a basis for which is hardly to be found under the USJFTA.

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210 See letter sent by James Love to Ambassador Susan C. Schwab, United States Trade Representative, of December 12, 2006, online: Consumer Project on Technology Homepage <http://www.cptech.org/ip/health/c/thailand/ustr12dec2006thailand.html> (date accessed: August 15, 2010). In this letter, Love argues that in addition to Chapter 28 USC 1498 of the US Code, the following provisions constitute a violation of the USJFTA:

- Mandatory patent licenses under Section 308 of the Clean Air Act. This statute is unfortunately not consistent with the provisions of the US FTA agreements negotiated with Jordan (2000), Singapore (2003), and Australia (2004).
- Compulsory licenses for patents “affected with the public interest” that are of primary importance in the production or utilization of special nuclear material or atomic energy, for non-military purposes. This statute is unfortunately not consistent with the provisions of the US FTA agreements negotiated with Jordan (2000), Singapore (2003), and Australia (2004).
- The Bayh-Dole Act march-in rights for patents on inventions conceived with federal funding,” (emphasis in original, citations omitted).


In summary, importation has been exceptionally admitted as the sole means acceptable for a right holder to discharge its working obligation. To the contrary, the Paris Convention recognizes the right to require local working of patented inventions, where importation could amount to an abuse of rights if it results, for example, in hindering local working.\textsuperscript{214} In addition, this obligation has not been abolished by the TRIPS Agreement. The Doha Declaration as well as the above-mentioned examples of WTO members stipulating local working, including the US (in certain Acts), attest to this conclusion despite the language of Article 27.1 of the agreement. Unfortunately, the obligations undertaken under the USJFTA considerably bring into question the legitimacy of establishing in the Patents Law of Jordan an important mechanism: to correct abusive non-working through the grant of CLs. The treaty did so since it stipulated that importation should constitute working.

3.3. Why Local Working is an Important Ground for Jordan to Establish

Several policy considerations make it rational for Jordan, as a small, upper middle income developing country, to institute a statutory provision allowing for the granting of involuntary licenses on the ground of non-working. In particular, the following objectives are critical: technology transfer, facilitation of voluntary licenses, and control of prohibitive drug prices. A brief discussion follows as to how establishing this measure would be conducive to these objectives.

3.3.1. Technology Transfer\textsuperscript{215}

One of Jordan’s main disadvantages is the size of its economy, around six million people. Despite enhanced patent protection for pharmaceuticals and other fields of technology, it would appear that factors other than such protection have had a detrimental impact on the flow of advanced, up-to-date technology to the country generally, including the local pharmaceutical industry. Given the size of the economy and the high cost associated with the development of new medicines based on newly innovated molecules,

\textsuperscript{214} See Penrose, supra note 32 at 141-3.
\textsuperscript{215} For details on what is meant by technology transfer in the context of pharmaceuticals, see Chapter Two.
it is self-evident, as Cohen noticed in regard to Israel, that the pharmaceutical industry in Jordan would not be in a “position to develop new medicines on a regular basis” if it does not “form part of a multinational corporation”.216

Accordingly, for local industry to develop, it needs access to and use of advanced technology developed by others, especially that which is under patent protection. Ideally, FDI and Technology Licensing (TL) constitute the preferable means for such access. In the case of Jordan (as I have shown in Chapter Two), these means have not so far demonstrated viable mediums through which technology finds its way to the local pharmaceutical industry.217

Hence, access to technology embedded in patented products needs to be secured. If patents are not voluntarily worked, compulsory working of a patented technology by a local manufacturer may achieve such access.218 In this case, CLs would allow licensees to learn about the patented technology through application on the plant level. This

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[217] The entirety of the capital invested in the local industry comes from national investment. Foreign investment, whether direct or through joint ventures, in this sector is close to nil. Furthermore, the industry has been having a difficult time concluding licenses on reasonable commercial terms, which would take into consideration the economic factors on the Jordanian as well as other markets in the region. There are, however, few local factories that do have licenses from MNCs. But, such contracts are mainly for packaging and distribution of formulated medicines and were mostly concluded before 1999 (the year on which the new Patents Law was promulgated). According to a senior manager of a local licensee:

[we] have several licensing agreements but most of them go back to before 1999 and those signed after 1999 had nothing to do with the FTA itself. It is our firm’s long standing policy to sign such strategic agreements whenever possible and beneficial. The FTA did not lead to any licensing agreements because it was a one-sided agreement. They told us that the FTA will be good for us, that it will lead to more innovation, joint ventures, licensing and R&D. It led to none of the above because stronger IP protection was never the problem. The problem itself was lack of resources, lack of sufficient R&D, lack of human skills and lack of infrastructure that are all necessary for innovation.

Cited in Hamed and Mohammed EL-Said, supra note 2 at 455.

[218] Articulating various ways for implementing the TRIPS Agreement by developing countries, which may be conducive of technology transfer thereto, Correa stated:

…the TRIPS Agreement leaves WTO Members certain room to adapt the national legislation to their particular needs and policy objectives. In implementing the Agreement, hence, it is important to take into consideration those aspects that may promote technology transfer and development. The following aspects may be considered along those lines.

a) Patents

[...]

• the establishment of compulsory licenses on various grounds.

practice, in turn, enables them to master, enhance, and build on the technology used: an innovative output. Therefore, these licenses facilitate transferring the needed technology, if not transferred through other means, and as such, represent an important factor of the innovation process.\textsuperscript{219} Compulsory licensing makes routine productive activities and cumulative learning at the plant level available to those who are not able to obtain it otherwise.\textsuperscript{220}

In fact, the transfer of technology that is essential for their development is one of the primary objectives behind the calls by developing countries and many scholars\textsuperscript{221} to enforce local working in these countries, including through the grant of CLs. CLs may increase not only static efficiency, but dynamic efficiency as well. As Correa argues,

the use of a patented process or the manufacturing of a patented product under a compulsory license can lead to follow-on innovations or new innovative concepts in the relevant technical field. Hence, while improving allocative efficiency, compulsory licenses may also have a positive effect on the future flows of innovations and dynamic efficiency.\textsuperscript{222}

Furthermore, compulsory working of patented inventions as a corrective measure contributes, in essence, to realizing the objectives and principles that the TRIPS Agreement seeks to accomplish. On the one hand, licenses contribute to exactly what Article 7 expects from not only protection of patents, but also from their enforcement - that is, contributing “to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.\textsuperscript{223} Involuntary licensing of non-worked pharmaceutical patents, on the other hand, represents a measure of the kind authorized under Article 8 of the agreement. In other

\textsuperscript{219} See, for example, Charles Cooper, “Relevance of Innovation Studies to Developing Countries” in Charles Cooper, ed., Technology and Innovation in the International Economy (Tokyo: United Nations University Press, 1994) 1 at 8; for an empirical evidence on the role of CL as a means of technology transfer, see Petra Moser & Alessandra Voena, “Compulsory Licensing: Evidence from the Trading with the Enemy Act” (December 12, 2009), online: SSRN <http://ssrn.com/abstract=1313867> (date accessed and downloaded: March 15, 2010).

\textsuperscript{220} See Cooper, ibid; also see Carlos M. Correa, “Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?” in Keith E. Maskus & Jerome H. Reichman, eds., International Public Goods and Transfer of Technology under Globalized Intellectual Property Regime (New York: Cambridge University Press, 2005) 227 at 250 [Can the TRIPS].

\textsuperscript{221} See, for example, Halewood, supra note 86; and see Correa, “Can the TRIPS”, ibid.

\textsuperscript{222} Correa, “Can the TRIPS”, ibid.

\textsuperscript{223} See the TRIPS Agreement, supra note 4 (emphasis mine).
words, it represents a measure necessary “to protect public health and nutrition, and to promote the public interest in sectors of vital importance to [Jordan’s] socio-economic and technological development, ...[and] needed to prevent the abuse of intellectual property rights by right holders or the resort to practices [which]...adversely affect the international transfer of technology”. 224

3.3.2. Combat Prohibitive Drug Prices

It might be contended that, even if it is true that CLs may secure access to, and application of, important technology otherwise unlikely to be found in an economy of Jordan’s size, 225 it is not economically viable for Jordan to manufacture medicines under such licenses. 226 Several factors may support this line of argument. First, there is no economies of scale due to the size of the local market. Second, expanding the market through exportation to offset the disadvantageous size of the market is seriously limited by the TRIPS Agreement, stipulating that production under CLs shall be predominantly for the supply of the domestic market. 227 Third, a CL shall be liable for termination “if and when the circumstances which led to it cease to exist and are unlikely to recur”. 228 This requirement increases the uncertainty about the future of the license by placing it under the control of right holders; thus, local manufacturers would not commit to a large fixed cost investment to exploit a license. And fourth, licensees shall pay right holders adequate remuneration (royalties) “taking into account the economic value of the authorization”, 229 which is also prone to the so-called “royalty stacking” (payment of

224 Ibid. (emphasis mine).
225 The following are usually cited as factors contributing to making compulsory-licensed products less economically attractive: payment of royalties, market share overshadowed by reputation and competition from branded products, technical knowledge of right holders, and for reasons of efficiency. For discussions of these factors and others, for example, see Jayashree Watal, “Pharmaceutical Patents, Prices and Welfare Losses: A Simulation Study of Policy Options for India under the WTO TRIPS Agreement” (2000) 23 (5) The World Economy 733 [Options for India].
227 See Article 31(f) of the TRIPS Agreement, supra note 4.
228 Ibid. para. (g).
229 Ibid. para. (h) (emphasis mine); Gervais argued that the phrase “economic values of such authorization” should be interpreted to mean that remuneration payable to right holders is the “normal cost”. That is
multiple royalties for several licenses to use one patented product)\textsuperscript{230} due to patent thicketts (situations where multiple patents may cover a single product). All these factors may contribute to making prices of compulsory licensed medicines unaffordable.\textsuperscript{231}

Although on their face these grounds might seem persuasive, they are not as compelling as depicted when carefully scrutinized. The issue of economies of scale applies not only to involuntary licenses, but to voluntary licenses as well. Such licenses, if any are granted to local manufacturers, are mainly concluded on a territorial basis.\textsuperscript{232} In addition, under CLs a manufacturer, arguably, can still export as much as 49% of its production.\textsuperscript{233} Furthermore, in cases when patented medicines are sold for high prices, besides not being locally worked, involuntary licenses may be used to import competitively much more affordable generic versions from other countries.

With regard to the uncertainty caused by the TRIPS’ provision requiring termination of licenses once the circumstances leading to their grant cease to exist, this concern is eliminated by linking the termination of licenses to the grounds of their issuance.\textsuperscript{234} Therefore, a failure to work may cease to exist only when right holders work their patents locally or grant voluntary licenses \textit{on reasonable terms}. Yet Article 31(g) of

\begin{itemize}
\item values paid through voluntary licenses in the country concerned. See Gervais, \textit{Drafting} History, supra note 14 at 252.
\item See Rozek & Rainey, “Broad-Based”, supra note 226.
\item Several studies have authenticated evidence that important patented inventions are in general not voluntarily licensed by right holders for a financial consideration. See Jayashree Watal, “Implementing the TRIPS Agreement on Patents Optimal Legislative Strategies for Developing Countries” in Owen Lippert, ed., \textit{Competitive Strategies for the Protection of Intellectual Property} (Canada: The Fraser Institute, 1999) 105 (citing authorities) available online at: <http://www.fraserinstitute.org/Commerce.Web/product_files/CompetitiveStrategiesIntellectualPropertyChapter5.pdf> (date accessed: November 20, 2010) [Legislative Strategies]; also see C. T. Taylor and Z. A. Silbertson, \textit{The Economic Impact of the Patent System. A Study of the British Experience}, (Cambridge: Cambridge University Press, 1973) at 180-186. It should be mentioned here that several local Jordanian Manufacturers mentioned limiting the territorial scope of licenses as a deterrent for concluding licenses with MNCs (several interviews by the author, Amman, Jordan from July 12, 2009 through September 8 of the same year).
\item Article 31 (f) of TRIPS stipulates that production under CLs be predominantly for the local market of the issuing country. The residual of this predominate production is argued to be up to 49 per cent. See Reichman & Hasenzahl, \textit{Historical Perspective}, supra note 37; and see Correa, \textit{Trade Related}, supra note 86 at 321.
\item See Watal, “Legislative Strategies”, supra note 232.
\end{itemize}
the TRIPS Agreement protects the legitimate interests of third parties (licensees) in such cases.\footnote{Article 31(g) of the TRIPS Agreement reads, in part, “authorization for such use [compulsory licensing] shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized”.} The interests of a third party, as Watal put it, “need not be restricted to disposal of excess products already produced”,\footnote{See Watal, “Legislative Strategies”, supra note 232.} but may include the investments and costs incurred by the licensee to work the licensed invention. Finally, on the issue of remuneration, most countries that granted CLs before the TRIPS Agreement to correct non-working abuses typically paid remuneration to right holders; the TRIPS Agreement only codified this practice, specifying that remuneration be adequate and based on the economic value of the authorization.

Furthermore, contrary to claims that medicines manufactured under CLs would be expensive, since they would be priced as high as their branded versions or even higher,\footnote{See Bird, infra note 339; Lybecker & Elisabeth, infra note 339; Edelman, infra note 426; Lippert, infra note 406; and see Rapp & Rainey, “Broad-Based”, supra note 226.} studies conducted to analyze the influence of CLs on drug prices in India, as well as in the context of historical experiences such as that of Canada, indicate the opposite. For example, Watal studied in 2000 the potential influence of the use of compulsory licensing in India, and she estimated “the welfare gains from just two compulsory licences with an assumption of 10 per cent market share for the licensee could be higher than price controls on all patented pharmaceuticals.”\footnote{See Watal, “Options for India”, supra note 225 at 745(emphasis in original); and see Jayashree Watal, Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It? Science, Technology and Innovation, Discussion Paper No. 8, Center for International Development, Harvard University, Cambridge, MA, USA, 2000) [Essential Medicines].} In Canada, where CLs were aggressively used\footnote{McFetridge reported that during the period lasting from 1969 through 1992, 613 compulsory licenses were granted to either manufacture or import patented medicines. See McFetridge, supra note 181 at 82; also see Christopher S. Harrison, “Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91” (2001) 26 North Carolina Journal of International Law and Commercial Regulation 457.} to promote access to medicines through the production of generics, medicine prices were the lowest among industrialized countries, mainly due to such use.\footnote{See Harrison, ibid.}

There are several reasons as to why the same experience might hold even in a small, upper middle income developing country setting like Jordan.\footnote{A very recent example is provided by Ecuador. In April of 2010, Ecuador issued a CL on Abbott Laboratories’ patented drug Ritonavir, an HIV/AIDS medicine sold under the brand-name Kaletra. Drugs provided under the CL were expected to sell at half the price of the patented, original drug. See Intellectual Property Watch, Ecuador Grants First Compulsory Licence, For HIV/AIDS Drug, 22 April 2010, by C.} First, relative to
average income, the cost of labor (an important cost factor) in a developing country tends to be much lower than that prevailing in the market of an exporting right holder (assumed as industrialized).\textsuperscript{242} Second, in a country such as Jordan with a relatively good pharmaceutical industrial infrastructure, the amount of fixed costs to work a licensed invention may not be so considerable as to constitute an obstacle to set prices on more affordable levels. Third, mechanisms for setting rates of royalties\textsuperscript{243} for involuntary uses of patented pharmaceutical inventions may be less than those reportedly demanded by leveraged, patent-backed right holders to conclude voluntary licenses.\textsuperscript{244} Last but not least, it has been argued that experience shows that the very existence of a statutory ground of CL may constitute adequate incentives for patentees to conclude voluntary

\textsuperscript{242} It should be noted that labor would include not only technical personnel, but also the entire chain of the process including that of pharmacists. In other words, the cost of labor encompasses all cost elements contributing to a medicine’ retail price, which are attributed to labor.

\textsuperscript{244} According to a study by the Organization for Economic Co-operation and Development (OECD), firms have reported that in some cases, royalty payments can exceed 20% of their net sales (see Organization for Economic Co-operation and Development (OECD), \textit{Genetic Inventions, Intellectual Property Rights and Licensing Practices, Evidence and Policies}, (Paris: OECD, 2002) at 15, online OECD Homepage \textless http://www.oecd.org/dataoecd/42/21/2491084.pdf\textgreater{} (date accessed: September 5, 2010)). In addition, a royalty that is as high as 25% was demanded by GlaxoSmithKline in South Africa before the courts intervened. See Biswajit Dhar & KM Gopakumar, \textit{Effect of Product Patents on the Indian Pharmaceutical Industry}, a study conducted by the Center for WTO Studies: the Indian Institute of Foreign Trade, at 18, online: Indian Institute of Foreign Trade: Center for WTO Studies Homepage \textless http://wtocentre.iift.ac.in/Papers/3.pdf\textgreater{} (date accessed: September 5, 2010) [Product Patents].
licenses on reasonable commercial terms, thus getting patented inventions worked locally.\textsuperscript{245}

### 3.3.3. Facilitate Conclusion of Voluntary Licenses

Studies have shown a decline in the number of voluntarily concluded licenses, a medium that usually involves not only the transfer of a technology, but also the necessary “know-how” related to the application and performance of the licensed technology. In particular, such a decline has been observed in technical fields with technology developing at a rapid pace.\textsuperscript{246} Instead, technology proprietors in such fields prefer to internalize their transactions.\textsuperscript{247} This practice may be the norm when would-be licensees present competitive threats beyond their local markets: that is, competition in regional and world markets.\textsuperscript{248}

The above-described characteristics apply to the pharmaceutical sector and manufacturers in Jordan. The local pharmaceutical industry operates in a field where newly developed technology is not difficult to absorb and apply, possesses a good industrial and technical infrastructure, including trained and skilled human capital,\textsuperscript{249} and

\textsuperscript{245} See Watal, \textit{Essential Medicines}, supra note 238 at 3.
\textsuperscript{246} See Nagesh Kumar, “Technology Generation and Technology Transfer in the World Economy: Recent Trends and Implications for Developing Countries” (1998) Science Technology Society 266.
\textsuperscript{247} Internalization occurs when technology is communicated to a local subsidiary, by acquisition of a local plant, or through forming joint venture with a local manufacturer. Internalization of technology transfer, generally, means the communication of technology intra-firms. In other word, it is the transfer that involves initiating an engagement in international trade through Foreign Direct Investment in international markets. In such a case, technology is transferred to affiliates located in international markets, but not to third parties. For more information on the issue, see Keith E. Maskus, “The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer” (1998) 9 Duke Journal of Comparative & International Law 109 [The Role]; also see Johannes G. Denekamp, “Intangible Assets, Internalization and Foreign Direct Investment in Manufacturing” (1995) 26(3) Journal of International Business Studies 493.
exports its products to over 60 countries around the world. Such properties may make technology proprietors less inclined to conclude licensing contracts with the local industry on reasonable commercial terms when leveraged in negotiations by their exclusive rights. Or, if they agree to conclude such licenses, right holders are likely to demand commercially unreasonable terms, including but not limited to, high royalty rates, making it not a worthwhile business for the local manufacturers. The existence of a statutory provision allowing for granting CLs based on insufficient or non-working would mitigate leveraged negotiations. It makes patentees more likely to conclude contracts that are economically viable to local, would-be licensees. Although a refusal to deal entirely or on commercially unreasonable terms as such, as will be discussed in the following section, may be adopted as a separate and independent ground of compulsory licensing, an application for a license under the non-working ground is preferred since an applicant may only need to prove that a patent is not worked.

Compulsory licensing is important to the economic development in Jordan since it contributes to local working of patented inventions. It fosters the transfer of foreign technology, facilitates the conclusion of voluntary licenses, and promotes access to medicines. However, instituting this ground may not accomplish its underlying objectives: namely, transferring advanced technology, reducing drug prices, and concluding license agreements. This measure remains unclear due to legal ambiguity under the TRIPS Agreement, and it may violate the USJFTA. Although a requirement of


See Dhar and Gopakumar, supra note 244 and accompanying text.

According to Watal “[the] very existence of statutory provisions on compulsory licenses may, in fact, be adequate to encourage voluntary licenses”, see Watal, Essential Medicines, supra note 238. It has been suggested that the compulsory licensing provision in Canada prior to 1993 contributed to the conclusion of voluntary licenses. This indication was derived since many applications for compulsory licensing were not pursued or were later withdrawn, which meant that a voluntary license had been concluded, and it was concluded that the local working provision resulted “in more extensive licensing” compared to what would otherwise have occurred. See McFetridge, supra note 181 at 79-80.

However, in accordance with Article 31(b) of the TRIPS Agreement, an applicant is also required to have “made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.” See the TRIPS Agreement, supra note 4.
local working may force a patentee works its patent locally, such working does not necessarily lead to cheaper medicines. This is particularly true in the case of Jordan in light of the size of its economy. That is, Jordanians might be better off importing a product if it is more expensive to manufacture locally, in satisfaction of a working requirement, or when compulsory local working may not result in transferring the technology concerned since owners would vigorously keep it guarded, thus preventing diffusion. With regard to the legal ambiguity under the TRIPS Agreement, it has been argued that a legislation enacting this ground would be in violation of the non-discrimination clause of Article 27.1, which stipulates that patents shall be available and patent rights enjoyable without discrimination as to whether products are imported or locally produced. As to the specific case of Jordan, providing for the ground of non-working locally in the Patents Law may violate the USJFTA, because the Agreement specified that importation shall constitute working. Nevertheless, the same objectives may be realized but based on a different ground: granting CLs based on circumstances or situations considered to represent the public interest in Jordan. A refusal to deal and high prices of medicines are two important examples that are legitimate to establish under the terms of the TRIPS Agreement and the USJFTA.254

4. Safeguard the Public Interest as a Ground for Compulsory Licensing

The Jordanian patent law restricts the grant of CLs exclusively to the circumstances mentioned in Article 26 of the law.255 The article does not contain a

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254 As I will explain in the next section, such grounds may be instituted as conducts of anti-competitive practices.
255 Article 26 of the Jordanian Patents Law reads: [the] Minister may grant a license to use a patent to third parties without obtaining the patentee’s consent in any of the following cases exclusively: A. If the use of the patent by the state authorities or licensed third parties is a necessity for national defense or emergency or for noncommercial public good provided that the patentee is notified as soon as it becomes possible. B.1. If the patentee doesn’t exploit it or exploits it insufficiently before the elapse of 4 years as of the application date or 3 years as of the granting date, the period to be applied is the one that elapses later. However, the Minister may grant the patentee an additional grace period if he deems that reasons beyond the control of the patentee have prevented exploitation. 2. For the purposes of item (1) of this paragraph, and without prejudice to the provisions of the related International Conventions, the importation of the subject goods of the patent to the kingdom shall be deemed
ground for the authorization of involuntary uses of patents when it is necessary to safeguard the public interest to protect public health. The public interest, however, is among the grounds of CL commonly found in the patent law of many countries. This ground has been given particular consideration in the field of public health to ensure that the patent system does not obstruct a timely access by the general public to the necessary medicines and treatments at affordable prices.

Given the elastic nature of the public interest as a legal concept generally, and in the context of patent law, in particular, and since the multilateral legal instruments concerned with the regulation of patents do not specify a definition of the public interest to be followed by their members, it would be useful to first consider the meaning of the concept as understood and applied by selected comparative authorities. I then pursue an analysis of the possible reasons that have led to the omission of this particular ground from Jordan’s Patents Law: namely, its obligations under the TRIPS Agreement and the USJFTA.

The Patents Law of 1999 was enacted to bring the Jordanian national system of patents into conformity with the minimum standards of the TRIPS Agreement. Whether establishing the protection of the public interest as a ground of CL is a legitimate exercise under the TRIPS Agreement, is a question that requires an examination of the relevant rules and practices of WTO members on this issue. With regard to Jordan, however, this also calls for an examination of the rules of the USJFTA on compulsory licensing. I will, therefore, examine the relevant USJFTA rules to determine if the agreement prevents adopting the public interest as a legitimate ground of CL. The analysis of the USJFTA rules will reflect subsequent practices of the parties. Especially, I emphasize the recent landmark decision of the Supreme Court of the United States in eBay Inc v. MercExchange, L.L.C. In this case, the Supreme Court emphasized that when determining whether or not to grant an injunction in patent infringement cases, lower
courts shall consider the four-factor equitable test,\textsuperscript{257} where the public interest is a fundamental factor of the test.\textsuperscript{258}

4.1. The Concept of the Public Interest

The establishment of any system of legal rules to regulate a given matter shall serve the public interest justifying the creation of such a system. In the patent law context, such an interest rests in advancing science and technology, which supposedly leads to social, industrial, and economic development.\textsuperscript{259} By their nature, however, exclusive patent rights restrict competition\textsuperscript{260} in patented products, which conflicts with the interest of the public in fostering competition. Given its impact on competition in patented and off-patent\textsuperscript{261} products, it is clear that granting patents involves a tension of two public interests: a competitive market, which patents limit, and enhancing scientific and technical knowledge as well as economic and industrial development, which patents are claimed to foster.\textsuperscript{262}

\textsuperscript{257} According to the Supreme Court, the four factors that a plaintiff ought to demonstrate, before granting an injunction, are: “\ldots: (1) that it has suffered an irreparable injury; (2) that remedies available at law are inadequate to compensate for that injury; (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction”. The Supreme Court further added that “The decision to grant or deny such relief is an act of equitable discretion by the district court, reviewable on appeal for abuse of discretion. (\ldots) Neither the District Court nor the Court of Appeals below fairly applied these principles” (emphasis mine). Ibid.

\textsuperscript{258} When considering injunctive relief, a US court shall consider the effect on the public if such injunction is granted. According to the forth factor of the equity test, the court may not issue an injunction where it would disserve the public interest.

\textsuperscript{259} See Penrose, supra note 32.

\textsuperscript{260} Although patent theory advocates the notion that patents enhance dynamic competition by promising inventors to award them exclusive rights, which would lead to more products and processes, the competition concept is used here narrowly to mean a faster, more affordable access to products placed in the market.

\textsuperscript{261} An example would be when patent leverage involves anti-competitive conduct as in cases of illegal tying.

\textsuperscript{262} Whether patent protection is a determinant factor in enhancing scientific and technical knowledge is a controversial issue that is not empirically proven. In fact, several studies indicated that less patent protection leads to more technical advancement and innovation. For more information on this issue, see Chapter 2. In particular, see for example, F.M. Scherer & Sandy Weisburst, “Economic Effects of Strengthening Pharmaceutical Patents Protection in Italy” (1995) 26 International Review of Industrial Property and Copyright Law 1009 at 1023-4; Margaret Kyle & Anita McGahan, “Investments in Pharmaceuticals before and after TRIPS” (2009) NBER Working Paper Series, Working Paper 15468 at 18-9, online: NBER Homepage <http://www.nber.org/papers/w15468> (date accessed: September 20, 2010); and see Nicola Lacetera & Luigi Orsenigo, “Political Regimes, Technological Regimes and Innovation in the Evolution of the Pharmaceutical Industry in the U.S.A. and in Europe” (2001) Paper
The fact that most of the world’s countries today maintain patent legal systems does not mean that this tension was resolved in favor of patents at the expense of other important interests. Countries have implemented effective safeguards into their patent systems to guarantee that the grant of patents constitutes a balanced mechanism, which does not put the interests of the public in jeopardy, fosters science and technology, and is capable of addressing abuses of patent rights. Abuses of rights such as non-working and anti-competitive practices involving patent rights are examples as to when patentees are considered to have disrupted this balance. Compulsory licensing has been envisaged, and thus instituted in the patent system, as one legal measure to restore this balance whenever distorted by abuses of rights. In addition, CLs have been stipulated, and indeed granted, to qualify exclusive rights in circumstances where no abuses are perpetrated. Generally, these circumstances have been developed under the legal concept of the public interest.

263 See Articles 7 and 8 of the TRIPS Agreement, supra note 4.
264 This would be the case by having non-working of patented inventions subject to CL as well as in the case of anti-competitive practices involving patent rights. See Articles 31 and 8 of the TRIPS Agreement, supra note 4.
265 Frederick M. Abbott et al., The International Intellectual Property System: Commentary and Materials, (Netherlands: Kluwer Law International, 1999) at 223. Moreover, Article 8 of the TRIPS Agreement reads:
1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

See Article 8 of the TRIPS Agreement, supra note 4. Also see Carlos M. Correa, “The International Dimension of the Research Exemption” (2004), online: The American Association for the Advancement of Science, Project on Science and Intellectual Property in the Public Interest (SIPPI) <http://sippi.aaas.org/Pubs/Correa_International%20Exception.pdf> (date accessed: October 5, 2010) [International Dimension].
266 See Reichman & Hasenzahl, Historical Perspective, supra note 37.
267 Ibid.
4.1.1 The Meaning of the Public Interest and Compulsory Licensing

As a legal concept, the public interest is an elastic notion reflecting different denotations relative to the social, economic, and political context of the country concerned. Therefore, the meaning of the concept varies among countries and even among different fields within the same country. Since not much has been written to define the public interest concept, determining what it is would indeed be a herculean task. In a patent law context, however, it is undisputed that maintaining a patent regime is assumed to represent a public interest, in so far as it functions as a means to an ultimate end: scientific, technological, industrial and, generally, economic development as well as the ensuing public benefits of using the patent system by way of theory or practice.

At the national level, the public interest manifests itself in pursuance of various objectives. For example, a country seeking to maximize its industrial production, thus industrial exports, may define its public interest to encompass objectives such as securing economic development by mandating local production in levels exceeding the scale of what may be considered working in the legal sense of the requirement. A public

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268 It should be noticed that the public interest is not restricted to the notion of protecting public health. This is so since the protection of public health indisputably represents an interest for the public. The notion is used here for subtle issues, in particular, with regard to measures such as compulsory licensing, which is conducive to the public interest. The scope of such available measures is a contentious subject matter - for example, whether countries can establish CLs to mitigate high medicine prices. Another example would be a refusal to deal by a patentee, which may cause a national industry to dwindle with negative impacts on the public interest in maintaining a secured flow of affordable medicines.


270 For various examples from different developed countries on legal provisions reflecting the public interest in authorizing CL, see James Love, Compulsory Licensing: Models For State Practice In Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord (Document prepared for the United Nations Development Programme, January 21, 2001, online: Consumer Project on Technology Homepage <http://www.cptech.org/ip/health/cl/recommendedstatepractice.html> (date accessed: September 15, 2010) [Compulsory Licensing].

271 See supra note 269.

272 Due to disparities in technological development between developed and developing countries, their respective public interests have always been in tension in setting international patent standards. This tension had been the norm even among industrialized countries when they dominated the international patent regime. On these disparities, see, for example, Michele K. Boldrin & David K. Levine, Against Intellectual Monopoly, ed. (Cambridge; New York: Cambridge University Press, 2008) at 212-242.

273 This was the patent policy of the United Kingdom until 1977. It has been envisaged that the public interest for the country rests in granting a compulsory license to an interested applicant if, following a refusal by a patentee to grant a license on reasonable terms, “a market for the export of the patented article manufactured in the United Kingdom is not being supplied:...or the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced...”. See Section 37(2) of the 1949 British Patent Act.
interest may also rest in opening new technological developments for the national industry to achieve goals of social and economic development policies.\textsuperscript{274,275} The public interest may also be served by limiting\textsuperscript{276} and restricting the exercise of patent rights – for example, denying product patent protection for food and pharmaceutical products.\textsuperscript{277}

Public health, mainly pharmaceuticals,\textsuperscript{278} has been an area that illustrates best the elastic nature of the public interest concept so far as patent rights are concerned. For some countries, an entire exclusion of all health-related inventions from patentability, whether products or processes, might serve the public interest. For others, however, this interest is served by excluding product patents, but not process patents. Yet, in some of the countries that adopted the latter path, they found it in their public interest to subject process patents to CLs.\textsuperscript{279} Still in others, although patents were available for health-related products and processes, they authorized CLs on both types of patents.\textsuperscript{280}

\textsuperscript{274} Such a policy may aim, among other things: to establish a competitive position for the national industry, or fortify an existing one; to promote or enhance exports of national production; or to serve a national social interest in both maintaining a secured access to low-priced products and maximizing to the fullest possible extent employment opportunities. See Ladas, supra note 32 at 430.

\textsuperscript{275} The following are instances where German courts have based their decisions to grant CLs on the finding of the public interest: “safer working conditions in coal mines; improved economy in coal mines as to output and prices; … supply of certain raw materials; better production of valuable material for scientific purposes; … better prophylactic treatment of gum diseases; promotion of export business by new methods”. See Fredrik Neumeyer, Compulsory Licensing of Patents under Some Non-American Systems, 85th Cong., 2d Sess. (1959) (Study No. 19), cited by Ladas, supra note 32 at 430.

\textsuperscript{276} Both international and national patent systems contain limitations on the patentability of certain subject matters. Instances of such matters were mentioned in Article 27(3)(a) and (b) of the TRIPS Agreement. These examples include, among others, “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” and “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.” See TRIPS Agreement, supra note 4.

\textsuperscript{277} This was a common patent policy in many of the worlds’ today developed countries such as Canada, France, Germany, Italy, Spain, and Switzerland. In addition, prior to the TRIPS Agreement, some 50 states did note protect pharmaceutical inventions by patents at all. In many, only process patents were provided. See UNCTAD-ICTSD, supra note 147.

\textsuperscript{278} The patent law of many countries would make a specific reference to medicines, drugs or products capable of being used as medicament and/or processes for the production of these substances. See infra, notes 279 and 280.

\textsuperscript{279} For example, this had been the case in Canada prior to 1993 and India until 2005.

\textsuperscript{280} Under the provisions of Section 41 of the 1977 British Patent Act, the Patents Comptroller, upon an application submitted to him by an interested person, may grant a compulsory license in an invention related, \textit{inter alia}, to medicines to make the concerned medicine available to the public at the lowest prices. See Ladas, supra note 32 at 431. Section 120 of the Israeli Patent Law of 1967, titled “Compulsory License for Medical Purposes”, contained similar provisions. The relevant text of the Section reads: (a) [subject] to the provisions of section 122, the Registrar may—if he was requested to do so and if that is necessary in order to give the public a reasonable quantity of medical supplies—grant a license for—
The flexible nature of the Public Interest concept, with respect to patents in the public health sector, was well captured by the words of Khan J. of the Supreme Court of Israel commenting in *Wellcome Foundation v Plantex Ltd.*\(^\text{281}\) that:

> [there] exist grave reasons against the creation of a monopoly by a patent in respect of medical treatment. We are confronted here with saving human life or alleviating human suffering and one should take great care lest the freedom of action of those who treat, be restricted by patent rights.\(^\text{282}\)

The non-discrimination clause of Article 27.1 of the TRIPS Agreement, however, seriously narrows the meaning of the public interest as a basis for excluding pharmaceuticals from patent protection or for restricting patent rights in this particular field. This means that neither the products nor the processes in pharmaceuticals can be *per se* denied patent protection in any of the WTO member countries based on the public interest.\(^\text{283}\) In other words, the meaning of the Public Interest concept, as a basis to restrict the availability of patent protection, is now confined within the contour of Paragraphs 2\(^\text{284}\) and 3\(^\text{285}\) of Article 27 of the TRIPS Agreement.

To sum up, before the TRIPS Agreement, many countries considered it in their public interest to either exclude pharmaceuticals from patent protection altogether or to

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(1) a patented product that can be used as a medicament or for the production of a medicament;
(2) a patented process for the production of a product said in paragraph (1);
(3) a patented device that can be used as a device for medical purposes or as part thereof.

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\(^{282}\) Ibid.

\(^{283}\) The least developed members are the only exception to this rule since the transitional period to implement their obligation with regard to pharmaceuticals was extended by the Doha Declaration until 2016. See Paragraph 7 of the Declaration, supra note 80.

\(^{284}\) Article 27.2 reads:

> [members] may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

See the TRIPS Agreement, supra note 4

\(^{285}\) For examples on non-patentable subject matters mentioned in Paragraph 3, see supra note 276.
make such protection available to process patents only.286 Authorizing a CL on a patented invention whenever needed also was perceived to advance that interest. However, statutory exclusion of entire fields of technology from patent protection or authorizing CLs on all patents of certain fields may no longer constitute a public interest as stipulated in Article 27 of the TRIPS Agreement. Nevertheless, this article does not restrict the freedom of WTO members to resort to the Public Interest concept as a ground for authorizing CLs on a case by case basis.287 Non-consensual use of patents is governed by the rules under Articles 30 and 31 and in accordance with the objectives and principles of the Agreement, as detailed in Articles 7 and 8, and in light of Articles 1.1 and 2.288 Accordingly, this chapter will next explore whether the TRIPS Agreement permits a WTO member to establish the public interest as a statutory ground of CL, or as a public law equity rule. I will discuss possible circumstances and modalities such as “refusal to deal” and “high medicine prices”, which might constitute a legitimate justification for issuing CLs based on the public interest.

4.2. Public Interest and Compulsory Licensing of Medicines under the TRIPS Agreement

Article 31 of the TRIPS Agreement contains most of the rules regulating CLs. The article elaborates a system of substantive conditions, limitations, and procedures which national legislation must implement and with which authorities must comply when authorizing CLs on patents. However, the article is silent as to what might represent a legitimate ground. Although laconic, this inexplicit language has led to political controversy as to what may constitute a legitimate ground under the TRIPS Agreement.

Central to that debate has been the question of whether a national legislation may establish circumstances other than those mentioned in Article 31, including a

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286 See supra notes 277 through 281.
287 Article 31 (a) of the TRIPS Agreement stipulates that “authorization of such use shall be considered on its individual merits”. See the TRIPS Agreement, supra note 4.
288 The relevant part of Article 1.1 reads: “[members] shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.” Under Article 2 of the TRIPS and by means of incorporation, Article 5 of the Paris Convention and state practice thereof is also applicable. See the TRIPS Agreement, supra note 4.
consideration of the public interest. Some have argued that the discretion of WTO members under Article 31 is confined to those grounds mentioned in Article 5A (2) of the Paris Convention: to prevent or discipline abuses of patent rights. They also add that the conditions applicable to licenses issued to redress abuses of rights under the same article equally apply to CLs authorized based on the public interest. That is, granting a CL on the public interest ground may only be justified when there are abuses by right holders of their exclusive rights.

There are many compelling arguments for why this is not the case and why the public interest is an independent ground distinct from abuse of rights. Hence, member countries are fully entitled to establish this ground in their respective legislation. They may also do so by any other available means, if in compliance with TRIPS’ rules and any other applicable WTO agreements or rules.

It is a TRIPS-compliant legislative practice to establish the public interest as a ground to compulsorily license patented inventions, including in pharmaceuticals. This measure, however, must not be specifically directed to patented pharmaceuticals or to any other field per se. Indeed, a statutory exception to patent rights for enhancing the public interest would be in compliance with the TRIPS Agreement if it is intended to address...
certain circumstances that are broadly defined and do not target specific fields or a particular class of patentees.  

4.2.1 TRIPS Allows the Public Interest as a Ground of Compulsory Licensing

Various TRIPS Articles espouse the entitlement of countries for adopting measures, including CLs, necessary to promote the public interest in sectors important to their socio-economic and technological development. For example, Article 8:1 of the Agreement reads:

[members] may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

This article makes equal reference to the protection of public health and to the promotion of public interest in sectors of vital importance to the socio-economic and technological development of WTO members. Such references indicate that promoting the public interest via CL authorizations in the pharmaceutical sector, as a sector critical to the socio-economic and technological development, falls under the general permission of this article. Because CLs may assist in mitigating prohibitive prices of necessary

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295 Interesting precedents that call attention to the conformity of statutory rules may be found in the laws of some developed countries. Examples may include: a patent term extension under the US Law is available only to pharmaceutical inventions due to delay in sanitary regulation; and both France and Belgium amended their laws to allow compulsory licensing on pharmaceutical patents for public health reasons. See infra notes 462 & 463.

296 Arguing his case for the possibility of granting compulsory licenses on the ground of failure to work as a legitimate means to transfer necessary technologies, Correa suggested that: “…-in line with Article 8.1 of the TRIPS Agreement—for the granting of compulsory licenses in qualified cases of local working, for instance, when such a lack affects the commercial or industrial development in the country of sectors of vital interest.” See Correa, “Intellectual Property”, supra note 142 at 9. Champ and Attaran also advocate the same view, see Champ & Attaran, supra note 38 at 387. A disputing stance over this matter is adopted by Carvalho. He states that the public policy measures referred to in Article 8 “… cannot be found in other provisions of the TRIPS Agreement. Article 8, as a matter of course, does not refer to …, compulsory licenses […] because those measures are already explicitly authorized in the Agreement…” See Nuno Pires de Carvalho, The TRIPS Regime of Patent Rights, (London/ The Hague/New York: Kluwer Law International, 2003) at 118.

297 See the TRIPS Agreement, supra note 4 (emphasis mine).

298 See Pacón, supra, note 289.
medicines by increasing competition, they, therefore, promote the public interest by providing more affordable medicines.

As a means for transferring advanced technology, CLs may promote the technological development of pharmaceuticals\(^{299}\) as a “[sector] of vital importance to … socio-economic…development”,\(^{300}\) thus, a promotion of the public interest. This point is relevant because maintaining a reliable manufacturing capacity removes a serious difficulty in making effective use of CLs under the TRIPS Agreement of the kind mentioned in Paragraph 6 of the Doha Declaration.\(^{301}\) The possession of industrial capacity induces patentees to consider their business strategies and hence refrain from practices that might be considered abuses if they are threatened by CLs. They then recognize that such a threat is backed by the necessary and proper industrial competencies.\(^{302}\)

In addition, Article 2 of the Agreement may provide a legal basis for instituting the public interest as a CL ground in order to promote the transfer of technology to, and the development of, the local pharmaceutical industry. The Article partially reads: “[in] respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967)”.\(^{303}\) This article incorporates into the TRIPS Agreement Article 5 of the Convention which contains the rules on the regulation of CLs. As discussed elsewhere in this chapter, many signatories to the Paris

\(^{299}\) Arnold articulated several reasons as to why counties have a legitimate interest to sustain and foster a national pharmaceutical industry. 1) The industry may help in the employment of many professionals such as chemists, physiologists, toxicologists, pharmacologists, pharmacists, doctors and many others; indeed it would assist in combating a serious brain drain problem. 2) “[A] domestic pharmaceutical industry could be a significant contributor to the national economy.” 3) Given that labor cost varies among different countries, a national pharmaceutical industry might be in a better position to produce medicines with prices matching average local income; thus making drugs more affordable. 4) As a result of the prodigious cost of developing a new medicine, small countries that are not a host for a multinational corporation are not capable of developing new medications. 5) For reasons of national defense, sustaining an internal pharmaceutical industry is a critical matter. See Gianna Julian-Arnold, “International Compulsory Licensing: the Rationales and the Reality” (1993) 33 IDEA: The Journal of Law and Technology 349 at 351.

\(^{300}\) See Article 8 of the TRIPS Agreement, supra note 4.

\(^{301}\) See Paragraph 6 of the Doha Declaration, supra note 80.


\(^{303}\) See Article 2(1) of the TRIPS Agreement, supra note 4.
Convention had established CLs of patented pharmaceuticals in accordance with Article 5 to promote their public interest. On the legitimacy of this practice within the framework of Article 5, Bodenhausen maintained that:

[the] provisions in paragraph (2) … do not deal with measures other than those whose purpose is to prevent the abuses referred to. The member states are therefore free to provide analogous or different measures, for example, compulsory licenses on conditions other than those indicated in paragraph (4) in other uses where the public interest is deemed to require such measures. This may be the case when patents concern vital interests of the country in the fields of military security or public health or in the case of so-called ‘dependent patents’.304

Finally, the legitimacy of establishing this measure may further be inferred from Article 31 of the TRIPS Agreement. As clearly indicated by the text of this article, drafters eschewed any attempt to restrict the grant of CLs to specific and predefined grounds.305 This approach was due, inter alia, to the fact that the patent law in many306 developed countries embraces provisions authorizing CL if it is considered conducive to the public interest. For example, Section 24-1 of the German patent law mandates the Patents Court to grant a non-exclusive license in cases where the applicant in question fails to obtain the consent of the right holder on reasonable conditions “usual in trade”, and where the “public interest commands the grant of a compulsory license”.307

Although the text of Article 31 unambiguously provides WTO members with the flexibility necessary to institute CL grounds of their choice,308 the Doha Declaration309

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304 See Bodenhausen, supra note 33 at 70 (emphasis mine).
305 Gervais reported that during the negotiations over the appropriate course with respect to establishing grounds of compulsory licenses, the negotiators weighed the options of either listing the grounds or not doing so and, in the end, they preferred the latter. See Gervais, Drafting History, supra note 14.
308 Patents on semi-conductor technology are the only exception to this freedom. According to Article 31(c), compulsory licenses can “only be for public noncommercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive” in the case of semi-conductor technology patents. See the TRIPS Agreement, supra note 4.
assertively attests to the validity of this right.\textsuperscript{310} This confirmation, in turn, extends to members’ preferences with regard to grounds based on the public interest. In light of the legal uncertainty on the legitimacy of authorizing CLs to redress abusive non-working of patents caused by Article 27.1, the public interest ground, in particular, has been the focus of growing importance.

In her “Implementing the TRIPS Agreement on Patents: Optimal Legislative Strategies for Developing Countries”, Watal advised that countries could implement the public interest ground in their national law in lieu of non-working. She argues that if compulsory licensing is authorized based on a finding of public interest, WTO members would avoid the legal ambiguity caused by the non-discrimination clause of Article 27.1.\textsuperscript{311} If, by making “non-local manufacturing” a statutory basis for issuing licenses, developing countries seek to realize either a transfer of technology\textsuperscript{312} and/or address a problem of high prices for patented medicines, Watal suggests that these objectives can be realized by making the public interest a legal ground for authorizing CLs.\textsuperscript{313}

\textsuperscript{309} After it proclaimed a general declaratory commitment to the espousal between the protection of public health and public policy measures, such as CLs, Paragraph 4 of the Declaration states: “we agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.[…] Accordingly, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

In Paragraph 5 (b), the Declaration makes a particular reference to the right of each of member to grant CLs and to “determine the grounds upon which such licences are granted” (emphasis mine). See the Doha Declaration, supra note 80.

\textsuperscript{310} This freedom relates to the establishment of the legal grounds. However, any established situation or circumstance shall be in full compliance with the provisions of the TRIPS Agreement. In particular, statutory grounds shall not be found in violation of the principles of “National Treatment” and “Most Favored Nation” as detailed under Articles 3 and 4 of the Agreement, respectively. In addition, any given established ground must not infringe the Non-Discrimination Clause of Article 27. That is, a ground which is directed against a specific field, foreign patentees, or the nationals of given WTO member would not constitute a legitimate ground.

\textsuperscript{311} See Watal, “Legislative Strategies”, supra note 232 at 111.

\textsuperscript{312} Normally, this would happen indirectly. The local working requirement would result in the right holder establishing a manufacturing plant within the territory of the patent-granting state. This, in turn, may lead to the transfer of the relevant technology. However, if it is disadvantageous to right holders to manufacture their patents locally, they would tend to seek potential licensees willing to work the patents. This latter scenario depicts an optimal route to achieve the transfer of necessary technologies, where right holders would also transfer the necessary know-how to their licensees. Such cooperation may not be obtained from right holders in cases of CL. See Correa, “Can the TRIPS”, supra note 220 at 247.

\textsuperscript{313} Watal does not make an explicit reference to making the public interest as ground of CL. Instead, she suggests instituting particular circumstances as legal grounds of CL in the national legislation of
Champ and Attaran concur with Watal’s argument on the legitimacy and superiority of the public interest ground. By means of articulating a hypothetical outcome of the US request for the establishment of a panel complaining about measures affecting patent protection in the Brazilian Industrial Property Law (local working requirement), and after speculatively finding against such measures, they noted:

[what], then, is to prevent Brazil from re-legislating, so as to delete the offending, discriminatory grounds of failure to work from its law, while replacing that provision with an open-ended discretion to issue compulsory licenses? Such a move would simultaneously cure the U.S. complaint, while arming Brazil with an even more wide-ranging power to grant compulsory licenses than before […]

[...] Even if we assume, for the sake of argument, that Article 27(1) is paramount, non-derogable, and imposes limitations of nondiscrimination on the exercise of Article 31, none of this forbids a law purporting to grant compulsory licenses in the ‘public interest’.

The previous analysis clearly indicates that according to the TRIPS Agreement’s rules Jordan had the discretion and freedom to establish in its law grounds such as a refusal to deal and high prices in the public interest. Establishing this statutory ground, unlike non-working, is free of legal uncertainty or ambiguity, and it does not contradict the TRIPS’s rules generally. The public interest ground is also much more flexible and may be adapted to accommodate unanticipated situations. However, Jordan’s discretion is subject to its obligations under the USJFTA. This agreement contains detailed provisions on this matter, which Jordan must not breach. Next I will examine whether the rules under the USJFTA were meant to enjoin Jordan from enacting the above-mentioned, public interest-based circumstances as legitimate grounds.

developing countries. For example, to secure the transfer of technology, she recommends making a refusal to license on reasonable conditions as a legal basis of CL. With respect to high prices, she is of the opinion of making the sale of patented medicines at unreasonably high prices per se a legal ground of CL. See Watal, “Legislative Strategies”, supra note 232 at 112-3.


315 See Champ & Attaran, supra note 38 at 392 (emphasis mine).
4.3. Compulsory Licenses on Public Interest Grounds: is it Legitimate under the United States-Jordan FTA? An Issue Illuminated by the US Supreme Court

Article 4(20) of the USJFTA enumerates an exhaustive list of specific circumstances that might constitute legitimate grounds for authorizing CL of patents by the agreement’s parties. The article begins by stating that “[neither] Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances”:

(a) to remedy a practice determined after judicial or administrative process to be anti-competitive;
(b) in cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or
(c) on the ground of failure to meet working requirements, provided that importation shall constitute working.316

There is no mention of the public interest or other grounds that might be justified on such a basis – for example, a refusal to deal and high medicine prices, which also may be considered as anti-competitive practices redressable through CLs.317 Nor does the list

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316 See the USJFTA Agreement, supra note 17 (emphasis mine).
317 Although neither the TRIPS Agreement nor the USJFTA defines what practice is anti-competitive hence allowing national authorities a considerable policy flexibility in determining the anti-competitive practice, there are objections to specifying these two circumstances as anti-competitive subject to CLs. As to the ground of unilateral refusal to deal, it is argued that it is the very nature of the right to license a patent to decide not to license and exclude competitors from exploiting the patented technology. Thus, it may not constitute an anti-competitive practice. In other words, if a patentee is exercising its rights under a patent, a refusal to deal may not constitute a ground for anti-competitive violation. In addition, in EU case law, a refusal to deal can only be considered abusive if it satisfies certain conditions: namely, the refusal should concern an indispensable product or serves; prevent the appearance of a new product (not a mere duplication); and is not justified. See IMS Health GmbH & Co OHG v. NDC Health GmbH & Co KG (Case C-418/01); [2004] All ER (D) 340. With regard to high prices charged by patentees, it is also advocated based on the function of the exclusivity of patent rights; charging higher prices represents the incentives underlying the grant of patent, which enables a patentee to recoup its investments and costs incurred in developing a patented product or serves. For a discussion on how developing countries can design their competition policy with regard to practices such a refusal to deal, including specifying this behavior as anti-competitive behavior subject to CL, see Carlos M. Correa, Intellectual Property and Competition Law: Exploring Some Issues of Relevance to Developing Countries (2007) (ICTSD Programme on IPRs and Sustainable Development, Issue Paper No. 21), online: International Center for Trade and Sustainable Development <http://ictsd.org/downloads/2008/06/corea_oct07.pdf> (date accessed: November 20, 2010) [Competition Law]; also see United Nations Development Programme (UNDP), Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement (New York: United Nations Development Programme, 2010), online: UNDP <http://apps.who.int/medicinedocs/documents/s17762en/s17762en.pdf> (date accessed: June 15, 2011).
implicitly indicate that CLs might be authorized by courts on the basis of grounds other than those listed, including the public interest. However, does that mean the parties to the Agreement may not authorize CLs based on other grounds, including the public interest, and by means other than a statutory provision?

There has been no formal interpretation of this article that would have addressed this question, thus it lacks a clear answer. Notwithstanding this fact, examples on the possibility of granting CLs on grounds other than those mentioned in the USJFTA under the current US law remains a reality. Yet the relatively recent decision of the US Supreme Court in eBay, Inc. v. MercExchange, L.L.C. 318 may provide the answer.

In this case, the US Supreme Court held that an injunction cannot be issued automatically upon finding of an infringement of a valid patent.319 Rather, an adjudicating court must apply the *equitable principles of the balancing test* developed and used under other areas of law (copyright law) in order to decide whether an injunction should be issued.320 As applied by courts of equity, the test mandates that before an injunction is issued, a plaintiff is required to demonstrate that: (i) it has suffered an irreparable injury; (ii) remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (iii) considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (iv) the public interest would not be disserved by a permanent injunction.

The last factor of the equity test is important and relevant to the argument advocated in the present chapter: CLs may be issued for the public interest. Demanding a plaintiff to prove that the public interest would not be disserved should an injunction be issued indicates that an injunction may not be ordered if the plaintiff fails, notwithstanding that it might have satisfied the other three factors.321 Such a conclusion is implicit in Justice Kennedy’s Concurring Opinion, joined by Justices Stevens, Souter, and Breyer. Justice Kennedy concluded that injunctions in such cases might not serve the public interest.322 He placed a particular emphasis on the significance of economic

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318 See eBay, supra note 211.
319 Ibid.
320 Ibid.
321 In this case, the District Court was found to have erred when it had not fully considered the irreparable harm element of the case.
322 Justice Kennedy elaborated this issue in his opinion saying:
consequences which may be associated with injunctions, in light of the fact that a patented invention may only represent a small component of an infringing product and given that a threat of injunctive remedy is utilized to achieve leverage in settlements or licensing negotiations. In addition, the court alluded to the legal question that injunctions are not required by the Patents Act which only says that courts “may” grant injunctions and “in accordance with the principles of equity.” This last point further confirms the relevance of the public interest in a patent law context.

Note the type of the public interest for the protection of which injunctions are not to be issued. These mainly include economic interests of third parties, interest which would be jeopardized if injunctions were to be issued. Thus, the public interest rests in preventing a service from being disrupted or becoming more expensive, because injunctive relief is employed to leverage licensing negotiations. If this is the case, then public interest would rest in denying an injunction to a prevailing patentee who, employing the leverage of such a remedy, charges unreasonable prices, making its products unaffordable to those in need. The same should apply to a patentee who demands commercially unreasonable terms, including high royalties, to license its patent to a willing local licensee. Therefore, the ruling in the eBay case is more relevant to cases involving, generally, public health-related inventions and pharmaceutical patents, in particular.

The relevance of this ruling to the above-mentioned USJFTA article rests in it essentially illustrating the authority of US courts to authorize effective CLs; to the

[an] industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees. [Citation omitted] For these firms, an injunction, and the potentially serious sanctions arising from its violation, can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent. When the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest.

See eBay, supra note 211 at 1842.

324 In Finisar Corp. v. DirecTV Group, Inc., [2006] U.S. Dist. LEXIS 76380, the District Court denied the patentee injunctive relief, upon finding of infringement of its patent, and instead ordered a compulsory license of $1.60 per Integrated Receiver Decoder, commonly referred to as a set top box, until the patent expired. Providing the reasoning for the ruling in the case, Judge Clark of the District Court for the Eastern District of Texas commented on the eBay Decision stating that “[what] the Supreme Court said isn’t
extent that CL is conceived of as an authorization of non-consensual use of a patented invention for a monetary remuneration, which is what denial of injunction entails.\(^{325}\) As a ground on which CLs might be issued, the public interest manifests itself in the denial of injunctions, which is the practical result of this decision.

Therefore, since it is subsequent to the USJFTA, it provides a legal precedent about a law that was in place\(^{326}\) at the time the agreement was concluded, and since the law remains unchanged at the time the decision was handed down, the eBay ruling is relevant to the interpretation of Article 4(20) of the USJFTA. In other words, as it is assumed that the US Patents Act should be in conformity with the country’s bilateral obligations, it is also assumed that national courts are supposed to apply domestic legislation in conformity with such obligations. Thus, the eBay decision should provide an understanding, or even an interpretation,\(^{327}\) of the agreement’s article on the US side, which Jordan should embrace and welcome.\(^{328}\)

In short, with this Supreme Court ruling, where injunctive relief in an infringement of a business method patent was denied mainly in the public interest, it is difficult to conclude that Jordan may not follow suit in cases of pharmaceutical patents on anything new, [they are] just reminding everybody to stop wandering off the path, get back to... how we’ve always done injunctions”. As cited in Manzo, supra note 213 at 71.

\(^{325}\) When a court does not grant an injunction, effectively a court is authorizing a compulsory license. It is so because such denial means preventing the patentee from resorting to a legal tool to enforce its right to exclude others from using its patented invention, on the one hand. And, on the other hand, when injunctions are not issued, courts would order the infringer to pay the patentee a monetary remuneration. In effect, this is what a compulsory license is: “[a] compulsory license is an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state”. See Arnold, supra note 299.

\(^{326}\) With regard to the statutory provisions on injunction, Section 283 of the Patent Act has been relied upon by courts since as early as City of Milwaukee v. Activated Sludge [1934] 69 F.2d 577 (7th Cir.).

\(^{327}\) On this point and with regard to the role of municipal courts in norm creation under International Intellectual Property norm setting, Dinwoodie said “[i]n the classical international intellectual property system, national courts played a relatively limited role in developing, interpreting or implementing international norms. However, in recent years national courts have become more involved in the construction of international intellectual property law.” Dinwoodie further maintained that “treaties did not, in any event, contain a comprehensive code that could substitute for general domestic legislation. National courts thus interpreted local intellectual property law, even if the content of that law had, in part, been influenced by international obligations” (emphasis mine). See Graeme B. Dinwoodie, “The International Intellectual Property System: Treaties, Norms, National Courts, and Private Ordering” in Daniel Gervais, ed., Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS Plus Era (Oxford; New York: Oxford University Press, 2007) 61 at 62, 68, respectively.

\(^{328}\) Although it was argued that the Supreme Court’s decision constitutes a violation of the USJFTA, it is not in the interest of Jordan to adopt such an argument. Rather, to strengthen and enhance policy tools necessary for access to medicines, Jordan should maintain a stand reflecting the argument advocated in this chapter.
the same ground in public health. This argument is much more compelling when public health is harmed by *abuses of exclusive patent rights* such as a refusal to deal on reasonable commercial terms\(^{329}\) or when patentees charge exorbitant prices for essential drugs, making them unaffordable for needy patients. Therefore, it is recommended that Jordan should amend its Patents Law to implement a language that would reflect the above flexibility. Namely, the law should *untie* the discretion of national courts in denying injunctions whenever it is found to be in the public interest not to issue an injunction, and to limit relief available for prevailing patentees to monetary damages only and on terms deemed reasonable by courts. Indeed, such a proposed amendment would be in full compliance with the TRIPS; it is even authorized by Article 44(2) in explicit terms:

> [notwithstanding] the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.\(^{330}\)

In summary, the above analysis clearly indicates that establishing insufficient or non-working as a ground for CL has been available to Jordan under the TRIPS Agreement. However, it has not been attainable for two reasons. On the one hand, it is surrounded with legal ambiguity in light of the non-discrimination clause of Article 27.1 and, on the other hand, Article 4(20) (c) of the USJFTA stipulates that importation should constitute working, which is the anti-thesis of the local working obligation. In addition,
this study concludes that this path has been available under the TRIPS Agreement, but would contradict the provisions of the USJFTA if implemented in the form of a statutory provision. Yet the objectives of mandating local working could be achieved through either providing for circumstances representing the public interest or establishing it as such a ground of CL as an appropriate alternative for Jordan. This route would not contradict the provisions of the USJFTA if Jordan were to amend the law to allow courts the discretion to deny a prevailing patentee injunctive relief on terms deemed reasonable by courts. Such discretion should be exercised in cases where issuing an injunction might disserve the public interest. Next, I will discuss whether Jordan has suffered, or has stood to gain, from establishing those grounds, the former being a claim by opponents of CL.331

5. Restricting Compulsory Licensing in Jordan: Gains or Losses?

Whether maintaining a CL regime is a policy harmful to the socio-economic development of a country remains a controversial issue. The persistence of the controversy might be attributed to the multiplicity of factors influencing the outcome of policy choices. Among the relevant factors is whether the country concerned possesses an innovative industry, relies mainly on generics production, or depends on importation to satisfy its pharmaceuticals needs. Another important factor is whether such a country lacks the capacity to manufacture pharmaceuticals altogether.332 Another example is the influence of maintaining a CL regime on the attractiveness of the economy concerned for foreign investment and/or the transfer of necessary technology and know-how. Therefore,


332 Paragraph 6 of the Doha Declaration addressed this particular situation. See the Doha Declaration, supra note 80. The mandate of Paragraph 6 led to the adoption of a decision in 2003 with the effect to suspend the application of paragraphs (b) and (f) of Article 31 of the TRIPS Agreement. See WTO, Decision of 30 August 2003, supra note 115. Subsequently, the Paragraph 6 solution culminated, in 2005, in proposing an amendment to the TRIPS Agreement, which is not yet effective; see WTO, Amendment of the TRIPS, supra note 129.
to anticipate the probable outcome with a degree of certainty might be difficult indeed.\footnote{Given the historical experience of countries where permissive compulsory licensing policies were adopted by countries such as Canada, it is very difficult to conclude with the notion that CLs would cause such an alleged outcome. In addition, many studies have shown that firms whose patents were subject to CLs did not suffer negative effects in their innovative activities. See, for example, Scherer, infra note 356. The impact of CL, when issued as an anti-trust remedy, on the pharmaceutical innovation was empirically studied by Chien. She empirically tested the assumption that CL reduces incentives to innovate. She compared the inventive activity, including rates of patenting and other measures, before and after six CLs in drug patents were issued during the 1980s and 1990s. She observed that “no uniform decline in innovation by companies affected by compulsory licenses and find very little evidence of a negative impact” on innovation. This observation is consistent with earlier empirical work such as that of Scherer. She concludes that her findings “suggest that the assertion that licensing categorically harms innovation is probably wrong.” See Colleen Chien, “Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?” (2003) 18 Berkeley Technology Law Journal 853.} All in all, opponents of CLs claim that establishing statutory grounds for the issuance of licenses beyond a set of particular and definite circumstances\footnote{The American government, besides its innovative pharmaceutical industry, has been advocating that the TRIPS Agreement permits the authorization of CLS only under the circumstances mentioned in Article 31 of the Agreement. These circumstances include: public non-commercial use, national emergency or other conditions of extreme urgency, remedy for anti-competitive practices, or dependent patents. See Article 31 of the TRIPS Agreement.} would negatively affect the economic development of the economy in question.\footnote{In a paper that received research funding from the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Rozek and Rainey argued against the view that developing countries should make maximum use of all flexibilities available to them under the provisions of the TRIPS Agreement, CL in particular. They warn that CL potentially has: harmful effects in those developing countries that adopt broad-based compulsory licensing of IPRS for pharmaceutical technologies…. That is,…inhibits that country from achieving the benefits of protecting IPRS, while imposing substantial costs. It …destroys the incentives for pharmaceutical firms to invest resources, to conduct research and development (R&D) on specific diseases, and to introduce new products into the country. It imposes costs on the national governments faced with having to approve and monitor the products produced by the licensees. …encourage copying by local firms which may grow accustomed to free riding on the innovative activities of the research-based pharmaceutical firms. In the long run, these local firms are actually denied opportunities to participate in technology transfer into their home countries. See Rozek & Rainey, supra note 226 at 464.} Proponents, however, disagree. They argue that CL is an essential element for maintaining a healthy balance of interests in a patent legislation.\footnote{See Correa, “Intellectual Property”, supra note 142 at 3; also see Carlos M. Correa, Intellectual Property Rights, the WTO and Developing Countries (New York: Zed Books, 2000) [Developing Countries].}

As this study has noted so far, Jordan has severely restricted the issuance of CLs exclusively to specific, limited circumstances.\footnote{See Sections 3 & 4 above.} This restrictive policy will not bring about development-enhancing means such as FDI and technology transfer alleged by those calling for restricting reliance on CLs in the pharmaceutical sector of developing
countries. Such a policy deprives Jordan from many benefits that otherwise would have been available through the utilization of CLs, especially, to advance sectors of vital importance to its socio-economic development, particularly the pharmaceutical manufacturing sector.

This section analyzes the likely effect on Jordan’s economic development had it adopted a permissive CL policy. The analysis proceeds by investigating two themes. The first provides an analysis of the alleged drawbacks of implementing such a policy. The aim here is to reach a judgment as to whether the alleged disadvantages are likely (or not) to materialize in the Jordanian context, in light of the WTO legal framework. The second theme builds on the previous section in seeking to make a case as to why Jordan stands to benefit from establishing various grounds for CL. It argues that such advantages lie in making the patent system one that not only provides patentees with monopolistic rights, but also a system whose fruits are realized by the public at large.

5.1. Costs that Jordan may have Sustained had it Established a Permissive Compulsory Licensing Regime

Although compulsory licensing has been, and probably will continue to be, a structurally essential element of international and national patent regimes, it has been claimed that adopting a policy permissive\(^\text{338}\) of establishing various CL grounds inevitably results in multiple socio-economic costs.\(^\text{339}\) The following are among such claimed costs. First, incentives provided to pharmaceutical innovators by patents will be compromised, afflicting the future of their investments with uncertainty, which results in less innovative output. Second, countries resorting to CLs would frustrate FDI in their pharmaceutical sector. This would be the case since right holders will avoid a legal

\(^{338}\) It should be noted that the meaning of the adjective “permissive” is confined to describe public polices adopting compulsory licenses on grounds that can be legitimately established under the TRIPS Agreement, but are not among those mentioned in Article 31 as illustrations or those to which the Agreement attached certain conditions and/or procedures for members abide by when implementing such measures in their legislation.

environment that is not business-friendly. Third, there is a risk that the prices of compulsory licensed goods may not be much less expensive than their patented equivalents because licensees are likely to “shadow price” patentees in pursuit of profit, which in turn creates a deadweight loss of its own. Fourth, costs of approving products and maintaining quality will increase. And fifth, countries adopting a CL policy run the risk of compromising their economy due to potential retaliation from the governments of the pharmaceutical patentees. Whether all, some, or none of these costs, however, would have materialized in Jordan had it instituted a meaningful CL system, will be investigated next.

5.1.1. Compulsory Licensing “Reduces Incentive to Innovate”

The prevailing view of investment in pharmaceutical R&D is that it is a very risky business. This risky nature has been the essential rationalization put forward to defend the strong protection of patents in pharmaceuticals. The incentives created by the chance of winning an exclusive right to the exploitation of an invention will be lessened by exposing originators of pharmaceuticals to CLs, since CL means a potential future replacement of the “monopolistic” profits by reasonable royalties. It is this line of economic logic to which opponents of CLs appeal in order to confine legitimate grounds only to those mentioned in Article 31 of the TRIPS Agreement.

This argument is flawed. It is based on the assumption that pharmaceutical patents would be subjected to broad and systematic licensing. To illustrate, note the following

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340 See Lybecker & Fowler, ibid.
341 It is estimated that in 2001 the funding for medical research and development globally was over $100 billion. It is also estimated that this number has increased to US$ 125.8 billion in 2003 and to US$ 160.3 billion in 2005; see Global Forum for Health Research, Monitoring Financial Flows for Health Research: Prioritizing Research for Health Equity, (2008) Figure 2.1 at 35, online: <http://www.globalforumhealth.org/content/download/480/3028/file/s14888e.pdf> (date accessed: March 15, 2010, on file with the author).
342 Although, in principle, the risk involved in pharmaceutical R&D is not higher than that of other fields of technology – including medical equipments, advocates of strong pharmaceutical patents maintain that the risk in pharmaceutical R&D stems from the high number of patented inventions that do not reach the market due to safety and/or ineffectiveness.
343 Bird and Cahoy explain this incentive-lessening effect of compulsory licensing as “the temporary or permanent deprivation of some part of a patent owner’s right to exclude disrupts the investment-backed expectation of the property right”. See Bird & Cahoy, supra note 90 at 284.
344 See Lybecker & Fowler, supra note 339; and see Alan O. Sykes, “TRIPs, Pharmaceuticals, Developing Countries, and the Doha ‘Solution,’” (2002) 3(1) Chicago Journal of International Law.
statement made by Rozek and Rainey,\textsuperscript{345} which speaks of such a presumption: “Forced licensing puts the innovator at a bargaining disadvantage and undervalues the technology. If technology is consistently and inherently undervalued, there is no longer any incentive to create new technologies. The innovator should decide when to license its technology. It should not be forced to make technologies available to third parties.”\textsuperscript{346} They accordingly conclude that “[compulsory] licensing destroys the incentive to innovate, reduces R&D, and, thus, limits the number of new or improved drugs that come onto the market”.\textsuperscript{347}

The concern over a consistent undervaluation of technology by having it potentially subject to forced licensing is simply impossible under the TRIPS Agreement.\textsuperscript{348} The Agreement outlaws all forms of systematic CL. According to Article 31(a), every non-consensual use of a patent “shall be considered on its individual merits”.\textsuperscript{349} Therefore, it is illegitimate for any TRIPS signatory to have in its legal system, whether in the form of statutory provisions, administrative orders, or denial of injunctive relief by the judiciary,\textsuperscript{350} what may literally or effectively amount to a systematic compulsory use of patented inventions. This does not mean, however, that the grant of CLs under the TRIPS Agreement is restricted to certain grounds as misleadingly

\textsuperscript{345} Such a statement reflects the position of the innovative industry about CLs on grounds other than those widely used in the US. The industry, however, is much more explicit on the issue. For example, in its 2001 Special 301 submission, The Pharmaceutical Research and Manufacturers of America (PhRMA) raised its objection to the authority granted under Vietnamese patent law to the National Office of Industrial Property to order CL in the following circumstances. “i) [If] a patent is not used, or is inadequately used, during the period of protection, [and] ii) if a prospective licensee has attempted to obtain a license for a patent, but the owner has refused ‘notwithstanding that a reasonable price has been offered,’…” PhRMA commented that it “believes that patent compulsory licensing systems are counter-productive except in cases of national emergency or other urgent circumstances”. See Pharmaceutical Research and Manufacturers of America (PhRMA) 2001, Special 301 Submission, online: PhRMA Homepage <http://international.phrma.org/international/PhRMA_2001_Special_301.pdf> (date accessed: March 17, 2010, on file with the author).

\textsuperscript{346} See Rozek & Rainey, supra note 331 at 477 (emphasis mine).

\textsuperscript{347} Ibid. at 470.

\textsuperscript{348} However, there might be a scenario where patents would be subject to consistent involuntary licensing. This situation may only occur if there is a consistent abuse of patent rights in a given territory.

\textsuperscript{349} See Article 31 of the TRIPS Agreement.

\textsuperscript{350} See, for example, Lily & Craven supra note 213. They criticize the decision of the US Supreme Court in eBay (supra note 211) and the decision of the US Federal Circuit in Kyocera Wireless Corp. v. International Trade Commission, [2008] 545 F.3d 1340 (Fed. Cir.). According to them, the decisions constitute an enforcement of patentees to accept a “compulsory-like-licenses as their only remedy for infringement”.

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claimed by the Pharmaceutical Research and Manufacturers of America’s (PhRMA) defendants.

In addition, it is very difficult to accept the notion that the incentive to innovate would be reduced when certain abuses of patent rights are established as CL grounds but not when other grounds are established. For example, CL to remedy anti-competitive practices (one of the most utilized mechanisms to force licensing of patented inventions in the US) is present in the legislation of most of the parties advancing the incentive-lessening claim against CL. If the objective is to provide the most incentives possible to a research-driven industry, then a stronger case can be made against making potential anti-competitive outcomes legal grounds for the authorization of CLs, as in the case of mergers. The reasoning is straightforward.

If establishing excessively high drug prices actually experienced in a given economy as a ground for CL would discourage innovation, then nothing should prevent CLs from generating such a “chilling effect” on innovation when they are granted based on a practice such as a merger between two patentees. The effect of the latter scenario is one that potentially would cause prices to increase, which is only a probable outcome in the future. Yet the latter scenario is widely recognized as a legitimate ground for CLs. In other words, the objective of granting CLs on such a ground is either to

351 Non-working, refusal to deal, and/or excessively high prices of patented drugs are some examples.
352 For example, there is no complaint against anti-competitive practices accusing them of reducing incentives to innovate when established as grounds of CLs.
353 The US, the members of the European Union, Japan, and Switzerland all may enforce compulsory licenses as a corrective measure if patentees engage in anti-competitive behaviors that involve patented inventions.
354 The expression “merger between two patentees” is used given, in the context of many antitrust cases involving intellectual property rights, particularly patents, consolidating parties are permitted to proceed with their merger on the condition that they license their relevant patents as an ex ante remedy for a potential market power. The number of so licensed patents may, in some cases, be in the hundreds. For examples of cases from the US Jurisdiction, see Scherer, Economic Effects, infra note 356; and Scherer, “Comment”, infra note 361; Scherer & Watal, infra note 358; and also see Chien, supra note 333.
355 Some have argued that setting high prices by right holders is a normal exercise of their exclusive rights. The essence of patent rights is to enable patentees to exclude others from the ability to compete with them in the “very market of [their] patented [products]”. It is argued, however, that this limitation on competition is mitigated by two things: 1) making the invention publicly available through disclosure in the patent application, which in turn serves as an input for further innovation; 2) combined, the disclosed information and the incentive to win a patent on a new development will serve competition by a dynamic effect contributing to the pool of competing products. See, for example, Jonathan B. Baker, “Beyond Schumpeter vs. Arrow: How Antitrust Fosters Innovation” (2007) 74 Antitrust Law Journal 575; also see Mark A. Lemley, “A New Balance Between IP and Antitrust” (2007) 3 Southwestern Journal of Law and Trade in the Americas 237. However, the innovation-lessening effect argument against CL is also applicable to the
preserve market competition or to prevent potential market power and dominance as a result of, say, a merger. In either case, it is hard to envisage an ultimate goal other than preventing the legal entity created by the merger from charging customer-patients monopolistic, high prices. Thus, the aim is to protect consumer interests by having access to goods with competitive prices and qualities. On the contrary, although it would be issued to address a reality where drug prices are prohibitive and beyond the reach of consumer-patients, legitimate CL has been opposed because of allegedly it lessening, or even diminishing, the incentives for R&D.

Empirical research and data call into question, or may technically negate, the claim that CLs would, in the long term, negatively impact the patent-provided incentives to undertake R&D, leading to less innovative output. The empirical skepticism refutes the critics’ claim even with respect to innovation in pharmaceuticals. Scherer examined whether US antitrust consent decrees (a settlement between two parties in the form of a court order) issued during the 1950s and 1960s had a measurable impact on the level and capability of licensors to innovate. His study concluded that despite their number, which exceeded 100 cases involving thousands of patents, these decrees had...
no measurable impact on innovation in pharmaceuticals or in the other fields of technology investigated by the study. In the context of understanding the relationship between the strength of national patent systems and the level of national innovation, Scherer cited evidence pointing out that during the period 1962-74 new medicines were more frequently launched in Britain ahead of their American release. This was the case despite the fact that there was CL of pharmaceuticals in Britain but not in the United States.

Even more compelling evidence comes from where CL has been used most: the United States. Scherer investigated the extent to which the grant of CLs affected expenditures on R&D by compelled licensors. In particular, he sought to explore whether such licenses destroy or diminish the incentive to commit investments by patentees in R&D activity. Scherer ran a statistical analysis on data related to seventy companies whose patents were subject to CLs. His analysis did not point to adverse effects on the companies’ R&D activities. On the contrary, relevant to other companies of comparable size, the R&D of the compulsory licensed companies experienced a significant increase.

As indicated by this last finding of Scherer, the long term effect of CL may indeed result in increased R&D activity and thus far more patenting activity. This positive effect is produced since CLs provide licensees with the necessary access to new technology, the chance for learning-by-doing, and the possibility of advancing accessed technology through further R&D. This technology-access role of CLs was recently tested in a study conducted by two scholars from Stanford University/Department of Economics. The
study sought to analyze the influence of the US Trading-with-the-Enemy Act (TWEA) on the rate of innovation of the American inventors in the chemicals industry, including pharmaceuticals. To do that, the authors examined the patenting activity in the United States Patents and Trademarks Office (USPTO) in the subclasses related to chemicals. They concluded that CL “has a strong and persistent positive effect on domestic invention”. In particular, the study found that in those subclasses “where at least one enemy-owned patent was licensed to a domestic firm under the TWEA, U.S. inventors produced an average of 0.3 additional patents per year after the TWEA (compared with subclasses that were not affected)”.

Furthermore, empirical data and evidence from Canada consolidate the above-mentioned findings. Subsequent to criticism and allegations from drug originators (mainly from the US) criticizing the Canadian CL scheme for negatively affecting the development of a Canadian innovative pharmaceutical industry, the Canadian Minister of Science and Technology formed a Royal Commission of Inquiry on the Pharmaceutical Industry – the so-called “Eastman Commission.” The Commission analyzed the effects of the country’s then CL system on innovation, which was considered one of the world’s most “vibrant” CL regimes (1923-1993).

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363 The Act was passed by the American Congress in November of 1917, 12 U.S.C. § 95(a). Section 10 of the Act legalized non-consensual use of patents taken by foreigners, provided that the patents “contributed to the war efforts”. Relaying on the authority provided in this section, the US Federal Trade Commission (FTC) granted licenses on patents owned by German nationals. In November of 1918, the Congress amended the TWEA Act authorizing the government to confiscate and sell patents and trademarks owned by German nationals. See Kathryn Steen, “Patents, Patriotism, and “Skilled in the Art” USA v. The Chemical Foundation, Inc., 1923-1926” (2001) 92(1) Isis 91 at 99.

364 See Moser & Voena, supra note 219 at 21 (emphasis mine).

365 Before 1987, the patent protection available in Canada for foods and medicines was only in the form of process patents. During the period 1923-1969, Section 41(3) of the Canadian Patent Act contained provisions providing for CL of patented processes used in the production of medicines. A license would be granted to authorize the use of the process concerned to manufacture the medicine in Canada. The Patent Act was amended in 1969. Section 41(4) of the Patent Act (R.S.C. 1970) and subsequently Section 39(4) of the 1987 Patent Act Amendment Act (R.S.C. 1985), provided for CLs for the use of a patented process for the manufacture the medicines concerned in, or to import them into, Canada.


367 See McFetridge, supra note 181 at 87-90.

368 See McFetridge, supra note 181 at 87-90.
In 1985, the Commission reported its detailed findings on the effects of applying the scheme with regard to the period 1969-1983. The Commission reported that 80% of all applications seeking compulsory authorization on pharmaceutical patents during the investigated period were approved leading, approximately, to an average of 20 licenses being granted annually. Ultimately, the Commission concluded the following. First, in 1983, the scheme reduced the cost of compulsorily licensed drugs by $211 million. Second, compulsory licensing was “an effective component of an appropriate patent policy for the pharmaceutical industry”. And third, which is the most relevant to the view advocated in the present chapter, the research-based Canadian pharmaceutical industry had not suffered adverse effects as a result of implementing the compulsory licensing scheme.

Furthermore, McFetridge reviewed the evolution, consolidation, and ultimately the abolition of the Canadian CL regime with the aim of evaluating the role of patent protection in influencing the level of R&D activity undertaken by the pharmaceutical industry. His analysis included CLs on the various grounds, which the Patent Act provided for prior to the 1993 reform. In particular, the following grounds were emphasized in his study: failure to work and the “preparation and [importation] of medicines”. Although he underlined the inability of the scheme to build a solid national pharmaceutical industry capable of innovating in new medicines and fine-chemicals, McFetridge recognized the regime’s contribution in establishing a national generic pharmaceuticals industry whose investment in R&D was on the rise.  

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369 Ibid.
370 See Reichman & Hasenzahl, Canadian Experience, supra note 190 at 38.
371 See McFetridge, supra note 181.
372 McFetridge cited leading generic-drug industrialists attesting to this outcome. For example, he stated the following:

[Apotex] argued that the government was terminating compulsory licensing just as the regime was about to bear fruit in the form of an innovative domestic drug industry. The scenario, according to Apotex, was that the profits derived from compulsory licences to import were used to finance entry into fine-chemical production and that the experience gained in that area was beginning to be applied to the development and manufacture of new drugs for domestic and foreign markets.

He also quoted Jack Kay, President of the Canadian Drug Manufacturers Association, testifying before the Senate Standing Committee on Banking, Trade and Commerce, stating that:

[it] is important not to lose track of the fact that, under compulsory licensing, what the government envisioned back in 1969 was that the generic industry would grow and mature from being copy-cats to being innovators. We are now at that stage where the two major companies, Novapharm and Apotex, are undertaking innovative research. We have new products which are under
McFetridge also found no negative impact of the scheme on the level of local R&D carried out by foreign firms then operating in the Canadian market.\textsuperscript{373} The increase in R&D expenditures that followed the 1987 Patent Act Amendment was “more likely part of the political bargain that eliminated compulsory licensing” but not as a direct result of that elimination. However, McFetridge anticipated the expenditures increase would “begin a slow decline”.\textsuperscript{374}

The available data on the impact of CLs and the non-patentability of pharmaceutical products on the establishment of an innovative drug industry in India \textit{contradict} the argument that CL schemes prevent the development of any innovative domestic industry. Lanjouw, in \textit{The Introduction of Pharmaceutical Product Patents in India: ‘Heartless Exploitation of the Poor and Suffering’?},\textsuperscript{375} provided data on the innovative activity of leading Indian pharmaceutical firms. The data reflect the firms’ activities during the early 1990s while the country was maintaining a patent law allowing \textit{CL of pharmaceutical process patents} (the only form of patents obtainable in India on pharmaceutical inventions until 2005). She reported stories of successful Indian firms, developed under a regime of lax patent protection, which also provided for CL. From these successes, the following examples are reproduced here. In 1991, Ranbaxy was successful in developing a new process to produce Cefaclor,\textsuperscript{376} a drug patented by Eli Lilly. Also, a research center devoted to work on the discovery of new chemical molecules was founded by the Reddy’s Research Foundation in 1992. Three years later, the institution filed its first two product patent applications in the United States for anti-cancer and anti-diabetes substances. And finally, as a Research Foundation with half of development for the treatment of cancer and AIDS but we require continued cash flow which was guaranteed to us under Bill C-22, which stated that there would be no negative change until 1996, to bring these products to fruition. [Citation omitted]

See McFetridge, supra note 181 at 86-7 and 99, footnote 27.

\textsuperscript{373} It was also the conclusion of the Eastman Commission that the CL of patented processes for the production in Canada, or importation therein, of drugs and fine-chemicals had not reduced foreign companies’ R&D activities in Canada. See Eastman, supra note 366.

\textsuperscript{374} Ibid. at 95.


\textsuperscript{376} Eli Lilly patented 56 different processes for the production of Cefaclor alongside a product patent which expired in 1992. Lanjouw quoted a Ranbaxy’s executive saying “56 processes were under patent (with Lilly) and we found the 57th”, ibid. at 28.
its research work devoted to the discovery of anti-cancer medications, Dabur filed four product patent applications: two in the UK and two in the US.377

In fact, the weak patent protection, partially attributable to maintain a CL scheme, prevailing in India before it implemented its obligations under the TRIPS Agreement, has been applauded for its positive impact on the Indian pharmaceutical sector generally and on the generics industry in particular.378 Sen studied the patterns of patenting during the period 1969-1985 to evaluate the impact of the 1970 Patents Law on India’s domestic inventive activity.379 He observed no negative effect on indigenous innovation since “the number of Indian [patent] applications remained steady over the period”380 to which the data relates.381

5.1.1. (a). Would Compulsory Licensing on Various Legitimate Grounds in Jordan Reduce Incentives to Innovate in New Pharmaceuticals?

Before addressing the question of whether or not having legal provisions to authorize the grant of CLs under various circumstances in the Jordanian Patents Law might reduce incentives for innovation, a brief review of the practice of resorting to CLs in Jordan prior to 1999 should provide some insight. Since the proclamation of its first patent legislation in 1953382 to the time of this writing, Jordan has never issued a single CL.383 This has been the case even though patent protection has been available for

377 Ibid. at 29.
378 See Biswajit Dhar and KM Gopakumar, *Post-2005 TRIPS Scenario in Patent Protection in the Pharmaceutical Sector: The Case of the Generic Pharmaceutical Industry in India* (Geneva, Ottawa: UNCTAD, IDRC and ICTSD, 2006) at 10 [Post-2005]. Dhar and Gopakumar, discussing the events and investigations (including parliamentary debates) that had led to the 1970 Patent Act of India, observed that the law is “considered as the basis for the development of a strong pharmaceutical industry in India”.
380 Ibid. at 144.
381 Contrary to the Conventional wisdom that strengthening patent protection induces inventive activity, which allegedly CL reduces (if considered as a sign of weakness of patent protection), Sen concurred with the findings of a Review Committee established by the Indian government that the 1970 Patents Act was passed to address some of the flaws of its predecessor, including “its failure to stimulate indigenous invention”, ibid. at 140 (emphasis mine).
383 Interview by the author with officials from the Jordanian Patents Office in Amman, Jordan on 30 July 2009.
pharmaceutical products and processes for the entire period except from 1986 until 1999, when only process patents were obtainable for pharmaceutical inventions. This reality requires more scrutiny as to why this case was so. This inquiry is prompted by two specific factors. First, the national pharmaceutical industry would have most needed CL of patented processes during that period, which was marked with rapid development of the industry. Second, the 1953 Patent Law contained broad and permissive grounds as bases to authorize CLs on patented inventions.

Three possible explanations may provide an answer to this phenomenon. First, because of the economy’s size, the modest technical capabilities of the local industry during the time period, the lack of product patents, and the cost of obtaining a patent registration, originators may simply have not bothered to patent their processes in Jordan. This explanation may have some merit based on the available statistical data on the patenting activity of both international and national inventors. From its inception through the beginning of 1997 (two years before the new Patents Law became effective), the Jordanian Patents Office had granted a total of 1,935 patents, including process and

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384 For details on the evolution of the pharmaceuticals industry, see Chapter Two.
385 The legitimate grounds of CL were regulated under Article 22. The article, titled “Compulsory Licenses and forfeiture”, reads:
1- anyone with interest may submit an application to the Patents Registrar indicating that the reasonable needs of the public in a patented invention are not being met, and accordingly requesting the grant of a compulsory license in or the forfeiture of the patent in question
5-for the purposes of this article, the reasonable needs of the public are particularly not met:
a- if any trade or industry or industrial or commercial enterprise is unfairly prejudiced or if demand for the patented invention or the product developed thereof is not reasonably met due to the patentee not manufacturing the patented article and offering it on reasonable terms.
b- if by reason of conditions imposed by the proprietor of the patent for the purchase of the patented article or on the grant of licences under the patent to use the article or the use of a patented process an industry or trade in the Kingdom is unfairly prejudiced.

387 See Chapter Two for details about the industrial capabilities of the local industry as it evolved over time.
388 See Amending Law No. 8 for the year 1986, which abolished, inter alia, pharmaceuticals product patents.
389 In addition to initial fees for registration, patentees would have to pay annual fees to maintain registration of their patents as well as fees paid to agents and attorneys.
product pharmaceutical patents.\textsuperscript{390} This figure increased during subsequent years: 2,486 patents were issued through 2008.\textsuperscript{391} Accordingly, even after the Patents Law was reformed in 1999, the number of patents granted by the Jordanian Patents Office has remained very small, relative to the number of patents granted globally.

The second potential interpretation, although not a realistic one, might lie with the local industry infringing on foreign-owned process patents. This option was not a sound choice for two reasons. First, patentees vigorously guard their proprietary assets in the pharmaceutical industry. Given patentees’ vigilance in guarding their rights, the absence of patent infringement cases challenging violations of their process patents would constitute evidence that no such infringements were taking place. In other words, if the national firms breached their rights (foreign and domestic patentees), there would have been cases brought in national courts, which did not happen.\textsuperscript{392} Second, the number of patents granted by the Patents Office in Jordan to foreigners was almost nil, which simply means that there were almost no patents to infringe or that the local industry managed to develop their own non-infringing processes.

A third and more likely explanation might rest in the triviality of the competitive threat posed by the local industry in both local\textsuperscript{393} and export markets during that time. This perception might be due to infancy in the local industry’s “copying” capabilities and

\textsuperscript{390} See WTO, \textit{Report}, supra note 16 at 55. According to this report, patents taken by foreigners were in various fields of technology, mainly in “pharmaceuticals, chemicals, solar energy, construction materials, machinery and mechanics, while patents issued to Jordanian nationals were mostly related to public safety, solar energy, electrical equipment, chemicals and mining”.

\textsuperscript{391} Of this number, 406 were granted during the period 2000-2008 after the enactment of the new Patents Law which restored pharmaceutical product patents. In addition, the figures include patents granted in all technological fields to both nationals and foreigners. Statistics available on the website of the Jordanian Ministry of Industry and Trade at: <http://www.mit.gov.jo/tabid/465/Statistics.aspx> (date last accessed October 15, 2010).

\textsuperscript{392} The only case, before 1999 and which the author is aware of, is a lawsuit initiated by Eli Lilly against a local generics manufacturer claiming that the latter had infringed on its patent. Unfortunately, the author was unable to examine the details of the case during the course of this research because the case file had been destroyed by the court system (after the lapse of 15 years counted from the date of the final judgement). In addition, when the author approached the national firm that was a party in the said case, he was informed that it had discarded the copy it used to maintain. (Interview by the author, 15 August 2009, Amman, Jordan).

\textsuperscript{393} 20 years later, the share of the local industry of the local drug market is still modest and in 2003 it was, according to WHO and Health Action International (HAI) document, only about 25%. See WHO/HAI Document No. WHO-EM/EDB/087/E, online: WHO, Regional Office for the Eastern Mediterranean <http://www.emro.who.int/dsaf/dsa786.pdf> (date accessed and downloaded: September 15, 2010, on file with the author); see also Bader, supra note 386.
activities. Hence, it could be that drug innovators tolerated violations of their patents.\textsuperscript{394} Such tolerance might, but not necessarily, be attributed to the fact that a number of the national manufacturers were, and some still are, agents representing several pharmaceutical MNCs in Jordan; thus, there would have been no interest on the representatives’ part to enforce breached patents. Nevertheless, the first explanation remains the most likely depiction of the situation given that the other two are mere speculations without evidence to support them. With this brief review in mind, we need to return to the potential negative impact on pharmaceutical innovation in Jordan that might be caused by establishing CL on the various kinds of grounds discussed earlier in this chapter.

In order to answer this question, we should have a firm comprehension of the nature and extent of indigenous innovative activity. In other words, assuming \textit{arguendo} that CL weakens innovation, is the innovative activity carried out by the Jordanian NIS\textsuperscript{395} at a stage of development and scale that is likely to suffer because of the enactment of legal provisions providing for CLs? Furthermore, would such a hypothetical cost outweigh the aggregate of several other potential benefits associated with providing for CLs in a small, upper middle income developing country setting?\textsuperscript{396} This last question is particularly relevant given the role of CL in transferring technology and increasing

\textsuperscript{394} This lack of enforcement, assuming it has existed, changed during the 1990s. As the national industry was establishing itself in the regional and, to a less extent, the international drug markets, the MNCs began to accuse the national industry of pirating its patents. In its 1999 Special 301 Submission, for example, PhRMA said:

A … survey of 17 multinational research-based companies shows that during a 36 month period, from January 1996-December 1998, Jordanian pirating companies have applied for or registered nearly 70 unauthorized copies of internationally patented pharmaceutical products. More than 50% of these pirated products are of American origin. The damage Jordanian pirate copies inflict on leading American products is enormous, estimated to be [although exaggerated] in the range of US$ 25,000,000 to 50,000,000 per year, especially in export markets in the Middle East and North Africa region.


\textsuperscript{395} For a discussion on the concept of National Innovation System, see Chapter Two.

\textsuperscript{396} These advantages may include: enhanced competition, more affordable prices, increased access to technology; they also may even encompass innovation.
innovation, as indicated earlier, in sectors such as pharmaceuticals in developing countries already suffering from a limited level of innovative activity.\textsuperscript{397}

As discussed in a different part of this thesis,\textsuperscript{398} the majority of R&D activities undertaken by most of the local drug companies had, prior to the current Patents Law, focused on process and dosage forms development.\textsuperscript{399} In light of the new legal environment, this type of activity has become inefficient from the standpoint of the industry since it does not contribute to their production portfolio, nor does it increase their exports to third markets.\textsuperscript{400} Therefore, the ability of the local industry to set up projects to develop their own innovative products will be significantly undermined if the industry abandons such activities, which in the past ensured them a constant cash flow used to finance the establishment and development of R&D units.\textsuperscript{401}

\textsuperscript{397} It is an established and uncontestable fact that most of the innovative activities in the pharmaceutical sector have been conducted, and will continue to be - at least in the foreseeable future, by the major pharmaceutical companies located in some of the world’s most advanced countries. See Commission on Intellectual Property Rights (IPR Commission), \textit{Integrating Intellectual Property Rights and Development Policy} (London: IPR Commission, 2002) at 15, online: IPR Commission<http://www.iprcommission.org/graphic/documents/final_report.htm> (date Accessed: October 20, 2010).

\textsuperscript{398} See Chapter Two for more details on the effects of patent protection on pharmaceutical innovation, with particular emphasis on the experience in the pharmaceutical sector in Jordan.

\textsuperscript{399} These kinds of activities were adopted by the companies for two reasons. First, since 1986 only process patents were available in Jordan for pharmaceuticals, but not the end product obtained through the process concerned. This incentivized the industry to legally develop its own processes or dosage forms to produce the same drugs. Second, the said activities were relatively associated with low cost, making it affordable given their limited resources. This situation changed following the enactment of the current Patents Law and its subsequent amendments in 2001 and 2007. Most persons interviewed by the author from the local pharmaceutical industry have stated that it is beyond their capacity to conduct advanced R&D with the potential of winning a patent. They simply say that such projects are out of their reach. In addition, when asked whether strengthening the Patents Law, including restricting compulsory licensing, had convinced them to change their strategies to focus efforts on, and increase resources allocated to, R&D activities in their budgets to develop new products or new uses of known products, most responded that they lack the required financial and trained human resources, and that their new strategy would be to continue producing generics.(Interviews by the author with several pharmaceutical companies in Jordan during the period July 12- September 9, 2009).

\textsuperscript{400} Ibid.

\textsuperscript{401} Commenting on the role of CL in securing a cash flow that was necessary for the development of the Canadian generic industry, Jack Kay - president of the Canadian Drug Manufacturers Association – testified before the Senate Standing Committee on Banking, Trade and Commerce (27:112; 20/1/93) that: [it] is important not to lose track of the fact that, under compulsory licensing, what the government envisaged back in 1999 was that the generic industry would grow and mature from being copycats to being innovators. We are now at that stage where the two major companies, Novapharm and Apotex, are undertaking innovative research. We have new products which are under development for the treatment of cancer and AIDS but we require continued cash flow which was guaranteed to us under Bill C-22, which stated that there would be no negative change until 1996, to bring these products to fruition.
The empirical data available on the robustness of patenting by locals (as indicated by the number of domestic patents\textsuperscript{402} obtained by Jordanian nationals or applicants who designated Jordan as their country of domicile) exhibit very limited inventive activity. During the period 2000–2008, only 10 patents were issued by the Jordanian Patents Office to applicants domiciled in Jordan.\textsuperscript{403} With limited innovative activity in the industry already, and based on evidence from the experiences of other countries that maintained CL regimes with no negative effects suffered, it might be reasonable and realistic to infer that providing for CLs on various grounds such as unreasonably high drug prices or refusal to deal - including also failure to work locally – is conducive to the public interest and would not prejudice the limited indigenous innovation.

However, one might argue that although the mentioned CL grounds would not impact innovation in Jordan given the state of its NIS, they would still dilute the R&D incentives provided by patents in other markets. This claim could have been true if Jordan would have been able to issue licenses pursuing industrial or trade policy objectives. Such a policy is no longer possible since it violates the obligations under Article 31(a) of the TRIPS Agreement that authorizing the non-voluntary use of patents “shall be considered on its individual merits”.\textsuperscript{404} In addition, due to the small size of the country’s economy, quantities produced under compulsory licenses would not be of a scale sufficient to have a measurable impact on the incentives to invent provided by local patents to foreign pharmaceutical developers. This would be the case despite the fact that

\textsuperscript{402} The phrase “domestic patents” is used to refer to patents issued by the Jordanian Patents Office, whether to Jordanian nationals or to foreigners.

\textsuperscript{403} Information was provided to the author by the Jordanian Patents Office via electronic message (email) following an interview with the Comptroller on August 24, 2009 in Amman, Jordan (on file with author). The Jordanian Patents Office only conducts a nominal examination of patent applications. Therefore, it would be fair to infer that relative to the number of patents issued by the national patent office, the number of patents granted to Jordanian nationals by foreign patent offices which are known for their rigorous search and examination would be much more less. For example, the patent office in Jordan has issued 10 patents to national applicants in 2008; however, the corresponding numbers issued by the US and EU patent offices for the same year are (0) and (5) respectively. For the data on the US patents, see U.S., Patent and Trademark Office (USPTO), Patent Counts by Country/State and Year: all Patents, all Types, January 1, 1977 -- December 31 (2008), online: US Patent and Trademark Office <http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cst_all.pdf> (date accessed and downloaded: March 27, 2010); and for the EU data, see EU, Patent Office, Annual Report (2008) at 76, online: European Patent Office <http://www.epo.org/about-us/publications/general-information/annual-reports/2008.html> (date accessed and downloaded: March 27, 2010).

\textsuperscript{404} See Article 31(a) of the TRIPS Agreement, supra note 4.
Article 31(f) of the TRIPS Agreement allows licensors to export part of their production, since quantities manufactured under a CL “shall be authorized predominantly for the supply of the domestic market”.\(^{405}\)

Having seen that establishing CLs in national legislation does not reduce the patent-provided incentives to invent, but might have a positive effect on innovation, I next explore the second claim against CL. Critics of CL claim that MNCs are deterred from investing in an economy adopting a legal policy permissive of involuntary use of patented inventions on grounds other than those mentioned under the TRIPS Agreement. Therefore, we need to determine whether CLs (as qualified by the complex set of conditions, limitations, and procedures under the TRIPS Agreement) are a factor of substantial weight that might prevent a company from directly investing in Jordan.

5.1.2. Compulsory Licensing might Compromise Chances of Attracting Foreign Direct Investment in the Pharmaceuticals Sector

The second assertion skeptics make against CL is that strong IP protection is necessary for developing countries to attract foreign investment since foreign firms are hesitant to invest in a given country if they are not confident of the protection level of their IP and investment. CL, as an “indication of weak protection” of proprietary rights, undermines such confidence; thus, it compromises the prospects of attracting FDI.\(^{406}\)

Opponents claim that in addition to CLs being a deterrent to future FDI, they also have a negative effect on current foreign investments.\(^{407}\) That is, pharmaceutical corporations which are obligated to license their patents or whose patented products are imported by third parties without their consent might, to borrow from Reichman, “vote with their feet”.\(^{408}\) They may react in one of the following ways. They might reconsider their plans, if any, to invest in the country concerned; they might refrain from introducing

\(^{405}\) Ibid. Article 31 (f).


\(^{407}\) See Lybecker & Elisabeth, supra note 339.

\(^{408}\) See Reichman, “Evaluating the Options”, supra note 147 at 256.
their future innovative products therein; or they might, as was the case in Thailand, cease investment entirely. Before evaluating what potential effects these scenarios might have in the context of the Jordanian pharmaceutical sector and in light of the legal rules governing CLs, an account of the interplay between the levels of protection afforded IPRs (including patents) under a given system and the rate of FDI inflows would assist in determining whether the same consequences may necessarily follow in Jordan.

The argument that developing countries should maintain strong IP protection to attract FDI has been questioned by recent empirical investigations. Studies by recognized economists including Carlos Primo Braga and Carsten Fink, Keith Maskus, and others have demonstrated that enhancing the protection of IPRs is less likely to result in attracting FDI if two factors are missing. First, it is necessary that a would-be recipient country of FDI has strong imitation capabilities to copy foreign innovative products and technologies. Without possession of such a capacity to copy, local competitors would be

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409 In 2007, Abbott Laboratories announced its withdrawal of registration applications for 7 of its new products (Brufen, Abbotic, Clivarine, Humura, Tarka, Zemplar, and Aluvia). That action was in retaliation against a grant of the compulsory license on its drug “Kaletra: an antiretroviral drug used on HIV/AIDS patients) by the government of Thailand. The company further threatened that it might hold its operations in the Thailand market. See Baker Brook, A New Low in the Pharma Drug Wars - Abbott Withdraws Seven Medicines in Thailand, of March 14, 2007, online: CPTech, IP Disputes in Medicine (date accessed: September 20, 2010). However, on March 16, 2007, Christian Brothers Investment Services, Inc. (CBIS) and 13 other faith-based institutional investors with approximately $35 million in Abbott Laboratories holdings responded to the company’s decision to withdraw the new drug applications from Thailand requesting that Abbott immediately reverse its decision. A joint statement issued by (CBIS) and the other 13 investors in part stated that “...To our knowledge, no pharmaceutical company has before withdrawn AIDS drugs in response to a pricing or licensing dispute. By keeping life-saving medicines like Kaletra off the shelves in Thailand, Abbott Labs is threatening the health of Thais who need access to these drugs...We are concerned that Abbott’s actions...have the potential to damage its reputation and impact the bottom-line” see Christian Brothers Investment Services, Inc. (CBIS), CBIS and ICCR Urge Abbott Labs to Keep HIV/AIDS Drug on the Shelf in Thailand, Press Release, online: CBIS Homepage (date accessed: September 20, 2010); also see Program on Information Justice and Intellectual Property, American University Washington College of Law, Timeline for Thailand’s Compulsory Licenses, Version 2, March 2008, online: Program on Information Justice and Intellectual Property Homepage (date accessed: August 15, 2010).

410 See Bird, supra note 339 at 211-13.


412 Maskus, supra note 247 at 130-131.

of a very minimal threat to the market interests of foreign corporations. Since the very objective of IP protection is to exclude those who are able to copy the protected subject matter from doing so, such protection becomes unnecessary when it is highly unlikely that copying would not occur. The pharmaceutical sector meets this condition partially as the local manufacturers have a qualified imitation capacity.

Second, it is necessary that the economy concerned represents a large market, which would provide foreign companies with the opportunity to realize economies of scale. The Jordanian pharmaceutical market is small, making it unattractive for foreign companies to invest directly in it. As explained in another part of this thesis, the strong protection provided to pharmaceuticals in Jordan prior to 1986 had not induced foreign firms to invest in the country. The same account holds true for the situation today. It has been almost 12 years since Jordan passed its patent law where the restriction on the issuance of CLs may fairly be considered among the most stringent globally, yet FDI in the pharmaceuticals sector is entirely absent.

5.1.3. Compulsory Licensees are Likely to “Shadow Price” Patentees in Pursuit of Profits, Creating a Deadweight Loss of Their Own

Skeptics of the CL of pharmaceuticals warn that it may not achieve the goal for which the system of CL was created: making life-saving medicines more accessible to destitute patients. They claim that drugs produced under CLs are not necessarily going to sell at lower prices compared to their branded, patented equivalents. Manufacturers producing under CLs are likely to “shadow price” the patentees’ drugs (the case when manufacturers of generics price their products just below the price of the original branded

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414 See Yu, Ibid. at 177.
415 See Heald, supra note 413 at 266.
416 See Chapter Two for analysis on the impact of patent protection on FDI.
417 The phrase “shadow price” was used by Reichman; see Reichman, “Comment”, supra note 408 at 253.
418 See Bird, supra note 339; Lybecker & Elisabeth, supra note 406; Edelman, infra note 426; Lippert, supra note 406; and see Rapp & Rainey, “Broad-Based”, supra note 226.
products); and licensees will price their products accordingly in pursuit of profit, which in turn creates a deadweight loss of its own.\textsuperscript{420}

In such a case, it is argued, CL becomes a tool for the transfer of wealth from the patentee to the compulsory licensee.\textsuperscript{421} It was further claimed that if the patentee, after using its patent without consent, decides to pull out of the license-issuing market, the licensee would no longer have an incentive to keep the old lower price and would modify its behavior, thus raising prices to those levels that were prevailing before the grant of the license. In addition, often it is not a local generics manufacturer who would be profiting from the license, but a foreign manufacturer.\textsuperscript{422}

Situations that might give rise to the grant of a compulsory license are various and multiple. It follows, therefore, that this claim is based on a generalized theme that CLs are issued to address high drug prices, which may not apply to other situations redressable through CLs. The claim is also based on several assumptions. At best, these assumptions, or at least some of them, may materialize in one country, but not necessarily in others. For example, this line of argument implicitly assumes that access to medicines is only impaired by high prices: that is not always the case. Before governments intervene and issue CLs to address high drug prices, it is assumed that the drugs in question are available therein. However, patients’ access to patented medicines might be impeded because the medicines are not available at all or the available quantities do not meet the reasonable needs of the market. In such a case, the first consideration by the grant of CLs is to make drugs available to those who need them. Of course drug prices are a concern, but here primacy is given to their availability.

\textsuperscript{419} See Reichman, “Comment”, supra note 408 at 253.
\textsuperscript{420} “Deadweight loss” refers to the loss that occurs when consumers who would buy a product cannot afford to do so because of the difference between the actual price charged and the marginal cost of the product.
\textsuperscript{421} In their article, Lybecker and Elisabeth alluded to this claim, stating that: [it] is worth noting that the Government Pharmaceutical Organization is not run as a non-profit entity, but rather as an increasingly profitable enterprise. In fact, the GPO hopes to double its 2005 revenue (10 billion baht) by 2010. Furthermore, Thai government officials would like to see the GPO compete with India's generic industry and become a "regional hub for the manufacture and export of copy medicines. [Citations omitted].

See Lybecker & Elisabeth, supra note 406 at 228-9.
\textsuperscript{422} Professor Bird cited an example of a “pirated Viagra” drug sold on the Argentinian market where the drug was manufactured in India, but not by an Argentinian manufacturer. See Bird, supra note 339 at 214.
As to the problem that licensees may set their prices just below those of the patentee, it may only occur exceptionally and for the following possible reasons. First, the pricing problem argument assumes that medicine prices are not regulated in the market concerned, which is not the case in the majority of developing as well as developed countries. Second, even if the prices of drugs are not regulated, it assumes that the patentee does not respond to its market share loss as a result of competition from the licensee: lowering its prices to gain back some of the decreasing revenue and share, unless the right holder decides to withdraw from the market altogether.

Third, as long as they are issued to address high prices, granting CLs is definitely not a determinative end, in and of itself. This should be true whether the recipient of the license is a local or a foreign manufacturer. Rather, CL is a means through which governments seek to bring drug prices down to levels that are affordable to their citizens, which, experience shows, may be attainable by the mere threat of and without the need to issue a license. In this case, prices would be reduced to levels acceptable for both the government and the right holder concerned and without having to deal with the scenario of a third person (licensee). The same outcome would be accomplished when a threat to issue a license is in response to a refusal by the right holder to deal, a practice that may

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423 Following threats from the Brazilian government to issue licenses for their patents on HIV/AIDS drugs, several MNCs offered up to a 40 per cent discount on the original prices. Bayer Inc., significantly lowered its price of Ciprofloxacin (Cipro) in 2001 following a threat by the United States government of a compulsory license on the Corporation’s patent, the US intended to stockpile the medicine as a defense against the then expected anthrax attacks. See Love, Recent Examples, supra note 212 at 3. Furthermore, Reichman cited several cases of major pharmaceutical patentees reaching agreements with host countries following a threat to issue a compulsory license by the latter. These examples included compulsory licensing procedures initiated by:


See Reichman, “Comment”, supra note 408 at 250.

424 However, sometimes the level of discounts offered by right holders might not meet the demands of the patent-issuing country that initiated procedures to issue a compulsory license, or that the discount is delayed until after the issuance of the license. For example, after the government of Thailand issued a compulsory license, for a government noncommercial use, on Merck’s drug Efavirenz, the company offered a substantial price cut. Despite this price cut, Merck’s new price was still about 20 per cent higher than the price of the Indian generic equivalent. See Abbott & Reichman, supra note 122 at 953.
be considered by many WTO members to constitute an anti-competitive behavior, liable to be disciplined by CL.425

Finally, the “price shadowing” claim is entirely hypothetical. The only example mentioned by Professor Bird as a practical illustration of the problem is a reference to pricing practices by pharmaceutical firms in Argentina. The products involved in the Argentinean example, however, were not generic medicines produced under CLs. They were “pirated” copies, according to the reference426 cited in Bird’s article. And the section of the cited reference, in which the issue of price shadowing was mentioned, is titled “Pharmaceutical Piracy Hurts Argentine Consumers”.427 Thus, there is no single example brought forward to make the case against CLs not leading to reduced prices.

With regard to Jordan, compulsory licensees simply cannot engage in “price shadow” since the prices of all medicines are regulated by the Jordan Food and Drug

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425 In 2004 and after a request from Cosmos Limited (Kenyan based pharmaceutical manufacturer) for authorization to produce Zidovudine, Lamivudine and Combivir, products of Boehringer Ingelheim (Germany) and Glaxo SmithKline for sale under compulsory licensing in the EAC region, the government of Kenya was about to issue compulsory licenses on the said products. Having realized the intention of the government of Kenya to grant the license, Boehringer hastened to conclude a voluntary license deal with Cosmos Limited to produce generic versions of its patented drug Nevirapine. See Brenda Pamela Mey, “Unfettered Consumer Access to Affordable Therapies in the Post-TRIPS Era: A Dead-End Journey for Patients? Kenya and India Case Studies” (2010) 13(3) Journal of World Intellectual Property 403 at 421-22. In addition, in 2003 and following a complaint filed by a civil society coalition, the Competition Commission in South Africa found two multinational pharmaceutical companies (GlaxoSmithKline and Boehringer Ingelheim) in breach of the Competition Law. The commission found that the two firms have abused their dominant market positions in their patented ARVs (zidovudine, lamivudine, and nevirpaine) since they had engaged in excessive pricing and also had denied competitors access to “essential facility” by refusing to license their patented ARVs. The Commission referred the case to the Competition Tribunal recommending the issuance of CLs on the drugs in question as well as punitive measures. Before the case was heard by the Competition Tribunal, both firms agreed to grant voluntary licenses. Furthermore, in 2007, South Africa’s Treatment Action Campaign (TAC) filed a complaint against a different pharmaceutical firm: Merck Sharp & Dohme (MSD), which has a patent on ARV efavirenz. TAC complained that MSD refused to license its patent on reasonable terms. MSD agreed to grant multiple licenses on its patent, and the case was not referred to Competition Tribunal. See, respectively, Tenu Avafia, Jonathan Berger & Trudi Hartzenberg, The Ability of Select Sub-Saharan African Countries to Utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries (Stellenbosch: Trade Law Center for South Africa (TRALAC), 2006) Working Paper No. 12, online: irps online <http://www.ipronline.org/unctadictsd/docs/Trade%20and%20Competition%20%203%20%206%20%20%20%20final%20Edited%202%202%202%20.pdf> (date accessed: June 15, 2011); and Treatment Action Campaign, TAC Complaint Increases Access to Efavirenz: MSD Finally Agrees to Grant Licenses on Reasonable Terms (2008), online: TAC website <http://www.tac.org.za/community/node/2329> (date accessed: June 15, 2011).


427 Ibid.
Administration (JFDA). The pricing system mandates that generics be priced at 20% less than their branded equivalents, which applies to products manufactured under CLs since such products are considered generics. This rule applies to compulsorily licensed products, whether locally manufactured or imported from a foreign source.\footnote{See JFDA, The Criteria and Standards Related to Drugs Pricing, Repricing and Objections to Pricing Decisions (adopted by JFDA on May 21, 2002), online: JFDA website <http://www.jfda.jo/custom/en/departments/2.doc> (date accessed: April 15, 2011). Article 5 of the Criteria stipulates that: [the] price of a generic drug to the Jordanian Public is determined as a result of applying any of the following mechanisms whichever is less: 
1. The price computed from applying Article (2).
2. The price computed from applying Article (3).
3. The export price to the Saudi Market, and if it is not registered there, its pricing shall be reviewed upon its registration and the agent is committed to provide the Administration with the price within a period not exceeding four months. Provided that the requested price does not exceed 80\% of the price of the originator drug when first registered and priced or upon re-pricing it by virtue of Article (16) or 80\% of it’s current price whichever is less (emphasis mine).}

Accordingly, this hypothetical social cost, as a shortcoming of CLs, would be entirely irrelevant had Jordan decided to adopt a compulsory licensing-oriented policy.

5.1.4. Countries Adopting Compulsory Licensing Policy Run the Risk of Compromising Their Economy Due to Potential Retaliation from Pharmaceutical Patentees’ Government

Developing countries consented to onerous obligations under the TRIPS Agreement, in part, to put down unilateral trade retaliatory actions,\footnote{See Carlos M. Correa, “Implementing TRIPS in Developing Countries” (1998) 189 Third World Economics 16-31.; also available online: Third World Network Homepage <http://www.twinside.org.sg/title/ment-cn.htm> (date accessed: August 4, 2010) [Implementing TRIPS].} which developed countries (the US, in particular) frequently used against them. However, it has been argued that the developing countries today still run the risk of such retaliation if they make use of their legal right under the Agreement to grant CLs. It is further maintained that retaliation may occur even if licenses are granted to protect public health.\footnote{See Edelman, supra note 426; Bird, supra note 339; and Lybecker & Elisabeth, supra note 418.} The potential of this risk is feared despite the unambiguous right of developing countries to recourse to CLs under the Agreement,\footnote{See Articles 31, 8, and 1.1 of the TRIPS Agreement, supra note 4.} which the Doha Declaration strongly confirmed.\footnote{See paragraph 4 of the Doha Declaration, supra note 80.} It is feared although the act of unauthorized unilateral retaliation violates
the Framework Agreement of the WTO\textsuperscript{433} and Article 23 of the Rules on Dispute Settlement Understanding.\textsuperscript{434}

Recent incidents confirm that this concern over retaliation is well founded legitimate, and - often times – retaliation is imminent. Two very recent examples speak for themselves. They are examples of developing countries using their legitimate rights to

\footnotesize{433} Paragraphs 1 & 2 of the Marrakesh Agreement Establishing the WTO reads:
1. The WTO shall provide the common institutional framework for the conduct of trade relations among its Members in matters related to the agreements and associated legal instruments included in the Annexes to this Agreement.
2. The agreements and associated legal instruments included in Annexes 1, 2 and 3 (hereinafter referred to as "Multilateral Trade Agreements") are integral parts of this Agreement, [which, of course, encompass DSU] \textit{binding on all Members} (emphasis mine).

See Marrakesh Agreement Establishing the World Trade Organization, April 15, 1994, 1867 UNTS 154; 33 ILM 1144 (1994) at art. II (2), online: \texttt{WTO Homepage <http://www.wto.org/english/docs_e/legal_e/legal_e.htm>} (date accessed: August 4, 2010). In addition, the WTO Panel in Sections 301-310 of the Trade Act of 1974 commented that:

[on this reading, the very discretion granted under Section 304, which under the US argument absolves the legislation, is what, in our eyes, creates the presumptive violation. The statutory language which gives the USTR this discretion on its face precludes the US from abiding by its obligations under the WTO. In each and every case when a determination is made whilst DSU proceedings are not yet exhausted, Members locked in a dispute with the US will be subject to a mandatory determination by the USTR under a statute which explicitly puts them in that very danger which Article 23 was intended to remove.]


\footnotesize{434} Article 23.1 reads:

[when] Members seek the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, and abide by, the rules and procedures of this Understanding.

Paragraph 2 further reads:

[in] such cases, Members shall:

(a) not make a determination to the effect that a violation has occurred, that benefits have been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement in accordance with the rules and procedures of this Understanding, and shall make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under this Understanding;

(b) follow the procedures set forth in Article 21 to determine the reasonable period of time for the Member concerned to implement the recommendations and rulings; and

(c) follow the procedures set forth in Article 22 to determine the level of suspension of concessions or other obligations and obtain DSB authorization in accordance with those procedures before suspending concessions or other obligations under the covered agreements in response to the failure of the Member concerned to implement the recommendations and rulings within that reasonable period of time.

See Annex 2 of The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts-Understanding on Rules and Procedures Governing the Settlement of Disputes [hereinafter: DSU].
issue CLs to provide their devastated population with needed treatments that, due to patent protection, were unaffordable. The first incident concerns Thailand. Thailand issued several CLs on drugs related to HIV/AIDS, cardiovascular treatment, and cancer during the period 2006-2007. The second example relates to the use of compulsory licensing on pharmaceutical patents by Brazil. In April 2007, after protracted negotiations with Merck (patentee), the Brazilian Minister of Health signed Decree No. 866, which declared a CL on Efavirenz for non-commercial, public interest purposes. The issuance of the license for Merck’s Efavirenz was subsequently officially announced by the Brazilian President Luiz Inácio Lula Da Silva on Brazilian national television.

Although Brazil has often been placed either on the “Special 301” report Watch or on the Priority Watch lists since 2000, Thailand was elevated to and placed under the 2007 “Special 301 Priority Watch List” in March of 2007. Furthermore, both


436 A compulsory license on Sanofi-Aventis’s drug Plavix (generic: Clopidogrel, a drug for the treatment of heart diseases) was issued by the government of Thailand on January 25, 2007. See Lybecker & Elisabeth, supra note 418 at 233.

437 Thailand health authorities announced compulsory licenses on four cancer drugs. The licensed drugs were Letrozole (a drug for the treatment of breast cancer), Docetaxel (used for breast and lung cancer), Imatinib (myeloid leukemia) and Erlotinib (used on patents with lung cancer). See The Nation (Thailand), Four More Marked for Talks (September 24, 2007), online: The Nation Homepage <http://nationmultimedia.com/2007/09/24/national/national_30049990.php> (date accessed: August 15, 2010).


439 Ibid.

440 In May 1, 2003, the US Trade Representative elevated Brazil, along with 10 other countries, to the Priority Watch List of its “Special 301” Report.

441 The first time after the conclusion of the Uruguay Round Brazil was ranked a Watch List country by the US Trade Representative was on May 1, 2000. See United States Trade Representative, Special 301 Report (2000) USTR Reports and Publications, Watch List, at 7, online: USTR Homepage <http://hongkong.usconsulate.gov/uploads/images/J6EH6KGM-c0kwdU0CSnXhA/usinfo_301_00-special.pdf> (date accessed: August 5, 2010).

442 Following a brief statement regarding intellectual property-related concerns about Thailand’s regime of intellectual property, the report stated the following on the issue of compulsory licenses:
countries’ exemptions from import tariffs offered under the Generalised System of Preferences (GSP) were removed by the American government on June 4, 2007. Despite denial by the USTR,\(^{443}\) apparently, as has been concluded by many, the removal of the tariff exemptions was in retaliation for these countries’ issuances of CLs on patented pharmaceuticals owned by American corporations.\(^{444}\)

Notwithstanding the reality that developed countries may commit acts similar to those of the US, developing countries, including Jordan, ought not to be intimidated by such conducts. They should stand their ground in defending their right to authorize CLs whenever it is in their interest. Several reasons support taking this path. First, as mentioned before, even if the issuance of a CL by a developing country may violate the TRIPS Agreement and may thus nullify or impair benefits provided by the Agreement\(^{445}\) (which should not be the case given the wording of Article 31 and the Doha Declaration), the retaliating member would be in violation of Article 23 of the WTO Dispute Settlement Understanding if it acts without authorization from the appropriate WTO bodies. This article stipulates that when WTO member countries seek “redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, and abide by, the rules and procedures of this

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\(^{443}\) The USTR was cited to have had claimed that the removal of the tariff exemptions of Brazil and Thailand is not retaliation for decisions of these countries to grant compulsory licenses on leading pharmaceutical products. Rather, the removal “follows reforms to the GSP system approved by Congress in December 2006 which placed a cap on each type of merchandise imported from any one country at US$185 million, or 75% of total U.S. import demand for that product.” See Ben Shankland, \textit{U.S. Retaliates After Thai, Brazilian Decisions on Pharmaceutical IP} (World Markets Research Centre: Global Insight, July 4, 2007).

\(^{444}\) See Bird, supra note 339; Lybecker, supra note 418; Reichman, supra note 423 at 258; and also see Abbott & Reichman, supra note 424 at 953-4.

\(^{445}\) See Article 64 of the TRIPS Agreement, supra note 4.
Understanding.” These rules and procedures require that complaints of such a violation must be brought before specified multilateral venues: WTO panels and appellate body.

Second, this kind of retaliatory action (placing countries on the Watch Lists of the “Special 301” Report) was subject to a WTO panel decision. In particular, the decision in United States - Sections 301-310 of the Trade Act of 1974 criticized the USTR for its past uses of Section 301 listing of countries for matters related to the TRIPS Agreement. In addition, the decision explicitly warned that sanctions would likely be authorized against such uses if they continue in the future. Therefore, it is the retaliating country that would most likely be found in violation of the WTO law, not the member granting the license. However, given that unilateral retaliation is a violation of the DSU rules and procedures and the Framework Agreement establishing the WTO, the victim country would be “entitled to self-help implicit in the power of an aggrieved party to suspend its obligations under the treaty in question, pending compensation for breach.”

Third, since the incidents of Brazil and Thailand, two important and related developments have occurred. On the 12th of July 2007 and at the conclusion of its debates on the issue of ratifying the amendment to the TRIPS Agreement, the EU Parliament adopted resolution No. P6_TA (2007)0353. While the resolution reflects the Parliament’s view that “the EU should expressly endorse full implementation in the developing countries of the flexibilities in the TRIPS Agreement as recognized in the Doha Declaration ‘to promote access to medicines for all’”, with the controversy surrounding the Thailand licenses “very much in mind”, the Parliament further “encourages the developing countries to use all means available to them under the TRIPS

446 See the text of Article 23.1, supra note 434.
448 Ibid. Reichman, supra note 423 at 259; and see Abbott & Reichman, supra note 424 at 954.
449 Ibid. Reichman.
450 Ibid.
452 Ibid. Paragraph I.
453 See Abbott & Reichman, supra note 424 at 955.
Agreement, such as compulsory licences and the mechanism provided by Article 30 thereof”. \footnote{454}

In May of 2007, an agreement was concluded between the USTR and the Congressional Leadership (Bipartisan Agreement on Trade Policy) aimed “at further ensuring that developing country free trade agreement partners are able to achieve an appropriate balance between fostering innovation in and promoting access to life-saving medicines.”\footnote{455} The Bipartisan Agreement required that the chapter on IP Protection of future FTA Agreements contains a “recognition that nothing in the chapter affects the ability of our FTA partners to take necessary measures to protect public health by promoting access to medicines for all, and a statement affirming mutual commitment to the 2001 Doha Declaration on the TRIPS Agreement and Public Health”.\footnote{456} This, of course, includes the freedom to establish grounds for and the issuance of CLs to make necessary medications more available and affordable in FTA developing partners such as Jordan.\footnote{457}

The fact that Jordan concluded an FTA agreement with the US does not affect the illegality of unilateral retaliation against the former by the latter. The USJFTA\footnote{458} contains a special mechanism for the settlement of disputes between the parties. Article 17(a) of the USJFTA mandates that the parties shall make every attempt to arrive at a mutually agreeable resolution through consultations, whenever:

(i) a dispute arises concerning the interpretation of this Agreement;
(ii) a Party considers that the other Party has failed to carry out its obligations under this Agreement; or
(iii) a Party considers that measures taken by the other Party severely distort the balance of trade benefits accorded by this Agreement, or substantially undermine fundamental objectives of this Agreement.\footnote{459}

\footnote{454} See supra not 451 at Paragraph 9 (emphasis mine).


\footnote{456} Ibid.

\footnote{457} Paragraph 5 (b) of the Doha Declaration on the TRIPS Agreement and Public Health reads: “[each] member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.” See the Doha Declaration, supra note 80 para. 5.

\footnote{458} See the USJFTA, supra note 17.

\footnote{459} Ibid. Article 17 (a).
If no resolution is reached through consultation, the matter shall be referred to a Joint Committee.\textsuperscript{460} Then, failing agreement, the disputed matter may be referred to a dispute settlement panel by either party.\textsuperscript{461} Therefore, unilateral retaliation by the US against Jordan may cross the line of legality not only under the WTO rules, but also under the provisions of the USJFTA.

In summary, besides being illegal, unilateral retaliation against developing countries using their legitimate right in instituting certain CL grounds and/or granting such licenses on patented pharmaceuticals has become a very difficult strategy to pursue. This outcome may, in part, be attributed to several developments, including the following. First, the EU Parliament Resolution and the Bipartisan Agreement referred to earlier. Second, countries such as France\textsuperscript{462} and Belgium\textsuperscript{463} have recently adopted legal measures expanding their powers to institute possible circumstances, based on which CLs may be issued on pharmaceutical patents for public health reasons. These new measures were not instituted based on Article 31 of the TRIPS Agreement. Rather, Belgium officials cited Articles 30, 28, and 8 of the Agreement as the legal basis for their right to establish the new measures.\textsuperscript{464} And third, since the adoption of the TRIPS Agreement, particularly after the Doha Declaration, many developing countries as well as developed

\textsuperscript{460} Ibid. Paragraph (b).
\textsuperscript{461} Ibid. Paragraph (c).
\textsuperscript{462} Article L. 613-16. of the Law No. 92-597 of July 1, 1992, on the Intellectual Property Code, as amended by Law No. 96-1106 of December 18, 1996, reads:

\begin{quote}
[where] the interests of public health demand, patents granted for medicines or for processes for obtaining medicines, for products necessary in obtaining such medicines or for processes for manufacturing such products may be subject to \textit{ex officio} licenses in accordance with Article L. 613-17 in the event of such medicines being made available to the public in insufficient quantity or quality or at abnormally high prices, by order of the Minister responsible for industrial property, at the request of the Minister responsible for health.
\end{quote}

An English translation of the quoted article is available on line, Consumer Project on Technology Homepage <http://www.cptech.org/ip/health/cl/france1.html> (date accessed: August 15, 2010).
\textsuperscript{464} Ibid.
countries have either threatened to issue CLs or granted them to enhance access to medicines for all.\textsuperscript{465}

6. Concluding remarks

Restricting the grounds of CLs in the Jordanian Patents Law to those specified in the TRIPS Agreement falls far short of utilizing the full range of grounds available under both the TRIPS and USJFTA agreements. The law favours patentees over the public interest in making medicines available for and affordable by all.

CL based on the ground of non-working is important to economic development in Jordan. It contributes to local working of patented inventions, it facilitates transferring foreign technology, it encourages the conclusion of voluntary licenses, and it promotes access to medicines. However, in light of the non-discrimination clause of Article 27.1, accomplishing these objectives by adopting this ground is subject to some ambiguity in the TRIPS Agreement. In addition, Article 4(20)(c) of the USJFTA stipulates that importation should constitute working, which is the anti-thesis of the local working requirement.

Nevertheless, the same objectives may be realized, but based on a different ground; specifically, granting CLs based on circumstances or situations considered to represent the public interest in Jordan. A refusal to deal and high prices of medicines are two important examples, each of which is legitimate to establish under the TRIPS and USJFTA agreements. This is an appropriate alternative for Jordan. This study concluded that this path is available to Jordan under the TRIPS Agreement, but would contradict the

\textsuperscript{465} The following quote from Reichman, citing several examples, reflects the expansive trend of countries resorting to compulsory licensing.

Beneath the surface, however, health ministries in a number of countries had quietly begun to use the threat of compulsory licenses to rein in the prices of selected medicines, particularly AIDS drugs. [footnote omitted] Because negotiated deals under threat of compulsory license are often kept secret, the surface calm appeared greater than it really was. Beginning in 2006, this calm was shattered by the sudden appearance of compulsory licenses on pharmaceuticals — or public threats thereof — in both the southern and northern hemispheres.

See Reichman, “Comment”, supra note 423 at 249-50. For more examples on countries resorting to compulsory licensing, see Love, \textit{Recent Examples}, supra note 212.
provisions of the USJFTA if implemented as a statutory provision. However, Jordan can meet its obligations under the USJFTA by amending its law to allow courts the discretion to deny a prevailing patentee injunctive relief on the terms they deem reasonable. Such discretion should be exercised whenever the issuance of an injunction might disserve the public interest. Finally, the grounds of refusal to deal and high drug prices can also be instituted as anti-competitive behaviors, redressable by CLs.

If Jordan had adopted a policy permissive of establishing a broader range of CL grounds, the multiple socio-economic costs claimed by opponents of CL would not have occurred. First, the grant of CLs does not compromise incentives provided by patent protection to pharmaceutical innovators since the TRIPS Agreement outlaws all forms of systematic CL. In addition, empirical studies and experiences in other countries that maintained CL regimes technically negate the claim that CLs would negatively impact such incentives. As to the particular case of Jordan, indigenous innovation in the pharmaceutical sector is limited; thus it is unlikely that CL causes negative effects. Second, resorting to CLs would not frustrate FDI in Jordan. The reformed Patents Law has been in force for almost 12 years. The restrictions on the issuance of CLs imposed by this law may fairly be considered among the most stringent globally, yet FDI in the pharmaceutical sector is entirely absent. Therefore, from a policy perspective, the FDI situation in Jordan cannot become any worse.

Third, as to the risk of compromising the national economy due to potential retaliation from governments of countries in which pharmaceutical patentees are based, it is important to emphasize that unauthorized unilateral retaliation is illegal under both the WTO Agreement and the USJFTA. Moreover, it has recently become a very difficult strategy to pursue. The right of developing countries to utilize all flexibilities available under the TRIPS Agreement has been supported by institutions such as the EU Parliament and the Bipartisan Agreement on Trade Policy between the USTR and the Congressional Leadership. In addition, developed countries such as France and Belgium have adopted legal measures expanding their powers to define possible circumstances for issuing CLs on pharmaceutical patents for public health reasons. And finally, many developing and developed countries have either threatened to issue or have granted CLs
to enhance access to medicines for all since the adoption of the TRIPS Agreement, particularly after the Doha Declaration.

Although CL and parallel importation may lead to the production and/or importation of more affordable medicines, access to medicines acquired by these means, and many off-patent drugs, may be frustrated if such products are not registered with the national health regulator and issued a marketing authorization. Registration, however, may necessitate reliance on the safety and efficacy data developed by the sponsors of original medicines. Article 39.3 of the TRIPS Agreement mandates the protection of such data against unfair commercial use and disclosure. An uninformed implementation of this obligation may result in preventing the registration with national health authorities of medicines produced under measures such as compulsory licenses or imported through parallel importation. This in turn would frustrate such measures as effective means in making affordable medicines more available. The nature, extent, and scope of the obligations under Article 39.3, and its equivalent under the USJFTA, will be explored in the next chapter.
“Like most good legislation, the Hatch-Waxman compromise was carefully designed for a specific situation, in a specific regulatory system. But our success here does not mean it is appropriate for other countries. That is why I am greatly alarmed by its inclusion in Free Trade Agreements...[a Hatch-Waxman-like data protection] would have the lethal effect of keeping drug prices in these countries unaffordable for many years longer than is the case now.”

Henry A. Waxman

CHAPTER FOUR

Pharmaceutical Regulatory Data Protection between TRIPS and USJFTA: Any Sense in Jordan’s Implementation?

1. Introduction

Among its various obligations under the TRIPS Agreement, Jordan had to implement the minimum standards of test data (TD) protection mandated by Article 39.3 of the Agreement. This article brought regulation of this matter, for the first time, under the ambit of both international trade law and intellectual property law, mandating that all WTO members must protect TD against unfair commercial use and disclosure. Besides its obligations under this article, Jordan must also comply with the provisions of Article

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3 Neither Articles IX & XX of the 1947 GATT (which contains provisions related to IP) nor the Paris Convention explicitly addressed the regulation of regulatory data as such.

4 Infra; also see ibid.
Although the USJFTA article refers to Article 39.3 of the TRIPS Agreement as its general framework, it obliges its parties to assume TRIPS-Plus measures. These measures require the agreement’s parties to protect, for three years, TD related to drugs constituting new uses for old chemical entities. The USJFTA also requires the protection of not only Regulatory Data (RD) submitted to the national regulators of its respective parties, but also data submitted to regulators of third countries. This obligation applies even if a foreign regulator does not require the submission of the data. In other words, Jordan is obliged to protect such foreign TD even if the safety and efficacy of a new drug, during national registration, are established by reference to a foreign registration issued for the same drug in order to execute the national registration.

To what extent, however, the obligations under the USJFTA have deviated from those required under Article 39.3 of the TRIPS Agreement remains unclear.

Jordan enacted Article 8 of the Trade Secrets and Unfair Competition Law to implement its obligations under both the TRIPS and the USJFTA agreements. The enforcement of this article is entrusted to the Jordan Food and Drug Administration (JFDA). The practice followed by JFDA provides Data Exclusivity (DE) to all information filed in dossiers for new drug applications. In this chapter, I argue that neither the TRIPS Agreement nor the USJFTA oblige Jordan to implement a DE regime. I also argue that Jordan is only under an obligation to protect TD data against unfair commercial use and disclosure.

Sponsors of applications of new medicinal products (hereinafter referred to as developers, originators, submitters, or sponsors) should demonstrate to national health regulators that their products are safe and efficacious for human medical use before such

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6 The USJFTA Article states that protection of regulatory data is “[p]ursuant to Article 39.3 of TRIPS”. See Article 4.22 of the USJFTA, ibid.
7 Ibid.
8 Ibid.
10 The term originator is used here to refer to the first applicant to seek a registration of a new drug with the pertinent national governmental agency.

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products are authorized for marketing. They establish the safety and efficacy of their new products by providing regulators with certain TD, which they develop by conducting two sets of tests, customarily characterized based on their progressive development time phases as: pre-clinical and clinical testing.

During the pre-clinical phase, developers test the new chemical entity in the laboratory and/or field animals to determine the toxicological, pharmacodynamic and pharmacokinetic properties of the entity. If these tests yield positive results on the non-toxicity of the entity and show signs of efficacious attributes, the originators formulate the new substance in a form administrable to humans, such as capsules, in order to proceed with the clinical stage. This stage requires permission from the regulator (investigation of new drug). The clinical stage is comprised of three progressive phases in which the types and numbers of participating human subjects change from phase to phase. If testing in this stage produces advantageous results, the sponsoring company may submit all the necessary TD generated from the various phases to health regulators in order to obtain market authorization for the drug.

The development of the safety and efficacy data is a costly undertaking. Although controversial, studies estimate the overall costs sustained by originators to place a medication on the market may reach up to $800 million per registered new chemical

11 For details on types, conditions, and requirements of applications to obtain an Investigational New Drug (IND) authorization, see U.S. Food and Drug Department (FDA), Investigational New Drug Application, online: FDA Homepage <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm> (date accessed: April 21, 2010).

12 In Phase I, various dosages of the drug are given to a small number of subjects, some of whom may be carrying the targeted disease. This phase is primarily aimed at investigating the effects of the drug and for a preliminary evaluation of its therapeutic effectiveness. Phase II involves an expanded sample of subjects and with extensive careful tests focusing on the drug’s efficacy. If tests from this phase show viable and promising results, testing is taken to the next level, Phase III. In this level, the investigational drug is administered to two groups of patients, considered to potentially benefit from the new drug, where involved subjects might number in the hundreds. From tests in this phase, developers seek to confirm the effectiveness of various dosages and in various patients’ age groups. In addition, they aim to determine any side effects that the drug might have, considering different factors such as gender, age, history of other illnesses, and drug interaction. See U.S., FDA, Conducting Clinical Trials, online: FDA Homepage <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ConductingClinicalTrials/default.htm> (date accessed: July 4, 2010).


entity, of which clinical trials represent a considerable share – estimated at sixty per cent.\(^{15}\) This estimate, however, incorporates expenses spent during various testing stages on trials of unsuccessful entities, including denied approvals by regulators.\(^{16}\) Given the size of the investment involved in generating the data, drug companies argue that their TD must be protected by conferring upon them a property right in the data, whereby third persons are prevented from relying on the data to market competing products. They add that without specific proprietary assignment, the data may remain unprotected. This is because of their nature as scientific information without technical advancement to qualify for protection as a patented invention\(^{17}\) - generated according to a set of regulator-predetermined rules and guidelines - and because such data must be submitted to regulators.

Protection afforded pharmaceutical TD has varied among the world’s countries. In jurisdictions such as the United States and the European Union, TD are protected by granting originators a *sui generis* property right for commercial use of the data.\(^{18}\) This exclusive right means that subsequent applicants seeking to register similar or identical products are banned from relying on the first applicant’s data to prove that their products are safe and effective, whether they are providing bioavailability studies or establishing bioequivalence. In practice, this prohibition is enforced by health regulatory agencies overseeing marketing authorization of new medicines. Regulators may refuse to approve a drug which relies on the TD of a reference medicine. Instead, they can require second applicants to submit either their own TD or proof of the originator’s consent to use of the data if they wish to market their products during the exclusivity term.\(^{19}\)

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\(^{16}\) Ibid. Also see Adams, supra note 14.

\(^{17}\) This does not exclude the possibility that such tests may lead to the discovery of new inventions. In such a case, discovered inventions, if they meet patentability requirements - for example, exhibiting industrial properties - may be protected by patents. Or, originators may request health regulators to keep such data confidential. In this latter case, the health regulators are under the duty to keep these data confidential, unless necessary to preserve the public interest.

\(^{18}\) See Section 2 for more details on both systems.

\(^{19}\) This option is not available for patented products in the US except under certain circumstances and in accordance with section §505(2) (A) (vii) of the US Federal Food, Drug, and Cosmetic Act; for details on this exception and others, see infra note 54.
Many of the world’s countries, however, do not protect pharmaceutical RD by DE. In these countries, health authorities may register a generic drug which establishes its safety and efficacy by reference to an earlier authorization, either national or foreign. This system is advocated based on the philosophy that regulation of health products through registration should not become a barrier to providing access to more affordable medicines or to otherwise legitimize competition. Instead, it is argued that registration regimes need to encourage the introduction of competitive products, which in turn would increase availability of less expensive medications.\(^{20}\)

However, the logic underlying regimes of DE, as advanced in jurisdictions where DE was adopted, is that developing RD through conducting laboratory tests and clinical trials to establish the safety and efficacy of a new chemical entity requires considerable financial investment and time. The grant of exclusive rights to exploit the data is thus necessary to enable the private entity to recoup the resources invested in generating the data. If the data are not protected by exclusivity, the firms would not have the appropriate incentives to shoulder the high costs involved in data development.\(^{21}\)

Recently, the protection of TD by health regulators in developing countries has become a matter of special importance to pharmaceutical manufacturers in developed countries. In particular, developed countries are calling for the termination of the practice whereby regulatory agencies allow reliance on originators’ data by subsequent applicants. They invoke Article 39.3 of the TRIPS Agreement.


The protection of TD is separate from, independent of, and often in addition to patent protection. However, since the ultimate function of DE is maintaining market exclusivity over newly introduced products, DE does not provide originators with added market exclusivity if the term of data protection elapses before that of the patent covering the product concerned. That is, the protection from competition arguably provided by patents is much stronger and longer compared to that provided by DE.

Therefore, DE is particularly relevant to two groups of products. First, products that are not patentable due to reasons related to either the novelty or the inventiveness requirements of patentability. For example, some countries do not consider a second medical use of an already patented product to be a patentable invention since such a use is considered a mere discovery that lacks inventiveness. This has been the case also with regard to biotechnological inventions, where patent protection has been difficult to obtain in the vast majority of countries. In fact, uncertainty about the patentability of these types of subject matters was a major reason to establish the system of DE in 1984 by the US Congress. The second group consists of products whose patents are about to expire or have expired and/or products that have not been protected by patents because such protection has not been available in the country where marketing authorization is being pursued. These situations occur mainly in developing countries because innovators of

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22 DE prevents the registration of subsequent competing products, mainly generics, by reference to data submitted by originators.
23 This argument is particularly strong under two conditions. First, the pharmaceutical product is registered during the early years of the patent life covering the product. Second, when a data exclusivity term is linked to the related patent term; that is data exclusivity would terminate with the conclusion of the patent/s with which the registered product is associated. This later case was the norm in some European countries (Greece, Portugal, and Spain) in accordance with the provisions of Article 10 (1)(a)(iii), the European Directive 2001/83/EC, which in part reads “[member] States are at liberty not to apply the six-year period beyond the date of expiry of a patent protecting the original medicinal product.” See EU, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, Official Journal L 311 , 28/11/2001 P. 0067 – 0128, online: EUR-Lex Homepage <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0083:EN:HTML> (date accessed: April 20, 2010, on file with the author).
24 Patent protection is stronger since it prevents competitors from using, offering for sale, selling, importing the patented subject matter. DE, however, does not prevent competitors from undertaking these acts.
26 This may also happen in a developed country context. That is, when the development phase of a product is exceptionally long after the date of a patent application. Under this scenario, the effective patent duration is significantly curtailed. However, when effective patent life is so reduced as a result of the regulatory process, many developed countries established a system according to which patent extension period
new medications launch their new products in the markets of developed countries much earlier than in their developing counterparts, or because pharmaceutical product patents are not available.\textsuperscript{27}

DE is especially relevant in developing countries, including Jordan, which until relatively recently did not provide for pharmaceutical product patents. The lack of patent protection in these countries has resulted in most of the medicines that are placed in their markets constituting a significant part of a considerable “pool” of unpatented pharmaceuticals. Accordingly, data protection has become the principal medium to obtain market exclusivity, hence the ability to raise the prices of life-saving drugs.\textsuperscript{28} To a large extent, this has been the case in Jordan since 2000.

Although the TRIPS Agreement establishes a regime of minimum legal standards of obligations, including these under Article 39.3, it does not create a uniform law. Given policy differences among WTO members on the protection of TD, determining what fulfils the minimum obligations under Article 39.3 has become a highly controversial issue. The contentious issue, as Correa put it, is “the extent to which the Agreement allows [WTO members] freedom to apply different approaches for test data protection and, in particular, the extent to which [protection other than exclusivity] is compatible with the minimum standards set forth by Article 39.3”.\textsuperscript{29}

The extent of the impact of TD protection on the affordability of medicines in Jordan and other developing countries depends in part on the legal model of protection a country adopts. If, for reasons other than multilateral or bilateral trade obligations and as demanded by developed countries such as the United States, Jordan implements an exclusivity regime, data protection unnecessarily limits competition in the vast majority of medicinal products and subsequently, of course, pushes up their prices. This effect may materialize in several scenarios. First, when regulators afford exclusivity to all data submitted by originators and for every newly registered pharmaceutical product calculated based on the time delay caused by regulation may be granted. See Section 2 for more details on DE in the US and the EU.

\textsuperscript{27} This was the case before the event of the TRIPS Agreement. However, following the end of the transitional period for all developing countries for implementing their obligations under the agreement, pharmaceutical product patents are available in all members of the WTO. See Article 65 of the TRIPS Agreement, supra note 2 at Paras. 2 & 4.

\textsuperscript{28} See OXFAM, infra note 248.

\textsuperscript{29} See Correa, “Unfair Competition”, supra note 20 at 70.
regardless of its patent status.\textsuperscript{30} Second, when DE is granted without tying protection to a carefully considered form of a \textit{priority period},\textsuperscript{31} calculated from the date of the first worldwide marketing authorization. Third, when DE is provided beyond the expiry date of a patent term. And fourth, if DE is enforced without providing for the necessary safeguards such as exceptions and waivers to prevent or address potential abuses by right holders.

To determine the nature, scope, and extent of protection that Jordan should afford TD, I will analyze the country’s obligations under the TRIPS and the USJFTA agreements. I will also consider the extent to which means other than DE would satisfy the requirements of both instruments. Moreover, to help clarify the current debates over this matter, this chapter proceeds as follows. Section 2 provides an overview of the evolution of DE, where I briefly explore the two main examples before TRIPS: the US example as set out by the Drug Price Competition and Patent Term Restoration Act (the so-called Hatch-Waxman Act), and the EU model under the 1987, 87/21/EEC Directive. In this section, I also review the relevant regime under the North American Free Trade Agreement (NAFTA) since it represents the first multilateral trade agreement to require exclusivity for pharmaceutical TD before the TRIPS Agreement. The NAFTA regime is reviewed based on the Canadian implementation of its obligations under the agreement and any jurisprudence thereon.

With the background of the prevailing DE regimes described in Section 2, Section 3 analyzes the protection mandated under the TRIPS Agreement. The analysis breaks down the provisions of Article 39.3 into the fundamental requirements of protectable TD as well as the particular conditions which data should satisfy to be considered eligible for protection. By breaking down these requirements, I show that the nature, scope, and extent of the obligation to protect TD under the TRIPS Agreement are neither identical to

\textsuperscript{30} Whether the product is not protected by a patent due to a \textit{per se} non-patentability, expiry, revocation, or simply because the inventor did not bother to apply for a patent in the first place, is irrelevant since such a linkage will prevent thwarting data protection to serve objectives other than those conceived of under data protection: as a means to help the originators to recoup their expenses. In particular, such a linkage would limit abuses of data protection by turning it to a legal means that facilitates monopoly.

\textsuperscript{31} A common practice followed by many countries providing for data exclusivity is to set a priority period or patent-like novelty requirement for data to be considered eligible for protection, which is based on the date of the first worldwide marketing authorization of a drug. Chile, Israel, Malaysia, Taiwan, and Turkey are several examples of countries where such requirement was stipulated; see infra notes 300, 301, 302, 303, and 304 and accompanying texts, respectively.
those prevailing in some developed countries at the time of signing the TRIPS Agreement, nor as broad as has been advocated by certain interest groups,\(^\text{32}\) supported by WTO members representing the interests of such groups.\(^\text{33}\)

Section 4 analyzes the extent to which the USJFTA has changed Jordan’s obligations towards TD under the TRIPS Agreement. In this section, I specifically examine the provisions of Article 4.22 of the USJFTA and compare them with the pertinent provisions in other selected FTAs signed by the United States. This analysis and comparison seek to determine the extent and scope of the obligations under the USJFTA, and whether DE is the only intended modality for implementing such obligations. I also investigate whether the USJFTA particularly prohibits JFDA from relying on data submitted by data originators to the agency itself or to foreign regulators in order to evaluate subsequent marketing applications for similar or identical pharmaceuticals.

Section 5 discusses the system of data protection in Jordan as established by the enactment of Article 8 of the Trade Secrets and Unfair Competition Law.\(^\text{34}\) The enforcement of this article is entrusted to the JFDA. The analysis includes an evaluation of the potential impact of DE on Jordanians’ access to medicines and on the pharmaceutical sector at large. I argue that the DE enforced by JFDA goes beyond the country’s international and bilateral obligations, leading, therefore, to negative impacts on access to medicines in Jordan. I then propose a calibration for the system of DE enforced by JFDA, recommending that Jordan introduce certain exceptions and waivers to data protection. Section 6 concludes this chapter and makes specific recommendations.

\(^{32}\) See the Pharmaceutical Research and Manufacturers of America (PhRMA), *Special 301 submission*, (2010), online: PhRMA Homepage <http://www.phrma.org/sites/phrma.org/files/attachments/2010_Special_301_Review_Submission_PhRMA_A_.pdf> (date accessed: April 19, 2010, on file with the author).

\(^{33}\) Both the US and the EU argue that protection of testing data against “unfair commercial use” means DE for at least five years. In addition, they both require in their bilateral agreements with developing and/or other developed countries, DE. For examples on agreements concluded by the US, see Article 17.10 of the US-Australia FTA, Article 15.10 of the US-Morocco FTA, Article 16.8 of the US-Singapore, infra note 244; the Partnership and Cooperation Agreements (PCA) between the EU and Ukraine and that being negotiated with India are illustrations on EU agreements. See Sandra Adamini et al., “Policy Making on Data Exclusivity in the European Union: From Industrial Interests to Legal Realities” (2009) 34(6) Journal of Health Politics, Policy and Law 979 at 987.

\(^{34}\) See supra note 9.
2. The Emergence of Pharmaceutical Regulatory Data Protection: Experiences Prior the TRIPS Agreement, National, Regional, and Beyond

Before concluding the TRIPS Agreement in 1994, there were three systems of data protection in the form of granting exclusive rights. The Hatch-Waxman Act\textsuperscript{35} of 1984 was the first national, systematic statutory regulation to provide exclusivity over the use of the TD of originators seeking to obtain marketing approval for their new products. The act protected data by preventing third persons, including the national regulatory agency,\textsuperscript{36} from relying directly or indirectly on such data to authorize the marketing of subsequent identical or similar medicinal products.\textsuperscript{37} The European Union followed suit in 1987 when it passed the 1987, 87/21/EEC Directive.\textsuperscript{38} The Hatch-Waxman Act and the EU Directive marked a fundamental shift in the legal protection of TD from protection against unfair competition, only as trade secrets, to the creation of a \textit{sui generis} system of an exclusive property right. TD exclusivity was also extended to both Canada and Mexico as parties to NAFTA\textsuperscript{39} which regulated the issue in Article 1711.5. These three pre-TRIPS instances of DE and the pertinent jurisprudence will be reviewed below.

2.1 Data exclusivity under the United States Law: The Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act)

\textsuperscript{36} Commonly, governments establish a specialized national agency entrusted with the task of reviewing all applications seeking approvals for marketing new medicinal products. These agencies ensure that new products are safe, effective, and of a quality for human use.
\textsuperscript{37} These subsequent products are mainly generics, “copy-cat” of the original “first” products. They try to obtain marketing approval from health regulatory agencies to their products by establishing, through certain bioequivalence studies, that their version of the drug is bioequivalent to the original product marketed by the first applicant and, thus, that it is safe and effective for human use. However, proving bioequivalence with the original does not, in and of itself, serve as a guarantee of the generics’ quality, which must be established to the satisfaction of the health agency.
Before the US Congress enacted the Hatch-Waxman Act in 1984, pharmaceutical TD were only protected as trade secrets against unfair competition in the same manner as all other confidential proprietary information. In order to explore the DE system initiated by the Hatch-Waxman Act, I briefly review the drug registration process followed by the US Food and Drug Department (FDA) as well as protection afforded to TD.

The Federal Food, Drug, and Cosmetic Act (FFDCA) was amended in 1962 (known as the Kefauver-Harris Amendments) to tighten the approval process for marketing new pharmaceutical products. According to the new procedures, the sponsor of a new pharmaceutical product was required to provide evidence of the safety and efficacy of the sponsored product before the issuance of a marketing authorization. Such proof would be developed principally through the conduct of pre-clinical and clinical studies. Prior to this amendment, pharmaceutical manufacturers only had to prove that the sponsored medicines were safe for human use. Generic medicines, i.e. products similar or identical to already approved products (reference medicines), faced less stringent requirements for obtaining marketing authorizations. Producers of generic medicines could establish the safety of their products by showing that they were identical or essentially similar to reference medicines. The 1962 amendment abolished the procedure of registration-by-comparison requiring sponsors of all new medicine marketing applications to submit a full New Drug Application (NDA), including generics.

This change made it much more difficult to register generics and obtain marketing authorization. In order to register generic medicines, the amendment required the sponsors of such products to submit a full and complete NDA. This meant that, to have a

42 See Cook, supra note 21 at 73.
43 Ibid.
44 The phrase “reference product” and/or its equivalent such as “reference medicine” or “reference drug” is used to mean the drug first registered with a regulator and in association with which a full application was submitted and usually sponsored by an originator.
46 See Cook, supra note 21.
successful marketing authorization, the only means available for producers of generic medications to prove the safety and efficacy of their products was to conduct their own laboratory tests and clinical studies. This rule, however, was not absolute. The amendment allowed certain exceptions for particular categories of generic drugs.

Exemptions from the submission of a full NDA fell into three categories, which could be authorized through two different, new mechanisms. The first procedure, known as the Abbreviated New Drug Application (ANDA), allowed sponsors of applications for generic drugs to demonstrate the safety and efficacy of their products by providing evidence that their products were the bioequivalent of authorized reference products. Applications for the generic versions of drugs approved before 1962 and generics of antibiotic drugs were filed under this procedure. The second procedure, known as Section 505(b)(2) or Paper NDA, permitted manufacturers of generics to demonstrate the safety and efficacy of their products by relying on the results of investigations that they did not conduct and without obtaining the permission of the sponsors of such investigations. This option was possible if the relied-on results were publicly available through published scientific literature.

With respect, however, to the Paper NDA, two difficulties made it impractical for approving generics. First, the necessary studies and data were not available for all original products. Second, with regard to products whose safety and efficacy data were obtainable through published literature, the available data would be deemed insufficient.

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47 During the 1960s and early 1970s, generics did not hold a competitive position in the American pharmaceuticals market. This reality is not mainly a consequence of the strict marketing requirement the 1962 FDCA imposed on generics, but due to the fact that most of the states maintained anti-substitution laws, physicians’ prescribing habits, and pharmacists dispensing behavior. See James J. Wheaton, “Generic Competition and Pharmaceutical Innovation: the Drug Price Competition and Patent Term Restoration Act of 1984” (1985-86) 35 Catholic University Law Review 433, at 442-46.

48 According to Section 505 (j) (8) (b) of the FDA Act, a generic drug is bioequivalent to a reference drug if there is no “significant difference” in the “rate and extent of absorption” of the generic drug. See also, 21 C.F.R. § 320.1(e); Food and Drug Administration, Bioavailability and Bioequivalence Studies for Orally Administered Drug Products — General Considerations, (2003), online: FDA Homepage <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070124.pdf> (date accessed: April 20, 2010, on file with the author).


50 Ibid. § 505(j).

51 Ibid. § 507. It should be mentioned here that extending the patent term afforded to pharmaceutical products under the Hatch-Waxman reform of the FDA Act did not apply to original antibiotics. However, this extension was only made available to these products since in 1997 by means of Section 125 of the Food and Drug Administration Modernization Act (FDAMA). See Public Law No. 105-115.
to register a generic version of an original drug if the FDA exercised its authority to request further studies. These two impediments made marketing approvals for generics through Paper NDAs “an uncertain and expensive undertaking.” In 1984, the trade secret framework used as the basis of TD protection was fundamentally changed. This reform to the FDA Act in 1984, codified as Section 355, created exclusivity protection for originators’ TD. According to the new system, not only are the sponsors of subsequent products banned from relying on such originators’ data to register similar or identical products, but also the FDA is now proscribed from evaluating subsequent products by relying on the data directly or indirectly.

Finally, the Act created three periods of exclusivity, two of which are related to TD. These two included: a) a five-year period of exclusivity calculated from the date of marketing approval of new pharmaceutical products containing “New Chemical Entity” (NCE), also called “New Molecule Entity” (NME); and b) a three-year period of DE


53 It was testified before the US Congress that after 1962, there were “150 drugs that were off-patent, but for which there were no generics because generic companies simply would not spend the time and money doing the clinical trials to get to market, and there were only fifteen “paper NDAs,” for post-1962 generics”. See Gilston, The Generic Patent Compromise, MED, Advertising News, Apr. 30, 1984, at 16-17, cited in Gerald Mossinghoff, “Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process” (1999) 54 Food and Drug Law Journal 187.

54 The third exclusivity is 180-day generic drug exclusivity. This exclusivity is granted according to the provisions of Section 505(j) of the FFDCBA based on a successful Abbreviated New Drug Application (ANDA) pursuant to the provisions of Section 505(b)(2) of the law. The exclusivity period, however, is not based on data protection. Instead, it is granted to the first generic drug approved in accordance with the mechanism created under Paragraph (iv) of Section 505(b)(2)(A). According to this section, a sponsor of a generic drug relying on this mechanism needs to submit one of four certifications mentioned in the section. Under Paragraph (iv) of Section 505(2)(A)(vii), a generic’s sponsor is required to certify that the listed patent/s associated with the reference drug is/are invalid. The paragraph reads “(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted”. Besides encouraging and fostering generic competition, this mechanism calls for a post-grant examination of issued patents. It does so by providing incentives to generics manufacturers to challenge potentially invalid patents.

55 As we will later see in this chapter, the stipulation that a drug contains a New Chemical Entity as a condition of data protection was also included under the TRIPS Agreement; however, there has been no agreement among WTO members as to the definition of what constitutes a new chemical entity.

56 The relevant part of section 505(e)(ii), in which the five-year exclusivity is enacted, reads:

[i]f an application submitted under subsection (b) for a drug, no active ingredient…of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this clause…no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or
calculated from the marketing approval date issued to a pharmaceutical product for a new therapeutic use or for indication of a previously approved entity whose approval is essentially dependent on the conduct of at least one new clinical investigation.\(^57\)

2.2. The European Legal Regime of Data Exclusivity

Before 1987, pharmaceutical RD in the EU were primarily protected as trade secrets\(^58\) similar to the prevailing American regime which existed prior to the 1984 reform of the FFDCA.\(^59\) The European regime of marketing authorization of pharmaceuticals was then governed by Directive 65/65/EEC (the 65 Directive), as amended by Council Directive 75/318/EEC of 20 May 1975 and Council Directive 87/21/EEC.\(^60\) The 65 Directive required all applicants for marketing authorization of

for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b),” (emphasis mine).

The only exception to the five-year period applies when an ANDA is submitted under paragraph (iv) (mentioned-above) with certification of patent invalidity or non-infringement. In such a case, the exclusivity term is shortened to a forty-eight month period.

\(^57\) This second type of data exclusivity was enacted by Paragraph (iii) new use of previously approved drugs, and Paragraph (iv) regarding an application containing a “supplement [that] contains reports of new clinical investigations … essential to the approval of the supplement…” of Section 505(e) of the law.

\(^58\) It should be mentioned here that the 1965 Directive did not explicitly mandate protection of testing data as trade secrets, and it seems that this issue (deciding on the proper legal mechanism to protect such data) was delegated to the legislators of the member sovereignties to decide. Nor did the Directive provide guidance as to whether the potential use of testing data to authorize a subsequent similar or identical medicinal product by regulatory agencies, directly or indirectly, would constitute a legitimate practice. See Judit Sanjuna et al., Protection of Pharmaceutical Test Data: A Policy Proposal (Consumer Project on Technology, 2006) at 10, on line: CPTech Homepage <http://www.cptech.org/ip/health/data/CPTech-Test-Data.pdf> (date accessed: April 20, 2010, on file with the author).

\(^59\) Although the practice under the regional system to register new medicinal products indicated that RD were protected as trade secrets by the 1965 Directive, national practices varied substantially. Ibid.

medicinal products to submit the necessary data from the “physico-chemical, biological or microbiological tests [;] pharmacological and [;] toxicological tests [; and] clinical trials”\(^{61}\) in support of their applications.\(^{62}\) Information obtained from these various tests was treated as trade secrets by national as well as regional health regulatory agencies (the European Medicines Agency (EMEA)). The data were protected against disclosure and in accordance with the rules of unfair competition.\(^{63}\) Hence, no proprietary rights were conferred on the first applicant who carried out the required tests and trials, and regulators relied on data to authorize subsequent, essentially similar medicinal products, at least indirectly.\(^{64}\)

In 1987, Council Directive 87/21/EEC of 22 December 1986 enacted DE for the first time in Europe. Article 1 of this Directive, codified as Article 4(8) of the 65/65/EEC Directive, contains the rules on the new regime. The Article requires a sponsor of a medicinal product that is “essentially similar” to an [“authorized product in the country concerned”] to submit its own data. The required data represent the “results of pharmacological and toxicological tests or the results of clinical trials” as well as the results of the relevant clinical trials if the period elapsed since the marketing date of the authorized product is:

(iii) less than six years and [the authorized drug] is marketed in the Member State for which the application is made; this period shall be extended to 10 years in the case of high-technology medicinal products\(^{65}\) […]” Furthermore, a Member State


\(^{62}\) A Medicinal Product is defined by Article 1(2) of Directive 65/65/EEC as “any substance or combination of substances presented for treating or preventing disease in human beings or animals.” The Article continues to add to the definition that “[any] substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product”. Ibid.

\(^{63}\) See infra.

\(^{64}\) The EU Commission noted in 1984 that “certain national authorities tended not to be too demanding in their assessment of the adequacy of published references, even where data on safety were incomplete”, cited in Cook, supra note 21 at 20; also see Sanjuan, supra note 52 at 8.

\(^{65}\) Most of the products designated as “high-technology medicinal products” in Part A of the Annex to the 1987/21 Directive are biotechnology based products. The relevant part of the Annex lists the following as high-technology products:

A. Medicinal products developed by means of the following biotechnological processes:
   - recombinant DNA technology,
may also extend this period to 10 years by a single decision covering all the products marketed on its territory where it considers this necessary in the interest of public health. Member States are at liberty not to apply the abovementioned six-year period beyond the date of expiry of a patent protecting the original product.”

Article 4(8) speaks of two periods of DE with various modalities, the length of which depends on the relevant product and/or member country of the European Union. The first period is ten years and is applicable to the following products: “high-technology medicinal products having been authorised according to the procedure laid down in Article 2(5) of Council Directive 87/22/EEC”, all medicinal products centrally authorized by the European regulatory agency EMEA, and all the medicinal products marketed in the territory of a member country if that member opts, by a single decision, for such extension and where it “considers this necessary in the interest of public health”. This last option has been adopted by Belgium, France, Germany, Italy, the Netherlands, Sweden, and the United Kingdom.

The second period covers six years of exclusivity that members may implement in relation to all medicinal products except those related to high-technology, specifically biotechnology (adopted by Austria, Denmark, Finland, Iceland, Ireland, Luxemburg, and Norway). Members have, however, the option to implement a qualified modality of this provision. In other words, member countries have the discretion “not to apply the six-year period beyond the date of expiry of a patent protecting the original medicinal product.”

- controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells,
- hybridoma and monoclonal antibody methods.


See supra note 619 (emphasis mine).


See supra note 65 for a list of the covered products.


With respect to Iceland and the Norway, the calculation of the DE period is triggered by the date of national marketing authorization not by any other European approval date, whether regional (EMA) or by the national agency of other European country.

See Cook, supra note 21 (table of countries) at 31.

See Article 4(8) (a)(iii) of Directive 87/22/EEC, supra note 60.
term of the patent claimed in the application submitted for the registration of the relevant product.\textsuperscript{73}

Although, as a rule under the provisions of the 1965 Directive, sponsors of all medicinal products were (and still are) required to submit a full application containing all the necessary efficacy and safety data, the directive allowed one exception to this rule. This exception, which is similar to the “Paper” NDA application under US law referred to earlier,\textsuperscript{74} allows producers of generics to establish the safety and effectiveness of their products by relying on data other than those developed and submitted by sponsors of original pharmaceuticals (reference products): i.e., data publicly available in published scientific literature.\textsuperscript{75} This exception was not repealed by the 1987 Amending Directive, and unlike the other “abridged procedure”\textsuperscript{76} which permit the submission of an application without presenting the results of pharmacological and toxicological tests or the results of clinical trials, there are no restrictions as to when such an application can be submitted.\textsuperscript{77} Arguably, therefore, this type of application can be submitted as soon as an applicant gathers the necessary and required data published in the literature.\textsuperscript{78}

\textsuperscript{73} See Cook, supra note21 at 29-30.

\textsuperscript{74} See above for a review of this type of application.

\textsuperscript{75} According to Paragraph (ii) of Article 4.8(a) of the 1965 Directive, applicants seeking to market new medicinal products shall not be required to provide the results of pharmacological and toxicological tests or the results of clinical trials if they can demonstrate “by detailed references to published scientific literature presented …that the constituent or constituents of the medicinal product have a well established medicinal use, with recognized efficacy and an acceptable level of safety”.

\textsuperscript{76} According to the provisions of Paragraph (iii) of Article 4.8(a), if a subsequent applicant can demonstrate that his medicinal product is “essentially similar to a product which has been authorized within the Community”, the applicant is exempted from providing the results of pharmacological and toxicological tests or the results of clinical trials as inscribed in Paragraph (a) of the same Article.

\textsuperscript{77} See Garland, supra note 67.

\textsuperscript{78} In practice, however, the issue is a complex one. An applicant availing himself of the scientific literature exception needs to prove that the constituent/s of the medicinal product has/have a “well established medicinal use” with recognized efficacy and an acceptable level of safety. To present such evidence solely based on published literature is a time consuming exercise which is dependent on satisfying certain factors. According to Cook (supra note 21 at 26-7), these factors include “the time over which the constituents were put into use; the quantitative particulars of the use; and the scientific interest in the constituents as well as the consistency of evaluation available by the relevant scientific community”. However, the rules governing this procedure were modified in 2004 by amending Directive No. 2004/27/EC. The amendment mandates, for relying on scientific literature in a marketing application of a medicinal product, that the applicant must “demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years” (emphasis mine). See Article 9 of the 2004 Directive, supra note 60; for a review of the new and amended provisions on DE, see Paul Garland & Hafliði Kristján Lárusson, “Data Exclusivity, Bolar Exemption and Generic Drugs in the EU” (2007) 29(4) European Intellectual Property Review 128.
2.3 Data Exclusivity under NAFTA: Canadian Perspective and Experience

With respect to the protection of TD, NAFTA constitutes the “crossover point” from the national and regional phases to multilateralism because it represents the first multilateral instrument to embrace provisions solely devoted to regulating this matter. Paragraphs 5 and 6 of NAFTA Article 1711 detailed this obligation.79 Pursuant to Paragraph 5, parties are obliged to protect against disclosure “undisclosed test or other data” the submission of which is required to prove that a medicinal product utilizing a “new chemical entity”80 is safe and efficacious if the generation of such data “involves considerable effort”.81 Paragraph 6 stipulates that subsequent applicants cannot rely on the confidential test and other data submitted by originators for a reasonable period of time if they do not have the originators’ consent to rely on the data.82

The nature and scope of this NAFTA obligation were subject to interpretation by the Canadian Federal Court of Appeal in Bayer Inc. v. Canada (Attorney General).83 In this case, the court concluded that “there is no limitation on Canada implementing an abbreviated approval procedure on the basis of bioequivalence and bioavailability studies”84 other than the obligation contained in the provisions of Article 1711, which is

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79 Paragraphs 5 & 6 of Article 1711 of NAFTA read:

5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

80 The NAFTA Agreement does not define the term “new”. Rather it delegates this issue to the legislator or regulatory bodies of its parties, without any limitation imposed on their freedom to opt for the definition they perceive as the most suitable to advance their interests.

81 Ibid.

82 Ibid.


84 Ibid. at para. 14.
“intended to protect trade secrets”. The court defined the protection affordable to undisclosed test and other data to be within the context of trade secrets entailing only an obligation of nondisclosure and ban on the actual, direct reliance and examination of originators’ confidential data by the Minister of Health.

The court contextualized the obligation to protect TD under trade secrets. It also articulated that the five-year DE is triggered only when a manufacturer of generics requests, as an option and in order to obtain a Notice of Compliance (NOC), Health Canada to actually examine the confidential data submitted in association with a reference drug. In other words, there is no call for an application of DE if the minister does not actually consult the data of the originator to evaluate the safety and efficacy of the generic submission. Such a consultation triggers DE, which results in the rejection of the generic application because, argues the court, “the safety and effectiveness of the generic product will only be established by reference to confidential information provided to the Minister by the innovator.” The court, however, clarifies that this is not the only means to establish the safety and effectiveness of a generic medicine. The court affirms that a possible mechanism to satisfy the sanitary requirements is by the subsequent applicant demonstrating that its product is bioequivalent to the originator’s product when compared with the publicly marketed products. The court adds that this method does not require regulators to rely on the confidential data of originators.

The appellant in this case, Bayer Inc., argued that inevitably the regulator relies on the confidential information filed by the innovator whenever a subsequent applicant compares its product with that of the innovator. This reliance would occur either directly, through actual examination of the data, or indirectly when the safety and effectiveness of a generic drug are demonstrated by comparison with the innovator’s product.

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85 Ibid. at para.15.
86 Ibid.
87 According to Health Canada, A Notice of Compliance is a “notification, issued pursuant to paragraph C.08.004(1)(a), indicating that a manufacturer has complied with sections C.08.002 or C.08.003 and C.08.005.1 of the Food and Drug Regulations. [And is] issued to a manufacturer following the satisfactory review of a [drug] submission”. See Health Canada, Drugs and Health Products: Notice of Compliance, online: Health Canada Homepage <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/index-eng.php> (date accessed: April 21, 2010).
88 See Bayer, supra note 83 at paragraphs 14 and 15.
89 Ibid. at para. 8.
90 Ibid. at para. 3.
Consequently, the issuance of a NOC to a generic applicant based on such a reading (the court’s interpretation) results in an interpretation of Subsection C.08.004.1.(1)\textsuperscript{91} of the Canadian Food and Drug Regulations\textsuperscript{92} (the Regulation) that is inconsonant with Paragraphs 5 and 6 of NAFTA Article 1711. The court examined whether the Regulations, as amended, complied with NAFTA obligations, and ultimately rejected this claim.

To further confirm that its interpretation of Subsection C.08.004.1(1) of the Regulations would not render it inconsistent with NAFTA, the court referred to the relevant passage of “The Regulatory Impact Analysis Statement”\textsuperscript{93} accompanying the amended Regulations. The statement explained the view of the Canadian government as to how Health Canada should implement the subsection concerned. According to the court’s reading of the statement, the clear intention of the Regulation was that reliance on the confidential information submitted by the first registrant and/or examination thereof to evaluate the safety and effectiveness of a subsequent submission is a mere option available to the regulator. This option is available alongside others, including a request

\textsuperscript{91} Subsection C.08.004.1.(1) of the Regulations, which contains the relevant provisions implementing the obligation provided for by NAFTA, provides that:

[where] a manufacturer files a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or a supplement to an abbreviated new drug submission for the purpose of establishing the safety and effectiveness of the new drug for which the submission or supplement is filed, and the Minister examines any information or material filed with the Minister, in a new drug submission, by the innovator of a drug that contains a chemical or biological substance not previously approved for sale in Canada as a drug, and the Minister, in support of the manufacturer’s submission or supplement, relies on data contained in the information or material filed by the innovator, the Minister shall not issue a notice of compliance in respect of that submission or supplement earlier than five years after the date of issuance to the innovator of the notice of compliance or approval to market that drug, as the case may be, issued on the basis of the information or material filed by the innovator for that drug (emphasis mine).

\textsuperscript{92} See the Food and Drug Regulations, C.R.C., c. 870, as amended by Section 204 of the NAFTA Implementation Act (1993) (Public Law No. 103-182).

\textsuperscript{93} An excerpt from the statement was cited by the court in Paragraph 10, and it reads:

[in] the case where the Drugs Directorate intends to rely on the data of the innovator to support safety and efficacy claims, and this would result in a delay in the issuance of the NOC, the Drugs Directorate will notify the second-entry manufacturer in advance of the review. The Drugs Directorate will give the second-entry manufacturer the option of supplying additional information to support the claim without relying on the data previously submitted by the innovator. If the manufacturer wishes to supply the required information directly, in accordance with the policy on management of information, the manufacturer will avoid the application of this provision.

See Food and Drug Regulations, C.R.C., c. 870, as amended by Section 204 of the NAFTA Implementation Act (1993) (Public Law 103-182).
to the generic manufacturer to submit further information to avoid an actual examination of the innovator’s data. Concurring with the conclusion of the lower court, the Court of Appeal persuasively maintained that it “would require that the Court read into the regulation the word ‘indirectly’ or some other modifier” to accept the appellant’s argument that there was an implicit examination of, and hence reliance on, the innovator’s confidential data whenever an applicant for a generic submission compares its product with that of the innovator.

The interpretation by the court in the Bayer case is particularly important since it may clarify the nature and scope of developing countries’ obligations under the TRIPS Agreement to protect pharmaceutical TD. It is also important because the Uruguay Round of GATT negotiations on TRIPS (Uruguay Round) were concomitant with those on NAFTA; the history of the TRIPS negotiations reveals that proposals on data protection advanced during the early phases reflected language similar to that utilized in NAFTA.

Despite some differences among the three systems discussed so far on data protection, developed countries came to the Uruguay Round having in mind their own regimes as a model for data protection. They came to the negotiations with a desire to extend their models to other GATT members. However, our next case of inquiry will be whether the TRIPS Agreement adopted any of these models in its final version as a result of these negotiations.

3. The TRIPS Agreement and the Protection of Test Data under Article 39.3

Section Seven of the TRIPS Agreement, titled “Protection of Undisclosed Information”, incorporates Article 39.3 which contains the provisions on the obligations to protect TD. Paragraph three refers to data related to pharmaceutical and agrochemical

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94 See Bayer Inc. v. Canada (Attorney General), supra note 83, paras.11-12.
95 The appellant in this case, Bayer Inc., argued that Subsection C.08.004.1(1) of the Food and Drug regulations should not be interpreted in a manner that is not consonant with the provisions of Paragraphs 5 and 6 of Article 1711 of NAFTA (ibid).
96 The term “rely” in the relevant clause of Paragraph 6 of Article 1711 of NAFTA that reads “no person other than the person that submitted them may …rely on such data in support of an application for product approval” is not part of the corresponding text of Article 39.3 of the TRIPS Agreement (emphasis mine).
products, which regulatory agencies require all the sponsors of new medicinal or agrochemical products to submit. With regard to pharmaceuticals, the obligations under this paragraph have become fundamentally contentious among members of the WTO. The dissension concerns the nature and scope of the obligation “crafted” by and within the sentences and terms of the paragraph. The United States and like-minded members (mainly EU and Switzerland) argue for DE as an intellectual property “right” established under Article 39.3.

The majority of WTO membership, including some developed countries such as Australia and Canada, disagree with this assertion. They maintain that the TRIPS Agreement does not provide for data exclusivity. Instead they argue it stipulates the protection of TD against “unfair commercial use” and disclosure. Both obligations fall under the general rules of protection against unfair competition and do not entail the creation of a proprietary right. Therefore, before I proceed to answer the question as to whether or not Jordan is committed to provide for DE, it is necessary to investigate the nature and scope of the obligations required under Article 39.3 of the TRIPS Agreement.

Article 39.3 represents a compromise accommodating different proposals submitted by various negotiating parties during the Uruguay Round. The text of the paragraph encompasses three principal issues. First, the paragraph characterizes the protected subject matter by setting certain requirements that data must satisfy to qualify

97 See the TRIPS Agreement, supra note 2.
98 It was until 1998 and after a pressure from the US government when Australia provided for DE. See infra note 327 any accompanying text.
99 See the response of the Canadian representative to the WTO to a question on Canada’s protection of undisclosed information during its Trade Policy Review (cited below on page 54, infra note 184).
100 See Correa, “Unfair Competition”, supra note 20 at 82.
101 Proposals on the protection of RD were mainly submitted by the US, EU, and Switzerland. Developing countries rejected the idea of protecting undisclosed information by means other than trade secrets. For an account on the different proposals made during negotiations, see Carvalho, supra note 21 at 243-258.
102 Surprisingly, developing countries maintained a rejectionist stand with respect to DE arguing that TD is protected as trade secrets and against unfair competition, but not as intellectual property.
103 Article 39.3 reads:

See Article 39.3 of the TRIPS Agreement, supra note 2.
for protection. Second, it contains a mandate to protect qualified data against unfair commercial use and disclosure. And third, it provides for a limited exception to the non-disclosure obligation. I shall address these three main components in turn.

3.1. Protected Data: The Required Properties

A precise determination of the protected subject matter under Article 39.3 is a fundamental step to ascertaining the extent and scope of WTO members’ obligations. Does the mandate extend to include all the data provided by originators, or is it limited to particular type(s) of data? Are there certain qualities or conditions that such data must conform to, or should the mere fact that the person submitting the data classifies them as protectable trigger an automatic basis for protection? To answer these questions, it is necessary to investigate precisely which data are intended for protection. Accordingly, I next discuss the criteria specified under Article 39.3 which TD must meet and against which eligibility for protection is judged.

Besides specifying “testing and other data” as the subject matter of protection, Article 39.3 identifies the following four prerequisites for any testing and other data to qualify for protection. First, submission of data must be required and necessarily lead to approval of the associated pharmaceutical product. Second, the data must relate to a product containing a chemical entity that is novel (new). Third, the data must be confidential and kept secret. And fourth, the data must require a considerable effort to generate.

3.1.1. Protection is limited to “Test or other Data”

Article 39.3 mentions two types of pharmaceutical regulatory data, usually submitted by originators to a health regulatory agency, which WTO Members should protect. These types are testing data and what the article refers to as “other data”. TD refers to information developed from two sources. The first source is pre-clinical testing,
which includes information developed by toxicological\textsuperscript{104} and pharmacological\textsuperscript{105} studies, involving laboratory techniques followed by testing the entity on animal subjects within a laboratory setting. The second source of TD is information generated from conducting clinical trials,\textsuperscript{106} which involve human subjects. Drug innovators conduct such trials to further test the effectiveness of a new chemical entity as observed during the pre-clinical study phases. With regard to “other data”, it may include, \textit{inter alia}, information related to processes and conditions of manufacturing, packaging, and storing of the medicinal product undergoing the approval process. Such data, however, qualify for protection only insofar as its submission is required and necessary to authorize the marketing of a new entity.

\subsection*{3.1.2. Data must be required and necessary for and lead to marketing approval}

Having TD submitted to health agencies is not, in and of itself, a sufficient basis for protection. Only data filed by sponsors of new entities as a condition to acquire marketing authorization for their entities are protected. If, therefore, undisclosed data are voluntarily submitted by a sponsor, health regulators assume no legal obligation to protect such data. In addition, data protection has no application when pre-marketing

\textsuperscript{104} Toxicological studies focus on the “study of the adverse effects of chemicals on living systems, whether they be human, animal, plant, or microbe. ‘Adverse effect’ can range from a life threatening injury to something that might be considered a minor annoyance”. See Thomas F. Schrager, \textit{What is Toxicology?}, online: ToxicologySource Homepage <http://www.toxicologysource.com/whatistoxicology.html> (date accessed: April 20, 2010).

\textsuperscript{105} Pharmacology is the study of the interactions that occur between a living organism and an exogenous chemical substance or entity that alter normal biochemical function of the organism. If the substance has medicinal properties, they are considered pharmaceuticals. Therefore, pharmacology is the study of drugs, of the body's reaction to drugs, the sources of drugs, their nature, and their properties.

\textsuperscript{106} In general, clinical investigations require adherence to strict guidelines that mandate, among other things, registration of trials with health authorities before the actual conduct of the study and continuous reporting of results. The trials are conducted in three phases. In phase one the new substance is given to a healthy small number of participants, mainly to determine that the substance is safe for human use. Phase two involves administering the new substance to a small group of patients to ensure that it is efficacious over existing drugs and that it does not cause unacceptable side-effects. Phase three is conducted by giving the substance to a large number of patients under medical supervision and for a defined period of time to establish the efficacy of the substance. The results of these trials are submitted for assessment and if positive may lead to marketing approval being granted. After release of the new substance in the market, a fourth phase of trials takes place, which takes place in hospitals and clinics. Another post-marketing investigation of new substances is usually conducted to identify possible side-effects that were not foreseen during the preceding four phases is called Safety Assessment of Marketed Medicines (SAMM) or Pharmacovigilance.
approval systems do not require pharmaceutical manufacturers to conduct all or part of the relevant tests to develop the necessary safety and efficacy data, which is the case in many developing countries. This exists, for example, when a regulatory regime only requires the submission of evidence indicating that the product undergoing registration is approved for marketing in a reference country, without requiring actual submission of the TD generated to register the entity in the reference country. The same also applies to instances when the actual practice of the regulator regarding the safety and efficacy of new entities is established based on the submission of evidence of foreign marketing authorization, or based on available published literature. In these cases, even if domestic regulations require the submission of TD, the data may not qualify for protection since such a requirement does not change the fact that the safety and effectiveness of medicinal products are actually established based on the reference authorizations.

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107 The phrase “reference country” is used to indicate a country that is listed by a health regulator as an acceptable point of reference with regard to, for example, pricing or marketing authorization.
109 This is the practice in many developing countries. They instruct sponsors of new drugs (agents or a representative for the originator) to include in their application dossiers evidence that their product is authorized for marketing in a reference country (usually in a developed country that maintains a vigorous system of marketing authorization). Such evidence is provided by submitting a document known as “free sale certificate” issued by the health regulator in the reference country.
110 It has been argued that when national health regulators rely on foreign approvals to establish the safety and effectiveness of new pharmaceuticals, the mandate contained in Article 39.3 of the TRIPS Agreement applies and that the relying regulator should protect the data against disclosure and unfair commercial use. This interpretation was reluctantly adopted (because of the modality verb may) by Carvalho on the basis that the country relying on a marketing approval in another country would be considered to have required indirectly the submission of the data. He argues that his conclusion is valid since “Article 39.3 is not about direct protection of test data but rather about prevention of parasitism and free riding”; see Carvalho, supra note 21 at 287.
111 This is typically the case in Jordan. Article 5 (a) of the Jordanian Criteria of Registration of Drugs, implemented by JFDA, reads “[the] application for registering a new drug and the equivalent drug registered at the Directorate shall be submitted by the concerned pharmacist in the drug store or by the technical manager of the local factory attaching thereto the file containing the completed documents by virtue of the requirements mentioned in Appendix No. (1).” Titled, “Requirements of the Drug Registration File”, Appendix No. (1) provides for a list of documents that a drug manufacturer should file as part of a new drug application:

4-a. New Drugs
1. Bio-availability study according to the instructions issued for this purpose, excluding therefrom, serums and vaccines products and biological products including allergy products.
2. Clinical Studies.
4. Periodic Safety Update Report from the producing company.
Article 39.3 explicitly protects such data based on the fact that they are submitted “as a condition of approving the marketing of pharmaceutical...products”. In other words, the article makes protection of data dependent on the outcome of the registration application. Hence, if a submission for marketing authorization fails to obtain approval, the associated data would be considered not to have met the conditions of protection under Article 39.3\textsuperscript{112} and thus would be disqualified for protection.\textsuperscript{113}

Part two of the appendix, however, requires applicants seeking marketing authorization of new pharmaceuticals to submit, among other things, the following:

2.a. Free Sale Certificate from the Country of Origin [...] containing the following:

[...]

4. A statement that the product is actually being sold in the Country of origin with the same composition, in case that it is not being sold there, to demonstrate the reasons for such, provided a Free Sale Certificate duly legalized is submitted showing that it is being actually sold in a country approved by the Administration with the same composition.

\textsuperscript{112} With regard to the obligation not to disclose, it should be mentioned that, even if the submitted data does not qualify for protection under Article 39.3, the regulator may still under the obligation to protect such data against disclosure, but as a trade secret.

\textsuperscript{113} This interpretation is in conformity with the EU legislation on this matter, although the protection required under the EU system is much stricter (data exclusivity) and has not been enacted as an implementation of the TRIPS Agreement. Under the EU Law, data submitted in association with an unsuccessful application may not be provided with protection. This rule is prescribed in Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 (The Regulation). Paragraph 11 of Article 14 of The Regulation stipulates:

[without] prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorised in accordance with the provisions of this Regulation shall benefit from an eight-year period of data protection and a ten-year period of marketing protection, in which connection the latter period shall be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies (emphasis mine).


(1) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(A) [...] ,

(B) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted, [...].
Confidential TD might lose protection not only as a consequence of unsuccessful submission, but also in case of a withdrawal of an approved submission. This might occur irrespective of the reasons leading to such a withdrawal, whether related to public health and safety concerns or as a matter of pure commercial considerations. The practice of ending data protection when applications are unsuccessful or withdrawn conforms to the laws enforced in jurisdictions where a *sui generis* proprietary right in TD is recognized.\(^\text{114}\)

### 3.1.3. Data must relate to a “new chemical entity”\(^\text{115}\)

The obligation to protect TD under Article 39.3 is confined to data submitted to register particular limited products. Namely, products containing *new chemical entities* that have not been marketed before in a pharmaceutical product.\(^\text{116}\) This condition means

\[^{114}\text{See Section 355(I) (1) (c) of Title 21 U.S.C. FFDCA, which reads:}
\[^{115}\text{It is relevant in this context to consider the definition of what constitutes a chemical entity in various settings to have a better comprehension of the scope of the obligation under Article 39.3 TRIPS and whether it does mandate DE. A determination is further relevant with regard to other forms of protection such as nondisclosure, since it delineates the protected subject matter, thus, provides all stakeholders of the pharmaceutical sector with clarity and certainty.}
\[^{116}\text{Whether the fact that a chemical molecule was marketed in therapeutic forms other than in a pharmaceutical product for humans would render such a molecule to lack novelty, for purposes of data protection, is an issue that depends on the practice adopted in every individual member country. However, Correa seems to rule out this option. He argues that the discovery of a use in pharmaceuticals for an entity that is known in another regulatory field might still be deemed a new chemical entity “since the chemical was already known. [and novelty] may be assessed within a particular regulatory framework and without}
that TD are eligible for protection only if submitted in association with a product that satisfies two conditions. The product must contain a chemical entity, and the entity must be “new”.

Consequently, the mandatory protection of TD does not apply if a product fails to measure up to one of these two conditions; for example, if the originator’s data relate to entities classified as non-chemical. Plants and animals, according to Carvalho, demonstrate typical illustrations of when an entity might not be chemical.

Determining whether an entity used in a pharmaceutical product is an active chemical molecule is less problematic than ascertaining whether such a chemical entity is “new” or “novel”. Article 39.3 does not define the term “new”. Thus, in accordance with regard to the fact that the same chemical may have been used in the context of another regulatory framework.” See Correa, “Protection of Data”, supra note 113 at 17.

With respect to new uses, indications, and/or new formulations (including concentrations, routes of administration, etc.) of old chemical entities, it has been argued that TD provided to a regulator in support of such submissions not only do not constitute new chemical entities – as will be explained when discussing the definition of the term “new” mentioned in the article - but also, as such, they do not constitute entities in themselves. To the contrary, the question as to whether data associated with new use or new routes of administration are protected or not does not rise since protection is only conditioned on the fact that there is approval for new product. In other words, when the mandate to protect TD is not linked to the requirement that the product undergoing authorization procedures contains an entity that is chemical and new. New uses of old entities would pass the novelty test only if the mandate under Article 39.3 were to indicate that it is sufficient to have a “new product registration” to trigger data protection, which is not the case. Article 15.10 of the Central American Free Trade Agreement (CAFTA), titled “Measures Related to Certain Regulated Products”, is an example of the latter modality. The relevant provisions of the article reads:

1. (a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided such information, to market a product on the basis of (1) such information or (2) the approval granted to the person who submitted such information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party.


It should be noted that the TRIPS Agreement does not specify which of the various constituents (a drug is made up of active and inactive – excipient – ingredients) formulating a pharmaceutical product should be an entity that is chemical and new. It seems that such a requirement applies only to the active ingredient. Accordingly, only the protection of data related to the active molecule or substance of a pharmaceutical product would be mandated. (An excipient is an inactive substance used as a carrier for the active substance in a pharmaceutical product. It aids the human body in absorbing the active substance; it helps to bulk up formulations that contain a very potent substance for dosage accuracy; and/or it aids in handling active ingredients in the manufacturing process to various degrees of importance and depending on the route of administration. In addition, excipients are used to stabilize the active ingredients once the later is purified and to prevent it from denaturing).

See Carvalho, supra note 21 at 287; he does not, however, extend the exclusion to genes and their genetically modified counter parts, since they “constitute chemical organic molecules”.

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Article 1.1 of the TRIPS Agreement,\footnote{120} WTO members have full discretion to determine the relevant criteria they deem fit within their own jurisdictions and based on which the novelty of chemical entities is deduced. As a result, standards differ among WTO members.

Generally, in the context of TD protection, WTO members may follow one of three novelty concepts to judge the newness of a chemical entity. These concepts are absolute novelty (universal), regional novelty,\footnote{121} or relative (local) novelty. Absolute novelty may mean that if an entity, as contained in a pharmaceutical product, was submitted to, or approved by, a health regulator of any country, such an undertaking would destroy the novelty of the entity rendering it old and known. This, in turn, disqualifies for protection data associated with, or provided to support the marketing of, a substance containing a known entity. Argentina is one of the WTO members who have adopted this concept.\footnote{122}

On the contrary, the United States followed a concept of relative novelty. The United States Department of Health and Human Services’ Food and Drug Administration (FDA) defines a new chemical entity as “a drug that contains no active moiety\footnote{123} that has been approved by FDA in any other application submitted under section 505(b) of the

\footnote{120} Article 1.1, TRIPS reads:

[members] shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice (emphasis mine).

\footnote{121} The centralized sanitary system for pharmaceuticals’ registration administered by the European Medicines Agency (EMEA) constitutes an example of such a modality; see Cook, supra note 21 at 16.

\footnote{122} See Article 4 of Law No. 24, 766, of December 1996, (Argentina: Undisclosed Information (Fair Trade Practices)), Law No. 24.766, 18/12/1996, online: WIPO Homepage<http://www.wipo.int/clea/en/details.jsp?id=103> (date accessed: May 21, 2010)). In the context of health-related data protection, the public policy maker should account for the following two elements if absolute novelty of chemical entities is opted for. First, a consideration should be given to the sanitary vigilance system in the country where the chemical entity is first registered. Second, one should consider how such a system would impact an early introduction of new pharmaceutical products containing new chemical entities. With respect to the issue of early introduction of an entity, it might be realized even though a country is adopting a relative (local) standard of novelty. As I will discuss later, this objective can be attained by inscribing a priority period calculated from the first international registration date of the concerned entity. If that new entity is not registered with the health regulatory agency of a third country within the priority period, it would lose its novelty, and no data protection shall be afforded to TD associated with it) for further details, see Section 5 below on Jordan’ implementation of data protection.

\footnote{123} The FDA defines an active moiety as “the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.” See infra, footnote 124.
Act.” Although this definition or a similar version of it has been adopted by various developed countries, it would preserve novelty for substances that would otherwise be considered old entities, which the TRIPS Agreement does not require. For example, according to the wording of this definition, protection of TD is determined based on the administrative act of marketing approval of the molecule concerned, but not dependent on the novelty or confidentiality of the submitted data. Hence, an old chemical substance would be considered a new entity if a new use (new indication) for it is discovered, which then entails data protection. The same would apply to new dosage forms, a drug’s new administration routes, combinations, crystalline forms, and isomers of present drugs to the extent that manufacturers are required to submit new safety and efficacy data for assessment and evaluation by the regulator.

3.1.4. Data must be confidential

Protection under Article 39.3 is not automatically granted when sponsors of new drugs submit the necessary TD and when the submitted data relate to new chemical entities. To qualify for protection, the data must also be confidential at the time of submission. If the data are disclosed and considered publicly available, then they are not protectable data, since they are not confidential. For example, if an applicant for a marketing authorization were required to provide data that happens to be publicly available (e.g., through published scientific literature) to establish the safety and efficacy of a sponsored product - a common practice in many developing countries - the regulator would be under no obligation to protect such data against unfair commercial use.

125 See Correa, “Protection of Data Submitted”, supra note 116 at 18 (arguing that for purposes of applying Article 39.3, TRIPS, it is not sufficient to only have a new method or use of a known chemical entity to entail application of the article. To call for data protection of testing information, the chemical entity itself must be novel, and if for any reason that entity lost its novelty, there would be no claim of data protection with regard to this particular entity in its “obvious form”).
126 See Carvalho, supra note 21 at 289.
127 According to Part 4(a)(3) of Appendix (1), “Requirements of the Drug Registration File”, to the Jordanian Criteria for Drugs Registration, applicants for pharmaceutical marketing approval are required to provide the “Scientific Studies published in global magazines”.
or disclosure. In other words, the regulator is not obliged either to prevent subsequent applicants from relying on the data or to refrain from disclosing them, even though the regulator required the submission of the data. Therefore, confidentiality would not be restored to data already published and publicly available regardless of whether such data are required by the regulator or are submitted voluntarily.

In addition, given that it is a requirement for protection, secrecy of TD must be preserved throughout the prescribed duration of protection. Hence, it is not enough to maintain the secrecy of data at the time of submission only. To ensure protection throughout the entirety of the protection term, data must be kept secret until the expiry of such term. If all or part of the protected data are disclosed, such disclosure would void the protection of the data for the remaining duration.

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128 This requirement is applicable not only to TD, but also to “other data” the submission of which is mandated by health agencies. Therefore, if a pharmaceutical manufacturer submits a description of the relevant “coating material” used to preserve the active chemical substance during or after the manufacturing process of the submitted product and that such description does not qualify as a trade secret, the concerned regulator is under no obligation to protect the said description against disclosure or to prevent subsequent applicants from using it.

129 With regard to the secrecy requirements of TD, the Chilean law is an illustrative example. For testing data to enjoy protection, the law mandates that it should satisfy the requirement of a trade secret as detailed in Article 39.2 TRIPS. Paragraph 2 of Article 39 of the TRIPS Agreement reads:

> [natural] and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices [footnote omitted] so long as such information:

- (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- (b) has commercial value because it is secret; and
- (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

See Article 39.2 of the TRIPS Agreement, supra note 2.

In Paragraph 4 of Article 89 (Law 19,996, of 2005), Chilean law requires the sponsors of new medicines to identify in their applications all the data they consider as undisclosed. Furthermore, under the Chilean regime of TD protection (particularly Decree No. 135, of 2005) the data originator shall precisely identify among submitted data “which studies in his view are undisclosed and in connection with which the following requirement have been met: that reasonable measures have been taken to keep them secret; and that those data are not generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question”. See Article 6 (A) & (B) of Chilean Decree, as cited in Carvalho, supra note 21 at 294. However, given the objectivity of the nature of whether submitted TD are confidential or disclosed, an identification of certain data as confidential by the originator is not final and is not obligatory on regulators to accept. Regulators as well as competitors have all means available to their disposal to scrutinize such identifications or declarations of confidentiality and may prove otherwise. See Correa, “Unfair Competition”, supra note 20 at 74.

130 Disclosure occurring after submission of data to a health regulator that might revoke confidentiality of the data is not restricted to acts of the first applicant. The same may result due to data being disclosed by another health regulator for public health reasons. Therefore, to conclude that any competitor may rely on
3.1.5. Data involve a considerable effort to generate

The last requirement which TD must satisfy to qualify for protection rests on the effort involved in generating them: it must be “considerable”. Article 39.3 does not define what constitutes “considerable effort” for purposes of implementing the agreement by members, nor does it clarify the concept by exemplifying particular types of effort involved in generating the data: economic, technical, or both. The article also lacks any guidance as to the factors that health regulators might consider in evaluating the significance of the efforts involved.

Therefore, WTO members have discretion to follow the factors that they deem appropriate for evaluating the reasonableness of the effort involved in generating particular data. They may opt for the extent of the associated costs and financial expenditures; or they may choose the intensity and difficulty (time spent and technical utilization) of the effort in question. Still, members may follow a combination of these two factors, where efforts would be regarded as considerable only when they satisfy a proportionality test as to the costs, intensity and difficulty of the efforts carried out to generate the data. If, based on the outcome of the proportionality test, the effort involved is declared inconsiderable, such an effort may not meet the conditions of protection specified in Article 39.3.

The preceding analysis illustrates unambiguously that data protection under Article 39.3 of the TRIPS Agreement does not apply automatically to all testing and other data submitted to national health regulators by sponsors of new drugs. Protection

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131 See Correa, Protection of Data, supra note 113 at 21.
132 As I will explain in another part of this chapter, several Free Trade Agreements (FTA) that the US has concluded with several developing countries have considerably altered this situation. For example, according to the provisions of the US-Morocco FTA, pharmaceutical regulatory data must be protected even in cases when the data are not required by the regulator of a party to the FTA. This would be the case when a party to the agreement requires the submission of evidence of prior approval of the product that is issued by another country. Furthermore, the requirement that the data should relate to a new chemical entity has been replaced with a much permissive one; namely, that the data relate to a new pharmaceutical product. This means the parties of the said agreement are obliged to protect data submitted in support of registering pharmaceutical products based on a new use of an old chemical entity. See Article 15.10 of the
should be afforded to data legitimately established as protectable subject matter only. Originators should unequivocally prove that their data have satisfied the aforementioned requirements: namely, that the data are required and necessary for marketing approval, relate to a new chemical entity, are confidential, and require considerable effort to generate. In such a case, health regulatory agencies are obliged to protect all eligible data against “unfair commercial use” and against “disclosure”.

3.2. Protect Data against What and How: “Unfair Commercial Use” or “Data Exclusivity”?

Article 39.3 stipulates that WTO members who require sponsors of new drug applications to submit protectable TD have two distinct obligations. Members must protect TD against “unfair commercial use” and against “disclosure”, unless disclosure is necessary to protect the public or all necessary steps are taken to ensure that the data are protected against unfair commercial use.

The nature, extent and scope of the obligation to protect data against unfair commercial use have been, and may remain, a matter of contention between countries. The debates concern what exactly is entailed by the phrase “unfair commercial use”. On the one hand, developed member countries such as the US, the EU, and Switzerland contend that protection against unfair commercial use is only attainable through the grant of an exclusive right over the use of TD to their originators. They add that the drafters of Article 39.3 meant to provide for this obligation. Accordingly, the protection of TD should be implemented in the form of DE, which effectively results in “marketing

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133 The words “protectable” and “legitimate” are used to refer to data that meet all the conditions described in Section 3.1, which Article 39.3 requires that TD satisfy before they are considered for protection.
135 The EU has contended that negotiators of the TRIPS Agreement clearly intended, based on the negotiations’ history, to provide for DE by opting for the language used in Article 39.3. See EU, European Commission, Questions on TRIPS and Data Exclusivity: an EU Contribution, (Spring 2001), quoted in Pharmaceutical Research and Manufacturers of America (PhRMA), Special 301” Submission, (2003) at A-4, online: PhRMA Home page <http://www.phrma.org/international/301.pdf> (date accessed: April 20, 2010, on file with the author).
exclusivity”.

On the other hand, a consensus exists among developing countries, various UN organizations, the British Commission on Intellectual Property Rights (IPR Commission), as well as many leading scholars that the scope of the obligation to protect TD against unfair commercial use is one that does not transcend the duty to

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136 For example, the following excerpt from PhRMA’s 2009 Special 301 Submission represents the view of those arguing for DE based on the protection against unfair commercial use: “TRIPS requires WTO Members to prohibit unfair commercial use of, or reliance on, regulatory data. The widely accepted mechanism for complying with this obligation is a data exclusivity regime which prevents regulatory authorities from prematurely allowing generic producers to rely on or otherwise use the originator’s proprietary data to gain approval of copies of the originator’s drug” (emphasis mine). See PhRMA, Special 301 Submission, (2009) at 33, online: PhRMA Home page (date accessed: April 20, 2010, on file with the author). A stronger statement was made in an earlier submission (2003) by the same organization. In that submission, PhRMA it argued that the TRIPS Agreement not only outlaws reliance by competitors, but also reliance by health regulators. The organization stated: “…the TRIPS Agreement recognizes that…During [the] period of exclusive use, the data cannot be relied upon by regulatory officials to approve similar products” (emphasis mine). Ibid. at 4.

137 For example, the WHO Commission on Intellectual Property Rights, Innovation and Public Health maintains that:

<article> 39.3 […] does not require the provision of specific forms of rights. … It does not create property rights, nor a right to prevent others from relying on the data for the marketing approval of the same product by a third party, or from using the data except where unfair (dishonest) commercial practices are involved.

Thus, the TRIPS agreement does not refer to any period of data protection, nor does it refer to data exclusivity”.


138 See Commission on Intellectual Property Rights (IPR Commission), Integrating Intellectual Property Rights and Development Policy (London: IPR Commission, 2002) at 50-1, online: IPR Commission (accessed: October 20, 2010). In particular, the commission confirms that [countries] may allow health authorities to approve equivalent generic substitutes by ‘relying on’ the original data. Developing countries should implement data protection legislation that facilitates the entry of generic competitors, whilst providing appropriate protection for confidential data, which may be done in a variety of TRIPS-compatible ways. Developing countries need not enact legislation the effect of which is to create exclusive rights where no patent protection exists or to extend the effective period of the patent monopoly beyond its proper term.

139 See Correa, “Unfair Competition”, supra note 20; Correa, “Protection of data”, supra note 113; Aaron, supra note 21; Reichman, “Undisclosed”, supra note 20; Reichman, “Rethinking”, supra note 21; Judit, infra note 214; and Weissman, infra note 265.
protect undisclosed information against “unfair competition” as provided for under article 10bis of the Paris Convention\textsuperscript{140} and Article 39.2 of the TRIPS Agreement.

Those who support DE as the only legal modality capable of protecting TD against unfair commercial use appeal, unsurprisingly, to economic and equitable considerations.\textsuperscript{141} They also refer to the history of negotiations of Article 39 and practices of particular WTO members since the conclusion of the TRIPS Agreement. This section will first analyze the meaning and nature of the obligation to protect TD against “unfair commercial use”. The analysis includes an interpretation of the relevant provisions pursuant to the principles of treaty interpretation (The Vienna Convention), “in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”\textsuperscript{142} The section then turns to explore the arguments advocating DE. I argue that neither the history of negotiations of Article 39 nor the subsequent practices of many WTO members provide a substantial basis to conclude that developing countries must provide for DE to fulfill their obligations in protecting TD against unfair commercial use.

3.2.1 Protection against “unfair commercial use” Defined

Debates on the protection of TD have focused on the meaning of the expression “unfair commercial use” found in Article 39.3. In particular, they focus on whether this expression means that WTO members are obliged to grant sponsors of new drugs an exclusive right over the use of their TD for a specified duration. Advocates of exclusivity claim that this duration should be for at least five years, similar to the statutory period implemented in the US.\textsuperscript{143} They add that the obligation to protect data against unfair

\textsuperscript{140} See Paris Convention for the Protection of Industrial Property, March 20, 1883, as revised at Stockholm, July 14, 1967, Art. 10bis.

\textsuperscript{141} The economic argument follows from the claim that originators of pharmaceuticals would lack or have insufficient incentives to conduct the pre- and clinical studies without DE. The equity-based claim appeals to the notion of free-riding: that is, since subsequent manufactures would rely on data that they do not generate, they would be unfairly benefiting from the “sweat of the brow” of the original drug sponsor. See Aaron, supra note 21.


\textsuperscript{143} According to Section 355(c)(3)(E)(ii) (Section 355 contains the provisions of the Drug Price Competition and Patent Term Restoration Act, known as the “Hatch-Waxman Act” [Public Law 98-417])
commercial use means preventing regulatory agencies from relying, directly or indirectly, on the first registrant’s confidential data for approving generic products. \[144\] The TRIPS Agreement, however, does not define what it means by the phrase “unfair commercial use”. Accordingly, the meaning of the phrase as well as the intention embedded therein must be pursued through interpretation. An interpretation of the expression “unfair commercial use” in light of its “ordinary meaning”, “context”, and the TRIPS Agreement’s “object and purpose” unequivocally indicates that the agreement does not require DE.

3.2.1.1 The meaning of “unfair commercial use”

Each of the three terms comprising the expression “unfair commercial use” was carefully chosen by the drafters of the TRIPS Agreement. This meticulousness was necessary to achieve a consensus on the extent of this obligation during the Uruguay Round of negotiations. \[145\] Accordingly, it is imperative to consider each of these terms to

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144 This has been the official view and stand of the US Trade Representative (USTR). In a 1995 statement, The General Counsel of the USTR has declared that the obligation contained in Article 39.3 to protect regulatory data is implemented when the data “will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorized by the original submitter of the data. Any other definition of this term would be inconsistent with logic and with the negotiating history of the provision” (emphasis mine). See Office of the General Counsel, U.S. Trade Representative, The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3, [unattributed paper for submission in bilateral discussions with Australia (May 1995)], cited in Correa, Protection of data, supra note 113 at 47. A similar argument was articulated by Bayer Inc. in Bayer Inc. v. Canada (Attorney General). The company claimed that the protection of its data includes preventing Health Canada from relying indirectly on its TD to approve a subsequent, similar medicinal product. See Bayer Inc., supra note 83.

145 Two alternative expressions were proposed during the TRIPS negotiations. The first proposal was made by the United States negotiators (during the first of the only two rounds of discussions related to the issue of data protection in the Uruguay Round (from 1989 to 1990)). The American proposal, under the general heading, “Trade Secrets” contained several suggestions on the protection of trade secrets. These suggestions included the subheading, “Conditions on Government Use”, which partially reads: “[t]rade secrets submitted to governments shall not be disclosed or used for the benefit of third parties”. See General Agreement on Tariffs and Trade (GATT), Suggestion by the United States for Achieving the Negotiating Objective, GATT document MTN.GNG./NG11/W/14?Rev.1 of October 17, 1988, online: WTO Homepage <http://www.wto.org/gatt_docs/English/SULPDF/92030039.pdf> (date accessed: April 20, 2010, on file with the author). The phrase “government use”, according to Carvalho, was rejected for it would have enjoined governments from carrying out all sorts of use of the data such as fair and non-commercial-related uses, which makes it “too restrictive” without using a qualifying term used after the word “use” (See Carvalho, supra note 21110 at 270). The second wording, which also was turned down by
determine what negotiators meant by this expression, and whether it implies that DE is the only acceptable means of protection as claimed by advocates of exclusivity.

**A. “Unfair” Use:**

It is obvious that the drafters of Article 39.3 selected the word “unfair” to qualify the scope of the obligation to a particular class of commercial employment of RD: unfair uses. Because the TRIPS Agreement does not define unfair commercial use, nor is there a singular international standard for determining the equitability of a given act/class of acts or uses, ascertaining unfairness of commercial use remains, as

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See GATT, Draft Agreement on Trade-Related Aspects of Intellectual Property Rights, GATT document MTN.1GNG/NG11/W/68 of March 29, 1990 at 13, online: WTO <http://www.wto.org/gatt_docs/English/SULPDF/92100042.pdf> (date accessed: April 20, 2010, on file with the author). The word exploitation in the above italicized phrase “unfair exploitation” was said to convey a technically problematic meaning: “the use or working of something for […] profit”. Given, according to Carvalho, that “Democratic governments … do not use data submitted by private citizens…” for profit; therefore, had negotiations agreed on using the above referred to phrase, would have resulted in considering all governmental uses to fall outside the mandated protection provided for under the final text language of Article 39.3. See Carvalho, supra note 21 at 270).

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The pressures existing in the various countries for the suppression of acts of unfair competition differ greatly. Generally, the development of law of unfair competition depends on active and intense competition in the marketplace by competing enterprises. It is the pressure of conflicting interests which leads to the establishment of clear rules of law. This pressure is not uniform in all countries and indeed it is evolving continuously (emphasis mine).
an objective issue, a matter of domestic law which may benefit from, and be informed by, well-recognized international norms and standards relevant to the particular field or practice concerned.149 This flexibility to determine domestically the fairness of certain uses of TD should be rationally and objectively exercised in the context of Article 39.1 and in light of Article 10bis of the Paris Convention, to which reference is made in Article 39.1 of the TRIPS Agreement.

According to paragraph 1 of Article 39 of the TRIPS Agreement,150 the protection of all undisclosed information, including “data submitted to governments or governmental agencies in accordance with paragraph 3”, falls within the discipline of unfair competition established under Article 10bis of the Paris Convention (1967). Paragraph 1 of Article 10bis states “[the] countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition”.151 Paragraph 2 of the same article defines unfair competition as “[any] act of competition contrary to honest practices in industrial or commercial matters”.152


150 Article 39.1 reads: “[in] the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3”. See the TRIPS Agreement, supra note 2 Art. 39.

151 See supra note 140.

152 Ibid. According to the World Intellectual Property Organization (WIPO), the repression of unfair competition is:

directed against acts or practices, in the course of trade or business, that are contrary to honest practices, including, in particular:

[acts] which may cause confusion with the products or services, or the industrial or commercial activities, of an enterprise;
False allegations which may discredit the products or services, or the industrial or commercial activities, of an enterprise;
Indications or allegations which may mislead the public, in particular as to the manufacturing process of a product or as to the quality, quantity or other characteristics of products or services;
Acts in respect of unlawful acquisition, disclosure or use of trade secrets;
Acts causing a dilution or other damage to the distinctive power of another's mark or taking undue advantage of the goodwill or reputation of another's enterprise.

Notwithstanding the clear intention of the TRIPS’ negotiators to protect TD only as undisclosed information within the context of unfair competition, directed against dishonest commercial and industrial practices perpetrated by competitors, some still hold that reliance on originators’ TD by national health agencies to evaluate subsequent similar or identical products constitutes an act of dishonesty. The logic of this claim is one based on the mere existence of an advantage accruing to a subsequent applicant as a result of regulators’ reliance on the data of the originator. It is not, however, based on a characterization of the act of reliance itself as intrinsically being dishonest commercial conduct; the illustrative list of practices mentioned in Paragraph 3 of Article 10bis of the Paris Convention would serve as examples of commercial practices that are inherently dishonest. In other words, reliance on the originator’s data provides second-entrants to the market with a considerable commercial advantage over originators. This advantage accrues since reliance on the data would save a subsequent applicant the costs, money and time, that it would otherwise incur to undertake tests and clinical trials necessary to develop its own data. Accordingly, reliance provides competitors with a free ride on originators’ efforts, making it “…intrinsically dishonest, although no acts of fraud or deceits are involved”. Therefore, the logic goes, such reliance constitutes an unfair practice.

As mentioned earlier, the TRIPS Agreement does not specify whether reliance of health regulators on originators’ TD to approve the marketing of a subsequent drug

153 See Meitinger, supra note 113 at 131 (following a description of how reliance on testing data would constitute a commercial disadvantage to originators, Meitinger states “It is apparent that, looking at the competing applicants, this leads to a commercially unfair imbalance between them. Since the only value of the test data is to prove safety and effectiveness of products in the marketing approval procedure, the prevention of free-riding of Article 39.3 TRIPS must also, and probably primarily, encompass this case”).

154 The Article lists the following: (i) all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor; (ii) false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor; (iii) indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods. See Article 10 of the Paris Convention, supra note 140.

155 See Carvalho, supra not 21 at 270 (Carvalho offers an extended understanding with regard to the notion of honesty to encompass the act of reliance by national health regulatory agencies on the originator’s testing data under the general notion of “unfairness”, which he claims, for the purposes of Article 39.3, remain the same as that under Articles 10bis (2) and 39.2 of the Paris Convention and the TRIPS Agreement respectively. However, there is nothing in the agreement that supports this extended meaning of dishonesty. In addition, had the TRIPS’ negotiators opted for this extended notion, they could have done so explicitly).
constitutes an act of unfairness; therefore, it is clearly a matter that the TRIPS Agreement left for national laws to determine. This option was chosen because establishing or determining what and when certain conducts are considered unfair is not governed by a definite international standard equally applicable to all countries of the world. In other words, unfairness is a notion relative to and associated with the values of a particular society as perceived in a particular point of time, hence it varies with place and time.\textsuperscript{156} In fact, a review of the history of negotiations on the TRIPS Agreement reveals that a proposal to create an absolute rule declaring the practice of reliance by health regulators on originators’ TD as unfair use was discussed during the Uruguay Round. However, this history indicates that negotiators rejected this proposal.\textsuperscript{157} Therefore, a good faith interpretation as what constitutes “unfair” commercial practice must consider this element to be an indication of the genuine intention enshrined in Article 39.3, not what some negotiators asked for.\textsuperscript{158}

\textsuperscript{156} See Ladas, supra, note 148.

\textsuperscript{157} A proposal of this kind was first advanced by the United States as part of its suggestion to achieve the negotiations objective contained in a GATT document, MTN.GNG./NG11/W/14?Rev.1, Suggestion by the United States for Achieving the Negotiating Objective, dated 17 October 1988; see supra note 145 and accompanying text. The same proposal was, although worded differently, included in the Draft TRIPS Agreement of December 3, 1990 (so-called Brussels Draft). The draft provision concerning testing data reads:

4A. PARTIES, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, PARTIES shall protect such data against disclosure, except where necessary to protect the public] (emphasis mine).

See GATT, Draft Final Act embodying the Results of the Uruguay Round of Multilateral Trade Negotiations: Revision, of 3 December 1990, GATT document MTN.TNC/W/35/Rev.1, online: WTO <http://www.wto.org/gatt_docs/1986_90.HTM> (date accessed: April 20, 2010, on file with the author). The emphasized text does not appear in the final version of Article 39.3, which provides a strong indication that it was rejected not only from being considered as unfair practice, but rejected altogether as a legitimate limit on the freedom of member states to rely on testing data.

\textsuperscript{158} Following an analysis of the legislative history and context of Article 39.3 of the TRIPS, including the relevant articles of the Paris Convention and NAFTA, Reichman emphasizes the interpretive importance of the fact that TRIPS’ negotiators rejected to incorporate into Article 39.3 a legal model similar to that adopted in NAFTA. He argues “\textit{A fortiori, refusal to adopt the NAFTA provisions on regulatory data submitted to governments under article 39.3 carries even greater interpretative weight, given that test data as a topic at the international level is of comparatively recent vintage, and that it is necessarily one on which no international consensus had yet been formed}” (emphasis mine); see Reichman, “Undisclosed”, supra note 20 at 7.
Bearing in mind that negotiators of the TRIPS Agreement have refused to limit reliance by governments on originators’ TD to register generic drugs, an interpretation of the term “unfair” in such a way as to encompass this particular practice means reading into Article 39.3 exactly what negotiators rejected. This reading would violate Article 31 of the Vienna Convention. Such interpretation would also amount, as Reichman phrases it, to “imposing unbargained-for trade concessions under a discredited ‘TRIPS plus approach’ that has no legal foundation whatsoever.” Reichman noted that any interpretation primarily favouring DE would contravene the letter and spirit of the ruling in the India Mail Box case. In this case, the Appellate Body emphasized the importance of Article 19 of the Understanding on the Settlement of Disputes (DSU) as well as Article 1.1 of the TRIPS Agreement. Whereas Article 19 provides that a WTO panel “cannot add to or subtract from the covered obligations”, Article 1.1 TRIPS states that “members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice”.

Given that the expression “unfair commercial use” is worded in language that makes it far less specific and compelling than language mandating DE, the interpretation principle of in dubio mitius shall be called into play here and, hence, we

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159 Beyond what Article 39.3 speaks of: disclosure and unfair commercial use.
160 See Reichman, “Rethinking”, supra note 21 at 10.
162 Ibid.
163 See Article 1.1 of the TRIPS Agreement, supra note 2; Indiapatent Protection, supra note 161 at 16.
164 Consider, for example, the text of Article 1711.6 of the NAFTA Agreement. The Article uses certain and unambiguous language to mandate DE obligations: “... no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission.” For the full text of Paragraphs 5 & 6 of Article 1711, see supra not 79. Notwithstanding the language of the article, the Canadian Court of Appeal concluded – unless there is an actual examination of the originator’s confidential data by the minister – that the NAFTA’s obligation places no “...limitation on Canada implementing an abbreviated approval procedure on the basis of bioequivalence and bioavailability studies.” See Bayer Inc., supra note 83 paras. 14 & 15.
165 The Appellate Body referred to the interpretive principle of in dubio mitius to be widely recognized in international law as a “supplementary means of interpretation” that has been expressed as: [the] principle of in dubio mitius applies in interpreting treaties, in deference to the sovereignty of states. If the meaning of a term is ambiguous, that meaning is to be preferred which is less onerous to the party assuming an obligation, or which interferes less with the territorial and personal supremacy of a party, or involves less general restrictions upon the parties.
“cannot lightly assume that sovereign states intended to impose upon themselves the more onerous, rather than the less burdensome, obligation”\textsuperscript{166} When such uncertain language exists in a treaty, a preference should be given to the meaning that is “less onerous to the party assuming an obligation, or which interferes less with the territorial and personal supremacy of a party, or involves less general restrictions upon the parties”.\textsuperscript{167}

Accordingly, it is difficult to conclude that DE was intended under Article 39.3 in light of the relativity of the word \textit{unfair}, the provisions of Article 39, and a fair account of the negotiations’ history. In particular, it was not intended to enjoin national regulators from relying on originators’ TD to authorize the marketing of subsequent generic versions. Nor, given the absence of WTO jurisprudence on the issue - a ruling by a panel\textsuperscript{168} or the Appellate body - can such a conclusion be based on “state practice”\textsuperscript{169} subsequent to the conclusion of the agreement.\textsuperscript{170}

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\textsuperscript{167} See supra note 165 and accompanying text.

\textsuperscript{168} A chance to have a panel and/or Appellate Body ruling on the issue was missed in 2002. In that year, the United States initiated a consultation on, \textit{inter alia}, Argentina’s compliance with Article 39.3 of the TRIPS Agreement as applied to pharmaceuticals and agrochemicals in accordance with the WTO Rules and Procedures Governing the Settlement of Disputes or Dispute Settlement Understanding (DSU). However, the two countries notified the Dispute Settlement Body (DSB) of the WTO of their mutual agreement on the disputed matters, including that of Article 39.3. The notification, in part, reads:

[the] Governments of the United States and Argentina have expressed their respective points of view on the provisions of Article 39.3 of the TRIPS Agreement, and have agreed that differences in interpretations shall be solved under the DSU rules. The Parties will continue consultations to assess the progress of the legislative process of approval of items 4, 5 and 6 of this notification, and in the light of this assessment, the United States may decide to continue consultations or request the establishment of a panel related to Article 39.3 of the TRIPS Agreement.

In addition, the Parties agree that should the Dispute Settlement Body adopt recommendations and rulings clarifying the content of the rights related to undisclosed test data submitted for marketing approval according to Article 39.3 of the TRIPS Agreement, and should Argentinian law be inconsistent with Article 39.3 as clarified by the above-mentioned recommendations and rulings, Argentina agrees to submit to the National Congress within one year an amendment to Argentinian law, as necessary, to put its legislation in conformity with its obligations under Article 39.3 as clarified in such recommendations and rulings.

WTO members did not adopt or follow a uniform approach in implementing their obligations under Article 39.3. While many of them\textsuperscript{171} do not provide for DE as the legal modality to protect TD, a considerable number of them assert that their obligations under Article 39.3 do not require protection of TD beyond preserving confidentiality.\textsuperscript{172} The following counties are among those members: Bolivia,\textsuperscript{173} Canada,\textsuperscript{174} Egypt,\textsuperscript{175} Japan,\textsuperscript{176}

\textsuperscript{169} As an elaboration on the rule contained in Paragraph 1 of Article 31 of Vienna Convention regarding the context of a treaty, Paragraph 2(b)(3) of the same article elaborates that:

3. There shall be taken into account, together with the context:

\[\ldots\];

(b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;

\[\ldots\].

See the text of Article 31 of the Vienna Convention, supra note 142.

\textsuperscript{170} Some have eluded to the United States’ practice of including in its bilateral trade agreements with developing countries a DE provision as constituting a state practice of the kind mentioned in Article 31.2(b)(3)(b) of the Vienna Convention.

\textsuperscript{171} Argentina, India, Russia, South Africa, Brazil, Venezuela, Pakistan, and many others only protect TD against disclosure and unfair commercial use. But, this protection may not prevent the relevant regulatory agency from relying on originators’ data in one form or another. For more details on TD protection in these and other countries, see PhRMA, \textit{Special 301 submission}, (2010) online: Knowledge Ecology International(formerly the Consumer Project on Technology) <http://keionline.org/sites/default/files/PhRMA_USTR-2010-0003-0245.1.pdf> (date accessed: April 20, 2010); International Federation of Pharmaceutical Manufacturers Association (IFPMA), \textit{A Review Of Existing Data Exclusivity Legislation In Selected Counties}, (2005), online: IFPMA<http://www.ifpma.org/documents/NR2799/DataExclusivity_2005.pdf> (date accessed: April 20, 2010); see UNCTAD-ICTSD, \textit{Resource Book}, supra note 108 at 533-7; and Carvalho, supra note 21 at 278-9.

\textsuperscript{172} This means that these countries do not find anything in Article 39.3 that would prevent them from relying on the originator’s testing data to authorize a subsequent medicinal product which contains the same new chemical entity of the originator’s product. And, implicitly, this means that if any of these countries protect testing data by exclusivity, it might not be due to the TRIPS Agreement but to a national public policy choice based on the interests of the member concerned. See Carvalho, supra note 21 at 278-9.


\textsuperscript{174} See infra note 184.

\textsuperscript{175} Egypt expressed its view that it understands the obligation under Article 39.3 as the:

[protection] of data against unfair commercial use’ must be interpreted in light of the Paris Convention (1967, Article 10 \textit{bis}) and the TRIPS Agreement Article 39.1. Such unfair commercial use would include that use which results from acts of competition that are contrary to honest commercial practices as indicated in the TRIPS Agreement Article 39.2 and the adjoining footnote. As to the use of data or relying on data of a previous applicant in the examination of similar products of a subsequent applicant, we reiterate that the law (still in draft form) is definitive in obligating the concerned regulatory authority to protect the data against disclosure and unfair commercial use.

India, Italy, Pakistan, Sir Lanka, Sweden, the Slovak Republic, and The Netherlands. For example, although Canada provides for DE, it responded to the question “[what] legislation or regulations exist to fulfill Canada’s obligations under Article 39.3 of the TRIPS Agreement?” by stating:

[there] is no requirement that Article 39.3 of the TRIPS Agreement be implemented by legislation or regulations. By administrative practice reflecting common law principles and consistent with Section 20 of the Access to Information Act, test or other data which are submitted to the Government of

176 See WTO document IP/Q3/IPA/1, of August 13, 1997, online: WTO
177 When asked about how it protects pharmaceutical TD against disclosure and unfair commercial use, the following answer was provided by India: “[common] law, service regulations and the provisions against disclosure of data in the Drugs and Cosmetics Rules[…] [in rule 53] provides that except for the purpose of official business or when required by a Court of law, an Inspector under the Drugs and Cosmetics Act, 1940 shall not without the sanction in writing of his official superior, disclose to any person any information acquired by him in the course of his official duties” (emphasis mine). See WTO, Review of Legislation: India, WTO document IP/Q/IND/1, IP/Q2/IND/1, IP/Q3/IND/1, IP/Q4/IND/1, of 8 October 2003, at 30, online: WTO
179 Pakistan stated that “[any] subsequent applicant would… not be given access to data or information submitted by an earlier applicant. See WTO, Review of Legislation: Pakistan, WTO document IP/Q/PAK/1/Add.1, IP/Q2/PAK/1/Add.1, IP/Q3/PAK/1/Add.1, IP/Q4/PAK/1/Add.1, of 9 June 2004, at 29, online: WTO
Canada, as a condition of approving the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities, are not disclosed to third parties.\textsuperscript{184}

In a communication to the TRIPS Council,\textsuperscript{185} the African Group along with many other WTO members vehemently rejected an interpretation of the obligations under Article 39.3 that would lead to any exclusive rights of the kind afforded to other intellectual property categories such as patents and copyright. They maintained:

Article 39.3 of the TRIPS Agreement leaves considerable room for Member countries to implement the obligation to protect test data against unfair competition practices. The Agreement provides that ‘undisclosed information’ is regulated under the discipline of unfair competition, as contained in Article 10bis of the Paris Convention. With this provision, the Agreement clearly avoids the treatment of undisclosed information as a ‘property’ and does not require granting "exclusive" rights to the owner of the data.\textsuperscript{186}

Accordingly, there has not been a “state practice” subsequent to the conclusion of the TRIPS Agreement that might be considered a ““concordant, common and consistent” sequence of acts or pronouncements which is sufficient to establish a discernable pattern that implies an agreement of the parties [to the TRIPS Agreement] regarding its interpretation”.\textsuperscript{187}

In sum, a good faith interpretation of Article 39.3, in accordance with the principles of treaty interpretation contained in Article 31 of the Vienna Convention,\textsuperscript{188}


\textsuperscript{186} Ibid. (emphasis mine).


\textsuperscript{188} Article 31, General Rule of Interpretation, of the Vienna Convention reads:

1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

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clearly indicates that the term “unfair” may not encompass the practice of authorizing the marketing of bioequivalent generic drugs by national health regulatory agencies based on their own or foreign previous approvals. This conclusion is consolidated further by the legislative history of Article 39.3 and the subsequent practice of WTO members. However, it is not enough to explore the meaning of the term “unfair” only to delineate the nature and extent of the obligation to protect TD against “unfair commercial use”; Therefore, I next consider the meaning of the term “commercial”.

B. Use of the Data must be “Commercial”

A consensus exists that the obligation to protect TD against unfair commercial use does not extend to all possible uses of the data by third parties, including governmental agencies. This obligation only covers uses that are commercial in nature. However, a disagreement exists as to whether the use of the data by health regulators, be it actual or virtual, to authorize generic medicinal products is a commercial use defined under Article 39.3. This disagreement is dominated by two major opposing views.

First, proponents who consider this regulatory practice to constitute a commercial use claim that originators develop the TD for a specific application: using the safety and efficacy data to obtain marketing authorization for the relevant medicinal product. They add that data pertinent to a particular product have no utility to manufacture or market

2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:

(a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty;

(b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.

3. There shall be taken into account, together with the context:

(a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;

(b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;

(c) any relevant rules of international law applicable in the relations between the parties.

4. A special meaning shall be given to a term if it is established that the parties so intended.

See Vienna Convention, supra note 142 Art. 31.
different products. Accordingly, they argue that the only\textsuperscript{189} envisaged and potential commercial use of the data is to support an application for marketing approval of a medicinal product. Therefore, national health regulators may not rely on TD submitted by the originator to authorize competing products. On the contrary, if they require originators to provide full and complete TD to establish the safety and effectiveness of an innovative medicinal product, regulators should not accept only the submission of bioequivalence data from competitors.\textsuperscript{190}

Opponents of this view argue that a government’s reference to originators’ data to evaluate the safety and effectiveness of similar products does not constitute a commercial use.\textsuperscript{191} Although reliance by regulators on the data leads to a new market entry, which represents a commercial result, such an outcome does not render a legitimate sovereign practice to constitute, as such, a commercial use.\textsuperscript{192} In addition, to characterize a particular use as commercial, it has to be carried out by an entity actually engaged in commerce. This characterization does not generally fit the legitimate regulatory functions of states involving marketing approval of medicinal products.\textsuperscript{193}

To regard reliance by regulators on originators’ TD as a commercial use of the data, is an ill-founded claim and lacks authority. First, it is based on a flawed argument that supporting an application for marketing is the only possible commercial use of the data. Second, it runs against an impartial interpretation of Article 39.3 in accordance with the principles of treaty interpretation since it fails to properly consider the negotiating

\textsuperscript{189} Meitinger contends that “[it] can even be said that the use of the data in market authorization procedures of subsequent applicants is the only ‘commercial use’ of the data that can logically be meant by the provision. Since the data are specifically created and compiled for the purposes of documenting approval requests, no other commercial use of them can be imagined”. See Meitinger, supra note 113 at 131-2.

\textsuperscript{190} Ibid; Carvalho, supra note 21 at 271; Razvan Dinca, “‘Bermuda Triangle’ of Pharmaceutical Law: Is Data Protection a Lost Ship?” (2005) 8(4) Journal of World Intellectual Property 517 at 528; PhRMA 2010, supra note 171; and Shamnad, Basheer, “Protection of Regulatory Data under Article 39.3 of TRIPS: the Indian Context”, Intellectual Property Institute (IPI), Forthcoming, at 28-9, online: SSRN <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=934269> (date accessed and downloaded: May 16, 2010). (In support of his claim that an interpretation of the expression “unfair commercial use” shall cover government’s direct and indirect reliance on originator’s testing data as constituting commercial use, Shamnad states that any other interpretation would “render the obligation to protect against ‘unfair commercial use’ redundant and impose a mere ‘non-disclosure’ obligation on the regulatory agency”).

\textsuperscript{191} See Correa “Unfair Competition”, supra note 20 at 78; Correa “Protection of Data”, supra note 113 at 29-30; Reichman, “Rethinking”, supra note 21 at 20-1; and Reichman “Undisclosed”, supra note 20 at 12.

\textsuperscript{192} See Correa “Unfair Competition”, supra note 20 at 78.

\textsuperscript{193} Ibid.
history of the relevant provisions. Third, it reads into Article 39.3 of the TRIPS Agreement something that is not there. I will elaborate on each of these three grounds.

It is not true that the one and only commercial use of TD is to support applications for marketing approval of medicinal products as claimed by proponents of DE. For example, pharmaceutical originators use their TD for other commercial purposes in order to enhance the marketability of their products, and they use them to influence prescribers’ decisions. Originators publish their TD, through peer-reviews, to emphasize the positive characteristics that data attribute to their products. 194 Alongside clinic visits, these publications may constitute the main source from which physicians derive their knowledge about a drug. 195 Describing how TD published in peer-reviews contribute to a physician’s decision in prescribing a drug, Professor Marley stated:

[commonly], when prescribers reach for their prescription pads, they choose an individual drug from a number of classes or from within the same class. They assume that the drug chosen is both efficacious and safe. *If they wish to check their assumptions, even though the licensing application is confidential, they will be able to find peer-reviewed efficacy and safety data in the literature.* 196

Even negotiators of the TRIPS Agreement thought of commercial uses of TD by governments other than for supporting marketing applications. Under the subheading “Government Use”, the Chairman’s Report on the Status of Work in the Negotiations, under Approach A to the protection of TD, listed the following:

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194 Professor Eadie (Emeritus Professor of Queensland University’s Medicine Department and a former chairman, Australian Drug Evaluation Committee) arguing that it is necessary to disclose TD submitted to health regulators said:

> [scientifically] valid information concerning trials with unfavourable outcomes would be available. These negative studies currently rarely reach the public domain. Toxicological data about drugs which have been rejected for marketing would provide a valuable additional resource for predicting, on the basis of analogy, potential problems with similar drugs (emphasis mine).

See M.J. Eadie, “The Secrecy of Drug Regulatory Information” (2002) 25 Australian Prescriber Review 78, at 78, online: Australian Prescriber <http://www.australianprescriber.com/magazine/25/4/78/9/> (date accessed: May 16, 2010). In fact, the non-publication of negative studies is a form of commercial use of the data which provides originators with marketing advantages. In addition, this negation shelters the originator from having negative campaigning by competitors, which would have had a determinant impact on the fate of the product altogether had such studies been disclosed.


196 Ibid. (emphasis mine).
3Ab.1 PARTIES which require that trade secrets be submitted to carry out
governmental functions, shall not use the trade secrets for the commercial or
competitive benefit of the government or of any person other than the right holder
except with the right holder's consent.197

Accordingly, commercial use of the data is not exclusively limited to supporting
marketing approvals. One would also think of government uses that might constitute
commercial undertaking, at least theoretically. For instance, data could be relied on to
register a drug manufactured under a compulsory license issued for the purpose of
governmental use. A second example would be the case where generic pharmaceuticals
are manufactured by state-owned enterprises. Furthermore, it would constitute a
commercial use, against which data should be protected, “if government employees
having access to the data submitted were subsequently to make use of the commercially
valuable know-how it conveyed”198.

This flawed “only commercial use” claim became the main basis for arguing that
an interpretation of the expression “unfair commercial use” could only mean reliance on
originator’s data by regulators; hence, TRIPS’ negotiators intended to protect TD against
such reliance.199 However, a review of the relevant GATT documents which record
negotiations on this issue leaves no doubt that negotiators refused to restrain this
particular practice by governments. This refusal was vehement and constant whenever
proposals were tabled by delegates advocating a ban on reliance by regulators on
originators’ data. The following historical facts strongly support this finding. First, the
US proposal to prevent governments from relying on TD as drafted under the subheading
“Conditions on Government Use” as part of the “Suggestion by the United States for

197 See GATT, Status of Work in the Negotiating Group – Charmin’s Report to the GNG, GATT document
198 See Reichman “Undisclosed”, supra note 20 at 12.
199 The adjective “commercial” covers not only activities considered commercial stricto sensu, but also
extends to those activities of complementary function, claims advocates of this view; see Shamnad, supra
note 190 at 29.
200 Given that provisions and articles of treaties such as the TRIPS Agreement, negotiated by diplomats, are
sometimes ambiguously drafted, does not suggest that such provisions or articles reflect the view of or
proposal made by a given party but not those of other parties. This is the case of the language used in many
provisions of the TRIPS Agreement, including, but not limited to, Articles: 6, 27.1, 30, and 31.
Achieving the Negotiating Objective” was rejected altogether by negotiating delegates of most countries.201

Second, as negotiations proceeded, the Swiss delegation tabled a similar proposal, but it met no acceptance whatsoever from the various delegates.202 However, in an attempt to soften opposition to this proposition, the EU delegate tabled a subsequent proposal that embraced comparable language, as revealed in documentation from the negotiations.203 The proposal, cited above,204 is partially reproduced as follows “(b) Contracting parties, when requiring the publication or submission of test or other data, the origination of which involves a considerable effort, shall protect such efforts against unfair exploitation by competitors.” The wording of this proposal does not suggest banning reliance on TD by regulators. In other words, the order of the terms comprising the text, in which the noun exploitation205 is followed by the word competitors, clearly indicates that it is the unfair “commercial use” by competitors, not use by governments, against which protection should be provided.

Third, disagreement on the issue evidently had persisted up until the time of the Brussels Draft TRIPS Agreement, of December, 1990.206 The Draft contained a provision on data protection, which bracketed207 a significant part of the text therein, including the following: “[the data may not be relied upon for the approval of competing products for a

201 See GATT document MTN.GNG./NG11/W/14?Rev.1, supra note 145 and accompanying text.
202 On the issue of governmental reliance, the proposal, in part, reads:
(v) […] Governmental agencies shall not be entitled to use the information for commercial purposes. They may disclose it only to the extent indispensable to inform the general public about the actual or potential danger of a product (emphasis mine).

203 Reference here is made to GATT’s document MTN.GNG/NG11/W/79, supra note 197 at 43. In this document, the Chairman identifying them by as A and B compiled the different proposals and expressions presented by the various negotiating delegates.
204 See EU proposal, supra note 145 and accompanying text (emphasis mine).
205 The concise Oxford Dictionary defines “exploit” as “1. Make use of and derive benefit from (a resource) [or] 2. Make use of unfairly; benefit unjustly from the work of”.
206 See supra note 157 and accompanying text.
207 The practice during the Uruguay negotiations was to place between brackets texts on which no consensus was achieved, indicating a disagreement. See Gilbert R. Winham, “An Interpretative History of the Uruguay Round Negotiations” in Patrick F. J. Macrory, Arthur E. Appleton, Michael G. Plummer, eds., The World Trade Organization : legal, economic and political analysis (New York: 2005 Springer, 2005) 3 at 7.
reasonable time, generally no less than five years[208] Such wording, had it survived, would have meant that the use of the data by governments would be covered and that data must be protected against this use as such. In other words, the unqualified phrase “the data may not be relied upon” would have banned reliance on originators’ data not only by competitors, but also by governments.

Having this phrase placed between brackets, however, indicates that negotiators were not willing to outlaw government reliance on originators’ data, which, ultimately, led to the whole bracketed text being dispensed with, as the text of the Final Draft Act of December, 1991 (Dunkel Draft) clearly demonstrates. The final Draft provision relating to data protection, which was largely adopted by Article 39.3 of the TRIPS Agreement, reads:

3. PARTIES, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, PARTIES shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Finally, the argument that governments’ reliance on TD constitutes a commercial use should be rejected since it constitutes a reading into Article 39.3 of obligations that are not contained in it nor intended therein, and which are even rejected by the drafters of the TRIPS Agreement. It seems that this line of argument has been interpreting Article 39.3 to include the language in the square-bracketed text mentioned earlier, which negotiators repudiated in the Dunkel Draft and, ultimately, the final text of Article 39.3 indicates. Since the article “cannot possibly mean what it would have meant had the bracketed text of the Brussels Draft of 1990 been carried over into either the Dunkel Draft or the Final Act of 1994”, it would amount to reading into the article the

208 Ibid. (emphasis mine).
209 Replacing the term “PARTIES” with the word “Members” was the only difference between the draft text and the final text of Article 39.3. See GATT, Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT document MTN.TNC/W/FA of 20 December 1991 (hereinafter “Dunkel Draft”), art. 39.3, online: WTO Homepage <http://www.wto.org/gatt_docs/English/SULPDF/92130093.pdf> (date accessed: May 16, 2010).
210 Ibid. at 75.
expurgated, bracketed text in order to characterize reliance as a “commercial” use. In addition, for an activity to be considered “commercial”, it should be carried out by a person actually engaged in commerce.\textsuperscript{213} Regulatory agencies are not involved in actual commerce. Therefore, it cannot be envisaged to argue that regulatory reliance on originators’ data represents a commercial use without explicit language indicating so.

\textbf{C. There must be a “Use” of Data}

Article 39.3 obliges WTO members to protect drug originators’ TD against unfair commercial \textit{use} without their consent. Therefore, there would be no recourse to Article 39.3, unless the complained-of conduct unambiguously constitutes a use of the data. The article, however, does not define the meaning of “use”, nor does it illustrate it by listing specific practices as prohibited uses; regulators’ reliance on the data of originators is, of course, not mentioned in the article. To determine whether such a practice constitutes a use of the data, an appreciation of how, in reality, regulators evaluate the safety and efficacy of generic medicinal products is constructive.

Correa has summarized the various approaches that regulators follow in evaluating generics for marketing authorization purposes. They include the following:

a) require the second-entrant to produce its own testing and other data or to obtain an authorization of use from the “originator” of the data;

[b…],\textsuperscript{214}

\textsuperscript{212} As to Bayer’s argument that “the Minister must explicitly or implicitly have examined and relied upon confidential information originally filed by the innovator”, the response of the Court of Appeal of Canada was that “[it] would require that the Court read into the regulation the word ‘indirectly’ or some other modifier to capture the idea that whenever a generic manufacturer files an ANDS [Abbreviated New Drug Submission] comparing its product to an innovator’s product”. The court also concluded that “[it] cannot read words into the regulation”. See \textit{Bayer inc.}, supra note 83 at Paras. 12 & 5, respectively.

\textsuperscript{213} See Correa, “Protection of Data”, supra note113 at 30; Ladas observed that:

\textit{[the] general clause of Article 10bis, in establishing as its foundation “honest usages,” looks to the relations between competitors and to the interests of customers, and these provide an objective test which reflects an evolving pattern of competition in most of the present world...By definition, competition in commerce refers to the efforts of two or more persons, acting independently, to secure the custom of third parties, with the results that one may increase the sale of his goods and reduce the sale of the goods of the other.}

See Ladas, supra note 148 at 1688, cited in Correa, ibid (emphasis added by Correa).

\textsuperscript{214} The omitted part of the quote reads: “allow the second-entrant to rely on the ‘originator’s’ data against payment of compensation to the ‘originator’ (when the ‘originator’ has not given his consent for the use of the data). I have omitted this approach since it has not been followed in the field of pharmaceutical regulation. This approach is implemented in the US in accordance to the provisions of the Federal
c) examine and rely upon the data submitted by the “originator” to evaluate the second-entrant application;

d) approve a second entry marketing application without examining or otherwise relying upon confidential information submitted by the originator.215

Since reliance on the data is consented to, authorizing a generic drug using the first mechanism is not a contentious issue. However, the other two mechanisms are problematic. Regardless of the approach followed, a threshold for a generic manufacturer seeking to register a product through any of these means is to establish an essential similarity216 between its product and the authorized reference product; bioequivalence,217 of course, is a necessity to satisfy the similarity conditions.218

Insecticide, Fungicide, and Rodenticide Act (FIFRA) enacted to protect human health and preserve the environment through regulating the use and sale of pesticides. According to this system, second entrants are granted a compulsory license on the testing data submitted by originators. Such a license would, generally, take effect during the last five years of the data exclusivity period (15 years). The originator has a right to compensation to be paid by the second entrant on the basis of cost sharing. See Section 136a of Subchapter ii of Chapter 6, 7 U.S.C; for a review of the FIFRA system and implementation thereof, see Judit Rius Sanjuan et al., A Cost Sharing Model to Protect Investments in Pharmaceutical Test Data, (2006), online: Consumer Project on Technology (presently Knowledge Ecology International) <http://www.cptech.org/publications/policybrief-no1-cost-sharing.pdf> (date accessed: May 16, 2010) [Cost Sharing].

According to Article 10 of Directive of 2001/83/EC, the test is that a subsequent applicant shall not be required to provide the results of toxicological and pharmacological tests or the results of clinical trials if he can demonstrate that his product is “essentially similar to a medicinal product authorized in the Member State concerned” (emphasis mine); see Directive 2001/83/EC, supra note 23 Art. 10(1)(a)(iii). The European Court of Justice held that a medicinal product is considered to be essentially similar to another “where it satisfies the criteria of having the same qualitative and quantitative composition in terms of active principles, of having the same pharmaceutical form and of being bioequivalent, unless it is apparent in the light of scientific knowledge that it differs significantly from the original product as regards safety or efficacy”. See E.C.J. R v Licensing Authority ex p. Generics, Case C-368/96, [1998] ECR I-7967 at Paragraph 36. According to this definition, if two products contain the same active moiety, notwithstanding in the form of different salts, esters, or other derivatives, they should be normally essentially similar. See Paul Garland, supra note 78.

The word bioequivalence “refers to the speed and absorption by the body of the pharmaceutical, the active principle or its therapeutic fraction”. See Jean-Yves Videau, “Generic Drugs: The Hidden Issues of Quality and Costs” (2000) 14 WHO Drug Information 77 at 79, online: WHO Homepage <http://apps.who.int/medicinedocs/pdf/h1463e/h1463e.pdf> (date accessed: July 4, 2010). Two products are regarded as being bioequivalent “if they are pharmaceutical equivalents or alternatives and if their bioavailabilities (i.e. the rate and extent of their absorption into the body and transfer to the site of action) after administration in the same molar dose are similar to such a degree that their effects, with respect to both efficacy and safety, will be essentially the same”. Ibid. at Para. 31.

Ibid.
The research-based industry and others argue that when a regulator registers a subsequent product pursuant to the practice depicted under case (d) above, the agency inevitably uses the originator’s data, at least implicitly. Such a claim, as the Canadian Court of Appeal correctly observed, would result in “invariably providing a minimum five years of market protection to an innovator when an ANDS [Abbreviated New Drug Submission] is filed by a generic manufacturer.” The court, even though Canadian law recognizes exclusivity, concluded that “[the] appellant’s [Bayer Inc.] argument reads out of the regulation the option given to the Minister as to whether or not to examine and rely on the confidential information filed by the innovator.” Accordingly, it is not realistic to contend that the regulator has used the originator’s TD when no actual examination of the data is involved. Furthermore, when regulators rely on either publicly available data, as published in scientific literature, or on foreign approvals issued to the reference drug, there is no use whatsoever of the data. In these cases, the data simply would not have been submitted to the regulator at all. In other words, how could the regulator use something not in its possession in the first place?

In sum, the above analysis has shown that under Article 39.3 of the TRIPS Agreement, WTO members are mandated to protect TD against unfair commercial use and disclosure, except if necessary to protect the public or when steps are taken to ensure the data are protected. This obligation does not necessarily mean protecting all the data provided to regulators by originators of new drugs. The data must be required by the regulator and must relate to a product containing a new chemical entity as its active molecule. Furthermore, the data must be confidential (undisclosed), and involve considerable effort to generate.

219 That is basically the argument of Bayer Inc. in, Bayer Inc. See, Bayer, supra note 83; PhRMA 2010 Special 301 Submission, supra note 171. The US was quoted claiming that “[article] 39 para.(3) means that generic companies are not allowed to derive commercial benefit from the innovator’s test data”(emphasis in original). See Correa, “Protection of Data”, supra note 113 at 32, citing Priapantja Priapantja, “Trade Secret: How Does This Apply to Drug Registration Data?” (2000) paper presented at “ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals”, Department of Health and World Health Organization, Jakarta, 24 May 2000, at 6.
220 See Bayer Inc., supra note 83 Para.9.
221 Ibid.
222 It has been argued that even when there is no direct reliance on the data (actually examining the originator’s dossier) an implicit reliance still constitutes a commercial use of the data whenever a generic product is registered by establishing its safety and effectiveness on the basis of its bioequivalence to the reference authorized product. See Bayer Inc., supra note 83.
However, Article 39.3 does not mandate WTO members to provide originators of TD with exclusive rights. DE is a TRIPS-Plus measure that goes beyond the minimum obligations to protect data against “disclosure” and “unfair commercial use”. This mandate may not comprise the practice of reliance on originators’ TD, without their consent, by health regulators. Such a practice, of course, is not unfair nor, as such, does it constitute a commercial use. Actually, it may not constitute a use of the data when the safety and efficacy of generic drugs are established without material examination of originators’ data, or when evaluation is based on foreign marketing authorization of a reference product. Under this last scenario, even indirect reliance by manufacturers of generics on an originator’s data does not constitute a use, since they “do not use the originator’s data—in fact they do not even have access to them”.223

Given that Jordan is not obliged under Article 39.3 to provide for DE, it becomes necessary to look into other possible reasons to explain why Jordan adopted a DE regime. The text of the USJFTA is a potential place to find an answer to this question. Accordingly, the relevant provisions of this particular agreement shall be examined next.

4. Is Data Exclusivity Mandated by the US-Jordan Free Trade Area Agreement?

The USJFTA is the first bilateral agreement providing TRIPS-Plus standards of IPRs protection, concluded by the US with a small developing country after singing the TRIPS Agreement in 1994.224 Relative to other covered topics, a considerable part of the


agreement’s text, Article 4, is devoted to the availability, acquisition, scope, maintenance, and enforcement of intellectual property rights.225 While Article 4 embraces the relevant provisions on intellectual property generally, Paragraph 22 “Measures Related to Certain Regulated Products” delineated the parties’ obligations vis-à-vis protection of TD.226 The paragraph also contains two footnotes, 10 and 11. As I will explain below, these footnotes added further commitments and extended the scope of the concept of “New Chemical Entity”, contained in the main text, to include new uses for old chemical entities.227

Thus, what exactly are the extent and scope of the obligations for the protection of regulatory data under this article and in light of its two footnotes? Without thorough

[225] See the USJFTA, supra note 5 Art. 4. The proliferation of FTA agreements such as the USJFTA after the creation of the WTO in 1994 led the WTO Secretariat, as part of its report on the seven Trade Policy Review of the of the United States, to report its concerns about certain risks associated with the growing number of “preferential” agreements signed by the US stating that:
[the] expanding U.S. preferential network could serve to draw its partners more closely into the multilateral trading system, the acknowledged ‘first-best’; however, care should be taken that negotiating and administrative resources are not distracted away from the multilateral system, that vested interests are not created that complicate multilateral negotiations, and that trade and regulatory structures attendant on preferential agreements do not hinder trade.

[226] Paragraph (22) of Article 4 of the USJFTA reads:
22. Pursuant to Article 39.3 of TRIPS, each Party, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products that utilize new chemical entities, [footnote omitted] the submission of undisclosed test or other data, or evidence of approval in another country, [footnote omitted] the origination of which involves a considerable effort, shall protect such information against unfair commercial use. In addition, each Party shall protect such information against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the information is protected against unfair commercial use (emphasis mine except the Italicized word “TRIPS”).

[227] See the USJFTA, supra note 5 Art. 4.

Footnotes 10 and 11 read, respectively:
10. It is understood that protection for “new chemical entities” shall also include protection for new uses for old chemical entities for a period of three years.
11. It is understood that, in situations where there is reliance on evidence of approval in another country, Jordan shall at a minimum protect such information against unfair commercial use for the same period of time the other country is protecting such information against unfair commercial use (emphasis mine).
analysis, some have referred to the USJFTA as mandating DE.\textsuperscript{228} I argue that it does not require Jordan to establish a regime that goes beyond protection against “unfair commercial use” and disclosure, as required under Article 39.3 of the TRIPS Agreement. The USJFTA provisions, however, modify certain conditions relating to protection-eligibility, and they require a minimum three-year period of protection for data related to “old chemical entities”.\textsuperscript{229}

The USJFTA mandates its parties to protect TD against “unfair commercial use”. However, it does not define the phrase “unfair commercial use”. Therefore, to determine the meaning, nature, extent, and scope of this obligation, the analysis will again appeal to the principles of treaty interpretation as detailed in Article 31 of the Vienna Convention: to give treaty words their ordinary meaning \textit{in their context} and in the light of its object and purpose. The main objective will be to ascertain whether Article 4.22 deviated from the standard of TD’s protection against “unfair commercial use” under the TRIPS Agreement as explained earlier, and, if this is the case, to what extent. In addition, the text of Article 4.22 will be compared with some of its counterparts in other selected FTAs concluded by the US.\textsuperscript{230}

4.1. Protection of regulatory data is “Pursuant to Article 39.3 of TRIPS”

Paragraph 22 begins with the proviso “\textit{Pursuant to Article 39.3 of TRIPS}”. This stipulation contextualizes the protection of RD under the USJFTA within the ambit of Article 39.3 of the TRIPS Agreement.\textsuperscript{231} Therefore, the above-analysis of the obligations under the TRIPS’ article is equally applicable to the interpretation of the USJFTA relevant provisions, unless the text clearly indicates otherwise. In addition, Article 1 of the USJFTA acknowledges the rights and obligations of the parties under all multilateral

\textsuperscript{228} See multiple references, supra note 224.
\textsuperscript{229} For the text of footnote10 of the agreement, see supra note 5.
\textsuperscript{230} Beside Jordan, the United States has free trade agreements with 16 countries that are in force: Australia, Bahrain, Canada, Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Israel, Mexico, Morocco, Nicaragua, Oman, Peru, Singapore, Trans-Pacific Partnership. In addition, it has signed another three free trade agreements with Colombia, Korea, and Panama that are not in force yet. See USTR website at: \url{http://www.ustr.gov/trade-agreements/free-trade-agreements} (date accessed: June 20, 2010).
\textsuperscript{231} See the text of the article, supra note 2.
agreements, including the TRIPS Agreement, to which both the US and Jordan are parties, declaring at paragraph 2:232

[the] Parties reaffirm their respective rights and obligations with respect to each other under existing bilateral and multilateral agreements to which both Parties are party, including the Marrakesh Agreement Establishing the World Trade Organization (“WTO Agreement”).233

This paragraph preserves the flexibility available under Article 39.3 of the TRIPS Agreement, unless otherwise tightened by Article 4.22 of the USJFTA and the two footnotes thereto. Changes to the requirements of protection were indeed made in the USJFTA. Whether these changes are tantamount to an obligation of DE is an issue that I will address by investigating the following points. First, I identify the subject matter, nature, and scope of the changes compared to the text of Article 39.3 of the TRIPS Agreement. Second, I determine if the identified changes necessarily intended to mandate the grant of an exclusive right over the use of TD.

4.2. Differences between Article 39.3 of the TRIPS and Article 4.22 of the USJFTA

Before singling out the differences between the USJFTA Article and its TRIPS counterpart, it is important to emphasize that the text of Article 39.3 of the TRIPS Agreement tracks that of Article 4.22 of the USJFTA almost word for word. With the exception of two footnotes, only two differences distinguish the compared articles. These include the proviso at the outset of the USJFTA paragraph, discussed above, and the disjunctive phrase “or evidence of approval in another country”, which requires the protection of not only confidential information submitted to the regulator of one of the parties to the agreement, but also of data submitted to third countries.234

The changes introduced by the footnotes are as follows. Footnote 10 expands the protection of TD to include data related not only to new chemical entities, but also to new

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232 It is worthwhile to mention here that the last FTA Agreement to have a provision identical or similar to Article 1.2 of the USJFTA was the United States-Dominican Republic-Central America Free Trade Agreement (CAFTA). However, subsequently concluded FTAs do not have the same provision, the United States – Australia and United States – Morocco FTAs are two examples.
233 See the FTA text, supra note 5 art.1.
234 See the text of Article 4.22 of the USJFTA Agreement, supra note 5.
uses for old entities. Footnote 11 mandates varying periods of protection, the duration of which depend on the country of a reference registration for the medicinal product undergoing the process of marketing authorization in either of the agreement’s parties.

4.2.1. Protection Coverage Expanded

Unlike the TRIPS Agreement, the USJFTA requires Jordan to extend protection coverage to data provided to foreign regulators. It also extends protection to data related to old chemical entities. Jordan must protect such data notwithstanding that they are neither required by nor submitted to JFDA. This extension of coverage ensued from equating the submission of evidence of approval in another country, as a condition of approving the marketing of a pharmaceutical product, with the requirement to submit undisclosed test or other data.

The purpose of this provision covers a JFDA regulatory practice precisely. To prove the safety and effectiveness of their pharmaceutical products, the agency used to, and still does, require originators of medicinal products seeking marketing authorization in Jordan to submit evidence of foreign approvals. Hence, Footnote 11

235 Ibid. footnote 10.
236 Ibid. footnotes 10 and 11.
237 Ibid.
238 Although the Criteria of Registration of drugs in Appendix 1 still have the submission of pertinent certificates of free sale listed as a requirement, JFDA maintains that it evaluates the safety, effectiveness, and quality of new drugs based on pre-and clinical information submitted by sponsors and not based on foreign issued approvals. (Interview with a high ranking JFDA official in Amman, Jordan on August 9, 2009 – conformed via electronic correspondence).
239 Part Two, “Certificates, Information and Administrative Documents about the Product”, of Appendix (1), “Requirements of the Drug Registration File” to the Criteria for Drugs Registration, requires persons applying to register a new drug in Jordan to submit a dossier that includes:

2-a Free Sale Certificate from the Country of Origin issued by the competent parties in accordance with the approved list of the Administration duly legalized with due observance to the text of Article (6) containing the following:
1- The trading name of the drug in the Country of Origin (in case the trading name differs from that in the Country of Origin, a clarification from the official competent parties is requested).
2- Number and date of registration or permission of marketing in the Country of Origin.
3-Names of the active and non active substance(s) and their concentrations.
4- A statement that the product is actually being sold in the Country of origin with the same composition, in case that it is not being sold there, to demonstrate the reasons for such, provided a Free Sale Certificate duly legalized is submitted showing that it is being actually sold in a country approved by the Administration with the same composition.
was intended to clarify the obligation to protect TD when there is reliance on foreign marketing approvals by Jordan,²⁴⁰ but not the US. It states “…Jordan shall at a minimum protect such information against unfair commercial use for the same period of time the other country is protecting such information against unfair commercial use”.²⁴¹ When there is reliance on foreign approvals, this obligation bans Jordan from denying protection to foreign-submitted TD against unfair commercial use on the basis that JFDA does not require the submission of the data or that the data is not submitted to JFDA at all.

For reliance on foreign approvals to trigger data protection, as provided for under the USJFTA, three conditions must be met. First, the safety and efficacy of the drug undergoing registration in Jordan is established by reliance²⁴² on a foreign marketing approval for the same drug. Second, the relied-upon foreign approval is granted based on a submission of the necessary TD by the originator. And, third, the law of the third country protects the foreign-submitted data (hereinafter FSD) against unfair commercial use, and such data still enjoy this protection when the drug concerned is registered with JFDA.

However, the mere reliance on a foreign approval does not by and of itself lead to the protection of FSD. To qualify for protection, the data must satisfy all the above discussed eligibility requirements under Article 39.3 of the TRIPS Agreement, reproduced in Article 4.22 of the USJFTA. Therefore, it logically follows that if the FSD

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²⁴⁰ The Agreement assumes Jordan to be the only party who relies on foreign approvals. Hence, this rule applies to Jordan only.

²⁴¹ See USJFTA, supra note 5 at footnote 11(emphasis mine).

²⁴² Footnote 11 speaks of “…situations where there is reliance on evidence of approval in another country”, where the noun “reliance” is not qualified by other terms. This indicates that it was meant to encompass reliance by both competitors and the regulator. Ibid. footnote 11.
do not satisfy all or any of these conditions, JFDA is not obliged to protect any ineligible data.\textsuperscript{243}

Moreover, it should be emphasized here that the mandate under the USJFTA to protect FSD does not prohibit reliance on foreign\textsuperscript{244} approvals by either the JFDA or by third persons to register a similar or identical product. This inference is valid when the USJFTA’s provision is compared with texts of other FTAs addressing the same subject matter. That is, whenever the parties to these agreements have intended to prevent regulators and/or manufacturers of generics from relying on foreign approvals, they have used explicit and unambiguous language.\textsuperscript{245}

\textsuperscript{243} This conclusion is based on the language of Article 4.22 of the USJFTA. In this article, the disjunctive phrase “or evidence of approval in another country” was placed right after the following: “[pursuant] to Article 39.3 of TRIPS, each Party, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products that utilize new chemical entities, [footnote omitted] the submission of undisclosed test or other data”. This language structure clearly indicates that requiring originators to submit evidence of marketing approval of their drugs in third countries is equivalent and tantamount to mandating them to submit undisclosed TD, related to a new chemical entity, the generation of which involves considerable efforts. Ibid.

\textsuperscript{244} It is reasonable to conclude that reliance on prior national approvals to register similar or identical products is not banned under the provisions of the USJFTA if we consider the language of Article 17.10 of the US-Chile FTA. The latter article prohibits the registration of generic medicines not only based on approvals granted to originators by foreign regulators, but also based on those of the Chilean regulator. The article states “of the approval granted to the party submitting such information”, without qualifying this ban only to foreign approvals. The relevant part of the article reads “...the Party shall not permit third parties not having the consent of the person providing the information to market a product based on this new chemical entity, on the basis of the approval granted to the party submitting such information” (emphasis mine). See The United States-Chile Free Trade Agreement, entered into force on January 1, 2004, Art. 17.10, online: USTR Homepage \textlangle http://www.ustr.gov/trade-agreements/free-trade-agreements/chile-fta/final-text\textrangle (date accessed: June 21, 2010).

\textsuperscript{245} For example, Article 15.10 of the Dominican Republic – Central American – United States Free Trade Agreement (CAFTA-DR) in part reads:

\begin{quote}
\textit{if} a Party permits, as a condition of approving the marketing of a new pharmaceutical...product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in the other territory, or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory (emphasis mine).
\end{quote}

See the text of Article 15.10 of The Dominican Republic – Central America – United States Free Trade Agreement, signed August 5, 2004, online: USTR Homepage \textlangle http://www.ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file934_3935.pdf\textrangle (date accessed: June 21, 2010); the US-Singapore Free Trade Agreement also contains a similar provision, which reads:

\begin{quote}
\textit{if} a Party provides a means of granting approval to market products specified in paragraph 1 on the basis of the grant of an approval for marketing of the same or similar product in another country, \textit{the Party shall defer the date of any such approval to third parties not having the consent of the party providing the information in the other country for a period of at least five years from
\end{quote}

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The USJFTA, in Footnote 10 to Article 4.22, broadens the scope of protection for new chemical entities to “include protection for new uses for old chemical entities”. This extension constitutes a TRIPS-Plus standard. The USJFTA, however, does not define what constitutes a new use. It leaves this issue to its members’ discretion, and for them to adopt the definition that they consider most appropriate for advancing their interests. This would include preventing abuses such as “evergreening data exclusivity” and limiting protection to data related to a new use that is considered a significant clinical benefit (new indication) compared to existing products.

4.2.2 Introducing Different and Confusing Minimum Time Periods of Protection

See Article 16.8(2) of the United States – Singapore Free Trade Agreement, entered into force on January 1, 2004, online: USTR Homepage (date accessed: June 21, 2010). Articles 17.10 (c) and 15.10 (1) of the US-Australia and of the US-Morocco Free Trade Agreements, respectively, contain similar rules on the prohibition of reliance on foreign approvals to establish the safety and efficacy of a similar or identical product. See the texts of both articles online: Official website of the USTR (date accessed: June 21, 2010).

246 Ibid. USJFTA, footnote 10.
247 See Section 5.1.2.1 below on a recent step in this direction.
248 In fact, this is exactly how some originators of pharmaceuticals intend to utilize protection of TD of old chemical entities. According to Oxfam, Merck (a US-based pharmaceutical company) tried to constrain local competition to one of its products (Fosamax, an osteoporosis medicine) on the basis of its DE. Once it secured DE on the 10mg capsule form of the drug, the company tried to introduce a new concentration of the drug, 70mg, to obtain a new exclusivity period. In addition, the company filed a lawsuit against a local manufacturer to prevent it from registering the new concentration form. See Oxfam International, All Costs, no Benefits: How the TRIPS-Plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicine, Oxfam Briefing Paper 102, March 2007, footnote 34, online: Oxfam Homepage (date accessed: June 21, 2010).

249 TD of new uses for old chemical entities became protectable in 2005, provided certain conditions are met. To be eligible for protection, the product in support of which such data are submitted must provide a significant clinical benefit, compared to existing therapies. This rule is introduced by Article 10.1 of Directive 2004/27/EC of March 31, 2004, which in part reads:

[the] ten-year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.

Analogous to the TRIPS Agreement, the USJFTA does not specify any particular duration of protection with regard to confidential data actually submitted to health regulators of the parties to prove that a product containing a new chemical entity is safe and effective. Accordingly, the parties to the agreement, particularly Jordan, are free to determine the duration of protection for this type of data. But, the accord mandates various durations of protection with regard to data not related to new entities and to data not actually submitted to JFDA, FSD. This requirement constitutes a TRIPS-Plus measure.

The USJFTA specifies the time duration of protection if the submitted data relates to the safety and efficacy of a new use of an old chemical entity, or if the national registration in Jordan is executed through reliance on a foreign marketing approval. While JFDA must protect for three years data related to the former case, the term of protection of the latter must be for the same period of time for which the data is protected in the reference country.

It should be noted that reference approvals (marketing authorizations issued by third countries) would be issued by different countries maintaining various protection durations. In turn, this obligation may lead to the enforcement of different periods of protection in Jordan. For example, if a pharmaceutical is registered in Jordan based on a marketing approval granted by EMEA, Jordan is then required to protect the TD submitted thereto for 10 to 11 years as this is the duration of data protection therein. Yet, if the relied-on approval is issued by the US FDA, a minimum period of three or five years must then be provided, depending on whether the product is based on a new chemical entity or constitutes a new use of an old entity, respectively. Clearly, if Jordan had implemented this provision, or had been pressured to do so in the future, the provision would have led to a cumbersome regulatory environment. In other words, it

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251 See Directive 2004/27/EC, supra note 60 Art. 10.1. In this Article, an eight-year DE was created with two-years ME added. In addition, the last provision of the mentioned Article extends ME to an eleventh year “...if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies".
would cause generic manufacturers and JFDA to lack certainty as to when data protection on various drugs expires; it would require JFDA to allocate considerable resources, which it does not have, to track the different time periods of protection related to various products; and it might be subject to abuse by pharmaceutical originators. Having explored the new elements contained in Article 4.22 of the USJFTA (extension of TD protection to include data related to old chemical entities and to FSD as well as requiring a minimum duration of protection), I next investigate whether and to what extent these changes have transformed the nature of the obligation to protect TD against unfair commercial use and disclosure to “data exclusivity”.

4.3. Protection of Regulatory Data under the USJFTA: Nature and Extent

Despite claims to the contrary, the obligation to protect TD under Article 4.22 of the USJFTA is of the same nature and extent as that under Article 39.3 of the TRIPS Agreement: protecting data against “disclosure” and “unfair commercial use” only. The USJFTA does not define the phrase “unfair commercial use”; nor does it clearly indicate an intention to alter the meaning of the phrase as it is understood under the TRIPS Agreement. In fact, the proviso at the outset of the USJFTA article (explained earlier) indicates quite the opposite. The proviso deferred to the TRIPS Agreement as forming an


253 See Pharmaceutical Research and Manufactures of America (PhRMA), Special 301 Submissions, 2006 and 2007 infra notes 290 and 291, respectively.
integral contextual framework to the USJFTA’s provisions on data protection. This means that if the USJFTA’s provisions are ambiguous, then it is imperative to refer to the TRIPS Agreement for interpretation.

Moreover, nothing in the USJFTA indicates the intention of its parties to limit such deference beyond expanding the scope of coverage of data protection to embrace FSD or data related to new uses of old chemical entities. Therefore, the USJFTA’s Article does not extend the TRIPS Agreement as to the nature of protection. This then means the above analysis of the phrase unfair commercial use, as it pertains to Article 39.3 of the TRIPS Agreement, is applicable to the obligations under the USJFTA. Thus, reliance by JFDA on either its own or foreign prior approvals, or on other means of its choice, does not violate Jordan’s obligations under the USJFTA to protect TD against unfair commercial use.

This interpretation finds further support in the texts of other FTA agreements concluded by the United States. Unlike the agreement with Jordan, where the obligation is to protect TD against “unfair commercial use”, the unambiguous and explicit mandate under all of these agreements is to protect originators’ data against reliance by third persons seeking to register a subsequent similar or identical medicinal product. For example, Paragraph 6 of Article 1711 of NAFTA delineates TD protection (besides nondisclosure) to have been granted when “no person other than the person that submitted them may, without the latter’s permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission.” This paragraph implicitly recognizes the rights of parties to institute or follow, based on bioequivalent studies, mechanisms other than reliance on the originator’s TD to prove a generic drug safe and effective. It reads, in part: “there shall be no limitation on any Party to implement abbreviated approval procedures [a procedure to register generics without submission of full TD reports] for such products on the basis of bioequivalence and bioavailability studies.” Based on NAFTA’s provisions and relevant case law, regulators may follow other mechanisms to evaluate the safety and

254 See the text of the relevant NAFTA Article, supra note 79 (emphasis mine).
255 See Bayer inc., supra note 83 at paras. 14 and 15.
256 See supra note 79.
257 See Bayer inc., supra note 83.
effectiveness of generics; for example, reliance on foreign approvals and/or a well
established medicinal use\textsuperscript{258} as attested to by available published literature, even if DE is
required.

Moreover, FTAs concluded by the US with developing and developed\textsuperscript{259} countries since the USJFTA entered into force in 2001 contain provisions analogous to
those of NAFTA. They use clear language stipulating that the obligation to protect
originators’ data means \textit{not to permit third persons to rely thereupon to market a similar
or identical product without the consent of the former}. The US-Singapore FTA, for
instance, in prescribing the obligation to protect TD states:

\textit{[if] a Party requires the submission of information\textsuperscript{260} concerning the safety and
efficacy of a pharmaceutical \dots product prior to permitting the marketing of such
product, the Party shall not permit third parties not having the consent of the
party providing the information to market the same or a similar product on the
basis of the approval granted to the party submitting such information”}.\textsuperscript{261}

Although the phrase “shall not permit third persons” might be interpreted to mean
that reliance by the regulator is not covered by the above-cited article, the prepositional
phrase “to market the same or similar product” leaves no doubt that reliance by the
regulator is particularly encompassed. Yet, the most recent FTA to enter into force, the
US-Oman agreement,\textsuperscript{262} was clearer and straightforward in specifically preventing the

\textsuperscript{258} See EU Directive 2004/27/EC, supra note 60 Art.10.
\textsuperscript{259} See the US-Australia FTA, supra note 244.
\textsuperscript{260} Comparing the interpretive consequences of using the expression “undisclosed information” in Article
17.10 of the US-Chile FTA to a dissimilar wording used by other FTAs, Roffe noted that:
[the Agreement] refers to “undisclosed information”, which seems to include a drafting closer to
NAFTA. This was perceived as an important accomplishment in the negotiations because the
original US proposals referred in general to “information”, whether undisclosed or not. In
addition, as the FTA does not provide for a definition of “undisclosed information” the one in
TRIPS (Article 39.2) should apply. This in itself is an important limitation on the scope of this
provision. However, the concept of “undisclosed information” in the FTA seems to be broader
than “undisclosed data” (as e.g. in CAFTA) or “undisclosed test or other data” (as for example in
the US agreements with Australia and Jordan), but not so wide as simple “information” (as in
the case of Singapore) (citations omitted).
\textsuperscript{261} See Article 16.8 of the U.S.-Singapore Free Trade Agreement, supra note 244 (emphasis mine).
\textsuperscript{262} See Agreement between the Government of the United States of America and the Government of the
Sultanate of Oman on the Establishment of a Free Trade Area, entered into force on January 1, 2009,
(date accessed: June 21, 2010).
Omani regulatory agency from evaluating generic drugs based on originators’ TD, prior approvals, or based on foreign marketing authorizations\(^{263}\) for a specified period.\(^{264}\)

It is difficult to argue that the obligation to protect TD against unfair commercial use required under the USJFTA encompasses a prohibition to authorize the marketing of a *generic version* of a drug when it contains a new chemical entity or when it is based on a new use of an old chemical molecule. This inference follows from a comparison with the above-cited various FTAs concluded before and after the USJFTA, and from following a good faith interpretation in accordance with the ordinary meaning given to the terms of the treaty in their context. This would clearly be the case if the safety and efficacy of the generic version are evaluated based on foreign marketing authorizations.

The preceding analysis shows that neither TRIPS nor USJFTA obligates Jordan to protect health TD by conferring upon their originators an exclusive right over the use of the data. Accordingly, it becomes necessary to investigate why Jordan provided for DE in Article 8 of the Jordanian Unfair Competition and Trade Secrets Law. Given that Jordan

\(^{263}\) Article 15.9(1)(b) reads:

(b) If a Party requires or permits, in connection with granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval in the other territory, the Party shall not, without the consent of a person that previously submitted the safety or efficacy information to obtain marketing approval in the other territory, authorize another to market a same or a similar product based on:

(i) the safety or efficacy information submitted in support of the prior marketing approval in the other territory; or

(ii) evidence of prior marketing approval in the other territory,

for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval of the new product in the territory of the Party.

\(^{264}\) The relevant article, in part, reads:

1. (a) If a Party requires or permits[to grant marketing approval for a new pharmaceutical …product], the submission of information concerning safety or efficacy of the product, the Party shall not, […], authorize another to market a same or a similar product based on:

(i) the safety or efficacy information submitted in support of the marketing approval; or

(ii) evidence of the marketing approval (emphasis mine).

Unlike prior FTAs, by using the word “permit”, the US-Oman FTA extends DE not only to data required or mandated by the regulator to prove the safety and effectiveness of a pharmaceutical product, but also to information voluntarily submitted by new drug sponsors. This in turn would mean that if submitted by the first applicant, information in the public domain such as scientific published literature will be subject to the exclusive use of the first applicant. Ibid. art. 15.9 (1) (a).
is a small developing country, such a national policy choice is perplexing, and may not find an explanation in or support from the teachings of the neo-classical trade theories. In other words, Jordan’s comparative advantage does not lie in DE. To the contrary, however, it rests in a legal modality\textsuperscript{265} that is less stringent and legitimately available under its international and bilateral treaty obligations.

In particular, the following factors, among others, should make a case against DE in Jordan. DE would restrict competition, if not creating monopolies, by preventing competitive generic medicines from market entry. Jordan is a poor, upper middle income developing country where considerable parts of the population are not covered by a universal health insurance system. In addition, the country hosts a growing local generics pharmaceutical industry which provides inexpensive medicines for about 35\% of the country’s medication demand; DE will compromise or delay the ability of the industry to register new generic drugs.\textsuperscript{266} Furthermore, since registration of a new drug in Jordan does not require the generation of data specific to the peculiarities of the Jordanian population or environment, obtaining marketing approvals from JFDA entails no further costs to make TD available. In other words, to market a new pharmaceutical product in Jordan, a pharmaceutical developer may not be required to conduct clinical studies other

\textsuperscript{265} To accommodate (as a compromise) the conflict between the fact that the TRIPS Agreement does not mandate DE, on the one hand, and the “free-rider” claim - when third persons rely on originators’ data - on the other hand, various versions of cost-sharing models have been proposed by some as an alternative measure for the protection of TD. Supporters of this approach argue that the facilitation of marketing of generics would foster competition in the pharmaceutical market, which in turn enhances access to medicine. They add that it would address the criticism against evaluating generics on the basis of originators’ data as an issue of free-riding; it does so since only if they make a relative contribution towards the costs incurred by originators to develop the data, manufactures of generics can rely on such data. It should be noted here that most of these models constitute a variation or a modification of the US system implemented under the FIFRA (supra note 214) regarding agrochemical regulatory data. Under this regime, second applicants, provided certain requirements are met, would be allowed to rely on originators’ data. Such reliance is authorized based on a system of mandatory and automatic compulsory licensing to authorize the use of data against a royalty paid to innovators. For more details on this approach, see Fellmeth, supra note 21; Judit Rius Sanjuan, et al., \textit{A Cost Sharing}, supra note 214; Robert Weissman, “Data Protection: Options for Implementation” in Pedro Roffe, Geoff Tansey & David Vivas-Eugui, eds., \textit{Negotiating Health: Intellectual Property and Access to Medicines} (London: Earthscan, 2006) 151; James Love, “Four Practical Measures to Enhance Access to Medical Technologies” in Pedro Roffe, Geoff Tansey & David Vivas-Eugui, eds., \textit{Negotiating Health: Intellectual Property and Access to Medicines} (London: Earthscan, 2006) 241; and also see Reichman, “Rethinking”, supra note 21 at 29-35.

\textsuperscript{266} For more information on these factors, see Chapter Two.
than those submitted to register the drug in any of the countries recognized by JFDA as a reference county.\(^{267}\)

With no legal obligations or a comparative advantage to provide for DE, it seems that pressure from its developed trading partners (in particular the US) coerced Jordan to implement a measure that is not only TRIPS-Plus, but an FTA-Plus. It was reported that for a successful conclusion of the USJFTA Agreement, the Office of the USTR demanded Jordan enact Article 8 of the Unfair Competition Law.\(^{268}\) In spite of vocal reservations from the industry as well as several state officials, “the regime had a different vision and saw it in the interest of Jordan to concede to all of the US demands”. This observation was made by a high-ranking Jordanian official who represented Jordan in the negotiations of accession to the WTO and the conclusion of the FTA with the US.\(^{269}\)

In sum, DE as provided for in Article 8 of the Unfair Competition Law has been a legal reality in Jordan since 2000. It is a form of monopoly and thus considered a “drastic

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\(^{267}\) According to the Criteria for Drug Registration in Jordan, the following countries are considered reference countries: The United States of America, Britain, Canada, Germany, France, Belgium, Switzerland, The Netherlands, Sweden, Austria, Japan, Australia, Finland, and Spain. See Criteria of Registration of Drugs, Serums, Vaccines and Biological Materials, the Renewal of Its Registration and the Cancellation of Any of Them, Appendix (8-A), subheading: “Drug Registration, Renewal of its Registration or its Pricing”, online: JFDA Homepage <http://www.jfda.jo/EN/Laws/LawInfo.aspx?id=507> (date accessed: June 24, 2010).


\(^{269}\) Quoted in Hamed and Mohammed El-Said, supra note 224 at 450. A similar story was also told to the author of this thesis by a different high-ranking official (interviewee) from the Jordanian Ministry of Industry and Trade during an interview in Amman/ Jordan on August 4, 2009. When the author asked the interviewee to comment on local manufacturers’ complaint that the government did not invite them to discuss the then draft USJFTA provisions, which was strongly believed to have a potential negative effect on access to medicine in Jordan, the interviewee responded that:

> [when] you sign a free trade agreement you have to give preferences to the other party to the agreement. Among the areas where preferences were granted by Jordan are TRIPs-Plus measures which included, *inter alia*, restriction of grounds for the issuance of compulsory licenses and the protection provided to regulatory data.

However, the interviewee proceeded to confirm that efforts were made by the government to reach out to the industry during the negotiation.

The government informed the pharmaceutical industry, through the Association of Manufactures, about progress in negotiations of both accession to the WTO and the USJFTA. They were consulted, and they were against some of the obligations, but the government had a take-it- all or-leave-it-all package, which we believed achieved a balance for our collective interests.
derogation to the principle of free competition”. It limits access to affordable life-saving medicines. It has also been reported in both the US and the EU that DE has been subject to abuses by originators of pharmaceuticals to prevent competition from generics.

However, developers of pharmaceuticals and WTO members who advocate their interests still argue for DE on economic and equitable grounds. They maintain that DE guarantees a recovery of the high costs incurred to develop the data (the incentive claim). Thus, allowing generics manufacturers, who did not sustain similar costs to develop their own TD, to “free ride” on the efforts of originators, unfairly provides the former with a competitive advantage (equity claims). In light of these conflicting interests and arguments, the next section argues that the implementation of DE in Jordan should be “engineered” with considerable delicacy, and articulates why such care is important.

5. Wisely Fine-tuned Implementation by JFDA is Needed

If Jordan is coerced into providing DE, its negative impacts can still be mitigated through the details of its implementation. This means JFDA needs to change how it

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271 See FTC study and other references, supra note 252 and accompanying text.
272 See European Commission, supra note 252.
273 How much actually the financial costs and time spent to develop the necessary safety and efficacy data of a given medicine is a controversial issue. The IFPMA reported in 2005 that US $800 million is the average cost to develop and introduce a new drug into the market, including the conduct of chemical, pharmacological, and toxicological testing, pharmacokinetics, pharmacodynamics and clinical research and testing. IFPMA added that it takes an originator an average of 10-15 years to complete these various tests. See IFPMA, A review of existing data exclusivity legislation in selected countries, Fourth Revised Version, January 2005), online: IFPMA Homepage (date accessed: June 21, 2010); Based on a 2000 data, DiMasi presented statistics indicating the cost of obtaining market approval in the US averages US$403 million out of pocket and US$802 million fully capitalized (i.e. accounting for the time value of money), where clinical trials and after-marketing surveys accounted for nearly 60% of the overall R&D costs. See DiMasi, Ronald & Grabowski, supra note 15. However, see Christopher P. Adams & Van V. Brantner, supra note 14, for disputing estimates. For various accounts about the duration of the pharmaceutical regulatory process involved in marketing authorization, where it was reported that approval time may take less than fourteen months, see Ariel Katz, “Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry” (2007) 14 (1) Michigan Telecommunications and Technology Law Review 1, footnote 15, citing authorities.
currently implements exclusivity. Changes should address flaws in a system that was
instituted after 2000, through which originators of pharmaceuticals have obtained
illegitimate exclusivity. Moreover, the changes shall ensure that DE is granted only to
products genuinely incentivized by exclusivity. As well, implementation should ensure
that effective measures are at the disposal of JFDA to prevent DE from becoming a
barrier to affordable medicinal products manufactured under or imported through legal
means such as compulsory licensing and parallel importation by third persons. In other
words, Jordan needs to recalibrate its DE system to minimize the impact it has had so far
on access to medicines. The modification, which I will suggest later, would not affect the
benefits derived by Jordan from maintaining a DE, if any; it would keep intact all
legitimate benefits to developers of drugs; and it would obviate unnecessary disputes with
pharmaceutical MNCs and the WTO members representing their interests.

5.1. Minimizing the Welfare Costs of Data Exclusivity

Several pharmaceutical-related problems followed the enactment of Article 8 of
the Unfair Competition Law and its subsequent implementation and enforcement by
JFDA. First, prices for medicines were reported to have risen considerably. According to
a study conducted by Oxfam International, prices increased by a minimum of 20% attributed, in part, to DE. Compared to the prices of equivalent medicines in Egypt, where
at the time no rules on DE were enacted, the costs of original drugs necessary to cure
serious illnesses were almost ten-fold in Jordan in some instances.274

Second, frequent complaints about regular unavailability, particularly in public
hospitals, of imported medicines for the treatment of chronic diseases such as cancer,
diabetes, asthma, high cholesterol, as well as cardiovascular diseases in general have
been reported by the national media.275 Third, most recent statistics on exportation of

274 See OXFAM, supra note 248 at 9-11.
275 For example, in a report in the Jordan Times Newspaper (a daily national newspaper published in
English) patients at Jerash Public Hospital were quoted as complaining that medicines such as “Daonil”
and “Glucophage” used to treat diabetic patients and “Zocor” and “Lipitor” used for high cholesterol
patients are missing regularly. See J. Irshaidat, “Patients Complain of Medicine Shortages in Jerash”
pharmaceuticals portray a dark picture of a declining trend.\textsuperscript{276} Of course, DE has had and continues to have a role in these negative outcomes. Therefore, how the enforcement of DE has contributed to these problems and how it can be part of the solution are discussed next.

5.1.1.  	extit{JFDA Contributed to the Problem}

As the national agency responsible for approving all new drugs for marketing in Jordan, JFDA was logically delegated the task of enforcing DE.\textsuperscript{277} The “Criteria of Registration of Drugs”\textsuperscript{278} detailed the requirements a drug must satisfy before it can be authorized for marketing. It also specifies when sponsors of generic medicinal products may submit their applications.\textsuperscript{279} Articles 5(b)\textsuperscript{280} and 9 (b)\textsuperscript{281} of the Criteria embrace the

\begin{itemize}
\item \textsuperscript{276} DE negatively impacts exportation by the local generic manufacturers. It prevents them from obtaining a Free Sale Certificate (a certificate endorsing that a product is authorized for marketing in the country issuing the certificate) necessary to get their products approved in third markets. During the first eight months of 2009, a decline of 11.4 per cent in exports was suffered by the industry. This trend has not stopped in 2010. According to a monthly statistical report and compared to exports during the first quarter of 2009, export of pharmaceutical decreased by 3 per cent during the first quarter of 2010. See Central Bank of Jordan, \textit{Recent Monetary & Economic Developments in Jordan} (May 2011) at 41, online, CBJ Homepage <http://www.cbj.gov.jo/uploads/monthly_english.pdf> (date accessed: July 04, 2011).
\item \textsuperscript{277} The contours of this task were drawn by the Drug and Pharmacy Law. The relevant part of Article 3(A) of this law reads:
\begin{enumerate}
\item It shall be prohibited to circulate any drugs, serums and vaccines unless after registering the same with the Ministry and passing the proper decision defining the prices for them according to the provisions of this law…].
\item It shall be prohibited to register any of the substances stated in Article (1) of this paragraph before the competent Committee has made sure that those substances are used safely and are active and of good quality.
\end{enumerate}

See the Drug and Pharmacy Law No. 80 for the year 2001, 4522 Official Gazette of December 13, 2001 at 5732.
\item \textsuperscript{278} See supra note 111.
\item \textsuperscript{279} This is the case with regard to generics whose safety and efficacy are established based on the TD of an original product.
\item \textsuperscript{280} Article 5(b) reads:
\[
[the] \text{application for registering the equivalent drug the data of which are protected or which is protected by a Patent Right during the last year at the latest before the expiry of the protection, shall be submitted by the concerned pharmacist in the drug store or the technical manager of the local factory attaching thereto the file containing the completed documents by virtue of the requirements mentioned in Appendix No. (1) and shall be placed in a sequence within the files of the equivalent drug the data of which are protected or which is protected by a Patent Right.}
\]

See supra note 111 Art. 5.
\item \textsuperscript{281} Article 9 (b) reads:
provisions with relevance to DE. While the former article dictates that an application for the registration of a generic product can only be filed with JFDA during the last year of the exclusivity period of an original\textsuperscript{282} drug, the latter stipulates that such application may not translate into an official registration except during the last six months of DE. Approvals based on such submitted applications may become effective after the expiry of the relevant exclusivity term.\textsuperscript{283}

Although, supposedly, its main task is to clarify the rules as contained in the pertinent superior legislative instruments (for transparency and administrative reasons), the criteria have failed to do so. For instance, the criteria do not define the subject matter protected by DE: that is, define data eligible for protection, specify conditions that data have to satisfy to qualify for protection, and elaborate on legitimate limitations, exceptions, and waivers to protection. It seems, unfortunately, that the agency deferred on this matter to Article 8 of the Unfair Competition Law. However, the provisions of Article 8 mirrored the language used in Article 39.3 of TRIPS with the necessary modifications to accommodate the TRIPS-plus measures required under Article 4.22 of the USJFTA. Accordingly, Article 8 only codifies the public policy choice on the protection of TD, and it does so using general language without elaborating on a technical definition of the protected subject matter. Hence, it contains ambiguous provisions, phrases, and words that inevitably require clarification to operationalise the mandate therein.

Instead, Article 8 internalized most of the ambiguities inherent in the TRIPS Agreement and the USJFTA articles discussed earlier, particularly with regard to the eligibility requirements. The following provisions of Article 8 are illustrative.

If an official party stipulated, for approving for the marketing of pharmaceuticals, or agrochemical products in which new chemical materials are used, the

\[\text{[the] Committee decides on any application of completed documents for registration of equivalent drugs the information of which is protected or which is protected by a Patent Right within a maximum period of (180) days before the expiry of the protection, provided that the resolution for registration is issued on the next day of the expiry of protection.}\]

\textit{Ibid. Art. 9.}

\textsuperscript{282} The Criteria use the phrase “new drug” to refer to original medicinal products registered for the first time in Jordan. With regard to a generic version of an already registered product, the criteria use the phrase “equivalent drug”), ibid. Art. 5(a).

\textsuperscript{283} Ibid. Art. 9(b).
submission of secret formulae or any data attained through considerable efforts such party should observe the following:

A. The protection of such data from the unclassified commercial use, through preventing any other person who did not obtain the applicant approval from depending thereon for marketing his pharmaceuticals and products except after 5 years as of the date of the applicant obtaining any approval for marketing his products. 284

Intuitively, before DE may properly be enforced, the following elements must be defined. First, what constitutes a chemical entity, as contained in a medicinal product, and when is a chemical entity considered “new”? Second, should sponsors of new drug applications verify or, at least, certify that their data are secret and confidential, or is it the default assumption that they are? And when should these data be considered not to be confidential or have lost such quality? Third, against what standards is the effort involved in the development of the sponsor’s data to be evaluated? Fourth, since the USJFTA expanded protection of data related to new chemical entities to include protection for data related to new uses for old chemical entities, when would a product constitute a new use and when might it not? Explicit and direct answers to these questions, among others, are not to be found either in the Unfair Competition Law or in the Criteria mentioned earlier. But, enforcement of DE by JFDA may provide some of the sought-after answers: all information submitted by an applicant to register a “new drug” 285 is protected by JFDA against unfair commercial use and disclosure. A drug is considered new in so far as it was not subject to prior approval by JFDA; 286 hence, TD related to a so classified drug are considered to have satisfied the requirements for protection.

284 English version of the quoted provisions was obtained from WIPO Collections of Laws for Electronic Access (CLEA), online: WIPO <http://www.wipo.int/clea/en/> (date accessed: May 21, 2010) (emphasis mine).
285 Interview conducted with a high-ranking JFDA official in Amman, Jordan, on August 9, 2009 (some of the information provided during that interview was confirmed by an electronic message).
286 Such an implementation is much stricter than what the law requires. In fact, to institute a practice of protecting TD of medicines just because such medicines have not been marketed in Jordan before, is tantamount to reading into the law what it does not say. In addition, if all medicines registered for the first time in Jordan are entitled to TE, then the requirements mentioned in Article 8 of the law become additive and unnecessary - which is not the case. In other words, such implementation would ‘sabotage’ whatever flexibilities retained through the USJFTA language – compared to that used in subsequent FTAs such as CAFTA Article 15.10. This CAFTA Article indicates that DE is conditional not on having testing data relating to a new chemical entity, but on “approving the marketing of a new pharmaceutical …product”. 328
As a result of this implementation, between 2002 and mid 2006 79% of 103 new medicinal products registered with JFDA were protected by DE, preventing any form of generic competition. In addition, compared to only 3 per cent of market value in 2002, following the enforcement of DE, the percentages of drugs without a generic equivalent in the Jordanian pharmaceutical market grew to 7.2, 9.1 and 9.4 in the successive years of 2004, 2005, and 2006, respectively. Finally, by the end of 2009, JFDA had provided over 400 pharmaceutical products with a five-year marketing exclusivity.287

5.1.2. Informed Enforcement to Streamline Data Exclusivity: a role for JFDA

5.1.2.1. Concepts of “New Use” and “New Chemical Entity”

Recognizing the devastating consequences of their DE enforcement, Jordanian authorities took action in 2006 to define what constitutes a new use for an old chemical entity. This action was in the form of a letter from the Minister of Industry and Trade to the JFDA.288 The letter clarified two important DE issues in Jordan as far as it relates to new use of old chemical entities.

First, the letter introduced an objective criterion for JFDA to follow when evaluating whether a medicinal product constitutes a new use. According to the new measure, a product based on an old entity may constitute a new use qualified for three-year DE only when such a product has “new therapeutic indications”: that is, if the new product represents a new medical indication not recognized before for the entity.

Commenting on this provisions, Abbott noted “[this] means that the first registrant of a medicine in a CAFTA Party may obtain protection for a chemical entity that is quite old and well known, provided that it was not previously registered in that CAFTA Party. This may substantially impede the introduction of generic equivalents” (emphasis mine). See Frederick M. Abbott, The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements, Quaker United Nations Office Occasional Paper 14 (April 2004) at 8, online: QUNO Home page <http://www.quno.org/geneva/pdf/economic/Occassional/TRIPS-Public-Health-FTAs.pdf> (date accessed: June 21, 2010) [Doha Declaration].


288 Official letter of the Minister of Industry and Trade, Implementation of Jordan’s Obligations Regarding Data Protection, No. 18/1/1/15331 of June 06, 2006, Ministry of Industry and Trade (in Arabic, a copy of the letter was obtained and is on file with the author).
Therefore, contrary to its practice before this letter, JFDA should disregard whether or not the chemical entity was marketed in Jordan as a determinative factor in affording DE. It should consider an entity old if it does not constitute a new medical indication, even if the entity concerned has never been authorized for marketing in Jordan before.

Second, since it stated explicitly what might not per se qualify as a “new use”, the letter provided certainty and closed many loopholes in the JFDA DE regime that represented a potential for abuses by originators. The letter specifies that “new dosage forms, concentrations, new strengths, new age groups, new forms of administration, crystalline forms, isomers, or the like” may not constitute new uses for old entities.289 The Pharmaceutical Research and Manufacturers of America (PhRMA), however, criticized290 Jordan over this legitimate administrative action despite the organization’s previous calls for the JFDA to adopt an institutional definition of the concept of “new use”. PhRMA also recommended placing Jordan on the 2006 “Special 301” Priority Watch List in its Special 301 submission to the USTR.291 One year later, expressing a rejectionist view about the newly adopted clarification in the above-mentioned ministerial letter, PhRMA alleged that “[t]he environment in the pharmaceutical sector deteriorated in 2006. Health officials took steps to reduce protection for undisclosed test and other data”.292

In June of 2009, despite dual pressures from PhRMA and the Office of the USTR,293 the government of Jordan took another important and necessary step forward,

289 Ibid. para. 4.
290 See Pharmaceutical Research and Manufacturers of America (PhRMA), Special 301 Submission 2007 (Washington, DC: PhRMA, February 2007) at 145-6.
291 In its submission for the 2006 Special 301, PhRMA complained that “[t]he FTA with the US requires 3-years of Data Exclusivity (DE) for new indications for previously approved chemical entities. However, the Jordanian Food and Drug Administration (JFDA) does not have a system in place to apply the additional 3-year protection for new indications”. See Pharmaceutical Research and Manufacturers of America (PhRMA), 2006 Special 301 Submission (Washington, DC: PhRMA, 2006) at 145, online: Consumer Project Home page <http://www.cptech.org/ip/health/trade/2005phrma301.pdf> (date accessed: June, 21, 2010).
292 Ibid. On the particularities of the letter, the agency added that “[i]n addition, a letter from the Ministry of Industry and Trade to JFDA in June 2006 clearly stated that there is no protection for clinical data related to the development of an old chemical entity, including new dosage forms, concentrations, new strengths, new age groups or new technologies. PhRMA members believe that such product developments involve significant research efforts which should be protected from unfair commercial use in line with the FTA and prior practice of the JFDA”.
293 For details about PhRMA’s actions, see supra notes 290, 291, and 292 and accompanying texts. According to various interviewees from different organizations, the Office of the USTR had a teleconference with Jordanian officials from the Ministry of Industry and Trade and from JFDA to discuss
demystifying and streamlining the implementation of DE by JFDA. The new step was geared towards an issue that has the most relevant bearing on the scope of protection afforded to TD: defining the concept of “new chemical entity”. This step was, again, executed in the form of a letter from the Minister of Industry and Trade to JFDA. On the basis of the minister’s letter, JFDA defines a new chemical entity as:

[the] medicine containing active molecule/s to which the physiological or pharmacological effect is attributed and whose active molecule/s date of first worldwide registration, individually or collectively, is not greater than 18 months, regardless any differences, for example: difference in salt, ester, ether, isomer, or any other derivatives. A medicine is considered to have the same chemical entity despite in different polymorph, metabolite, enantiomer, solution, […] method of use, formulation, or concentration. (Original is in Arabic, translation is mine).

This definition exhibits a Solomon thoughtfulness, and if properly enforced, would mitigate some of the negative implications of the DE mentioned earlier. The definition would preserve DE, as originally envisaged, to genuine and substantial therapeutic benefits and advancements that lack protection, for whatever reason, through other legal instruments such as patents or trade secrets. It would also make original drugs more available (though often unaffordable) in a timely manner. The new definition would prevent abuses of DE by originators, enhance healthy competition from generics, and improve access to more affordable medications in Jordan and elsewhere. The following three elements would explain how the new definition might help to alleviate some of the disadvantages of DE.

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294 Unfortunately, the author could not, despite several attempts, obtain a copy of this letter. A JFDA’s public notice referred to the letter as “decision of Minister of Industry and Trade, adopted in consultation with expertise from JFDA”. See Jordan Food and Drug Administration (JFDA), Public Notice: Defining New Chemical Entity, No. 2/9/1/17645 of June 16, 2009, online: JFDA Home page <http://www.jfda.jo/Publications.aspx?lang=ar> (date accessed: June 21, 2010) (a copy was obtained from JFDA on August 12, 2009, on file with the author) (original in Arabic, translation mine).

295 Ibid.

296 When DE was first legislated through the provisions of the Hatch-Waxman Act in 1984, it was seen as a tool to encourage “the development and testing of unpatentable pharmaceuticals.” In particular, biotechnological “inventions” and second uses of old conventional chemical entities were at the core arguments of those who advocated adopting the measure. See Reichman, “Rethinking”, supra note 21 at 37 citing Allergan Inc. v. Alcon Labs., [2003] 324 F.3d 1322, 1325 (Fed. Cir.), cert. denied, 540 U.S. 1048 (2003).
A. Exclusivity only for Genuine Advancement and for Investment in Research

Based on the new concept, only the active chemical molecule(s) of a drug as it is first registered worldwide and to which the medicinal function (physiological and pharmacological effect) of the product is attributed may constitute a new entity. It follows that two sets of chemical substances are not considered new entities and, hence, may not serve as a basis for a DE claim. The first set includes all inactive molecules (incipients). The second set encompasses alterations and/or modifications of previously registered molecules such as polymorphs, metabolites, enantiomers, methods of use, and/or formulations. It might be inferred that the second set is excluded because it encompasses substances that are not sufficiently different from the active molecule in its original form to be considered new entities as such.297

B. Greater Availability of Original Pharmaceuticals

The new concept mandates that for a chemical entity to be considered new and worthy of protection by exclusivity, it must be registered in Jordan no later than 18 months calculated from the date of its first worldwide marketing approval. This registration “deadline”, referred to by some as a “Windows of Opportunity”298 or “waiting period”299 has become a common standard in many countries with a statutory mandate for DE; for example, Chile,300 Israel,301 Malaysia,302 Taiwan,303 and

297 See Carvalho, supra not 21 at 288, criticizing the inclusion of an ester and salts of old substances into the definition of “new drug substance” prepared under the auspices of the International Conference on Harmonization (ICH).
298 Ibid. at 279.
301 In Israel, TD are protected by exclusivity for five years counted from the date of registration in Israel, or for five years and six months counted from the earliest registration date in one of a set of reference countries, whichever is shorter. This means the duration of the available window, following third country registration, is only six months. See the relevant Israeli regulation on this matter, Article 47D (b) (2) of the Pharmacist Ordinance [New Version], 1983, as amended in 2005, cited in PhRMA’s 2010 Special 301 Submission, supra note 32 at 90; Mark S. Cohen and Tal Frieman, “Data Exclusivity in Israel” (2003) Business Briefing: Pharmagenerics at 1-2 (available also online at <http://www.touchbriefings.com/download.cfm?fileID=491&action=downloadFile> (date accessed: June 2003).
Turkey.\textsuperscript{304,305} The main objective of this requirement is to encourage multinational drug manufacturers to expedite local submissions and marketing of their innovative medicines promptly after their first worldwide marketing authorization. This requirement, in turn, should balance the DE system, making its “benefits” (introduction of new drugs) available in a timely fashion to Jordanian patients if they must sustain the heavy cost of marketing exclusivity.

In addition, confining the priority period to maintain the novelty of entities would, on the one hand, block prolongation of exclusivity through extraterritoriality of DE on new medicines. On the other hand, it should prevent two crippling would-be effects. The first effect materializes when a drug is not marketed at all in Jordan because the originator not only does not register it itself, but also prevents others from doing so based on its foreign exclusivity;\textsuperscript{306} or when the originator registers the product, but does not

\textsuperscript{304} See PhRMA,\textit{ 2010 Special 301 Submission}, supra note 32 at 158. In Malaysia, TD are protected by exclusivity for five years counted from the date of registration in the originating country. This means that for a drug to enjoy the entire term of this exclusivity, it has to be registered in Malaysia on the same day it is registered in the country of origin. See “Malaysia, FTA: Malaysia Imposes Terms on Data Exclusivity for US Pharmaceuticals”\textit{ New Straits Times} (April 19, 2007), online: bilaterals.org Home page <http://www.bilaterals.org/spip.php?article7951> (date accessed: July 4, 2010).

\textsuperscript{305} According to the law in Taiwan, TD submitted in order to obtain an approval for marketing of a drug might not be protected by DE if the registration of such a drug in Taiwan is applied for after three years counted from the first worldwide registration. See Article 40.2 of the Pharmaceutical Affairs Law Amendment, of February 5, 2005; cited in PhRMA,\textit{ 2010 Special 301 Submission}, supra note 32 at 160.

\textsuperscript{306} Although effectively have the same result, the legal basis of the waiting periods established under the Chilean, Israeli, and Jordanian systems differs from that followed by Malaysia, Taiwan, and Turkey. According to the former, the prescribed “priority” is necessary to preserve the novelty of the chemical entity without which the chemical substance would lose data protection. In the latter set of countries, however, the waiting period is to mark the calculation of the protection’s duration, but does not affect the novelty of the entity undergoing registration.

\textsuperscript{306} This troubling scenario was imposed by the US on some FTA partners. For example, Article 15.10 of the Dominican Republic – Central America Free Trade Agreement (DR-CAFTA) provided that “...a Party may require that the person providing the information in the other territory seek approval in the Party within 5 years after obtaining marketing approval in the other territory.” The provision actually gives originators a five-year period during which they are not mandated to register the drug in a CAFTA party, and they can prevent third persons from doing so based on their foreign registrations. In other words,
market it. To address the latter case, the JFDA should have the legal and administrative authority to waive\textsuperscript{307} DE if no reasonable ground is provided to justify the lack of marketing and distribution of the product concerned. The second effect is that DE may preclude the introduction of and competition from generics for as long as ten years. Such conduct would constitute a conspicuous and outrageous abuse of data protection now deterred by the newly adopted concept.

C. Contains Abuses, Enhances Competition, and Improves Medicines Affordability

The new concept should help in containing potential abuses of the DE system. Besides the group of derivatives currently not protected by exclusivity under the aforementioned definition of “new use”, the newly adopted concept of “new chemical entity” would prevent “evergreening exclusivity”.\textsuperscript{308} It does so since it excludes from DE minor or trivial changes/alterations of known, old entities, used to prevent legitimate generic competition. Examples of these derivatives may include: salt, ester, ether, and isomer; polymorphs, metabolites, enantiomers, solutions, methods of use, formulations, or concentrations. In addition, disqualifying these derivatives as a new entity will clearly shrink the “pool” of chemical substances serving as a basis for second use claims. In other words, for a second use claim of a product to stand, intuitively, the chemical substance contained therein should have already been recognized as a new entity.

Unless they are protected by patents, denying these derivatives DE protection should decrease the number of generics banned from gaining market authorization. This, in turn, increases marketing authorizations issued for low-priced generics, leading the pharmaceutical market to become more competitive and medicines to become affordable.

\textsuperscript{307}For more details, see the relevant part on exceptions and waivers below.

\textsuperscript{308}“Evergreening exclusivity” is an informal expression used to describe a common tactic that is used to seek additional data protection in respect of certain aspects or modifications of an already marketed product. For an explanation of the expression in the context of patents, see Brian Whitehead et al., “Practice Point: Managing Generic Competition and Patent Strategies in the Pharmaceutical Industry” (2008) 3(4) Journal of Intellectual Property Law & Practice 226 at 227.
and available, not only to the affluent, but also to the poor and needy. In addition, export of affordable drugs to other countries will most likely increase.

Despite their potential positive effects on the availability and affordability of medicines and in mitigating some of the negative impacts of DE on public health, the above-discussed measures are not enough. While over 350 medicines have been classified by JFDA as new chemical entities with 5-year exclusivity,\textsuperscript{309} many, of course, have been granted three-year DE as a second use of old entities.\textsuperscript{310} The lack of generic competition for these medicines in a small, upper middle income developing economy such as Jordan could still have a devastating impact on public health and local industry, as a stable source of affordable medicines. To assist in alleviating the severity of this impact, Jordan should subject DE protection to certain exceptions and waivers.

5.1.2.2. Exceptions to and Waivers of Data Exclusivity are Inevitable

As a “private right”,\textsuperscript{311} the exclusive right to rely on TD is not absolute. It is not immune from being subject to exceptions and, ultimately, being overridden whenever the public interest necessitates – for instance, to protect public health. Integrating specific safeguards in the system of DE protection is vital for the system as an instrument intended to enhance the social welfare of the society. Carvalho rightly states that “[this] protection … is subject to particular constraints, which naturally dictate a diminution in rights that might not be justified as regards other types of rights.”\textsuperscript{312}

\textsuperscript{309} See USAID, supra note 287, where JFDA was cited to have maintained that it had provided over 300 pharmaceutical products with five-year DE; (the number, of course, increased since then, and more than 50 pharmaceutical products have been granted exclusivity); see also JFDA, New chemical Entity Registered (2005-2009), online: JFDA Home page <http://www.jfda.jo/Download/News/105_168.do> (date accessed: July 4, 2010).
\textsuperscript{310} According to Oxfam International, the following are examples of products granted a three-year DE by JFDA: Forlax, Cancidas, Enbrel, Topamax, Gonal F, Xyzal tab, Humira, Risperida, Diovan, Singular, Novoseven, Atacandtab, Celebrex cap, Remicade vial, Exlon cap, Viend tab, Exelon cap, Nasonex nasal spray. See supra note 248 at Appendix 2.
\textsuperscript{311} The private nature of all intellectual property rights was recognized by the TRIPS Agreement in the fourth paragraph of its preamble. It states “[members…] Recognizing that intellectual property rights are private rights” In the context of the TRIPS Agreement, it is argued that although the Agreement considered undisclosed information as an intellectual property subject matter, there is no mandate to grant an exclusive right in the use of the data. See Carlos M. Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (Oxford, New York: Oxford University Press, 2007) at 375. [Commentary]
\textsuperscript{312} See supra note 110 at 307.
constraints could not be more justifiably compelling than it is for protecting the fundamental and human-inherent right to health.\textsuperscript{313} Accordingly, based on comparative law and experience, the following measures ought to be integrated in the Jordanian regime of DE enforced by JFDA.

5.1.2.2 (a) Exceptions

Besides establishing publicly available published literature as a valid basis for evaluating the safety, effectiveness, and quality of generics, JFDA should require originators to certify that their TD are “undisclosed”.\textsuperscript{314} The agency should also implement a general exception to data protection for the protection of public health as allowed under the TRIPS and the USJFTA agreements in cases of national emergency or extreme urgency and in case of a public health related crisis. By and large, Jordan should consider implementing the following measures.

5.1.2.2 (a) (I) Compulsory Licensing and Parallel Importation

Public health safeguards such as compulsory licensing and parallel importation\textsuperscript{315} are, as discussed in Chapter Three, among the flexibilities available under the TRIPS Agreement. Similar to all pharmaceutical products, medicines obtained through these measures must be registered with the competent health agency and proven safe and effective before they are authorized for marketing. This is not reasonably possible, unless the safety and effectiveness of those medicines are established through reliance on

\begin{itemize}
\item This is a requirement before data can be protected under Chilean law. See Judit Rius, \textit{CPTech Response to 2006 PhRMA “Special 301” Submission for Chile} (March 2006), online: Knowledge Ecology International Homepage <http://keionline.org/node/638> (date accessed: July 4, 2010).
\item Although Jordan effectively prohibits the parallel importation of patented drugs without the patentee’s consent, this importation, as discussed in Chapters One & Three, is still possible through compulsory licenses.
\end{itemize}

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originators’ TD. DE may, thus, obstruct the registration and, subsequently, marketing authorization of so obtained drugs if the originators do not consent to the use of their data.\footnote{In a letter to Congressman Levin, recognizing the obstructionist effect of the various FTA Agreements on this particular matter, the USTR wrote “[…if…] a drug is produced under a compulsory license, and it is necessary to approve that drug to protect public health or effectively utilize the TRIPS/health solution, the data protection provision in the FTA would not stand in the way.” See letter from USTR General Counsel John K. Veroneau to Congressman Levin (dated July 19, 2004), cited in Carsten & Reichenmiller, supra note 224 at 3.}

If no exception is established to break this “impasse”, DE will potentially frustrate any utility derived from these patent-related measures, leading to adverse repercussions to public health. Hence, such outcome would violate the letter and spirit of the Doha Declaration on Public Health.\footnote{Paragraph 4 of the declaration reads:

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Member’s right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

See WTO, \emph{Declaration on the TRIPS Agreement and Public Health}, WTO document WT/MIN(OI)/Dec/2, 20 November 2001 [Doha Declaration].} It would also undermine the objectives underlying the proposed amendment to the TRIPS Agreement.\footnote{For the text of the proposed amendment, which adopted the waiver contained in the 2003 General Council Decision into a permanent solution to the problem of difficulties caused by Article 31(f) of the TRIPS Agreement, see WTO, \emph{Amendment of the TRIPS Agreement}, WTO document WT/L/641 of December 8, 2005, online: WTO website <http://www.wto.org/english/tratop_e/trips_e/wtL641_e.htm> (date accessed: June 25, 2011).}

Therefore, when a drug is protected by a patent, reliance on originators’ data must be available to register products manufactured or imported under compulsory licenses. Despite its commercial nature, this reliance is an equitable and fair use of the data because a drug produced or imported under a compulsory license is the product of the originator. In addition, reliance in such cases principally would be necessitated by the same public health-related grounds relied on to grant the compulsory license in the first place, including drugs high prices.\footnote{Demanding compulsory licensees to redevelop the safety and effectiveness data contradicts the policy objectives underlying certain grounds of compulsory licenses such as high prices or the involvement in anti-competitive practices by right holders.}

Furthermore, calculating the value of payable...
remuneration to a patentee for involuntary use of its patent would be assumed to have encompassed a consideration for using the pertinent TD.\footnote{320}

The relevant Jordanian regulations are also short of the necessary legal measures\footnote{321} to address abuses of DE exclusivity of unpatented medicines by registering generic copies, imported or manufactured locally. For example, the regulations do not specify the legal means to register so-obtained medicines when originators of TD do not actually commercialize their products for a given duration\footnote{322} after being granted sanitary approvals. The same is also true if the products are only marketed in insufficient quantities, sold for prohibitive prices,\footnote{323} or if originators are found to have perpetrated anticompetitive conduct that directly or indirectly involve their data.\footnote{324} At least in Brazil, Chile and Saudi Arabia, the pertinent legislation entitles the competent authorities to rely on the originators’ TD if certain circumstances of the kind mentioned above arise.\footnote{325}

Based on the above discussion, it becomes evident that Jordan needs to establish measures to permit reliance by JFDA on originators’ TD when circumstances such as those mentioned earlier arise. If data related to an off-patent product are used involuntarily, a reasonable payment needs to be made to the originator. The amount of the payment may be calculated on a cost-sharing basis. However, no such remuneration

\footnote{320}{A reference to an unnamed developing country that provided a 1% compensation for use of TD involved in the compulsory licensing of two pharmaceutical patents; see Carvalho, supra note 21 at 283, footnote 601.}

\footnote{321}{The New Drug Registration Criteria are completely silent as to what might be the response in such cases. In addition, no anticipated administrative response is envisaged, so far, by JFDA. This inference is based on an answer the author received from JFDA stating that the agency “currently” does not have exceptions. This answer, by a JFDA’ official, was in response to the following question by the author: “are there any instances where JFDA has the discretion to place exceptions and/or limitations on data protection?” (Interview with a high-ranking JFDA official in Amman, August 9, 2009, and confirmed via electronic message (email) on Sunday, June 6, 2010).}

\footnote{322}{While Saudi Law allows involuntary use of the data if marketing does not take place within a “reasonable period”, determined by sanitary authorities, Brazilian Law sets a waiting period of three years from the national registration date. However, under Chilean Law, this period is one year only. For references, see infra note 325.}

\footnote{323}{See Carvalho, supra note 21 at 310.}

\footnote{324}{See Infra.}

\footnote{325}{With regard to Brazil, see Articles 7 and 8 of Law No. 10,603, of December 17, 2002 applicable to TD related to products of veterinarian and agro-chemical products, cited in Carvalho, supra note 21 at 310-311. With regard to Saudi Law applicable to this matter, see Article 6 of the \textit{Regulation for the Protection of Confidential Commercial Information}, issued by the Minister of Industry and Trade No. 3218, of May 5, 2005, as amended, online: Home page of Saudi Ministry of Industry and Trade \texttt{<http://www.mci.gov.sa/circular/46-3.asp>} (date accessed: July 4, 2010). The amendment was introduced to delete a provision which had authorized reliance on TD when a duplication of the tests to develop the required safety and efficacy information causes unnecessary suffering to humans or animals.}
should be made in cases of wrongdoing by originators, for instance, engagement in anticompetitive practices or unjustifiable lack of commercialization.

5.1.2.2 (a)(II) Other Exceptions

Comparative law on DE comprises examples of other exceptions to safeguard matters of public interest. For example, the law in Israel allows reliance by the competent regulatory authority on originators’ data for registering a generic medicine when it is intended for exportation only, but not for local consumption.326 The Australian health regulator also used to issue certificates of free sale, based on bioequivalence with original products, to facilitate exportation of generics to third countries where these certificates were recognized.327 Both of these unchallenged measures constitute availability under the TRIPS agreement and would arguably increase access to more affordable medicines. In both examples, the measure was effective for several years after the countries concerned submitted their relevant laws to the WTO for verification of compliance with the TRIPS Agreement.

Furthermore, nothing in the TRIPS Agreement or the USJFTA proscribes Jordan from providing for a similar exception, especially with respect to off-patent products.328 Based on the territoriality of data protection, which means that protection is confined to the territory of the sovereign state providing such protection, issuing a certificate of free sale to register a drug in another market329 does not constitute an unfair use of the data

326 See Pugatch, supra note 301 at 20. He observed that the concerns of the USTR over the Israeli regime of DE are that “…it allows generic-based pharmaceutical companies to rely on the registration data of the original drug for export purposes”. The Israeli government insists on maintaining this measure, as paraphrased by Pugatch, because “it is committed to maintaining the advantage of its local generic industry to be able to export generic products abroad”.

327 In April of 1998 and following an investigation under Special Section 301 of the US Trade Act, the Australian Therapeutic Goods Legislation Act was amended (Law No.34, 1998) leading, inter alia, to the termination of this practice) see UNCTAD-ICTSD, Resource Book, supra note 108 at 533.

328 Exportation is not one of the patentee’s exclusive rights enumerated under the TRIPS Agreement or granted by national law of WTO members. For a discussion on the right to export as it relates to patented products, see Daya Shanker, “The Paragraph 6 Solution of the Doha Public Health Declaration and Export under the TRIPS Agreement” (2004) 7(3) Journal of World Intellectual Property 365.

329 Given that most of the world’s least developed countries (LDCs) may not protect pharmaceutical TD until 2016 since Paragraph 7 of the Doha Declaration allowed them to defer implementation of Section 7 of the TRIPS Agreement “with respect to pharmaceutical products” until that date, establishing an exception to data protection for export is relevant for advancing access to inexpensive medicines in devastated countries, and it helps the local industry to create economies of scale. See Paragraph 7 of Doha Declaration,
despite its commercial nature. For example, the European regulation “On Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems” waived exclusivity protection when registration relates to a generic drug manufactured in accordance with the regulation. Finally, the agreement between the USTR and the Congressional Leadership (Bipartisan Agreement on Trade Policy) contains language supportive of the above recommended exceptions. The agreement states “developing country FTA partners may implement exceptions to normal rules for protecting test data if necessary to protect public health”.

With regard to the exception in this specific case, it should not extend to disclosure of TD to second applicants. The purpose of the exception is to make affordable medicines available, which can often be accomplished without disclosing the data. The reason as to why the data need not be disclosed is because disclosure destroys its confidentiality, which may result in disproportionate harm to the originator (loss of future opportunities to protect the data in different countries). Thus, only in limited exceptions, such as the protection of public health, can the regulator divulge data to a second applicant.

### 5.1.2.2 (b) Waivers


330 See Carvalho, supra note 21 at 313.

331 Article 18.2 of the Regulation reads:

2. If a request for any of the above procedures concerns a product which is a generic of a reference medicinal product which is or has been authorised under Article 6 of Directive 2001/83/EC, the protection periods set out in Article 14(11) of Regulation (EC) No 726/2004 and in Articles 10(1) and 10(5) of Directive 2001/83/EC shall not apply (emphasis mine).


Since the ultimate public objective behind providing for data protection is to place new molecules (developed as safe and effective pharmaceuticals) in the market, there is indeed a public interest in waiving this protection when the attainment of its objective is compromised. Therefore, JFDA may waive DE on grounds of the public interest, allowing the registration of generic pharmaceuticals by direct reliance on originators’ TD. In particular, the public interest should embrace the following grounds:

(A) if, without a reasonable justification, a product is not marketed in Jordan within six months calculated from its registration date, or if it is marketed in quantities that do not meet the reasonable demand of the public, or if available, the product is sold for unreasonably high prices;

(B) if, without a reasonable cause, and after being actually marketed, a product ceases to be available on the national market for an uninterrupted six-month period, or if the same period results from multiple and shorter durations; and

(C) if an application to register a medicinal product is abandoned before or after a sanitary approval for marketing is issued by JFDA.333

6. Concluding Remarks

This chapter has addressed the question as to whether the DE regime implemented in Jordan under Article 8 of the Trade Secrets and Unfair Competition Law and enforced by JFDA is mandated by the TRIPS Agreement or the USJFTA. I argued and demonstrated that neither the obligations under Article 39.3 TRIPS nor those under Article 4.22 of the USJFTA require DE. Both sets of provisions only require the protection of such data against unfair commercial use and disclosure, which does not entail DE.

As to the nature and scope of the obligation to protect data against unfair commercial use under the TRIPS Agreement, I have reviewed and analyzed the different versions of the text of Article 39.3 TRIPS and the several proposals advanced during negotiations. The analysis has shown that the historical evolution of the text of the article

333 In the case where the data is not submitted to JFDA, the priority period of 18-months should be allowed.
during the Uruguay Round does not support the argument that protection against unfair commercial use means DE. In addition, a textual analysis and interpretation of the provisions of Article 39.3 TRIPS in accordance with the rules on treaty interpretation also support my argument.

Contrary to the practice followed by JFDA, the obligation to protect TD does not cover all the data which drug originators provide to the organization. Data eligible for protection must satisfy certain requirements. The data must be required by the regulator and must relate to a product containing a new chemical entity (or a new use of an old entity under the USJFTA) as its active molecule. Furthermore, the data must be confidential (undisclosed), and must have involved considerable effort to generate.

The same can be equally argued with regard to the nature of the obligations under the relevant article of the USJFTA. This agreement contains certain changes to the conditions of protection delineated under the TRIPS’ article. Specifically, the USJFTA extends protection against unfair commercial use and disclosure to data related to new uses of old chemical entities and to data submitted to foreign health regulatory authorities when there is reliance on a foreign marketing authorization issued based on such data. Although these changes may translate into serious implications for public health in Jordan – for example, higher drug prices and erecting barriers to generics competition of mostly off-patent medicines - I demonstrated that the USJFTA does not transform these obligations from protection against unfair commercial use and disclosure to data exclusivity.

Furthermore, the protection of data against unfair commercial use may not comprise the practice of reliance on originators’ data, without their consent, by JFDA. This practice, of course, is not unfair nor, as such, does it constitute a commercial use. Actually, it may not constitute a use of the data when the safety and efficacy of generic drugs are established without material examination of originators’ data, or when evaluation is based on foreign marketing authorization of a reference product. Under this last scenario, even an indirect reliance by a manufacturer of generics on an originator’s data does not constitute use, since they do not have access to the data, let alone the opportunity of using them.
Therefore, I strongly recommend that JFDA adopt in the “Drugs Registration Criteria” (DRC) the definitions of what constitutes a new chemical entity and new uses of old entities which were discussed in this chapter. It is further recommended that JFDA discontinue its current practice, whereby data submitted by sponsors of new drug applications are assumed to have met protection requirements; sponsors must be required to demonstrate that their data meet all conditions of, and requirements for, protection. This must be in addition to the incorporation of specific reasonable exceptions to and legitimate grounds for the revocation of protection under the relevant Jordanian legislation.

Therefore, I recommend in particular the following reforms: (1) allow reliance on originators’ data to register drugs produced or imported under compulsory licenses or obtained via parallel importation. (2) Allow the registration of a generic drug by reliance on the originator’s data when the product associated with the latter is sold for an unreasonably high price, when the originator perpetrates anticompetitive conduct that directly or indirectly involves the data, when the originator ceases marketing its products locally, and when the quantities provided are insufficient for meeting local demand. If, however, originators’ data are used involuntarily, a reasonable payment should be made by the producer of the generics. The amount of the payment may be calculated on a cost-sharing basis. Yet no such remuneration should be made in cases of wrongdoing by the originator; for instance, if it engages in anticompetitive practices or an unjustifiable lack of, or insufficient, commercialization. Furthermore, with regard to the protection of data related to patented products, I recommend that the term of protection must be linked with and capped by the patent term of protection. This limitation is necessary to make timely use of the early working exception to patent rights. The objective underlying this exception is to market generic copies of a patented medicine right after its patent expires. If data protection is allowed beyond the expiry date of a patent, then the goal of this exception may be frustrated by unnecessary delay of generics’ entry to market.

In addition, this thesis recommends that JFDA includes the following circumstances as grounds for the revocation of data protection in the Jordanian DRC:
(A) if, without a reasonable justification, a product is not marketed in Jordan within six months calculated from the local registration date, or if the marketed quantities are insufficient for meeting reasonable local demands, or, if available, the product is sold for unreasonably high prices;

(B) if, without a reasonable cause, and after being actually marketed, a product ceases to be available in the local market for an uninterrupted six-month period, or if the same period results from multiple shorter durations throughout the entire term of protection; and

(C) if an application to register a pharmaceutical product is abandoned before or after a sanitary approval for its marketing is issued by JFDA.

Besides preventing abuses of data protection such as “evergreening”, these proposed measures should maintain the balance between the interest of the public at large and those of the originator. The measures should alleviate some of the economic burden of providing data protection by allowing more competition in the drug markets. Most of the forgoing recommendations with regard to the Jordanian protection of test data are equally applicable to other developing countries regardless of their developmental states or levels of income.
Conclusion and Recommendations

This thesis has investigated, and taken as its starting point, the obligations under the TRIPS Agreement to provide for minimum standards for the protection of IPRs. In particular, this thesis has focused on the Jordanian experience in the pharmaceutical sector with implementing these minimum standards as well as IP obligations required under the USJFTA that go beyond those of the TRIPS Agreement. The thesis concludes that the implementation and enforcement of strong patent protection, including limitations on the utilization of available flexibilities, have not been conducive to the promotion of technological innovation and to the transfer and dissemination of technology. Instead, implementing TRIPS and the USJFTA resulted in serious adverse outcomes such as increasing drug prices, unavailability of essential medicines in some public hospitals for serious diseases, and a dwindling local pharmaceutical industry as a partial consequence of an inability to access advanced, patented technology on reasonable commercial terms. This further has limited the availability of affordable, competitive generic drugs in the Jordanian market. Therefore, if one were to generalize from the Jordanian experience in the pharmaceutical sector, this thesis could be read as yet another indictment of globalization, or criticizing its current form, particularly the implementation and enforcement of strong patent protection, including limitations on the utilization of available flexibilities in developing countries. However, I have shown that despite many of its flaws, the TRIPS Agreement provides particularly necessary legal means and policy tools for mitigating some of the harmful social and economic implications arising from its implementation. I have also shown that most of these measures are available for Jordan despite the additional limitations imposed by the USJFTA.

As I have discussed in Chapter One, developed and developing countries have long disagreed on the nature, scope, and extent of some of the obligations under the TRIPS Agreement. This has been particularly the case about the issue of exhaustion of IPRs, the non-discrimination clause of Article 27, and the protection of pharmaceutical
TD. They are also in disagreement about the extent of WTO members rights to utilize certain flexibilities such as exceptions to patent rights – for example, compulsory licensing where there are appropriate grounds, abusive non-working, high drug prices, refusal to deal, and/or the public interest - and the legitimacy in allowing parallel importation under the Agreement. These disagreements remain unsettled. This is particularly true when such flexibilities are invoked by developing countries to make life-saving medications affordable for their poor citizenry. The contentiousness continues despite the clarifications and confirmations provided by the Doha Declaration on TRIPS and Public Health of the right of all WTO members to use the disputed flexibilities.

This thesis examined the debates surrounding the disputed obligations and flexibilities in the context of Jordan, a small, upper middle income developing country. Specifically, the thesis analyzed the following three related questions. First, what has been the influence of enforcing strong patent rights on the quality and level of R&D activities, innovation, and on the “quality” or “quantity” of technology transfer to the pharmaceutical sector in Jordan? Second, to what extent do developing countries have the right to implement certain legal measures such as parallel importation and providing for particular grounds of compulsory licensing such as abusive non-working, high drug prices, refusal to deal, and/or the public interest; and the right, when necessary, to invoke such grounds? And, third, what are the nature and scope of the obligations under Article 39.3 to protect pharmaceutical TD against “unfair commercial use” and disclosure as well as the impacts of these obligations on access to off-patent and patented medicines?

I argued that rigorous utilization by Jordan (as well as other like developing countries) of the policy tools and measures provided by, and available under, the TRIPS Agreement should help mitigate high medicine prices and provide a viable solution for the inability of the Jordanian pharmaceutical sector to access advanced technology as a result of rigorous implementation and enforcement of the TRIPS obligations. I demonstrated that most of these policy tools are still available for Jordan to implement despite considerable limitations imposed by the USJFTA on Jordan’s discretion to utilize such measures. I further showed that it is not that these measures are not legitimately available for utilization under the agreements concerned, but that these agreements are employed as a political platform and “whip” by the Pharmaceutical Research and
Manufacturers of America (PhRMA) and certain developed countries supporting its interests to deter developing countries from implementing and invoking the relevant measures when necessary.

**Specific Conclusions and Recommendations**

1. *Increased Pharmaceutical-related R&D, Innovation, and Technology Transfer Has Not Materialized Post-Adoption of Strong Patent Rights*

   The analysis in Chapter Two of this thesis has shown that the levels of pharmaceutical R&D and innovation have not thus far increased in Jordan after almost 11 years of enforcing the TRIPS-Plus Patents Law of 2000, nor is there any indication that the rate of technology transfer has increased. This outcome calls into question the appropriateness of strong patent protection as a policy for inducing more investment in pharmaceutical R&D and innovation when enforced in countries where the pharmaceutical sector is underdeveloped and non-innovative. Drawing on the concept of a National Innovation System (NIS), this thesis has illustrated the relevance of a country’s stage of development in allowing patents to function as incentives. Even if patents are unquestionably assumed to represent necessary incentives for the private sector to invest its resources in R&D, the pharmaceutical NIS of Jordan is underdeveloped and lacks the capabilities to respond to such incentives.

   I have noted that private firms in Jordan have structured their R&D activities to serve their business model: the production of generics. To sustain their businesses, the local firms have maintained R&D units designed for undertaking research in three areas: formulation and stability studies, bio-equivalence studies, and process development research. The firms have not focused on synthesizing new molecules and on the development of innovative products. R&D projects for potentially innovative outcomes are associated with high costs because of the intensity of research required and the extent of time needed for development, which explains the results shown in this study that the local firms have not increased their spending on, or investment in, R&D following the enactment of the new law, partially since they lack the necessary financial and technical resources to undertake such projects.
I have also noted that R&D undertaken by the public sector - which is another NIS element comprising public research centers, laboratories, and universities - is relatively immature. Besides inadequate financing and scarcity of specialized research centers, the following factors have contributed to this reality: inadequate management in research design, quality, and standardizations; lack of integration with the private sector; and finally, lack of trust among personnel within and among these institutions to exchange research results and to cooperate in designing, forming, and executing research projects. Further, universities host the preponderance of Jordan’s scientific and technical capital. They, however, focus on basic science and the production of academic papers, but applied research lacks priority and is marginalized. In addition, a nonexistent linkage between the public and private NIS elements to coordinate, cooperate, and integrate R&D projects has exacerbated the already weak state of R&D in Jordan.

Because there is no noticeable positive effect on levels of R&D and innovation, it is obvious that the new patent regime has not transformed the sector from an imitative to an innovative one. Numbers of patents issued to Jordanian inventors by national and foreign patent offices confirm this conclusion. A comparison of these numbers of patents issued before enacting the new law with those obtained since its date of enforcement reveals them to be relatively unchanged. To the contrary, I have shown that strong patent protection may have a negative impact on local innovation, since it prohibits imitative activities which are important for the process of “learning through application”. In addition, strong patent protection hampers the ability of local pharmaceutical firms to develop the necessary capabilities for problem solving, “learning to learn”, which, in turn, enables the firms to improve their productivity and to adapt product, process and organizational technologies already developed elsewhere to local conditions.

This thesis has demonstrated that enforcing the new patent regime has not only failed to incentivize more local investment in R&D and the generation of innovative technologies, but also has failed to induce the transfer of foreign technology to Jordan. I have demonstrated that local pharmaceutical manufacturers had a history of winning license contracts even when pharmaceutical product patent protection was not available in Jordan prior to 2000, but the new regime has not induced MNCs to conclude more licenses with the local firms. I also found that FDI in the local pharmaceutical sector has
always been absent, and, hence, has not contributed to transferring and diffusing advanced technology to the local sector.

This evidence is in line with the findings of, and arguments advanced by, several studies which have shown that the level of protection afforded to patents in a given country is only one of the numerous factors that might influence owners to license out their advanced technologies. Indeed, other factors may include: the local investment environment of a potential licensee’s country, state of competition from other innovative or generic companies, available skills and expertise of its labor force and its efficiency, regulatory and governance polices, and market openness. They may also include the level of imitative capacity of the local firms (the stronger such capacity is the less likely the chance of licensing since MNCs fear competition that could result from such licenses). On the supply side, firms’ endowments such as size, scale of business, and complementary commercial capabilities are also important factors in explaining licensing activity.

Given that the new patent regime has failed to advance the development of technology locally and has not encouraged foreign owners to transfer their technology to the local sector, this study recommends that Jordan should make maximum use of all flexibilities available to it under the TRIPS Agreement and the USJFTA. This recommended strategy should facilitate access to technology, partially through actual application, leading to the development of the local manufacturing capacity in Jordan. As recognized by the WHO 2008 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI), such capacity contributes to tackling the problem of access to essential medicines in Jordan and other developing countries with manufacturing capacities in the field of pharmaceuticals.¹ In turn, the recommended strategy should contribute to the economic development of Jordan and other like developing countries. It also should help in mitigating high drug prices leading to higher rates of access to medicines by making available more competitive drugs.

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2. Implementing and Invoking Circumstances as Grounds of Compulsory Licensing and Parallel Importation

The analysis provided in this thesis showed that Jordan’s policy of providing narrowly defined statutory grounds for issuing compulsory licenses and of limiting parallel importation under the Patents Law is erroneous. This policy is supported neither by a grounded understanding of the rights and measures available under the TRIPS Agreement and USJFTA, nor by a thorough appreciation of the possible static and dynamic social gains from enacting such measures, which include access to more affordable drugs and facilitation of access to advanced technology. This is especially true concerning the compulsory licensing ground of non-working of patents. I have shown that this ground is legitimate under the TRIPS Agreement and should be invoked to correct abusive, outright non-working of patents. Invoking this ground is necessary for the following. First, it facilitates the transfer of, and access to, advanced technology. In that regard, compulsory working is critical for the development of the local pharmaceutical industry when it lacks the capacity to develop the needed technology by itself, when it is prevented from using such technology because of patents, and when it is denied indirect diffusion of such technology through, for example, spillovers yielded by locally worked patents. In addition, this ground would enable a local firm to learn about a patented technology through application at the plant level and to master, enhance, and build on technology that is not available through other means such as voluntary licenses.

Second, this ground should facilitate the conclusion of voluntary licenses between patentees and local firms on reasonable commercial terms. This would be the case, based on experiences in other developing countries, since patentees tend to negotiate licenses on better terms for them (relative to those determined by domestic judicial or administrative authorities). Third, instituting this ground for compulsory licensing should increase the availability of more affordable medicines. This should happen when compulsory licenses are issued to local firms operating with the competitive advantage of lower labor costs, which enables them to offer the licensed product at competitively lower prices. If it is not economically viable to have the licensed product produced locally, compulsory licenses can be issued to import cheaper versions from third
countries as available. Furthermore, ultimately, to avoid having their patents compulsorily licensed, patentees may willingly reduce their prices.

However, I have also shown that instituting this ground may not sometimes lead to a transfer of advanced technology and lower drug prices. The legitimacy of providing for this ground in the law remains unclear due to the legal ambiguity created by the non-discrimination Clause under Article 27.1 of the TRIPS Agreement. This ground may also violate the USJFTA. I have illustrated that forcing a patentee to work its patent locally does not necessarily lead to cheaper medicines. This concern is particularly salient in the case of Jordan due to the size of its economy. In addition, Compulsory local working may not result in transferring advanced technologies because owners would vigorously keep their know-how, necessary for working patented technology, guarded to prevent diffusion. With regard to the legal ambiguity under TRIPS, it has been argued that legislation enacting this ground would be in violation of the non-discrimination clause of Article 27.1 TRIPS which stipulates that patents shall be available and patent rights enjoyable without discrimination as to whether products are imported or locally produced. As to the specific case of Jordan, providing for the ground of non-working locally in the Patents Law violates the USJFTA, because the Agreement specified that importation shall constitute working.

Accordingly, I recommend that Jordan defines when an importation by a patentee would not constitute working of its patent. Specifically, I recommend amending the Jordanian Patents Law to add the following provision to Article 22(b) of the Law.

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2 Article 22 of the reads:

[the] Minister may grant a license to use a patent to third parties without obtaining the patentee’s consent in any of the following cases exclusively:

A. If the use of the patent by the state authorities or licensed third parties is a necessity for national defense or emergency or for noncommercial public good provided that the patentee is notified as soon as it becomes possible.

B. 1. If the patentee doesn’t exploit it or exploits it insufficiently before the elapse of 4 years as of the application date or 3 years as of the granting date, the period to be applied is the one that elapses later. However, the Minister may grant the patentee an additional grace period if he deems that reasons beyond the control of the patentee have prevented exploitation.

2. For the purposes of item (1) of this paragraph, and without prejudice to the provisions of the related International Conventions, the importation of the subject goods of the patent to the kingdom shall be deemed utilization of the patent.

C. If the patentee exercises his rights in such a way as to prevent others from competing fairly.
22(b) (3) Notwithstanding the provisions of Paragraph (b) (2), importation does not constitute exploitation if the imported quantities do not meet the reasonable demands of the local market, and/or when the imported products are sold for unreasonably high prices.

Under the above recommended provision, a patent would be considered not worked and may be redressable through issuance of a compulsory license by the competent authority under the described circumstances. My recommendation may help redress the problem of expensive medicines by making them available under compulsory licenses as produced by a local firm or through importation. Admittedly, however, this solution is inadequate given that it does not solve the problem of access to advanced technology.

To deal with the issue of access to non-worked technologies through compulsory licensing, this study has found that enacting “the public interest” as a compulsory licensing ground may make such access possible. If a patentee fails to work its patented technology, refuses licensing of it to a local firm on reasonable commercial terms, and if it is in the public interest to have this technology worked locally, it is then a matter of public interest to establish such an outright refusal as a ground of compulsory licensing. This thesis has demonstrated that enacting the public interest ground remains a legitimate measure for Jordan to implement, since it is available under the TRIPS Agreement and the USJFTA, especially concerning public health. Specifically, compulsory licensing on the ground of the public interest is among the measures allowed for Jordan under Article 8 of the TRIPS Agreement, and Article 5 of the Paris Convention (incorporated by reference under Article 2 of TRIPS), in order to promote the public interest in the local pharmaceutical sector which is of vital importance to the socioeconomic and technological development of the country. This ground has been utilized in the laws of various WTO members. And finally, Article 31 of the agreement does not limit the rights of WTO members to provide for the public interest ground, which the Doha Declaration recognized.

Under the USJFTA, the decision of the US Supreme Court in the landmark eBay, Inc. v. MercExchange, L.L.C. case, and several subsequent rulings by lower courts,
supports the validity of the issuance of compulsory licenses by Jordan to advance its public interest. In eBay, the US Supreme Court ruled that injunctive relief may not be available to a patentee in a patent infringement case when it is in the public interest not to grant such a relief even though the patent concerned is valid and an infringement is established. This case, essentially, represents a form of *de facto* compulsory licensing (with royalties set by the courts). Moreover, the ruling in this case is relevant since it is an application and enforcement of a party’s (United States) statute that was in force when the USJFTA was concluded, and remains unchanged. Therefore, this case should provide an interpretation of the agreement on the US side and must be equally valid for Jordan. Accordingly, in order to prevent automatic grant of injunctions (interim and permanent) upon finding of an infringement, this thesis recommends amending Article 33 of the Jordanian Patents Law “Precautionary and Other Measures” that reads:

A. The owner of a patent registered in the Kingdom may request the court to do the following while it reviews the lawsuit provided that he submits with the application a bank or monetary guarantee accepted by the court:
1. To stop the infringement.
2. To make a precautionary seizure of the products subject of the infringement wherever they are.
3. To preserve the infringement evidence.

This article should be amended by adding the following after paragraph A (3):

4. The court may grant the measures described under items 1 and 2 of this Paragraph in accordance with the public interest.

The availability (or not) of pharmaceutical industrial capacity in developing countries has a determinative effect on the viability of compulsory licenses as a useful measure in either mitigating high drug prices or securing access to advanced technology. In countries with insufficient or no manufacturing capacity, it is highly unlikely that establishing the grounds of non-working locally or refusal to license would lead to technology transfer either through local working or licensing. This is also true if the aim of compulsory licensing is to influence patentrees to lower prices; however, compulsory licenses may be effective in such countries when invoked to authorize the importation of cheaper generic copies of a patented medicine as available from third-country markets. In
this case, compulsory licenses can lead to competitive market entry, which may influence patentees to reconsider their pricing strategies. Therefore, this thesis strongly suggests that these countries should institute in their legislation the grounds of non-working and high prices. This thesis further recommends and encourages such countries to consider a patent as not worked when the medicines covered by the patent are not provided to the local market at reasonable prices, where affordability must be factored in the determination of the reasonability of prices.

The same might also be accomplished by directly instituting high prices as a compulsory licensing ground. In such countries, parallel importation may also represent a viable alternative, avoiding some of the complex prerequisites involved in adopting compulsory licenses. This would also apply to Jordan in instances where the local industry lacks the necessary manufacturing and technical capacities to produce particular medicines or when local production is not economically viable. Accordingly, this thesis recommends legalizing parallel importation in Jordan. Ideally, this would be achieved in Jordan by repealing Paragraph (B) of Article 37 of the Patents Law, which was added as an amendment to the Article in 2001 and reads:

B. In spite of the inclusions of paragraph (A) of this article and without prejudice to the provisions of the related International conventions, importation of any goods covered by patent of invention from a licensee shall be banned if the licensing contract prohibits him from exporting to the kingdom, provided that the patent owner notify in writing the Customs Administration and the Registrar in this respect. The Registrar shall, at the expense of the patent owner, publish this notification in at least one of Local daily gazettes; and the applicable legislations shall apply to this case.

The recommended repeal will remove the legal obstacle created by this paragraph, which conditions the legality of any parallel importation upon the consent of the patentee, including importation by, or from, licensees. The paragraph constitutes a de facto ban on parallel importation and repealing it will eliminate this restriction on parallel importation of more affordable drugs.
3. The Protection of Pharmaceutical Testing Data and Access to Medicines

With regard to the obligation to protect pharmaceutical TD, this thesis has found that so far it is the implementation of this obligation in the form of data exclusivity by Jordan that has restricted competition in the local drug market and limited access to more affordable generic versions of mostly off-patent medicines. The thesis has demonstrated that neither the provisions under Article 39.3 TRIPS nor those under Article 4.22 of the USJFTA mandate data exclusivity, as currently implemented under Article 8 of the Jordanian Trade Secrets and Unfair Competition Law and enforced by JFDA. Both sets of provisions only require the protection of such data against unfair commercial use and disclosure, which does not entail data exclusivity.

The finding of this thesis regarding the nature and scope of the obligation to protect TD against unfair commercial use is based on analyzing the different versions of the text of Article 39.3 of the TRIPS Agreement and the various proposals advanced during negotiations. In addition, the rules on treaty interpretation support my argument.

I arrived at the same conclusion with regard to the relevant article of the USJFTA. The USJFTA contained some changes to the conditions of protection delineated under the TRIPS article for the protection of TD. These changes comprised the extension of protection against unfair commercial use and disclosures to data related to new uses of old chemical entities and to data submitted to foreign health regulatory authorities when there is reliance on foreign marketing authorizations issued based on such data. Although these changes may have serious implications for access to medicines in Jordan, I demonstrated that the USJFTA does not transform the obligations of Jordan from protection against unfair commercial use and disclosure to data exclusivity.

Therefore, this thesis strongly recommends that JFDA includes in the “Drugs Registration Criteria” (DRC) the definitions of what constitutes a new chemical entity and new uses of old entities that were discussed in Chapter Four of this thesis. I further recommend that JFDA discontinues its current practice by which data submitted by sponsors of new drug applications are assumed to have met protection requirements. Instead, sponsors should be required to demonstrate that their data meet all the conditions of, and requirements for, protection. This should be in addition to the incorporation of
specific reasonable exceptions to, and legitimate grounds for the revocation of, data protection under the relevant Jordanian legislation(s).

Therefore, I recommend in particular the following reforms: (1) allow reliance on originators’ data to register drugs produced or imported under compulsory licenses or obtained via parallel importation. (2) Allow the registration of a generic drug by reliance on the originator’s data when the product associated with the latter is sold for an unreasonably high price, when the originator perpetrates anticompetitive conducts that directly or indirectly involve the data, when the originator ceases marketing its products locally, and when the quantities provided are insufficient for meeting local demand. If originators’ data are used involuntarily, a reasonable payment should be made by the generics producer. The amount of the payment may be calculated on a cost-sharing basis. However, no such remuneration should be made in cases of wrongdoing by the originator; for instance, if it engages in anticompetitive practices or an unjustifiable lack of, or insufficient, commercialization. Furthermore, with regard to the protection of data related to patented products, I recommend that the term of protection must be linked with and capped by the patent term of protection. This limitation is necessary to make timely use of the early working exception to patent rights. The objective underlying this exception is to market generic copies of a patented medicine right after its patent expires. If data protection is allowed beyond the expiry date of a patent protection, then the objective of this exception may be frustrated by unnecessary delay of generics’ market entry.

In addition, this thesis recommends that JFDA includes the following circumstances as grounds for the revocation of data protection in the Jordanian DRC. (1) If, without a reasonable justification, a product is not marketed in Jordan within six months calculated from the local registration date, or if the marketed quantities are insufficient for meeting reasonable local demands, or, if available, the product is sold for unreasonably high prices; (2) If, without a reasonable cause, and after being actually marketed, a product ceases to be available in the local market for an uninterrupted six-month period, or if the same period results from multiple shorter durations throughout the entire term of protection; and
(3) If an application to register a pharmaceutical product is abandoned before or after a sanitary approval for its marketing is issued by JFDA.

Besides preventing abuses of data protection such as “evergreening”, these proposed measures should maintain the balance between the interest of the public at large and those of the originator. The measures should alleviate some of the economic burden of providing data protection by allowing more competition in the drugs market. The forgoing recommendations with regard to the Jordanian protection of test data are all equally applicable to other developing countries regardless of their developmental state or level of income.

4. What Other Developing Countries Can Learn from the Jordanian Experience

Jordan’s history of enforcing strong patent protection in the pharmaceutical sector can assist in developing guidelines for other developing countries. However, such guidelines may be influenced by the local peculiarities and conditions of each developing country concerned. These influences would include, for example, the level and potential of local R&D activities, innovative capacities, availability of industrial capabilities in pharmaceuticals, and level of income.

To date, there is no evidence that strong patent protection of pharmaceutical inventions has had a positive impact on levels of local R&D activities and rates of innovation in Jordan. Learning from this experience, other developing countries might be cautious in accepting the argument that such protection may positively influence the level and quality of R&D activities and innovation in their own contexts; it is unlikely that the outcome of such protection in many of these countries would be different than that in Jordan and for the same reasons. Intuitively, therefore, developing countries which are obligated to implement the minimum standards of the TRIPS Agreement should resist demands from developed countries to protect patents beyond the minimum standards of the agreement, whether through bilateral trade agreements or a more restrictive interpretation of their obligations under the TRIPS Agreement. However, it is possible that the relationship between the strength of a patent system and the levels of R&D and innovation might not apply to certain developing countries, specifically those possessing
advanced R&D capacities and the necessary complementary assets to commercialize their inventive output.

Developing countries should also not be enticed by the unproven claim that strong patent rights are a prerequisite for technology transfer and FDI. The Jordanian experience shows that it takes more than strong patent rights for technology owners to transfer their technology; a robust enforcement of patent rights in Jordan since 2000 has neither induced technology owners to conclude more licenses with the local industry nor encouraged them to invest their technology directly in the local sector. Yet this may not be the case in developing countries which have different market endowments. For example, the fact that strong patent protection has not resulted in the pharmaceutical industry in Jordan gaining more licensing contracts might be attributed to the size of the economy which may make it economically unviable for the industry to conclude such licenses. Alternatively, this might also be attributed to the patent law in Jordan which stipulates that a patentee may discharge its working obligations through importation. This, in turn, might have emboldened patentees to demand unreasonable terms or not to license their inventions. Therefore, the Jordanian experience may not be replicated in countries which have much larger economies, stricter working requirements, and/or a refusal to license as a ground for compulsory licensing.

Another lesson that developing countries can draw from the Jordanian experience is to avoid limiting parallel importation and the grounds for compulsory licensing. In the pharmaceutical sectors of developing countries, such a limitation would render the patent system vulnerable to abuses by patentees (particularly foreign ones), impair local communities from reaping the benefits of the patent system, and have negative effects on social welfare. The absence from the Jordanian Patents Law of grounds such as non-working of patents has resulted in protecting certain groups from legal consequences, namely, right holders who do not work their patents locally themselves and those who do not do so through licensing agreements. Therefore, developing countries with significant pharmaceutical industrial capabilities should not follow the Jordanian example in limiting such grounds. Providing for compulsory licensing on the ground of non-working may not compel patentees to work their inventions locally, whether due to a lack of economic viability in setting up their own plants in such countries or to form joint ventures with
locals, or for other reasons. However, it may encourage patentees to work their patents through granting voluntary licenses to local manufacturers on commercially reasonable terms. Consequently, this would fulfill at least two objectives. First, it would facilitate access to advanced technology for local manufacturers at reasonable cost because patentees agree to license on less onerous terms and royalties acceptable to local would-be licensees or to have such terms set by courts in the course of granting compulsory licenses. Second, local production involving such reasonable technology cost and access to lower labor costs would make this production much less expensive and affordable to patients in developing countries. This in turn would lead to higher access rates to essential medicines. The same objective may also be accomplished by establishing refusal to license as a compulsory licensing ground, or other grounds on the basis of the public interest. This would be the case in developing countries with large economies. Given the size of their economies and in light of the requirement under Article 31(f), these countries arguably have the advantage of being able to export substantial quantities of production under compulsory licenses (up to 49 per cent), making it economically sound for potential licensees to offer competitive prices and yet be able to make profits.

However, due to the lack of economies of scale in small developing countries with a local pharmaceutical industry, prices of products manufactured under compulsory licenses may still be more expensive than those of imported branded products originating from patentees. This would likely be the case whether licenses are granted based on the above grounds or the ground of high drug prices. Nevertheless, this reality does not necessarily mean that compulsory licensing is ineffective in making more affordable medicines available for these countries. Such countries can issue licenses to import patented medicines from third markets as available. In addition, at least regarding countries lacking industrial capacities, a solution was found under the mechanism established by the 2003 Decision and the 2005 pending amendment to the TRIPS Agreement, which permitted such countries to request a third country to issue a compulsory license for the single purpose of exporting to them.

Therefore, the availability (or not) of pharmaceutical industrial capacity in developing countries has a determinative effect on the viability of compulsory licenses as a useful measure in either mitigating high drug prices or securing access to advanced
technology. In countries with insufficient or no manufacturing capacity, it is highly unlikely that establishing the above-mentioned grounds would lead to technology transfer either through local working or licensing. This is also true if the aim of compulsory licensing is to influence patentees to lower prices of their products; however, compulsory licenses may be effective in such countries when invoked to authorize the importation of cheaper generic copies of a patented medicine from third-country markets. In this case, compulsory licenses can lead to competitive market entry, which may influence patentees to reconsider their pricing strategies. This thesis further recommends and encourages such countries to consider a patent as not worked when the medicines covered by a patent are not provided to the local market at reasonable prices and quantities, where affordability must be factored in the determination of the reasonability of prices. The same might also be accomplished by directly instituting high prices as a compulsory licensing ground. In such countries, parallel importation may also represent a viable alternative, avoiding some of the complex prerequisites involved in adopting compulsory licenses.

The third lesson to be drawn from the Jordanian case involves the implications for developing countries of implementing their obligations under Article 39.3 of the TRIPS Agreement. This article requires them to protect pharmaceutical testing data against unfair commercial use and disclosure. Developing countries should resist interpreting these obligations to mean data exclusivity. The Jordanian experience has shown that such legal interpretation will most likely result in serious implications for access to affordable medicines, since it considerably limits competition in the market of not only patented, but also off-patent medicines. Instead, these obligations can be fulfilled by protecting only the confidentiality of such data in the framework of unfair competition: against dishonest commercial and industrial practices perpetrated by competitors.

In addition, health regulators in developing countries should stipulate that the protection of testing data is contingent on satisfying all the requirements under Article 39.3 of the TRIPS Agreement. Therefore, regulators should not assume that submitted data are eligible for protection; rather, the sponsors of new drug applications should be required to prove that their data are eligible for protection. In this regard, these countries are encouraged to adopt a strict definition of what constitutes a new chemical entity.
whose novelty (newness) should be linked to the first world application to market a pharmaceutical product (absolute novelty). Developing countries, therefore, should not extend the definition of new chemical entity to a new use for an old entity. Thus, they are encouraged to exclude from protection data related to derivatives of known drugs such as new dosage forms, new administration routes, combinations, crystalline forms, and isomers. It is also recommended that they provide for reasonable exceptions to and grounds for the revocation of data protection. Similar to those recommended above for implementation in Jordan, this thesis is of the view that other developing countries should specify the following measures in their law: (1) allow reliance on originators’ data to register drugs produced or imported under compulsory licenses or obtained via parallel importation; (2) allow the registration of a generic drug by reliance on the originator’s data under certain circumstances – for example, when the product associated with the latter is sold for an unreasonably high price, when the originator perpetrates anticompetitive conducts that directly or indirectly involve the data, when the originator ceases marketing its products locally, and when the quantities provided are insufficient for meeting local demand.

The TRIPS Agreement is not as rigid as PhRMA and some developed countries have claimed. Developing countries’ negotiators were successful during the Uruguay Round in maintaining very important flexibilities in the Agreement and these measures were part of the compromised reached between developed and developing countries to conclude the Agreement. Developing countries, thus, are entitled to full use of these measures, and I have argued that it is in their interest to do so. They need to take their rights seriously, and they should resist intimidation by developed countries who try to deprive them of their rights through various means such as free trade agreements. They also should challenge any sort of economic and political retaliations that are not accordingly authorized by the WTO. These types of retaliations are illegal if not accordingly authorized by the WTO Dispute Settlement Body in accordance with the rules on Dispute Settlement Understanding.

Despite the conclusion of this thesis that strong patent protection, including limitations on the utilization of available flexibilities, has not been conducive to the promotion of technological innovation and to the transfer and dissemination of
technology, it might have not been long enough, or due to peculiarities of the Jordanian case, for such protection to produce its positive effects. Furthermore, the recommendation with regard to implementation of as many flexibilities as possible is likely to conflict with the reality of political economy. In other words, since there has not been a single instance of Jordan issuing a compulsory license or allowing the parallel importation of drugs, implementing or invoking such measures by Jordan may cause a political uproar or backlash, particularly from PhRMA and developed countries. Therefore, the stability of the recommendations of this thesis may be an uphill battle, but can succeed if the government of Jordan commits to standing firmly by its rights in the face of strenuous political opposition.
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APPENDIX


A. The Patents Office

1- Why did the government decide to amend the Patent Law in 1986? Where did the proposal for the amendment come from? Was it the industry or the government, if it was the government which ministry?

2- What were the utilized grounds on which the amendment was advanced?

3- What are the adopted standards for the examination of patent applications’ patentability requirements- novelty, inventive step, and industrial applicability- containing pharmaceutical product or process, in particular, an application the subject of which is a new use of a known product?

4- Article 2 of the law was amended in 2007 to give effect to the patent cooperation treaty (PCT); what were the anticipated benefits of the amendment?

5- In Article 22/b.1 of the law the phrase “external causes” was used to justify a delay of a patent exploitation by the patentee, why was not the term “reasonable” instead of “external” used instead?

6- In Article 22/b.2 of the law importation is considered “exploitation”, thus it is no longer mandatory to locally work a patent, consequently, the lack thereof is not a ground on which a compulsory license can be issued, why did the law exclude non-working as a ground for compulsory license grant?; taking in consideration the Brazilian and the American- in certain cases- patent laws which mandate local working of patents?

7- Article 22 spilled out few grounds for the grant of compulsory licenses, however, the article, through the 2007 amendment, made that list “exclusive” why, and what were the necessities to be met by that exclusivity?

8- Would the Minister consider, for example, excessive prices of certain medicines and refusal to license, on reasonable terms, grounds for compulsory licenses grant?

9- Since 2000, have you received applications for compulsory licenses concerning pharmaceuticals?

10- Since Jordan had to implement all the legal standards contained in the TRIPS Agreement before becoming officially a WTO member and that it could not avail itself of any transitional periods regarding pharmaceuticals and food stuff, why does the Patents Law still has to provide for exclusive marketing rights for patents applicants as prescribed in Article 36/D?
B. Pharmaceutical Companies:

First: The years leading to the 1999 Patents Law:

1. Were you involved in the discussions over the Patents Law reform which was required for Jordan to accessed to the WTO, if not, have you tried to communicate your view to the relevant entity: the Jordanian Association of Manufacturers of Pharmaceuticals and Medical Appliances (JAPM), the Ministry of Health, the Ministry of Trade, and/or the Negotiating Team?
2. What were the shortcomings of the Patents Law that you have advised against?
3. Before 1999, what were the difficulties that you had faced in concluding licenses, if any, from the (Multinational Corporations) MNCs\(^1\) due to the lack of patent protection in Jordan?

Second: The years following the enactment of the 1999 patent law:

1. What do you think of the new Patents Law?
2. How does the Research Exception to patent rights, contained in Article 21/c of the Patents Law, benefit you, and have you so far used this exception?
3. How does the 1999 Patents Law facilitate, or stifle, the development goals of your organization?
4. Since the year 2000, have you sought and thus been granted a license for leading drugs by the MNCs?
5. How does your organization perceive R&D following the new law?
6. How important to your organization are publications of patents applications, domestically or internationally, for technical details to employ in future R&D projects, or to examine the validity granted patents?
7. How did the Law impact your organization’s production and export since 2000?
8. Can you describe how the MNCs operate in the Jordanian market since 2000?
9. How do you find the application of the patentability requirements by the local Patents Office?

\(^1\) Multinational Corporations, or some times referred to as TNCs (Transnational corporations).
C. Food and Drugs Administration:

11- What is the process followed by your institution to register a new drug, brand and generic?
12- How do you register generic drugs applying for marketing approval while reference drugs, foreign or domestic, still protected by patents?
13- In processing the registration mentioned in question two, how do you find out about whether the substance, which is the subject of registration, is protected by a proprietary right or not?
14- For how long would not you accept an application for marketing a generic drug that relies on an innovator’s efficacy and safety data?
15- For the purposes of acquiring marketing approval for their products, are applicants required to demonstrate the utility off their products?
16- How do you price medicines?
17- How do representatives of international pharmaceutical manufacturers perceive your pricing methodology?
18- What are the aspects of your pricing mechanisms that you would like to reform?
D. **King Hussein Cancer Center (KHCC):**

1. What are the sources that supply your institution with medicines for Cancer?
2. How accessible are Cancer medications in Jordan?
3. Were there any medicines for the treatment of Cancer that had been placed in the international market and became available in the local market after 2000 as a result of patent protection?
4. Relative to those prevailing before 2000, are prices of Cancer medicines the same, lower, or higher?
5. Do you think the protection provided by the new Patents Law has enhanced domestic research devoted to finding new medicines to treat Cancer or to improving existing ones?
6. Does your organization have an adopted policy in relation to patenting the results of research conducted by its staff members and other associated researchers?
7. How would you describe cooperation and relations, if any, between your organization and the local pharmaceutical industry in exchanging both research expertise and results?
E. Competition Directorate:

1- How does your directorate work?
2- How would you describe the interplay between Jordan Competition Law and Patents Law?
3- According to the Competition Law, what would constitute an anti-competitive practice under article 22.C of the Patents Law?
4- What provisions in licensing agreement are considered anticompetitive according to the Jordanian Law?
5- If consistent with your confidentiality rules, have you received any complaints regarding pharmaceutical MNCs conduct of anti-competitive behavior in Jordan, if yes, what was/were the practice(s) complained of?
6- Article 5/A of the competition Law No. 33 reads “Practices, alliances and agreements, explicit or implicit, that prejudice, contravene, limit or prevent competition, shall be prohibited”. In a licensing agreement of a patented product or process what would constitute a “Limitation” or “prevention” of competition?
7- How would you decide a status of “Dominant Position” of a firm, as mentioned in Article 6 of the Competition Law, and what are factors that you would consider in making decision thereof?
8- Can you provide examples of business activities in the pharmaceutical sector which would constitute a behavior that “weaken competition” in Jordan?
2. Consent Form and Ethics Approval

University of Toronto
Participant Informed Consent

Dear Participant,

I am conducting this research as part of my doctoral dissertation at the University of Toronto Faculty of Law. The purpose of my dissertation is to understand the implications of implementation, by Jordan, of the minimum protection standards of the World Trade Organization’s (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. The dissertation will try to find whether Jordan has benefited or lost from this implementation and how. To do so, I am using the Jordanian 1999 Patents Law and its interplay with the pharmaceutical sector in Jordan as a case study.

My hypothesis is that the Pharmaceutical Sector in Jordan will experience a negative impact due to the new law. Given your status as stakeholder in the Jordanian Pharmaceutical sector, your experience with the law enforcement process, and/or your knowledge of the application phase of the law, I have contacted you to be a participant.

Being a participant in this study means you will take part in a semi-structured interview which will approximately last for 50 minutes. During the interview, I am going to ask questions as to your experience and knowledge with regard to your participation in debating, drafting, applying, and/or implementing the Patents Law.

I am not aware of any risk (financial, social, physical, or psychological) resulting from participation in this study. In addition, I do not think there will have a direct benefit from it. Accordingly, your participation is absolutely for pure scholarly research purposes.

Your are not obliged to discuss, reveal or mention anything that you opt not to. Upon your participation, all information gathered via this interview will be maintained confidential unless you make otherwise intention expressly as to waive this confidentiality or anonymity. I will be taking notes during the interview, but no recording device will be utilized. Throughout the study, notes will be kept, when not present for study by me, in a safe premise that is only accessible by me. You have the right not to answer any question, and/or to withdraw or discontinue with the interview at any time.

Regarding any questions about your rights as a participant in this study, you might contact the University of Toronto Office of Ethics at ethics@utoronto.ca or 416-978-3273.

If you have any inquiries as to the study, please do not hesitate to contact me, Said Abuhammad, at said.abuhammad@utoronto.ca or 617-884-4445.

Sincerely,

Said Abuhammad

(PLEASE SEE REVERSE SIDE)
CONSENT FORM

Please read the following statement, and indicate that you agree by signing below.

1. I agree to be interviewed by Said Abuhamm as part of his doctoral research.
2. I have had the nature of his research explained to me, and I have had a chance to have my questions answered.
3. I have been given a copy of this form to keep for my records.
4. I have been offered the opportunity to receive a short description of the completed dissertation and/or scholarly publications.
5. I understand that it is my right to withdraw from the research, decline to answer any question or to discontinue with the interview at any time, without any adverse consequences.
6. Please choose one of the following:

   - I agree that the information I provide in the interview may be attributed to me personally and quoted or cited by Said Abuhamm in his dissertation and/or other scholarly publications. If I am quoted or if views are attributed to me personally, I reserve the right to review a draft version of the quotations or attributions before being utilized in the dissertation or any other scholarly publication.

   - I wish to remain anonymous in the dissertation and/or other scholarly publications. My remarks may be quoted or cited and attributed to a person of my occupation or institutional affiliation, as long as I am not personally identifiable by name, position, or context.

   - I wish my remarks to remain confidential and anonymous; they may not be quoted or cited in the dissertation and/or other scholarly publication, nor may my participation be identified by name, position, institutional affiliation or context.

7. (Signed) I have received and read a copy of this consent form. I understand the above information and I want to be a participant in this study.

Participant’s name (print): __________________________ Date: __________________________
University of Toronto
Office of the Vice-President, Research
Office of Research Ethics

PROTOCOL REFERENCE #23697
April 28, 2008

Prof. Arab Katz
Faculty of Law
University of Toronto
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Mr. Saeid Abouhairam
Lecturer, Law
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Toronto, ON M5S 2C5

Dear Prof. Katz and Mr. Abouhairam:

Re: Your research protocol entitled “Implications of the TRIPs Agreement’s Implementation for the Pharmaceutical Sector in Developing Countries: A Jordanian Perspective”

We are writing to advise you that a member of the Social Sciences, Humanities & Education Research Ethics Board has granted approval to the above-named research study, for a period of one year, under the REB’s expedited review process. Please ensure that you submit an Annual Renewal Form or a Study Completion Report at least 30 days prior to the expiry date of your study.

The consent document (received April 27, 2008) has been approved for use in this study.

Any changes to the approved protocol or consent materials must be reviewed and approved through the amendment process prior to its implementation. Any adverse or unanticipated events should be reported to the Office of Research Ethics as soon as possible.

If your research has funding attached, please contact the relevant Research Funding Office in Research Services to ensure that your funds are released.

Best wishes for the successful completion of your project.

Yours sincerely,

[Signature]

Dean Sharpe, Ph.D.
Research Ethics Officer, Social Sciences and Humanities

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