TRIPPING OVER PATENTS:
AIDS, ACCESS TO TREATMENT
AND THE
MANUFACTURING OF SCARCITY

by

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ABSTRACT

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With an estimated 4.7 million—or approximately one-in-nine—people living with HIV/AIDS, South Africa is in crisis. Understanding that its ability to turn the tide against the epidemic in large part hinges on whether the majority of people with HIV/AIDS will have access to treatment, this thesis explores the extent of regulatory flexibility permissible under the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). I argue that despite the international harmonization of intellectual property law, countries like South Africa are permitted by TRIPS to take certain regulatory steps to ensure the accessibility of essential treatments. When properly interpreted in accordance with recognized principles of international law and in the light of the Constitution of the Republic of South Africa, 1996, TRIPS does not prevent—but rather contemplates and permits—the taking of certain legal steps to ensure meaningful reductions in drug prices.
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INTRODUCTION

HIV causes AIDS.¹ This much we know. We also know that while the treatment of opportunistic infections associated with HIV infection may serve to delay the inevitable onset of AIDS, but for the intervention of highly active antiretroviral therapy (HAART),² HIV infection results in the gradual but inevitable decline and ultimate failure of a body’s immune system.³ In almost all cases, only with antiretroviral interventions are people with HIV/AIDS able to lead longer and healthier lives.⁴

That AIDS has reached pandemic proportions also is beyond dispute. Described by the United Nations General Assembly Special Session on HIV/AIDS (UNGASS) as a “global emergency” on account of its sheer scale and impact, AIDS is recognized as a formidable threat to human life, dignity and the enjoyment of fundamental human rights.⁵ In particular, the pandemic is recognized as a threat to social and economic

² Antiretroviral drugs—drugs that specifically target HIV infection itself rather than the opportunistic infections that are associated with HIV/AIDS—are combined in various different treatment regimens that collectively are known as HAART (see Ward, supra note 1 at 68-69).
³ Ibid.
⁴ Approximately five per cent of all people with HIV have survived for more than 10-12 years without antiretroviral treatment and without showing signs of HIV infection (ibid. at 77).
development. But despite its global nature, not every region is equally threatened by the pandemic’s potentially devastating consequences.

Of the estimated 36.1 million people with HIV/AIDS globally, approximately 25.3 million—or 70 per cent—live in sub-Saharan Africa, a region with only 10 per cent of the world’s total population. Not only is sub-Saharan Africa the most adversely affected region, it is arguably also the region least able to deal with the consequences of such an epidemic. In this light, it is not surprisingly that the UNGASS Declaration sees the African epidemic as a “state of emergency”, threatening development, political security and the very fabric of society. As such, AIDS in sub-Saharan Africa is recognized as a threat requiring “urgent and exceptional national, regional and international action”.

The South African context

With an estimated 4.7 million—or approximately one-in-nine—people living with HIV/AIDS, South Africa is in crisis. From an estimated 90 000 AIDS-related deaths in 2000, experts predict that this number could rise to an annual figure of over 380 000 by

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6 Ibid.
8 Ibid. at 5.
10 UNGASS Declaration, supra note 5 at para. 8.
2005, increasing to more than 630 000 per annum by the end of the decade. This context is further complicated by the racially divided and unequal health sector inherited from South Africa's apartheid past, which was characterized by strengthening government control rather than improving health or providing an efficient and efficacious health care service. Resources were distributed along racial lines, with access to health care consequently being determined primarily by racial classification. In particular, health care workers were trained to serve a white elite, with a focus on hospital care at the expense of primary health care. Unsurprisingly, programmes for disease prevention and control were weak.

In addition to the sheer scale of the epidemic and the apartheid legacy reflected in health care inequities and skewed priorities, the impact of AIDS may be greater in South Africa because of its more developed economy, reliant on an already extremely small—and increasingly depleting—skills base. While difficult to assess the degree to which AIDS will have an impact on South Africa, both at the local (community or household) level and at the macro economic level, three conclusions may be reached. First, the epidemic will result in a significant rise in morbidity and mortality. Second, an increase in illness and death will inevitably have negative economic and social consequences. Third, the

15 Whiteside & Sunter, supra note 9 at 67.
16 Ibid. at 82.
17 Ibid. at 81.
18 Ibid. at 82.
majority of AIDS-related deaths will be of young economically active adults.\textsuperscript{19} Because a sizeable percentage of South Africa’s population fall within this category of people, AIDS has the potential to devastate social, economic, and human development.\textsuperscript{20} In short, South Africa faces an emergency that threatens to render the struggle for and ultimate attainment of democracy worthless.

Some twenty years into the pandemic, we are only now starting to see encouraging signs of global action. Although possibly a case of “too-little-too-late”, the \textit{UNGASS Declaration} nevertheless represents a significant shift forwards. But words now need to be translated into real action, accompanied by a significant freeing up of resources to fund such action. In short, such “an unprecedented global crisis” calls for an “unprecedented response”, or what Kofi Annan sees as a “profound change in the conduct of community, national and international affairs”. For the United Nations Secretary-General, this is a “new kind of commitment that goes beyond the ordinary.” The stakes could not be any higher. “For the future of humanity,” Annan argues, “we must be willing to make that commitment.”\textsuperscript{21}

We know that we must act, but how and in what way? Should we prioritise certain public health interventions? How do we make the best use of limited resources? In resource-poor countries, some may argue, attention should be focused on the prevention of HIV transmission: a focus on treatment diverts attention and resources away from where they

\textsuperscript{19} \textit{Ibid.} at 70
\textsuperscript{20} \textit{Ibid.} at 58. See also Malcolm Steinberg et al., \textit{supra} note 13.
are most needed. Such an argument, however, fails to consider two important points. First, in the fight against the pandemic, it has long been recognized that the protection of human rights is a key element in the prevention and containment of HIV infection. Second, evidence suggests that the most effective way to address the pandemic is by the use of a comprehensive and holistic approach that includes prevention, treatment and care.

But there is an additional, arguably more important reason to provide treatment, based not on considerations of utility but rather principle. South Africa is a constitutional democracy based, in large part, on the foundational value of human dignity. That human dignity forms such an integral part of the new constitutional order is no coincidence.

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22 See UNAIDS, *HIV/AIDS and Human Rights: International Guidelines* (New York: United Nations 1998), online: UNAIDS <http://www.unaids.org/publications/documents/human/law/hriight2e.pdf> (date accessed: 10 January 2001) [hereinafter UNAIDS Guidelines]. The so-called AIDS paradox, which links HIV prevention with a rights-based approach to public health, has been described by Justice Kirby of the High Court of Australia as follows: "[O]ne of the most effective laws we can offer to combat the spread of HIV which causes AIDS is the protection of persons living with AIDS, and those about them, from discrimination. This is a paradox because the community expects laws to protect the uninfected from the infected." (Michael Kirby, "AIDS & the Law" (1993) 9 S. Afr. J. Hum. Rts. 1 at 3 – 4). A rights-based approach also includes the recognition of the right to life and the right to the highest attainable standard of health as human rights.

23 For example, a Médecins Sans Frontières (MSF) programme to prevent mother-to-child transmission of HIV in Khayelitsha (Cape Town) has seen the availability of treatment leading to a dramatic increase in voluntary testing for HIV, the rapid development of HIV/AIDS support groups in the poverty-stricken community and the decrease in stigma associated with HIV/AIDS. These are all key elements in the prevention of new infections (Eric Goemaere, "South Africa: how access to treatment helps prevent the spread of HIV", online: Médecins Sans Frontières (MSF) <http://195.114.67.76/msf/accessmed/accessmed.nsf/html/4DTSR2?OpenDocument> (date accessed: 18 December 2000). See also Edwin Cameron, "Involvement of People Living with HIV/AIDS—How to Make it More Meaningful" (Second National Conference for People Living with AIDS, Durban, South Africa, 10 March 2000), online: Consumer Project on Technology <http://www.cptech.org/ip/health/sa/cameron.html> (date accessed: 10 December 2000), where the author notes that treatment provides hope, and in so doing, assists in addressing the stigma that surrounds HIV/AIDS; Paul Farmer, *Infections and Inequalities: The Modern Plagues* (Berkeley: University of California Press, 1999), where the author argues that prevention interventions will be most effective as part of a holistic public health intervention which includes treatment (*ibid.* at xxi-xxii).
Indeed, the Constitution of the Republic of South Africa, 1996 \(^{24}\) "asserts dignity to contradict our past in which human dignity for black South Africans was routinely and cruelly denied." \(^{25}\) In addition, the Constitution asserts dignity "to invest in our democracy respect for the intrinsic worth of all human beings." \(^{26}\)

South Africa is blessed with a Bill of Rights \(^ {27}\) that is distinctive in two fundamental ways: in respect of the nature of rights protected and the extent of protection guaranteed. \(^ {28}\)

But it is in its guarantee of social and economic justice that the Constitution distinguishes itself, implicitly rejecting the traditional characterization of a bill of rights "as a shield and not as a sword". \(^ {29}\) It does this not merely by entrenching justiciable social and economic rights, but also by mandating the state to "respect, protect, promote and fulfil the rights in the Bill of Rights." \(^ {30}\) These obligations apply to all rights, whether classified as civil, political, social or economic.

There are two levels at which these positive obligations operate. First, the state is to create an enabling framework by putting in place laws and regulations so that individuals

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\(^{24}\) Where it is necessary to distinguish the Constitution of the Republic of South Africa, 1996 from the Constitution of the Republic of South Africa, 200 of 1993 [hereinafter the interim Constitution], the former is referred to as the 1996 Constitution. Where no such distinction is necessary, it is simply referred to as the Constitution.


\(^{26}\) Dawood, supra note 25.

\(^{27}\) Chapter 2 of the Constitution is the Bill of Rights.

\(^{28}\) For example, the right to be protected from unfair discrimination not only expressly recognizes sexual orientation as a protected ground, but also guarantees protection both against the state and natural and juristic persons (sections 9(3) and (4)).


\(^{30}\) Section 7(2).
will be able to realize their rights free from interference. This obligation does not entail the direct provision of money, resources or services, the state being seen as a facilitator rather than as an actual provider.31 Second, the state may be obliged to provide “positive assistance, or a benefit or a service[,] . . . creating the conditions in which the rights can be realised by the individual”,32 which may even extend to the direct provision of basic resources or services where a failure to do so would result in a denial of the realization of rights.33 The nature and extent of the obligation, however, would be dependent on the actual formulation of the right.34

The Constitution brings to democratic South Africa a “culture of justification”, requiring “every exercise of [public] power . . . to be justified”.35 In such a culture, “the leadership given by government rests on the cogency of the case offered in defence of its decisions, not the fear inspired by the force at its command.”36 In short, what the Constitution demands of government is that it account for its actions and decisions, providing standards in the Bill of Rights against which to measure their justification.37

In this light, the constitutional guarantee of the right of access to health care services38 takes on special significance. While the full extent and nature of the state’s obligations in

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31 De Vos, supra note 29 at 83.
32 Ibid. at 86.
33 Ibid.
34 Ibid.
35 The concept of the Constitution as entrenching a “culture of justification” is ascribed to Etienne Mureinik (Etienne Mureinik, “A Bridge To Where? Introducing the Interim Bill of Rights” (1994) 10 S. Afr. J. Hum. Rts. 31 at 32). Mureinik’s vision of the Constitution was adopted by the Constitutional Court in Harken v. Lane NO and Others 1998 (1) SA 300 (CC) [hereinafter Harken].
36 Mureinik, supra note 35.
37 See ibid. at 33.
38 Section 27.
respect of HIV/AIDS treatment remains unclear, it is at minimum required to take reasonable steps towards creating the legal framework necessary for accessing affordable treatments for HIV/AIDS. A failure to provide the necessary enabling environment for the treatment of people with HIV/AIDS, which in certain circumstances will extend to the actual provision of resources, strikes at the very heart of the Constitution, for the “deepest violation of another person’s humanity is to deprive that person of the means to remain healthy, to fight off illness and to live—or die—in reasonable comfort and dignity.”

The extent of the epidemic is compounded by a clear lack of responsible political leadership, most visible in South African President Thabo Mbeki’s public questioning of the link between HIV and AIDS. Warning of the dangers of giving credibility to “this voodoo science”, a prominent South African intellectual branded Mbeki’s actions as “irresponsibility that borders on criminality”. Another noted that “[i]n our national struggle to come to grips with the epidemic, perhaps the most intractably puzzling episode has been President Mbeki’s flirtation with those who in the face of all reason and evidence have sought to dispute the etiology of AIDS.” While there is no reason to

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40 In this regard, perhaps the most visible manifestation of Mbeki’s controversial stand was the appointment of a panel of “experts” to investigate a number of issues related to HIV/AIDS, in particular “[w]hat causes the immune deficiency that leads to death from AIDS”. See the terms of reference in South Africa, The Presidency, Presidential AIDS Advisory Panel Report (March 2001) at chapter 1.1, online: Unwembi’s Resource of South African Government Information <http://www.polity.org.za/govdocs/reports/aids/advisory_PANEL.htm> (date accessed: 14 July 2001).
believe that senior officials within the Department of Health give any credibility to the “dissident” position on the link between HIV and AIDS, it is clear that Mbeki has not abandoned his controversial stand.

Further, South Africa seems to be lacking the political will to invest the requisite resources in public health care. While the transition to and the early years of democratic rule in South Africa witnessed substantial growth (both in real and per capita terms) in public sector health care funding, as well as a reallocation of resources to primary health care interventions, public sector health care is now characterized both by a falling per capita health sector funding and a decline in primary health care expenditure.

Access to treatment

This thesis is premised on the assumption that South Africa’s ability to turn the tide against the AIDS epidemic in large part hinges on whether the majority of people with HIV/AIDS will have access to essential medicines for treating both HIV infection and

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44 In a recent television interview, when questioned whether he was willing to take an HIV test, Mbeki responded as follows: “[T]he matter of whether I would take an HIV test is irrelevant. It might be dramatic and make newspaper headlines. . . . I do not believe that publicity stunts help in addressing health needs of our people.” For Mbeki to take an HIV test would be tantamount to him “confirming a particular paradigm”. (South Africa, The Presidency, Transcription of e tv interview with President Thabo Mbeki (24 April 2001), online: The Presidency <http://www.gov.za/president/> (date accessed: 14 July 2001).)

45 Stephen Thomas et al., “Chapter 5: Public Health Sector Financing”, in Ntuli et al., supra note 13. This shift is attributed to the current macro-economic policies of the South African government. The authors argue that the new macro-economic policy adopted in June 1996, known as the Growth, Employment and Redistribution Strategy (GEAR), “would appear to be quite hostile to the achievement of equity in the health sector.” (Ibid.)
opportunistic infections associated with HIV/AIDS. It is further premised on two interrelated arguments. First, the single biggest barrier to treatment other than lack of political will remains high drug prices. Second, the single biggest barrier to cheaper prices is the strict enforcement of patents.

Meaningful reductions in prices are achievable in two distinct ways. First, the cooperation of the patent holder may be sought either by governments seeking to enter into agreements for the supply of affordable medicines, or by manufacturers seeking voluntary licenses for the production, marketing and sale of generic alternatives, subject to a royalty payment. Second, the state may regulate prices, either directly or indirectly. Direct regulatory mechanisms include price controls on the sale of pharmaceutical products and the parallel importation of patented products from where they are sold at the lowest international price. Indirect price regulatory mechanisms seek to take full

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46 Whiteside & Sunter argue that the scale of the epidemic in South Africa means that the country cannot focus exclusively (or even largely) on preventative interventions, but is forced to deal with the consequences of HIV infection (Whiteside & Sunter, supra note 15 at 66).

47 For a discussion of additional barriers, see Richard P. Rozek & Nicola Tully, “The TRIPS Agreement and Access to Health Care”, (1999) 2 J. World I.P. 813. The authors argue that “[i]n many instances, the prices of pharmaceuticals are not the cause of access problems. If the patient does not have access to a physician, or lacks accurate information, prices are irrelevant.” (Ibid. at 818). While the affordability of drugs is clearly not the only barrier to effective treatment, what remains clear is that for as long as drugs remain out of reach for most people with HIV/AIDS, governments have little incentive to put systems in place to deal with efficient distribution and strict compliance with often complicated drug-taking regimes. Further, for as long as drugs remain inaccessible, the debate about health system infrastructure remains purely academic. In addition, for many people with HIV/AIDS, particularly in a country like South Africa, high drug prices are the only obstacle in the way of access to treatment.

48 Brazil remains the clearest example of this point. For further information on the correlation between weaker patent protections and increased access to essential drugs, see Tina Rosenberg, “Look at Brazil”, online: The New York Times Magazine <http://www.nytimes.com/library/magazine/home/20010128mag-aids.html> (date accessed: 6 March 2001).

49 While the manners of regulation may be distinct, their operation will often be cumulative. The very existence of coercive regulatory measures may serve as an incentive for patent holders to negotiate meaningful price reductions, or voluntary licenses on terms favourable to both generic manufacturers and the public.

50 Such mechanisms are central to the Medicines and Related Substances Control Amendment Act, 90 of 1997 [hereinafter Medicines Act], the substance of which was under dispute in the recently abandoned case of The Pharmaceutical Manufacturers’ Association and Others v. The President of the Republic of South
advantage of market processes by ensuring the introduction of real competition in the form of generic manufacturers. This thesis focuses on three forms of indirect regulatory mechanisms: compulsory licenses, early working provisions and exclusions from patentability. All three mechanisms share one characteristic: the earlier introduction of generic competition, intended to result in sustainable price reductions as the brand name pharmaceutical industry is forced to compete for its market share.

Two obstacles potentially stand in the way of a suitable framework to give full effect to these regulatory mechanisms. First, the government has yet to demonstrate that it has the political will to fundamentally revisit the existing intellectual property (IP) framework. Second, the World Trade Organization (WTO) agreement on IP rights (IPRs)—TRIPS—has strengthened the international protection of IP so as effectively to narrow the scope of national patent policies. This thesis will show that despite the international harmonization of IP law, countries like South Africa are permitted by TRIPS to take

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Africa and Others, case no: 4183/98, High Court of South Africa (Transvaal Provincial Division) March 2001 [hereinafter PMA]. Parallel importation often works off the back of strong price controls in other jurisdictions.

51 A compulsory license is an authorization to use a patent without the patent-holder’s permission (Sara M. Ford, “Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents” (2000) 15 Am. U. Int’l L. Rev. 941 at 942). In the pharmaceutical sector, a compulsory license would entitle the licensee to manufacture generic versions of a patented drug or to import such products from where they are legally manufactured, either by the licensee itself or by another generic manufacturer. Early working provisions, on the other hand, ensure the introduction of generic copies of a patented product to the marketplace as soon as patent protection expires, by permitting certain forms of conduct that would otherwise constitute patent infringement. For example, such conduct may include the use of the patented product in satisfying regulatory approval requirements (see infra text accompanying notes 438-440). Finally, excluding an intellectual object from patentability means precluding that object from being granted any form of patent protection.

52 While the Medicines Act (the legislation under attack in the PMA case) reflects some degree of political will, its passage was accompanied by a simultaneous strengthening of IP rights in the Intellectual Property Laws Amendment Act, 38 of 1997.


54 For example, pre-TRIPS Brazil completely excluded pharmaceutical products from patentability.
certain regulatory steps to ensure the accessibility of essential drugs, which include but are not limited to compulsory licensing, early working provisions and exclusions from patentability.

The thesis lies at the intersection of the two potential obstacles, for the reluctance to fundamentally revisit the existing IP framework may very well be driven by an uninformed or misinformed understanding of South Africa's international obligations under TRIPS, coupled with a fear of having to defend government policies before the WTO.\textsuperscript{55} The aim of this thesis, therefore, is to determine the extent of regulatory flexibility permissible under TRIPS as a necessary but only first step in the development of an appropriate regulatory framework that will ensure the accessibility of essential drugs. It is my argument that when properly interpreted in accordance with recognized principles of international law and in the light of the Constitution, the Universal Declaration of Human Rights (UDHR)\textsuperscript{56} and the International Covenant on Economic, Social and Cultural Rights (ICESCR),\textsuperscript{57} TRIPS does not prevent—but rather contemplates and permits—the taking of certain legal steps to ensure meaningful reductions in drug prices.\textsuperscript{58}

\textsuperscript{55} One need go no further than the PM case, supra note 50, to see the chilling effect of threatened action. Just by lodging court papers and without obtaining any order of court, the Pharmaceutical Manufacturers' Association of South Africa successfully prevented a democratically elected government from implementing legislation for over three years.


\textsuperscript{58} Such an approach is mandated by the Constitution, and is permissible in terms of international law. See Chapters 2 and 3, below. While such regulatory flexibility may go some way in permitting a variety of state responses to the epidemic, it nevertheless does not go so far as to permit unrestrained flexibility.
A utilitarian approach to engagement

Implicit in my approach to TRIPS is an acceptance that much is to be gained from working within the international trade regime. This “acceptance” is utilitarian in nature, in that it is guided by an understanding that the strategic choice of engagement should in no way be seen as lending legitimacy to or support for the status quo. Indeed, it is my belief that international trade law should have no role in the regulation of domestic standards of IP protection. Nevertheless, the utilitarian approach to international trade does raise numerous issues. For example, does working within the international trade regime preclude action targeting the rules of the regime itself? Are the benefits of engagement sufficient to justify the legitimization of a regime believed by many to be inherently illegitimate? In short, what is the utility of engagement in a legal system of questionable legitimacy when engagement may serve to legitimize the system itself?

South Africa is no stranger to this debate. A little over 18 years ago, Raymond Wacks began a public discussion on the role of judges under apartheid. In a lecture given at the University of Natal (Durban), Wacks made the call for judges of conscience to resign from the bench, arguing that if a “judge is to square his conscience with his calling, there would appear to be no choice open to him but to resign.”

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60 While in no way suggesting that the WTO is comparable to the apartheid regime, serious questions regarding its legitimacy do arise.
61 23 March 1983.
controversial call struck at the heart of the progressive practice of law in South Africa, giving rise to heated debate.63

Despite his call for their resignation, Wacks recognized that “even within the narrow compass permitted to them, judges can, and do dispense justice”.64 Indeed, he was quick to point out several examples that would seem to undermine his position.65 Nevertheless, despite the importance of such legal victories to the affected parties themselves, as well as those indirectly affected by the decision, the essential injustice at the core of the apartheid legal system remained intact. In addition, judges had very little “discretion in the strong sense”,66 for in apartheid South Africa, the law’s penumbra of uncertainty was very narrow indeed.67

In reply, John Dugard acknowledged that the scope for judicial discretion might at times be so limited “that the good that a moral judge may do is outweighed by the harm done by his participation in and legitimation of the system.”68 Nevertheless, Dugard found

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64 “Judges and Injustice”, supra note 62 at 280.
65 Ibid. at 280-81.
66 Ibid. at 281-82.
68 “Reply to Wacks”, supra note 63 at 291.
sufficient room to manoeuvre within the "interstices of the apartheid legal order"\(^{69}\) to justify continued engagement within the system, not only for judges, but also for lawyers and legal academics.\(^{70}\)

The Wacks-Dugard debate is not simply about the role of judges in wicked legal systems. While the judicial decision-making process serves as the focus of the debate, the implications of the questions it raises resonate far beyond the role of judges in apartheid South Africa.\(^{71}\) It strikes at the very heart of our understanding of the nature of law and legal reasoning, and at the role of law in achieving a society based on justice. For Dugard, as for Wacks, the value or danger of engagement lies in its utility.\(^{72}\) As David Dyzenhaus notes, the only justification for choosing to work exclusively outside the system would be "that there is virtually no room to work against the system from within".\(^{73}\)

If there is one lesson that can be learnt from apartheid South Africa, it is that law may effectively be used in support of larger human rights struggles.\(^{74}\) "Because the [South African] regime used legal institutions to construct and administer apartheid", Richard Abel explains, "it was vulnerable to legal contestation."\(^{75}\) In its very use of the law as the

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\(^{69}\) Ibid. at 291.

\(^{70}\) Ibid. at 293.


\(^{72}\) "The value of resignation or participation can be assessed only in the context of its utility." (Ibid. at 293.)

\(^{73}\) "Judging the Judges", *supra* note 63 at 505.


\(^{75}\) Abel, *supra* note 74 at 3. Dugard also recognizes that apartheid South Africa’s respect for legal rules (and not the Rule of Law) provided the opportunities. For him, the pivotal role of law in the apartheid state
primary tool of oppression, therefore, apartheid South Africa provided the space for the
development of what Geoffrey Budlender terms an "active human rights 'industry'."76
As E.P. Thompson notes, "[t]he essential precondition for the effectiveness of law, in its
function as ideology, is that it shall display an independence from gross manipulation and
shall seem to be just. It cannot seem to be so without upholding its own logic and criteria
of equity; indeed, on occasion by actually being just."77

Despite the obvious differences, there are interesting parallels to be drawn between the
legal struggles against apartheid and legal struggles against the negative effects of
globalization. While member states of the WTO have seemingly undertaken their
international trade obligations voluntarily, one cannot but question the impact of unequal
bargaining powers between the developed and developing worlds—and the promise by
the former of the latter's access to its markets—on member states' decisions to join the
global trade regime. Further, membership of the WTO is conditional on the full
acceptance of most WTO agreements, without reservation.78

Notwithstanding the problematic international trade regime and the questionable benefits
of membership for developing countries, democratic South Africa has chosen to be a

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76 Budlender, supra note 74.
78 See General Agreement on Tariffs and Trade — Multilateral Trade Negotiations (The Uruguay Round):
Final Act Embodying the results of the Uruguay Round of Trade Negotiations (15 December 1993), (1994)
33 I.L.M. 1 [hereinafter WTO Agreement] at 2. The WTO Agreement has four annexes, the first three of
which are integral parts of the agreement. Annex 1 deals with substantive trade agreements on trade in
goods, trade in services and trade-related aspects of IPRs. Annex 2 deals with dispute resolution, with
annex 3 providing for a process of multilateral surveillance of national trade policies. Only annex 4 deals
with agreements that are not necessarily binding on member states (ibid.).
member of the WTO, having repeatedly stated that it intends to honour its international trade obligations. This, in a sense, makes the decision to work within the WTO system an easy one. While recognizing that the international trade regime will form the site of intensifying political struggles, this thesis will show that in the field of IP, sufficient space exists to make engagement worthwhile. Building on the fine tradition of noted South African academics such as Dugard and Dyzenhaus, this thesis attempts to show that by working within the system, by pushing the boundaries of the penumbra in support of a broader human rights struggle, considerable gains towards realizing the goal of full access to essential treatments for HIV/AIDS in South Africa may be made. In short, the thesis is a case study of how domestic constitutionalism, informed by the struggles of our past, can be harnessed to hold back an ever-encroaching and increasingly hostile international economic order.

Overview

This thesis begins in chapter 1 with an evaluation of the theoretical underpinnings of IP in general, focussing on the justification of pharmaceutical patents in particular. Chapter 2 introduces TRIPS, asking what is meant by the imposition of minimum standards of IP protection, and whether certain provisions that allow for the adoption of weaker patent protection than generally required are properly characterized as deviations from the

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79 South Africa was a participant in the Uruguay Round of Trade Negotiations. Even though the WTO Agreement was negotiated prior to the first democratic elections in 1994, the first post-apartheid Parliament chose to ratify the WTO Agreement.
80 See e.g. “Joint Statement of Understanding Between the Republic of South Africa and the Applicants” (19 April 2001), online: International Federation of Pharmaceutical Manufacturers’ Association <http://www.ifpma.org/pdfifpma/Sajointstatement.pdf> (date accessed: 15 July 2001), where the “government of the Republic of South Africa reiterates its commitment to honour its international obligations including the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).” This statement was issued after the applicants in PMA withdrew their case.
minimum standards, or rather as integral parts of the agreement as a whole. Understanding how best to characterize the agreement serves as the backdrop to the development of an approach to interpretation.

Chapter 3 shifts the focus from the international law arena to the domestic constitutional context, with a focus on the status of TRIPS in South African law and the protection of property rights under the Constitution. Chapter 4 narrows the focus to Articles 31, 30 and 27.2 of TRIPS, the provisions under which compulsory licensing, early working provisions and exclusions from patentability are respectively regulated. Finally, this thesis concludes with a brief assessment of the way forward, which includes (but is not limited to) the development of an appropriate regulatory framework.
CHAPTER ONE: JUSTIFYING INTELLECTUAL PROPERTY

The traditional characterization of a patent is that of a “monopoly on knowledge”.\(^\text{81}\) Where such knowledge is commercialized, the granting of a patent serves to exclude all competitors from a particular market. As a direct consequence of the exclusion of competitors, patents usually result in higher cost products.\(^\text{82}\) But this conception of a patent is not universally shared. While “almost everyone refers to a patent as a monopoly”,\(^\text{83}\) some commentators question why patents are not understood in the same way as any other exclusive rights in property. As all private property rights give rise to exclusion, it is argued that the monopoly element ascribed to patents is common to all such rights.\(^\text{84}\)

Patents are, however, unlike other forms of property rights, because knowledge, unlike other forms of property, is not a scarce resource, but rather is “infinite in time and space.”\(^\text{85}\) From a social justice point of view, by creating property rights in knowledge and thereby manufacturing scarcity, we render knowledge less valuable.\(^\text{86}\) But it is this construction of scarcity that is central to the commodification of knowledge. Scarcity of knowledge allows for it to be accorded commodity status, and thereby treated as

\(^{82}\) Ibid.
\(^{84}\) Ibid.
\(^{86}\) See ibid. at 126.
property. Once accorded commodity status, knowledge is free to command a price. Only then will consumers “value” such knowledge.\textsuperscript{87}

In the fight for access to essential medicines to treat HIV/AIDS, a question is often asked regarding the justifiability of breaking patents, of violating fundamental rights. But this question mischaracterizes the nature of property rights in patents. For example, South African patent law is in part based on the recognition that “the limited statutory monopoly afforded a patentee is seen as a means of encouraging inventors to put their inventions into practice.”\textsuperscript{88} An “essential quid pro quo of the theory” is that the grant of statutory exclusivity must be to the benefit of the public.\textsuperscript{89}

Quite clearly, the public interest served by the grant of the patent is an integral feature of the state guaranteed protection. The question to be asked, therefore, relates rather to the justifiability of the grant of the IPR itself. As a state-sponsored guarantee of market exclusivity, a patent has to be justified. If its grant is not in the public interest or lacks a public value, its very existence is under threat.\textsuperscript{90}

Understanding the very nature of a patent helps to shift the focus away from the “theft” of property to one questioning the justification for granting IP protection in the first place.

\textsuperscript{88} Syntheta (Pty) Ltd (formerly Delta G Scientific (Pty) Ltd v. Janssen Pharmaceutica NV and Another 1999 (1) SA 85 (SCA) at 881.
\textsuperscript{89} Ibid. at 881-J [emphasis in original].
The onus of justifying limits on knowledge thus falls on those who seek to restrict its maximal use.\textsuperscript{91} The discourse of fundamental rights, on the other hand, “works to obscure the contingent nature of the patent”.\textsuperscript{92}

In this chapter, I look at two theories of justification for the protection of IPRs. This sets the stage for an analysis of pharmaceutical patents in general, with a particular focus on the protection of patents pertaining to antiretroviral drugs in the developing world. The purpose behind this analysis is to set the context within which the TRIPS agreement is to be evaluated and interpreted. An understanding of the theoretical underpinnings of IPRs is central to the approach to the interpretation of TRIPS I adopt in the following chapter.

1.1 Two theories of justification

Two kinds of justifications for the protection of IPRs dominate the TRIPS debate: the first deals with fair compensation, the second with the relationship between the protection of IPRs and incentives to innovate.\textsuperscript{93} In this section, I will show why the first, Lockean in its focus on people owning the fruits of their labour, is inherently problematic. I will also show why the second, essentially instrumentalist in nature, is both fundamentally flawed and paradoxical.

\textsuperscript{92} Weissman, supra note 87 at 1087.
\textsuperscript{93} Trebilcock \& Howse, supra note 81 at 308. Vaver notes “the paradox inherent in the fact that supporters of inventive activity often react so vehemently when any move to modify, inventively or otherwise, a system devised in the seventeenth century.” (Vaver, supra note 85 at 117.)
1.1.1 Fair compensation

The appeal to Locke probably has more to do with issues of “ideological legitimacy” than reasons of theoretical consistency or logic.\(^{94}\) For while Locke “remains a powerful totem”,\(^{95}\) the particular character and nature of IPRs means that they cannot necessarily be treated on the same basis as more traditional forms of property such as land.\(^ {96}\) In particular, the development of IP never takes place in a vacuum.\(^ {97}\) Indeed, creative activity takes place within a broader context, placing limits on the extent to which the contributions of other creators can be minimized, or rendered insignificant.\(^ {98}\) As a result, justifying IP on the basis of a labour theory of property may paradoxically undermine the regime itself.\(^ {99}\) Drahos explains:

Concentrating on the labour of individuals might extinguish the possibility of private ownership of abstract objects altogether. Within an interdependent, differentiated society the labour of any one individual is made possible by the labour of others. If we define a direct contribution of labour in terms of a contribution that enables the production of an abstract object, this forces a recognition of the fact that many ostensibly individually owned abstract objects are in reality collectively owned by virtue of joint labour.\(^ {100}\)

In addition, Locke’s theory is subject to two provisos under which labour justifies property rights in a thing produced. First, after the appropriation of a thing from a state


\(^{95}\) *Ibid.*

\(^{96}\) See May, *supra* note 87 at 46-47. May suggests that the attempt to understand IP on the same basis as material property is a mechanism for asserting—rather than establishing—legitimation. (*Ibid.*, at 47).

\(^{97}\) Trebilcock & Howse, *supra* note 81 at 308. While the development of more traditional forms of property such as land may not take place in a vacuum either, other contributors to the property development are rewarded for their labour or other contributions. The creator of IP, on the other hand, merely appropriates the prior work of others.

\(^{98}\) See *ibid*.

\(^{99}\) Drahos, *supra* note 94 at 52.

\(^{100}\) *Ibid.*
of nature, there must be "enough and as good left in common for others."¹⁰¹ In other words, as long as others are left no worse off as a result of one's appropriation, there can be no objection to owning the fruits of one's labour.¹⁰² It has been argued that patents fall foul of this proviso in that those who independently come up with the same invention as one already patented cannot patent, sell or indeed even use their inventions.¹⁰³ More importantly, if the granting of IPRs is to make people's lives better, but as a result of the grant the protected product is only available to a segment of the population that needs it, then those who do not have access are worse-off relative to those who have access.¹⁰⁴ As such, the proviso is violated once again.

Second, Locke subjects the legitimate acquisition of property rights to a prohibition against spoilage,¹⁰⁵ thus limiting wasteful appropriations of property.¹⁰⁶ Simply put, one must not take more than one can use. Once again, IPRs run afoul of a Lockean proviso, as the full exercise of rights in IP prevents certain beneficial uses of the protected products. Such activity may be categorized as wasteful as the nature of intellectual objects means that "everyone could use and benefit from [them] concurrently."¹⁰⁷ The extent to which those excluded from the use of the intellectual objects could benefit

¹⁰² Hettinger, supra note 91 at 44. For further discussion of Locke's first proviso, see Robert Nozick, Anarchy, State and Utopia (New York: Basic Books, 1974) at 175-82.
¹⁰³ Hettinger, supra note 91 at 44. Hettinger notes that proving independent discovery would be difficult, but points to Nozick's suggestion regarding a restriction on patent periods "to the time it would take for independent invention", which would be substantially shorter than the period for which patents are generally granted (ibid.). In this regard, see Nozick, supra note 102 at 175-82.
¹⁰⁵ "As much as any one can make use of to any advantage of life before it spoils; so much he may by his labour fix a Property in." (Locke, supra note 101 at chapter V, section 31.)
¹⁰⁶ Hettinger, supra note 91 at 44.
¹⁰⁷ Ibid.
determines the extent of the wastefulness. Thus limited access to life-saving drugs means that the grant of IPRs in such products is highly wasteful.

Even working on the assumption that a labour theory of property justifies fair compensation, it does not necessarily follow that fair compensation can be equated with what the market will pay for the intellectual object in question. The difficulty with the equation is that in large part demand of others—and not the labour of the creator of the object—determines the market value. The market value of new intellectual products depends on factors such as patent length and extent, the ability to pay of those who need the product, and the availability and price of substitutes, if available. Thus the claim that one's labour justifies market-value compensation is in essence a claim of right to a "socially created phenomenon". While a labourer may have a prima facie right to benefit from the fruits of his or her labour by possession or personal use, the labour theory of property in no way supports a right to profit through the market.

An issue seldom addressed—much less explained—by those advocating strong IP protection, is whether property rights—and the form in which they are frequently invoked—are indeed the appropriate form of compensation. Simply put, there is no

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108 Ibid.
109 Locke's productivity argument applies only in the state of nature. Further, Locke also recognized that government has the right to regulate heavily once commonwealth over an object has been established:

> Whoever therefore, from thenceforth, by Inheritance, Purchase, Permission, or otherwise enjoys any part of the land, so annexed to, and under the Government of that Commonwealth, must take it with the condition it is under; that is, of submitting to the Government of the Commonwealth, under whose Jurisdiction it is, as far forth, as any Subject of it (Locke, supra note 101 at Chapter VIII, section 120 [emphasis in original]).

110 Drahos, supra note 94 at 52.
111 See Hettinger, supra note 91 at 38-39.
112 Ibid.
inevitable nexus between compensation and proprietary entitlements.\textsuperscript{113} If we are to accept that invention justifies reward, it is by no means clear what form the reward should take. Indeed, it has been argued that it is a mistake "to conflate the created object which makes a person deserving of reward with what that reward should be."\textsuperscript{114}

Locke's labour theory of property forms a particularly weak basis for the justification of IPRs. Further, despite the fundamental rights rhetoric, the fair compensation argument in essence centres on the \textit{extent} of protection and the \textit{level} of compensation. Implicit in this claim for IP protection is a clear recognition that other interests form an integral part of the process by which the nature and scope of such protection is determined.\textsuperscript{115}

\subsection*{1.1.2 Incentives to innovate}

The second argument in defence of IPRs, with its focus on the link between compensation and incentives to innovate, advances the claim that little incentive to innovate exists when others can reap the rewards from the investment at little or no cost—the so-called "free-rider" problem.\textsuperscript{116} But for the benefits associated with the

\textsuperscript{113} Trebilcock \& Howse, \textit{supra} note 81 at 308.

\textsuperscript{114} Hettinger, \textit{supra} note 91 at 41 [footnotes omitted]. Hettinger explains: "If property rights in the very things created were always an appropriate reward for labor, then ... parents would deserve property rights in their children. Many intellectual objects (scientific laws, religious and ethical insights, and so on) are also the sort of thing that should not be owned by anyone." (\textit{Ibid.}) Hettinger points out that even Locke "put limits on the conditions under which labor can justify a property right in the thing produced." (\textit{Ibid.} at 43) It is beyond the scope of this thesis to deal with such exceptions.

\textsuperscript{115} Trebilcock \& Howse, \textit{supra} note 81 at 308.

\textsuperscript{116} \textit{Ibid.} at 309. It this regard, it is interesting to note that imperial China, for example, "achieved spectacular outcomes in science and innovation, yet it did not rely on intellectual property rights or a customary equivalent." Eighteenth century England, on the other hand, adopted this "distinctly instrumental" justificatory approach to IP (Drahos, \textit{supra} note 94 at 14-15). For a more detailed account of the basis of early English IP law, see Drahos, \textit{ibid.} at 29-33. But, warns May, "[o]nly by conceiving of the public benefit as exclusively the promotion of innovation can pharmaceutical patents appeal to an instrumental justification. To conceive of the public interest as the right to health undermines the[se] arguments" (May, \textit{supra} note 87 at 101).
protections of IPRs, it is argued, innovation would not take place. This issue deserves closer analysis.

This economic justification of IP is at once both "the most vulnerable and the most subtly rigorous". It is vulnerable as in many cases it opens itself up to attack for failing to maximize social utility. At the same time, however, its strength lies in its appeal to market efficiency and economic motivation. By depicting problematic patterns of distribution as examples of market failure requiring state intervention, it is able to deflect attention away from what may be symptomatic of a deeper, more fundamental flaw within the IP regime itself.

IPRs have been described as "liberty-inhibiting privileges" that place duties on the holders of such rights. If the right is granted for a particular purpose, the argument goes, then it must follow that the holder of that right has a duty to exercise it in a way that does not undermine the purpose sought by granting the right in the first place. In other words, the right may only be exercised in a way that gives effect to the struck bargain, and in no other way. In this way, the privilege inhibits the holder of the right from doing with it exactly what he or she pleases. The rights holder's liberty in relation to his or her property is thereby inhibited.

117 May, supra note 87 at 61.
118 See ibid. See also ibid. at 63.
119 Drahos, supra note 94 at 220.
120 See ibid. at 220. Drahos also refers to a non-instrumental justification based on intrinsic duties in support of this point (ibid. at 221). A similar line of thinking was expressed in Special Equip. Co. v. Coe, (1945) 323 U.S. 386, where a four judge minority characterized a patent as "a privilege 'conditioned by a public purpose'." (Ibid. at 415). But see e.g. Hartford-Empire Co. v. United States, (1945) 323 U.S. 386, where a narrow majority of the US Supreme Court held that a "patent is property, protected against appropriation both by individuals and by government" (ibid. at 415); Schenck v. Notron Corp., 713 F.2d
But this understanding of IPRs as being justified on the basis of their instrumental value is not without problems. Indeed, the instrumental approach is both fundamentally flawed and paradoxical, for it restricts the current use of inventions for the purpose of increasing the development and thus future availability of new inventions, which in turn, will be subject to the same restrictions on their use. In other words, the patent system is justified by "slowing down the diffusion of technical progress . . . [to ensure] that there will be more progress to diffuse."\textsuperscript{121}

Nevertheless, it is difficult to argue that IP protection does not provide incentives to innovate. This thesis does not attempt to make such a claim. Instead, I argue that the extent and nature of protection granted by IPRs remains suspect, for it is questionable whether strong IPRs "increase the availability and use of intellectual products more than they restrict this availability and use".\textsuperscript{123} On the one hand, the sheer cost of the innovation process would often present as an insurmountable obstacle in the absence of IP protection or any comparable reward system. On the other hand, however, there comes a point at which sufficient incentives to innovate exist, with increased IP protection serving no public interest. Indeed, there seems to be little evidence to support the hypothesis that extended periods of IP protection even spur innovation. In fact, some

\textsuperscript{782} (Fed. Cir. 1983), where the United States Court of Appeals for the Federal Circuit held that a "patent right is but the right to exclude others, the very definition of 'property'." (Ibid. at 786, n.3.)
\textsuperscript{121} Hettinger, supra note 91 at 48.
\textsuperscript{123} See Hettinger, supra note 91 at 49. See also Vaver, supra note 85, where the author argues that "if the allocation of these property rights is simply a means to an end, namely, to make the fruits of creativity and research available to users, then one must ask if the means is the most effective way to that end." (Ibid. at 101.)
commentators argue that innovation is fuelled by the "looming expiration" of IP protection.\textsuperscript{124}

Further, where IPRs do provide incentives to innovate, they are reliant on the existence of a market to support the purchase of the protected intellectual objects. Where the requisite purchasing power does not exist, IPRs play no role in spurring either innovation or the commercialization of intellectual objects. This goes some way to explain why present pharmaceutical research, for example, focuses on "drugs to grow hair, relieve impotence and otherwise brighten life, and not on the epidemics and pandemics of the South".\textsuperscript{125}

1.2 Justifying pharmaceutical patents

Having established that the theoretical underpinnings of strong IP protection are questionable at best, the analysis now shifts towards pharmaceutical patents, already identified as the single biggest reason behind high drug prices. In this section I analyse the justifications advanced in support of strong pharmaceutical patents, with a particular focus on access to antiretroviral drugs in the developing world. In so doing, I come to the conclusion that there is little justification for strong patent protection of antiretroviral drugs in such countries. Ironically, many of these countries are home to the largest and potentially most devastating AIDS epidemics.

\textsuperscript{125} Harms, supra note 90 at 453 [footnote omitted]. But see Richard T. Rapp & Richard P. Rozek, "Benefits and Costs of Intellectual Property in Developing Countries" (1990) 24:5 J. World T. 75, where the authors claim that patent and trademark protection is vital to create an "incentive for pharmaceutical firms to devote local resources to R&D" (ibid. at 86). It is difficult to see how patent protection could ever be an incentive to develop drugs for which there is no market.
1.2.1 Patents, free markets and government intervention

As a result of the effective exclusion of all others from the market, the holder of a patent is—to a large extent—able to set the price of the patented innovation. When demand for innovations is elastic, market forces may temper this ability to set prices. Demand for essential products, however, is relatively inelastic. For example, if a life-saving drug is needed, it does not matter how expensive the drug is, for people will be prepared to pay whatever they can afford—and very often even more—for access to that particular drug. Inelasticity of demand means that market forces (operating in the absence of real competition) may only marginally affect price setting, leaving a patent holder almost free to set the price, with the full knowledge that desperate people will make severe sacrifices to purchase the much needed drug. In many cases, particularly in the developing world, such sacrifices will not be enough to access these essential drugs.

It is not surprising that such issues do not feature in the justification advanced by the brand-name pharmaceutical industry in support of high prices: but for the ability to charge such prices, the industry argues, crucial research and development (R&D) will not take place.¹²⁶ Although pharmaceutical companies often claims that theirs is a risky game, statistics paint a somewhat different picture. Whether viewed on the basis of return on revenues, assets or shareholders’ equity, the brand-name industry is the most profitable of all sectors.¹²⁷ As Dr. Marcia Angell argues: “An industry whose profits

¹²⁷ In 1999, for example, the US pharmaceutical industry recorded the following profits: 18.6 per cent return on revenues, 16.5 per cent return on assets and 35.8 per cent return on shareholders’ equity (“Fortune
outstrip not only those of every other industry in the United States, but often its own research and development costs, simply cannot be considered very risky.\footnote{128}

But why should the pharmaceutical industry be penalized for being profitable, just because it produces drugs and not, for example, widgets? Is there any principled basis for differential treatment? The reality is that this industry receives preferential treatment in at least two related areas of regulation outside of patent protection.\footnote{129} First, much of the early R\&D is either funded by public money or conducted by public institutions, with the industry only becoming involved at a later stage when the research indicates promising results.\footnote{130} In particular, it is widely acknowledged that most HIV/AIDS research in the US is federally sponsored, primarily by the National Institutes of Health (NIH).\footnote{131} Second, the industry enjoys very favourable tax incentives. In the US, for example, in addition to R\&D costs being tax deductible, so too are the often very large

500: America's Largest Corporations”, online: Fortune Magazine

\url{http://content.nejm.org/cgi/content/short/342/25/1902} (date accessed: 19 July 2001). Bale, however, argues that the share of total R\&D expenditure by the pharmaceutical industry is substantially larger than that in any other industrial sector (Harvey E. Bale, Jr., “Patent Protection and Pharmaceutical Innovation” (1996-97) 29 N. Y. U. J. Int'l L & Pol. 95 at 98). What Bale fails to factor in, however, is the profitability of the industry—the costs expended on R\&D yield returns way in excess of other industries.

\footnote{129} These two areas are in essence different aspects of the same basic point. In essence, direct public subsidy of R\&D is indistinguishable from indirect subsidies in the form of tax credits—in both cases, the profitable work of industry is supported using public money.


marketing costs. As Moore observes: "It would be difficult to find another industry manufacturing products essential to maintaining human life that have used the federal government’s protection and assistance to so burden the consumer."\textsuperscript{133}

Notwithstanding preferential treatment in these areas, principled justifications exist for treating the industry differently. First, pharmaceutical products are qualitatively different from widgets, relating directly to the human right to health. Second, free market forces do not control the pharmaceutical market.\textsuperscript{134} While the industry claims that it should be free—as any other industry—to operate at the highest profit level that the market will sustain free from government interference, it fails to recognize that the ordinary principles of supply and demand do not apply to this sector, that the consumer’s freedom of choice regarding the purchase of drugs is all but absent.\textsuperscript{135} Further, without government intervention in the form of patent law, the pharmaceutical industry would look very different from that which we see today. In particular, but for government intervention, pricing structures would be unrecognisable.

\textsuperscript{132} Angell, supra note 128. Angell points out that for the period 1993-96, while the average tax rate of major US industries was 27.3 per cent of revenues, the pharmaceutical industry was taxed at the much lower rate of 16.2 per cent. For a discussion of the types of tax breaks afforded brand-name companies in the US, see Moore, supra note 130 at 157-58. See also Evan Ackiron, "Patents for Critical Pharmaceuticals: The AZT Case", (1991) 17 Am. J. L. & Med. 145 at 156-58. Regarding the Canadian situation, it is interesting to see Canada, Annual Report of the Patented Medicine Prices Review Board (Ottawa: Patented Medicine Prices Review Board, 2000), online Patented Medicine Prices Review Board <http://www.pmprb-cepmb.gc.ca/ar-99e.html> (date accessed: 2 December 2000) which quotes figures supplied by the Conference Board of Canada as indicating that of eleven countries examined, including the US, Canada maintains the most favourable tax system for R&D (ibid. at 36).

\textsuperscript{133} Moore, supra note 130 at 154. For an interesting case study of both public funding and tax relief regarding the development of the antiretroviral drug AZT, see Ackiron, supra note 132 at 166-67. Regarding the development of antiretroviral drugs in general, see Love, supra note 130.

\textsuperscript{134} This is as a result of the monopoly created by the patent system as well as the nature of pharmaceutical products. This is discussed in further detail below.

\textsuperscript{135} See Moore, supra note 130 at 154.
If we accept that the private sector has a significant role to play in the development of innovations, then it follows that the patent system, in so far as it provides an incentive to innovate, may be a necessary and justifiable form of government intervention.136 Government’s role as regulator or facilitator, however, is to act in the public interest, and not in the interest of private players.137 Thus in so far as regulation of the pharmaceutical industry is concerned, the role of government should be limited to providing the level of regulation necessary to achieve the fine balance between continued innovation and public interest, and no more.138 While government has an interest in facilitating some level of profitability, for as long as essential life-saving drugs remain inaccessible to the majority of people, it has no legitimate role in ensuring that the pharmaceutical industry remains as profitable as it is—that is for the industry to do on its own, through better management, efficiency of operation and sound investment, not through a government-sponsored guarantee of supra competitive prices.139

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137 Government is not precluded from acting in the interest of private players where that is indeed in the public interest.

138 This argument relates solely to government’s role as regulator, and should not be understood to imply that government’s role is restricted to regulation.

139 It is important to recognize that the commercial success of any innovation may indeed be more a result of “superior marketing, management, and similar factors than of the invention itself.” (Kenneth W. Dam, “The Economic Underpinnings of Patent Law” (1994) 23 J. Legal Stud. 247 at note 7, citing Robert P. Merges, “Commercial Success and Patent Standards: Economic Perspectives on Innovation” (1988) 76 Calif. L. Rev. 803.) Indeed, the grant of a patent does not necessarily lead to market domination. For example, Glaxo-Wellcome’s Zantac achieved market domination in the field of anti-ulcer drugs despite arriving on the market five years after the introduction of the anti-ulcer drug Tagamet by then competitor SmithKline Beckman. The Economist describes this as “a triumph not of research . . . but of marketing” (“Glaxo: Coping with unwelcome news”, The Economist 343:8014 (26 April 1997) 59).
If the protection of IPRs is indeed the chosen mechanism by which incentives to conduct R&D are created, there is no reason why a patent regime cannot balance the legitimate needs of society regarding access to innovations with the provision of sufficient incentives to undertake R&D. It is not only possible, but also desirable, that the patent system provides sufficient incentive to innovate, but no more. The public interest is served by ensuring access to essential drugs for all, not just for the wealthy or those with drug insurance. If people do not have access to life-saving drugs it makes little sense to provide incentives for their innovation.

1.2.2 Antiretroviral drugs in Africa

Even if one were to accept the “incentives to innovate” argument without any reservations, it is difficult to see how this argument extends to the strict enforcement of IPRs in “marginal” markets, such as the market for antiretroviral drugs in Africa. Despite the extent of the AIDS pandemic in sub-Saharan Africa, the African market accounts for little more than one per cent of total worldwide sales of pharmaceutical products. In such a situation, the profits obtained are unlikely to have any impact on

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140 It would be naïve to believe that there are no potential negative effects of government intervention, whether by way of a change in the manner of regulation, the extension of existing regulatory regimes or by deregulation. However, these will always have to be balanced against the public interest in increasing access to essential medicines. In relation to price regulation in other industries, Moore talks of the production of “increased red tape, heavy burdens on the private sector, a lack of accountability for decisions made by regulatory industries, and overall inefficiency.” (Moore, supra note 130 at 161). Such results are by no means inevitable—bureaucracies may be streamlined, decision-making made accountable and efficiency introduced through various incentive mechanisms. Notwithstanding his findings, Moore still argues that the “inherent costs of government regulation will be more than offset by the benefits created by this regulation.” (Ibid.)

141 The term “marginal” market should not be read to infer that there is no need or demand for antiretroviral drugs in Africa. Indeed, the opposite is true. The term “marginal” refers to the ability to purchase such drugs at the prices currently charged.

further innovation. The presence or absence of such marginal markets can in no way have any impact on incentives to innovate.

The patent industry's real concern, however, cannot be the threat to IPRs in Africa per se, but the impact on lucrative markets in wealthier countries, accompanied by the fear that cheaper drugs may flood such markets. The latter concern is misplaced. It fails to recognize that despite weak or no patent protection for pharmaceutical products in countries such as India and Brazil, the existence of strong generic drug industries in such countries has not resulted in the flooding of lucrative markets in North America, Western Europe and Japan. Similarly, the existence of weaker patent protection in Canada prior to 1987 did not result in the flooding of the US market.

The impact on lucrative markets, however, is indeed of concern to the profitability of the brand-name industry. If access to essential drugs justifies the weakening of IPRs in developing countries, what about those who are unable to access drugs in wealthier nations? While antiretroviral drugs may be reaching increasing numbers of people with HIV/AIDS in the north, high drug prices nevertheless remain a significant barrier to universal access in such countries, particularly where public health care systems to cover the costs of such medicines are non-existent, limited, or under-funded. While the pressure on the industry may be focused on the developing world, it seems highly probable that winning access in poorer nations will not end the debate, merely shift its

143 See Trebilcock & Howse, supra note 81 at 311-12.
144 In the US, for example, the Medicaid programme (established in 1965 to cover certain costs of medical care for poor people) covers less than half of all poor Americans (Sara Rosenbaum, "Mothers and Children Last: the Oregon Medicaid Experiment" (1992) 18 Am. J. L. & Med. 97 at 99).
focus and attention. Nevertheless, at the level of economic analysis, it remains easier to justify much weaker protections where there is little to no risk of affecting incentives to innovate, particularly given the industry’s focus on the alleged nexus between strong IP protections and such incentives.145

This argument, however, should not be understood as advocating in defence of high drug prices in lucrative markets. This argument is usually based on the assumption that only crises of the magnitude of the sub-Saharan AIDS pandemic would justify departures from strong IP protection, and then only in countries where the market share is so insignificantly small as to make little impact on the profitability of the patent industry. Despite particularly high levels of poverty in developing countries such as India, China and Brazil, significant markets (with substantial growth potential) are nevertheless to be found in such countries. Leaving aside the disproportionate impact of the AIDS pandemic on sub-Saharan Africa, there seems little justification to prevent access to essential drugs in Latin America and Asia while simultaneously facilitating access for similarly situated people in Africa.

1.3 Getting the balance right

In this chapter, I have argued in support of weak to no patent protection for antiretroviral drugs in developing countries. While indeed drawing attention to certain aspects of the African market for drugs in support of such a conclusion, the analysis does not stand or

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145 There may be further concerns that explain the industry’s obsession with protecting marginal markets at all costs. First, such markets may not always remain marginal. Second, the development of a strong generic drug industry in countries such as India, Brazil, Thailand and South Africa may ultimately lead to the development of a brand-name industry to rival the domination of US- and European-based brand-name companies. These concerns, as with those mentioned in the body of this thesis, are purely speculative.
fall on the basis of the existence or absence of such conditions. The central issue at stake is whether a fine balance between incentives to innovate and access to the products of such innovation has been reached. Such a balance cannot be achieved if a "one-size-fits-all" approach to IP protection is followed.

In essence, I argue that strong patent protection for essential drugs can only be justified where such protection is necessary for bringing such intellectual products to the market. Where, for example, countries are in a position to subsidize the purchasing of or facilitate access to essential drugs, and indeed do so, stronger IPRs may be justifiable if such government intervention will indeed result in facilitating access for poor people. But where strong patent protection serves as an insurmountable barrier to access, little justification for its existence is to be found.
CHAPTER TWO: INTERNATIONAL LAW

That the international harmonization of standards of IP protection has taken place within the paradigm of free trade is not without great irony and paradox, given that IP, by definition, "is about restricting trade in certain goods." Indeed, prior to the establishment of the WTO, which saw the passage and adoption of TRIPS, IPRs had not been seen as a trade issue. But this was to change: the round of trade talks leading up to the WTO’s formation in 1994 saw the United States spearheading the movement to have IPRs included as an integral part of the Uruguay Round Final Act.

The US interest in expanding the trade arena to include IPRs was threefold: first, to ensure the international protection of IPRs at the same level as that which US-based companies would receive back home; second, to deal with the non-enforcement of existing international obligations and the perceived lack of any credible institutional framework for the resolution of IP disputes; and third, to ensure that the extension of IPRs to new technology-based forms of innovation would follow the developed country model.

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146 Weissman, supra note 87 at 1069. Reflecting similar concerns when describing the incorporation of IPRs into the North American Free Trade Agreement (NAFTA), economist Abraham Rotstein notes that "[i]nstead of creating a freer trade environment . . . NAFTA can only further extend the control of the Canadian generic pharmaceutical sector by foreign multinationals and thus reduce competition." (Abraham Rotstein, "Intellectual Property and the Canada-U.S. Free Trade Agreements: The Case of Pharmaceuticals" (1993) 8 I.P.J. 121 at 133.)


148 Trebilcock and Howse, supra note 81 at 320-21. In many respects, TRIPS represents a victory for the US—in particular, the applicability of the Dispute Settlement Understanding to TRIPS, which provides the much sought after binding dispute resolution mechanism (See General Agreement on Tariffs and Trade—
Looked at from a trade perspective, however, it remains doubtful whether all countries should be required to maintain the same level of IP protection. What constitutes a valuable economic activity to any one country in relation to innovation depends on circumstances and conditions particular to that country. As such, a rational IP policy would in large part be based on whether a country’s comparative advantage lies in innovation or rather in imitation and adaptation of other innovations. Further, a rational policy would need to consider not only the interests of innovators, imitators and adaptors, but also the interests of consumers.

High levels of IP protection are usually associated with correspondingly high levels of development. But as the lead economist for trade policy at the World Bank notes, strong IP protection has traditionally only been implemented in countries already at an advanced stage of development. Nevertheless, even if it were to be shown that strong IP protection leads to development, it is by no means clear that limited resources should be expended on developing and supporting a regulatory framework necessary to create and enforce IP protections. For even if one were to accept the economic arguments in favour of minimum standards for international trade, including the removal of discriminatory trade barriers such as tariffs and quotas, it does not necessarily follow that

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149 Trebilcock and Howse, *supra* note 81 at 307.
150 *Ibid.* at 308.
151 See generally Rapp & Rozek, *supra* note 125.
153 See *ibid.*
IP protection should be increased. Indeed, trade experts are quick to note that the net result of increased IP protection may actually be a reduction of domestic economic welfare, and possibly even a reduction of global economic welfare. Increased patent protection, therefore, may result in little beneficial innovation at the cost of substantial welfare losses to consumers.\(^{154}\)

Nevertheless, TRIPS has ensured that—at least for now—IP protection is an integral part of the international trade regime. That TRIPS does not sit comfortably within classic trade theory is, however, of relevance to the interpretation of key provisions within the agreement and obligations arising from their application. This chapter, therefore, approaches the characterization of the agreement on the basis that where possible, TRIPS is to be seen as giving expression to general principles of trade theory. In addition, with the proper characterization of TRIPS firmly in mind, this chapter seeks to develop an approach to the agreement's interpretation.

2.1 Characterizing TRIPS

TRIPS is generally understood as an agreement that imposes minimum standards of IP protection.\(^ {155}\) Implicit in such an understanding is that signatories are free to determine the degree to which IP protection over and above that which is specifically required may

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154 See e.g. Robert Howse, “The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times”, (2000) 3 J. World I.P. 467 at 493. See also Ruth L. Gana, “Prospects for Developing Countries Under the TRIPs Agreement” (1996) 29 Vand. J. Transnat'l L. 735, where the author points out that a refusal to set high levels of protection cannot simply be viewed as exploiting the innovative work of others, but rather as “a natural use of the patent system, which like other categories of intellectual property, has historically served as a means to accomplish national welfare objectives.” (Ibid. at 747 [footnote omitted].)

155 “In respect of each of the main areas of intellectual property covered by the TRIPS Agreement, the Agreement sets out the minimum standards of protection to be provided by each Member [state].” (WTO, “Overview: the TRIPS agreement”, online: WTO <http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> (date accessed: 20 July 2001).)
be provided. Indeed, TRIPS expressly permits member states to “implement in their law more extensive protection than is required by [the] Agreement.”\textsuperscript{156} Yet TRIPS also expressly allows for the imposition of weaker IP protection in certain circumstances.\textsuperscript{157} This apparent contradiction gives rise to two issues regarding the permissibility of regulatory flexibility. First, what is meant by minimum standards? Second, what is the proper characterization of those provisions within TRIPS that expressly allow for the imposition of weaker IP protection than generally required? Are these provisions deviations from the general standards, or are they more properly characterized as integral parts of the agreement as a whole? These issues are addressed below.

\textit{2.1.1 Unpacking minimum standards}

Integral to any IP regime is a balancing of competing interests, which, in the case of TRIPS, finds expression in Article 7 dealing with objectives:

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.

Article 7 does not reflect any significant shift in thinking on the relationship between the protection of IPRs and the right to the benefits of scientific advancement. Indeed, this delicate balance finds expression both in the UDHR and the ICESCR,\textsuperscript{158} the latter of

\textsuperscript{156} Article 1.
\textsuperscript{157} Articles 27, 30 and 31, quoted in full in the general appendix, below.
\textsuperscript{158} Article 27 of the UDHR provides for “protection of the moral and material interests resulting from any scientific, literary or artistic production”, qualified by a corresponding right “to share in scientific advancement and its benefits”. Article 15 of the ICESCR reflects a similar balancing of rights and interests. Both Articles are quoted in full in the general appendix, below.
which also protects the right to the highest attainable standard of health,\textsuperscript{159} which means that the balancing process under the ICESCR takes place within the context of states being obligated to foster access to health care.

If we are to attempt to balance these seemingly conflicting interests, we need to realize that balancing never takes place in a vacuum. What may appear as just and equitable in Canada, with its particular public health system, level of economic and technological development and public health concerns may seem wholly inappropriate in the context of a developing country such as South Africa. TRIPS is in essence about balancing competing interests in a manner which recognizes the importance of technological transfer and social and economic welfare. It follows, therefore, that the level of technology and the state of people’s health and social welfare—which will inevitably vary from country to country—must play integral roles in determining what system of IP protection is appropriate for any particular country.\textsuperscript{160}

This is further supported by Article 1 of TRIPS, which allows for member states—when giving effect to the provisions of TRIPS—to “be free to determine the appropriate method of implementing the provisions . . . within their own legal system and practice.”


\textsuperscript{160} The General Agreement on Tariffs and Trade (GATT) also operates on such an understanding. See e.g. Trebilcock & Howse, supra note 81, where the authors discuss the concept of “special and differential status” (ibid. at 34-35) and deal with trade and developing countries (ibid. at 367-94).
Lending additional support to this argument is Article 8.1, which allows for such member states to “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”. Article 8.1 is qualified in that measures permitted remain subject to the requirement that they “are consistent with the provisions of [TRIPS].” Implicit in this proviso is that certain provisions give effect to health, nutrition and welfare concerns. Seen in this light, it is difficult to see TRIPS as doing anything but setting the broad framework within which countries are given flexibility to design their own reasonable responses, rather than as a set of rigid rules that disrespects difference.

2.1.2 “Exceptions”

Article 28 of TRIPS sets out the exclusive rights that are conferred on patent holders, with Article 33 providing a minimum of twenty years protection for such rights from the date of patent filing. Rigid application of these rights for such a period of time will, in many cases, frustrate the objectives and principles of TRIPS. That these foundational Articles clearly indicate that TRIPS’ primary role is the balancing of competing interests—and not the protection of IPRs—suggests that those provisions which cut back on the exclusive rights of patent holders are better characterized as integral components of the agreement than as departures from an established norm. But for these mechanisms, Articles 7 and 8 would be devoid of any real meaning in a large number of situations.

161 Article 28 is quoted in full in the general appendix, below.
162 The objectives and principles of TRIPS are set out in Articles 7 and 8 respectively, quoted in full in the general appendix, below.
Recent WTO jurisprudence, however, seems to contradict such a finding. In the only decision so far to give content to one of these provisions, the WTO panel in *Generic Medicines* held that “[t]he word ‘exception’ by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made.” In similar vein—although arguing that TRIPS provides substantial flexibility—Robert Weissman characterizes TRIPS as mandating the “adoption of U.S.-style patent laws”, although containing “a number of exceptions and loopholes.”

*Generic Medicines* is not, however, in line with WTO jurisprudence. Indeed, the Appellate Body of the Dispute Settlement Body (DSB) in *Hormones* expressly held that “merely characterizing a treaty provision as an ‘exception’ does not by itself justify a ‘stricter’ or ‘narrower’ interpretation of that provision than would be warranted by examination of the ordinary meaning of the actual treaty words, viewed in context and in light of the treaty’s object and purpose, or, in other words, by applying the normal rules of treaty interpretation.”

According to *Hormones*, therefore, the scope of any

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163 Article 30. This provision is dealt with in detail at chapter 4 and is quoted in full in the general appendix, below.
164 *Canada—Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R, 17 March 2000, online: WTO <http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm> (date accessed: 20 July 2001) at para. 7.30 [hereinafter *Generic Medicines*]. If this is so, it is difficult to understand the necessity of the term “limited” if an exception is by nature limited. The panel dealt with this issue by holding that “[w]hen a treaty uses the term ‘limited exception’, the word ‘limited’ must be given a meaning separate from the limitation implicit in the word ‘exception’ itself. The term ‘limited exception’ must therefore be read to connote a narrow exception – one which makes only a small diminution of the rights in question.” (Ibid.)
165 Weissman, *supra* note 87 at 1096 [emphasis added].
166 The DSB includes both WTO panels and the Appellate Body.
particular “exception” depends not only on the text of the agreement, but also on the relationship between the “exception” itself and the agreement as a whole.

In similar vein, the Appellate Body in *Reformulated Gasoline* held that the relationship between the “affirmative commitments” and the general exceptions clause in the *General Agreement on Tariffs and Trade* (GATT) can only be fully understood within the framework of the GATT as a whole, including its object and purpose. In that case, the Appellate Body held that whether a particular measure would run afoul of the general exceptions clause could only be evaluated after a careful analysis of the particular factual and legal context of that particular dispute, while at the same time recognizing the intent of WTO members as expressed in the text of the agreement itself.\(^{168}\)

Further, international law more broadly supports the finding that exceptions should not necessarily be narrowly construed. As will be shown below, the approach adopted in *Hormones* and *Reformulated Gasoline* is completely consistent with international law principles of treaty interpretation.\(^{169}\) In addition, TRIPS uses the term “exception” only in reference to Article 30—exclusions from patentability in terms of Articles 27.2 and 27.3, as well as compulsory licensing in terms of Article 31, are framed in somewhat different language, expressly avoiding the use of the term “exception”. Thus at least in so far as Articles 27.2, 27.3 and 31 are concerned, and arguably also in the case of Article


\(^{169}\) See infra text accompanying note 174.
30, the mechanisms that cut back strong patent protections perform a crucial role in giving effect to the objectives and principles of TRIPS.

2.1.3 Towards a proper characterization

While many international trade rules provide sufficient space for regulatory flexibility,\textsuperscript{170} the recent international harmonization of IP law—as expressed in TRIPS—quite clearly gives rise to a more explicit interference with national policies.\textsuperscript{171} Nevertheless, such interference only goes so far as to set out a minimum standards default position: in the absence of good reason, a member state is bound by the agreement to confer certain exclusive patent rights for a twenty year period, on all "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".\textsuperscript{172} The default position is a compromise position. It recognizes that for the purposes and objectives of TRIPS to be given full effect, flexibility is crucial. It allows for member states to respond to legitimate public interest concerns in a manner that takes cognisance of the context within which these interests are to be given effect, but at the same time ensures that such flexibility is to be exercised in a rational and responsive way.

2.2 Approaches to Interpretation

What constitutes a good reason to depart from the minimum standards of IP protection guaranteed by TRIPS is that which is recognized in Articles 27.2, 27.3, 30 and 31 of the

\textsuperscript{170} Such flexibility may not, however, give rise to discrimination against foreigners (Howse, \textit{supra} note 154 at 493).

\textsuperscript{171} \textit{Ibid}.

\textsuperscript{172} Article 27.1.
agreement as such. In addition to determining when a member state may depart from the "affirmative commitments" in TRIPS, these provisions also determine the nature and extent of the departure from the minimum standards default position. Thus, to a large extent, the flexibility afforded member states depends on the manner in which such provisions are interpreted. In this section, therefore, I develop an approach to the interpretation of TRIPS.

The starting point in any discussion of WTO treaty interpretation is Article 3.2 of the Dispute Settlement Understanding (DSU), which provides that all WTO agreements—including TRIPS—are to be interpreted in accordance with the customary rules of interpretation of public international law. In Reformulated Gasoline, the Appellate Body held that this means that the general rule of interpretation in the Vienna Convention on the Law of Treaties—which provides that "[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"—is applicable. Until this point, the universal application of the Vienna Convention in international trade law had been seen as somewhat problematic given that many WTO members—the US in particular—are not parties to that convention. Any confusion, however, was clarified in Reformulated Gasoline where it was decided that the general rule of interpretation in

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173 See supra note 148.
175 Supra note 168 at 15-16.
Article 31 of the *Vienna Convention* “has attained the status of a rule of customary or general international law”\(^{177}\)

It has been argued that the correct approach to the interpretation of TRIPS is to first look at the text of the provision in question, to be followed by an analysis of the object and purpose of the agreement if the meaning of the text is unclear, capable of multiple interpretations, or if circumstances dictate that “confirmation of the correctness of the reading of the text is desired.”\(^{178}\) Such an approach follows the Appellate Body decision in *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, where it was held that the intentions of the parties found expression in the words of the agreement.\(^{179}\)

The objectives of TRIPS, as reflected in Article 7, do not include the protection of IPRs per se, but rather see the protection of IPRs as a means to achieving these goals.\(^{180}\) In essence, the objectives of TRIPS are the promotion of technological innovation, the transfer and dissemination of technology, and the benefit of both producers and users of

\(^{177}\) *Reformulated Gasoline*, *supra* note 175 at 17. In similar vein, the Appellate Body has held that “Article 32 of the *Vienna Convention*, dealing with the role of supplementary means of interpretation, has also attained the same status.” (Japan—Taxes on Alcoholic Beverages, Report of the Appellate Body, WT/DS8/AB/R; WT/DS10/AB/R; WT/DS11/AB/R, 4 October 1996, online: WTO <http://www.wto.org/english/tratop-e/dispu_e/distab_e.htm> (date accessed: 20 July 2001) at 10 [hereinafter *Japanese Taxes*].)

\(^{178}\) Cameron & Gray, *supra* note 176 at 256.


technological knowledge. These objectives are to be achieved in a way that is “conducive to social and economic welfare” as well as to “a balance of rights and obligations”\(^{181}\). For despite the need for “reliable, comprehensible and enforceable” rules,\(^{182}\) it has been recognized by the Appellate Body that “WTO rules are not so rigid or so inflexible as not to leave room for reasoned judgements in confronting the endless and ever-changing ebb and flow of real facts in real cases in the real world. They will serve the multilateral trading system best if they are interpreted with that in mind.”\(^{183}\) In short, the contextual approach to interpretation requires flexibility in interpretation.\(^{184}\)

While Article 31 of the Vienna Convention may be the starting point in any interpretive exercise, it is often reliant on other basic principles of treaty interpretation to give it full meaning. In addition, its textual and contextual approach to treaty interpretation may in many cases not provide sufficient guidance for addressing issues such as the relationship between TRIPS and international law more broadly, and the issue of whether, how and on what basis treaty interpreters should defer to the national decisions, whether legislative, executive or judicial. The following sections in this chapter, therefore, focus on these particular aspects of treaty interpretation.

2.2.1 Basic principles of treaty interpretation

In recognition that treaty provisions may often be capable of more than one meaning, international law has developed numerous rules of treaty interpretation to give guidance

\(^{181}\) Article 7.
\(^{182}\) Cameron & Gray, supra note 176 at 258.
\(^{183}\) Japanese Taxes, supra note 177 at 35.
\(^{184}\) Cameron & Gray, supra note 176 at 258.
to treaty interpreters. The common thread linking such rules is that the choice of preferred interpretation is to be made on a principled basis that supports rather than undermines the goals of the treaty itself. In the following section, I look at two such principles of treaty interpretation, and what they mean for regulatory flexibility.

2.2.1.1 Principle of effectiveness

Flowing from contextual interpretation required by customary international law, the principle of effectiveness recognizes that if a treaty is open to two possible interpretations, the one which best gives effect to the objects and purposes of the treaty should be preferred over that which undermines such objects and purposes.\(^{185}\) In relation to TRIPS, this means that where a provision is capable of two possible interpretations, the one that best gives effect to the objectives of technological innovation, the transfer and dissemination of technology, and the mutual advantage of producers and users of technological knowledge, should be preferred. In particular, the interpretation that best balances these seemingly conflicting objectives in a manner respectful of and "conducive to social and economic welfare", which in effect facilitates access to essential medicines, takes preference over that which undermines this crucial goal.\(^{186}\) In addition, the principle of effectiveness requires that all terms of a treaty be given full meaning and effect, thus ensuring that provisions are not reduced to redundancy or uselessness.\(^ {187}\)

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\(^{185}\) The principle of effectiveness is also known by the maxim *ut res magis valeat quam pereat.*

\(^{186}\) Cameron & Gray, *supra* note 176 at 256.

2.2.1.2 In dubio mitius

The principle of *in dubio mitius* requires that if more than one possible interpretation can be ascribed to an ambiguous term, preference be given to the meaning that is less onerous on the party assuming an obligation.\(^{188}\) Recognized in *Hornbones* as a "supplementary means of interpretation",\(^{189}\) the principle in essence defers to the "sovereignty of states" when the extent of the international obligation that has been voluntarily assumed is unclear. In such circumstances, the principle recognizes that the interpretation that places fewer restrictions on the contracting party should be preferred.\(^{190}\) In relation to TRIPS, where obligations regarding the levels of IP protection to be granted are unclear and capable of more than one possible meaning, the interpretation that facilitates regulatory flexibility is to be preferred. However, a contextual approach to interpretation limits the operation of this principle in that regulatory flexibility can only be exercised in a manner that gives effect to the recognized objectives of the agreement, such as where regulatory flexibility is required to facilitate access to essential drugs.

2.2.2 Relationship between TRIPS and international law

The fact that WTO agreements have the same status as other treaties in international law is important in determining the appropriate relationship between agreements such as TRIPS and international law more broadly.\(^{191}\) However, as a creature of treaty, the DSB primarily functions to interpret WTO agreements in the settlement of disputes between member states. Its jurisdiction is therefore limited, being empowered to apply only the

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\(^{188}\) Cameron & Gray, *supra* note 176 at 256.

\(^{189}\) *Hornbones*, *supra* note 167 at para. 165.


\(^{191}\) Cameron & Gray, *supra* note 176 at 252.
provisions of WTO Agreements, and not international law more broadly. Nevertheless, it cannot do so in a vacuum. Indeed, the Vienna Convention requires that treaty interpretation take into account “any relevant rules of international law applicable in the relations between the parties”.

Application of this principle is to be seen in Hormones, where the Appellate Body recognized that the GATT “is not to be read in clinical isolation from public international law.” In practice, this means that where possible, an agreement such as TRIPS is to be interpreted in accordance with international law more broadly. It therefore follows that TRIPS is to be read in the light of international human rights instruments such as the UDHR and the ICESCR. Thus while this thesis does not directly invoke any of these international human rights instruments in support of particular constructions of relevant treaty provisions, it does proceed on the assumption that where possible, provisions are to be interpreted in a manner that gives effect to the right of access to essential medicines.

In the case of HIV/AIDS, this includes all drugs necessary for the treatment of opportunistic infections, as well as antiretroviral drugs for the treatment of HIV infection itself.

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192 Ibid. at 264.
193 Article 31.3(c).
194 Hormones, supra note 167 at 17.
195 The ICESCR recognizes a right to the highest attainable standard of health as well as limited IPRs. The World Health Organization (WHO) recognizes that this right to health includes a right of access to essential medicines. See World Health Organization “Globalization, TRIPS and access to pharmaceuticals” (2000) 3 WHO Policy Perspectives on Medicines, online: WHO <http://www.who.int/medicines/library/edmgeneral/6pagers/PPM03%20ENG.pdf> (date accessed: 1 August 2001).
2.2.3 Deference to national decisions

The implementation of international obligations is, at minimum, reliant on the willingness of sovereign states to co-operate by accepting limitations on their freedom to legislate and implement national policies. But for effective and uniform implementation, such states have to be willing to allow for treaty interpretation by an international tribunal. Nevertheless, a popular argument suggests that some deference to national decisions (whether legislative, executive or judicial) may be necessary, even in relation to treaty interpretation. While recognizing that “[s]ome trade-off is necessary”, the difficulty lies in determining the manner and circumstances within which this deference is to be exercised. In particular, on what basis should powers be appropriately allocated, and in what circumstances should sovereign states be free to govern?

Such questions raise the issue of when an international tribunal such as the DSB should overrule a domestic interpretation of international obligations, and when it would be appropriate to defer to the national interpretation. Deferring to national decisions does not necessarily mean adopting a weak standard of review or level of scrutiny. In essence, the type of deference proposed in the next section would subject the national decision to a strong level of scrutiny, and would not stand in the way of a high standard of review. Indeed, the type of deference proposed relates only to treaty interpretation and not to the question of whether the national policy in question is in accordance with such an interpretation.

197 Ibid. at 212.
198 Ibid.
199 See ibid.
200 This issue is linked to—but is distinct from—the principle in dubio mitius.
The DSU itself is silent on this issue, although certain clauses have been seen by some to support a "cautious approach" to treaty interpretation, which limits the extent to which the DSU can overrule domestic policy choices.201 Such a cautious approach finds expression in Laurence Helfer’s analysis of the relevance of jurisprudence developed by the European Court of Human Rights under the European Convention of Human Rights, which he sees as providing a useful guide to the approach to interpretation under TRIPS.202 Arguing in the context of copyright law that an attempt to balance the rights of protection with rights of access justifies a very strong degree of deference,203 Helfer points out that TRIPS jurists should recognize that national actors are far better placed to balance such competing goals. Such recognition would grant to national courts, legislatures and administrative bodies "a wide margin of appreciation to set the balance they consider appropriate."204

Seeing the tension in copyright issues as a clash between free expression and IP protection, Helfer cautions that if treaty interpreters were to limit the regulatory flexibility necessary for states to achieve their free expression goals, they would run the risk of "asking states to act in contravention of their own constitutional or human rights obligations and to place the interests of foreign intellectual property owners over the civil

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203 Ibid. at 14.
204 Ibid.
and political liberties of their own citizens."\textsuperscript{205} Regarding the inherent tensions between foreign economic interests and citizens' freedoms, Helfer's argument appeals to the Calvo Doctrine, implicitly rejected by current international economic law in so far as it resolves these tensions only by insisting on equality of treatment according to the local rule.\textsuperscript{206} As mentioned above, TRIPS is generally understood as an agreement that imposes minimum standards of IP protection,\textsuperscript{207} with its genesis lying in the push by US-based companies to ensure the international protection of IPRs at the same level as that which they would receive back home.\textsuperscript{208}

While the new international economic regime clearly moves in the opposite direction to the Calvo Doctrine, moving local rules "up" to the international (usually US) standard, Helfer's argument relating to the potential clash with domestic constitutions does have support in international law, with Article 46.1 of the \textit{Vienna Convention} providing that "[a] State may not invoke the fact that its consent to be bound by a treaty has been expressed in violation of a provision of its internal law regarding competence to conclude treaties as invalidating its consent unless that violation was manifest and concerned a rule

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\begin{footnote}\textsuperscript{205} \textit{Ibid.} at 15.\end{footnote}
\begin{footnote}\textsuperscript{206} Based on the theories of the nineteenth century Argentinean diplomat Carlos Calvo, the core ideas of the Doctrine have been described as follows: First, that sovereign states, being free and independent, enjoy the right, on the basis of equality, to freedom from "interference of any sort"... by other states, whether it be by force or diplomacy, and second, that aliens are not entitled to rights and privileges not accorded to nationals, and that therefore they may seek redress for grievances only before the local authorities. These two concepts of non-intervention and absolute equality of foreigners with nationals are the essence of the Calvo Doctrine (Donald R. Shea, \textit{The Calvo Clause: A Problem of Inter-American and International Law and Diplomacy} (Minneapolis: University of Minnesota Press, 1955) at 19-20.).\end{footnote}
\begin{footnote}\textsuperscript{207} See \textit{supra} text accompanying note 155.\end{footnote}
\begin{footnote}\textsuperscript{208} See \textit{supra} text accompanying note 148.\end{footnote}
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of its internal law of fundamental importance." The difficulty in developing principles according to which treaty interpreters should defer to the decisions of national players is removed by Article 46.1, which clearly shows that states are not bound by those provisions of treaties that are in clear conflict with their constitutions. Thus faced with a choice between various possible interpretations, a treaty interpreter should therefore prefer the interpretation that is consistent with the relevant national constitution to any alternative interpretation that is inconsistent with that constitution.

A principled approach to deference would also consider the purpose for which the particular national policy was intended. A greater degree of deference would be required when a member state is discharging its constitutional or other international law duties, or when it is legislating in respect of TRIPS-recognized public policy goals, such as public health and technology transfer. Less deference would be justified in other circumstances, such as practices that are essentially protectionist in nature.

2.2.4 Moving towards treaty interpretation

This thesis recognizes that TRIPS sets out a minimum standards default position, and that in the absence of good reason, a member state is bound by the agreement to confer

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209 The extent to which the Vienna Convention reflects customary international law remains unclear. Oppenheim’s International Law, for example, states that “many provisions of the Vienna Convention reflect rules of customary international law which are binding as such quite apart from the Convention; . . . other provisions of the Convention may themselves be expected in time to acquire the force of rules of customary law.” (Oppenheim’s International Law, supra note 190 at 1199 [footnotes omitted].) This has been recognized by the Constitutional Court in Harksen v. President of the Republic of South Africa and Others 2000 (2) SA 825 (CC) at para 26 [hereinafter Harksen’s extradition].

210 In countries where the legal system is based on the principle of constitutional supremacy, a national constitution is clearly an “internal law of fundamental importance.” (See Harksen’s extradition, supra note 209 at para. 27.)

211 As will be shown, such an interpretation is mandatory under South African constitutional law. However, as the DSB’s jurisdiction is limited, it should not attempt to ascribe a particular interpretation to relevant provisions of the constitution in question, but should show deference in this regard instead.
certain exclusive patent rights for a twenty year period.\textsuperscript{212} Having set out my approach to interpretation, it is clear that before the relevant provisions can be analysed, there is a need to set out the South African constitutional context. The following chapter does this, asking the question whether—and if so, to what extent—South African constitutional law has any impact on the interpretation of South Africa's international obligations under TRIPS, and consequently any impact on regulatory flexibility crucial in facilitating access to essential drugs.

\textsuperscript{212} See \textit{supra} text accompanying note 172.
CHAPTER THREE: SOUTH AFRICAN CONSTITUTIONAL LAW

Much of the debate surrounding the protection of IPRs and access to essential drugs is whether a particular regulatory mechanism—such as compulsory licensing or complete exclusion from patentability—is permissible under TRIPS. The assumption underlying this debate is that member states party to TRIPS, whether by legislative or executive acts, may not act in any way contrary to the provisions of the agreement. While international law rightly recognizes that international obligations generally trump domestic laws, even where the domestic law regards the conclusion of the particular treaty in question as invalid, it also recognizes that a treaty is not binding if it constitutes a “manifest” violation of a rule of a domestic law of “fundamental importance”. As mentioned above, a supreme constitution clearly constitutes a domestic law of “fundamental importance”.

But what constitutes a “manifest” violation? When may a violation of a constitutional provision serve to invalidate the international obligation assumed? There is much controversy regarding the extent to which constitutions can be invoked to invalidate a treaty obligation, with three main positions dominating the debate. The first position views the validity of international obligations as always being subject to constitutional limitations. This position has been criticized because of the inherent insecurity it brings. The second position subjects the validity of international obligations only to “notorious” constitutional limitations. The third position views states as being bound irrespective of

\(^{213}\) Article 46.1 of the Vienna Convention. See supra text accompanying notes 209-210.
their constitutional limitations. This position is often subject to two qualifications: first, the other state to the dispute should not be aware of the failure to comply with a constitutional limitation; second, the “irregularity” must not be “manifest”.

It is the qualified third position that forms the basis of the Vienna Convention’s definition of a “manifest violation”. According to Article 46.2, “[a] violation is manifest if it would be objectively evident to any State conducting itself in the matter in accordance with normal practice and in good faith.” In dealing with a country that expressly regulates the relationship between international and domestic law in its constitution, normal practice and good faith dictate that a country recognize the national limitations on treaty making powers as expressed in that country’s supreme law. It would be objectively evident to any state that a country does not have the authority to accede to certain provisions of a treaty if, on a proper construction of its constitutional provisions relating to treaty making powers, it lacks that authority.

Indeed, while not ascribing a definitive meaning to the proviso in Article 46 of the Vienna Convention, South Africa’s Constitutional Court has held it to be unlikely that “an international agreement entered into in breach of the provisions of a national constitution that govern international agreements would constitute anything but a ‘manifest’ violation concerning a law of ‘fundamental importance’.”

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215 The test in Article 46.2 is objectivity, not obviousness.
216 Harken’s extradition, supra note 209 at para. 27. This argument is not only limited to the authority to negotiate or to conclude treaties that in substance violate the Constitution. Unless ratified in accordance with the procedures set out in section 231(2) of the Constitution, a treaty has no binding effect.
This chapter deals with two issues. First, in order to determine the extent to which South Africa is bound by TRIPS, it investigates how the Constitution regulates the relationship between international and domestic law. In particular, it examines whether the Constitution grants to those entrusted with negotiating, ratifying and implementing international obligations the power to bind the state in a manner that violates the substantive provisions of the Constitution. In other words, what does the Constitution have to say regarding provisions of international law that violate any of its provisions? I will show that the power to bind the state does not extend to acceding to provisions of international treaties that violate the Bill of Rights. In addition, I will show that international treaties validly negotiated and ratified under the interim Constitution may nevertheless lack validity if they serve to violate any provision of the 1996 Constitution.

The analysis of the relationship between international and domestic law is relevant in so far as the impact of the Constitution on treaty interpretation is concerned. While this thesis does not advance the argument that TRIPS violates the Constitution, \(^\text{217}\) it is premised on the argument that when interpreting the TRIPS-compliance of legislation, regulations or executive action, a treaty interpreter is obliged to prefer an interpretation of TRIPS in line with the Constitution. If a provision of an international agreement can be rendered non-binding if it violates the Constitution, it naturally follows that the government's TRIPS obligations must be interpreted in the light of the Constitution, both

\(^{217}\) In consequence of the withdrawal of action by the applicants in *PMA* (see *supra* note 50), the South African government committed itself to abide by its TRIPS commitments (*supra* note 80). Given South Africa's commitment to the global trade regime, the unconstitutionality argument (if successful) may lead to problematic consequences. In this regard, see the effect of the Colombian Constitutional Court's striking down of a bilateral treaty investment on the basis that the treaty violated certain provisions of the Colombian Constitution, in David Schneiderman, "Constitutional Approaches to Privatization: An Inquiry into the Magnitude of Neo-Liberal Constitutionalism", (2000) 63:4 L. & Contemp. Probs. 83 at 106-08.
by the South African government and by the DSB. For TRIPS to be interpreted "in the light of the Constitution" means looking to the Constitution for guidance when a provision is unclear, ambiguous or subject to more than one possible interpretation.

The second part of this chapter examines the relevant South African constitutional context, in particular looking at the ways in which it may have an impact on the interpretation of obligations arising under TRIPS. Given that the Constitution guarantees the right of access to health care services, as well as rights to equality, dignity and life,218 and that the state has certain positive obligations in respect of such rights,219 it is arguable that South Africa is obliged to take full advantage of whatever flexibility is provided by TRIPS in establishing the necessary regulatory framework for the realization of access to essential drugs for treating HIV/AIDS.

As a result of these obligations, it appears that as far as possible, TRIPS is to be interpreted so as to give effect to the right of access to essential drugs. The Constitution, however, also protects certain property interests in section 25. It is therefore important to understand the nature and extent of the private property protections in order to understand how the Constitution balances the right of access with the right to property. Where the Constitution expressly protects a particular property right, the right of access is to be read subject to that express property protection. It is for this reason that the analysis in chapter 4, particularly in relation to Article 31 of TRIPS and compulsory licensing, in large part relies on section 25 of the Constitution for guidance.

218 Sections 27, 9, 10 and 11 of the Constitution respectively.
219 See supra text accompanying notes 29-34.
3.1 The status of international agreements in South African law

In South Africa’s case, the status of international agreements is expressly regulated by the Constitution. In relation to the status of TRIPS in South African law, three questions arise. First, can the Constitution be interpreted to insulate any international agreement against its substantive provisions? In other words, are international obligations binding even when they violate the Constitution? Second, what is the nature of the binding obligations? Do they limit Parliament’s constitutional power to pass legislation in the same way as do the provisions of the Bill of Rights, or are international obligations only binding between states internationally? Third, can an international agreement validly entered into under one constitutional regime be rendered non-binding by the subsequent adoption of a new constitutional regime? In short, even though it is assumed that TRIPS was fully compliant with the interim Constitution, did the adoption of the 1996 Constitution have any impact on the validity of the international obligations arising from the ratification of TRIPS? The following section deals with these three questions in turn.

3.1.1 Limiting international obligations

Consider the following hypothetical example. It is 2009, and South Africa is plagued by an increasing number of Zimbabwe-style land invasions. Facing increasing pressure from the US administration that it protect the property interests of multinational companies, and eager to show the world that Johannesburg is the ideal venue for the 2016 Summer Olympic Games, the South African government begins to roll out a programme of reform aimed at increasing investor confidence in South Africa. Fearing a backlash at

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220 Section 231.
the upcoming general elections, and already unpopular for having pushed through a constitutional amendment allowing a President to run for a third term of office, the government decides against another constitutional amendment and opts instead to sign the Protection of Private Property Agreement (POPPA), a multilateral agreement between the newly independent Republic of Québec, the Republic of South Africa and the United States of America, which Parliament subsequently ratifies by a narrow majority.

In terms of Article 10 of POPPA, private property may only be expropriated upon the payment of full market value compensation. Section 25 of the Constitution, on the other hand, expressly authorises “just and equitable” compensation following expropriation, which, depending on the circumstances, may be either higher (or more frequently) lower than full market value. In addition, section 25(5) places a positive obligation on the state to “take reasonable legislative and other measures . . . to foster conditions which enable citizens to gain access to land on an equitable basis.”

The ratification of POPPA leads to a split in the ruling African National Congress (ANC), which loses the subsequent national elections to an alliance of leftist parties lead by the Congress of South African Trade Unions (Cosatu). The first legislative act of the new Parliament is to pass the Access to Land Act that expressly incorporates the “just and equitable” provisions of section 25 of the Constitution. Soon thereafter, following administratively fair procedures, land owned by a multinational corporation (which was obtained during the dying days of apartheid at a fraction of the market price in return for having remained in South Africa when many other multinational companies divested) is

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221 See infra text accompanying note 332.
expropriated. Compensation is paid, but this amounts to a tenth of the current market value of the property. With the backing of the US administration, the corporation launches an urgent application in the High Court arguing that the Access to Land Act violates POPPA, therefore being ultra vires the legislative authority of Parliament. The Cosatu-led government opposes the application, arguing that POPPA is only binding in so far as it is consistent with the Constitution. If Article 10 were to preclude Parliament from giving effect to the Constitution, the government argues, this would effectively mean that the ratification of POPPA amounted to a constitutional amendment, which Parliament would not have passed.

As ratification takes place by simple majority of both houses of Parliament, such a process would be in violation of the procedural requirements of the Constitution regarding constitutional amendments.\textsuperscript{222} For a constitutional amendment to have any force, a two-thirds majority in both Houses of Parliament is required. Thus while the 1996 Constitution fails expressly to provide that international agreements are subject to its provisions—perhaps signalling a departure from the interim Constitution—an understanding of the potential impact of international agreements on substantive provisions of the 1996 Constitution suggests that if such a departure from the clear provisions of the interim Constitution were indeed intended, one would have expected that such a shift be made express. This is not the case. Thus while obligations arising from the ratification of international agreements may appear to be binding, such obligations cannot—in effect—amend the Constitution.

\textsuperscript{222} Section 74(2) of the Constitution. Section 74 is quoted in full in the general appendix, below.
3.1.2 The nature of binding international obligations

The extent to which international agreements are binding under the Constitution does not resolve the argument that Parliament is precluded from legislating in contravention of South Africa's international obligations. While it is clear that South African courts "must prefer any reasonable interpretation of... legislation that is consistent with international law over any alternative interpretation that is inconsistent with international law", it nevertheless remains unresolved whether a binding international agreement may otherwise be invoked in a domestic court when that agreement has not yet been incorporated into municipal law. Thus, in my hypothetical example, would a court even have the jurisdiction to strike down the Access to Land Act if it indeed violates binding international obligations? Or in other words, would the provisions of POPPA preclude Parliament from enacting its new land legislation?

In the Azapo case, an argument was made that the amnesty provisions of the Truth Commission Act violated South Africa's international obligations to prosecute the perpetrators of gross human rights violations. The Constitutional Court rejected this claim, holding that "[t]he issue to be determined... is whether [the provision] of the Act is inconsistent with the [interim] Constitution. If it is, the enquiry as to whether or not international law prescribes a different duty is irrelevant to that determination." Where international law and international treaties are relevant, the Court held, is "in the interpretation of the Constitution itself, on the grounds that the lawmakers of the

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223 Section 233 of the Constitution.
224 Promotion of National Unity and Reconciliation Act, 34 of 1995, colloquially referred to as the Truth Commission Act.
225 Azanian Peoples Organisation (AZAPO) and Others v. President of the Republic of South Africa and Others 1996 (4) SA 671 (CC) [hereinafter Azapo].
226 Ibid. at para. 26.
Constitution should not lightly be presumed to authorise any law which might constitute a breach of the obligations of the State in terms of international law." Of particular importance is the finding that international conventions and treaties are not enforceable at the instance of private individuals “until and unless they are incorporated into the municipal law by legislative enactment.”

The Court’s position was in part influenced by the express language of the interim Constitution, which stated that “[a]ll rights and obligations under international agreements which immediately before the commencement of this Constitution were vested in or binding on the Republic within the meaning of the previous Constitution, shall be vested in or binding on the Republic under this Constitution, unless provided otherwise by an Act of Parliament”. Parliament, therefore, had express authority to “override any contrary rights or obligations under international agreements entered into before the commencement of the [interim] Constitution.”

The rationale behind such a provision was to ensure that a democratically elected government would not necessarily be bound by problematic agreements entered into by the apartheid government. Implicit in this argument, however, is that new international

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227 Ibid.
228 Ibid. [footnote omitted]. Dugard suggests that this means that “in a challenge to the constitutionality of a statute involving a rule of international law[,] it is the duty of the court to ascertain the content of the rule and to seek to give an interpretation to the Constitution that accords with this rule; and . . . only if this is impossible because of a clear consistency between the rule of international law and the Constitution . . . [is] the latter . . . to prevail” (John Dugard, “Is the Truth and Reconciliation Process Compatible with International Law: An Unanswered Question” (1997) 13 S. Afr. J. Hum. Rts. 258 at 266-67). Interestingly, section 233 of the Constitution—adopted after the Azapo judgment was handed down—encapsulates Dugard’s approach to the matter.
229 Section 231(1) [emphasis added].
230 Azapo, supra note 225 at para. 27. Mahomed DP. also pointed to section 231(4) of the interim Constitution, which allowed for that constitution or even an Act of Parliament to override binding rules of customary international law (ibid.).
agreements entered into under the *interim Constitution* are binding on the state, and these international obligations cannot be overridden by statute. Indeed, the 1996 Constitution does not grant to Parliament an equivalent authority to override international agreements.

But that does not help to define what the term “binding” means. Is the state bound in that Parliament cannot legislate in conflict with international obligations, or is the state merely bound as between nations? Dugard supports the latter interpretation, arguing that binding treaties domestic courts, but rather “might be employed as a guide to the interpretation of an ambiguous statute or as evidence of a customary rule of international law”. This appears to be the consensus position amongst leading authorities on the subject.

If a binding international agreement were to preclude Parliament from enacting legislation in conflict with its terms, the agreement would take on quasi-constitutional status. Thus, by a simple majority, Parliament may serve to do that which it is precluded from doing without following the procedural requirements regarding constitutional amendments. The power to preclude future Parliaments from legislating in particular ways (without amending the Constitution) is in essence a power to legislate higher order, quasi-constitutional statutes. Unless expressly provided for in the Constitution, it would seem beyond the powers of Parliament to pass such higher order laws. Indeed, since the Constitution expressly empowers Parliament to bind the state by way of the ratification of

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232 See e.g. *Oppenheim’s International Law*, supra note 190, where it is argued that “[a] national law which is in conflict with international law must in most states be applied as law by national courts, which are not competent themselves to adapt the national law so as to meet the requirements of international law... Furthermore, if a state’s internal law is such as to prevent it from fulfilling its international obligations, that failure is a matter for which it will be held responsible in international law.” (*Ibid.* at 84.)
233 See section 74 of the *Constitution*. 
an international agreement, one would expect to see such express language if Parliament were empowered to bind future Parliaments without following the necessary procedures required in amending the Constitution. No such express authorization exists.

3.1.3 New Constitution, old obligations

To be binding under the 1996 Constitution, an international agreement such as TRIPS (having been ratified by Parliament in 1995, almost two years prior to the date upon which the 1996 Constitution took effect) is at minimum dependant upon whether it was binding under the interim Constitution.234 For purposes of this thesis, I will assume that this was indeed the case.235 What then of the fundamental differences between the interim Constitution and the 1996 Constitution? In particular, the 1996 Constitution entrenches social and economic rights, in contrast to the exclusive focus of the interim Constitution on civil and political rights. It is possible, therefore, that TRIPS may not have violated any provisions of the interim Constitution (and thus be fully binding under that constitution), and yet violate the right of access to health care services under the 1996 Constitution, for example.

The 1996 Constitution not only keeps alive international agreements ratified under the interim Constitution, but also international agreements ratified prior to 1994 and subsequently kept alive by the interim Constitution. A finding that the substantive provisions of the 1996 Constitution have no impact on the validity of pre-existing treaty

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234 Section 231 of the interim Constitution dealt with the “[c]ontinuation of international agreements and status of international law”.
235 The relevant constitutional provision is section 231(5), which states that “[t]he Republic [of South Africa] is bound by international agreements which were binding on the Republic when this Constitution took effect.”
obligations could have the effect of keeping in place agreements entered into by the apartheid government, notwithstanding that adherence to such obligations may oblige the state to take action that is prohibited by the Constitution.\textsuperscript{236} If the Constitution contemplated such problematic scenarios one would have expected that it would expressly deal with such issues. This is not the case. Indeed, there is nothing in the Constitution to suggest that it contemplates the preservation of international obligations that run counter to its values, norms and rights, particularly when the Constitution itself proclaims that it is the "supreme law" of South Africa.\textsuperscript{237}

Further, any legislation validly enacted under the interim Constitution may nevertheless be challenged as unconstitutional under the 1996 Constitution.\textsuperscript{238} If TRIPS were to be immune from review under the 1996 Constitution, notwithstanding that certain provisions of the agreement may be found to be inconsistent with that Constitution (although valid under the interim Constitution), Parliament would be precluded by the Constitution from giving legislative effect to binding international obligations. That the Constitution would contemplate such a scenario is absurd. It would not make any sense to bind South Africa at the international level and yet preclude Parliament from giving effect to the state’s international obligations.

\textsuperscript{236} While customary and public international law—in particular international human rights law—were often seen as tools to combat the apartheid regime, international law more broadly also includes the various bilateral and multilateral agreements entered into by the apartheid regime. In allowing for international obligations to be overridden by statute, section 231(1) of the interim Constitution implicitly recognizes the potentially problematic nature of many of these agreements.

\textsuperscript{237} Section 2.

\textsuperscript{238} See e.g S. v. Rens 1996 (1) SA 1218 (CC) [hereinafter Rens] and S. v. Twala (South African Human Rights Commission Intervening) 2000 (1) SA 879 (CC) [hereinafter Twala]. Although the Constitutional Court held in Twala that the right to a fair trial in the 1996 Constitution did not overrule the validity of its decision in Rens, which was based on a differently worded right to a fair trial under the interim Constitution, implicit in the Court’s decision is that a statutory provision validly enacted under the transitional constitutional era could nevertheless be struck down if it violates the 1996 Constitution.
The only legitimate purpose served by section 231(5) of the Constitution, which states that “[t]he Republic [of South Africa] is bound by international agreements which were binding on the Republic when this Constitution took effect”, is to facilitate a smooth transfer between the old order and the new: to ensure that international commitments were not rendered null and void merely because they were not given binding effect according to procedures mandated by either constitution. It seems fair to conclude that all international agreements, including those ratified under the interim Constitution, are binding only in so far as they are consistent with the provisions of the 1996 Constitution.239

3.2 The protection of private property

While the primary role of TRIPS is the balancing of competing interests necessary to promote technological innovation, and to transfer and disseminate technology,240 it is no secret that the primary mechanism chosen to achieve these objectives is the protection and enforcement of IPRs.241 In the previous chapter, I concluded that where a provision of TRIPS is unclear, ambiguous or subject to more than one possible interpretation, the focus shifts to an analysis of how the Constitution regulates such a matter. It therefore follows that central to the determination of the Constitution’s impact on the interpretation

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239 In practice, however, a provision of international law will very often be easily incorporated into the scope of a particular right. The protections offered by the Constitution will very often exceed those offered under international law. As Scott and Alston argue: “Human rights treaties must be viewed, presumptively, as floors for national human rights protections, not ceilings.” (Craig Scott and Philip Alston, “Adjudicating Constitutional Priorities in a Transnational Context: A Comment on Soobramoney’s Legacy and Grootboom’s Promise” (2000) 16 S. A. J. Hum. Rts. 206 at 232).

240 As Article 7 points out, these objectives are to benefit both “producers and users of technological knowledge”. In addition, the objectives are to be reached “in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.

241 See supra text accompanying and following note 162.
of obligations regarding standards of IP protection under TRIPS is an understanding of the nature and extent of private property protections under the *Constitution*.

But what is the significance of the requirement in section 39(1)(b) of the *Constitution* that international law be considered when interpreting provisions of the *Bill of Rights*? Indeed, not only does the *Constitution* have an impact on the interpretation of international obligations, but international law has an impact on constitutional interpretation.\(^{242}\) How then do we make sense of this seemingly mutually reinforcing interpretation process? Are we dealing with a chicken and egg scenario?

Consider the following example. TRIPS requires that a patent holder be paid “adequate remuneration”—or compensation—following the grant of a compulsory licensing.\(^{243}\) The *Constitution*, on the other hand, requires “just and equitable” compensation to be paid once property has been expropriated.\(^{244}\) Does the analysis start with the *Constitution*, or with TRIPS? Do we first determine whether the *Constitution* regards the granting of a compulsory license as an expropriation and then ascribe a meaning to “adequate remuneration” consistent with the *Constitution’s* requirement of “just and equitable” compensation, or do we consider the obligation to compensate flowing from TRIPS as an indication that section 25 of the *Constitution* regards the grant of a compulsory license as an expropriation?

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\(^{243}\) Article 31(b).

\(^{244}\) Sections 25(2)(b) and (c).
While there is merit in both arguments, _Azapo_ makes it clear that the starting point in such an analysis is the _Constitution_ itself. This is supported by section 233 of the _Constitution_, which requires that legislation be interpreted, where possible, in a manner consistent with international law. Implicit in the requirement is that only legislation—and not the _Constitution_—is subject to such a process. In addition, the process of constitutional interpretation only needs to consider international law, but not necessarily to follow it. Thus, in the compulsory licensing example, the starting point is a determination of whether the _Constitution_ itself regards the granting of a compulsory license as an expropriation of property. That TRIPS requires compensation in such circumstances is but a factor to consider in making such a determination.

The nature of the property interests in section 25, and how and to what extent they are given protection, will have a substantial impact on the interpretations of Articles 27.2, 30 and 31 of TRIPS, and subsequently on the measures that may be implemented by the state in discharging its obligations regarding access to essential drugs for treating HIV/AIDS. In the following section, therefore, I examine the scope of the property protections in the _Constitution_.

### 3.2.1 Scope of property protections

The property protections in section 25 of the _Constitution_ read as follows:

245 See supra text accompanying notes 226-227.

246 See the _Government of the Republic of South Africa and Others v. Grootboom and Others_ 2000 (1) SA 46 (CC) [hereinafter _Grootboom_], where the Constitutional Court found that “international law can be a guide to interpretation but the weight to be attached to any particular principle or rule of international law will vary. However, where the relevant principle of international law binds South Africa, it may be directly applicable.” (Ibid. at para. 26 [emphasis added and footnote omitted].)

247 The full text of section 25 is quoted in the general appendix, below.
(1) No one may be deprived of property except in terms of law of general application, and no law may permit arbitrary deprivation of property.

(2) Property may be expropriated only in terms of law of general application—
(a) for a public purpose or in the public interest; and
(b) subject to compensation, the amount of which and the time and manner of payment of which have either been agreed to by those affected or decided or approved by a court.

The scope of protection provided by section 25 is dependant on two inquiries. First, does the Constitution recognize the interest in question as property? If so, does the Constitution recognize the regulation or alleged infringement of the property right in question as a deprivation of property or as an expropriation of property? This characterization is crucial in determining the extent of protection offered if indeed the interest is recognized as constitutional property. The following sections explore these issues in greater depth.

3.2.1.1 Defining property

That the constitutional concept of property extends to IPRs remains an untested proposition. In the Certification judgment,\textsuperscript{248} for example, the Constitutional Court dismissed an objection that the Constitution's failure expressly to recognize a right to IP was in contravention of the requirement that the Constitution protect "universally accepted fundamental right[s], freedom[s] and civil libert[ies]."\textsuperscript{249} The Court was silent on the issue of whether IPRs are nevertheless protected under the general property protections of section 25. However, this is in contrast to a similar objection being lodged


\textsuperscript{249} Ibid. at para. 75.
against the Constitution’s failure expressly to protect “the right freely to marry and to establish family life”,\textsuperscript{250} where the Court pointed out that various provisions of the text, while not expressly protecting such a right, would nevertheless both “directly and indirectly support the institution of marriage and family life.”\textsuperscript{251} It is unclear whether this means that IPRs are not protected under section 25, or simply that the constitutional principles did not mandate express IP protection. For the purposes of this thesis, I assume that that the latter construction is applicable.

Whether IPRs fall within the concept of constitutional property raises the broader issue of what constitutes constitutional property. While the Constitution may not serve as the source of all private property rights, many of which are creations of common law or statute, it certainly provides the authority for their protection.\textsuperscript{252} While most commentators agree that the constitutional concept of property is different from the traditional private-law concept,\textsuperscript{253} either assuming that this is the case,\textsuperscript{254} or advocating

\textsuperscript{250} Ibid. at para. 96.
\textsuperscript{251} Ibid. at para. 101.
\textsuperscript{252} The Constitution is not a codification of existing rights, but rather the source from which existing rights gain their force:

There are not two systems of law, each dealing with the same subject-matter, each having similar requirements, each operating in its own field with its own highest Court. There is only one system of law. It is shaped by the Constitution which is the supreme law, and all law, including the common law, derives its force from the Constitution and is subject to constitutional control (Pharmaceutical Manufacturers Association of SA and Another: in Re Ex Parte President of the Republic of South Africa and Others 2000 (2) SA 674 (CC) at para. 44 [hereinafter Pharmaceuticals]).

In Pharmaceuticals, it had been argued that the common law grounds of administrative review remained unaffected by the constitutional right to just administrative action. In coming to the conclusion that the common law derives its force from the Constitution, the Constitutional Court held that “common-law principles that previously provided the grounds for judicial review of public power have been subsumed under the Constitution and, insofar as they might continue to be relevant to judicial review, they gain their force from the Constitution.” (Ibid. at para 33.)

\textsuperscript{254} See Johan de Waal, Iain Currie & Gerhard Erasmus, The Bill of Rights Handbook 2d (Kenwyn, South Africa: Juta & Co., Ltd., 1999) at 399.
such a position, they do not agree on which of these statutory and common law rights should be recognized as interests worthy of constitutional protection.

André van der Walt argues that section 25’s protection of private property interests cannot be limited to those categories of rights recognized by the law prior to the new constitutional era. While not necessarily supporting the concept of constitutional property, he argues that if property is indeed to be protected, considerations of fairness preclude privileging “those who have independent access to property over those whose primary source of property is the state.” This raises the controversial issue of whether welfare rights are protected by section 25.

If the Constitution is indeed about the development of a “culture of justification”, a strong argument works against the creation of rigid categories for determining whether a particular right or interest qualifies as property for the purposes of constitutional protection. Comparative case law suggests that in general, the focus should be placed on the justification of property infringements rather than on the definition of property

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256 See Van der Walt, supra note 253 at the text accompanying note 293.
257 Matthew Chaskalson, “The Problem With Property: Thoughts on the Constitutional Protection of Property in the United States and the Commonwealth” (1993) 9 S. Afr. J. Hum. Rts. 388 at 407. Chaskalson argues that such a concern, however, is complicated by South Africa’s history of state expenditure “around the needs of white South Africans”, and the pre-transition phase leading up to South Africa’s first democratic elections in 1994 which saw “a headlong rush to transfer state resources into white hands before the state [was] made subject to democratic control.” (Ibid. at 407-08.) The formulation of section 25 in the Constitution has addressed such a concern. The absence of a provision in the Constitution of Namibia similar to section 25(3) of the South African Constitution made it impossible for the courts to allow post-independence Namibia to recover questionable donations to the value of R8 million (then worth over USS 3 million) made by the Administrator-General shortly before independence (See Government of the Republic of Namibia v. Cultura 2000 1994 (1) SA 407 (NmS)).
258 Supra note 35.
Thus instead of relying on predetermined categories, Van der Walt argues that South African courts should follow the international trend and “be lenient in answering this particular question”. On his approach, broad recognition of property interests would then focus attention on the “legitimacy and justifiability” of the regulatory provision in question. Such an analysis, he argues, would avoid the use of problematic categorizations of property without paralysing the state and thereby preventing effective and necessary regulation.

As tempting as Van der Walt’s analysis may be, it is problematic. First, it decontextualizes the property clause. The entrenchment of a constitutional property clause was a source of much controversy during the constitutional negotiations, which were characterized by two conflicting viewpoints regarding the constitutional protection of property rights. On the one hand, the ANC saw the entrenchment of property rights as potentially entrenching existing inequitable and racially skewed patterns of property ownership. The ANC’s aim was to ensure that property rights would not stand in the way of land reform programmes. On the other hand, the then National Party sought to protect the property of white South Africans from any future redistribution programmes. Seen in this light, section 28 of the interim Constitution is a “political compromise between

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259 Van der Walt, supra note 253 at 30-31. This approach does not apply if “the protection of a particular right or interest is really controversial or uncertain.” (Ibid.) For examples of such a broad interpretation given to the term property, particularly in Commonwealth jurisdictions such as Australia, India and the Caribbean, see the cases cited ibid. at 37, n. 28.
260 Ibid. at 55.
261 Ibid.
262 De Waal, Currie and Erasmus, supra note 254 at 398 [footnote omitted]. The controversy was very much alive during the drafting of the Constitution by the Constitutional Assembly.
264 Stumbling Towards Section 28, supra note 263.
these two viewpoints in terms of which a right to property was included . . . but the extent of the protection that it gave to existing property rights was circumscribed." Section 25 of the 1996 Constitution attempts to strike a similar balance.

In addition to the decontextualization of the property clause, Van der Walt’s analysis raises problematic assumptions regarding the scope of the Bill of Rights, in that his broad definition of property assumes that certain state-created rights would, in the absence of protection under section 25, be left without constitutional protection. This assumption fails to recognize the nature and extent of socio-economic rights, and their implications for the concept of property. In particular, the Constitution recognizes rights to “fair labour practices” and basic and further education, as well as rights of access to “land on an equitable basis”, adequate housing, health care services, sufficient food and water, and social security, the last of which includes “appropriate social assistance” where people are “unable to support themselves and their dependants”.

At a minimum, these socio-economic rights place an obligation on the state and all other persons—whether natural or juristic—“to desist from preventing or impairing the right” in question. In addition, those rights in respect of which the state has obligations to

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265 De Waal, Currie and Erasmus, supra note 254 at 398, n.1. See also Chaskalson & Lewis, supra note 255 at 31-2. While the intent of the framers of the Constitution is not conclusive, the drafting history provides an indication that the highly qualified property rights give effect to a political compromise.

266 De Waal, Currie and Erasmus, supra note 254 at 399.

267 Section 23(1).

268 Sections 29(1)(a) and (b).

269 Section 25(5).

270 Section 26(1).

271 Section 27(1)(a).

272 Section 27(1)(b).

273 Section 27(1)(c).

274 Grootboom, supra note 246 at para. 34.
realize progressively are subject to the principle of non-retrogression. This means that powerful justifications would have to be advanced to support any measures that cut back on the socio-economic rights already enjoyed by people.\textsuperscript{275} In this way, the Constitution protects many state-created rights.

It is difficult to imagine which state- or employer-created rights do not find protection under these socio-economic guarantees. Interests such as pensions, unemployment insurance, health care benefits, housing benefits and salaries would all be protected. Given the express protections provided in these socio-economic rights, understanding that all rights are "inter-related and mutually supporting",\textsuperscript{276} and understanding the nature of the compromise at the heart of the property clause's genesis, it seems that there would be no purpose served by protecting welfare rights as forms of constitutional property.\textsuperscript{277}

Another position sees constitutional property "as those resources which are generally taken to constitute a person's wealth, and which are recognized and protected by law."\textsuperscript{278} This position is somewhat qualified by restricting the protections of section 25 to vested rights.\textsuperscript{279} Recognizing that "[i]n modern economic life, physical property in general and land in particular, has lost its status as the defining attribute of wealth", the position sees private wealth as consisting primarily of personal rights such as shares, private pension benefits, life insurance policies and IP. A failure to recognize such interests as property

\begin{itemize}
  \item \textsuperscript{275} See \textit{ibid.} at para. 45.
  \item \textsuperscript{276} \textit{Ibid.} at para. 23.
  \item \textsuperscript{277} Where section 25 does deal with socio-economic rights, it does so expressly in sections 25(5), (6) and (7).
  \item \textsuperscript{278} De Waal, Currie and Erasmus, \textit{supra} note 254 at 404.
  \item \textsuperscript{279} \textit{Ibid.} at 405. Such a position was adopted by the Zimbabwe Supreme Court in \textit{Chairman of the Public Service Commission v. Zimbabwe Teachers Association} 1996 (9) BCLR 1189 (ZS).
\end{itemize}
"would leave a great deal, if not most, of people’s assets unprotected from confiscation by the state." For Matthew Chaskalson and Carole Lewis, the test is "whether, as a matter of policy, prevailing morality and, of course, as a matter of physical possibility, a resource should be ‘propertized’.

On either test, there would be no basis for denying constitutional protection to IPRs.

This thesis assumes that IPRs are indeed protected by section 25. But merely determining that IP protection falls within the scope of section 25 in no way explains the extent of protection offered by that section, for at the heart of constitutional property lies the distinction between deprivations and expropriations. Indeed, depending on how an interference with existing property rights is characterized, different consequences flow, such as differing strengths of protection and standards of review.

However, before examining this distinction in order to understand how the Constitution regulates certain types of interferences with property rights contemplated by TRIPS, the analysis shifts towards the extent of protections granted by section 25. As mentioned above, the nature of the property interests in section 25, and how and to what extent they are given protection, will have a substantial impact on the interpretations of Articles 27.2, 30 and 31 of TRIPS, and subsequently on the measures that may be implemented by the state in discharging its obligations regarding access to essential drugs for treating HIV/AIDS.

\(^{280}\) De Waal, Currie and Erasmus, supra note 254 at 404.

\(^{281}\) Chaskalson & Lewis, supra note 255 at 31-6 [footnote omitted].
3.2.1.2 Extent of property protections

In essence, modern constitutions may guarantee three main categories of property protections: protection against uncompensated expropriations, a “claim of eligibility to hold property”, and a “claim to have property.”\(^{282}\) The first of these claims is expressly recognized in section 25, with the second finding implicit recognition in that section\(^{283}\) as well as section 9’s guarantee of equality rights.\(^{284}\) The third finds “a degree of recognition” in section 25(5) of the property clause itself, which places positive obligations on the state regarding the promotion of land redistribution,\(^{285}\) as well as in various other socio-economic provisions in the *Bill of Rights* such the right of access to adequate housing.\(^{286}\)

Despite its seemingly clear language, however, section 25 is nevertheless open to various interpretations regarding the extent of protection it provides. At minimum, it is a protection against arbitrary deprivations and expropriations of property, with expropriations being further protected by having to be accompanied by “just and equitable compensation”,\(^{287}\) as well as a guarantee that the principle of legality will be respected.\(^{288}\) But what of the argument that the requirements within sections 25(1), (2) and (3) should be regarded merely as threshold requirements, and not as limiting the

\(^{282}\) De Waal, Currie and Erasmus, *supra* note 254 at 399-400.

\(^{283}\) Implicit in section 25 is a right to hold property, such that a prohibition on private ownership of property would constitute a limitation on the right (*Certification*, *supra* note 248 at para. 72).

\(^{284}\) De Waal, Currie and Erasmus, *supra* note 254 at 399-400.

\(^{285}\) Ibid.

\(^{286}\) See *supra* text accompanying notes 267-277.

\(^{287}\) The *Constitution* does not make it plain whether the property right in section 25 applies to juristic persons such as drug companies. For a comprehensive analysis of this issue, see Van der Walt, *supra* note 253 at 66. For the purposes of this thesis, it is assumed that juristic persons may invoke the right.

\(^{288}\) Both deprivations and expropriations may only take place “in terms of law of general application”. See *infra* text accompanying notes 311-314.
scope of the interests protected? To a large extent, the answer to this question depends on what purpose can be ascribed to the section 25 guarantees.

While property protections in private law serve the purpose of shielding private rights from unwarranted interference, constitutional protection of property rights serves a somewhat different purpose. At the heart of the Constitution's property guarantees is the attempt to strike a "just and equitable balance" between private property rights and the public interest. The tension to be resolved is the inevitable clash between private interests in unfettered use and public interests in the control and regulation of such use.

In addition to providing protections against arbitrary deprivations and expropriations of property, the new constitutional order also serves to undo the distortions resulting from apartheid land policies, and to "promote the establishment and maintenance of a more just distribution of property and of greater access to and security of tenure in land." Nevertheless, while many of its provisions may give rise to "transformational possibilities", I will show that the property protections in section 25 remain "highly qualified and circumscribed".

As has been repeatedly mentioned, the purpose of the protections must be determined having regard to the particular negotiating history leading up to the adoption of the

289 Van der Walt, supra note 253 at 105.
290 The purposive approach to constitutional interpretation was adopted in S. v. Makwanyane and Another 1995 (3) SA 391 (CC) at para. 9 [hereinafter Makwanyane].
291 See Van der Walt, supra note 253 at 67.
292 Ibid. at 69.
293 Ibid. See e.g. section 25(5).
294 De Waal, Currie and Erasmus, supra note 254 at 415 n.38.
Constitution, and the particular struggles over the inclusion and exact wording of a constitutional property provision. To ignore the framers' "intent" on this issue would only serve to undermine the essence of the new constitutional order, setting up irresolvable conflicts between the rights of the privileged few and those of the disadvantaged majority.

In order to answer the threshold question, it is important to determine whether—and if so in what circumstances—the general limitations enquiry of section 36 applies to the property clause. It seems highly unlikely that a deprivation or expropriation that fails to satisfy the specific requirements in sections 25(1), (2) or (3) would ever be able to satisfy the specific requirements of section 36,295 which provides that rights "may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom".296 Given that there is nothing in the text to suggest that the general provisions of section 36 do not apply to the property clause,297 Van der Walt argues that the requirements in section 25 and the general limitation provisions in section 36 apply cumulatively.298 One practical effect of his conclusion is that the right in section 25(1) may indeed be violated by a rational deprivation of property, if the deprivation fails the

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295 See Van der Walt, supra note 253 at 97.
296 Section 36 is quoted in full in the general appendix, below.
297 Ibid. at 95.
298 Ibid. Van der Walt raises a second concern:
If the party who relies on the validity of the limitation succeeds in justifying the limitation in terms of the specific limitation provisions only, what justification is there for the dispute to end there? Why should the party who relies on the invalidity of the limitation not be allowed to plead that, even though the limitation is valid in terms of the (perhaps merely formal) specific limitation provisions, it is still questionable in terms of the general limitation provision; a provision that after all embodies the spirit and purpose of the bill of rights and the whole constitution? (Ibid.)
proportionality test of section 36.\textsuperscript{299} According to this construction, therefore, section 25(1) precludes all deprivations of property, not only arbitrary deprivations of property, unless such deprivations can satisfy the strict requirements of section 36.

On Van der Walt’s construction, once an interference with property rights has been established, the state is obliged to show that the “threshold” requirements of sections 25(1), (2) and (3) have been met. If it succeeds in its argument, the holder of the affected right has an opportunity to demonstrate that—notwithstanding the satisfaction of the “threshold” requirements—the limitation of property rights is nevertheless unjustifiable or unreasonable.\textsuperscript{300} On his construction, therefore, applicants would have to prove the non-justifiability of a particular provision,\textsuperscript{301} which runs counter to the widely accepted view of the Constitution as entrenching a “culture of justification”,\textsuperscript{302} which places the onus on government to justify its exercise of public power.

A more conventional view, however, is that sections 25 and 36 operate independently of each other. But even those who support such a construction agree that the two-stage approach required by the standard limitations analysis would be difficult to apply in relation to property rights.\textsuperscript{303} This is as a result of many of the section 36 criteria having been included within the scope of the section 25 rights themselves,\textsuperscript{304} which results in the reason for the infringement having to serve as the justification thereof if section 36 is

\textsuperscript{299} Ibid. at 98.
\textsuperscript{300} Ibid.
\textsuperscript{301} De Waal, Currie and Erasmus, supra note 254 at 415 n.38.
\textsuperscript{302} Supra note 35.
\textsuperscript{303} See De Waal, Currie and Erasmus, supra note 254 at 414.
\textsuperscript{304} Ibid.
ever to be of use.\textsuperscript{305} Thus, for example, on a construction of section 25 that sees the right as merely a protection against arbitrary deprivations of property, for section 36 to have any purpose, it would have to be able to be shown that a particular deprivation of property, although arbitrary, is nevertheless reasonable. Similarly, an expropriation done neither for a public purpose nor in the public interest could hardly be seen as “justifiable in an open and democratic society”. It is highly unlikely, if not impossible, that any violation of the section 25 rights could ever be justified.\textsuperscript{306}

Chaskalson and Lewis do not see a problem with a constitutional enquiry which “may in effect be confined to the terms of section 25 itself.”\textsuperscript{307} For them, the complication arises as a result of section 25(8)’s express reference to section 36(1), which seems to suggest that section 25 rights are not ordinarily capable of limitation under the general limitations clause. Indeed, if all section 25 rights were subject to limitation in accordance with section 36(1), there would be no need to single out land and water reform measures in section 25(8). “The notion of illimitable rights”, argue Chaskalson and Lewis, “is not one which fits well within the scheme of . . . [the Bill of Rights]”.\textsuperscript{308} In practice, however, courts may hold that all section 25 rights are subject to limitation, notwithstanding that such a construction would render the second part of section 25(8) “largely superfluous”.\textsuperscript{309} Thus the purpose served by section 25(8) may be only symbolic, “emphasiz[ing] the constitutional value attached to land and water reform”.\textsuperscript{310}

\textsuperscript{305} Ibid.
\textsuperscript{306} Ibid. Chaskalson & Lewis do seem to contemplate circumstances in which a violation of the narrow rights may indeed be found to be justifiable. (See Chaskalson & Lewis, supra note 255 at 31-27.)
\textsuperscript{307} Chaskalson & Lewis, supra note 255 at 31-27 [emphasis added].
\textsuperscript{308} Ibid.
\textsuperscript{309} Ibid. [footnote omitted].
\textsuperscript{310} Ibid. at n.3.
3.2.1.2.1 Requirement of generality

Common to the protections against arbitrary deprivations and expropriations of property is the requirement of legality. While the full extent of the requirement remains unclear, at minimum it serves a three-fold purpose: first, to ensure that legal rules that limit rights are accessible; second, to ensure that such rules are sufficiently clear to enable the reasonable person to regulate his or her conduct accordingly; and third, to ensure that laws apply generally. While all three are relevant to the constitutionality of any regulatory framework, it is the requirement of generality that seemingly poses the greatest obstacle to the regulation of a particular industry.

However, implicit in the Constitutional Court decision in Prinsloo is that issues relating to the differential treatment of particular industries are dealt with by the Constitution’s guarantee of equality. In short, mere differentiation is permissible as long there is a rational explanation for its existence and it does not constitute “unfair discrimination”. Thus singling out a particular sector—such as the pharmaceutical industry—for differential treatment is not prohibited per se. Read in this light, the requirement of

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311 President of the Republic of South Africa and Another v. Hugo, 1997 (4) SA 1 (CC), at para. 102, per Mokgoro J. One of the key issues in this case was the status of the President’s constitutional pardoning power. Despite Mokgoro J.’s somewhat controversial and broad definition of what qualifies as a law of general application, which does not necessarily reflect the Court’s position on the matter, the general purpose of the requirement of legality (as expressed in her judgment) does not seem to be in dispute. See also Dawood, supra note 25 at para. 47. For a thorough discussion of the requirement, see generally Philippa Reyburn, The Constitutional Requirement of Legality in Limitation of Human Rights (LL.M. Thesis, University of Toronto (1999) [unpublished].
312 Prinsloo v. Van Der Linde and Another 1997 (3) SA 1012 (CC) at para. 17 [hereinafter Prinsloo].
313 See infra text accompanying notes 319-321.
314 See also the discussion on the TRIPS requirement of non-discrimination at the text accompanying notes 354-365, infra.
generality can be seen to add little to the differential treatment analysis other than a proscription on lawmaking that singles out particular players within particular industries.

3.2.1.2.2 Deprivations of property

In general, deprivations of property are in essence mere restrictions on the use of property, such as building regulations, land-use planning controls and environmental conservation laws. More specifically, section 25(1) prevents arbitrary state interference with property. In short, section 25(1) is “a right not to be arbitrarily deprived of property; . . . not a right not to be deprived of property at all”. While South African courts have yet to interpret this provision in any detailed way, the Constitutional Court has examined the non-arbitrary requirement implicit in the Constitution’s guarantee of equality before the law and equal protection of the law in some detail.

In Prinsloo, the Court held that that the Constitution requires the state to act rationally, which in relation to differentiation means that the state “should not regulate in an arbitrary manner or manifest ‘naked preferences’ that serve no legitimate governmental purpose, for that would be inconsistent with the rule of law and the fundamental premises of the constitutional State.” For differentiation to violate the equality guarantee, at

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315 Van der Walt, supra note 253 at 102. While deprivations technically also include expropriations of property, for the purposes of this section, deprivations refer only to those deprivations which are not subject to the stricter requirements of section 25(2) and (3), that is deprivations falling short of expropriations.

316 Ibid. at 102.

317 De Waal, Currie & Erasmus, supra note 254 at 412 [footnote omitted].

318 While this jurisprudence was initially developed under section 8 of the interim Constitution, the Court held in National Coalition for Gay and Lesbian Equality and Another v. Minister of Justice and Others 1999 (1) SA 6 (CC) that this jurisprudence was nevertheless applicable to matters arising under the equality guarantee of the 1996 Constitution (ibid. at para. 15).

319 Prinsloo, supra note 312 at para. 25.

320 Ibid. at para. 25. The phrase “naked preferences” can be traced back to Sunstein who argues that “[w]hen a naked preference is at work, one group or person is treated differently from another solely
minimum there must be "no rational relationship between the differentiation in question and the governmental purpose which is proffered to validate it." Applying this jurisprudence to section 25, it is clear that the right in section 25(1) is not infringed if the deprivation of property is rationally connected to a legitimate governmental purpose.

What acting rationally means depends on the scope of rationality review in South Africa. Marcus and Chaskalson place rationality review in perspective, pointing out that it is a particularly "deferential" standard of review, that a finding of irrationality is likely to be made only rarely, and that in fact such a finding has only been made on one occasion. Whatever rationality review may entail, it is clear that it does not entail any form of proportionality analysis. Indeed, a rational provision need not satisfy the test for reasonableness, which lies at the heart of the proportionality analysis.

because of a raw exercise of political power; no broader or more general justification exists." (Cass R. Sunstein, "Naked Preferences and the Constitution" (1984) 84 Colum. L. Rev. 1689 at 1693.)

321 Prinsloo, supra note 312 at paras. 25-26 [footnotes omitted]. "[W]hile the existence of such a rational relationship is a necessary condition for the differentiation not to infringe [section] 8, it is not a sufficient condition; for the differentiation might still constitute unfair discrimination . . ." (ibid.).

322 As the non-arbitrary requirement encompasses both procedural and substantive non-arbitrariness, it is not only the substance of the law that has to be rationally connected to the legitimate government purpose, but also the procedures employed (See De Waal, Currie & Erasmus, supra note 254 at 409).

323 G. Marcus & M. Chaskalson, PMA, supra note 50 (Intervener’s factum at paras. 4.4-4.6 and 4.10), online: Treatment Action Campaign <http://www.tac.org.za/pharmaceuticals.txt> (date accessed: 2 August 2001).

324 See New National Party of South Africa v. Government of the Republic of South Africa and Others 1999 (3) SA 191 (CC) at para. 122 [hereinafter New National Party]. Sunstein notes that "rationality review is . . . characterized by extremely deferential means-ends scrutiny." (Sunstein, supra note 320 at 1697.)

325 Pharmaceuticals, supra note 252 at para. 90.

326 See Pharmaceuticals case, ibid. The particular circumstances of that case are particularly instructive.

An Act of Parliament was brought into force before the necessary schedules—upon which the Act depended for the safe regulation of potentially harmful drugs—had been promulgated. Further, the President himself approached a court to have his decision to bring the Act into force set aside as it was not possible to reconvene Parliament prior to the upcoming general elections.

3.2.1.2.3 Expropriations of property

Two main conditions attach to the use of the expropriation power granted in terms of section 25. The first relates to the purpose or reason behind the expropriation, the second in relation to the obligation to provide compensation. I deal with these two conditions in turn.

Expropriations may only be carried out “for public purposes or in the public interest”.$^{328}$

At first glance, it seems as if the two concepts are indistinguishable. Expropriations for “public purposes”—such as the building of roads, bridges and hospitals—are easily defined in contrast to expropriations intended to benefit a private individual or a group of individuals.$^{329}$ But what of an expropriation carried out to benefit the public at large, which nevertheless results in the benefit of a particular individual, the likely result of any land reform programme? This may not amount to a public purpose, but would clearly be in the public interest.$^{330}$ Therefore, to dispel any doubt in this regard, section 25(4) states that the public interest is to be interpreted so as to include “the nation’s commitment to land reform” and “reforms to bring about equitable access to all South Africa’s natural resources”.$^{331}$

In addition to the public purpose or public interest requirement, section 25(3) also imposes an obligation to provide “just and equitable compensation”, which need not necessarily be market-value compensation. This is made clear by the reference in section

$^{328}$ Section 25(2)(a) of the Constitution.


$^{330}$ De Waal, Currie & Erasmus, supra note 254 at 412.

$^{331}$ Ibid.
25(3) to numerous factors that may serve to reduce (or in certain circumstances even to inflate) market-related compensation to what would be just and equitable in the circumstances. In addition, there may well be circumstances that justify very low or no compensation at all.332

3.2.1.3 Distinguishing between deprivations and expropriations

Having determined the extent of protections provided by section 25, I now examine the distinction between deprivations and expropriations of property in order to understand how the Constitution regulates certain types of interferences with property rights contemplated by TRIPS. The starting point in such an analysis is Harken's case, which saw the Constitutional Court attempting to give content to the distinction between the terms deprivation and expropriation as used in section 28 of the interim Constitution:333

The word 'expropriate' is generally used in our law to describe the process whereby a public authority takes property (usually immovable) for a public purpose and usually against payment of compensation. Whilst expropriation constitutes a form of deprivation of property, section 28 makes a distinction between deprivation of rights in property, on the one hand . . . , and expropriation of rights in property, on the other . . .334

Without any regard for context, the Court referred to the common law understanding of expropriation, finding that "[t]he distinction between expropriation (or compulsory acquisition as it is called in some other foreign jurisdictions) which involves acquisition of rights in property by a public authority for a public purpose and the deprivation of

332 ibid. at 413.
333 Although the text of section 28 of the interim Constitution differs from that of section 25 of the Constitution, the jurisprudence developed on the basis of the former provision must remain valid. In essence, the reformulated property clause retains the same distinction regarding deprivations and expropriations of property.
334 Harken, supra note 35 at paras. 32-33.
rights in property which fall short of compulsory acquisition has long been recognised in our law.”\(^{335}\) With apparent approval, the Court referred to *Beckenstrater* where it was held that—

the ordinary meaning of “expropriate” is “to dispossess of ownership, to deprive of property” . . .; but in statutory provisions, . . . it is generally used in a wider sense as meaning not only dispossess or deprivation but also appropriation by the expropriator of the particular right, and abatement or extinction, as the case may be, of any other existing right held by another which is inconsistent with the appropriated right.’\(^{336}\)

*Harksen* relies on Commonwealth jurisprudence to support this finding.\(^{337}\) According to this jurisprudence, it has been argued that expropriation requires both dispossesssion by the state, with a corresponding acquisition of rights, either by the state itself or a third party. Deprivations, on the other hand, do not affect ownership, but rather impose restrictions on use. Most controversially, however, the jurisprudence holds that “restrictions may go as far as to constitute an effective extinction of property rights. However, as long as the rights are merely extinguished and are not acquired by the public authority the extinction does not amount to an expropriation.\(^{338}\)

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\(^{335}\) *Ibid.* at paras. 32-33 [footnotes omitted].

\(^{336}\) *Beckenstrater* v *Sand River Irrigation Board* 1964 (4) SA 510 (T) at 515A-C [hereinafter *Beckenstrater*].

\(^{337}\) See De Waal, Currie and Erasmus, *supra* note 254 at 407. Indeed, the Constitutional Court expressly cited jurisprudence from India and Zimbabwe in coming to its decision (*Harksen, supra* note 35 at paras. 34-35). While Commonwealth jurisprudence may have developed in this way, it is interesting to note that international law may be moving in the opposite direction, towards the recognition of a doctrine of constructive or indirect expropriation. In this regard, see David Schneiderman, “Investment Rules and the New Constitutionalism” (2000) 25 L. & Social Enquiry 757 at 776, citing M. Sornarajah, *The International Law on Foreign Investment* (Cambridge, England: Cambridge University Press, 1994) at 296.

\(^{338}\) De Waal, Currie and Erasmus, *supra* note 254 at 407-08. See *Government of Malaysia v. Selangor Pilot Association* [1978] AC 337 (PC), which is indirectly referred to in *Harksen* and which supports its conclusion. In that decision, the Privy Council held that despite the fact that the effect of the impugned legislation was to extinguish the association’s goodwill (by prohibiting private companies or individuals from operating pilotage services in state-owned harbours), there was no compulsory acquisition of property as there had been no transferral, take over or acquisition of the goodwill.
Such a position is to be contrasted with Van der Walt’s view that the essence of an expropriation is that it gives rise to compensation, and not—as is usually assumed—that acquisition of property is involved. According to this view, dispossessions of property are to be categorized on the basis of the impact on the property holder, not on the fate of the property in question. Nevertheless, while Harksen does not turn on whether the state had actually acquired property, but rather whether the impugned provision could have the effect of taking property away from its rightful owner, the clear implication from the judgment is that an expropriation cannot be effected without a corresponding acquisition of title.

The Harksen dictum is troubling on two fronts. First, the Court seems to have rather too quickly accepted that “expropriation” equals “compulsory acquisition”, without even attempting to discern if the choice of the term expropriation, rather than the more commonly used term “compulsory acquisition”, is of any significance. Second, while Beckenstrater must clearly be considered in determining whether the term expropriation in the Constitution includes both the dispossession and acquisition of rights, it must be approached with caution, as the Constitution is not a mere codification of existing rights. Most troubling, nowhere in the judgment is there an appreciation of what purpose is served by the requirement that there be an actual acquisition of title following dispossession.

339 Van der Walt, supra note 253 at 116.
340 See Harksen, supra note 35 at paras. 36-37. In Harksen, the impugned provision was a statutory mechanism under insolvency law that temporarily transferred ownership of the property seemingly belonging to a solvent spouse to a state official, in order to determine whether it actually belonged to the solvent spouse or in fact to her spouse’s insolvent estate.
341 As Harksen did not turn on this issue, it is surprising that the Court would be prepared to make such a finding when the facts of the case did not even support a dispossession of property.
On a plain reading of sections 25(1), (2) and (3), there seems to be no reason to restrict expropriations to circumstances in which acquisition of property rights follows dispossession. If anything, the choice of the word expropriation seems to suggest a concept different from the Commonwealth notion of compulsory acquisition. In addition, the narrow definition of what constitutes property for the purposes of section 25, the specific constitutional requirement implicit in section 25(8) that all provisions of the section are to be interpreted in a way that does not undermine land and water reform, and flexibility in regard to compensation would seem to suggest that there is no reason to read the term expropriation narrowly. The state's authority to implement land and water reform seems to be sufficiently insulated from attack.

If the Constitution is about entrenching and developing a culture of justification, there must be a principled basis upon which one can make the claim that a regulation which effectively extinguishes property rights to serve the broader public interest should be treated any differently from a similar dispossession which is accompanied by state acquisition of that property. Given that the distinction between acquisition and extinction of rights could theoretically entitle the state to do through regulation what it is prohibited from doing through expropriation, that is, to take property away without ensuring just and equitable compensation, such an interpretation must be approached with extreme caution.

342 The choice of “expropriation” instead of “compulsory acquisition”, however, may have more to do with jurisprudential continuity (the term “compulsory acquisition has never been a part of South Africa's common or statutory law) than a conscious decision to depart from the post-colonial experiences of countries such as Zimbabwe and Malaysia.
343 Supra note 35.
The key to this constitutional puzzle is the purpose served by the requirement that there be an actual acquisition of title following dispossessin. It is not particularly difficult to see the problematic nature of the US doctrine of regulatory takings, which sees a regulation that “goes too far” as constituting an expropriation requiring compensation. The uncertainty created would clearly have a chilling effect on any land or water reform programme. Courts would not have the opportunity to test whether considerations of justice and equity demand a low level of compensation when government decides not to risk embarking on any constitutionally suspect programme. The mere threat of regulation being categorized as an expropriation would be sufficient to put the breaks on reform programmes. Thus section 25(8)’s command that “[n]o provision of . . . section [25] may impede the state from taking legislative and other measures to achieve land, water and related reform, in order to redress the results of past racial discrimination” seems to suggest an interpretation that avoids such problematic scenarios. Further, another factor supporting a narrower construction is the US experience showing that a regulatory takings doctrine inevitably leads to a jurisprudence of “ad hocism”,

It is easy to see why the doctrine of regulatory takings is inappropriate in a South African context. It is more difficult, however, to counteract the argument that recognizing a total extinction of rights as an expropriation—as opposed to a mere regulation that “goes to far”—does not bring with it the same problems. This would seemingly not entail the

344 See U.S. v. General Motors Corp. (1944) 323 U.S. 373, where the US Supreme Court held that “[g]overnment action short of acquisition of title or occupancy has been held, if its effects are so complete as to deprive the owner of all or most of his interest in the subject matter, to amount to a taking.” (Ibid. at 378.)

345 Although the US Supreme Court has identified various factors to be taken into account in determining whether a regulation amounts to a taking, the “inquiry into whether a taking has occurred is essentially an ‘ad hoc, factual’ inquiry.” (Ruckelshaus v. Monsanto Co (1983) 467 U.S. 986 at 1005 [hereinafter Ruckelshaus].)
drawing of arbitrary lines, creating uncertainty as to whether government has gone too far in its regulation, but rather serve to protect against an easily identifiable category of state action.

The issue of what constitutes an extinction of rights, however, is particularly complex. The complication arises in that property is ordinarily understood as being constituted by a “bundle of rights”. At what point in the regulation of property does the extinction of any of the incidents of rights constitute an extinction of the property itself? By nature, the regulation of rights automatically leads to the extinction or deprivation (and subsequent acquisition) of certain incidents of rights ownership. In essence, therefore, it is extremely difficult to distinguish between extinctions of rights and regulatory takings. Either both must be regarded as expropriations, or neither.

Recognizing that the concept of expropriation goes so far as to include indirect or constructive expropriations would also signify a strengthening of the pre-constitutional property rights regime. Given the compromise reached regarding the constitutional protection of private property, and the particular concerns regarding land and water reform, it seems unlikely that—in the absence of express recognition—the Constitution indeed goes this far. This may seem difficult for property holders to accept, but it is very much in line with the nature of the compromise made in 1993. It therefore follows that for a regulation of property to be considered as an expropriation in South Africa, two essential elements must be satisfied: dispossession and acquisition.

346 Ibid. at 1011.
3.2.2 Compulsory licenses and expropriation

In this section on the protection of private property, I have explored the concept of constitutional property, the distinction between deprivations and expropriations of property, and what a categorization as one or the other would mean for the rights holder. The analysis now shifts back to the international arena, and what the analysis so far may mean for the interpretation of international obligations under TRIPS, particularly the set of conditions that have to be met before a compulsory license can be granted. This example is chosen because Article 31 of TRIPS—which regulates compulsory licenses—raises the issue of compensation, which arguably lies at the heart of constitutional property in South Africa.347

Under US law, it is most likely that the granting of a compulsory license would constitute an expropriation, subject to compensation.348 In Ruckelshaus, for example, the US Supreme Court held that the disclosure of a trade secret, without the authority of the holder of the trade secret, amounts to a taking. Holding that “[t]he right to exclude others is generally ‘one of the most essential sticks in the bundle of rights that are commonly characterized as property’”,349 the Court emphasized that “central to the very definition of the property interest” in a trade secret is the right to exclude others, and that “[o]nce the

347 In terms of TRIPS, compensation is payable only in relation to compulsory licenses. Quite clearly, there is no requirement to compensate pursuant to the provisions of Articles 27.2 and 30. While the regulatory mechanisms permitted by these articles may constitute expropriations under the Constitution, this thesis is primarily concerned with the interpretation of TRIPS in the light of the Constitution, and not the interpretation of the Constitution per se. As such, these issues lie beyond the scope of this chapter.
348 For example, one commentator has stated that the grant of a “compulsory license can result in a de facto expropriation of the patent.” (Marshall A. Leafer, “Protecting United States Intellectual Property Abroad: Toward a New Multilateralism” (1991) 76 Iowa L. Rev. 273 at 286.) Another argues that “[e]ven if compulsory licenses do not acquire the constitutional dimensions of a taking, they still have been considered ‘a totally inappropriate expropriation of private property.’” (Cole M. Fauver, “Compulsory Patent Licensing in the United States: An Idea Whose Time has Come” (1988) 8 J. Int’l L. & Bus. 666 at 681.)
349 Ruckelhaus, supra note 345 at 1011.
data that constitutes a trade secret are disclosed to others, or others are allowed to use those data, the holder of the trade secret has lost his property interest in the data.\textsuperscript{350}

If the state were to acquire a patent at the expense of a patent holder, this would clearly amount to an expropriation. The patent holder would no longer be able to manufacture and market the invention protected by patent. As the product would still be under patent, no-one else would be entitled to manufacture the patented product in the absence of a license, voluntarily or compulsorily acquired. The grant of a compulsory license, on the other hand, would extinguish the exclusivity of the patent, but would nevertheless not prohibit the patent holder (or anyone else) from manufacturing and marketing the invention.\textsuperscript{351} On the basis of \textit{Ruckelshaus}, therefore, it follows that the grant of a compulsory license would amount to a taking of the property right in a patent. On the basis of the narrower construction of expropriation proposed earlier in this chapter, however, the answer is not at all clear.

The fact that TRIPS requires compensation in such circumstances is but a factor to consider in determining whether a compulsory license amounts to an expropriation of property.\textsuperscript{352} However, to show that the grant of a compulsory license amounts to an expropriation under South African law, the dispossession of rights has to be accompanied

\textsuperscript{350} \textit{Ibid.} [footnote omitted]. The Court continues to describe that despite the fact that the data retain usefulness even after disclosure, the economic value of the property right lies in the competitive advantage gained as a result of "exclusive access to the data", with "disclosure or use by others of the data . . . destroy[ing] that competitive edge." (\textit{Ibid.} at 1012.)

\textsuperscript{351} This assumes that the exclusion from patentability is not accompanied by a further restriction prohibiting commercial exploitation, such as that seemingly required by Article 27.2 of TRIPS. Such a condition would, in effect, mean that the patent had been "compulsorily acquired".

\textsuperscript{352} See \textit{supra} text accompanying note 246.
by a corresponding acquisition of rights.\textsuperscript{353} In the following section, I will argue that it is unlikely that the grant of a compulsory license be considered as an expropriation because it cannot be characterized as such. Three considerations support such a finding.

First, compulsory licensing leads to the extinction of the right to exclude, not its acquisition. As a result of the grant of a compulsory license, the patent holder loses the right to exclude all others from manufacturing, using, marketing or selling the patented product without its permission. Generic competitors, on the other hand, acquire the right to manufacture, use, market and sell the patented product. However, while these competitors clearly acquire rights at the expense of the patent holder, it cannot be said that they acquire that which is taken away. The right to exclude is simply extinguished, not acquired.

Second, while compensation following an expropriation is usually paid by the state, in this case the royalties which flow as a direct result of the granting of a compulsory license would be paid by the generic manufacturer of the compulsory licenses product, by the person benefiting from the “expropriation”. In addition, the state’s role in the dispossession is limited to providing the requisite statutory framework necessary for the dispossession to take place. The state takes no active role in the dispossession of rights.

\textsuperscript{353} In practice, a standard expropriation of patent rights will seldom occur in the context of a country like South Africa when it deals with the pharmaceutical industry. This would require the state to take over the patent, either manufacturing and marketing the patented product itself, or taking over the patent and granting voluntary licenses. The latter option is highly unlikely given the much simpler and less controversial option of permitting compulsory license applications.
Third, while the patent holder may no longer exclude others, he or she still occupies a preferential position regarding the property right in the intellectual object itself. Real loss of exclusivity would mean that the patent holder and all generic manufacturers have equal access to and use of the information. This is not the case following the grant of a compulsory license, precisely because of the obligation to pay compensation. The right to exploit the exclusivity of the patent is merely replaced with a right to receive royalty payments. In essence, this amounts to little more than a price control mechanism.

On balance, it seems unlikely that the Constitution would recognize such a deprivation of rights as an expropriation. However, even if the grant of a compulsory license does not amount to an expropriation under section 25 of the Constitution, it is nevertheless still appropriate to have reference to section 25(3) in determining what constitutes "adequate remuneration" under Article 31 of TRIPS. The strongest protection patent holders would have under South African law is if the granting of a compulsory license were to be considered as an expropriation. Thus the upper limit of "adequate remuneration" is what the Constitution considers "just and equitable compensation" following an expropriation. If the grant of a compulsory license does not amount to an expropriation of property, adequate remuneration may be equal to or less than "just and equitable compensation", but never greater. For the purposes of this thesis, therefore, it is important to treat the granting of a compulsory license as an expropriation of property—as envisaged by section 25 of the Constitution—to determine the upper limit of compensation required by Article 31.354

354 This argument applies only to compulsory licensing regimes implemented following the grant of broader patent rights. Insofar as existing patent legislation permits certain limitations of IPRs, such as the granting
3.3 The Constitution and TRIPS

This chapter has examined the relationship between international agreements and the Constitution, coming to the conclusion that all such agreements, including those ratified under the interim Constitution, are binding only in so far as they are consistent with the provisions of the 1996 Constitution. While not advancing the argument that TRIPS violates the Constitution, the analysis in the following chapter is premised on the finding that where a provision of the agreement is unclear, ambiguous or subject to more than one possible interpretation, it is to be interpreted in a manner that best gives effect to the Constitution.

In addition, this chapter has examined the manner in and the extent to which the Constitution protects private property. Understanding how the Constitution regulates private property rights provides much guidance in determining the extent of regulatory flexibility permissible under TRIPS. The detailed analysis of the property protections in section 25 of the Constitution thus provides the backdrop against which Articles 27.2, 30 and 31 of TRIPS are to be analyzed.

of compulsory licenses, the right cannot be infringed when the limiting provisions are triggered, as the scope of the right is inherently narrow.
CHAPTER FOUR: EXPLORING REGULATORY FLEXIBILITY

The issue of discrimination is key to the question of what type of regulatory framework would be permissible under TRIPS. In short, the question to be answered is whether it is permissible to design provisions such as a compulsory licensing scheme solely in relation to pharmaceutical products, given that TRIPS provides that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced”.\(^{355}\) This, argues the pharmaceutical industry, prohibits member states from adopting compulsory licensing regimes that specifically target the pharmaceutical industry without being applicable to other sectors.\(^{356}\) In *Generic Medicines*, however, the WTO panel rejected this line of thinking, noting that the use of the term discrimination in Article 27.1 refers to “the unjustified imposition of differentially disadvantageous treatment”,\(^{357}\) and not mere differentiation.

The second part of Article 27.1, which deals with the issue of discrimination, is made subject to Articles 65.4, 70.8 and 27.3 alone. By specifically mentioning these provisions, in particular Article 27.3, it is clear that the scope of this second part of Article 27.1 is in no way affected by Article 27.2, the so-called “public health

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\(^{355}\) Article 27.1 [emphasis added].


\(^{357}\) *Generic Medicines*, supra note 164 at para. 7.94.
exception”. 358 Quite clearly, Article 27.2 cannot be used to escape the requirement that there be no discrimination as to field of technology. That Article 27.2 clearly contemplates the differential treatment of industries that have an impact on health and environmental concerns, such as the pharmaceutical industry, supports the finding that prohibited discrimination means something more than differential treatment.

If the maximization of domestic welfare is at the core of social policy, 359 then it seems absurd to suggest that a single level of IP protection for all technologies or industries would suffice. This accords with strong consumerist views that TRIPS should not be interpreted as requiring a "one-size-fits-all" patent law. 360 At the heart of maximizing domestic welfare in the context of IPRs is the trade-off between innovation and imitation. The right balance to achieve that maximization depends on the nature of the technology or industry involved. 361 As Michael Trebilcock and Robert Howse argue, "a rational country would have different levels of protection for different industries, representing different trade-offs between innovation and imitation in each industry, depending on where its comparative advantage lies." 362 Indeed, legitimate social and economic objectives may require narrower IP protections in a particular industrial sector. 363

358 For a detailed analysis of this provision, see section 4.3 below on exclusions from patentability.
359 Given the provisions of the UDHR that bind all countries (as customary international law), it is arguable that the maximization of domestic welfare must be at the core of social policy, as this is really the raison d’etre for the existence of governments.
360 See e.g. Trans-Atlantic Consumer Dialogue, "TACD Recommendations on Health Care and Intellectual Property and European Commission Services’ Responses", online: Consumer Project on Technology <http://www.cptech.org/ip/health/country/cr-health2000.rt> (date accessed: 25 July 2001) where it is argued that "[t]he language in 27.1 ... should not be interpreted as preventing countries from addressing public interest concerns in patents, when provisions to address those public interest concerns are consistent with the TRIPS framework.”
361 Trebilcock & Howse, supra note 81 at 309.
362 Ibid. at 311. See Trebilcock & Howse’s description of how Japan achieved a balance between imitation and adaptation of certain innovations and the parallel strategic use of IP protection (ibid.).
363 Howse, supra note 154 at 505.
Implicit in the TRIPS principle that members may “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”\textsuperscript{364} is the recognition that, at minimum, states may draw a distinction in their regulatory frameworks between essential and non-essential products. Indeed, it has been argued that the fundamental flaw within many IP regimes is that they “fail to recognize that not all intellectual objects are essential.”\textsuperscript{365} The nature of pharmaceutical products and the purpose for which they are produced and consumed provide a principled basis for differential treatment. In the context of the AIDS pandemic, it would appear that a regulatory regime that targets the pharmaceutical industry could hardly be seen as an “unjustified imposition of differentially disadvantageous treatment.”\textsuperscript{366}

Regulatory flexibility, in terms of which countries would be permitted to depart from the minimum standards requirements of TRIPS, is to be found in Articles 27.2, 30 and 31 of the agreement. But as with any legal text, these provisions are open to interpretation. In this chapter I analyse these provisions in detail in order to determine the extent and nature of regulatory flexibility permitted by TRIPS. I come to the conclusion that despite the

\textsuperscript{364} See Article 8(1).
\textsuperscript{365} Ostergard, supra note 104 at 162.
\textsuperscript{366} Even advocates of strong IPRs recognize that—at least in theory—IP law should not impose standard rules across all industries. Mark Groombridge, for example, notes that the appropriate balance of incentives is influenced by factors such as demand, R&D costs and the structure of a particular market. As a result, the ideal solution would see the tailoring of specific IP rules for particular products, or at least particular industrial sectors. In practice, however, Groombridge argues that this is not possible (Mark A. Groombridge, “The TRIPS Trade-Off: Reconciling Competing Interests in the Millennium Round” (1999), 2 J. World I.P. 991 at 996 [footnote omitted]). While it may be impossible to tailor specific rules for particular products, there seems to be no reason why it would not be possible to design specific rules for particular sectors. Indeed, legislation frequently regulates in such a way.
limitations placed by TRIPS on national policy makers, much regulatory flexibility is to be found within the “interstices” of the law.

4.1 Compulsory Licensing under Article 31

Article 31 of TRIPS regulates compulsory licensing.367 While it remains unclear whether Article 31 is the only provision dealing with compulsory licensing,368 what does seem clear is that compulsory licenses issued as indirect price regulation mechanisms are regulated by Article 31. The debate about compulsory licensing, however, is not about whether TRIPS permits compulsory licensing, but when and in what circumstances it does so.

Before investigating the relevant conditions set out in Article 31, however, it is important briefly to address the issue of anti-competitive practices, as part of the regulatory flexibility afforded by Article 31 is dependant upon whether or not a particular practice has been determined as being anti-competitive.369 This raises the difficult question of

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368 For a thorough account of the history of compulsory licensing and the circumstances within which compulsory licenses are generally granted, see Michael Halewood, “Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law” (1997) 35 Osgoode Hall L. J. 243 at 263 – 272. Halewood argues that compulsory licensing is permissible under both Articles 30 and 31 of TRIPS, and that while the articles are mutually exclusive, in relation to compulsory licensing, they are mutually exclusive only in so far as the classes of compulsory licenses with which they deal are concerned (ibid. at 266).

369 TRIPS permits the determination to take place either by judicial or administrative process (see Articles 31(c) and (k)).
what constitutes an anti-competitive practice in the field of patent law, given that patents, by their very nature, serve to exclude competition from the market place.

TRIPS provides no definition of what constitutes an anti-competitive practice. However, given the flexibility afforded by Article 1, which empowers member states “to determine the appropriate method of implementing the provisions of [TRIPS] within their own legal system and practice”, it seems reasonable to conclude that such states are free to define the term for themselves, provided such a definition of anti-competitive behaviour is not an indirect mechanism for dispensing with what would otherwise be required.

4.1.1 Anti-competitive practices in South Africa

South African competition law recognizes that all people will benefit from an efficient and competitive development-oriented market that balances producer, consumer and worker interests.370 In particular, it supports a market “in which consumers have access to, and can freely select, the quality and variety of goods and services they desire”.371 To give effect to this goal, the Competition Act is to be interpreted in a way that gives effect to its purposes,372 which include the provision of “competitive prices and product choices”373 and “advanc[ing] . . . social and economic welfare”.374

370 Preamble to the Competition Act, 89 of 1998.
371 Ibid.
372 Section 1(2)(a) [emphasis in original].
373 Section 2(a).
374 Section 2(c). In the context of the HIV/AIDS epidemic, the constitutional right of access to essential drugs underpins regulation of the pharmaceutical industry.
In relation to an industry such as pharmaceutical products, the *Competition Act* shares concurrent jurisdiction with the *Patents Act.* As a result of the concurrent jurisdiction exercised over the pharmaceutical industry by the two statutes, activity expressly authorized by the one cannot be rendered nugatory by the provisions of the other. In short, the two Acts have to be read as working in tandem with each other. Thus the very nature of a patent, which is to grant an exclusive right to a patent holder to manufacture, sell, import or market a particular product, cannot be seen as necessarily giving rise to anti-competitive practices per se. In short, the ordinary exercise of a patent’s rights of exclusivity cannot be seen as a prohibited practice under the *Competition Act."

This does not mean, however, that all actions flowing from the exercise of patent rights are not subject to the control of the *Competition Act.* To read the concurrent jurisdiction in such a way would be to render such concurrency as meaningless. For example, dominant firms\footnote{Act 57 of 1978. The *Competition Act* also shares concurrent jurisdiction with other statutes such as the *Trademarks Act,* 194 of 1993. As this thesis is concerned only with patents, a discussion of the relationship between competition and trademark law lies beyond its scope. Section 3(1A) of the *Competition Act* regulates the concurrent jurisdiction.} are prohibited from engaging in any “exclusionary act”,\footnote{A firm is said to be dominant if it either controls a certain percentage of a particular market, or if it has “market power” (section 7), defined in section 1(1)(xiii) as the power “to exclude competition or to behave to an appreciable extent independently of its competitors, customers or suppliers”.} defined as “an act that impedes or prevents a firm from entering into, or expanding within, a market.”\footnote{Section 8(c).} The ordinary exercise of a patent does exactly this—it excludes competitors from entering the market. However, as the *Patents Act* also provides for the granting of compulsory licenses in certain circumstances,\footnote{Section 1.} any practice or conduct that frustrates
the ordinary working of such compulsory licensing provisions may be viewed as “exclusionary” and therefore prohibited by the *Competition Act*.

Further, certain pricing practices that often flow directly from the exclusion of competitors by the exclusionary nature of patent protection are not immune from the operations of the *Competition Act*’s prohibition against prohibited practices. Given the *Patents Act*’s silence on such issues, it necessarily follows that the *Competition Act* regulates prohibited practices such as charging an “excessive price” to the detriment of consumers” and engaging in prohibited price discrimination which is likely to have the effect of “substantially preventing or lessening competition.” In part, the prohibition against price discrimination prevents a dominant firm from discriminating between different purchasers on the basis of price. This is particularly important in South Africa, where the two-tier health system has seen private sector prices of pharmaceutical products substantially higher than the prices offered to the public sector. The result of this practice has been to ensure that many people who do not qualify for (or are unable to access) the public sector are denied access to necessary medications.

As mentioned above, this thesis is based on the assumption that the single biggest barrier to accessing essential treatments for HIV/AIDS remains high drug prices. In this regard, competition law may play an essential role. However, as this thesis is concerned only with indirect price regulatory mechanisms, the type of anti-competitive practices

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380 Section 8(a) [emphasis in original]. Section 1 of the *Competition Act* defines an “excessive price” as “a price for a good or a service which—

(aa) bears no reasonable relation to the economic value of that good or service; and

(bb) is higher than the value referred to in subparagraph (aa).”

381 Section 9.
mentioned here are relevant only in so far as they affect Article 31 and the conditions relating to the grant and use of compulsory licenses.

4.1.2 The relevant conditions in Article 31

The relevant conditions set out in Article 31 are as follows:

1. The compulsory license is to be non-exclusive and non-assignable;\(^{382}\)

2. The decision to issue the license and the decision regarding "adequate remuneration" are both subject to independent review;\(^{383}\)

3. Before a compulsory license can be issued, the prospective licensee must try to obtain a voluntary license on reasonable terms, which includes the payment of compensation. In certain circumstances, however, such as a national emergency or "other circumstances of extreme urgency", this condition is waived, as well as when the compulsory license is issued to remedy an anti-competitive practice;\(^{384}\)

4. The compulsory license can only be used for the purpose for which it was issued, and for as long as this purpose exists,\(^{385}\) with the license liable to be terminated if and when the reason for which it was issued ceases to exist and is unlikely to reoccur—the latter condition is subject to the "legitimate interests" of the licensees being given adequate protection;\(^{386}\)

\(^{382}\) Articles 31(d) and (e).

\(^{383}\) Articles 31(i) and (j). It is clear that the review does not have to be judicial in nature. The essence of the requirement lies in the independent nature of the review.

\(^{384}\) Articles 31(b) and (k). The determination of anti-competitiveness must be made by either judicial or administrative process.

\(^{385}\) Article 31(e).

\(^{386}\) Article 31(g).
5. Authorization for compulsory licensing must be considered on the individual merits of each case.\textsuperscript{387}

6. The use of the compulsory license must be "predominantly" for the supply of the domestic market—this condition may be waived when the compulsory license is issued to remedy an anti-competitive practice;\textsuperscript{388} and

7. The patent holder must be paid "adequate remuneration" (compensation), taking into account "the economic value" of the license and the need to correct anti-competitive practices.\textsuperscript{389}

While certainly limiting the scope for flexibility, there is no reason why these conditions cannot be incorporated into a regulatory framework such that they provide the conditions under which compulsory licenses can be issued and used, rather than being seen as placing restrictions on their grant and use.\textsuperscript{390} For example, instead of stipulating that an application for a compulsory license cannot proceed unless the applicant has taken all reasonable steps to secure a voluntary license, a failure to obtain a voluntary license from a patent holder on reasonable terms and within a reasonable period of time would entitle a generic company to apply for and be granted a compulsory license.\textsuperscript{391} In practice, express statutory provisions would regulate what constitutes a reasonable time limit,\textsuperscript{392} as

\textsuperscript{387} Article 31(a).
\textsuperscript{388} Articles 31(f) and (k). Once again, the determination of anti-competitiveness must be made by either judicial or administrative process.
\textsuperscript{389} Article 31(h).
\textsuperscript{390} See Jayashree Watal, "The TRIPS Agreement and Developing Countries: Strong, Weak or Balanced Protection?" (1998) 1 J. World I.P. 281 at 297.
\textsuperscript{391} Ibid. [footnote omitted].
\textsuperscript{392} Ibid. at 298, n.62. Legislation may provide, for example, that a particular number of days following the date of application for a voluntary licence constitutes a reasonable time limit.
well as what constitutes reasonable terms. Failure to agree to such terms within the prescribed (limited) time framework would then entitle the generic manufacturer, for example, to apply for and be granted the license.

Most of the conditions in Article 31 do not pose significant barriers to the introduction and efficient operation of compulsory licensing regimes in addition to those already imposed by the Constitution itself. While some of the procedural requirements could involve substantial delays and "militate against swift responses to what is a serious crisis", it is not clear that the safeguards inherent in constitutional rights such as those relating to just administrative action and access to courts, for example, would pose any less of a hurdle. Nevertheless, in designing an appropriate regulatory framework, substantial regard should be had for streamlined, fast-tracked processes that balance procedural safeguards with the need for quick and decisive action. There is no reason to believe that TRIPS does not permit such a balance to be struck, particularly given the express freedom granted to member states "to determine the appropriate method of implementing the provisions".

The first and second conditions—relating to non-exclusivity, non-assignability and reviewability—are largely uncontroversial and clear, and are not discussed further here. The third, fourth and fifth conditions—relating to voluntary licenses, scope and purpose,

393 The terms of the voluntary license could relate to the extent of the royalty to be paid, the mechanism for determining a reasonable royalty, and what factors would justify departing from this particular royalty arrangement.
394 See Weissman, supra note 87 at 1113.
396 Sections 33 and 34 respectively.
397 Article 1.
and individual merits—are less clear and require some discussion. The final two conditions—relating to domestic supply and compensation—are particularly controversial and unclear, and form the focus of the following discussion.

4.1.2.1 Voluntary licenses

The requirement that a voluntary license first be sought should not give rise to substantial delay. As mentioned above, a regulatory framework could limit the potentially crippling impact of the voluntary license requirements by providing express statutory definitions of what constitutes a reasonable time limit and what constitutes reasonable commercial terms. In the absence of such express statutory guidance, the latter requirement would most certainly provide the main stumbling block to the resolution of this requirement.

Regarding access to essential drugs used to treat either HIV infection itself or opportunistic infections associated with HIV/AIDS, South Africa clearly finds itself either in a “national emergency” or “circumstances of extreme urgency”, and is thus not required first to seek voluntary licenses. Even where such urgency or emergency does not exist, as may be argued (perhaps unconvincingly) in relation to other essential drugs, no measures need be taken to obtain a voluntary license if the license is for “public non-commercial use”. Thus if the government were to issue a compulsory license to itself or a public authority, the voluntary license requirement would not have to be satisfied. Further, the requirement regarding voluntary licenses need not be applied if the purpose

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398 Weissman, supra note 87 at 1113.
399 See supra text accompanying notes 390-393.
400 Article 31(b).
behind the application for a compulsory license is to remedy an anti-competitive practice.  

4.1.2.2 Scope and purpose

In general, Article 31 does not limit the grounds upon which compulsory licenses can be issued. Nevertheless, TRIPS places certain restrictions on the scope and purpose of compulsory licenses. These should pose few problems for the compulsory licensing of pharmaceutical products. As Weissman argues: "[t]he circumstances giving rise to the compulsory scheme — poverty, high incidence of disease, etc. — are not likely to cease any time soon." This is particularly true in the South African context, and unfortunately particularly true regarding the AIDS epidemic.

If the grant of a compulsory license is to be construed as an expropriation, the Constitution limits the purposes for which compulsory licenses can be granted, as in terms of section 25, property may only be expropriated "for a public purpose or in the public interest". Notwithstanding this limitation, it is hard to see how the grant of a

401 Article 31(k).
402 See e.g. Carlos M. Correa, "Implementing the TRIPS Agreement in the Patents Field: Options for Developing Countries" (1998) 1 J. World I.P. 75 [hereinafter “Implementing the TRIPS Agreement”] where the author points out that although TRIPS expressly refers to certain grounds for the granting of compulsory licenses, it “does not limit the Members’ right to establish compulsory licenses on other grounds not explicitly mentioned therein” (ibid. at 93). This position is strengthened by the express restriction of compulsory licenses in the field of semi-conductor technology to “public non-commercial use or to remedy a practice determined . . . to be anti-competitive”, which implicitly recognizes that compulsory licenses may be granted for any purpose in other areas of technology (Article 31(c)). See also Watal, supra note 390, where the author points out that “there are no restrictions whatsoever on the purposes for the grant of compulsory licenses, although there is a reference to some grounds in Articles 7, 8 and 31 of TRIPS.” (Ibid. at 296-97.)
403 Weissman, supra note 87 at 1113.
404 A drop in drug prices would not justify the revocation of a compulsory license. A fall in drug prices would have to be accompanied by a guarantee that they “are unlikely to rise again to unreasonable levels” (Watal, supra note 390 at 299). Further, it remains “TRIPS-compatible to protect the legitimate interests of the compulsory licenses who may have made a considerable investment or preparation for using the invention.” (Ibid.)
compulsory license so as to make essential drugs more accessible could be seen as anything but being in the public interest, particularly in the context of the South African AIDS epidemic.

4.1.2.3 Individual merits

The requirement that authorization for the “other use of the subject matter of a patent without the authorization of the right holder . . . be considered on its individual merits” clearly restricts the issuing of compulsory licenses to a case-by-case basis. This does not mean, however, that compulsory licenses can only be issued one at a time. As long as the facts relevant to each particular patented product are considered, there seems to be no reason why multiple licenses cannot be issued in any single court or administrative tribunal application. This would allow, for example, a single application by a generic pharmaceutical manufacturer for compulsory licenses for the entire class of antiretroviral drugs, as long as each drug was considered separately.

A further issue raised by the “individual merits” requirement is whether the initial grant has to be after application to court, an administrative agency or the relevant government department itself. Since TRIPS itself is silent on this point, it can hardly be said that any particular scheme is required.405 Furthermore, as mentioned above, member states have substantial freedom regarding the implementation of obligations.406 It would seem that as long as the process chosen in fact incorporates an individualized review of the particular

405 But see Weissman, supra note 87 at 1113, where he argues that this provision requires “a government agency to oversee the compulsory licensing scheme, even where it maintained a strong presumption that it would require licensing for most drugs.”
406 Article 1.
compulsory licensing application and complies with domestic administrative law principles, there can be no challenge to the chosen mechanism. Thus while there may be good policy arguments in favour of judicializing the entire process or delegating the function to a statutory body, the exact mechanism chosen resides with the relevant member state at the legislative level of government.

4.1.2.4 Domestic supply

It is in requiring that the issuing of a compulsory license be “predominantly” for the supply of the domestic market that Article 31(f) of TRIPS provides one of two major potential stumbling blocks for compulsory licensing regimes. Where countries lack the capacity or infrastructure to manufacture their own generic products, such products may be sourced from countries where compulsory licenses for their manufacture have been issued, where certain obligations under TRIPS have not yet come into force, or from countries outside the TRIPS agreement. As “membership of the WTO is becoming universal”, the third option is rather limited. While the second option is still available until 2006, it is of little assistance in ensuring a sustainable supply of generic products, integral to any antiretroviral intervention programme. As a result, therefore, only the first option is of any real significance. The crisp issue thus raised by the domestic supply requirement is the extent to which TRIPS permits the export of products manufactured in one country under a compulsory license to another.

407 See Article 66, which gives a least-developed country like India until 2006 before the majority of obligations under TRIPS become operational.
408 Subramanian, supra note 395 at 326.
409 Correa argues that “[i]n many cases, the only effective way of using a compulsory license would be through importation.” (“Implementing the TRIPS Agreement”, supra note 402 at 95.) The text of TRIPS makes it clear that compulsory licensing is not limited to mere production. Article 31 makes this clear in that it provides for “other use of the subject matter of a patent without the authorization of the right holder”,
Arvind Subramanian reads the requirement to mean that a country in which a compulsory license had been issued would only be able to export a small part—"much less than 50 percent"—of their total production of the generic product. But is this what is meant by the restriction that the license be used "predominantly for the supply of the domestic market"? Given the purpose, objects and structure of the agreement as a whole, and the characterization of TRIPS as providing a minimum standards default position that can be breached where good reason exists, it seems unlikely that the domestic supply requirement in Article 31(f) would place such arbitrary limits on exportation in the absence of any express provisions indicating what proportion of generic products may be exported. The provision is unworkable unless one is able to determine a principled basis upon which the domestic supply requirement is to be resolved.

What is clear is that, at minimum, Article 31(f) precludes a country from issuing compulsory licenses if the main purpose behind the issue is to facilitate the export of locally manufactured generic products. Thus, for example, an affluent country like Australia—with a relatively small population with HIV/AIDS—would be prohibited from issuing compulsory licenses for manufacturing antiretroviral drugs if the main purpose behind the issuing of such licenses was to service an export market. What is not so clear is where the line between permissible and impermissible exports is to be drawn.

In the following section, I will show that on a contextual analysis of the requirement, all

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with "other use" being defined in footnote 7 of TRIPS as referring to "use other than that allowed under Article 30." Article 30, in turn, speaks about providing "limited exceptions to the exclusive rights conferred by a patent", which are defined in Article 28(1) to include importation, either of a product or of a "product obtained directly by [a patented] process".

\[410\] \textit{Ibid.}
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that Article 31(f) requires is that the main purpose behind the issuing of a compulsory license is to supply the domestic market, which can be done either by production or by importation.

Two difficult cases arise. First, are large countries such as India—with internal markets of a sufficient size to support a wholly domestic market without resorting to exports—entitled to export products manufactured under a compulsory license to other countries, such as South Africa? If they are able to do so, in what circumstances and under what conditions may they issue compulsory licenses for export? Second, are smaller countries such as South Africa—arguably unable to support a wholly domestic market without resorting to exports—entitled to export products manufactured under compulsory license to other countries, such as Botswana, Uganda or El Salvador? I deal with these two scenarios in turn, starting with the latter.

4.1.2.4.1 Small domestic markets

Article 31(f) requires that compulsory licenses be used predominantly to supply the domestic market. Thus the main or leading element of the use of the compulsory license is the supply of the domestic market. Clearly, this does not preclude exports per se. Implicit in the requirement that the domestic market be supplied is that the use of the

411 In the case of India, which is not yet bound by most of the TRIPS obligations, the only legal barrier to the exportation of generic drugs is the compulsory licensing requirements of a particular country to import such generic products. However, this will change in 2006.
412 For a discussion on South Africa’s generic pharmaceutical industry, a key player in any compulsory licensing regime, see infra note 441.
413 Something is predominant if it “predominates” (The Oxford English Dictionary, 2d ed., s.v. “predominant”). To “predominate” is to “be the stronger, main, or leading element; to prevail, preponderate”, or to “have or exert controlling power, to lord it over; to surpass in authority or influence, to be superior” (ibid., s.v. “predominate”) [emphasis in original].
compulsory license will indeed facilitate domestic supply in a way that supports the reason for granting the license in the first place. Thus in relation to compulsory licenses issued to increase access to essential treatments for HIV/AIDS, for example, the issue to resolve is the extent to which exports are a necessary component of domestic supply. In other words, to what extent is domestic access reliant on a need to export?

The benefits of expanding markets are obvious. Economies of scale dictate that by selling in a number of countries, the costs of drug production can be reduced significantly. With sufficient competition, low costs translate directly into accessible products. Similarly, without sufficiently sized markets, increased competition cannot be supported. As compulsory licenses cannot be exclusive, manufacturers of generic drugs will need a sufficiently sized market to remain competitive.

In order to address a local epidemic by way of compulsory licensing, the regime has to be commercially viable, which by necessity means that producers of generic drugs must be able to expand their markets internationally, even if the result is greater export than domestic sales. But for the ability to sell beyond the borders of South Africa, a compulsory license to manufacture patented drugs may bring few of the benefits of such a regime. Thus the very purpose behind the grant of the compulsory license, which is the introduction of generic competition, may indeed be frustrated if the domestic supply requirement is interpreted to preclude sizeable exports. By necessity, the test cannot be reduced to the unnuanced, mathematical equation proposed by Subramanian.
4.1.2.4.2 Large domestic markets

Where a country is able to support a wholly domestic market without resorting to exports, the issue is somewhat more complex. While the benefits of expanding markets are nevertheless still applicable, in essence the issue raised here is less about local sustainability than about exporting generic products to countries where such products are not manufactured themselves. Nevertheless, if countries such as India are precluded from exporting to countries where compulsory licenses have been issued, but due to a lack of infrastructure or technology (or some other valid reason) there is no viable option of local production, then the granting of such licenses is all but useless in those countries.414

The right to grant compulsory licenses for the importation of generic products is contingent on the production of such products by other countries where compulsory licenses for this purpose have been granted. If a country such as India were not allowed to export compulsorily licensed products, in the absence of a country such as South Africa exporting generic products so as to sustain its own local industry, countries will have no source for the importation of generic products, rendering the compulsory license in the importing country ineffective. While there is no guarantee that such countries will indeed grant compulsory licenses, where TRIPS-compliant patent legislation permits the granting of such licenses resulting in the availability of affordable medicines, it seems unduly formalistic to read the domestic supply requirement as precluding the export of these legally manufactured products.415

414 The compulsory license in India to manufacture and distribute locally would be of much value domestically.
415 But see Subramanian, supra note 395 at 327-28. The author's argument that TRIPS precludes such imports is in part influenced by a misunderstanding of the conditions in Article 31, reflected in his assertion
4.1.2.5 Compensation

In the previous chapter, it was argued that the strongest protection patent holders have under the Constitution is if the granting of a compulsory license amounts to an expropriation. While I concluded that it is unlikely that the Constitution recognizes such a deprivation of property rights as an expropriation, I also argued that in terms of South Africa’s international obligations, the upper limit of the “adequate remuneration” requirement is what the Constitution considers as “just and equitable compensation” following an expropriation of property. For this reason, therefore, it is important to apply the provisions of section 25(3), which set out the factors that have an impact on the determination of what is just and equitable in the circumstances.

The factors to be considered in such an analysis do not constitute a closed list. Indeed, they are merely examples of “relevant circumstances” which are to be considered in achieving “an equitable balance between the public interest and the interests of those affected”.

Thus, in determining what is just and equitable in the circumstances, a decision-maker must consider the current use of the property, the history of the acquisition and use of the property, the extent of direct state investment and subsidy in that India cannot “suspend its IP laws because of an AIDS crisis in Africa.” (Ibid.) As mentioned above, the emergency or “extreme urgency” requirement pertains only to whether a voluntary license has to be sought before the compulsory license can be issued. When India’s TRIPS obligations come into effect in 2006, it will not be precluded from issuing compulsory licenses for antiretroviral drugs simply because the Indian AIDS epidemic may not be considered as a national emergency or a situation of extreme urgency, in itself a questionable conclusion.

416 Section 25(3).
417 Section 25(3)(a).
418 Section 25(3)(b).
the acquisition and beneficial capital improvement of the property,\textsuperscript{419} the purpose of the expropriation,\textsuperscript{420} and the market value of the property.\textsuperscript{421} I will deal with these factors below.

4.1.2.5.1 Current use of the property

IP that is being used primarily to reap profits and not to benefit the broader public good amounts to a use of such property that undermines the rationale behind the statutory grant of IP protections in the first place. Thus if it were to be shown that the prices of patented drugs in South Africa are significantly higher than the same products sold in comparable countries, this would tend to suggest profiteering giving rise to compensation below market value. Even lower levels of compensation would be in order if it were to be established that the same drug were being sold in developed countries at prices below that charged in South Africa.\textsuperscript{422}

It is not only accessibility of drugs that is relevant to this enquiry. As TRIPS recognizes technology transfer as an important objective of IP protection, investment in the form of manufacturing plants would seem to suggest that the local manufacturing of a patented drug would place a brand-name company in a stronger position than its counterpart that merely imported the drug, and in a substantially stronger position than a company that held a patent but neither manufactured nor imported the patented product. While TRIPS

\textsuperscript{419} Section 25(3)(d).
\textsuperscript{420} Section 25(e).
\textsuperscript{421} Section 25(3)(c).
\textsuperscript{422} The strong opposition to the parallel importation provisions in the Medicines Act, as seen in the PMA case, would tend to suggest that prices of patented products in South Africa are higher than in other countries. This is indeed the case. For detailed information in this regard, see Carmen Perez-Casas, Affidavit in PMA, supra note 50, online: Treatment Action Campaign <http://www.tac.org.za/affidiv.doc> (date accessed: 16 August 2001).
generally does not allow for local working requirements, which condition patent protection on domestic production, it implicitly recognizes that the investments of patent holders are to be considered in such an analysis. If patent protection is to be granted to ensure that investments in R&D are secure, then the level of investment is central to any determination of compensation following the expropriation of patent rights. While compensation is not a reward, it is thus arguable that the greater the investment, the stronger the case for compensation.

4.1.2.5.2 History of acquisition

In terms of section 25 of the Constitution, land acquired under apartheid in terms of discriminatory legislation would be subject to a particularly low level of compensation payable upon its expropriation. The Constitution thus regards unfairly acquired property as not particularly worthy of compensation. Similarly, it follows that the development of drugs as a result of the appropriation of indigenous remedies that peoples in a particular country may have used for generations or even centuries would justify lower levels of compensation, if the indigenous peoples were not adequately compensated. Similarly, existing drugs for which a new use has been found—resulting in the granting of a new patent—would fall within this factor’s reach. In relation to drugs more broadly, this factor gives effect to the recognition that innovation does not take place in a vacuum, but rather builds on the work of others and depend on strong societal support and investment

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424 Zidovudine (AZT) is an example of such a drug. See Ackiron, supra note 132 at at 166-67.
in human capital. The nature of innovation is thus a factor to consider in treating the expropriation of IPRs as distinct from expropriations of other forms of property.

4.1.2.5.3 State investment and subsidy in the acquisition

The use of public funds in the development of drugs is a factor that would justify in and of itself a lower level of compensation. As was mentioned above, much of the early—and financially very risky—R&D is actually funded by public money: many brand-name companies only become involved at the stage when the research indicates promising results. Regarding antiretroviral drugs, it is widely acknowledged that most HIV/AIDS research in the US is federally sponsored, primarily by the National Institutes of Health (NIH). Thus in relation to antiretroviral drugs in particular, there is a strong case for substantially reduced levels of compensation.

While public investment in drug development is a factor to consider, what of the argument that section 25(3)(d) is concerned only with South African public funds? On a purposive and contextual interpretation of section 25, however, taking into consideration the requirement that compensation be “just and equitable” in the circumstances, it seems fair to conclude that the state investment factor is based on the premise that it is not just or equitable to be compensated for the loss of property acquired at the expense of others. Thus the source of the public funds is largely irrelevant to the analysis.

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425 Trebilcock & Howse, supra note 81 at 308.
426 Marcia Angell, supra note 128.
427 See supra text accompanying note 131.
4.1.2.5.4 Purpose of the expropriation

In the case of access to essential drugs for HIV/AIDS, compulsory licenses would most frequently be granted in order to bring prices down. If such a compulsory licensing regime is to have any meaning, it must be able to deliver cheaper, affordable drugs. If a generic manufacturer were forced to pay a high royalty to a patent holder for the use of the compulsory license, the purpose of the license would be frustrated. Compulsory licenses issued for other purposes, such as anti-competitive practices unrelated to issues of drug access, may not justify as low royalty payments.

4.1.2.5.5 Market or economic value

Article 31 requires that the "economic value" of the grant of the compulsory license be considered when determining the amount of compensation. In essence, this requirement begs the question: value to whom? Weissman suggests that the reference to economic value must be the economic value to the licensee, for if one were to define adequate remuneration as the market value of the patent, there would be no need for the compulsory license. In such circumstances, any rational patent holder would generally have no objection to the grant of a voluntary license.

Further, if one were to consider the economic value of the authorization solely on the basis of the loss to the patent holder, such an evaluation may in reality be difficult to determine. The economic loss to a patent holder would be equal to the difference between the profits that would have been made in the absence of the grant of the

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428 Weissman, supra note 87 at 1114.
429 Ibid.
compulsory license and the profits to be made in circumstances of increased competition. This would require certain assumptions to be made about future market conditions, such as whether other competitive products are being or are likely to be developed. Further, given that only non-exclusive compulsory licenses may be granted, the biggest unknown factor is whether other companies are likely to apply for compulsory licenses—loss of profits will most likely increase the further the market for that compulsorily licensed drug moves away from the initial duopoly granted.  

Value to the licensee remains the only feasible “market value” that may be ascertained. While this is also difficult to measure, most of these problems could be overcome if compensation were linked to actual profits. Such proposals are by no means new. Indeed, in its 1985 recommendation that Canada retain its compulsory licensing regime, the Canadian Commission of Inquiry on the Pharmaceutical Industry suggested that payments to an envisaged Pharmaceutical Royalty Fund, to be financed by generic companies holding compulsory licenses, would be linked to the value of each licensee’s actual sales of compulsorily licensed products in Canada.

\footnote{Andrew Scott, “Developing Countries and Compulsory Licensing of Pharmaceuticals under the WTO TRIPS Agreement” (December 2000) [unpublished, on file with Professor Michael Trebilcock, University of Toronto Faculty of Law] at 12.}

\footnote{Scott raises a third alternative—that being the economic value of the patent to potential purchasers (Scott, \textit{supra} note 430 at 12). While the language of Article 31 is capable of such a meaning, the extreme difficulties in assessing such an economic value must preclude this approach. Nevertheless, the concerns of potential purchasers and their relative incomes may also be taken into account, given that “economic value” is but an example of factors to be considered in determining what constitutes “adequate remuneration”.

\footnote{Scott, \textit{supra} note 430 at 13. Scott raises certain problematic assumptions about “generally lower financial reporting standards in develop[ing] countries.” Even if true, such an argument cannot be applied to South Africa.

4.1.3 Implications for South Africa

In the case of essential drugs used to treat both HIV infection and opportunistic infections associated with HIV/AIDS, South Africa would be able to authorize the grant of compulsory licenses without the need for first seeking voluntary licenses. Such a compulsory licensing regime may be either for importation (from countries such as Thailand, India and Brazil, where generic antiretroviral and other drugs are legally produced) or for manufacture, or both. In the case of the latter, such licenses would be to supply both domestic and foreign markets. In addition, the granting of compulsory licenses would—in many (if not all) cases—be subject to the payment of particularly low compensation, expressed most probably as a percentage of the licensee’s profits.\textsuperscript{434} If such a regime were to be implemented, compulsory licensing of these drugs would go some way to making drugs more accessible, an integral component of any rational public health programme to address the AIDS epidemic. Or even if it were to be used only sparingly, its mere existence on the statute books may be “adequate to encourage the voluntary conclusion of licenses.”\textsuperscript{435}

4.2 Early working provisions under Article 30

Although most patent regimes now provide only for a minimum 20-year term of patent protection,\textsuperscript{436} the extent of patent protection provided generally results in the effective extension of this period. As products under patent may only be used or manufactured by

\textsuperscript{434} Given the individualized nature of the application process and the list of relevant factors used to determine the amount of compensation, such an evaluation should ideally not take place by a simple mathematical formula. However, this may prove to be unworkable, which would justify a formulaic approach, perhaps with room for exceptions in the case of certain classes of products such as antiretroviral and other essential drugs.

\textsuperscript{435} Watal, supra note 390 at 300. While the Patents Act deals with compulsory licensing, it arguably provides greater protection to IPRs than is required under Article 31 (see section 56 of the Patents Act).

\textsuperscript{436} See Article 33 of TRIPS, quoted in full in the general appendix, below.
the patent holder, generic manufacturers are only able to begin production once the patent has expired. The manufacturing period required to build up a sufficiently sized inventory to enter the market effectively extends market exclusivity for the patent holder. In the case of pharmaceutical products, however, a second factor precludes the early entry of generic competition—regulatory approval. Such a process can effectively delay generic entry for a number of years as the operation of a patent precludes generic drug manufacturers from beginning the drug regulatory approval process until the patent has expired.

Early working provisions, such as Bolar and stockpiling exceptions, have one thing in common—the introduction of generic copies of a patented product to the marketplace as soon as patent protection expires. In the United States, for example, the Bolar exception is used to allow generic manufacturers of drugs to make use of a patented product for the purposes of seeking regulatory approval without incurring liability for patent infringement. As a result, generic manufacturers are able to complete regulatory approval requirements during the life of the patent, subsequently being in a position to market their drugs on the first day of patent expiration. This is clearly desirable from a

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437 A stockpiling exception would allow for the manufacture of generic products towards the end of the term of patent protection, such that upon patent expiry, sufficient stock of the generic product would be available for immediate sale. Without the exception, production of the generic product would only be permitted upon patent expiry.

438 In the case of drugs, the most crucial delay is caused by regulatory approval. Actual production time of generic drugs may vary, depending on the capacity of generic companies, but will most likely not result in delays of the magnitude of those caused by regulatory processes.

consumer perspective, given that the entry of generic competition translates into lower product prices.\footnote{As mentioned above, the looming expiration of a patent is seen as an incentive to innovate. Thus, at minimum, the introduction of generic competition upon patent expiry can in no way be seen as a disincentive to innovate. Indeed, it seems as if this may serve to stimulate innovation (see supra text accompanying note 124).} While price reductions may provide sufficient reason to implement such policies in South Africa, particularly given the right of access to essential medicines implicit in the right of access to health, another equally valid reason exists: the development and nurturing of a strong domestic generic pharmaceutical industry. To a large extent, the availability and affordability of generic medicines in developing countries is reliant on its existence. Production costs in developed countries may often be substantially higher. In addition, high drug prices may result from factors such as transportation costs and fluctuating currencies. As a general rule, therefore, the only guarantee of a sustainable source of affordable generic medicines is to ensure the viability of a strong domestic generic pharmaceutical industry.

For as long as other countries make use of the Bolar exception, South Africa would be wise to implement similar domestic provisions in order to protect its domestic generic pharmaceutical industry.\footnote{Fortuitously, South Africa has a relatively strong domestic generic drug industry. For example, a domestic company with generic drugs as its core competency is currently the largest listed pharmaceutical company on the Johannesburg Stock Exchange (JSE Securities Exchange) ("Information for Investors: FY2000 Final Results", online: Aspen Pharmacare, <http://www.pharmacare.co.za> (date accessed: 29 July 2001) at 1, 5). With a 50 per cent share in the generic market, Aspen Pharmacare is currently the largest supplier of generics to the state, which buys around 80 per cent—in terms of volume—of all drugs sold in South Africa. Currently, generic usage in government hospitals stands at 31 per cent (ibid. at 6). In addition, Aspen claims that it is "extremely well placed to be a provider of affordable generics to the rest of Africa." (Ibid. at 7.)} Generic products developed and manufactured in those countries that permit Bolar exceptions will clearly be on the South African market years...
before domestic counterparts can legally be developed, given that the Patents Act does not permit early working provisions. As a result, little incentive exists to develop generic drugs locally.\textsuperscript{442}

While compulsory licenses can be used to make drugs more affordable, it is only with the full introduction of generic competition that prices of drugs can be brought down to the lowest possible price the market can bear. While many key antiretroviral drugs used in the fight against HIV/AIDS are still subject to patent protection for a number of years, the patents on a number of key drugs in the fight against HIV/AIDS, such as Pfizer’s Diflucan (fluconazole) and Glaxo SmithKline’s Retrovir (zidovudine or AZT),\textsuperscript{443} are nearing expiration.\textsuperscript{444} The introduction of Bolar and stockpiling exceptions in South African law would clearly provide greater access to such drugs upon the imminent expiration of their patents.

\textsuperscript{442} Alfred B. Engelberg, “Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness? A Political, legislative and Legal History of U.S. Law and Observations for the Future” (1999) 39 IDEA 389 at 412. Indeed, Aspen Pharmcare recognizes that “[t]he lifeblood of a generics company is new products and \textit{first-to-market status}” (“Information for Investors: FY2000 Final Results”, \textit{supra} note 441 at 7 [emphasis added]).

\textsuperscript{443} Fluconazole is used to treat vaginal, oropharyngeal and oesophageal forms of thrush, as well as cryptococcal meningitis. These infections are common amongst people with HIV/AIDS (\textit{Ward, supra} note 1 at 130-33, 134-35). AZT is often used in combination with other antiretroviral drugs in HAART (\textit{ibid.} at 70-71, 82-85), as well as on its own for the prevention of HIV transmission from mother to child (\textit{ibid.} at 231).

4.2.1 Introducing Article 30

Article 30, under which the Bolar and stockpiling exceptions would have to fail if they are to be found TRIPS-compliant, provides as follows:

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 holder, taking account of the legitimate interests of third parties.445

The extent of regulatory flexibility afforded by Article 30 relies on the provision’s interpretation. Common to many interpretations of the provision is the claim that it should not be interpreted in a manner that undermines the substantive patent provisions of TRIPS,446 in a manner that serves to “emasculate the general principles established in the agreements.”447 That an exception should not be interpreted to “emasculate” an agreement does not necessarily mean that it should be construed narrowly,448 given that the general principles to be considered in such an analysis are those set out in Article 7 of TRIPS, which speak to the forging of an appropriate balance of interests. Indeed, the

445 It has been argued that there is “ample” evidence to support the finding that Article 30 was both designed and intended by the US to insulate its Bolar exemption from attack. Even if this is correct, such a finding in no way supports the claim made by Canada in Generic Medicines that the negotiating history supports the finding that Article 30 was adopted specifically to permit Bolar exceptions. In order to do so, the evidence would have to show that the parties to the negotiating process generally accepted such a position. In Generic Medicines, however, the panel found that “there was no documented evidence of the claimed negotiating understanding” and that it could therefore not found a decision on whether Canada’s regulatory review exceptions fell within the scope of Article 30 of TRIPS on the basis of the negotiating history (Generic Medicines, supra note 164 at para. 7.47).


447 Ibid. at 661.

448 In fact, as was mentioned above, the Appellate Body in Hormones expressly held that such an approach to exceptions was in conflict with customary international law principles of interpretation (see supra, text accompanying note 167).
very existence of Article 30 "amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments."\(^{449}\)

The WTO panel decision in *Generic Medicines* suggests that while Bolar exceptions can be justified under Article 30, the very same provision precludes the adoption of stockpiling exceptions.\(^{450}\) *Generic Medicines* dealt with three key issues: first, whether in terms of its TRIPS obligations Canada is permitted to allow for the "manufacturing and stockpiling of pharmaceutical products without the consent of the patent holder during the six months immediately prior to the expiration of the 20-year patent term";\(^{451}\) second, whether the same international obligations permit legislation relating to the "development and submission of information required to obtain marketing approval for pharmaceutical products carried out without the consent of the patent holder", a Bolar-type exception;\(^{452}\) and third, whether "by treating patent holders in the field of pharmaceutical inventions by virtue of these provisions less favourably than inventions in all other fields of technology" Canadian patent law violated the anti-discrimination provision in Article 27.1 of TRIPS.\(^{453}\)

In this section I will show that not only does Article 30 permit both Bolar and stockpiling exceptions, but also that the very basis upon which the WTO panel upheld Canada's Bolar-type exception is fundamentally flawed. As has been argued above, TRIPS does

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\(^{449}\) *Generic Medicines*, *supra* note 164 at para. 7.26.

\(^{450}\) See *ibid*. This decision was not taken on appeal, and has recently found its way into Canadian domestic law (see *Regulations Repealing the Manufacturing and Storage of Patented Medicines Regulations*, S.O.R./00-373).

\(^{451}\) *Generic Medicines*, *supra* note 164 at para 3.1.

\(^{452}\) *Ibid*.

\(^{453}\) *Ibid*. For a discussion of the non-discrimination requirement, see *supra* text accompanying notes 355-366.
not restrict the circumstances in which compulsory licenses may be issued, but rather controls the procedures by which such licenses are issued and the conditions attached to their issue. Further, as will be shown in the next section, TRIPS allows for complete exclusion from patentability in certain restricted circumstances. The common thread linking these articles is the recognition that TRIPS allows for particularly radical departures from the minimum standards default position in strictly controlled circumstances. This is the context within which Article 30 must be evaluated. In this light, it would seem inconsistent to suggest that Article 30 is to be read as a narrow exception. Given the flexibility afforded member states in Article 1, it would be surprising to argue that Article 30 must be interpreted in a way that would prevent member states from creating the necessary balance in their respective contexts.

4.2.2 The relevant conditions in Article 30

In Generic Medicines, the panel held that Article 30 contains three conditions, that these conditions “be interpreted in relation to each other”, and that to avoid redundancy, a separate meaning be attached to each of the three conditions.454 While a plain reading of the text supports such a finding, as does the principle of effectiveness, it does not support the finding made by the panel that these three conditions are as follows:

(1) the exception must be ‘limited’;
(2) the exception must not ‘unreasonably conflict with normal exploitation of the patent’; [and]
(3) the exception must not ‘unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties’.

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454 Ibid. at para. 7.21 [footnote omitted].
455 Ibid. at para 7.20 [footnote omitted].
The structure of Article 30 means that the legitimate interests of third parties are to be considered at every step of the process, and not just in relation to the legitimate interests of patent holders. If the latter construction were correct, one would expect to see a comma inserted after "normal exploitation of the patent". A plain reading of the article leads to the conclusion that when limited exceptions are provided, the legitimate interests of third parties are to be taken into account. Further, in providing such limited exceptions, there must be no unreasonable conflict with normal exploitation and no unreasonable prejudice to the legitimate interests of patent holders.

It is not only the syntax of Article 30 that supports such a reading. A contextual reading of the provision, in the light of the objectives of TRIPS as set out in Article 7—in particular those relating to the "mutual advantage of producers and users of technological knowledge" and the promotion and protection of IPRs "in a manner conducive to social and economic welfare"—leads to a similar conclusion. A reading of Article 30 that does not acknowledge the legitimate interests of third parties at each step of the balancing process would be an interpretation that is in conflict with the foundational principles of the agreement.

In arguing that the provision "potentially provides for very broad exceptions", Weissman argues that unlike other trade "exceptions", Article 30 does not limit the purposes for which the article may be invoked. At first glance this appears to be correct, given that the provision merely states the conditions under which such exceptions may be made,

456 Such as Article XX of the GATT and Article 27.2 of TRIPS.
457 Weissman, supra note 87 at 1108. Nevertheless, he agrees that Article 30 clearly places conditions on its use, as it "was not intended as an all-purpose opt-out from TRIPS patent rules." (Ibid.)
failing to mention the purposes for which such exceptions are permissible. Read in context, however, Article 30 implicitly recognizes that it cannot be invoked for simply any purpose, as this would serve to negate the very essence of the agreement.

I have argued above that member states are obliged to consider the legitimate interests of third parties when they invoke Article 30. Such interests are those that are recognized in international law, such as the right to the highest attainable standard of health in Article 12 of the ICESCR and the right to share in scientific advancement and its benefits in Article 27 of the UDHR, as well as third party interests expressly recognized in TRIPS itself, such as social and economic welfare. As a result, therefore, Article 30 can only be invoked if the rationale underlying the policy choice is based on such a recognized third party interest. Thus the need to deal with medical emergencies following the outbreak of disease would clearly fall under Article 30, as would the need to make essential drugs affordable.458

I have so far argued that Article 30 allows for limited exceptions only in relation to the pursuit of certain recognized goals, and only under certain conditions. In addition, in determining what constitutes a limited exception, and what meaning is to be attached to each of the other two conditions, I have argued that legitimate third party interests are always to be considered. With such an understanding, the analysis now shifts to the interpretation of the three conditions.

458 See Gana, supra note 154 at 755.
4.2.2.1 Limited exceptions

One reading of Article 30 supports the finding that the meaning of the term “limited” is defined within the provision itself, such that the express conditions set out may be seen to define what constitutes a limited exception. This reading, which assumes that the term can contribute little in terms of principle and substance in addition to that already provided in the subsequent conditions, would render the term superfluous.\footnote{Weissman, supra note 87 at 1109.} A second construction, which attempts to give independent meaning to the term “limited,” sees it as preventing the use of Article 30 “to defeat the TRIPS Agreement on patents altogether.”\footnote{Ibid.} On this basis Weissman argues that various policy options (including early working requirements), all of which are “limited” to pharmaceuticals, would survive, as they do not place restrictions on patents in other fields.\footnote{Ibid.} A third reading sees the term as placing substantially greater constraints on the use of Article 30. Without giving an exact definition of what would constitute a limited exception, the panel in Generic Medicines found that any exception which resulted in a “substantial curtailment of [the exclusionary rights] cannot be considered a ‘limited exception’.”\footnote{Generic Medicines, supra note 164 at para. 7.36. In addition, the panel found that it “could not accept . . . that an exception can be regarded as ‘limited’ just so long as it preserves the patent owner’s exclusive right to sell to the ultimate consumer during the patent term.” (Ibid. at para. 7.44.)}

None of these three interpretations is particularly convincing. If the principle of effectiveness is to be taken seriously, with the term “limited” having independent force, the first interpretation is to be avoided. The second lacks any textual, contextual or principled basis to explain its purpose. Finally, the third interpretation considers the meaning of the term only in relation to the exclusionary rights of the patent holder,
without regard to the policy goals or purposes for which the exception is to be used, without considering legitimate third parties interests.\(^{463}\) Indeed, even though the very existence of Article 30 signifies a consideration of “legitimate, competing policy interests”, the panel’s analysis of the term “limited” in Generic Medicines confined itself to a consideration of “how much the rights holder might lose, not in how much society might gain, from a given exception. It never asked what scope the exception might require to achieve the social purposes at issue.”\(^{464}\) In addition, if the term “limited” is to have independent force, then it cannot relate to the impact of such a provision on the exclusionary rights of a patent holder. As Article 30 expressly states that exceptions to TRIPS cannot unreasonably prejudice patent holder interests, the term “limited” has to mean something else.

South African constitutional jurisprudence is particularly helpful if we draw an analogy between Article 30 and section 36 of the Constitution. Both provisions in essence set out the conditions that justify a limitation of entrenched rights, recognizing that certain broader concerns may indeed justify departing from strict levels of protections. In addition, both recognize that the fundamental objectives of the documents of which they form integral parts may indeed be undermined by the strict application of rights. Seen in this light, and recognizing that under South African law international obligations are to be

\(^{463}\) Howse, \textit{supra} note 154 at 496. Indeed, the panel found that “‘limited’ is to be measured by the extent to which the exclusive rights of the patent holder have been curtailed.” (Generic Medicines, \textit{supra} note 164 at para. 7.29.) Howse rightly points out that “it is something of a mystery as to how the Panel could find the testing exception sufficiently narrow but not the stockpiling exception”, given that but for the Bolar exception, generic entry of drugs following patent expiry could effectively extend the patent for three years, whereas the stockpiling exception, applicable only during the last 6 months of the life of the patent, would only serve to counter an effective 6 months of patent extension, if as long as that at all (Howse, \textit{supra} note 154 at 498).

\(^{464}\) Howse, \textit{supra} note 154 at 496.
read (where possible) as being in accordance with the Constitution, section 36 provides appropriate guidance for the development of a principled basis for the interpretation of the term "limited" in Article 30.

Under the Constitution, a right can only be limited if it satisfies the proportionality test of section 36. Without a long explanation of the balancing process that takes place under section 36, suffice it to say that in essence a limitation of a constitutionally entrenched right is only permissible when the limitation is sufficiently tailored to suit the purpose for which it was invoked so that the extent of the limitation is proportional to the result sought.\footnote{465} On this approach, and recognizing that legitimate third parties interests are to be considered when invoking Article 30, it necessarily follows that there has to be a connection between the exception and the purpose for which the exception is invoked, such as technology transfer, social and economic welfare or health concerns. In addition, the exception would have to be sufficiently tailored to its purpose to satisfy the proportionality principle.\footnote{466} In so doing, an independent meaning can be given to the term “limited” that prevents the exception from being used to “emasculate” the treaty, while at the same time ensuring that it gives effect to the objectives expressly set out in the agreement.

\footnote{465} See S. v. Manamela and Another (Director-General of Justice Intervening) 2000 (3) SA 1 (CC) at paras. 32-34; Dawood, supra note 25 at para. 40. See also Weissman, supra note 87 at 1111, where he argues that for policy options that invoke Article 30, they need to be “carefully calibrated so as not to unreasonably or excessively infringe patent holder rights”. The mere existence of less intrusive means to achieve a particular result does not necessarily mean that the limitation is insufficiently tailored to suit its purpose. The existence of less restrictive means is but one of the considerations relevant to the limitations analysis (see Manamela, ibid. at para. 94).

\footnote{466} Such requirements may or may not result in narrow exceptions. In theory, for example, a substantial curtailment of the right may be justified if indeed the circumstances so demand.
It has been argued that the Bolar Amendment violates TRIPS in that the harm done to the brand-name pharmaceutical industry is disproportionate to the public benefit, particularly given that there are less invasive means of providing "cost-effective" drugs to the public. On this argument, Article 30 is violated when alternatives to benefit the public exist.\(^{467}\) Nevertheless, even if Article 30 were to be read as importing a least intrusive means test, rather than the weaker proportionality test in section 36 of the Constitution that merely considers such alternatives as a factor—and not a requirement—in the overall analysis, this would not serve as a reason to preclude the use of early working provisions in South Africa. Indeed, of the various policy options available, early working requirements are substantially less intrusive than price controls, parallel imports and other acceptable regulatory mechanisms. In addition, given the marginal nature of the drug market in Africa as a whole, it would be difficult to show that a Bolar exception in South African law would have any noticeable impact on the brand-name industry, particularly given the existence of the Bolar Amendment itself.

4.2.2.2 Unreasonable conflict with normal patent exploitation

The reach of the second condition depends to some extent on what is meant by "normal" patent exploitation, but largely by what constitutes "unreasonable" conflict with such exploitation. Regardless of the exact meaning to be attached to the first term, the true bite of this condition lies in the term "unreasonable" because the balancing of conflicting interests and concerns inherent in any test for reasonableness is central to the justification or otherwise of any particular early working provision. Nevertheless, this section deals with both these two issues in turn.

\(^{467}\) See Milenkovich, supra note 439 at 776.
In *Generic Medicines*, the term "normal" was interpreted with reference to patent holders’ anticipated economic returns flowing from market exclusivity. In general, the panel argued, patent holders could expect to enjoy market exclusivity even beyond the 20-year period guaranteed by TRIPS, given that their exclusive rights include the manufacturing of patented products. As a result, the exclusivity obtained until generic competitors are able to come to market constitutes part of normal exploitation.  

This is a difficult argument to follow if one is to give any content to the distinction between the second and third conditions, a necessary consequence of the application of the principle of effectiveness which requires that all terms of a treaty be given full meaning and effect, ensuring that provisions are not reduced to redundancy or uselessness. Indeed, that the third condition expressly recognizes patent holder interests suggests that normal exploitation of a patent means something different from the extent of patent exploitation permitted. Thus, for example, Cynthia Ho proposes that normal patent exploitation includes typical activity associated with the holding of a patent, whereas the "legitimate interests" of the patent holder would include all other interests

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468 *Generic Medicines*, supra note 164 at paras. 7.55-7.56. Howse disagrees, providing a complex and complicated analysis of the interplay between Articles 1.1, 28 and 33, coming to the conclusion that that what Article 1.1 provides is that “a Member may act to avoid the operation of the TRIPS Agreement from leading to effective protection in excess of that explicitly and legally guaranteed in the Agreement.” (Howse, supra note 154 at 499-500.) This is a difficult argument to follow, given that a plain reading of Article 1.1 is that the requirements of TRIPS serve as a floor rather than as a ceiling, with member states who wish to afford IPRs stronger protection not being precluded by TRIPS from doing so, as long as they do not violate any provisions of TRIPS in affording such higher protection. It may thus be possible to argue that certain types of TRIPS-plus legislation, which do not give effect to the principles and objects of TRIPS, are not TRIPS-compliant. It is difficult to see how Article 1.1 can be used to support an argument that the normal exploitation of a patent does not carry the meaning ascribed to it by the panel.

469 Ho, supra note 446 at 664.

470 Ibid. at 662.
that ordinarily flow from the holding of a patent.\textsuperscript{471} In the context of medical procedure patents, for example, she notes that as it would be uncommon for the patent holder to refuse to license to others, even though the exclusive nature of the patent would permit such action, the normal exploitation of a medical procedure patent would include typical activity such as licensing.\textsuperscript{472}

In addition, the approach adopted in \textit{Generic Medicines} leads to illogical results, most noticeable in the artificial distinction drawn between Bolar and stockpiling exceptions. In striking down the stockpiling exception, the panel held that certain rights of exclusivity, “granted to all patent owners, and routinely exercised by all patent holders”, would inevitably extend market exclusivity following patent expiration, and that this could not be considered as “abnormal”.\textsuperscript{473} However, the extension of market exclusivity as a result of regulatory requirements “is not a natural or normal consequence” of patent protection, but rather “an unintended consequence of the conjunction of the patent laws with product regulatory laws”.\textsuperscript{474} It is this interface between patent protection and the regulatory process that results in a “greater-than-normal” period of market exclusivity.\textsuperscript{475}

There is no basis for drawing a distinction between regulatory approval delays and all other delays caused by the prohibition on use during the patent’s life, particularly when the text provides no basis for such a distinction and indeed supports a different construction altogether. At issue is not what seemingly prohibits the introduction of

\textsuperscript{471} \textit{Ho, supra} note 446 at 664. \textit{See also, Weissman, supra} note 87 at 1110.
\textsuperscript{472} \textit{Ho, supra} note 446 at 662.
\textsuperscript{473} \textit{Generic Medicines, supra} note 164 at paras. 7.56-7.57.
\textsuperscript{474} \textit{Ibid.}
\textsuperscript{475} \textit{Ibid.}
generic products upon patent expiration, but rather the nature of patented products, which unlike many other forms of IP, cannot be automatically reproduced. The source of the delay thus lies in the patent itself, and not in the regulatory approval per se. In addition, any simple distinction is complicated by the fact that regulatory approval may be integrally related to the safety and quality of production methods, and not the intellectual object itself. Such regulatory concerns may have an impact on the speed with which the requisite stock may be manufactured.

Of greater concern, however, is that the ability to produce the requisite stock is, to a large extent, dependent upon levels of economic development. While the Canadian stockpiling exception only brought generic medicines to the market on average three weeks earlier than would have been the case without the exception, the same cannot be said for all generic manufacturers. As a result of a prohibition on stockpiling, therefore, the extension of market exclusivity is most pronounced in those countries that can arguably least afford the delay. Indeed, in those countries where production is most likely to take longer, any delays in the introduction of lower cost generic products “might have significant health consequences, if not in certain cases deadly ones.”

As mentioned above, however, the true bite of this part of Article 30 lies in the reasonableness test in terms of which the particular regulatory mechanism is to be justified. According to this test, the Canadian stockpiling exception can be distinguished from the Bolar exception in that it interferes with patent exploitation without any

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476 Howse, supra note 154 at 500.
477 Ibid.
corresponding benefit for third parties. This is so because even though it only takes three weeks for Canadian generic manufacturers to build the requisite inventory, the stockpiling exception provided a six-month window for production.\textsuperscript{478} It is clearly unreasonable to allow for such an extended period of stockpiling when a much shorter period would achieve exactly the same results. Nevertheless, while it may be unreasonable in the context of a developed country to allow for such a lengthy stockpiling exception, this does not necessarily mean that in the case of a country like South Africa, a similar stockpiling exception is similarly unreasonable.

4.2.2.3 Unreasonable prejudice and the legitimate interests of the patent holder

If the reference to the “legitimate” interests of patent holders is to have an independent meaning, as the principle of effectiveness demands, it must be that what the third condition includes is limited to those interests recognized by international law and TRIPS itself. This is because the only legitimate measure of wide recognition is what international law recognizes as legitimate interests.\textsuperscript{479} Indeed, the panel’s conclusion that these interests must be merely “compelling” and widely recognized simply begs the question.\textsuperscript{480}

\textsuperscript{478} This also violates the “limited” exception test proposed above in that the six-month stockpiling period is not sufficiently tailored to the legitimate purpose sought. To ensure that stocks of generic products are available immediately upon expiration of the patent, it would be sufficient in the Canadian context to provide a safe harbour of one to two months.

\textsuperscript{479} Such interests include the “protection of the moral and material interests resulting from any scientific, literary or artistic production” found in Article 27 of the UDHR and the right to “benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author” in Article 15(1)(c) of the ICESCR.

\textsuperscript{480} See Generic Medicines, supra note 164 at para. 7.82.
For the panel, the fact that the interests of the patent holder are mentioned before the interests of third parties means that "[o]ne cannot even begin to consider what third-party interests might be without first of all ascertaining 'the legitimacy and weight of the patent owner's legitimate interests.'"\textsuperscript{481} Weissman, on the other hand, argues for such interests to be narrowly construed. Regarding the pharmaceutical industry, he sees "pervasive" government subsidies, the extent of poverty in the developing world that contributes to the inaccessibility of important drugs, and conditions in such countries that render people more susceptible to disease and illness as reasons for a narrow construction.\textsuperscript{482}

Neither approach is particularly helpful. The focus of the third condition is on the balancing of independently defined interests, and on the reasonableness of prejudicial regulatory action. The issue at stake is whether the benefits to consumers justify the prejudice suffered by patent holders. In essence, given the benefits of the impugned regulatory measure and the purpose for which it is employed, the question to ask is whether the prejudice that results be considered unreasonable. Clearly, third party interests are relevant in determining whether the regulatory action is reasonable, but not in defining what the agreement recognizes as the legitimate interests of patent holders. Similarly, these interests cannot define what TRIPS recognizes as legitimate third party interests. Indeed, as was mentioned above, the requirement that such third party interests be considered is not limited to the third condition alone, but operates at every step of the Article 30 analysis.

\textsuperscript{481} Howse, \textit{supra} note 154 at 501, citing \textit{Generic Medicines}, \textit{supra} note 164 at para. 7.60. Even if there were substance in such an argument, which fails to consider the very nature of TRIPS as being the balancing of interests, it is dependant on a decontextualized, strained reading of Article 30.

\textsuperscript{482} Weissman, \textit{supra} note 87 at 1111.
4.2.3 Implications for South Africa

It is difficult to see how Bolar and stockpiling exceptions, sufficiently tailored to achieve their intended results, can be considered as being unreasonable. Given that TRIPS itself expressly allows for far more invasive measures, such as compulsory licensing and complete exclusion from patentability, it is unreasonable to suggest that these regulatory mechanisms may not be employed. However, that they may be employed does not mean that any early working provision is insulated against attack—it would have to be sufficiently tailored to meet a need recognized as legitimate by TRIPS or international law more broadly, such as the right to the highest attainable standard of health in Article 12(1) of the ICESCR. In addition, its use would have to be justified in relation to the particular circumstances and context within which they are to be invoked. This may mean that early working provisions may not be applicable to non-essential drugs, but would most certainly apply to antibiotic, antifungal and antiretroviral drugs central to HIV/AIDS treatment.

4.3 Exclusion from patentability under Article 27.2

Article 27.2, which seemingly offers considerable flexibility in emergency situations, provides as follows:

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 to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.
At first glance, the provision seems to ensure that TRIPS does prevent state action necessary to prevent potential public health or environmental disasters. Patent protection may be denied when the granting of such protection would have serious consequences, such as the loss of human, animal or plant life. On closer examination, however, two questions arise. First, what is the relationship between this provision and Article 27.1? Second, what is the exact scope of the exclusion from patentability permitted? In short, when and under what conditions does TRIPS permit an absolute lack of patent protection? These two issues are addressed below.

4.3.1 Relationship between Articles 27.1 and 27.2

Article 27.2 is in essence not an exception, but rather serves to narrow the subject matter to which the substantive provisions dealing with patents apply. Such a construction finds support in Article 27.1, the first part of which requires patent protection “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” and is made subject to the provisions of Articles 27.2 and 27.3. Quite clearly, Article 27 contemplates two categories of inventions: those in respect of which the minimum standards of protection are to apply, and those in respect of which protection may—but need not—be given. Articles 27.2 and 27.3 define the latter category of inventions. Thus for those inventions that fall within the scope of Articles 27.2 and 27.3, the provisions of Article 27.1 relating to the availability of patent protection are not applicable.483

483 For a discussion of the relationship between Article 27.2 and the second part of Article 27.1, see supra text accompanying note 358.
4.3.2 The scope of Article 27.2

Two matters serve to complicate the interpretation of the scope of Article 27.2: first, whether the exclusion from patentability is reliant on a ban on any commercial exploitation of the invention; and second, the meaning to be ascribed to the term "necessary". In the next section I will argue that Article 27.2 allows for certain inventions to be excluded from patentability without requiring a ban on commercial exploitation, and that the test for necessity merely requires that less restrictive means be considered, in a manner akin to the sufficiently tailored test proposed in relation to the phrase "limited exception" in Article 30.

4.3.2.1 Commercial exploitation

In essence, Article 27.2 enables states to deny patents altogether when they have legitimate health or environmental reasons to do so. Thus a legitimate reason would enable a country to deny a patent to a particular drug or to all drugs. However, most commentators link the denial of patentability to a "ban" on commercial exploitation of the invention. Such a construction undoubtedly limits the scope of the provision's use. On this basis, the best use of the provision for accessing essential drugs would be the non-commercial production and distribution of drugs by a state-owned marketing board, a parastatal entity, or non-profit manufacturers. A non-commercial programme

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484 Weissman, supra note 87 at 1100.
485 See e.g. Christopher S. Mayer, "The Brazilian Pharmaceutical Industry Goes Walking From Ipanema to Prosperity: Will the New Intellectual Property Law Spur Investment?" (1998) 12 Temple Int'l & Comp. L.J. 377, where he argues that "a denial or patentability in turn requires rejection of commercial exploitation of the invention." (Ibid. at 383.) See also Watal, supra note 390 at 288-89; "Implementing the TRIPS Agreement", supra note 402 at 86.
486 Weissman, supra note 87 at 1100.
487 Ibid.
in collaboration with international agencies such as the World Health Organization (WHO) or UNAIDS would also permissible.

Carlos Correa offers a somewhat tempered version of this interpretation. While the interpretation he puts forward still relies on an objective finding that the commercial exploitation of the invention should be prevented, he notes that "[t]he refusal of protection . . . does not necessarily lead to the exclusion of commercialization."488 Similarly, Dan Leskien and Michael Flitner argue that Article 27.2 "does not require an actual ban of the commercialization as a condition for exclusions; only the necessity of such a ban is required."489 On their construction, all that would be required of a member state to justify an invention's exclusion from patentability is a demonstration of the necessity of preventing commercial exploitation, without having to show that domestic law prohibited such commercialization. In support of their construction, they point to the qualification in the latter part of the provision that expressly states that the objective assessment required in no way depends on the existence of national laws prohibiting commercialization.490

490 Leskien & Flitner, supra note 489.
While the plain language of the provision may indeed support such a construction, it is difficult to comprehend an interpretation that requires a certain state of affairs to exist before an invention may be excluded from patentability, but without an expectation that the state invoking the provision will also ensure that commercial exploitation is prevented. If a state decides not to prohibit commercial exploitation, this must clearly cast substantial doubt on the finding that it was necessary to prevent commercial exploitation in the first place, and thereby put the state in a position to invoke Article 27.2.

The problem with a literal interpretation that requires a ban on commercial exploitation is that the provision will be of little benefit where it is most urgently needed, as the strict conditions of its use will either deter many states from using it, or will in fact preclude many others from using it precisely because they lack the necessary capacity to manufacture and distribute drugs non-commercially. In all likelihood, those states least equipped to make use of the provision will be the very states most in need of its invocation. Conversely, those who would be in a position to use the provision may not need to do so. Thus, on the standard construction, Article 27.2 would be of no use where it could most likely be of most benefit.

In addition, the literal construction requires Article 27.2 to take on a coercive character rather than the definitional role it was designed to have. The rational pharmaceutical company would rather enter into public/private partnerships with resource-strapped countries to produce drugs at cost than risk the loss of their patent. In many countries,
such as South Africa, two-tier health care systems seemingly allow for special arrangements with the public health care sector while leaving the private health care market untouched.\textsuperscript{491} Similarly, such a rational actor would rather grant voluntary licenses, or accept the existence of compulsory licensing legislation, than risk total patent loss.

This thesis proposes a third approach to the article’s interpretation, which identifies two issues that require resolution. First, does Article 27.2 refer to commercial exploitation per se, or is it limited to the commercial exploitation of a patent? As the purpose of Article 27.2 is to remove patent protection where such protection stands in the way of averting a potential public health or environmental disaster, the second construction seems more appropriate. However, the structure of the provision itself seems to militate against such a construction.

Second, does Article 27.2 refer to the necessity to exclude any form of commercial exploitation, or rather the commercial exploitation of an invention \textit{as permitted by TRIPS}? Such exploitation always requires patent protection, but also permit the existence of voluntary and compulsory licenses, as well as a number of exceptions permissible under Article 30. These are all ways in which TRIPS envisages the commercial exploitation of inventions.

A potential obstacle to such an interpretation is that Article 30 uses the term “normal exploitation”. Clearly, the term “commercial exploitation” must refer to something other

\textsuperscript{491} Competition law, however, has the potential to put an end to such practices.
than "normal exploitation". These are distinguishable concepts. It is submitted that the former concept refers to ways in which a patent may be exploited commercially, such as through market exclusivity, voluntary licenses and compulsory licenses, whereas the latter refers to that which is usually done.\textsuperscript{492} Thus, for example, the issuing of a compulsory license is no longer part of the normal exploitation of an invention in Canada, despite the fact that it is a recognized method of commercial exploitation under TRIPS.

Another factor supporting this construction is that in certain provisions of TRIPS, the agreement speaks expressly about "public non-commercial use". Thus, for example, Article 31(c) speaks of restricting the granting of compulsory licenses in the field of semi-conductor technology to two instances, one of which is for "public non-commercial use". If Article 27.2 were similarly intended to allow for inventions that have been excluded from patentability to be restricted to public non-commercial use, one would have expected to see similar language to that used in Article 31(c).

On the proposed construction, a country would be able to invoke Article 27.2 where it was shown, for example, that even making use of compulsory licensing would not be sufficient to avert the pending public health or environmental disaster, either because of an inability to finance compensation or else because the procedures under the required compulsory licensing provisions would not allow for a sufficiently timely response. The result of such a move would be to open the market to competition immediately, which

\textsuperscript{492} See the discussion above in section 4.2. regarding early working provisions under Article 30.
would allow for the erstwhile patent holder, generic manufacturers and the state (if it had the capacity) to produce the required invention.

This interpretation achieves a more equitable balance between the rights of patent holders and the public interest, being more to the “mutual advantage of producers and users of technological knowledge”, as required by Article 8. A prohibition on commercial exploitation would in effect amount to more than the extinction of any rights of exclusivity—it would constitute an effective expropriation of property without any compensation.493 Had such a drastic step been intended in Article 27.2, one would have expected the text to be more explicit about the conditions of exclusion from patentability.

4.3.2.2 Necessity

Article XX of the GATT provides for general exceptions to the agreement.494 Some of the measures that are permissible in terms of this provision may only be invoked if it is necessary to do so.495 This necessity requirement has lead to the development of the “least-trade-restrictive” test, which some commentators believe will substantially influence the interpretation of Article 27.2 of TRIPS.496 It is by no means clear, however, that such jurisprudence should be applied in this particular context, given that the “least-trade-restrictive test” has been developed in the context of “limited and conditional” exceptions.

493 Read in the light of the Constitution, such a dispossession of rights—accompanied by the state’s acquisition thereof—would require compensation. That Article 27.2 does not require compensation in such circumstances suggests that the provision does not constitute an expropriation. If so, this is another reason why the argument in support of public non-commercial use cannot be sustained.
494 Article XX is quoted in full in the general appendix, below.
495 See Articles XX(a), (b) and (d).
to the GATT. Article 27.2 on the other hand, is not an exception, but rather serves to define the extent of patentable subject matter.\footnote{497}

While Article 27.2 defines the extent of patentable subject matter, it does so in a negative way, placing the onus on the member state invoking its use to justify such use. Indeed, its purpose is to cut back on the reach of patent rights in circumstances where a member state is able to show that such actions are justifiable. In so doing, it operates in very much the same way as the limitations clause of the Constitution. Given that South African law requires international obligations to be read (where possible) as being in accordance with the Constitution, the limitations clause accordingly provides appropriate guidance for the interpretation of the term “necessary” in Article 27.2.

In Makwanyane’s case, the Constitutional Court gave content to section 33 of the interim Constitution, the predecessor to section 36 of the Constitution.\footnote{498} In so doing, it ascribed a meaning to the term “necessary” in the context of the limitations of entrenched rights, holding that where the interim Constitution required the limitation to be necessary, the proportionality analysis had to consider “whether the desired ends could reasonably be achieved through other means less damaging to the right in question.”\footnote{499}

\footnote{497} Weissman, \textit{supra} note 87 at 1107 [emphasis in original and footnotes omitted]. In support of a “less stringent reading” of the term, he quotes the following legal definition:

This word [necessary] must be considered in the connection in which it is used, as it is a word susceptible of various meanings. It may import absolute physical necessity or inevitability, or it may import that which is only convenient, useful, appropriate, suitable, proper, or conducive to the end sought. It is an adjective expressing degrees, and may express mere convenience or that which is indispensable or an absolute physical necessity (\textit{Black’s Law Dictionary}, 6th ed., s.v. “necessary”, cited in Weissman, \textit{supra} note 484 at 1107, n. 214).

\footnote{498} See Section 33(1) of the interim Constitution.

\footnote{499} Makwanyane, \textit{supra} note 290 at para. 104 [emphasis added]. It is interesting to note that the wording of section 36(1) of the Constitution is substantially based on Chaskalson P’s judgment in Makwanyane. The
Quite clearly, the necessity test in South African limitations jurisprudence is not as strict as a “least-trade-restrictive” test. The mere existence of less damaging (or less intrusive) means does not automatically translate into a finding of unconstitutionality. According to this test, a country would not have to show that it had no alternatives under TRIPS, such as the granting of compulsory licenses, but rather that it would not be reasonable to expect the state to limit its response to the impending emergency, as there are good reasons to believe that such a less intrusive approach may not suffice. In essence, the test is whether a decision to invoke Article 27.2 is reasonable, but not necessarily correct.

4.3.3 Options for South Africa

South Africa could follow a conservative path and choose to invoke Article 27.2 by taking over the ownership and manufacturing of certain pharmaceutical products itself. Such a solution seems infeasible, given the limited capacity of state facilities. The time and resources necessary to put state laboratories in a position to make full use of Article 27.2 may not prove to be a wise use of limited resources. Further, while the state may be able to conclude agreements with either brand name or generic drug manufacturers for the production of drugs at cost, the sustainability of such ventures would always be at risk.

The most appropriate invocation of Article 27.2 would avoid this classic method of expropriation. Legislation could provide for a process whereby crucial medicines, such consideration of “means less damaging to the right”, although formulated primarily in relation to those rights that enjoyed stronger protection under the interim Constitution, has in effect been extended to all rights under the 1996 Constitution.
as antiretroviral drugs, were removed from patent protection. The removal of patent protection would automatically open up the market to all, without prohibiting the former patent holder from continuing to produce and market its product. Such a provision may be limited in application, its use being permitted only when the state is facing a public health emergency such as the HIV/AIDS epidemic.
CONCLUSION

In 1997, more than twelve years after he became infected with HIV, Edwin Cameron fell ill with the symptoms of full-blown AIDS. After successful treatment of his opportunistic infections, he started full antiretroviral therapy. Since then, with relatively minor adjustments, he has lead a “vigorous, healthy, and productive life”.500 Indeed, he not only served as an acting judge on the Constitutional Court from 1999 until 2000, but since December 2000 has served as a permanent judge of appeal on the Supreme Court of Appeal, South Africa’s second highest court.501

In 2000, almost ten years after became infected with HIV, Christopher Moraka died at the age of 44, leaving behind his partner Nontsikelelo (living with HIV), an 11-year-old daughter, six siblings and two parents.502 As an organizer for the Treatment Action Campaign in the Cape Town township of Nyanga, Christopher’s work included support for other people living openly with HIV/AIDS, active campaigning for access to treatments, working with health care workers in the township’s clinics and hospitals, and the lobbying of Parliament.503 But unlike Cameron, Christopher Moraka could not afford either proper treatment for his opportunistic infections or full antiretroviral therapy. Without the resources, Christopher access to health care services simply did not exist.

500 “Deafening Silence”, supra note 42.
502 Christopher’s second child had died of an AIDS-related illness in 1996.
In his address to the opening plenary session of the XIIIth International AIDS Conference in Durban, South Africa in July 2000, Cameron was quick to point out that he “exist[s] as a living embodiment of the iniquity of drug availability and access in Africa”, and that his mere presence “embodies the injustices of AIDS in Africa”. Addressing the delegates at the conference, Cameron stated: “Amid the poverty of Africa, I stand before you because I am able to purchase health and vigour. I am here because I can afford to pay for life itself.”

In exploring the “interstices” of international trade law, this thesis has assumed that South Africa’s ability to turn the tide against the AIDS epidemic in large part hinges on whether or not the majority of people with HIV/AIDS will have access to essential medicines for treating both HIV infection and opportunistic infections associated with HIV/AIDS. Perhaps more importantly, this thesis recognizes that the sheer scale of the epidemic means that lack of access to essential treatments will not only serve to undermine social and economic development, but will perpetuate—and perhaps even exacerbate—the legacy of apartheid. Indeed, lack of access may serve to undermine the fundamental basis of South Africa’s constitutional democracy, given that for as long as “[m]illions of people are living in deplorable conditions and in great poverty”, the aspiration “to transform our society into one in which there will be human dignity, freedom and

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504 “Deafening Silence”, supra note 42.
505 See supra text accompanying notes 42-44.
506 This is as a result of the racial and gender profile of the South African epidemic. See generally, Whiteside & Sunter, supra note 9.
equality, [which] lies at the heart of our new constitutional order[,] . . . will have a hollow ring."

Recognizing that the single biggest barrier to treatment other than lack of political will remains high drug prices, and that the single biggest barrier to cheaper prices is the strict enforcement of patents, this thesis has explored the extent to which countries such as South Africa are permitted under international trade law to take certain regulatory steps to ensure the accessibility of essential drugs. Further recognizing that TRIPS has strengthened the international protection of IP so as effectively to narrow the scope of national patent policies, this thesis has shown that despite the international harmonization of IP law, countries such as South Africa are permitted by TRIPS to take certain regulatory steps to ensure the accessibility of essential drugs.

In particular, this thesis has explored the TRIPS-consistency of various indirect price regulatory mechanisms crucial in accessing essential drugs both for treating HIV and for opportunistic infections associated with HIV infection. This thesis has argued that TRIPS sets a minimum standards default position which will allow countries to offer substantially weaker patent protections if good reason for such weaker protection exists. It has also argued that the provisions in TRIPS that allow for the adoption of weaker patent protection are properly characterized as integral parts of the agreement as a whole. Further, it has argued that voluntarily assumed obligations under international agreements are binding only in so far as such obligations do not violate the Constitution. Further,

507 Soobramoney v. Minister of Health (KwaZulu-Natal) 1998 (1) SA 765 (CC) at para. 8.
508 See supra text accompanying notes 52-54.
such obligations are binding only in the international arena—they may only be invoked in
domestic courts as interpretive tools.

In general, however, the regulatory framework in South Africa undermines the
accessibility of essential medicines by treating such products as it would any other
patented products. For example, despite being drafted with competitive sectors in mind,
the \textit{Competition Act} provides no assistance in determining what excessive pricing,
discriminatory pricing and exclusionary acts in the patents arena mean.\footnote{See generally \textit{supra} text accompanying notes 370-381.} Similarly, the
\textit{Patents Act} treats applications for compulsory licenses for essential life-saving drugs in
the same way as it does similar applications for swimming-pool cleaning machines.\footnote{See \textit{e.g.} section 56 of the \textit{Patents Act}.}

But the news is not all bad news. Central to the \textit{Medicines Act}\footnote{\textit{Supra} note 50.} is the introduction of
direct price regulatory mechanisms that are limited in their application to pharmaceutical
products, as well as the parallel importation of patented medicines.\footnote{These provisions were recently under attack in the \textit{PMA case (ibid.)}. However, before the matter was to
be heard, the application was unconditionally withdrawn. In this regard, see “Joint Statement of
Understanding Between the Republic of South Africa and the Applicants”, \textit{supra} note 50.} There is no reason
why such an approach cannot be extended to indirect price regulatory mechanisms such
as compulsory licensing, early working provisions and exclusions from patentability.

This thesis recognizes that the full exploitation of regulatory mechanisms permissible
under TRIPS would go some way in making drugs more accessible and that such a
regulatory framework is an integral component of any rational public health programme
to address the AIDS epidemic. Quite clearly, the implementation and active use of such a

regime may very well provide the impetus needed to turn the tide against the epidemic, reminding the world that the right to life should not be dependant on ability to pay, that lives come before profits.

Nevertheless, this thesis does not take the discussion beyond the realm of what is permissible. Quite clearly, it leaves open a detailed analysis of the existing regulatory framework, as well as any alternative framework. In addition, it does not explore how such a regulatory framework—if indeed adopted—can be given full effect. In short, this thesis does not explore how the broader legal framework may be employed to encourage a reluctant leadership to take its constitutional obligations seriously. These areas of work remain unexplored, but hopefully for not much longer. If the proud tradition of South African legal activism is to be continued, we will have to find creative ways of using the law as a tool of social change, and as a weapon for ensuring that the right of access to essential treatments becomes a reality for every person with HIV/AIDS.
Constitutional provisions

Section 7: Rights
(1) This Bill of Rights is a cornerstone of democracy in South Africa. It enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom.
(2) The state must respect, protect, promote and fulfil the rights in the Bill of Rights.
(3) The rights in the Bill of Rights are subject to the limitations contained or referred to in section 36, or elsewhere in the Bill.

Section 9: Equality
(1) Everyone is equal before the law and has the right to equal protection and benefit of the law.
(2) Equality includes the full and equal enjoyment of all rights and freedoms. To promote the achievement of equality, legislative and other measures designed to protect or advance persons, or categories of persons, disadvantaged by unfair discrimination may be taken.
(3) The state may not unfairly discriminate directly or indirectly against anyone on one or more grounds, including race, gender, sex, pregnancy, marital status, ethnic or social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language and birth.
(4) No person may unfairly discriminate directly or indirectly against anyone on one or more grounds in terms of subsection (3). National legislation must be enacted to prevent or prohibit unfair discrimination.
(5) Discrimination on one or more of the grounds listed in subsection (3) is unfair unless it is established that the discrimination is fair.

Section 8 of the interim Constitution: Equality
(1) Every person shall have the right to equality before the law and to equal protection of the law.
(2) No person shall be unfairly discriminated against, directly or indirectly, and, without derogating from the generality of this provision, on one or more of the following grounds in particular: race, gender, sex, ethnic or social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture or language.
(3) (a) This section shall not preclude measures designed to achieve the adequate protection and advancement of persons or groups or categories of persons disadvantaged by unfair discrimination, in order to enable their full and equal enjoyment of all rights and freedoms.
(b) Every person or community dispossessed of rights in land before the commencement of this Constitution under any law which would have been inconsistent with subsection (2) had that subsection been in operation at the time of the dispossession, shall be entitled to claim restitution of such rights subject to and in accordance with sections 121, 122 and 123.

(4) Prima facie proof of discrimination on any of the grounds specified in subsection (2) shall be presumed to be sufficient proof of unfair discrimination as contemplated in that subsection, until the contrary is established.

Section 25: Property

(3) No one may be deprived of property except in terms of law of general application, and no law may permit arbitrary deprivation of property.

(4) Property may be expropriated only in terms of law of general application—

(a) for a public purpose or in the public interest; and

(b) subject to compensation, the amount of which and the time and manner of payment of which have either been agreed to by those affected or decided or approved by a court.

(5) The amount of the compensation and the time and manner of payment must be just and equitable, reflecting an equitable balance between the public interest and the interests of those affected, having regard to all relevant circumstances, including

(a) the current use of the property;

(b) the history of the acquisition and use of the property;

(c) the market value of the property;

(d) the extent of direct state investment and subsidy in the acquisition and beneficial capital improvement of the property; and

(e) the purpose of the expropriation.

(6) For the purposes of this section—

(a) the public interest includes the nation's commitment to land reform, and to reforms to bring about equitable access to all South Africa's natural resources; and

(b) property is not limited to land.

(7) The state must take reasonable legislative and other measures, within its available resources, to foster conditions which enable citizens to gain access to land on an equitable basis.

(8) A person or community whose tenure of land is legally insecure as a result of past racially discriminatory laws or practices is entitled, to the extent provided by an Act of Parliament, either to tenure which is legally secure or to comparable redress.

(9) A person or community dispossessed of property after 19 June 1913 as a result of past racially discriminatory laws or practices is entitled, to the extent provided by an Act of Parliament, either to restitution of that property or to equitable redress.

(10) No provision of this section may impede the state from taking legislative and other measures to achieve land, water and related reform, in order to redress
the results of past racial discrimination, provided that any departure from the provisions of this section is in accordance with the provisions of section 36(1).

(11) Parliament must enact the legislation referred to in subsection (6).

Section 28 of the interim Constitution: property
(1) Every person shall have the right to acquire and hold rights in property and, to the extent that the nature of the rights permits, to dispose of such rights.
(2) No deprivation of any rights in property shall be permitted otherwise than in accordance with a law.
(3) Where any rights in property are expropriated pursuant to a law referred to in subsection (2), such expropriation shall be permissible for public purposes only and shall be subject to the payment of agreed compensation or, failing agreement, to the payment of such compensation and within such period as may be determined by a court of law as just and equitable, taking into account all relevant factors, including, in the case of the determination of compensation, the use to which the property is being put, the history of its acquisition, its market value, the value of the investments in it by those affected and the interests of those affected.

Section 27: Health care, food, water and social security
(1) Everyone has the right to have access to —
   (a) health care services, including reproductive health care;
   (b) sufficient food and water; and
   (c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.
(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
(3) No one may be refused emergency medical treatment.

Section 36: Limitation of rights
(1) The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including —
   (a) the nature of the right;
   (b) the importance of the purpose of the limitation;
   (c) the nature and extent of the limitation;
   (d) the relation between the limitation and its purpose; and
   (e) less restrictive means to achieve the purpose.
(2) Except as provided in subsection (1) or in any other provision of the Constitution, no law may limit any right entrenched in the Bill of Rights.

Section 33 of the interim Constitution: Limitation of rights
(1) The rights entrenched in this Chapter may be limited by law of general application, provided that such limitation —
(a) shall be permissible only to the extent that it is –
   (i) reasonable; and
   (ii) justifiable in an open and democratic society based on freedom and equality; and
(b) shall not negate the essential content of the right in question, and provided further that any limitation to –
   (aa) a right entrenched in section 10, 11, 12, 14 (1), 21, 25 or 30 (1) (d) or (e) or (2); or
   (bb) a right entrenched in section 15, 16, 17, 18, 23 or 24, in so far as such right relates to free and fair political activity,
        shall, in addition to being reasonable as required in paragraph (a)(i), also be necessary.
(2) Save as provided for in subsection (1) or any other provision of this Constitution, no law, whether a rule of the common law, customary law or legislation, shall limit any right entrenched in this Chapter.
(3) The entrenchment of the rights in terms of this Chapter shall not be construed as denying the existence of any other rights or freedoms recognised or conferred by common law, customary law or legislation to the extent that they are not inconsistent with this Chapter.
(4) This Chapter shall not preclude measures designed to prohibit unfair discrimination by bodies and persons other than those bound in terms of section 7 (1).
(5) (a) The provisions of a law in force at the commencement of this Constitution promoting fair employment practices, orderly and equitable collective bargaining and the regulation of industrial action shall remain of full force and effect until repealed or amended by the legislature.
   (b) If a proposed enactment amending or repealing a law referred to in paragraph (a) deals with a matter in respect of which the National Manpower Commission, referred to in section 2A of the Labour Relations Act, 1956 (Act 28 of 1956), or any other similar body which may replace the Commission, is competent in terms of a law then in force to consider and make recommendations, such proposed enactment shall not be introduced in Parliament unless the said Commission or such other body has been given an opportunity to consider the proposed enactment and to make recommendations with regard thereto.

Section 39: Interpretation of Bill of Rights
(1) When interpreting the Bill of Rights, a court, tribunal or forum –
   (a) must promote the values that underlie an open and democratic society based on human dignity, equality and freedom;
   (b) must consider international law; and
   (c) may consider foreign law.
When interpreting any legislation, and when developing the common law or customary law, every court, tribunal or forum must promote the spirit, purport and objects of the Bill of Rights.

The Bill of Rights does not deny the existence of any other rights or freedoms that are recognised or conferred by common law, customary law or legislation, to the extent that they are consistent with the Bill.

Section 74: Bills amending the Constitution

1. Section 1 and this subsection may be amended by a Bill passed by—
   (a) the National Assembly, with a supporting vote of at least 75 per cent of its members; and
   (b) the National Council of Provinces, with a supporting vote of at least six provinces.

2. Chapter 2 may be amended by a Bill passed by—
   (a) the National Assembly, with a supporting vote of at least two thirds of its members; and
   (b) the National Council of Provinces, with a supporting vote of at least six provinces.

3. Any other provision of the Constitution may be amended by a Bill passed—
   (a) by the National Assembly, with a supporting vote of at least two thirds of its members; and
   (b) also by the National Council of Provinces, with a supporting vote of at least six provinces, if the amendment—
      (i) relates to a matter that affects the Council;
      (ii) alters provincial boundaries, powers, functions or institutions; or
      (iii) amends a provision that deals specifically with a provincial matter.

4. A Bill amending the Constitution may not include provisions other than constitutional amendments and matters connected with the amendments.

5. At least 30 days before a Bill amending the Constitution is introduced in terms of section 73(2), the person or committee intending to introduce the Bill must—
   (a) publish in the national Government Gazette, and in accordance with the rules and orders of the National Assembly, particulars of the proposed amendment for public comment;
   (b) submit, in accordance with the rules and orders of the Assembly, those particulars to the provincial legislatures for their views; and
   (c) submit, in accordance with the rules and orders of the National Council of Provinces, those particulars to the Council for a public debate, if the proposed amendment is not an amendment that is required to be passed by the Council.

6. When a Bill amending the Constitution is introduced, the person or committee introducing the Bill must submit any written comments received from the public and the provincial legislatures—
(a) to the Speaker for tabling in the National Assembly; and
(b) in respect of amendments referred to in subsection (1), (2) or 
(3)(b), to the Chairperson of the National Council of Provinces for 
tabling in the Council.

(7) A Bill amending the Constitution may not be put to the vote in the National 
Assembly within 30 days of—
(a) its introduction, if the Assembly is sitting when the Bill is 
introduced; or
(b) its tabling in the Assembly, if the Assembly is in recess when the 
Bill is introduced.

(8) If a Bill referred to in subsection (3)(b), or any part of the Bill, concerns only 
a specific province or provinces, the National Council of Provinces may not 
pass the Bill or the relevant part unless it has been approved by the legislature 
or legislatures of the province or provinces concerned.

(9) A Bill amending the Constitution that has been passed by the National 
Assembly and, where applicable, by the National Council of Provinces, must 
be referred to the President for assent.

Section 231: International agreements

(1) The negotiating and signing of all international agreements is the 
responsibility of the national executive.

(2) An international agreement binds the Republic only after it has been approved 
by resolution in both the National Assembly and the National Council of 
Provinces, unless it is an agreement referred to in subsection (3).

(3) An international agreement of a technical, administrative or executive nature, 
or an agreement which does not require either ratification or accession, 
entered into by the national executive, binds the Republic without approval by 
the National Assembly and the National Council of Provinces, but must be 
tabled in the Assembly and the Council within a reasonable time.

(4) Any international agreement becomes law in the Republic when it is enacted 
into law by national legislation; but a self-executing provision of an 
agreement that has been approved by Parliament is law in the Republic unless 
it is inconsistent with the Constitution or an Act of Parliament.

(5) The Republic is bound by international agreements which were binding on the 
Republic when this Constitution took effect.

Section 231 of the interim Constitution: continuation of international agreements and 
status of international law

(1) All rights and obligations under international agreements which immediately 
before the commencement of this Constitution were vested in or binding on 
the Republic within the meaning of the previous Constitution, shall be vested 
in or binding on the Republic under this Constitution, unless provided 
otherwise by an Act of Parliament.

(2) Parliament shall, subject to this Constitution, be competent to agree to the 
ratification of or accession to an international agreement negotiated and 
signed in terms of section 82 (1) (i).
(3) Where Parliament agrees to the ratification of or accession to an international agreement under subsection (2), such international agreement shall be binding on the Republic and shall form part of the law of the Republic, provided Parliament expressly so provides and such agreement is not inconsistent with this Constitution.

(4) The rules of customary international law binding on the Republic, shall, unless inconsistent with this Constitution or an Act of Parliament, form part of the law of the Republic.

Section 233: Application of international law

When interpreting any legislation, every court must prefer any reasonable interpretation of the legislation that is consistent with international law over any alternative interpretation that is inconsistent with international law.

TRIPS provisions

Article 1: Nature and Scope of Obligations

1. 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.

2. For the purposes of this Agreement, the term “intellectual property” refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.

3. Members shall accord the treatment provided for in this Agreement to the nationals of other Members.1 In respect of the relevant intellectual property right, the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the WTO members of those conventions.2 Any Member availing itself of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention

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1 When “nationals” are referred to in this Agreement, they shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights (the “Council for TRIPS”).

Article 2: Intellectual Property Conventions
1. 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).
2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

Article 7: Objectives
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.

Article 8: Principles
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.

Article 27: Patentable Subject Matter
1. Subject to the provisions of paragraphs 2 and 3, 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.5 Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. 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.

5 For the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful” respectively.
3. Members may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) 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. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

**Article 28: Rights Conferred**

1. A patent shall confer on its owner the following exclusive rights:
   (a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
   (b) where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using that process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

**Article 30: Exceptions to Rights Conferred**

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.

**Article 31: Other Use Without Authorization of the Patent Holder (compulsory licensing)**

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
   (a) authorization of such use shall be considered on its individual merits;
   (b) 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. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national
emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly:

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(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.

Article 33: Term of Protection
The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.8

Article 66: Least-Developed Country Members
1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

Other international law provisions

Article 3.2 of the DSU: General Provisions
The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements.

Article 27 of the UDHR:
(1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.

8 It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.
(2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

Article 12 of the ICESCR:
1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
   (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
   (b) The improvement of all aspects of environmental and industrial hygiene;
   (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
   (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

Article 15 of the ICESCR:
1. The States Parties to the present Covenant recognize the right of everyone:
   (a) To take part in cultural life;
   (b) To enjoy the benefits of scientific progress and its applications;
   (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.
3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.
4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and cooperation in the scientific and cultural fields.

Article 31 of the Vienna Convention: General rule of interpretation
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.
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.

Article 32 of the Vienna Convention: Supplementary means of interpretation
Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:
(a) leaves the meaning ambiguous or obscure; or
(b) leads to a result which is manifestly absurd or unreasonable.

Article 46 of the Vienna Convention: Provisions of internal law regarding competence to conclude treaties
1. A State may not invoke the fact that its consent to be bound by a treaty has been expressed in violation of a provision of its internal law regarding competence to conclude treaties as invalidating its consent unless that violation was manifest and concerned a rule of its internal law of fundamental importance.

2. A violation is manifest if it would be objectively evident to any State conducting itself in the matter in accordance with normal practice and in good faith.

Article XX of the GATT: General Exceptions
Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
(a) necessary to protect public morals;
(b) necessary to protect human, animal or plant life or health;
(c) relating to the importations or exportations of gold or silver;
(d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices;
(e) relating to the products of prison labour;
(f) imposed for the protection of national treasures of artistic, historic or archaeological value;
(g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption;

(h) undertaken in pursuance of obligations under any intergovernmental commodity agreement which conforms to criteria submitted to the CONTRACTING PARTIES and not disapproved by them or which is itself so submitted and not so disapproved;*

(i) involving restrictions on exports of domestic materials necessary to ensure essential quantities of such materials to a domestic processing industry during periods when the domestic price of such materials is held below the world price as part of a governmental stabilization plan; Provided that such restrictions shall not operate to increase the exports of or the protection afforded to such domestic industry, and shall not depart from the provisions of this Agreement relating to non-discrimination;

(j) essential to the acquisition or distribution of products in general or local short supply; Provided that any such measures shall be consistent with the principle that all contracting parties are entitled to an equitable share of the international supply of such products, and that any such measures, which are inconsistent with the other provisions of the Agreement shall be discontinued as soon as the conditions giving rise to them have ceased to exist. The CONTRACTING PARTIES shall review the need for this sub-paragraph not later than 30 June 1960.

* The exception provided for in this sub-paragraph extends to any commodity agreement which conforms to the principles approved by the Economic and Social Council in its resolution 30 (IV) of 28 March 1947.

**Article 5.A of the Paris Convention for the Protection of Industrial Property: Patents: Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licenses.**

(1) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.

(2) 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.

(3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

(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.

(5) The foregoing provisions shall be applicable, mutatis mutandis, to utility models.
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