The Politics of Canada's Access to Medicines Regime: the Dogs that Didn't Bark

by

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Abstract

Decisions to reform pharmaceutical policy often involve trade-offs between competing social and commercial goals. Canada's Access to Medicines Regime (CAMR), a reform that permits compulsory licensing for the production and export of medicines to developing countries, aimed to reconcile these goals. Since it was passed in 2004, only one order of antiretroviral drugs, enough for 21,000 HIV/AIDS patients in Rwanda for one year, has been exported. Future use of the regime appears unlikely.

This research aimed to examine the politics underlying the formation of CAMR. Parliamentary committee hearing transcripts from CAMR's legislative development (2004) and from CAMR's legislative review (2007) were analyzed using a content analysis technique to identify how stakeholders who participated in the debates framed the issues. These findings were subsequently analyzed using a framework of framing, institutions and interests to determine how these three dimensions shaped CAMR's final policy design.
In 2004, policy debates were dominated by two themes: intellectual property rights and TRIPS compliance. Promoting human rights and the impact of CAMR on innovation were hardly discussed. With the Departments of Industry Canada and International Trade as the lead institutions, the goals of protecting intellectual property and ensuring good trade relations with the United States appear to have taken priority over encouraging generic competition to achieve drug affordability. The result was a more limited interpretation of patent flexibilities under the WTO Paragraph 6 Decision. The most striking finding is the minimal discussion over the potential barriers developing country beneficiaries might face when attempting to use compulsory licensing, including their reluctance to use TRIPS flexibilities, their desire to pursue technological development and the constraints inherent in the WTO Paragraph 6 Decision. Instead, these issues were raised in 2007, which can be partly accounted for by a greater representation of the interests of potential beneficiary country governments.

While the Government attempted to strike a balance between drug affordability and intellectual property protection, it designed CAMR as a last resort measure. Increased input from the developing country beneficiaries and shifting to institutions where the right to health gets prioritized may lead to policies that better achieves affordable drug access.
Acknowledgements

No one told me that this would be one of life's big tests…. or if they did, I didn't believe them. Looking back, I'm thankful that it was. At so many points, this thesis forced me to search for truths far deeper than the topic of my thesis. As life's big tests will undoubtedly continue, I'm grateful for the strength and wisdom that I've gained throughout this process, and for this, I have so many people to thank.

First and foremost, I would like to thank my husband and my best friend, Nazim. His endless encouragement, support and love sustained me through this PhD. You helped me up whenever I fell down, you helped me step back when my eyes were too close to page, and you held my hand when things got tough and scary. What a privilege to have shared these graduate years with you. Your wisdom, strength and optimism are behind every word of this thesis and I too, without an ounce of hesitation, dedicate this thesis to you. Thank you.

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Finally, to the PhD students of the world… when in doubt, just remember what Woody Allen once said:

"If you're not failing every now and again, it's a sign you're not doing anything very innovative."
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<tr>
<td>3TC</td>
<td>2',3'-dideoxy-3'thiacytidine (lamivudine)</td>
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<tr>
<td>ART</td>
<td>Anti-retroviral therapy</td>
</tr>
<tr>
<td>ARV</td>
<td>Anti-retroviral drugs</td>
</tr>
<tr>
<td>AZT</td>
<td>azidothymidine (zidovudine)</td>
</tr>
<tr>
<td>BQ</td>
<td>Bloc Québécois</td>
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<td>CAMR</td>
<td>Canada's Access to Medicines Regime</td>
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<td>CGPA</td>
<td>Canadian Generic Pharmaceutical Association</td>
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<td>CIDA</td>
<td>Canadian International Development Agency</td>
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<td>CHAI</td>
<td>Clinton Health Access Initiative</td>
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<td>CHLN</td>
<td>Canadian HIV/AIDS Legal Network</td>
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<tr>
<td>CUPE</td>
<td>Canadian Union of Public Employees</td>
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<tr>
<td>DFAIT</td>
<td>Department of Foreign Affairs and International Trade</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>FTA</td>
<td>Free Trade Agreement</td>
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<td>FTAA</td>
<td>Free Trade Area of the Americas</td>
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<tr>
<td>GATT</td>
<td>General Agreement on Tariffs and Trade</td>
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<tr>
<td>GFATM</td>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
</tr>
<tr>
<td>GTAG</td>
<td>Global Treatment Access Group</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome</td>
</tr>
<tr>
<td>ICESCR</td>
<td>International Covenant on Economic, Social and Cultural Rights</td>
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<tr>
<td>IFPMA</td>
<td>International Federation for Pharmaceutical Manufacturers Association</td>
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<tr>
<td>IPIC</td>
<td>Intellectual Property Institute of Canada</td>
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<tr>
<td>MP(s)</td>
<td>Member(s) of Parliament</td>
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<tr>
<td>MSF</td>
<td>Médecins Sans Frontières</td>
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<td>NAFTA</td>
<td>North American Free Trade Agreement</td>
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<td>NDP</td>
<td>New Democratic Party</td>
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<tr>
<td>NGO</td>
<td>Non-governmental Organization</td>
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<td>NSI</td>
<td>North-South Institute</td>
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<tr>
<td>NVP</td>
<td>nevirapine</td>
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<tr>
<td>OECD</td>
<td>Organization for Economic Co-operation and Development</td>
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<tr>
<td>PEPFAR</td>
<td>U.S. President's Emergency Plan for AIDS Relief</td>
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<tr>
<td>PMPRB</td>
<td>Patented Medicines Prices Review Board</td>
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<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
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<tr>
<td>Rx&amp;D</td>
<td>Canada's Research-Based Pharmaceutical Companies</td>
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<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>TRIPS</td>
<td>Trade-Related Aspects of Intellectual Property Rights</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
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<tr>
<td>UNAIDS</td>
<td>The Joint United Nations Programme on HIV/AIDS</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children's Fund</td>
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<tr>
<td>USTR</td>
<td>United States Trade Representative</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WHO PQP</td>
<td>World Health Organization Prequalification Project</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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Chapter 1: Introduction

The global inequity in access to medicines continues to persist despite an increase in international efforts over the last decade. WHO estimates from 2004 remain the same with approximately two billion people still lacking regular access to essential medicines (World Health Organization, 2004)(Frost & Reich, 2008). For example, more than 5 million of an estimated 9.5 million people living with HIV/AIDS in low and middle-income countries remain without access to antiretroviral therapy (UNAIDS, 2009).\(^1\) The inequity in drug access extends to chronic diseases as well, with one study finding access levels of 7.5% to medicines for the treatment of cardiovascular disease, diabetes, chronic respiratory disease, glaucoma and palliative cancer care in six low- and middle-income countries (Mendis et al., 2007).

There are many factors that contribute to these drug access inequities. The cost of drugs is a major obstacle, due to either the poverty of individuals and governments or high prices on the supply side (Frost & Reich, 2008). Health systems infrastructure and capacity is a major obstacle, with inadequate facilities and lack of trained health professionals making it difficult to treat patients. Corruption in the pharmaceutical sector is a problem as well, with counterfeit drugs and substandard medicines diverting scarce resources away from governments (Kohler, 2007). Inappropriate drug use is a problem, which includes inappropriate prescribing by health professionals, inappropriate medicine use, and poor compliance by the end user (Frost & Reich, 2008). These are only some of the barriers to drug access and as such, it is not a 'single failure' problem (Frost & Reich, 2008). The lack of drug access is often the result of a combination of failures in the market, and with the government and non-governmental agencies.

Crafting policy in this area is challenging precisely because drug access is a multi-faceted and complex issue. Just as there are many ways to think about and define drug access, there are many ways to address the problem, and from a political perspective, every

\(^1\) In December 2008, over 4 million people needing ARV treatment in low and middle income countries were receiving it, up by about 1 million from the previous year.
solution favors some groups more than others. With vested interests at stake, how drug access and its potential solutions are framed becomes a highly charged political exercise.

In order to reach a solution, an issue must be defined to some extent; however, every definition and simplification emphasizes some aspects of the problem at the expense of others (Schön & Rein, 1994). Each definition rules out some policy options while making other policy options more acceptable. The analysis of stakeholder framing can expose what policy options were ruled out from the beginning, what policy options were actually considered, what issues or arguments stakeholders and governments failed to consider in a policy debate, and finally, how all of these factors influenced the outcome of the policy debate.

Moreover, different institutions value these frames and interests differently and public policy literature suggests institutions are a key determining factor in how the problem and the alternatives available are framed and which ones matter more than others (Baumgartner & Jones, 1993; Schattschneider, 1964; Stone, 2002). Institutional structures and processes influence how a problem is defined in the first place, which defines what is at stake, who the interested parties are, and what ideas get privileged over others. Altogether, institutions, framing, and interests influence the trade-offs that participants in the policy conflict will have to make, which ultimately restricts the policy outcome.

This research aims to examine how framing, institutions and interests can determine the contents of a policy debate on drug access and influence the final policy product. The case under consideration is Canada's Access to Medicines Regime (CAMR), which implements the WTO Paragraph 6 Decision (World Trade Organization, 2003b). In theory, CAMR allows Canadian generic manufacturers to produce patented medicines under a government-issued compulsory license for export to developing countries (Government of Canada, 2007); however, the bill is considered by many as an inadequate method to encourage improved drug access (Attaran, 2007; Cohen-Kohler, Esmail, & Cosio, 2007; Elliott, 2008). Since it was passed in 2004, it took three years for a group of
civil society advocates and one Canadian generic company, Apotex, to produce and export a drug order under CAMR. These efforts resulted in one order of antiretroviral tablets, enough to treat 21,000 HIV/AIDS patients in Rwanda for one year (Elliott, 2008). Apotex has since stated that it is unwilling to use CAMR again unless fundamental changes are made to the regime (Apotex, 2008). These outcomes have led many health activists to view CAMR as a poorly designed regime (Cohen-Kohler et al., 2007; Elliott, 2006; Médecins sans Frontières, 2006). Meanwhile, Canada's Rx&D, the association representing the Canadian research-based industry, describes CAMR as "fair, functional and efficient" (Canada's Research-Based Pharmaceutical Companies, 2009).² Clearly, what one stakeholder group views as a cumbersome, bureaucratic and complex process is viewed by others as simple and effective, which illustrates that the definition of what an efficient regime should look like is dependent upon whose perspective is taken. In this context, no absolute barriers to the regime can be identified. Instead, each perception of CAMR's efficiency or lack thereof is fundamentally linked to a particular stakeholder group, their policy goals and interests.

**Research Questions**

This research aims to answer the following questions:

1. How did stakeholders frame access to medicines in the case of Canada's Access to Medicines Regime?
2. How did framing, institutions and interests interact and determine the final policy design of Canada's Access to Medicines Regime?

To answer these questions, a conceptual framework of framing, interests and institutions will be used. Frames are defined as "a policy position resting on underlying structures of belief, perception and appreciation," (Schön & Rein, 1994). Interests are defined as the preferences of actors, which depend upon the potential effects of a policy (Stone, 2002). Institutions are defined as "recognized patterns of behavior or practice around which

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² In a recent letter to the editor, they stated that "It took exactly two months to complete all the necessary steps to permit Apotex to license a product for export for humanitarian purposes, process involving no fewer than nine patents held by three different Canadian innovative biopharmaceutical companies. In contrast, it took almost a year for Apotex to produce and send the medicine to Rwanda."
expectations converge,” (Krasner, 1983). I posit that these three factors interacted and influenced the policy development of CAMR.

This theoretical framework is implemented through a three stage analytical process:

1) literature review of policy literature to determine the different ways in which drug access in developing countries can be framed and to provide the policy context in which CAMR was formed.
2) content analysis of the Standing Committee Hearings on Industry, Science and Technology in 2004 and in 2007 to determine which stakeholders participated in the debate and how they framed the issues.
3) analysis of the content analysis results through the framework of framing, institutions and interests to determine how all of these factors interacted to influence the debate and the final policy product.

The following section provides a brief overview of the findings from this research.

**Summary of Findings**

In the 2004 debates, I find that the debates centered around two themes: intellectual property protection and TRIPS compliance. Due to framing and institutional factors, policy design decisions that increased intellectual property rights ultimately prevailed. By framing the problem as the Paragraph 6 Decision, the Liberal government immediately channeled the debate into the Departments of Industry Canada and International Trade, whose mandate, policy legacy and preferences favoured a more restrictive interpretation of the TRIPS Agreement. Consequently, a number of issues that could have been raised were pushed out of the debate including pharmaceutical innovation, Canadian domestic economic interests and human rights.
A comparison between the 2004 and 2007 debates reveals that issues identified as barriers to the implementation of CAMR in 2007 were not discussed in 2004. In relation to the generic industry's participation, these issues included: protracted voluntary license negotiations, restrictions on the duration, quantity and number of countries per compulsory license, the threat of litigation and the profit-limitations. In relation to developing country governments' participation, these issues included: the lack of institutional capacity in developing countries to use the regime, CAMR's lack of congruence with developing country procurement practices, developing country governments' desire to pursue the local production of medicines and technology transfer, and political or economic pressure placed on developing countries by more powerful countries to avoid using TRIPS flexibilities altogether. Perhaps most importantly, civil society and the generic industry identified the WTO Paragraph 6 Decision itself as the fundamental problem. Given these findings, the criteria against which CAMR was evaluated in 2007 were somewhat different than the criteria used to formulate CAMR in 2004.

The reasons why these issues were not discussed in 2004 is related to the nature of the legislation that was up for debate in 2004 and also related to the range of stakeholders that actually participated in the debate. I argue that the draft legislation severely narrowed down the policy alternatives from which stakeholders had to choose. As Kellow states, "the enemy of what you want more, is what you want less," (Kellow, 1988); the government's inclusion of the right of refusal into the draft legislation forced stakeholders to set aside some other policy alternatives. Furthermore, I argue that if developing country government representatives had participated in the 2004 consultations, some of these demand side issues may have been mentioned, at the very least. Civil society and the generic industry's failure to raise the problem with the WTO Decision itself (at least during the public consultations) is likely due to the fact that they wanted to make an

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3 Civil society, the generic industry and to some extent, government bureaucrats, identified a number of major impediments of the regime. The listed barriers were based on their positions during the 2007 hearings, and triangulated by information from their 2007 consultation submissions and the Standing Committee's final report to the Government.
imperfect decision work. Moreover, raising this issue may have sabotaged the introduction of a humanitarian compulsory licensing regime in Canada altogether.

These findings suggest that in passing and reviewing CAMR, the Liberal and Conservative Governments appear to have further entrenched the limited use of compulsory licensing by incorporating it into domestic law. This helps explain the limited success of the bill. While civil society and the generic industry may have won a battle in getting the Canadian Government to introduce compulsory licensing as a policy tool to pursue affordable drug access in developing countries, the policy context in which the legislation was crafted along with the rules and norms of the Paragraph 6 Decision itself, ultimately led to a limited applicability from the perspective of both civil society and the generic industry.

Overview

This thesis proceeds as follows. Chapter 2 describes the theoretical framework that guides the analysis. It elaborates on the framework of framing, interests and institutions described above and shows that all three aspects can play a role in policy-making. To help structure actors’ discourse and relate it to their policy goals, Stone's four-goal framework – equity, security, liberty, and efficiency - is introduced and explained through the lens of drug access. Chapter 3 outlines the methodology employed, the data collected and analysis techniques, while discussing the limitations of this approach. The chapter explains the literature review, which aimed to describe the interests and frames that could have been involved in the CAMR policy debates. The use of content analysis helps uncover the policy content of the CAMR Parliamentary Standing Committee hearings in 2004 and 2007. Then, the results of the content analysis are analyzed through the lens of framing, interests and institutions to determine how these factors interacted and ultimately influenced CAMR's formation and design.

Chapter 4 describes the main actors, frames, interests and institutions that are involved in global access to medicines and intellectual property debates and provides the policy
context for the CAMR debates. Explanations of the WTO TRIPS Agreement, the Doha Declaration, the Paragraph 6 Decision and CAMR are also provided.

Chapter 5 briefly outlines the coding framework used for the content analysis and relates them to Stone's four-goal policy framework. Chapter 6 describes the results of the content analysis. While quantitative results suggest that stakeholders appear to be arguing in favor of certain specific goals, qualitative results will show that these goals are fundamentally linked to underlying policy objectives that may or may not be explicitly articulated in policy debates. Chapter 7 discusses these results in the context of the theoretical framework to answer: how did framing, interests and institutions influence the policy formation of Canada's Access to Medicines Regime? The discussion concludes that the institutional constraints of the TRIPS Agreement and the policy preferences of Industry Canada and International Trade had the most significant influence on the debate. Chapter 8 summarizes the content analysis results of the policy debates in 2007. Chapter 9 analyzes these results in the context of the theoretical framework to conclude that the most significant factor appears to have been the preference of the Conservative Government to maintain the status quo and leave CAMR unchanged, which falls in line with the aggressive approach that was adopted in their foreign policy with respect to intellectual property protection. From the perspective of framing, the major point of divergence between stakeholders was their definition of what an efficient regime should look like. Chapter 10 summarizes the findings and discusses the implications of this research on global drug policy.
Chapter 2: Theoretical Framework

This chapter will outline the theoretical framework that informs the analysis in the thesis. Howlett et al argues that the greatest insights into policy contents and processes arise from the study of three particular dimensions of policy-making: policy actors, structures and institutions, and ideas (Howlett, Perl, & Ramesh, 2009). This research focuses on these dimensions through a framework of framing, institutions and interests. Within this framework specific assumptions are made. The framing component uses Stone's four-value framework to analyze actors' discourse during the policy debates (Stone, 2002). "Institutions" focuses on the structures and processes that facilitate, constrain and influence the state and societal interests. Lastly, the conception of interests emphasizes the mobilization and organization of interests. All of these components are described in detail below.

Framing

In this research, a frame is defined as a “policy position resting on underlying structures of belief, perception and appreciation.” (Schön & Rein, 1994). It is a powerful story about a situation, which shapes the public's understanding of an issue. Each frame is a different interpretation of reality that “selects and names different features and relations that become the ‘things’ of the story,” (Schön & Rein, 1994). From this perspective, problems cannot be described objectively (Dery, 1984). Instead, problems are intentionally and strategically defined. Relationships between these few salient features are drawn to finish this process of ‘naming and framing’, which in essence simplifies an otherwise overwhelmingly complex reality.

Framing matters to policy formation because frames can constrain action (Bhatia & Coleman, 2003). By emphasizing certain aspects of a situation, and not others, framing immediately narrows down a policy debate to a bounded set of policy alternatives. For example, if a policy-maker frames the problem of drug access as caused by weak health systems infrastructure, then the debate immediately gets funnelled towards the discussion
of policy alternatives that could address this cause such as increased foreign aid, capacity-building programs and the assistance of NGOs and private actors in the distribution and delivery of medicines (UN Millennium Project, 2005). Other policy alternatives that may improve drug access, such as improved financing for medicines, compulsory licensing to improve drug affordability, or addressing physician prescribing to improve appropriate drug use, may not be considered.  

By defining the problem and its causes, framing takes us through the ‘normative leap’ from what ‘is’ to what ‘ought’ to be (Schön & Rein, 1994) and immediately restricts the solutions that can be chosen. 

This research aims to examine framing in the case of Canada's Access to Medicines Regime, to make the multiple perspectives of the situation explicit and identify the tacit assumptions made by actors about values and facts. The goal is not to combine these perspectives to identify the "best" or "most accurate" definition of the problem and its potential solutions. The goal is to achieve a more comprehensive and critical understanding of problems and to make explicit the values and interests any definition promotes (Stone, 2002). 

Stone argues that political struggles typically revolve around four main abstract policy goals: equity, efficiency, security and liberty (Stone, 2002). At face value, most people would agree that these goals are worth pursuing. The use of these ideas in policy debates suggests that a common goal between stakeholders exist; however, in practice, these concepts only provide language with which stakeholders argue their positions. It is the definition of these goals and how best to achieve them that triggers political conflict. In the case of addressing the inequity in drug access in developing countries, everyone agrees it is a problem worth addressing. The dispute lies in how to solve the problem, which is fundamentally related to what goals they value most.

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4 That said, the institutional context plays a role on policy content as well. The influence of institutions will be addressed further on in this chapter. 

5 Obviously, numerous other values can be and are a part of policy debates; however, these four ideas are useful for understanding the trade-offs that governments face between policy goals.
These four policy goals serve as the conceptual framework for this research to guide the analysis and discussion of the issues that come up in policy debates about access to medicines. By identifying and understanding the main dimensions under which these goals can be defined and interpreted, the values underpinning any frame can be better understood. The following section discusses the concepts of equity, security, liberty and efficiency and illustrates how they can help better explain the influence of framing on policy debates in the area of drug access.

**Equity**

Politics is often about the distribution of resources and as such, it often involves the question of equity. Equity can be defined as "even-handed treatment" or treating similar cases in similar ways. (McLean, 1996) Stone defines equity as a 'fair distribution' (Stone, 2002). Equality, on the other hand, refers to that part of a distribution that is uniform. The concepts of equity and equality are related because a distribution that is considered equitable can contain both equal and unequal elements. For example, a drug insurance scheme, which calculates individual deductibles based upon income-level, could be considered equitable or fair because deductibles between individuals are an equal proportion of their income. But this insurance scheme is unequal insofar as the absolute amount paid by each individual is different. In this sense, the question of what a fair distribution entirely depends upon the perspective you take. A useful way of thinking about how equity has been defined in any case is by asking the following three questions: who are the recipients, what is being distributed and what are the social processes by which distribution is determined (Stone, 2002)?

In politics, the definition of who the recipients of resources should be is often based upon membership to a particular community, group, demographic or income-level (Stone, 2002). Still, no classification avoids the problem of defining group boundaries, membership or the how that membership is determined since none of these definitions is absolute. For example, under TRIPS, exceptions are made for countries that are classified as least-developed under the UN Development Index and these countries get an additional ten years to strengthen their institutions to meet TRIPS obligations. The rule is
equal insofar as it treats all least-developed country members the same but is unequal by giving less-developed countries more time to get their institutions and laws up to TRIPS standards.

In defining equity, items are often defined along a continuum, the boundaries of which can get challenged (Stone, 2002). Drug formularies are a good example. Hospitals or insurance schemes usually define a basket of pharmaceutical products that will be covered. They are forced to make decisions on the inclusion or exclusion of products under their formularies, often using the criterion of cost-effectiveness as one of the guiding variables. On a more global level, the WHO Essential Drugs List was established to help guide countries in devising their national drug strategies and cost-effectiveness is one of its main criteria (World Health Organization, 2009); however, the exclusion of a drug that is not cost-effective may leave out treatment options that are the last resort for some patients who have failed on other therapies. There are many expensive second or third-line antiretroviral drugs that are not on the list, simply because they do not meet the criteria of cost-effectiveness and because the List includes other first and second-line treatment options instead. Any criterion around which items are defined ends up leaving some recipients at a disadvantage.

The policy analyst's third question in relation to equity is whether the process by which an item gets distributed is fair (Stone, 2002). Whether or not a process is fair is entirely dependent upon what standard is used; since no standard is independent, there is always room for debate and disagreement.

Security

In its simplest form, security can be defined as basic human needs (Stone, 2002). In politics, security is often defined in military or economic terms (International Relations dictionary). With the rise of globalization, security has encompassed many other dimensions of need, including that of access to health care goods and services (Lee, Buse, & Fustukian, 2002). Since politics often involves competing claims about security, the
definition of what is needed is open for interpretation. Furthermore, who should bear the cost of ensuring this security becomes the subject of debate.

"In conflicts over security, the central issues are what kind of security government should attempt to provide; what kinds of needs it should attempt to meet; and how the burdens of making security a collective responsibility should be distributed." (Stone, 2002)

As Stone explains, need is a relative concept because individuals, communities and societies can place different values on resources, then raising the issue of whether needs should be measured in relation to a fixed standard or a relative one (Stone, 2002). For example, poverty can be conceptualized in absolute or relative terms. Defining poverty in absolute terms would be in relation to a specified threshold of income or resources.\(^6\) In contrast, relative poverty could be measured compared to the income or resource levels of others in a reference group, state or worldwide. Need can also be direct or instrumental. Direct needs are immediate needs such as food, water and shelter and generally require redistribution (Stone, 2002). Instrumental needs are those that equip an individual or society for the future, such as rights and liberties, opportunities and powers, and income and wealth and may also require redistribution (Rawls, 1971; Stone, 2002).

Drug access can be considered a security issue to the extent that it saves lives, the HIV/AIDS pandemic providing a clear illustration of this. But drug access's relationship with human security goes beyond simply saving lives. Pharmaceuticals can improve a person's quality of life to facilitate the capacity to participate meaningfully in society. From that perspective, drug access is both a basic and an instrumental need; to the extent that drug access not only saves lives but improves quality of life, drug access can provide

\(^6\) The UN defines the poverty line as "...a level of income (or spending) required to purchase a minimum amount of essential goods such as food, clothing, shelter, water, electricity, schooling and reliable healthcare." [http://www.undp.org/poverty/devglossary_main.shtml#MNOP](http://www.undp.org/poverty/devglossary_main.shtml#MNOP) Date accessed: 13 March 2010.
a basic level of human security to equip an individual or, even an entire country's population, for the future.\footnote{Where one draws the boundaries around what medicines are considered necessary depends upon what standards are used. For further explanation, see the discussion in Chapter 4 and 5 regarding the "list of medicines".}

Given the importance of medicines access to the sustenance of life and well being, access to essential medicines is a human right. From a legal perspective, this right is enshrined in both Canadian domestic and international law. Section 7 of the Canadian Charter of Rights and Freedoms guarantees the right to "life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice."\footnote{See Canadian Charter of Rights and Freedoms: \url{http://laws.justice.gc.ca/en/charter/1.html#anchorbase:1_l-1-gb:s:2} [Date accessed 5 May 2010].} Internationally, the right to health is recognized by many international and regional treaties, including the International Covenant on Economic, Social and Cultural Rights (ICESCR) which provides the grounds for states legal obligations towards the right to health (Office of the United Nations High Commissioner for Human Rights, 1966). Article 12.2 extends this right to access to medicines\footnote{General Comment 14 of May 2000 explicitly links Article 12.2(d) to the provision of essential drugs. See Hogerzeil \textit{et al}, 2006.}.

**Liberty**

Liberty can be defined as 'freedom', 'exemption from restraint' or 'the power of acting as one pleases' (Thatcher, McQueen, & Webster, 1980). Liberty conflicts typically arise in public policy in response to the question of when governments should be allowed to interfere with individual choice and activity in the name of community or society (Stone, 2002). These conflicts raise issues such as what harms to individuals, communities or groups warrant government restraints on liberty? Should the liberty of individual actors, group actors or corporations be restrained? How should this be done? The idea of liberty is fundamentally a socially constructed concept and by extension, cultural history and context inform what harms are privileged and which ones are punished.
As a state-defined property right, intellectual property protection is an issue of liberty. It should be noted that intellectual property rights were not established on the basis of natural or moral rights (May & Sell, 2006). The state offers protections to inventions as intellectual property in return for disseminating this creativity to society and to further others' creations and innovations to an even larger extent (Doern & Sharaput, 2000). Furthermore, the protection of intellectual property is the mechanism that many governments use to stimulate research and development in many sectors, including the pharmaceutical industry. Through patent protection, the innovator obtains exclusive marketing rights over their invention over a defined period of time (DiMasi & Grabowski, 2007). In theory, the promise of an exclusive marketing period provides the inventor with an incentive to innovate (DiMasi & Grabowski, 2007). The profit made during this period also provides a return on the investment, which can cover sunk costs and be used towards future research. The average cost of R&D towards a new drug is a controversial question, with estimates ranging from as little as $175 million USD to more recent estimates of $2 billion USD (Angell, 2004; Light & Warburton, 2005).

### Efficiency

The problem in politics is that the claim of efficiency can be challenged based upon how it is defined. In its most simple terms, efficiency is about getting the most output given a certain input (Stone, 2002). It is also about reducing waste, increasing productivity, speed, quantity or quality. As a fundamentally comparative concept, efficiency is a criterion for judging the merits of different ways of doing things (Stone, 2002). Generally, conflicts can arise over four primary questions: who gets the benefits, who bears the burdens of a policy, how do we measure the costs and values of a policy and how can we best organize human activity to yield the most efficient outcomes (Stone, 2002)?

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10 May and Sell argue “…the industrialized countries built much of their economic prowess by appropriating others’ intellectual property; with TRIPS this option is foreclosed to future industrializers…states and companies whose comparative advantage lies in imitation stand to lose under the new regime.” (May & Sell, 2006) India is a prime example of a country that has pursued technological development in the area of pharmaceuticals, assisted by the lack of product patents until 2005.

11 Angell argues that the higher estimate is due to the way the authors calculate this cost: the authors focused on drugs that are developed entirely within the drug company itself (as opposed to licensing it from another company), they incorporated opportunity costs, and their estimates were in pre-tax dollars.
Efficiency can be understood by examining the outputs and the inputs (Stone, 2002). The output of any program requires clarification of: what the precise objective of the program should be; how multiple objectives should be valued and compared; and how the different objectives benefit different stakeholders or groups. Inputs can be evaluated in the same way: where do we draw the boundary on inputs into the equation; how do we measure the inputs and how do we account for, if at all, the opportunity costs of resources used as inputs? Every answer to these questions favours one conception of efficiency and discounts others, which in turn serves some people's interests and not others, meaning that efficiency is always a political claim.

Allocative efficiency is a commonly used concept in policy debates. Formally defined, allocative efficiency is the most fundamental goal of perfectly competitive markets (Perloff, 1999). If the free market works perfectly, allocative efficiency occurs when the resources we have are best deployed to meet all our needs and wants. From the perspective of policy formulation, most implementation issues up for debate are issues of efficiency. Decisions on how best to design a policy to achieve a given outcome are, by definition, questions on how best to achieve efficiency. For example, the issue of medicines diversion can be framed as an efficiency issue; when medicines do not arrive at the place they were intended, this creates delay and waste in the system. Issues of pharmaceutical procurement often espouse the goal of efficiency, as the goal is to maximize scarce resources in relation to a population's drug needs. In the case of CAMR, particularly during 2007 debates, there was a large degree of disagreement around the question of what an efficient regime would look like: the answer depended upon what standard was used to compare the process.

Institutions

This research assumes that institutions are the "actual structures or organizations of the state, society and the international system."(Howlett et al., 2009) Institutions refer to government structures and agencies as well as the formal and informal rules that exist internationally and domestically. Institutions include policy venues in which negotiations
and decision-making over policy occurs (Baumgartner & Jones, 1993) but can also include the treaties and agreements between countries. These institutions embody norms, ideas and principles, which have informal and formal rules, compliance procedures and standard operating practices (Hall, 1986). Recognized patterns of behaviour and practice accompany institutions, around which expectations converge (Krasner, 1983). These rules and practices mediate and structure relationships between various individuals and groups that have a stake in the policy at hand. Institutions structure and constrain political situations, and can shape and influence the behaviour of actors as well as government.

To ensure policy adoption, governments often try to control the debate by keeping much of the policy development process private. As Howlett et al (2009) describe, policy deliberations mostly occur in secret within the bureaucracy, which denies other policy actors the chance to effectively oppose its plans but also denies powerful actors the ability to bias the outcome. In the case of CAMR, the drafting of the initial legislation, Bill C-56, occurred exclusively behind closed doors with stakeholder consultations conducted under confidentiality agreements.12 Schattschneider argues that at early stages of policy deliberation, powerful actors have an incentive to restrict the so-called "scope of conflict" (Schattschneider, 1964):

"...in very small conflicts, the relative strength of each contestant is known in advance; stronger actors might bully weaker ones without much resistance, if the weaker knows it will lose. Therefore, there's a big incentive for stronger actors to restrict the scope of conflict at the beginning...[h]owever, weaker actors can be fighters and might be quick to involve the audience in the conflict; in this case, stronger actors may hesitate in bullying them. This shows that the audience is the part of every conflicts equation, and the balance of forces in any conflict is not a fixed equation until everyone is involved." (Schattschneider, 1964)

Although the standing committee hearings regarding Bill C-9 in 2004 were public, they occurred at a later stage in the policy development process, at which point the stakeholders were already constrained by the government's earlier policy design choices. In this sense, policy-makers try to manage the scope of conflict to ensure adoption of their policy (Schattschneider, 1964). By choosing the policy venue and framing the policy problem at hand, governments restrict who the interested stakeholders might be, their access to the debate, what arguments have more legitimacy than others, which then restricts the policy alternatives available. Of course, policy-makers manage the scope of conflict in order to get things done; however, this can prevent some interested participants from contributing to the policy debate. As Schattschneider says, "the definition of alternatives is the supreme instrument of power; the antagonists can rarely agree on what the issues are because power is involved in the definition. He who determines what politics is about runs the country because the definition of alternatives is the choice of conflicts, and the choice of conflicts allocates power."

Generally speaking, institutions treat conflict unequally (Schattschneider, 1964). For example, at the global level, discussions held amongst global civil society activists advocate the use of compulsory licensing to achieve a sustainable supply and price reductions for antiretroviral medicines (t'Hoen, 2009) and some governments and institutions place this goal as a top priority. In 2007, Thailand issued compulsory licenses on the grounds of public interest, defending their decision on the grounds of human rights and public health (Steinbrook, 2007). As a multilateral institution, the World Health Organization hears the voices of developing countries who argued in favour of using TRIPS flexibilities such as compulsory licensing and parallel importing to not only address their public health needs but to pursue local production of medicines and technology transfer. The institutional mechanisms allowed the WHO to pass strongly-

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13 WHA 52.19 Revised Drug Strategy (1999) calls upon countries “…to ensure equitable access to essential drugs and review options under international agreements to safeguard access to these medicines.” (Sell, 2006:49). See also: EB 115/2005/REC 2, pp. 93-103: “Antiretrovirals in Developing Countries"
worded resolutions that encourage countries to use such flexibilities to pursue public health goals.\textsuperscript{14}

In other venues, the use of these flexibilities is discouraged. The United States Trade Representative discourages the use of such policy instruments, claiming that they threaten innovation and that other policy tools such as aid or helping improve infrastructure should be pursued.\textsuperscript{15} The establishment of the TRIPS Agreement and the World Trade Organization effectively favoured the idea that protecting intellectual property would facilitate increased trade and development while the lack of intellectual property protection in the developing world was tantamount to theft and piracy (Sell & Prakash, 2004). The debates around TRIPS and access to medicines are discussed in more detail in Chapter 4.

Institutions play a large role in influencing the scope of conflict, and several factors at the international and domestic levels played key roles in the development of CAMR. CAMR was the implementation of a waiver under the WTO TRIPS Agreement. The expectations and norms around the interpretation of the Agreement played a major role in CAMR's development. From a domestic standpoint, several government agencies participated in the development of CAMR, with Industry Canada and Foreign Affairs playing a leading role. These institutions have preferences, a policy history and specific mandates, which ultimately affected who could access the policy consultation, what groups had relative strength and what policy goals had more weight, all of which must be considered when assessing the influences on the public policy process.

\textbf{Interests}

This research assumes that interests mobilize around the potential effects of a policy and that mobilization is more likely when an issue affects a group of individuals intensely and less so around issues that affect them mildly (Stone, 2002). This is related to Olson’s

\textsuperscript{14} Note that although the WHO may hear a more diverse set of voices, given the politics of the institution, it may not act on what it hears.

\textsuperscript{15} See: Comments by United States representative; Meeting Minutes of the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines. 10 July 2001. IP/C/M/31
theory of the logic of collective action, which posits that no incentives exist for individuals to work towards goods, services or programs that benefit many people (Olson, 1971). He states, “…unless the number of individuals in a group is quite small, or unless there is coercion or some other special device to make individuals act in their common interest, rational self-interested individuals will not act to achieve their common or group interests,” (Olson 1971:2). In this sense, an issue that affects a group intensely is a concentrated interest, and an issue that affects a group mildly is a diffuse interest (Wilson, 1995). Stone argues that whether something is a diffused or concentrated effect is also a function of the way it is framed. She argues that each side in a policy debate tries to gain the most power and it is often the weaker side that tries to bring in outside help, by reframing an issue. Consequently, one important dimension of a policy debate is the contest between which group can portray itself as being the weakest, in order to gain outside help from either government or powerful interest groups not yet involved in the policy debate. The relevance of this to the policy process is that different combinations of diffused and concentrated interests can lead to very different policy debates.

According to Schattschneider, three major factors determine who will get involved in the policy debate: visibility, intensity, and direction (Schattschneider, 1957). Visibility refers to whether a particular group or individual has enough information about the policy proposal. Is the policy proposal public knowledge or is it disseminated to a select few? Is the interest group or individual organized enough and does it have enough resources to participate in this policy debate? Some associations, non-profit agencies, individuals or stakeholders may not have the resources available to be able to send an individual to Industry Canada to advocate for their interests. Others, like business firms or associations, are well-funded and well-organized and therefore better positioned to participate in policy-making. They also tend to have direct access to some government officials and can obtain up-to-date and detailed information about policy proposals.

Intensity refers to the degree to which a group is attached to a policy issue (Schattschneider, 1957). From the group's perspective, what are the costs and benefits of the policy? If the intensity is high, then the group will likely participate in the policy
debate. In the case of CAMR, the research-based industry may have perceived huge costs from this policy, as it may have invited generic competition into their potential markets. The generic industry's participation is less clear; they did not appear to gain much from their participation in this policy debate aside from a positive public relations outcome. This will be discussed in more detail later in the findings.

Direction refers to the extent that the policy issue is relevant to the group or individual (Schattschneider, 1957). The policy issue must be important enough for the group to get involved in because, as Kellow states, "what we want more is the enemy of what we want less" (Kellow, 1988). Stakeholders will get involved in less important debates only if they are not engaged with conflicts that are more important to them.

To assess the interests at stake in the CAMR debate, this research addresses questions such as: What were the policy preferences and objectives of state and societal actors in this policy field? How receptive are the institutions to interest group pressure? What was the nature of the interest groups involved?

**Summary**

This chapter outlined the framework of framing, interests and institutions that is used in this study. In terms of institutions, this research focuses on the institutional structures and processes at both international and domestic levels including the WTO TRIPS Agreement, Canada's relations with other states especially the United States, and Canada's domestic institutions, in particular, the Prime Minister and the Ministries of Industry, Foreign Affairs and Trade, and Health. With respect to the interests involved in CAMR, this research examines societal interests, some of which include business firms, nongovernmental organization and the mass media, and their interaction with one another and the state. Finally, in terms of framing, to help understand actor discourse and how it relates to their interests, Stone's four-goal framework – equity, security, liberty, and efficiency - was discussed. Overall, all three aspects – framing, institutions and interests - can play a role in policy-making.
Chapter 3: Research Design and Methodology

The Single Case Study Design

This research aims to examine how framing, institutions and interests determined the contents of the policy debates over Canada's Access to Medicines Regime and how they influenced the final policy product. Answering these questions requires an investigation of what factors might be involved in the policy formation process, many of which can only be assessed qualitatively. The case study method allows such exploration since it is particularly effective at dealing with the 'how' and 'why' questions, the answers to which will inform a comprehensive description of the policy development and content of CAMR (Yin, 2003). It is an effective method of researching contemporary phenomena where actors have discretionary behaviour, and allows for detailed and holistic investigation. Case studies are methodologically flexible in that a range of measurement techniques can be used and facilitates the use of different data sources from multiple perspectives. From an epistemological perspective, this research assumes the critical realist tradition, which assumes that human beings can observe a distinct objective reality but a degree of subjectivity unavoidably affects the observations of human social behavior (Blackburn, 2005). Ultimately, the goal of this case study is to better understand and inform policy-making on drug access. Canada’s implementation of the WTO Paragraph 6 Decision resulted in a policy regime that is currently not serving those developing countries in need. By understanding the political factors that shaped Canada’s Access to Medicines Regime, this research aims to better inform policy-making so that it ultimately makes a more meaningful impact on global drug access.

Yin describes two main limitations of the case study methodology (Yin, 2003). The first limitation is its potential to allow biased views to influence the results and analysis. The ways to minimize bias include the examination of data collection techniques by additional researchers, using multiple sources of data, and review of results with key informants. The second main limitation of the case study is it provides little basis for scientific generalization. Instead, case studies are analytically generalizable; in other
words, it can provide the basis to postulate a new theory or inform an existing theory, which can become the basis for examining other cases.

Why a researcher chooses to study a particular case helps put the research in the appropriate context and helps guide data collection and analytic strategies. Case selection depends upon its relationship to existing theory or what is empirically known about the particular problem. Yin (2003) outlines three types of cases based upon their relationship to theory or empirical literature: 1) the extreme or unique case, 2) the revelatory case and, 3) the critical case. Extreme cases are those that are worth analyzing simply out of the fact that they are rare and that they differ the most from theory or empirical findings. The revelatory case is that which focuses on a phenomenon which may be prevalent in society, but for one reason or another (for example, inaccessibility to data or research subjects), has not been studied. Such investigations can lead to significant case studies on phenomena that were previously poorly understood.

The proposed research positions CAMR as a critical case. The critical case is most similar to existing theory and is used to confirm, challenge or extend a theory with clear propositions and circumstances under which these propositions hold. Such cases must meet all the conditions for testing the theory. As described in the previous chapter, the main theoretical assumption of my research is that the essence of policy conflicts between intellectual property and access to medicines lies in the political struggle over the definition of the problem and in the end, the definition of alternatives. The definition of the problem defines the interested parties, defines what is at stake and allocates the role of “bully and underdog”. Ultimately, these factors define the alternatives from which participants in the policy conflict will have to choose, which highly conditions the policy outcome. By focusing on framing in the CAMR case, the proposed research aims to confirm, challenge or extend this theory, in the context of the policy conflict between intellectual property and access to medicines.
**Case Definition and Data Collection Boundaries**

The next major step in designing a case study is defining the case itself. A case, whether it is an event, phenomenon, individual, group or society, exists or occurs in a bounded context that needs to be defined clearly to focus the research. These boundaries should be informed by the primary research questions and the conceptual framework (Miles & Huberman, 1994; Yin, 2003).

Miles and Huberman identify six criteria that need to be met when defining the boundaries of a case: 1) the chosen sample and data must correspond to the conceptual framework and research questions, 2) the study phenomena must be able to appear, in principle, 3) the conceptual framework or representativeness of the sample should aim to enhance the generalizability of the findings (*i.e.*, its relation to literature), 4) the design must be able to achieve "believable descriptions and explanations", 5) the sampling plan must be feasible in terms of time, resources and access to individuals and 6) the sampling plan must be ethical. When studying a policy, it can be challenging to define a clear beginning and endpoint. Actors' perspectives on policy beginnings and ends can vary which makes it important for the researcher to remain flexible in defining the boundaries as the research proceeds.

**Research Questions**

This research aims to answer the following questions:

1. How did stakeholders frame access to medicines in the case of Canada's Access to Medicines Regime?
2. How did framing, institutions and interests interact and determine the final policy design of Canada's Access to Medicines Regime?

As was described in Chapter 2, the theoretical framework that guides this inquiry is based upon the interaction and influence of framing, interests, and institutions. In particular, this research focuses on framing and how institutions and interests structured and mediated its
influence. To determine how stakeholders framed access to medicines (Research Question 1), the following two sub-questions further guided the analysis:

1) What are the potential frames and interests that could have been involved in the debate on medicines access in developing countries?

2) What were the actual frames and interests involved in the debate over Canada's Access to Medicines Regime?

As will be described in more detail below, sub-question 2 was answered using a content analysis technique, and sub-question 1 informed the development of the codebook for the content analysis. To facilitate the discussion of the case definition and data collection and analytic strategies, the following sections have been organized to correspond to these two sub-questions outlined above.

**Potential Frames and Interests**

The first question of this case study aimed to assess the policy debate that 'could have been'. In other words, to better understand the context for the CAMR debate, debates that have addressed the same topic were examined to see what issues arose, how they were framed, and who participated in these debates. In this study, the topic was defined as access to medicines in developing countries and intellectual property protection; however, these topics often encompass more than those two issues, addressing the broader issues of pharmaceutical innovation, health and global development. To get a broad representation of interests and frames and to get an understanding of the important events that led to the formation of CAMR, purposive sampling of peer-reviewed literature, policy documents, media articles and web-based material was used. Purposive sampling is the selection of information-rich cases in a strategic and purposeful way (Patton, 2002). To achieve this goal, the criterion and data sources were defined. Sampled material had to address one of the following topics: 1) access to medicines in developing countries and intellectual property, 2) access to medicines and intellectual property issues in Canada, or 3) Canada's Access to Medicines Regime. The following data sources were searched:
• Transcribed records of House of Commons debates regarding CAMR (Hansards)
• Media reports and articles about Canada's Access to Medicines Regime
• Press releases and submissions about CAMR
• Policy documents and website content from Canadian and international governmental agencies, and global health and trade organizations (non-profit, private philanthropic and industry associations) about access to medicines in developing countries and intellectual property protection
• Peer-reviewed and grey literature about access to medicines in developing countries (see "References").

Not only did this provide a context for the different ways that medicines access and intellectual property can be framed, but it also identified individuals, groups, organizations or countries that had a potential stake in the outcome of this policy. By defining the range of stakeholders that may have had a vested interest in CAMR, this study could better identify what groups and individuals the CAMR policy consultation process may have left out and probe why this happened.

**Literature Review**

A literature review is a written summary of peer-reviewed articles, books, documents and other materials that describes the past and current state of information and it organizes the literature into topics (Creswell, 2005). The review was performed to achieve two specific objectives: 1) to identify and describe the potential frames and interests that could have been involved in the debate on medicines access in developing countries (Subquestion 1) and 2) to describe key events, institutions and the political and economic context within which CAMR developed to inform the final analysis (policy context). Document selection was purposive (as described above), pulling from the data sources listed above. The literature review served as the basis for the development of the codebook, described further below, which was used in the second stage analysis.
**Actual Frames and Interests**

The second stage of analysis addressed what actually happened in the CAMR debates. In other words, who participated in the debate (*i.e.*, interests) and what did they say (*i.e.*, frames)? To answer these questions, a comprehensive sampling strategy was used within specifically designated data boundaries. Data collection focused on two hearings of the Parliamentary Standing Committee on Industry, Science and Technology. The first set of hearings consulted stakeholders on draft legislation *Bill C-9, An Act to Amend the Patent Act and Food and Drugs Act*. These hearings took place from February 24, 2004 to April 22, 2004. The second set of hearings reviewed the implementation and outcomes of the same legislation, now known as *Canada's Access to Medicines Regime*, from April 16, 2007 to April 23, 2007. These are publicly available and well-defined data sources that informed who took part in the hearings (actors) and what they said (frames) leading up to the formation of the legislation and during the mandatory legislative review. Results from the literature review augment these findings, to identify all stakeholders who contributed to the consultations and any additional frames they might have added. These hearings were available as verbatim transcripts. Data excluded from this stage were reports produced by actors, actors' submissions and media coverage; however, these documents were taken into account in the literature review.\(^{16}\)

**Mixed Method Content Analysis**

A content analysis was used to analyze the frames that actors expressed through the government consultation process. This technique can be viewed along a continuum: on one end, it is a positivist and heavily quantitative approach and on the other, it is a constructivist and ethnographic approach. Each approach to content analysis is located at a different point along the continuum and emphasizes different elements. On the positivist end, classical content analysis, with its roots in the linguistic and communication disciplines, assumes texts are ‘packets of communication’ (Miller & Alvarado, 2005) or 'containers of meaning' (Krippendorff, 2004), which can be categorized and then counted. Classical content analysis is used when the researcher

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\(^{16}\) A separate study analyzed the media coverage and these results informed this research.
wants to ask the questions: “what” and “how many” (Morgan, 1993). From the constructivist point of view, content analysis is similar to other qualitative techniques such as ethnography, grounded theory or phenomenology that assume a more naturalistic approach (Denzin & Lincoln, 2003; Hsieh & Shannon, 2005; Strauss & Corbin, 1998). These approaches view text as both communication and context. Naturalistic qualitative content analysis allows the researcher to answer “what and how many” but also “how” and “why” through its analysis of the context of the text (Morgan, 1993). The nature of qualitative content analysis ultimately depends upon where on the interpretative spectrum one’s research lies (Hsieh & Shannon, 2005; Morgan, 1993).

This study adopted a mixed method approach to the content analysis, which involved two distinct stages and two distinct assumptions: first, a quantitative content analysis was performed assuming positivist approach (Krippendorff, 2004); second, the theme contents were summarized assuming a critical realist approach (Blackburn, 2005). First, quantitative content analysis was chosen because it allows for a more explicit view of patterns that lead to the associations and conclusions. Counting the codes permitted the comparison of who said what on a macro-level: the level of emphasis that stakeholders placed on various issues was one indicator of what their key interests were in this policy debate. This quantitative content analysis produced categorized sections of text according to theme and stakeholder. The textual contents of these categorized sections were then summarized qualitatively (Chapters 6 and 8). These summaries provided context to the quantitative results, which then provided a second level of detail on stakeholder interests and more comprehensively answered the question of how stakeholders framed access to medicines in the case of CAMR. Furthermore, the political context obtained through the qualitative summaries provided an important backdrop by which to understand specifically what factors ultimately shaped Canada's implementation of the Paragraph 6 Decision.

It is for these reasons that a mixed methods content analysis was used—the quantitative results alone were deemed inadequate to explain the outcomes (Creswell and Plano Clark 2006). Summarizing the text-based data within each theme would enrich the frequency
counts, providing a qualitative description of its contents. Furthermore, by obtaining more detail on what stakeholders' positions were in relation to these goals, whether or not they framed these goals positively or negatively, and what other issues they may have framed these themes as, would provide a clearer picture of stakeholders’ interests and the political factors which shaped CAMR.

Stage 1: Quantitative Content Analysis

Given the fact that the meaning of words, phrases and paragraphs can differ to some extent depending upon the reader, the particular interpretation of the text used in this study was made explicit through the construction of the codebook. As Krippendorff states, "the purpose of all analytical constructs is to ensure that texts are processed in reference to what is known about their use". The validity of the analysis (i.e. codebook), therefore, is dependent upon how relevant it is to the research and policy literature within which the codebook is based. Validity of the quantitative content analysis will be discussed in further detail below.

Three different types of quantitative content analysis can be done: text-driven, problem-driven and method-driven content analyses (Krippendorff, 2004). Problem-based content analysis is used when a researcher wants to answer a question about a real world phenomenon. The question is neither motivated by questions exclusively within the text (text-driven) nor by the desire to explore a new analytic method (methods-driven). In problem-based content analysis, what the researcher looks for within the text otherwise known as the analysis design, must be based upon theory or empirical findings about the real world problem. The literature review described in the previous section aimed to assess empirical findings and relevant theory to inform the analytic framework (i.e., the codebook), which guided the content analysis.

Units of Analysis

Krippendorff (2004) defines three different levels of units of analysis: sampling units, recording units and context units.
Sampling units are "units that are distinguished for selective inclusion in an analysis." Content analysts must define sampling units so that a) connection across sampling units, if they exist, do not bias the analysis; and b) all relevant information is contained in individual sampling units, or if it is not, the omissions do not impoverish the analysis," (Krippendorff, 2004). This study’s content analysis assumed that a set of hearings by the parliamentary standing committee is the equivalent of one sampling unit.

Recording units are what most ethnographic qualitative researchers mean when they refer to the size of codeable sections of text or 'chunks'. This can range from words, sentences, paragraphs or entire documents (Miles & Huberman, 1994). Many qualitative researchers determine the size by themes; in other words, codeable blocks of data are 'monothematic chunks of sentences' or paragraphs that are large enough to encompass one idea (Miles & Huberman, 1994). Krippendorff (2004) says that recording units are "…the smallest units that bear all the information needed in the analysis, words being perhaps the smallest meaningful units of text." In this study, recording units were defined as paragraphs. Codes were categories of words or phrases that have something in common, a common reference. This analysis coded an entire paragraph if the relevant keywords or phrases were mentioned; therefore, in many cases, paragraphs were coded multiple times to identify passages of text where the concept was mentioned. This permitted the researcher to explore coded text for more nuanced meaning.

Context units are simply sections of documents or text that help the coders extract the meaning from these recording units (Krippendorff, 2004). In other words, it is the context for the chunk and it helps coders identify the recording units. Generally, the smaller the context unit is, the more reliable the categorization of the chunk is by multiple coders. In determining its size, a context unit should be as large as is meaningful (which adds to validity) and as small as is feasible (adding to reliability). In this study, the context unit was defined as a set of parliamentary standing committee hearings given the multiple issues up for discussion and their interrelationships in the CAMR policy debates.
Codebook Development: Reliability and Validity of the Content Analysis

The construction of a codebook served several goals within this first stage of quantitative content analysis: it ensured transparency and explicitness about the themes being searched for, it increased the reproducibility of the analysis and it provided a means by which to assess the validity of the content analysis, which is elaborated upon below.

The creation and development of a codebook involved the following steps: 1) consultation of the literature to develop an initial list of themes and corresponding keywords (literature review), 2) application of the initial codebook to samples of data, 3) adjusting themes and keywords based upon these initial results (to be described below), and then 4) proceeding by coding the entire set of documents. In practice, however, the process of codebook development is not as straightforward, requires significant backtracking between the literature and the data and requires expert opinion on the structure and content of the codebook from researchers who are familiar with the subject matter. The codebook is not finalized until all of the data is coded and the categories and keywords are validated by other researchers.

The development of categories for the codebook was based upon the frames identified in the literature review and was guided by the original research questions and theoretical framework. Basing the codebook in the literature was the first step to ensuring the validity of the content analytic framework. Krippendorff (2004) notes that "by deriving categories from established theories of the contexts of their analyses, researchers can avoid simplistic formulations and tap into a wealth of available conceptualizations." Two researchers17 created an initial coding scheme consisting of overarching themes or variables of interest. This preliminary thematic framework allowed initial categorization of the data. Then, the researchers applied this preliminary to a diverse sample of data. The documents were individually coded by each researcher. Inter-rater reliability between the two was calculated as:

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17 LE and a student colleague, RM.
Reliability = \( \frac{\text{# of agreements}}{\text{Total # of agreements and disagreements}} \)

After coding one sample document, an inter-rater reliability of 30% (7/23) was achieved. Discrepancies were due to both random human error and lack of clarity. The researchers discussed the coding line-by-line and resolved discrepancies through discussion. Based upon these discussions, adaptations were made to the codebook. Over the course of five months, ten more rounds of revising and coding 13 sample documents was done, with inter-rater reliability increasing from 46 to 80%. The ultimate goal of refining the codebook was to make it explicit enough that anyone who was given a brief background of the study would code the data in a similar fashion. After the tenth round, we achieved an IRR of 80%, a level that is deemed acceptable (Krippendorff, 2004; Miles & Huberman, 1994).

To confirm the validity of the content analysis codebook, three experts in the field\(^\text{18}\) reviewed the codebook and provided additional feedback regarding the categories listed in the codebook. As a result, one more theme was added and two definitions were clarified. To ensure reliability would not be affected by the revised codebook, additional sample documents were coded by two researchers until an IRR of 80% was achieved (reached after three sample documents were coded). Eighty percent inter-rater reliability is deemed acceptable when manually coding (Krippendorff, 2004; Miles & Huberman, 1994).

Subsequently, one researcher\(^\text{19}\) coded the full set of documents using text-analysis software, NVivo,\(^\text{20}\) and reviewed all text coded to ensure consistency of coding. To ensure little to no content was missed, all transcripts were searched for keywords and phrases using the text query function in NVivo, and then manually coded if deemed relevant. The codebook is described in Appendix 1.

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18 JCK, RD and JL.
19 LE
20 See: QSR International, Available at: http://www.qsrinternationalcom
Stage 2: Summarizing the Themes

The quantitative analysis produced frequency counts of themes across all stakeholders and also generated coded sections of text corresponding to each theme, otherwise known as "nodes". To provide a qualitative description of these themes, summaries were abstracted from each node. First, nodes were generated from NVivo divided by stakeholder group. These nodes were then printed, reviewed and summarized as follows: first, the researcher reviewed the entire node contents for each stakeholder group. Then, key patterns and themes were highlighted on the printed summaries and key documents. Summaries were then developed based upon these key patterns and themes, and quotes were extracted to best represent the contents of each node. The summaries were developed with the following goal in mind: to assess what position the stakeholder group assumed in relation to the theme itself, what key relationships the stakeholder group was drawing between the theme and other issues, and what quotes were representative of the stakeholder group's discourse on that theme. The qualitative summaries are displayed by stakeholder group in Chapters 6 and 8.

Case Study Standards of Quality

This research was a qualitative case study, using a mixed method content analysis. Given this design, case study as a whole is judged by the standards of qualitative research. From the mixed method perspective, the quantitative content analysis should be viewed as an embedded component of the qualitative case study (Creswell and Plano Clark 2006). As a separate component, the validity and reliability of the quantitative content analysis was achieved in relation to the positivist tradition. As discussed earlier in this chapter, reliability was ensured through achieving an inter-rater reliability of 80% and confirmed through a computerized search for keywords followed by a manual review of all nodes to ensure consistency of coding. Validity was ensured through a codebook that was based upon the literature, constructed with another researcher, and validated by expert review. But as part of the larger case study, the quantitative content analysis contributes to the quality of the qualitative case study as well, and as such, it will be assessed in relation to these standards as well.
The norms and standards for judging the quality of qualitative research vary widely. Depending upon which epistemological tradition the researcher follows, she will use different terminology and definitions. Even so, Miles and Huberman (1994) neatly combined standards from both ends of the positivist-naturalist continuum by grouping quality criteria into four general categories. Given this flexibility incorporated into Miles and Huberman's approach, the quantitative content analysis can be assessed from this perspective as well. They base these categories in the critical realist tradition (Blackburn, 2005), the tradition in which the case study is based. The four general criteria that qualitative research should aim to uphold are described below.

**Objectivity**

First, objectivity, also known as confirmability, refers to minimizing researcher bias and maintaining "relative neutrality". In the proposed research, objectivity was pursued by explicitly defining the methods and procedures to provide an 'audit trail', by using two separate coders to create the content analytic framework (codebook), by linking conclusions with condensed data in an explicit fashion and by explicitly considering rival hypotheses.

**Reliability**

Second, reliability, also known as dependability or auditability, is the degree of consistency and stability of research procedures across time, researchers and methods (Miles & Huberman, 1994). For the content analysis, reliability can be broken down into three aspects: stability, reproducibility, and accuracy (Krippendorff, 2004). Stability refers to the extent that a coding procedure yields the same results on repeated trials. The review of manual coding along with the computerized keyword search ensured a high degree of stability. Reproducibility is the extent to which different researchers code the data in the same way, which is also known as inter-coder reliability. By providing an explicit 'audit trail' of categorization procedures, codebook and validity checks, any other researcher should be well-equipped to reproduce the results. Finally, accuracy is the
extent to which the classification of a text corresponds to an accepted standard. The accepted standard in this research project is the codebook, therefore any deviations in accuracy would be due to errors such as spelling mistakes while searching or human error in application of the explicit categorization procedures.

**Internal Validity**

Internal validity, otherwise known as credibility or authenticity, refers to whether the research findings are authentic and reflect the concepts and research questions posed in the study (Miles & Huberman, 1994). For the content analysis, internal validity was achieved through the use of multiple researchers to validate the codebook. Krippendorff (2004) refers to this as "semantic validity". Given the fact that the codebook represents a specific interpretation of concepts found in the literature, internal validity was strengthened by obtaining expert opinion on the categories, their associated keywords and their capacity to answer the research questions posed in the study.

For the case study as a whole, triangulation using different data sources (literature review sources including standing committee hearing submissions, Parliamentary debates (Hansards), press releases, media reports, policy documents and peer reviewed literature) was used to attain internal validity. Areas of uncertainty were identified and conflicting data were compared and reconciled.

**External Validity**

External validity, also known as transferability or fittingness, is the question of generalizability: to whom do these findings apply? In research with a small sample size or a single case study, the extent to which the findings are transferable to other populations or contexts or theories is up to the reader to decide. The key, however, is to explicitly describe the study boundaries, sample and methods to provide readers with enough information to apply the findings to other contexts (Miles & Huberman, 1994). In addition, comparison with theory and background literature examining similar questions was performed (Yin, 2003). Applicability of the findings to other contexts was discussed.
In relation to the content analysis, Krippendorff (2004) refers to sampling validity or representativeness as the degree to which a sample of texts accurately represents the population of phenomena in which place it is analyzed. For the content analysis, a full sample of texts was used (otherwise known as a census) therefore sampling validity is not an issue. Some argue that the use of publicly available documents raises the issue of information bias: some information will be suppressed and not be made public (Miller & Alvarado, 2005). This research assumed this bias exists and instead, focuses on how it manifests itself in relation to politics. By constructing a codebook based upon a wider literature, the aim was to place this bias in a greater context and see how politics influenced the content of these records.  

Utilization

The fifth quality criterion is utilization, otherwise known as application or action orientation. Utilization is the criterion that the research is useful for participants or 'consumers' of the research (Miles & Huberman, 1994). To transfer knowledge to policy-makers, the results have been made intellectually and physically accessible to health policy-makers, advocates and the research community. Interim results were presented at an invitation-only workshop in Ottawa in 2009 with government, industry and NGO representatives working on CAMR. Subsequently, results will be made publicly available through publication in peer-reviewed journals such as Health Affairs, HealthCare Policy, Social Science and Medicine, and Globalization and Health.

21 One limitation of the Content Analysis is the uniqueness of the codebook (may limit the extent of comparability of content analysis results). Given the fact that most literature in this area fails to detail their qualitative analysis explicitly and follows general qualitative analysis procedures, the codebook will provide greater context for the results and may in fact improve the ability to extrapolate these results into other contexts.
Chapter 4: Background and Policy Context

The previous chapters outlined the theoretical framework and the design and methodology used in this study. Using a theoretical framework of framing, interests and institutions, this research aims to examine how stakeholder framing influenced the policy development of Canada's Access to Medicines Regime. Two techniques are used to reach this research objective: a literature review and a content analysis. The following section outlines the literature review, which aims to address the following question: prior to the 2004 standing committee hearings, how have stakeholders framed access to medicines? In doing so, this section outlines the range of issues and actors that are involved in debate on drug access and patents. These issues are discussed in relation to the four-goal framework of equity, security, liberty and efficiency, to illustrate how these ideas can be used to justify policy alternatives and decisions.

The TRIPS Agreement

In 1989, the Uruguay Round of the GATT negotiations began, which by 1995, resulted in the formation of the World Trade Organization (WTO) and a new global intellectual property regime called the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. As part of the formation of the WTO, a global minimum standard for intellectual property protection was made into law in the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) (World Trade Organization, 2006b). The TRIPS Agreement was an unprecedented agreement in scope that delineated a minimum standard for intellectual property protection across most of the globe. TRIPS institutionalized the policy goal of liberty defined as intellectual property rights. In return, countries could pursue their goals of a strong domestic economy through access to global markets and increased technology transfer to least-developed countries. These policy goals took their roots in the principles of the efficiency of free, unfettered markets.

Specifically, the TRIPS Agreement outlines the minimum standards of all WTO Member countries for the protection of intellectual property rights (World Trade Organization,
Pursuant to TRIPS, patent holders are given a limited set of rights that includes exclusive marketing rights for a set duration of time. TRIPS obligations include 20 years of patent protection from the inventor's filing date (Article 33), patent rights free of discrimination against the origin of invention or production (Article 27.1), and exclusive marketing rights for the entire patent duration (Article 28) (Correa, 2002). Transitional periods are granted before TRIPS requirements for patent protection must be met with the deadline for least-developing country members set at 2016 (Articles 65 and 66) (World Trade Organization, 2006a).

Sell argues that the global movement to link intellectual property to trade issues was the result of a lobby coalition of 'intellectual property-heavy' industries seeking to reduce the appropriation of its products in the developing world (Sell & Prakash, 2004). The research-based pharmaceutical industry was a large part of this lobby coalition, as they were concerned with the generic production of patented pharmaceutical products. Profitability and competitiveness appears to have been the research-based pharmaceutical industry's primary concern. In the 1970s, the research-based industry was in financial trouble with more stringent regulations contributing to a rise in research and development costs, with a drop in the number of new drugs approved for commercial use, and with patents on over fifty percent of the industry’s top selling 200 drugs due to expire in 1980 (Kanji, 1992). Within this context, the research-based pharmaceutical industry formed a coalition with other intellectual property-heavy industries such as the electronics, computers, software and entertainment industries, to begin more aggressively lobbying for global intellectual property rights (Sell & Prakash, 2004).

By 1986, the intellectual property coalition successfully lobbied U.S., European and Japanese governments to include intellectual property rights in the Uruguay Round of the GATT negotiations, which mark the first time that intellectual property rights were linked to trade issues on a global scale (Sell & Prakash, 2004). The success of the intellectual property lobby appears to have been related to how they framed the issues: the lack of intellectual property protection worldwide was to blame for the declining economic competitiveness of the United States and other Western nations. Sell argues that this
The initiation of the Uruguay Round did face some opposition from developing countries with manufacturing capacity, such as India, Brazil, and Argentina, among others, who were concerned about the impact of TRIPS on their ability to continue to develop technologically as well as the impact on the price of pharmaceuticals (t'Hoen, 2009). From this perspective, their argument against a global standard of intellectual property protection was two pronged: one, in the name of public health, and two, in the name of facilitating technological development. Seeing as most countries technological capacity, including the United States, in the 20th century was established through the appropriation of other countries' inventions (May & Sell, 2006), these appear to be legitimate concerns.

In this context, one of the major debates in establishing TRIPS focused on where to draw the line between protecting the property of inventors and facilitating technological development in developing countries. To date, civil society views the TRIPS requirements in facilitating technology transfer as limited and ineffective (t'Hoen, 2009).

While negotiations were underway to establish the WTO and the TRIPS Agreement, the global health community started to notice and acknowledge the scope and severity of the HIV/AIDS pandemic. In fact, Matthews argues that the severity of the HIV/AIDS pandemic was partially responsible for bringing the issue of affordable drug access and its relationship to patent protection into the global spotlight (Matthews, 2004b). At the time, antiretroviral therapy was available but the price was out of reach of most in the developing world. GlaxoSmithKline released the first antiretroviral drug onto the market (AZT) at a price of $10,000 per patient per year (Nolen 2006). The high costs of antiretroviral therapy coupled with the inability of most in the developing world, where HIV/AIDS hit the hardest, to pay for these medicines, alerted the global health community of the potential impact that the TRIPS Agreement might have on drug access.

22 Concern was also raised about the price of agrochemicals.
But the Uruguay Round of the GATT negotiations began largely out of sight and mind of the international health community. It was not until 1996 that the World Health Organization began to get involved in trade and intellectual property issues, at which point the World Health Assembly gave the WHO a mandate "to report on the impact of the work of the World Trade Organization (WTO) with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate," (t'Hoen, 2009). In the following year, the WHO issued its first guidelines to assist developing countries in their implementation of TRIPS, highlighting flexibilities permitted to facilitate access to medicines (Velasquez and Boulet, 1998). Among these were the use of compulsory licensing and parallel importing.

**The TRIPS Exceptions to Facilitate Drug Access**

TRIPS grants limited flexibility around patent rights to Member countries to address public health needs.23 Article 31, otherwise known as "compulsory licensing", permits a government to issue a third-party license without the patent-holders' consent. Articles 8.1 and 6 permit "parallel importation", where a product is imported from another jurisdiction and resold without the consent of the patent-holder.

**Compulsory Licensing**

The premise underlying compulsory licensing is the price advantage of generic competition. In general, the higher the number of generic competitors in a market, the greater the differential between the lowest and highest price for the same drug product.24 Médecins Sans Frontières reports that the prices of antiretroviral therapy in the developing world decreased to the lowest unprecedented levels as a result of global generic competition, particularly coming from Indian manufacturers (Médecins sans Frontières, 2007). In the context of increasing intellectual property, compulsory licensing

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23 Provisions also exist to prevent or remedy anti-competitive practice (Articles 8.2, 31(k) and 40). Article 30 permits an early working provision, which allows generic companies to obtain product approval and enter the market immediately upon patent expiration.

is a tool that governments are permitted to use under the TRIPS Agreement to drive drug costs down and meet their public health needs.

The research-based industry does not reject these claims; however, they are opposed to the routine use of compulsory licensing based upon its potential for several harmful effects. Rozek argues that compulsory licensing: 1) reduces prospects for economic growth in developing countries that adopt it; 2) kills the incentives for pharmaceutical firms to innovate and to introduce new products into the country; 3) encourages free-riding by imitator firms and denies local firms the opportunity to participate in technology transfer in these countries; and 4) generally demonstrates "a lack of respect for intellectual property rights," (Rozek, 2000). Given these potential consequences, the research-based industry and its supporters oppose "broad-based compulsory licensing" arguing that compulsory licensing, as stipulated by Article 31 of the TRIPS Agreement, is intended to be of limited use, mainly to address anti-trust issues.²⁵

Instead, supporters of tighter controls over intellectual property rights advocate partnerships with the industry towards freer access to drugs through tiered pricing and when needed, voluntary licensing arrangements (Attaran, 2004; Noehrenberg, 2003; Rozek, 2000). In fact, many of those who oppose compulsory licensing or parallel trade argue that the systemic problems in the health care system are the fundamental barrier to drug access. Attaran's research in the area of drug patents is a key foundation of this argument (Attaran & Gillespie-White, 2001; Attaran, 2004). In finding that patenting was rare for 319 products on the WHO's Model list of essential medicines in 65 low- and middle-income countries, he argued that patents do not prevent drug access. Instead, efforts should be directed towards "the greater causes of epidemic mortality."

Global civil society rejects these claims on several grounds. First, they argue that the research does not factor in combination antiretroviral therapy; in which case the recommended treatment regimen was patented in almost three-quarters of countries

²⁵ The specific conditions of the use Article 31 are: national emergency or other conditions of extreme urgency, public non-commercial use, possible remedy for anti-competitive practices or dependent patents.
surveyed, representing 81% of Africa's AIDS burden (Boelaert et al., 2002). Second, when TRIPS will be fully implemented, new medicines will be patented all over the world. Given this prospect, the use of TRIPS safeguards to produce or import lower-priced generics is critical to the success of AIDS treatment programs. Finally, civil society advocates addressing the determinants of health but they maintain that permitting compulsory licensing must not preclude these efforts. Focusing on a multi-pronged approach, they argue in favor of increased financing for infrastructure and comprehensive treatment programs while maximizing resources through generic prices (UN Millennium Project, 2005).

**Parallel Importation**

Parallel importation is "cross-border trade in a patented product, without the permission of the manufacturer…. [it] takes place when there are significant price differences for the same good in different markets." (t'Hoen, 2009) Parallel importation is legal under the TRIPS Agreement (World Trade Organization, 2006b) and the Doha Declaration reaffirms countries rights to both compulsory licensing and parallel importation of medicines to achieve access to medicines for all (World Trade Organization, 2001). Still, due to the higher standards of intellectual property protection required in bilateral and regional trade agreements, parallel importing has been curtailed in many countries over the past two decades (t'Hoen, 2009).  

The research-based industry's concern with parallel importation is that it would undermine their sales in developed country markets, as well as new markets in developing countries. These market losses could occur from the sale of cheap generic medicines for a large profit (Matthews, 2004a) or through the sale of lower-priced patented medicines into countries where the same patented medicines are priced higher.  

Their argument is based upon three premises: 1) parallel trade is a disincentive to pharmaceutical companies who seek to engage in discriminatory pricing arrangements  

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26 Although parallel importation is still widely practiced in the European Union.  
27 The cross-border trade in patented pharmaceuticals between the United States and Canada is one such example.
with poorer countries; 2) parallel trade taxes regulatory officials as it threatens the loss of control over regulatory standards and gives rise to quality control problems; and, 3) parallel trade is a channel through which counterfeit medicines can be distributed (Bale Jr, 1998).

Proponents of parallel trade argue that the practice actually benefits society overall and reject claims that it threatens innovation (Outterson, 2005). Furthermore, while parallel trade may discourage companies from price discrimination, global efforts are underway to deal with the regulatory burden of imported pharmaceuticals into countries with inadequate regulatory capacity. For example, the WHO Prequalification Project (WHO PQP) was established in 2001, which permits manufacturers globally to submit pharmaceutical applications for WHO PQP approval. Many African countries require WHO PQP as a precondition to large scale procurement as do several global financing sources such as the Global Fund for HIV/AIDS, Tuberculosis and Malaria (GFATM). Regarding the issue of counterfeit medicines, by linking the practice of parallel importation to counterfeits and smuggling, a practice legally pursued to the TRIPS Agreement has been given connotations of corruption and abuse.

During the negotiations that led to the 2001 Doha Declaration, the United States and the European Commission (EC) operationalized the research-based industry's concerns over parallel importation of products manufactured under compulsory licensing. The EC proposed that safeguards be put in place with generic manufacturers and importers taking measures including making medicines clearly distinguishable through special labeling, marking and packaging (Matthews, 2004a). Similar measures were incorporated as part

28 See: WHO Prequalification Program, Programme Information, available at: [http://apps.who.int/medicinedocs/index/assoc/s14087e/s14087e.pdf](http://apps.who.int/medicinedocs/index/assoc/s14087e/s14087e.pdf) [Date accessed 7 May 2010].
29 The GFATM requires that "any single- or limited-source pharmaceuticals procured with GFATM funds must have been prequalified by the WHO." See: WHO Prequalification Program, Programme Information, available at: [http://apps.who.int/medicinedocs/index/assoc/s14087e/s14087e.pdf](http://apps.who.int/medicinedocs/index/assoc/s14087e/s14087e.pdf) [Date accessed 7 May 2010].
30 There are also concerns about linking the regulation of diversion to Notice of Compliance regulations in the process of approval for generic medicines. This practice has been heavily criticized by global civil society. See: (L. Esmail, Elliott, & Foster, 2007).
31 The Doha Declaration will be discussed later in this chapter.
of the WTO Paragraph 6 Decision, where parallel importation has been reframed as diversion and subsequently made illegal.

**Global Civil Society and Access to Medicines**

In the late 1990s, global health activists argued that developing countries faced significant pressure – from the pharmaceutical industry and from some developed countries – against using compulsory licensing and parallel importation (Velasquez, Correa, & Balasubramaniam, 2004). Actions by the United States as well as the multinational research-based industry tend to support these claims. On February 18, 1998, 39 multinational research-based pharmaceutical companies filed a lawsuit against the South African Government challenging Section 15 of their Medicines and Released Substances Control Act which allowed parallel importation and compulsory licensing to protect public health under certain conditions (Barnard, 2002). That same year, the United States Trade Representative (USTR) placed South Africa on its Special 301 Priority Watch List and initiated trade sanctions against South Africa for Section 15 as well as its approval of generic versions of Taxol (As a possible TRIPS Article 39.3 violation). Eventually, the pharmaceutical manufacturers withdrew their lawsuit and the USTR dropped its sanctions.

Barnard argues that global civil society helped achieve this outcome by expanding the scope of conflict to include the public and mass media and by framing the pharmaceutical industry's greed as holding "hostage" of "millions of powerless poor" (Barnard, 2002). After the coalition received "friends of the court status' and threatened to expose further negative publicity about the companies' financial practices, the pharmaceutical manufacturers withdrew their lawsuit. Other scholars like Drezner (Drezner, 2007) argue

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32 Velasquez et al argue that "this request arose from a growing sense of frustration among developing country Members of the WTO at the spate of pressures employed by the pharmaceutical industry and certain developed country Members to impeded developing country Members' application of the public health safeguards of the TRIPS Agreement to ensure access to life-saving medicines. These disputes ranged from litigation and the treat of legal action in national courts to the initiation of dispute settlement proceedings."

that these outcomes were achieved mainly because the U.S. government increasingly viewed the HIV/AIDS pandemic as a national security threat. In the U.S. institutional context, framing a public health as a national security issue is one situation in which intellectual property rights might be traded-off. As will be discussed later, the post-9/11 Anthrax scare led to almost similar outcomes.

Eventually, a group of African countries, led by the WTO representative of Zimbabwe, asked the TRIPS Council for a special discussion on access to medicines and the TRIPS Agreement to obtain clarity and understanding on the relationship between the two and in response to the pressures that they were facing when attempting to use TRIPS flexibilities.34

WTO meeting minutes and academic literature show that country representatives took two distinct sides at these meetings.35 The African Group argued that nothing in TRIPS could prevent countries from taking measures to protect their public health interests, including measures such as compulsory licensing and parallel importing.36 Compulsory licensing could be done on any grounds, including "public interest" or "in cases of national emergency". Meanwhile, the United States led a group of 'like-minded countries' in arguing that TRIPS already contained enough flexibility for country governments to address their public health needs (Abbott, 2002); however, the only explicit support that the U.S. issued was in favour of these measures in Sub-Saharan African countries in the case of HIV/AIDS. These two groups justified their positions based upon very different conceptions of security. The African group valued health goals through immediate access to affordable drugs but also couched their arguments in terms of the transfer of technology to facilitate socioeconomic and technological development.

34 See: Comments by Ambassador Boniface Chidyausiku (Zimbabwe) (on behalf of the African Group); Meeting Minutes of the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines. 10 July 2001. IP/C/M/31
35 For details on these debates, see: Meeting Minutes of the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines. 10 July 2001. IP/C/M/31
36 See: Comments by Ambassador Boniface Chidyausiku (Zimbabwe) (on behalf of the African Group); Meeting Minutes of the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines. 10 July 2001. IP/C/M/31
"Rather than being seen as an end in itself, IPR protection is intended as a means to benefit society as a whole. The mere existence and the protection of IPR, such as patents, does not necessarily result in the fulfillment of the objectives of the TRIPS Agreement. The experience of the past six years since the Agreement was established provides clear evidence of this. In the context of public health, patent rights should be exercised coherently to the mutual advantage of patent holders and the users of patented medicines, in a manner conducive to social and economic welfare and to balance rights and obligations."  

At the TRIPS Council session, the United States still espoused the security goal of addressing the problem of infectious diseases, especially HIV/AIDS, but the means by which to address it fundamentally differed in comparison to the African Group. As opposed to promoting drug access through reducing the liberty of patent-holders and permitting compulsory licensing and parallel importing, they advocated increasing drug access through protecting the liberty of patent-holders, which would encourage innovation and lead to new treatments for disease. They advocated additional measures to improve drug access that did not restrict the patent rights of the research-based pharmaceutical industry.

First, they framed the problem of drug access as a broad development issue, with a lack of infrastructure being one of the most fundamental problems. Second, they framed the solutions as encouraging health technology innovation to ensure treatments are available and bilateral and international aid in support of a more comprehensive approach that improves health system infrastructure. The means by which this would be accomplished was through abiding by TRIPS and providing the incentive of market exclusivity and profit-maximization to encourage innovation along with the benefit of foreign direct investment.

37 See: Comments by Ambassador Boniface Chidyausiku (Zimbabwe) (on behalf of the African Group); Meeting Minutes of the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines. 10 July 2001. IP/C/M/31

38 See Comments by United States representative to the TRIPS Council: Meeting Minutes of the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines. 10 July 2001. IP/C/M/31

39 See Comments by United States representative to the TRIPS Council: Meeting Minutes of the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines. 10 July 2001. IP/C/M/31
Aid in the form of comprehensive programming is often advocated and implemented to help address infrastructure and capacity issues in resource-poor settings. While much of the health community agrees about the importance of this kind of holistic approach to medicines access (UN Millennium Project, 2005), conflict arises when aid as comprehensive programming is framed as a trade-off with addressing issues around drug affordability, particularly in relation to patents. The research-based industry contributes a large amount of financing, programmatic support and donations to facilitating drug access in developing countries40 but the industry tends to frame these philanthropic programs as a substitute for supporting measures that might impose more limits on their intellectual property rights (Henry & Lexchin, 2002). Meanwhile, many developing country governments view their right to use patent flexibilities to pursue medicines access as fully compatible with the continuation of industry-supported aid programs.41

**The Doha Declaration and The Paragraph 6 Decision**

By November 2001, the WTO unanimously agreed upon the Doha Declaration, which contained language that clearly placed the health priorities of access to affordable drugs over the protection of intellectual property.

"The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

(World Trade Organization, 2001)


41 See: Comments by Ambassador Boniface Chidyausiku (Zimbabwe) (on behalf of the African Group); Meeting Minutes of the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines. 10 July 2001. IP/C/M/31
Two months before the unanimous declaration, the United States faced a threat of Anthrax after the September 11th attacks. These attacks led both the United States and Canada to threaten the use of compulsory licensing to increase stocks of ciprofloxacin. Both countries stopped short of implementing this measure and the Minister of Industry Allan Rock quickly distanced himself from the decision (McGregor, 2002). Once again, the potential of a national security interest almost trumped the liberty of patent-holders but in this case, the compulsory licensing threat was revoked. Health activists argue that these measures illustrated the double standard that some Western countries held themselves up to, making the Doha Declaration achievable (Abbott, 2002; Elliott, 2006).

After the Doha Declaration, one issue was still left unresolved: how would countries that did not have sufficient pharmaceutical manufacturing capacity benefit from the compulsory licensing flexibility provided in TRIPS? The so-called "Paragraph 6" dilemma was yet another divisive debate pitting a group of countries led by the U.S. and the EU against a group of developing countries, which included India and Brazil (Abbott, 2005). The debates on Paragraph 6 and where countries stood becomes relevant to the Canadian debate because some of the arguments and debates that were resolved in this venue were reintroduced in the Canadian context.

Abbott describes the negotiations that led to the Paragraph 6 Decision. Essentially, a debate unfolded over the scope of patent-holder liberties that countries would be allowed to curtail and how this would be done, to ensure affordable drug access (Abbott, 2005). Canada sided with a group of countries that was led by the United States and included Australia, Japan and Switzerland. Among the terms for compulsory licensing for export that the U.S.-led group advocated were: first, that the Paragraph 6 Decision should only be used for HIV/AIDS, malaria, TB and "other epidemics" as stated in Paragraph 1 of the Doha Declaration; second, the Paragraph 6 Decision should only be used by a defined set of countries; third, the Decision should be limited to "emergencies"; fourth, to ensure

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42 Letters containing anthrax spores were mailed to two Democratic U.S. Senators and several news media offices. The spores killed 5 people and infected 17 others.

43 See CP-Tech website for more information: http://www.cptech.org/ip/health/cl/cipro/

44 This position was also supported by the EU.
the Decision was "not for commercial gain" and fifth, whether the solution would fall under an Article 31(f) or Article 30 solution. Essentially the battle was over issues relating to equity and efficiency: first, who would benefit from the Decision and under what conditions; second, whether or not generic companies would be allowed to make a profit.

The fight on the issue of the scope of diseases was possibly the most contentious issue throughout these negotiations with the US walking out on negotiations on December 16, 2002, the day of the deadline, over this particular issue (Abbott, 2005). The issue was clear: defining what list of diseases could and couldn't be eligible for compulsory licensing was a controversial issue, suggesting that some diseases or conditions were not urgent or important enough to warrant compulsory licensing. In fact, the US insisted that the Paragraph 6 Decision should be limited to HIV/AIDS, malaria, tuberculosis and other infectious diseases of "comparable gravity and scale" and demanded that asthma, diabetes, and cancer should be excluded. What became obvious is that the US-led alliance on this issue had a vested security interest in addressing these three major infectious diseases and preventing compulsory licensing from encroaching on the lucrative chronic disease market of the research based industry.45

The issue was finally settled over 8 months later on August 30th, 2003, with the understanding that a Chairperson's text would accompany the Paragraph 6 Decision "…which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented."(World Trade Organization, 2003a). Furthermore, the final Decision did

45 A representative from the IFPMA, Eric Noehrenberg, argued that the Paragraph 6 negotiations were being "hijacked [by the] commercial interests of copy producers in some mid- to high-income countries." He continues: "[t]hese interests have turned the debate away from AIDS drugs for poor countries, instead of trying to deform this process into promoting copies of all drugs for all countries, including industrialized countries." He argued that given the lack of purchasing power in poor countries, imitator companies would take advantage of the system and produce drugs for rich countries, proposing that these companies would go so far as "..to copy drugs such as Viagra or heart disease drugs for richer countries..." While it is possible that imitator industries would game the system, civil society activists viewed such allegations as preposterous.
not specify any list of diseases, certain countries agreed to opt out of the arrangement, and Article 31(f) was the solution.46

Ultimately, the Paragraph 6 Decision debates were over liberty, efficiency, security and equity: how much could governments restrict intellectual property rights to achieve generic competition to facilitate drug affordability? The equity issues involved the questions of how and to whom these benefits would get distributed and what the scope of these benefits would be.

**Canada's Policy Legacy in Pharmaceuticals and Intellectual Property**

Canada has a history of using compulsory licensing towards the production and importation of pharmaceutical. In recent history, the Liberal Government amended its Patent Law to better facilitate compulsory licensing in 1969, after a series of reports identified patent protection as one of the major contributors to high drug costs in Canada (Lexchin, 1997).47

As Doern and Sharaput explain, Bill C-190 was framed as a tool to improve affordable access to medicines through encouraging competition and was part of a larger effort to contain escalating drug costs (Doern & Sharaput, 2000). The Liberal Government's primary argument for compulsory licensing was that the immediate welfare of the general public took priority over the private interests of the research-based pharmaceutical industry and creating incentives for innovation. More specifically, they framed the trade-offs on three different dimensions: first, it was about balancing pharmaceutical innovation with the dissemination of its products; second, it was about balancing industry profits with the health and welfare of society through equal access to health care; and, third, it was about balancing industrial autonomy with intervention and regulation. The

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46 During the Paragraph 6 negotiations, developing countries with local manufacturing capacity were in favor of addressing the Paragraph 6 dilemma with an Article 30 approach, viewed as a more flexible mechanism to allow compulsory licensing for export. In opposition, the United States and the European Commission (EC) advocated a more limited approach under Article 31(f). Quite early on in the negotiations, these developing country representatives abandoned Article 30, realizing that the US and EC would be unwilling to accept this approach. See Abbott, 2005.

47 Compulsory licensing to manufacture was a part of the Patent Act since 1923.
government explicitly traded off the liberties of patent-holders on the basis of securing access to affordable drugs and the health and welfare of society.

During the introduction of Bill C-190, the Liberal Government did not appear to anticipate the emergence of the Canadian generic drug industry (Doern & Sharaput, 2000); however, Canada's generic pharmaceutical manufacturing industry grew as a result of widespread compulsory licensing of pharmaceutical products (Jenish, 2003). From 1969 to 1992, Canada issues 613 licenses import or manufacture medicines under compulsory license (Reichman & Hasenzahl, 2003). Robert Kaplan, a cabinet minister under the Trudeau government and subsequently a lobbyist for the generic industry, described the compulsory licensing policy decision as follows: "We were a receiver of pharmaceutical innovation rather than a generator. The drug companies were unhappy about it, but we thought they were bluffing and that they would consider Canada a good place to provide their products." (McGregor, 2002) The Government did not believe Canada was losing anything from an economic competitive standpoint and given Canada's negligible role in pharmaceutical innovation, the government did not see compulsory licensing making any impact on the R&D budgets of the innovative pharmaceutical industry. From the government's perspective, the only thing this policy decision traded away were the profits of the patent-holding companies (Doern & Sharaput, 2000).

The story changed significantly in 1987, when Conservative Prime Minister Brian Mulroney signed the Free Trade Agreement (FTA) with the United States (Lexchin, 1997). Bill C-22, which amended the Patent Act and extended patent protection to 17 years in Canada, is viewed by some as linked to Canada's accession to the Free Trade Agreement with the United States and heavy lobbying by the multinational pharmaceutical industry (Lexchin, 1983). The Mulroney government justified the change in patent law on the three basic premises: it reconciled domestic regulation with internationally mandated standards; it boosted R&D in Canada; and it incorporated Canada as a contributor to global pharmaceutical R&D (Doern & Sharaput, 2000). These arguments mark a dramatic shift in frames from the 1960s, which defined pharmaceutical
innovation as a long-term health security issue and as a resource shared by a global community. Now that Canada would contribute to global R&D, it could legitimately access to new drugs. From a domestic economic standpoint, the government wanted to steer Canada towards a more competitive, "knowledge-based economy" and in return, it would receive access to more open U.S. markets (Doern & Sharaput, 2000).

While the Mulroney government traded away one of its mechanisms to contain drug costs, it gained a new one. As a concession to removing compulsory licensing in 1987, Canada introduced the Patented Medicines Prices Review Board (PMPRB) (Doern & Sharaput, 2000). The PMPRB is an independent quasi-judicial tribunal, which limits the prices set by manufacturers for all patented medicines sold in Canada to ensure they are not excessive.48 Among its price control functions, it requires that the price of new 'blockbuster drugs' introduced onto the market be less than the median price of seven OECD countries.49 Despite the fact that Canada traded away its policy tool to limit the intellectual property rights of patent-holders, it still had a mechanism to somehow control the escalation in drug costs.

Bill C-91, introduced in 1993, was required for Canada's accession to the North American Free Trade Agreement (NAFTA) and the World Trade Organization (WTO) (Doern & Sharaput, 2000). It effectively abolished compulsory licensing from Canada's mechanisms to contain escalating drug costs.

Overall, Canada's history of intellectual property protection in the area of pharmaceuticals is one of shifting priorities and policy tools. While the Liberal Government's introduction of compulsory licensing in the 1960s was deliberately framed as a mechanism to contain drug costs through increased competition, the Conservative Government's limitation and eventual repeal of compulsory licensing in 1987 and 1993 were explicitly linked to the benefits of free trade and a movement towards a knowledge-

49 Breakthrough drug prices are limited to the median of the prices for the same drugs charged in other specified industrialized countries that are set out in the Patented Medicines Regulations (France, Germany, Italy, Sweden, Switzerland, U.K. and the U.S.).
based economy. These policies gave patent-holders more rights through longer durations of patent protection; 20 years with Bill C-91. This shift in Canada occurred in a context of a global movement towards increasing standards of intellectual property protection and the promotion of the idea of building competitive, knowledge-based economies.

**Canada's Place in the Global Access to Medicines Debate**

During this time, Canada's position on the global stage was mixed. In 1998, the Canadian representative at the World Health Assembly expressed concern over the impact of patent protection on drug prices.

"...experience had shown that those in the health sector needed to play a much more active part, both individually and collectively, in international trade discussions. Regrettably, industrial or intellectual property considerations often took precedence over health concerns in current trade negotiations..." (Velasquez et al., 2004)

In 2000, at the International AIDS Conference in Durban, South Africa, the Minister of International Co-operation issued Canada's support of "...international agreements to make lower priced generic AIDS drugs accessible to developing countries, especially in cases of emergencies..."  

Canada issued an ambiguous message but by and large supported the U.S. position during these negotiations using a slightly different discourse. They supported a balance between protecting inventors' rights and providing flexibility under the TRIPS Agreement to allow governments the policy space to address their health and social priorities. In doing so, they referred to the WTO ruling in the case of the EU against Canada.

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51 See Comments by Canadian representative to the TRIPS Council: Meeting Minutes of the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines. 10 July 2001. IP/C/M/31
"…we believe that in the EU case against Canada – Patent Protection of Pharmaceutical Products – the Panel came to a balanced and sensible decision in favour of Canada's "regulatory review exception". The Panel clearly determined that there is scope for flexibility in the TRIPS Agreement. Certainly in arguing our defence, Canada called upon the balance that exists between the rights of those creating the inventions and health and social priorities. That balance, and the flexibility in the TRIPS Agreement, plays an important part in finding a solution to the HIV/AIDS health crisis. But we must also note that without effective patent protection we will not have research and development and new medicines and solutions to help solve health crises/pandemics."52

Canada's statements and actions vis-à-vis patents and pharmaceuticals support the perception that under the Liberal government, Canada maintained a complex balance in order to facilitate its own health and social goals. However, in the case of developing countries, this professed "balance" weighed in favour of the liberty of patent holders. Drug access would be achieved through encouraging innovation, aid programs and addressing health system infrastructure. Research and development required the incentives provided by patent protection and tax breaks. In contrast with U.S. rhetoric, they spoke of the security goal of affordability and applauded the voluntary price reductions from the research-based industry. They encouraged movement towards a global differential pricing scheme but underlined the goal of preventing the diversion of these medicines back into profitable markets. As a security issue, HIV/AIDS was the disease of focus.

Canada's Implementation of the WTO Paragraph 6 Decision

On September 10, 2003, the CGPA wrote a letter to Pierre Pettigrew, Minister of International Trade, requesting that the government change its patent laws to allow for

52 See Comments by Canadian representative to the TRIPS Council: Meeting Minutes of the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines. 10 July 2001. IP/C/M/31
the manufacture of generic drugs, subsequently reported in the Globe and Mail. In this letter, they framed drug access as developing countries access to affordable generic drugs. The means by which to get there was implementation of the Paragraph 6 Decision and removal of so-called "export restrictions" of the Canadian Patent Act.

"Currently, these export restrictions prohibit the production and export of products under Canadian patent protection, even if the product is not protected in the country where it is to be sold."54

The generic industry was lobbying in favour of the security goal of drug affordability for Sub-Saharan Africa for "health crises" and HIV/AIDS. Security would be achieved through efficiency, as defined by generic drug production and trading off patent-holders' rights and liberty. Within the same letter, the CGPA brought up the issue of the Free Trade Area of the Americas (FTAA) negotiations that considered incorporating patent term restoration, thereby granting more market exclusivity to patent-holders. They argued against this increase in liberty on the basis of the security of Canadian's affordable drug access as well as the security of the domestic economy through a strong Canadian generic pharmaceutical industry.

Coincidentally, Stephen Lewis was the scheduled keynote speaker at the Canadian HIV/AIDS Legal Network's annual meeting shortly after the CGPA's letter, on September 12, 2003. Prior to his keynote address, Richard Elliott, the Director of the Canadian HIV/AIDS Legal Network, proposed to Lewis that they push the Canadian government to implement a change in the legislation regarding generic exports. Lewis mentioned the issue briefly during his keynote address and one week later at the

54 CGPA Letter to Pierre Pettigrew, Minister for International Trade, September 10, 2003, "Re: Canada's Implementation of Doha Agreement and FTAA Negotiations"
55 The Free Trade Area of the Americas (FTAA) was an "effort to unite the economies of the Americas into a single free trade area...in which barriers to trade and investment will be progressively eliminated." See: http://www.ftaa-alca.org/Alca_e.asp
International Conference of HIV/AIDS and Sexually Transmitted Infections in Africa (ICASA) in Nairobi.

“If a major Western government would undertake the simple legislative amendment allowing for the production and export of generic antiretrovirals, it would make a tremendous difference for Africa,” he said yesterday in Nairobi. “It would save millions of lives, it would cost nothing and it's such an easy thing to do.” (Nolen, 2003)

Stephanie Nolen, a reporter for the Canadian national newspaper, The Globe and Mail, reported Stephen Lewis' call to the Canadian federal government to amend its Patent Act to implement the Paragraph 6 Decision (Nolen, 2003). Her report shows that Lewis framed the ultimate goal as addressing the global HIV/AIDS pandemic. The problem, he argued, was the insufficient supply of affordable, generic antiretroviral drugs to meet the WHO three-by-five initiative57. He called on the federal government to put patent rights in the backseat by amending Patent Law to "allow the large-scale production of generic drugs". Doing so would meet Chrétien's commitment to fight AIDS, would be congruent with the Canadian public's humanitarian sentiments and would be in line with Canada's domestic economic capacity, given its large generic industry. The move would also change the political atmosphere by having a G7 government curtail patent rights in support of poor countries' welfare. He did not see the legislation trading-off with Canada's domestic research-based industrial capacity. He pushed the government by emphasizing that they were quick to trade-off patent-holder liberties when it came to Canadian's access to drugs during the anthrax scare.

“I realize that this is difficult,” Mr. Lewis said. “I'm not prepared to argue about it while people are dying. . . . Remember how [then-health-minister] Allan Rock was prepared, in a snap, to waive patent law for low-cost drugs when there was

57 “The "3 by 5" initiative, launched by UNAIDS and WHO in 2003, was a global TARGET to provide three million people living with HIV/AIDS in low- and middle-income countries with life-prolonging antiretroviral treatment (ART) by the end of 2005.” See: http://www.who.int/3by5/en/
the anthrax scare? If you can do that for Canadians, why not for Africans?" (Nolen, 2003)

Elliott reiterated these frames in a subsequent op-ed with a few additional arguments (Elliott, 2003a). The trade-off was simple: Canada's Patent Act would be amended to curtail patent-holders' rights and eliminate the export restrictions to permit compulsory licensing in specific situations. The goal was to eliminate the vast suffering and economic toll of HIV/AIDS and also, tuberculosis, malaria and "other illnesses". The legislation would be geared towards countries that lacked domestic manufacturing capacity, as described in the Paragraph 6 Decision. Elliott argued that Canada's implementation of the Paragraph 6 Decision would also fulfill Canada's commitment at the UN in its Declaration of Commitment on HIV/AIDS and would be completely in line with Canada's international trade obligations. Elliott also suggested that the initiative would send "a strong signal, from a wealthy country, that the health of the developing world will not always be sacrificed to placate multinational corporations."

Despite all of this, Elliott argued that Canada impeded the realization of improved drug access throughout the negotiations leading up to the WTO Paragraph 6 Decision. He stated:

"…wealthy players like the U.S., the European Union, Switzerland and Canada, acting in the interests of multinational pharmaceutical companies, repeatedly tried to weaken proposals from developing countries -- even going so far to argue that any solution could only apply to generic medicines to treat certain diseases, leaving poor people with an illness not on the "approved" list to suffer and die without treatment." (Elliott, 2003a)

He also acknowledged the Paragraph 6 Decision itself as containing barriers to drug access but suggested it could be implemented in a way that would still be able to help countries.
"The WTO deal is imperfect. It creates too much red tape, too many procedural hoops for countries to jump through. And it sets up too many opportunities for governments beholden to 'big pharma' to challenge sovereign developing countries in their attempts to make use of the agreed-upon procedure. But despite its flaws, the deal could, if robustly implemented with a minimum of interference, help countries circumvent patent restrictions and import generic versions of patented medicines if they cannot manufacture them within their own borders."(Elliott, 2003a)

At this stage, for civil society, it was about trading off a negligible amount of liberty from the research-based industry in return for providing the security of affordable, generic drug access for HIV/AIDS, tuberculosis and malaria in poor, developing countries that cannot manufacture medicines. It was also about fulfilling political commitments, about sending a political signal that a strong G7 country will support the prioritization of public health over intellectual property rights.

The following day, the Globe and Mail’s front page follow up with the headline: Ottawa heeds call on AIDS (Scoffield & Chase, 2003). Although the government had yet to issue an official announcement, reporters’ questions towards Industry Minister Allan Rock and Foreign Affairs Minister Bill Graham brought forth the government’s plan:

“...I’d like to see it happen as soon as we can. I think it’s consistent with the Prime Minister’s African agenda, and it would show leadership on the part of Canada to support global health concerns.”58

“I think we need to accept Stephen Lewis’s challenge.”59

At the time, Prime Minister Chrétien was in his final two months in office. Chrétien announced that he would step down from the leadership of the Liberal Party in February

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58 Allan Rock, Minister of Industry, quoted by the Globe and Mail.
59 Bill Graham, Foreign Minister, quoted by the Globe and Mail.
2002, at which time he initiated a foreign policy agenda that was more progressive\textsuperscript{60}: he doubled Canada's aid contribution by increasing the aid budget by 8% per year; he announced that Canada would ratify the Kyoto Accord; as Chair of the 2003 G8 summit in Kananaskis, he put Africa at the forefront of his agenda; and, he became a strong leader of NEPAD, the New Partnership for Africa's Development and ended up pursuing a "more activist international agenda, particularly in the area of aid and development" in his last year in office. On the surface, facilitating compulsory licensing to allow increased access to affordable medications in developing countries falls in line with this activist international policy legacy Chrètien is argued to have left. That Parliament passed the legislation as "The Jean Chrètien Pledge to Africa Act", illustrates the high profile that this legislation took. Schattschneider says that the visibility of an issue is one of the key variables that affect policy outcomes (Schattschneider, 1957). Given the international attention related to this legislation from celebrities and high profile public figures such as Bono (rock star and anti-poverty activist), Kofi Annan (UN Secretary General), and Carol Bellamy (UNICEF) – the Liberal government received significant visibility.\textsuperscript{61}

Initially, the International Federation for Pharmaceutical Manufacturers and Associations (IFPMA)\textsuperscript{62} responded with stinging criticism, stating that the Canadian government was trading off the country's domestic economic interests, threatening pharmaceutical innovation, and eroding intellectual property rights in return for very little (Chase & Fagan, 2003). They framed the real problems in the developing world as those of health systems infrastructure and lack of development. Harvey Bale, the Director-General of the IFPMA at the time was quoted in the Globe and Mail as saying that the initiative was "window-dressing", it "won't solve a thing" and that it would erode patent protection and would affect domestic R&D investment.

It will be a “negative black eye for Canada” that will “very well affect the investment climate,” Mr. Bale said (Chase & Fagan, 2003).

\textsuperscript{60} Fraser, Graham. "Foreign policy in the Chretien years." Policy Options, February 2006, pp67-72.
\textsuperscript{61} Media reports indicated Chrètien's desire to pass the legislation in time for South African President Mbeki's visit to Canada and before parliament adjourned. (Toronto Star, Nov. 5, 2003)
\textsuperscript{62} The IFPMA represents "the R&D pharmaceutical industry, including the biotech and vaccine sectors." See: http://www.ifpma.org/
Mr. Bale questioned whether the Liberal government, even if it did introduce legislative changes, would be doing much to help Africa. He argued that the real need of Africa was more money for medical infrastructure. He did not see the need for another international supplier of cheap drugs, as India was already serving that role and was being matched by research-based manufacturers supplying drugs at no profit or below cost.

Canadian drug-makers jumping into the fray will simply be “undercut by the Indian generic companies, the Chinese generic companies, and others,” Mr. Bale said. India is so cheap a manufacturing centre that it already supplies large amounts of active drug ingredients to higher-cost centres like Canada (Chase & Fagan, 2003).

Only 2 weeks after these inflammatory remarks made by Harvey Bale, both the IFPMA and Canada's Research-Based Pharmaceutical Companies (Canada's Rx&D) came out with a more conciliatory tone, stating support for the legislation. On October 1, 2003, the IFPMA and Rx&D release "Partnership for Developing Countries", reiterating their commitment to the problems of the developing world (Canada's Research-Based Pharmaceutical Companies, 2003). They publicly endorsed Canada's decision but framed it as only applicable to a certain list of diseases.

"Rx&D welcomed the WTO Decision to strike a balance between addressing the needs of the poorest countries while ensuring the protection of intellectual property, which in turn fosters the future development of new therapies." ....The Decision relates to the provision of generic medicines to treat HIV/AIDS and other life-threatening diseases such as tuberculosis and malaria. The global pharmaceutical industry has been at the table internationally on this issue and is pleased to cooperate with Canadian officials."(Canada's Research-Based Pharmaceutical Companies, 2003)

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63 Canada's Rx&D is "the association of leading research-based pharmaceutical companies..." See: https://www.canadapharma.org/en/default.aspx
During the month of confidential backroom meetings with government officials, media reports were coming out about some of the policy alternatives that the government was considering. Among these included the reintroduction of U.S.-led interpretations of equity and liberty concerns. Reports stated that the government was considering limiting their initiative to "health emergencies" and to a set of diseases (Fagan, 2003). Access to Information documents show that civil society opposed these measures requesting the government to remove these clauses and others that other contentious issues, such as: 1) wording that refers to the legislation as only for humanitarian purposes; 2) a restricted list of eligible medicines; 3) allowing NGOs to contract directly with Canadian generic manufacturers.64 These measures show how the Liberal government was defining to whom and under what circumstances, increased equity in drug access would be attained: for a set of infectious diseases, for some countries, and only if they were facing a 'health emergency'.

Throughout the fall, opposition parties criticized the Liberal Party in Parliament over the apparent delay in introducing the legislation but it was clear early on that the Liberal initiative would receive all-party support. With this last session of Parliament under the leadership of Prime Minister Jean Chrétien ending in November, opposition parties accused the Liberal party of "botching" the initiative and getting tied up in interest group politics, despite the urgency of the cause.

Finally, on November 6, 2003, the Liberal government introduced Bill C-5665, An Act to Amend the Patent Act and the Food and Drugs Act.66 Over the course of the next few days, each party issued its concerns about the legislation and by doing so, effectively framed what drug access meant to them.

65 The legislative initiative was first tabled in Parliament as Bill C-56 and then reintroduced in the following session as Bill C-9.
Overall, there was not a lot of difference between the parties in how they framed the initiative and the issues that were raised. On the whole, parties framed the purpose of the initiative as increasing access to medicines in developing countries, particularly in Africa to HIV/AIDS, malaria, tuberculosis and other epidemics. All parties spoke of the devastating effects of the HIV/AIDS pandemic in Africa, the scale of human tragedy, the suffering, the deaths, and the social and economic impact. Still, parties differed slightly in terms how they defined the security, equity, liberty and efficiency issues that were relevant to this debate.

The NDP came out particularly strong with respect to their stance on liberty issues. They accused the Liberal government of pandering to the research-based pharmaceutical industry's interests with the inclusion of the right of refusal, a clause introduced at the last minute by the Liberal Government that gave patent-holders' the right to take over generic company contracts under the regime.

"...the NDP has been pressing for drug legislation that will provide relief to millions in Africa suffering from AIDS. We now have a bill before us that is seriously flawed and in fact is a big giveaway to big pharma."

They argued that the clause prevented the flow of affordable medicines as it would block and dissuade generic companies from participating in the initiative. The NDP also showed their support of the Canadian NGOs by acknowledging their work in developing countries and at home, in advocating for change.

The Bloc Quebecois issued a much more complex position, prioritizing security over liberty but still advocating a balance between these goals. On top of the overall push for access to affordable AIDS drugs, the Bloc Quebecois's major security concerns were quality, innovation and ensuring that the legislation did not "interfere in the domestic

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68 For a detailed discussion of the right of refusal, see: (Elliott, 2003b)
market” through threatening Canadian's access to medicines and domestic economic interests. Through citing a policy statement by the NGO Oxfam, the Bloc seemed to support the idea that the liberty of patent-holders interfered with the security of affordable drug access in Africa, and that these liberties should be curtailed.

"Oxfam…issued a release saying…that the proposed mechanisms for suspending patents can represent major progress in the fight against diseases since the high cost of patented drugs is the main cause of death for 14 million people each year."70

They also opposed the right of refusal. Notably, an individual Bloc MP issued a slightly different position, stating that the legislation must ensure a balance between access to affordable medicines and encouraging innovation and R&D.

The Bloc supported Oxfam's concerns about how equity was being interpreted in the implementation, opposing any limited lists of medicines or countries and stating that the legislation should not be limited to public health emergencies. Citing efficiency concerns, the Bloc emphasized that the legislation should not be used for commercial purposes and the importance of preventing diversion and abuse of the regime.

In contrast, the Conservative Party seemed to reflect more of the research-based pharmaceutical companies' interests. In their support of the initiative, they acknowledged that the Paragraph 6 Decision permitted the limitation of patent holder liberties for the purpose of increasing access to affordable generic drugs in poor countries.

"In August 2003, the World Trade Organization agreed on legal changes that would make it easier for poorer countries to import the cheaper generic drugs

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made under compulsory licensing if they are unable to manufacture the medicines
themselves."71

That said, they, applauded the efforts of the research-based industry in issuing voluntary
licenses, the most recent being GSK's license to AspenPharmacare in September for the
production of antiretroviral drugs. Their statements supporting drug affordability and
patent flexibilities were balanced by emphasizing the importance of other security issues
such as poverty, nutrition, clean water and infrastructure.

"We in the Canadian Alliance hope the government recognizes that drugs are only
one component of improving care in African countries and other developing
nations that have been ravaged by HIV/AIDS, malaria and tuberculosis. Poverty,
distribution problems, and a lack of medical care continue to compound the
problem of public health crises in these countries. While we support the provision
of cheaper drugs, we must look at it, as I have said, in a very holistic manner."72

They also focused on the importance of encouraging innovation and ensuring that the
legislation achieves a balance between the two security objectives of innovation and
affordable drug access.

From an equity perspective, the Conservative party emphasized the inequity in disease
burden in these countries and the particular vulnerability of women to HIV/AIDS. They
advocated the legislation's use in "health emergencies". Also, they applauded the
research-based industry's aid efforts in providing low-cost drugs to developing countries.

The Liberal government introduced the measure in the context of global health leadership
and Canada's aid initiative and Chrétien's focus on Africa and its development. Bill C-56
was a humanitarian initiative, rhetoric that exists in the WTO Paragraph six decision, but

that was attributed to the Canadian government's philosophy. The legislation was about respect and the moral obligation to assist those in need.

"All those who have the privilege of living in a healthy environment should turn to those in need and help them. These people have a right to the same human respect, they need our help and they need to live." 73

From an equity perspective, the Liberals' aid and this Paragraph 6 implementation would help address the gap in welfare between the North and the South. More specifically, Bill C-56 would meet the security goal of increasing drug affordability, for HIV, TB malaria and other epidemics.

The Liberal government maintained that intellectual property rights would be maintained and that they would "fully respect the Patent Act". They encouraged other countries to follow suit.

"Today, we are setting an example, but we are also inviting other western countries to imitate Canada and do what we are doing today." 74

**The Liberal Government Tables Bill C-56**

The Liberal government publicized its legislative initiative in an opinion editorial piece in the Toronto Star (Graham, 2003). Bill Graham, the Minister of Foreign Affairs, framed the legislation almost exclusively in terms of the HIV/AIDS pandemic. In terms of equity, he spoke of the injustice of the global response to HIV and the inequitable access to medicines worldwide. In terms of security, by increasing access to affordable medicines, the decline in social development, economic progress, strained health care systems and international security would start to be addressed.

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"Taking this step is essential to prevent HIV/AIDS and other infectious diseases from subverting efforts Canada and other nations are trying to make on major global issues. The impact of HIV/AIDS in particular is threatening to undermine social development, economic progress and security in many developing regions."(Graham, 2003)

The government acknowledged other ways of addressing HIV/AIDS including prevention efforts and access to care and support but affordable medicines was a key component of a more comprehensive approach. The legislation was also framed in terms of human rights.

"The current initiative sets a unique global standard on the frontiers of public health and human rights."(Graham, 2003)

Graham mentioned the importance of innovation but clearly prioritized access to affordable medicines in developing countries as something more important.

"We all benefit when intellectual property rights provide incentives for innovation. But the problem is that sick people in poor countries cannot wait until new medicines are affordable. With these lives at stake, government should responsibly intervene to ensure that medicines are available to those unable to pay market price."(Graham, 2003)

The article makes clear that the government did not necessarily see themselves as providing medicines for the entire developing world. The rhetoric suggests that the government openly acknowledged that the legislation played an important symbolic role, which might then have worldwide impact.

"If other developed countries follow suit, millions of lives will be saved, and a precedent will be set for similar arrangements in other areas when principles of international commerce conflict with basic human needs."(Graham, 2003)
The research-based industry responded to Bill C-56 with a positive tone. Rx&D released a press statement on November 6th proclaiming its support of the federal government's efforts to formulate this initiative.

"Canada's Research-Based Pharmaceutical Companies (Rx&D) and the Government of Canada share a common objective: to provide medicines to countries in need."  

The statement illustrates a common goal but as Stone said, it's only the language with which to battle for underlying policy objectives.

Through the emphasis of their philanthropic programs, the research-based industry illustrated their commitment to improving the equity of drug access and health care in the developing world.

They supported the goal of "providing and distributing affordable medicines" but also reframed the security issues beyond drug access to include health systems capacity and infrastructure issues.

"Getting the medicines to the destination is a first step. There also needs to be a strong distribution network in place, proper physician supervision and adequate medical facilities."  

Their fundamental role as pharmaceutical innovators was stressed in providing new medicines and improving the quality of health care to Canadians. They argued that over 90% of the medicines were developed by the research-based pharmaceutical industry.

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75 Canada’s Research-Based Pharmaceutical Companies (Rx&D). Press release: "Rx&D Supports Drug Legislation for Developing Countries. OTTAWA (November 6, 2003).
76 Canada’s Research-Based Pharmaceutical Companies (Rx&D). Press release: "Rx&D Supports Drug Legislation for Developing Countries. OTTAWA (November 6, 2003).
They highlighted their role in the domestic economic, stating that over 60 member companies providing jobs to more than 23,000 Canadians.

The industry framed Bill C-56 as "respecting and allowing a role for the innovative pharmaceutical industry." 77

The CGPA framed the purpose of Bill C-56 in very different terms. Access to medicines was about providing "low-cost, Canadian-made generic pharmaceuticals to developing countries in times of health crises." 78 The CGPA highlighted the quality and affordability of Canadian generic drugs, arguing that they were priced, on average, 45% less than their brand name equivalents. In this way, the generic companies helped the government achieve the goal of controlling health care costs.

With regard to specifics of the legislation, the CGPA opposed the right of refusal, which provided brand-name companies with the option of taking over contracts already negotiated with developing countries.

"If the brands want to reduce their prices for developing countries they should just do it. They shouldn't be allowed to wait and see if a generic is going to produce it." 79

They also linked patent protection to a threat to the domestic economy. The export provisions of the Patent Act prevented generic companies from manufacturing and exporting drugs to countries where patents do not exist, which forces the Canadian

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77 Canada's Research-Based Pharmaceutical Companies (Rx&D). Press release: "Rx&D Supports Drug Legislation for Developing Countries. OTTAWA (November 6, 2003).
generic industry to locate their manufacturing facilities abroad, resulting in job and investment loss.

The generic industry emphasized the goal of efficiency, by arguing that bringing a drug to market is expensive and takes time, implying that they cannot justify making such investments without a return on their investment.

Civil society on the other hand responded with mixed criticism. Médecins Sans Frontières (MSF) accused the government of failing to measure up to the stated intent of the legislation. From their perspective, the main purpose of the legislation was to achieve efficiency through generic competition.

"...the experience of Médecins Sans Frontières is that real competition is what drives down the prices of essential medicine, which is a key to treating patients." 80

They argued that the right of refusal clause threatened generic competition by reducing the incentives that are needed for generic companies to enter the procurement process.

"…it will reduce the incentive for generic manufacturers to enter a bidding competition." 81

The legislation granted increased liberty to patent-holders by giving them two chances to match an offer of a generic drug company: one before the legislative mechanism is pursued and a second within the legislation. As civil society alleged, it was more intellectual property protection than required by TRIPS.

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From an equity perspective, MSF demanded that the legislation be applicable to all countries and all medicines.

The Canadian HIV/AIDS Legal Network assumed an identical position to MSF's but argued on slightly different grounds. The purpose of the WTO Paragraph 6 mechanism was to ensure that generic companies could obtain licenses to produce and export cheap generic drugs to countries that could not produce drugs themselves. Security would be achieved through increasing access to affordable generic medicines. The right of refusal was inefficient by blocking generic competition and removing any incentives for their participation. They demanded its removal, which would be TRIPS compliant, another liberty goal. The right of refusal was the "fatal flaw".

Other security goals included protecting human rights and ensuring the prevention, care treatment and support of HIV/AIDS patients.

"We fully support action to improve access to affordable medicines in developing countries, as a matter of fundamental human rights. Now we need to make sure Canada, as the first country in the world to take this step, doesn't undermine its own initiative and set a bad global precedent."  

From an equity perspective, they applauded the government for removing requirements of emergency and restrictions on diseases but demanded the removal of the list of medicines on the basis of efficiency and liberty: countries needed the flexibility and sovereignty to determine what drugs would best meet their public health needs.

It was agreed in Parliament that Bill C-56 would go to committee for review and the Parliament recessed for the year.

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Canada's Access to Medicines Regime: A Summary

Canada's Access to Medicines Regime (CAMR) implements the WTO Decision on the Implementation of the Paragraph 6 Decision of the TRIPS Agreement into Canadian domestic law (World Trade Organization, 2003b). It amended the Patent Act and Food and Drugs Act to allow the limited use of government-issued, third-party licensing in Canada for humanitarian purposes. Specifically, it permits Canadian generic drug manufacturers to produce a "lower-cost version of a patented drug or medical device for export to developing countries that do not have the capacity to manufacture such products." (Government of Canada, 2007) The following section explains how CAMR works, based upon the requirements outlined by the Government of Canada on the CAMR-related website (Government of Canada, 2007).

How CAMR Works

Countries must fall into one of three schedules and their eligibility depends on their status as a developing or least-developed country on the UN Human Development Index and whether or not they are a member of the WTO. Eligible medicines are in turn listed in Schedule 1, many of which are those needed for the treatment of HIV/AIDS, malaria, and tuberculosis. Through a procedure under the Governor in Council, countries can request the addition of a medicine or product. NGOs can use the regime to distribute medicines to another country only if they obtain an authorization from the importing country government.

A pharmaceutical company who wishes to apply for a compulsory license must first "enter into a sales agreement with an eligible importing country for the purchase of a specified amount of an eligible product listed on Schedule 1." 84 Second, it must submit an application for authorization to Canada's Commissioner of Patents and declare that the company has sought a voluntary license from the patent-holder. 85 The declaration must identify the product, its patent status in the importing country and include a copy of the

85 The requirement specifies a maximum of 30 days for these negotiations.
importing country's notification to either the World Trade Organization or the Canadian Government of its intention to use the WTO Paragraph 6 Decision.86

Upon receiving the compulsory licence, the pharmaceutical company must meet all anti-diversion requirements, determine the royalty payment due to the patent holder, and establish a website with up-to-date details regarding the shipment.87 A compulsory licence is valid for two years with a one-time two-year renewal if the specified quantity has not yet been shipped. Patent-holders can challenge a license if they believe it is being used for "commercial purposes"88 or if diversion of the medicines occurs, which then leads to the termination of the license.89


Shortly after CAMR was passed, stakeholders issued press releases and statements reflecting their position on the structure of the regime. In rhetoric, most stakeholders supported the regime aside from Médecins Sans Frontières. All stakeholders had concerns about specific aspects of the legislation.

Prime Minister Paul Martin personally issued a press release on the legislation, which illustrated his personal commitment to the legislation.

86 Otherwise referred to as "country notification".
87 The information includes: "the name of the licensed product, as set out in Schedule 1, and, if applicable, the strength, dosage form and route of administration; its distinguishing characteristics; the identity of the importing country; the amount to be manufactured and sold for export; information identifying every known party who will be handling the product while it is in transit from Canada to the importing country; and the export tracking number and number of the bill of lading for each shipment."

88 This is referred to as the "Good Faith Clause". Patent holders can challenge a compulsory licence if they can prove that "the average price of the licensed drug or medical device is 25 percent or more of the average price of the equivalent patented product in Canada. The licence holder has an absolute defence if the licence holder can establish that the average price of the drug or medical device remains less than its direct supply cost, plus 15 percent."

89 Additional grounds under which a patent-holder can challenge the license include: if any information in the application is inaccurate; if the license holder fails to meet the conditions of the license including: "establishing and maintaining a website; providing for all shipments an export notice to the patent holder, the importing country and the purchaser; paying the prescribed royalty to the patent holder; or, providing the patent holder and the Commissioner of Patents with a copy of any supply agreement related to the licence."; if the exported product exceeded the specified quantity; "if the product was used by a non-WTO member country for commercial purposes; or if the country failed to adopt anti-diversion measures as specified by Article 4 of the Decision."
"Bill C-9, reinstated in February 2004, provides for lower cost medicines for HIV/AIDS, malaria, tuberculosis and other epidemics which are ravaging developing countries, especially in Africa."\textsuperscript{90}

Martin framed Bill C-9 as a move of international leadership, a moral action linked to "the finest tradition of Canada". He acknowledged that the Right of Refusal was a "sticking point" and supported the government's choice to remove it.

The research-based industry cited "overall support for the principles" of the legislation, framing it as a compassionate initiative but identifying outstanding problems with the bill, namely the Equal Opportunity to Supply.

"While expressing his disappointment that Non-Government Organizations (NGOs) do not wish to have Rx&D member companies' full participation in the provision of medicines under the bill, Rx&D President Russell Williams stated that what is most important is getting affordable medicines to the developing countries as quickly as possible."\textsuperscript{91}

They emphasized their desire to ensure that the regime "remains a humanitarian venture" and is not used for commercial purposes, and to ensure the regime is "open", "transparent" and "curbs diversion".\textsuperscript{92} Maintaining their oft-cited position, they emphasized that drug affordability is only one part of the problem, stating that Bill C-9's success must be judged in the context of other health system infrastructure improvements.

In contrast, the generic industry responded with discouragement stating that the governments amendments were not enough and that some of the new amendments opened up a "hornets' nets of potential court battles". They were primarily concerned about two new clauses in the legislation that would allow brand name companies to sue the generic companies in federal court if they thought that the contract was "commercial in nature" or if they thought they deserved higher royalty payments. The litigation clauses were framed as a disincentive since generic companies won't spend time and money fighting over these contracts.

"We’re worried about the precedent,” said Jim Keon, President of the CGPA. “In the past, brand companies sued Nelson Mandela’s government to stop generic drugs from being shipped to South Africa, and it is clear they won’t hesitate to take Canadian generic companies to court. Brand companies will use the litigation, and the threat of litigation entrenched in these amendments, to dissuade generic companies from pursuing contracts."94

The other major problem they identified was the two year limit on compulsory licenses (with one time renewal). Not only was it a disincentive for generic companies but it made the regime less attractive to developing countries. Still, they emphasized their continued support of the developing world through their donations to NGOs of "millions of dollars annually".

Civil society's response was mixed. The Global Treatment Action Group (GTAG) issued a press release commending the government on an important initiative but urging other countries to avoid the flaws in the Canadian model, saying it created restrictions that were not contained in the WTO Decision.95 Namely, it identified the list of medicines, Name attached

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the uncertainty over whether fixed-dose combination antiretrovirals would be made available, and that the legislation was ultimately weakened by last minute amendments that make it difficult for NGOs to contract directly with a generic manufacturer.

"Maintaining a list ultimately threatens the ease of access to medicines, and undermines the proper authority of developing countries to determine their own health needs."\(^{96}\)

“We hope other governments follow Canada’s demonstrated will to act”, said Richard Elliott, Director of Legal Research and Policy of the Canadian HIV/AIDS Legal Network. “But they must be careful to avoid replicating the weaknesses still found in this bill, such as a limited list of medicines eligible for export, vague conditions on countries importing medicines from generic suppliers, and provisions that give brand-name pharmaceutical companies privileges beyond anything negotiated at the WTO.”\(^{97}\)

MSF separated itself from GTAG’s statement by issuing its own press release, condemning the legislation. They stated that "Canada failed the international community", it set a "dangerous international precedent" and it is "nothing more than an example of how the Canadian government ultimately prefers to protect the rights of patent holders over patients."\(^{98}\) They argued that the legislation would not improve the inequity in affordable drug access in developing countries.

"The Bill contains several critical flaws, which will make the production of generic medicines and their exportation to developing countries very difficult, even impossible in some cases. In particular, the flaws include a list of medicines, which does not even include first-line AIDS fixed-dose combination treatment

drugs, and a clause that could stop NGOs from importing medicines into developing countries.”

Despite MSF's scathing remarks, it tried to use the regime in good faith. MSF made a commitment to purchase an order of drugs under two conditions: 1) that a compulsory licence is obtained in Canada; and, 2) that an importing country found. From 2004 until 2008, MSF spearheaded a drug order with the Canadian generic drug-maker Apotex for a fixed-dose combination antiretroviral drug for export. These four years involved continued advocacy efforts mainly by MSF and CHLN. This involved identifying a drug needed in the field (3-in-1 antiretroviral AZT/3TC/NVP), finding a willing Canadian generic manufacturer, formally requesting the addition of the antiretroviral to CAMR’s list of eligible medicines, negotiations with the government on a fast-track quality and safety review, ensuring WHO prequalification and most importantly, finding a country willing to use the regime.

After months of work with MSF missions worldwide and various country governments, MSF could not find a country willing to use the regime. MSF stated that most countries were reluctant given the threat of trade sanctions from the United States (Médecins sans Frontières, 2006).

Meanwhile, Apotex initiated voluntary license negotiations with the four patent-holders required to make the product. While they started negotiations in June 2006, they did not receive a compulsory license until September 20, 2007. The reasons for the delay are somewhat controversial but government bureaucrats suggest that there was confusion on whether or not the voluntary license negotiations had officially started because an importing country was not yet been identified.

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Civil society used the media opportunity provided by the International AIDS Conference hosted in Toronto in 2006, to raise awareness about CAMR's delays and the fact that the legislative review process had yet to take place. MSF and CHLN initiated another new round of media coverage, which raised awareness about the regime. They sent two distinct messages: 1) CAMR does not work and needs to be amended and 2) MSF’s attempt to use CAMR is proof that fundamental reform of the WTO August 30th Decision is required to allow the production of affordable generic medicines (Médecins sans Frontières, 2006).

In response to this media coverage, the Conservative government publicly committed to initiating the mandatory legislative review process during the International AIDS Conference. Health Minister Tony Clement stated:

"The review was to start in 2007…and clearly that is unacceptable. I have ordered an immediate top-to-bottom review of the legislation."\(^{101}\)

Industry Canada issued a consultation paper in November 2006 requesting that interested parties make written submissions regarding CAMR (Government of Canada, 2006). The purpose of the consultation paper as described was "to solicit comments as to how the regime can better deliver on Canada's commitment to improve access to less expensive medicines...while remaining compliant with World Trade Organization (WTO) rules."\(^{102}\)

Industry Canada listed 28 specific questions regarding various aspects of the legislation which addressed the following issues: eligible importers, eligible pharmaceutical products, country notification, Health Canada's drug review, the compulsory licensing application process, the duration of the licence, royalties, the "Good Faith Clause", the quantities permitted for exported under the licence, anti-diversion measures, and grounds

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\(^{102}\) "As a first step in the Government's accelerated statutory review of Canada's Access to Medicines Regime (CAMR), the purpose of this paper is to solicit comments as to how the regime can better deliver on Canada's commitment to improve access to less expensive medicines that are urgently needed to treat HIV/AIDS, malaria, tuberculosis, and other epidemics in developing and least-developed countries, while remaining compliant with World Trade Organization (WTO) rules."
for termination of the licence. Participants were asked for any additional comments as well.

Many more written responses were submitted to the federal government compared with the 2004 consultation. 31 submissions were received: 11 from the research-based pharmaceutical companies worldwide, 5 from research-based industry associations, 2 from the generic industry (only Canadian-based), 9 submissions from civil society, 3 submissions by government MPs and 1 from the Canadian Chamber of Commerce (see Appendix 2). From these submissions, the federal government selected certain individuals to testify at the Standing Committee Hearings in April 2007.

Immediately prior to the Standing Committee Hearings, the Canadian HIV/AIDS Legal Network and the North South Institute held an expert consultation with a range of international stakeholders in attendance, including key federal bureaucrats responsible for leading the review process: Doug Clark from Industry Canada and Brigitte Zirger from Health Canada. The CHLN and NSI issued a report and summary recommendations based upon the report to Industry Canada and Health Canada on how to improve CAMR and policy recommendations (L. Esmail et al., 2007).

After the legislative review was complete, the Standing Committee issued its report to the Minister of Industry, summarizing stakeholders' recommendations to each consultation issue, without the Committee itself recommending a specific course of action (House of Commons Standing Committee on Industry, Science and Technology, 2007). The Conservative Government waited until July 2007 to issue its report and announce no further changes to the regime (Industry Canada, 2007). The Minister's report concluded that it was too soon to judge the efficacy of the regime and until that took place, they did not recommend any further changes. The announcement went largely unnoticed in the media and the issue faded out of the public's attention.
Summary

This chapter aimed to illuminate the range of stakeholder involvement and framing on access to medicines and intellectual property protection. This section outlined the involvement of a range of potential actors from international governmental organizations, the research-based and generic pharmaceutical industries, a relatively well-organized and cohesive global civil society and a range of country governments. The main pattern that became evident is that access to medicines, as a security issue, has been framed as either a short-term affordability issue or a long-term innovation issue and these frames tend to be accompanied by framing liberty of patent-holders as either facilitating or blocking drug access, respectively. What frame is given more weight depends upon the institutional, political and economic context and the range of interests involved in the policy debate.
Chapter 5: Coding Framework for Content Analysis

After the key themes were identified (as described in the Methods, Chapter 3), they were categorized within the four-goal framework of equity, security, liberty and efficiency (Stone, 2002). While some themes could have been categorized in more than one goal, the assignment of a theme to a policy goal was based upon how the theme was framed in the context of the policy debates. The following section outlines the definition of each theme that was used to code the data and explains the assignment of each themes to its respective policy goal and briefly highlights the key issues based upon the literature reviewed in Chapter 4 (Appendix 1, Codebook).

Equity Issues

Issues that fall under the umbrella of drug access can be categorized as issues that pertain both to equity and security. As it relates to the distribution of pharmaceuticals among populations, groups or countries, drug access is an issue of equity. If framed as a basic need of a population, drug access can be viewed as a question of security.

By definition, every issue of security can be framed as an issue of equity, if framed in the context of distribution. In this thesis, what distinguished issues of equity from security was the explicit reference to a redistribution of resources, goods or services. Under this definition, the issues of aid, list of medicines, list of countries and equal opportunity to supply, were categorized as issues of equity. The rationale for this choice will now be further developed.

Aid

Aid was defined as "any form of assistance or help given to developing countries towards improving their country, quality of life, and increasing drug access. Aid can come from countries, organizations, companies/corporations or individuals. It also includes technical assistance and cooperation and support." As aid involves the redistribution of resources to the disadvantaged, it was categorized as an issue of equity. When it comes to the question
of drug access, the debate around aid centers mainly on what the aid is comprised of, whether it is enough, and its sustainability as a long-term solution. Financing for medicines is one way of facilitating drug access by addressing the end-users' ability to pay; however, most members of the health community agree that existing levels of financing remain inadequate (UN Millennium Project, 2005). The current global financial crisis has exacerbated the situation by shrinking donor budgets and scaled back commitments (Orsi & d'Almeida, 2010), resulting in a decrease of already inadequate levels of financing, threatening treatment scale-up programs across the developing world. Specific to debates over intellectual property protection and drug access, conflict arises when aid as comprehensive programming is framed as a trade-off with addressing drug affordability through patent flexibilities. Meanwhile, many developing country governments view their right to use patent flexibilities to pursue medicines access as fully compatible with the continuation of industry-supported aid programs.

**List of Medicines**

CAMR's List of Medicines was defined as "the scope of drugs eligible under CAMR." By identifying the drug(s) which would ultimately be produced and exported under the regime, the List of Medicines was an issue of equity. Historically, in opposition to the efforts of developing countries in negotiations leading up to the Doha Declaration, the EC and U.S. promoted the restriction of the Paragraph 6 Decision to a scope of diseases (Abbott, 2005). Making reference to Paragraph 1 of the Doha Declaration, which "recognizes HIV/AIDS, tuberculosis and malaria, among other epidemics," the U.S. explicitly suggested that the Doha Declaration applies only to these diseases. Developing country representatives expressly rejected these attempts, pointing to Paragraph 4, which refers generally to "the protection of public health and access to medicines for all," Paragraph 5, which recognizes that countries have the freedom to determine the grounds upon which compulsory licenses are granted, and Paragraph 6, which refers to 'products in the pharmaceutical sector' and makes no mention of a list of diseases.
List of Countries

CAMR's List of Countries was defined "as the list of eligible countries, otherwise known as Schedules 2, 3 and 4." These schedules restrict the use of CAMR to States that are members of the WTO or are considered least-developed according to the UN Development Index (Government of Canada, 2007). During the WTO Paragraph 6 negotiations, the EC and US called for specific limitations on eligible importing countries (Abbott, 2005). Their main concerns appeared to be with higher-income countries and middle-income countries, proposing lists of countries based upon manufacturing capacity and level of income; however, these were rejected by negotiators. Upon conclusion, an Annex was appended to the Paragraph 6 Decision, which specified those countries that independently acknowledged their intention not to use the system, or only in emergency situations.

Equal Opportunity to Supply

The "equal opportunity to supply" was defined as "the research-based industry's counterproposal to the right of refusal." The equal opportunity to supply defined equity as a fair bidding process, arguing that as a patent-holder they should receive an opportunity to compete for a potential developing country contract. Since this proposal was introduced during the 2004 parliamentary committee debates, nothing was known about its contents.

Security Issues

These issues are defined as basic human needs (Stone, 2002). Unsurprisingly, a number of security issues were raised in the debates over drug access since many developing countries lack basic needs. As a result, policy debates often involve disputes over what basic needs should take precedence.
**Drug Affordability**

Drug affordability was defined as "references to drug costs, expensive or cheap drug prices, or pricing policies." The original intent behind CAMR was to facilitate drug affordability (Government of Canada, 2003), an issue which can be viewed as a basic need. Drug affordability is one critical component of drug access identified by many health experts (Frost & Reich, 2008; World Health Organization, 2004).

In terms of drug patents and affordability in developing countries, controversy resides between achieving affordability through generic competition or tiered pricing. While voluntary price reduction strategies from the research-based industry have resulted in significant price reductions, they have not been able to meet the prices achieved through open market competition between multiple firms. In relation to the prices of anti-retroviral drugs, first-line therapy has benefited from market competition while second and third line antiretroviral drugs run significantly higher, at rates such as 610 and 1660 USD per patient per year (Orsi & d'Almeida, 2010). Prices in middle-income countries can run significantly two to three times higher (Orsi & d'Almeida, 2010).

**Development**

Development was defined as "…basic facilities, services and installations needed for the functioning of a community or a society." Issues coded as development included aspects such as: infrastructure, clean water, food, education, a skilled work force, institutional capacity, good governance and technology transfer. In debates over drug access, opponents of compulsory licensing often cite development as the primary barrier to drug access, which, in their view, should ultimately be dealt with first (Chase & Fagan, 2003). In contrast, proponents of compulsory licensing do not agree that addressing development-related barriers and drug affordability are mutually exclusive solutions. From the developing country government perspective, technological development has been a goal since the 1950s in the context of permitting flexibilities in patent law to facilitate technology transfer and the building of local production capacity.
The Canadian Domestic Economy

References to the Canadian domestic economy were defined as "any references to the relevance or implications of the pharmaceutical industry to the domestic economy of Canada. Examples include jobs, employment, and investment." State security is largely dependent upon having a strong economy (Evans & Newnham, 1998). As mentioned earlier, Canada's research-based and generic pharmaceutical sectors are comparable to the extent that they invest domestically in applied R&D, but the research-based industry provides most of the investment capital in basic pharmaceutical research.

In 2003, the PMPRB reported the lowest percentage of spending on basic research by the research-based industry in Canada since reporting started in 1998: expenditures on basic research fell by 9.3% in 2003 relative to 2002, totaling $180 million in 2003 and representing 15.7% of current R&D expenditures. Most R&D spending continued to be on applied research, with $630 million (55.1%). Meanwhile, the generic industry's self-reported statistics in 2003 were $250 million expenditures in 2003 on research and development (15% of domestic sales spent on R&D).

Human Rights

"Human rights", as they relate to medicines, were defined as "any discussion of human rights, including references to international covenants, treaties or laws." Human rights "specify the minimum conditions for human dignity and a tolerable life," (McLean, 1996). The right to health is recognized by many international and regional treaties, including the International Covenant on Economic, Social and Cultural Rights (ICESCR) which provides the grounds for states legal obligations towards the right to health (Office of the United Nations High Commissioner for Human Rights, 1966). Article 12.2 extends this right to access to medicines.

106 General Comment 14 of May 2000 explicitly links Article 12.2(d) to the provision of essential drugs.
**Pharmaceutical Innovation**

Innovation was defined as "...discovery, research and development (R&D) of new pharmaceuticals and other medical technologies." Pharmaceutical innovation fulfills a basic need insofar as it facilitates drug access. The discovery of new medicines is a key component in decreasing morbidity and mortality, although it depends upon the nature of the innovation.

**Drug Quality and Safety**

Drug quality and safety is another key component of securing drug access and as such, is a basic need within any drug system (Frost & Reich, 2008). If a drug is not safe, then it can cause undue harm to populations. In relation to drug access in developing countries, there often exists a debate over what quality standards and regulatory controls must be used in relation to generic production of antiretrovirals.

**Liberty Issues**

Liberty issues typically arise in public policy in response to the question of when governments should be allowed to interfere with individual choice and activity in the name of community or society (Stone, 2002). In the context of debates over drug access in developing countries, liberty issues typically involve topics related to intellectual property rights.

**Intellectual Property Rights**

A key liberty issue in the drug access debate is the idea of intellectual property protection, which is the mechanism that many governments use to stimulate research and development in many sectors, including the pharmaceutical industry.\(^\text{107}\) As discussed

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\(^{107}\) May and Sell argue “…the industrialized countries built much of their economic prowess by appropriating others’ intellectual property; with TRIPS this option is foreclosed to future industrializers…states and companies whose comparative advantage lies in imitation stand to lose under the new regime.” (May and Sell 2006:158). India is a prime example of a country who has pursued technological development in the area of pharmaceuticals, assisted by the lack of product patents until 2005.
previously, debates over intellectual property and drug access focus on where to draw boundaries with respect to the liberty of patent-holders in order to promote social welfare.

The WTO TRIPS Agreement

The TRIPS Agreement outlines the minimum standards of all WTO Member countries for the protection of intellectual property rights (World Trade Organization, 2006b). TRIPS obligations include 20 years of patent protection from the inventor's filing date (Article 33), patent rights free of discrimination against the origin of invention or production (Article 27.1), and exclusive marketing rights for the entire patent duration (Article 28) (Correa, 2002).

TRIPS institutionalized the idea that intellectual property rights should be protected in exchange for access to global markets. Pertinent to drug access, the so-called "TRIPS flexibilities" of compulsory licensing and parallel importation raise controversy over the extent to which countries' use of these flexibilities is TRIPS compliant. Others point to the Doha Declaration, which reaffirms all WTO Members rights to determine the grounds upon which these flexibilities will be used and that they should be used to facilitate access to medicines for all.

In addition to TRIPS, the United States has signed several bilateral and regional trade agreements that require higher standards of intellectual property protection than what is outlined by TRIPS including restrictions on compulsory licensing and parallel importation.108

The Right of Refusal

The right of refusal was defined as "the proposal of the Liberal Government to give patent-holders the right to take over negotiated contracts between Canadian generic firms

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108 Some of these include the Central American Free Trade Agreement (CAFTA), the U.S.-Singapore Free Trade Agreement, the U.S.-Chile Free Trade Agreement, the U.S.-Morocco Free Trade Agreement, and the U.S.-Peru Trade Promotion Agreement. For further details, see t'Hoen 2009.
and developing countries." The issue was framed in relation to patent-holders' rights, making it a liberty issue.

**Developing Country Pressure**

Developing Country Pressure was defined as "references to pressure/lobbying put on developing country governments from other countries, institutions or companies", ultimately to persuade them to avoid using TRIPS flexibilities. In this thesis, developing country pressure was categorized as a liberty issue, as it can be viewed as an infringement on the sovereignty of a state to exercise its legal right to pursue TRIPS flexibilities.

**Efficiency Issues**

As discussed earlier, efficiency can be defined as getting the most output given a certain input and is essentially a criterion for judging the merits of different ways of doing things (Stone, 2002). Debates about drug access are replete with references to the goal of efficiency.

**Diversion**

Diversion was defined as "the situation in which pharmaceuticals that are intended for a specific market are diverted to a different market and sold at a higher price. This includes reimportation and discussion of mechanisms to prevent diversion (anti-diversion) including marking and labeling." In the case of CAMR, diversion was framed as an issue of efficiency. Anti-diversion measures effectively protect the re-exportation of the lower-priced drug into more lucrative markets.

**Litigation**

Litigation was defined as "threats or taking legal action either against pharmaceutical companies or originating from the companies." This refers in particular to patent-holders' litigation against generic companies over patent infringement. Stiglitz blames litigation as one of the fundamental inefficiencies of the patent system, as it causes high
administrative costs and ultimately reduces welfare of society by preventing the timely access to more affordable, generic medicines (Stiglitz, 2007). From the patent-holders' perspective, litigation is one of the primary methods by which they have recourse over possible property infringement, making it a liberty issue. Typically, in debates over drug access, litigation is framed as inefficiency within the pharmaceutical system.

**Market Competition**

Market competition was defined as "competition in a market between firms" and in the case of drug access, it often refers to generic competition. In economic theory, open market competition is one of the requirements to achieving efficiency. In the case of drug access, generic competition almost always brings drug prices down, particularly as the number of competitors increases (Médecins sans Frontières, 2009). The policy debates around market competition mirror the debates found about the pros and cons of compulsory licensing since advocates of compulsory licensing rely on the premise of market competition to yield lower drug prices. As a general rule, the more generic firms competing, the larger the price reductions. For example, over eight years, increased competition from Indian- and Thailand-based manufacturers lowered the price of the first-line antiretroviral regimen d4T/3TC/NVP from 12,000 to 88USD per patient per year (Orsi & d'Almeida, 2010). Lower prices mean that medicines budgets can treat more people, potentially for a longer period of time. In contrast, opponents of compulsory licensing argue that introducing 'early' generic competition into the market does not allow patent-holders to recoup their costs and hurts innovation by discouraging inventors from future R&D (DiMasi & Grabowski, 2007; Rozek, 2000). Instead, opponents of early generic competition support voluntary price reductions or voluntary licensing programs to generic manufacturers, which allow patent-holders to define the terms under which the generic manufacturer can compete.

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109 Allocative efficiency is the most fundamental goal of perfectly competitive markets (Perloff, 1999). Efficiency is attained when markets are open, competitive and free of regulation. This philosophy assumes that actors are ultimately self-interested and respond in a rational manner to profit and utility maximization incentives. Even though the existence of intellectual property rights implies market imperfections, the idea of efficiency is often used in policy debates, where some actors aim to promote increased generic competition and correspondingly, a reduction of intellectual property rights.
**Pharmaceutical Procurement**

Procurement was defined as "discussion of pharmaceutical procurement practices, protocols or laws." From the demand side, one of the major goals during the procurement stage is to achieve efficiency. Among the principles of "good procurement practices" include procurement in bulk to achieve economies of scale and competitive procurement to achieve the lowest price possible (Management Sciences for Health, 1997). A useful approach to public procurement is 'pooled procurement', where a number of countries delegate their drug purchasing to a regional body (UN Millennium Project, 2005). The Paragraph 6 Decision subsection 6(i) permits compulsory licences to supply regional trade groups (World Trade Organization, 2003b). This allows small countries with insufficient market potential to reap the advantages of bulk purchasing. From the supply side, procurement issues tend to relate mainly to the tendering systems under which pharmaceutical companies can bid (Management Sciences for Health, 1997). Depending upon the purchaser, different tendering processes exist. For example, under the Global Fund for HIV/AIDS, TB, and Malaria, all purchases require international tenders to be posted, to allow the winner of the tender to go to the lowest possible bidder.

**Profits**

Profits were defined as "any discussion of profit, defined as financial gain after all investments and costs are taken into account; discussion of return on investment." Profits are a fundamental motive driving the efficiency of free markets. In relation to the WTO Paragraph 6 Decision, the main issue at hand was the "Good Faith Clause", incorporated into the WTO Chairperson's Statement (World Trade Organization, 2003a). This clause states that "…the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives," (World Trade Organization, 2003a). Developing country WTO members and associated NGOs were not pleased with the incorporation of this element given the unlikelihood that a private pharmaceutical manufacturer would conduct the R&D, manufacture and supply a product without the

**Eligible Importers**

"Eligible importers" was defined as "the possibility of having NGOs import the medicines, contracting directly with or purchasing the medicines directly from Canadian generic companies." This issue was raised specifically in relation to the design of CAMR, as NGOs requested that they be incorporated into the legislation, as permitted, to enter a contract directly with a generic producer. Since NGOs are one of the major distributors of medicines in resource-poor countries (UN Millennium Project, 2005), the incorporation of their role could be viewed as facilitating the efficiency of the regime.

**CAMR Outcomes and Uptake**

"CAMR Outcomes and Uptake" was defined as "any discussion about why CAMR was not working." This included issues of developing country "uptake", awareness among developing countries about the regime, and questions regarding what the potential barriers might be. During the 2007 consultation, CAMR's efficiency was the subject of much debate and the degree to which participants viewed CAMR as efficient depended upon what standard was used to compare its process.
Chapter 6: Content Analysis of Policy Debates in 2004

Outline

Chapter 4 provided an overview of the major issues and actors involved in policy debates about access to medicines in developing countries and intellectual property protection. Following the methodology outlined in Chapter 3, these issues were then incorporated into a codebook and categorized according to Stone's four-goal framework as illustrated in Chapter 5.

This section presents the results of the content analysis. As a reminder, the content analysis systematically analyzed the Standing Committee Hearings on Bill C-9, now known as CAMR. The goal of this analysis was to determine the framing content of these hearings to ultimately uncover how stakeholders framed access to medicines in the case of CAMR.

The first section of this chapter presents tables describing frequency with which stakeholders discussed certain themes and issues. This quantitative presentation provides an accurate picture of the policy goals and themes that drove the debate. Subsequently, a qualitative summary of each stakeholder's comments is presented to illustrate how each stakeholder framed the themes and issues. The combination of these results provide the foundation for Chapter 7, which analyzes these statistics and qualitative framing contents in the theoretical framework of ideas, interests and institutions to determine how framing, interests and institutions interacted and influenced the final policy product.

Introduction

As mentioned earlier, the codebook outlined the major themes that arise during policy debates about access to medicines in developing countries (Appendix 1). These themes were categorized according to Stone's four policy goal framework: equity, security, liberty and efficiency. Equity issues, defined as issues relating to fairness of distribution,

\[110\] See Chapter 3 for an explanation of the analysis.
include aid to developing countries, the research-based industry's proposed equal opportunity to supply, and Bill C-9's list of medicines and list of countries. Security issues, defined as basic needs, included development, drug affordability, drug quality and safety, human rights, domestic economic issues and innovation. Liberty issues, defined as freedom or exemption from restraint, included intellectual property, the WTO TRIPS Agreement, the right of refusal and developing country pressure. Efficiency issues, defined as obtaining the most output for a certain input, included diversion, litigation, market competition, procurement issues, profits, eligible importers and CAMR output and uptake.

In 2004, a range of witnesses testified before the standing committee. The stakeholder groups below represent all of the witnesses who testified. The criteria used to categorize witnesses into stakeholder groups were group membership (for institutional interest groups) or their historical affiliation with other groups and their policy positions (for issue-oriented interest groups). Government representatives fell into three major categories: 1) the ruling government, which includes cabinet members and government bureaucrats and 2) Members of Parliament (MPs) on the standing committee, which included 8 MPs representing the Liberal party, 4 representing the Conservative Party of Canada (CPC), 2 representing the Bloc Quebecois (BQ), and 1 representing the New Democratic Party (NDP), presided over by a Chair from the Liberal party. Civil society consisted mostly of non-profit aid organizations and few academics who often advocate alongside these groups. The research-based and generic pharmaceutical industries are membership-based groups.

The frequency statistics presented at the beginning of this chapter represents how often each stakeholder group mentioned a concept or policy issue. The unit of analysis is a complete session of hearings, which in the case of 2004, includes 6 hearings from February 24, 2004 to April 22, 2004. Due to the nature of standing committee hearing

111 The Development theme encompasses issues such as poverty, financing, clean water, nutrition, infrastructure, technological development and technology transfer. See Chapter 3, Methods.
procedure (explained in detail below), concept frequency is partially dependent upon the questions posed by the committee members (MPs), which somewhat directs what issues are included in the policy debate. Based upon data collection from the Canadian HIV/AIDS Legal Network website¹¹³ and documents obtained through the Canadian HIV/AIDS Legal Network's request for access to information, six individuals or organizations issued written submissions only: 2 academics, two independents, one French NGO and the Canadian Union of Public Employees (CUPE) (Appendix 2). In addition, some stakeholders issued written submissions in addition to their verbal testimony at the hearings, which allowed them more freedom to frame the issues.¹¹⁴ The structure of the standing committee and the procedural aspects of the hearings effectively filtered out some stakeholders and some ideas from participating in the debate.

The hearing transcripts analyzed below reflect the Committee Stage, when the serving MPs of the Parliamentary Standing Committee on Industry, Science and Technology heard witnesses and subsequently examined the bill clause by clause. Then, the Committee submitted a report to parliament recommending the bill be accepted with certain amendments. This is only a cross-section of the discourse but it is a representative sample of the issues that were up for debate, which are a function of the ideas, interests and institutions that were involved in this policy process from the beginning.

The next section presents the results describing frequency with which stakeholders discussed certain themes and issues (Tables 1-6). This quantitative presentation provides an accurate picture of the policy goals and themes that drove the debate. Subsequently, a list of specific design decisions along with stakeholders', politicians' and Government's positions on the issues are listed in Tables 7, 8 and 9. Lastly, a qualitative summary of each stakeholder's comments is presented to illustrate how each stakeholder framed the themes and issues.

¹¹³ Starting in February 2004 and running through the entire period for the case study.
¹¹⁴ Chapter 4 covers the major issues and concepts that stakeholders raised in their written submissions and press releases.
Content Analysis Results (Tables) - 2004

Table 1: Proportion of Debates Coded by Policy Goal (2004)\(^1, 2\)

<table>
<thead>
<tr>
<th>Policy Goal</th>
<th>Total Words</th>
<th>Total %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity</td>
<td>37187</td>
<td>34%</td>
</tr>
<tr>
<td>Security</td>
<td>20642</td>
<td>19%</td>
</tr>
<tr>
<td>Liberty</td>
<td>51497</td>
<td>47%</td>
</tr>
<tr>
<td>Efficiency</td>
<td>24921</td>
<td>23%</td>
</tr>
</tbody>
</table>

\(^1\) The denominator = 108536 words (i.e. total number of words in ALL 2004 debates)  
\(^2\) These percentages aggregate all stakeholders and political parties. Percentages represent proportion of text where specified themes were found. Paragraphs often made reference to more than one concept; therefore paragraphs were often coded for multiple themes.

Table 2: Proportion of Debates Coded by Policy Goal by Stakeholder (2004)\(^1, 2, 3\)

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Research-based (n=3622)</th>
<th>Generic (n=2938)</th>
<th>Civil Society (n=31610)</th>
<th>Government (n=19956)</th>
<th>IPIC (n=3327)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity</td>
<td>61%</td>
<td>30%</td>
<td>37%</td>
<td>40%</td>
<td>0%</td>
</tr>
<tr>
<td>Security</td>
<td>27%</td>
<td>30%</td>
<td>33%</td>
<td>15%</td>
<td>21%</td>
</tr>
<tr>
<td>Liberty</td>
<td>37%</td>
<td>58%</td>
<td>48%</td>
<td>53%</td>
<td>85%</td>
</tr>
<tr>
<td>Efficiency</td>
<td>28%</td>
<td>41%</td>
<td>24%</td>
<td>24%</td>
<td>32%</td>
</tr>
</tbody>
</table>

\(^1\) n = total number of words per testimony of stakeholder group. Unit of analysis = stakeholder-testimony.  
\(^2\) Percentages represent proportion of text where specified themes were found. Paragraphs often made reference to more than one concept; therefore paragraphs were often coded for multiple themes.  
\(^3\) IPIC stands for the Intellectual Property Institute of Canada.

Table 3: Proportion of Debates Coded by Policy Goal by Political Party (2004)\(^1, 2\)

<table>
<thead>
<tr>
<th>Political Party</th>
<th>Liberals (n=25593)</th>
<th>Conservatives (n=7864)</th>
<th>Bloc Quebecois (n=5467)</th>
<th>NDP (n=8159)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity</td>
<td>31%</td>
<td>31%</td>
<td>26%</td>
<td>32%</td>
</tr>
<tr>
<td>Security</td>
<td>11%</td>
<td>10%</td>
<td>4%</td>
<td>11%</td>
</tr>
<tr>
<td>Liberty</td>
<td>50%</td>
<td>30%</td>
<td>27%</td>
<td>38%</td>
</tr>
<tr>
<td>Efficiency</td>
<td>20%</td>
<td>16%</td>
<td>33%</td>
<td>12%</td>
</tr>
</tbody>
</table>

\(^1\) n = total number of words per testimony of stakeholder group. Unit of analysis = stakeholder-testimony.  
\(^2\) Percentages represent proportion of text where specified themes were found. Paragraphs often made reference to more than one concept; therefore paragraphs were often coded for multiple themes.
Table 4: Proportion of Debates Coded by Theme (2004)\(^1,2\)

<table>
<thead>
<tr>
<th>Theme</th>
<th>Total</th>
<th>Total %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aid</td>
<td>12454</td>
<td>11.50%</td>
</tr>
<tr>
<td>List of Countries</td>
<td>11553</td>
<td>10.60%</td>
</tr>
<tr>
<td>List of Medicines</td>
<td>13417</td>
<td>12.40%</td>
</tr>
<tr>
<td>Equal Opportunity to Supply</td>
<td>2251</td>
<td>2.10%</td>
</tr>
<tr>
<td><strong>Security</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Affordability</td>
<td>8973</td>
<td>8.30%</td>
</tr>
<tr>
<td>Development</td>
<td>8118</td>
<td>7.50%</td>
</tr>
<tr>
<td>Domestic Economy</td>
<td>151</td>
<td>0.10%</td>
</tr>
<tr>
<td>Human Rights</td>
<td>1572</td>
<td>1.40%</td>
</tr>
<tr>
<td>Innovation</td>
<td>2195</td>
<td>2.00%</td>
</tr>
<tr>
<td>Quality and Safety</td>
<td>2488</td>
<td>2.30%</td>
</tr>
<tr>
<td><strong>Liberty</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>34540</td>
<td>31.80%</td>
</tr>
<tr>
<td>Developing Country Pressure</td>
<td>594</td>
<td>0.50%</td>
</tr>
<tr>
<td>Right of Refusal</td>
<td>11576</td>
<td>10.70%</td>
</tr>
<tr>
<td>WTO or TRIPS</td>
<td>20052</td>
<td>18.50%</td>
</tr>
<tr>
<td><strong>Efficiency</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diversion</td>
<td>6590</td>
<td>6.10%</td>
</tr>
<tr>
<td>Litigation</td>
<td>2726</td>
<td>2.50%</td>
</tr>
<tr>
<td>Market Competition</td>
<td>5545</td>
<td>5.10%</td>
</tr>
<tr>
<td>Procurement</td>
<td>3330</td>
<td>3.10%</td>
</tr>
<tr>
<td>Profit and ROI</td>
<td>4921</td>
<td>4.50%</td>
</tr>
<tr>
<td>Eligible Importers</td>
<td>4717</td>
<td>4.30%</td>
</tr>
<tr>
<td>CAMR Outcomes and Uptake</td>
<td>0</td>
<td>0.00%</td>
</tr>
</tbody>
</table>

1 The denominator = 108536 words (i.e. total number of words in ALL 2004 debates)
2 These percentages aggregate all stakeholders and political parties. Percentages represent proportion of text where specified themes were found. Paragraphs often made reference to more than one concept; therefore paragraphs were often coded for multiple themes.
Table 5: Proportion of Debates Coded by Theme by Stakeholder (2004) \(^1,2,3\)

<table>
<thead>
<tr>
<th>Theme</th>
<th>Research Industry</th>
<th>Generic Industry</th>
<th>Civil Society</th>
<th>Government</th>
<th>IPIC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aid</td>
<td>41%</td>
<td>25%</td>
<td>17%</td>
<td>13%</td>
<td>0%</td>
</tr>
<tr>
<td>List of Countries</td>
<td>1%</td>
<td>0%</td>
<td>7%</td>
<td>11%</td>
<td>0%</td>
</tr>
<tr>
<td>List of Medicines</td>
<td>0%</td>
<td>4%</td>
<td>12%</td>
<td>18%</td>
<td>0%</td>
</tr>
<tr>
<td>Equal Opportunity to Supply</td>
<td>22%</td>
<td>1%</td>
<td>2%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Security</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug affordability</td>
<td>12%</td>
<td>19%</td>
<td>15%</td>
<td>2%</td>
<td>19%</td>
</tr>
<tr>
<td>Development</td>
<td>8%</td>
<td>0%</td>
<td>17%</td>
<td>5%</td>
<td>0%</td>
</tr>
<tr>
<td>Domestic Economy</td>
<td>0%</td>
<td>4%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Human Rights</td>
<td>0%</td>
<td>0%</td>
<td>4%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Innovation</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>4%</td>
<td>0%</td>
</tr>
<tr>
<td>Quality and Safety</td>
<td>3%</td>
<td>9%</td>
<td>1%</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td><strong>Liberty</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>23%</td>
<td>44%</td>
<td>25%</td>
<td>41%</td>
<td>63%</td>
</tr>
<tr>
<td>Developing Country Pressure</td>
<td>0%</td>
<td>0%</td>
<td>2%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Right of Refusal</td>
<td>10%</td>
<td>8%</td>
<td>16%</td>
<td>7%</td>
<td>18%</td>
</tr>
<tr>
<td>WTO or TRIPS</td>
<td>21%</td>
<td>13%</td>
<td>27%</td>
<td>22%</td>
<td>11%</td>
</tr>
<tr>
<td><strong>Efficiency</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diversion</td>
<td>13%</td>
<td>0%</td>
<td>2%</td>
<td>10%</td>
<td>9%</td>
</tr>
<tr>
<td>Litigation</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>7%</td>
<td>6%</td>
</tr>
<tr>
<td>Market Competition</td>
<td>4%</td>
<td>13%</td>
<td>11%</td>
<td>1%</td>
<td>11%</td>
</tr>
<tr>
<td>Procurement</td>
<td>15%</td>
<td>6%</td>
<td>4%</td>
<td>2%</td>
<td>5%</td>
</tr>
<tr>
<td>Profit and ROI</td>
<td>3%</td>
<td>7%</td>
<td>4%</td>
<td>6%</td>
<td>4%</td>
</tr>
<tr>
<td>Eligible Importers</td>
<td>0%</td>
<td>14%</td>
<td>6%</td>
<td>3%</td>
<td>0%</td>
</tr>
<tr>
<td>CAMR Outcomes and Uptake</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

\(^1\) n = total number of words per testimony of stakeholder group. Unit of analysis = stakeholder-testimony.
\(^2\) Percentages represent proportion of text where specified themes were found. Paragraphs often made reference to more than one concept; therefore paragraphs were often coded for multiple themes.
\(^3\) IPIC stands for the Intellectual Property Institute of Canada.
### Table 6: Proportion of Debates Coded by Theme by Political Party (2004)^1,2

<table>
<thead>
<tr>
<th>Theme</th>
<th>Liberals</th>
<th>Conservatives</th>
<th>Bloc Quebecois</th>
<th>NDP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aid</td>
<td>3%</td>
<td>8%</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>List of Countries</td>
<td>18%</td>
<td>14%</td>
<td>10%</td>
<td>11%</td>
</tr>
<tr>
<td>List of Medicines</td>
<td>12%</td>
<td>14%</td>
<td>8%</td>
<td>16%</td>
</tr>
<tr>
<td>Equal Opportunity to Supply</td>
<td>2%</td>
<td>0%</td>
<td>6%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Security</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug affordability</td>
<td>6%</td>
<td>1%</td>
<td>0%</td>
<td>7%</td>
</tr>
<tr>
<td>Development</td>
<td>2%</td>
<td>5%</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>Domestic Economy</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Human Rights</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Innovation</td>
<td>2%</td>
<td>3%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Quality and Safety</td>
<td>1%</td>
<td>1%</td>
<td>0%</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Liberty</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>36%</td>
<td>22%</td>
<td>20%</td>
<td>25%</td>
</tr>
<tr>
<td>Developing Country Pressure</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Right of Refusal</td>
<td>10%</td>
<td>9%</td>
<td>2%</td>
<td>8%</td>
</tr>
<tr>
<td>WTO or TRIPS</td>
<td>15%</td>
<td>5%</td>
<td>8%</td>
<td>10%</td>
</tr>
<tr>
<td><strong>Efficiency</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diversion</td>
<td>7%</td>
<td>5%</td>
<td>14%</td>
<td>1%</td>
</tr>
<tr>
<td>Litigation</td>
<td>1%</td>
<td>4%</td>
<td>7%</td>
<td>2%</td>
</tr>
<tr>
<td>Market Competition</td>
<td>4%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Procurement</td>
<td>1%</td>
<td>3%</td>
<td>1%</td>
<td>4%</td>
</tr>
<tr>
<td>Profit and ROI</td>
<td>7%</td>
<td>0%</td>
<td>0%</td>
<td>3%</td>
</tr>
<tr>
<td>Eligible Importers</td>
<td>3%</td>
<td>4%</td>
<td>11%</td>
<td>3%</td>
</tr>
<tr>
<td>CAMR Outcomes and Uptake</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

1. n = total number of words per testimony of stakeholder group. Unit of analysis = stakeholder-testimony.
2. Percentages represent proportion of text where specified themes were found. Paragraphs often made reference to more than one concept; therefore paragraphs were often coded for multiple themes.
<table>
<thead>
<tr>
<th>Design Decisions</th>
<th>Research-Based Industry</th>
<th>IPIC</th>
<th>Generic Industry</th>
<th>Civil Society</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right of refusal</td>
<td>Allow patent-holders to compete against generic companies for contract.</td>
<td>Patent-holders should compete and outbid generic companies for contracts, with payment of a finder's fee.</td>
<td>Require early notification of patent-holder of generic’s intention to negotiate with importing country.</td>
<td>Remove right of refusal.</td>
</tr>
<tr>
<td>The list of medicines</td>
<td>No comment.</td>
<td>Maintain list but ensure additions go through advisory committee with all stakeholder groups represented.</td>
<td>Remove list of medicines.</td>
<td>Remove list of medicines.</td>
</tr>
<tr>
<td>The list of countries</td>
<td>Include non-WTO members that are least-developed countries.</td>
<td>No comment.</td>
<td>No comment.</td>
<td>Remove restrictions on eligible importing countries.</td>
</tr>
<tr>
<td>Duration of license</td>
<td>Only one license renewal should be permitted and such renewal should be for a limited and specified period.</td>
<td>No comment.</td>
<td>No comment.</td>
<td>Duration of license should reflect duration of generic contract with importing country.</td>
</tr>
<tr>
<td>The list of medicines</td>
<td>No comment.</td>
<td>No comment.</td>
<td>No comment.</td>
<td>No comment.</td>
</tr>
<tr>
<td>Termination of license</td>
<td>Patent-holders should have a right to challenge the validity of a license.</td>
<td>Patent-holders should have a right to challenge the validity of a license.</td>
<td>No comment.</td>
<td>Patent-holders should not have the right to challenge licenses.</td>
</tr>
<tr>
<td>Quantity exported under license</td>
<td>No comment.</td>
<td>No comment.</td>
<td>No comment.</td>
<td>No comment.</td>
</tr>
<tr>
<td>Information provided in compulsory license application</td>
<td>Generic should post information about contract and shipment on its website.</td>
<td>No comment.</td>
<td>Do not require generic to report patent information about importing country and WTO notification.</td>
<td>No comment.</td>
</tr>
<tr>
<td>Profit limits</td>
<td>No comment.</td>
<td>No comment.</td>
<td>No comment.</td>
<td>No comment.</td>
</tr>
<tr>
<td>Health Canada approval of generic products</td>
<td>Health Canada should approve all drugs; comparison only with products approved in Canada.</td>
<td>No comment.</td>
<td>Health Canada should approve all drugs.</td>
<td>Health Canada approval should permit approval of generic drugs in absence of Canadian reference product.</td>
</tr>
<tr>
<td>Royalty rates</td>
<td>2% royalty rate is not TRIPS compliant; should be considered on a case by case basis.</td>
<td>2% royalty rate is not TRIPS compliant; should be considered on a case by case basis.</td>
<td>Cap royalty rate at 2%.</td>
<td>Cap royalty at 4% but allow variance on a case by case basis.</td>
</tr>
<tr>
<td>Diversion</td>
<td>Proactive tracking, special packaging/colouring/shape; criminal penalties; pre-export inspections.</td>
<td>No comment.</td>
<td>Health Canada does not need to inspect whether antidiversion measures have been met.</td>
<td>No comment.</td>
</tr>
<tr>
<td>Who can procure medicines</td>
<td>No comment.</td>
<td>No comment.</td>
<td>NGOs should be eligible to procure medicines.</td>
<td>NGOs should be eligible to procure medicines.</td>
</tr>
</tbody>
</table>
Table 8: Politician Positions on Policy Design (2004)

<table>
<thead>
<tr>
<th>Design Decisions</th>
<th>Liberal Government</th>
<th>Liberal MPs</th>
<th>Conservatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right of refusal</td>
<td>Maintain right of refusal.</td>
<td>Proposed right of refusal, explored early bidding/notification.</td>
<td>Remove right of refusal but ensure compliance with Article 31(b).</td>
</tr>
<tr>
<td>The list of medicines</td>
<td>Maintain list of medicines with procedure to amend</td>
<td>Maintain list of medicines with procedure to amend under</td>
<td>Maintain list of medicines with procedure to amend under Governor in Council.</td>
</tr>
<tr>
<td></td>
<td>under Governor in Council; create expert advisory</td>
<td>Governor in Council; create expert advisory committee.</td>
<td>Allow parliamentarians to participate.</td>
</tr>
<tr>
<td></td>
<td>committee.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The list of countries</td>
<td>Maintain list of countries with procedure to amend</td>
<td>Maintain list of countries with procedure to amend under</td>
<td>Maintain list of countries with procedure to amend under Governor in Council.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of license</td>
<td>Duration of license should be 2 years.</td>
<td>Duration of license should be 2 years with a one-time renewal.</td>
<td>No comment.</td>
</tr>
<tr>
<td>Termination of license</td>
<td>Patent-holders should have right to challenge licenses;</td>
<td>Patent-holders should have a right to challenge a license; but</td>
<td>No comment.</td>
</tr>
<tr>
<td></td>
<td>decrease discretion by Commissioner of Patents.</td>
<td>decrease discretion by Commissioner of Patents.</td>
<td></td>
</tr>
<tr>
<td>Quantity exported under</td>
<td>No comment.</td>
<td>No comment.</td>
<td>No comment.</td>
</tr>
<tr>
<td>license</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information provided in</td>
<td>No comment.</td>
<td>Generic should post information about contract and shipment on</td>
<td>No comment.</td>
</tr>
<tr>
<td>compulsory license</td>
<td></td>
<td>its website.</td>
<td></td>
</tr>
<tr>
<td>application</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Profit limits</td>
<td>Patent-holders should be permitted to challenge license if</td>
<td>Patent-holders should be permitted to challenge license if</td>
<td>No comment.</td>
</tr>
<tr>
<td></td>
<td>average price is 25% or more than the Canadian equivalent.</td>
<td>average price is 25% or more than the Canadian equivalent.</td>
<td></td>
</tr>
<tr>
<td>Health Canada approval of</td>
<td>Health Canada should approve all drugs.</td>
<td>No comment.</td>
<td>Concern about eligible drugs without reference product in Canada.</td>
</tr>
<tr>
<td>generic products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Royalty rates</td>
<td>No comment.</td>
<td>No comment.</td>
<td>2% capped royalty rate is not TRIPS compliant.</td>
</tr>
<tr>
<td>Diversion</td>
<td>Proactive tracking, special packaging/colouring/shape;</td>
<td>Proactive tracking, special packaging/colouring/shape;</td>
<td>Strong anti-diversion measures should be incorporated.</td>
</tr>
<tr>
<td></td>
<td>criminal penalties; pre-export inspections.</td>
<td>criminal penalties; pre-export inspections.</td>
<td></td>
</tr>
<tr>
<td>Who can procure medicines</td>
<td>Permit NGOs to procure medicines.</td>
<td>NGOs should receive permission from the importing country</td>
<td>No comment.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>government to procure medicines.</td>
<td></td>
</tr>
<tr>
<td>Design Decisions</td>
<td>Bloc Quebecois</td>
<td>NDP</td>
<td>Final Policy Design Decision</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>----------------------------------------------------</td>
<td>---------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Right of refusal</td>
<td>Remove right of refusal; explored early bidding/notification.</td>
<td>Remove right of refusal.</td>
<td>Removed right of refusal and no early notification/bidding included.</td>
</tr>
<tr>
<td>The list of medicines</td>
<td>Concerned about list of medicines.</td>
<td>Remove list of medicines; proposed several additions to the list.</td>
<td>Maintained list of medicines; Governor in Council procedure added to amend list.</td>
</tr>
<tr>
<td>The list of countries</td>
<td>Concerned about list of countries; proposed several additions to the list.</td>
<td>Remove list of countries; proposed several additions to the list.</td>
<td>Maintained list of countries; Governor in Council procedure added to amend list.</td>
</tr>
<tr>
<td>Duration of license</td>
<td>No comment.</td>
<td>Eliminate 2-year limit on licenses.</td>
<td>2 years with a one-time 2 year renewal.</td>
</tr>
<tr>
<td>Termination of license</td>
<td>No comment.</td>
<td>No comment.</td>
<td>Patent-holders can challenge the validity of a license to terminate.</td>
</tr>
<tr>
<td>Quantity exported under license</td>
<td>No comment.</td>
<td>No comment.</td>
<td>Quantity of drugs must be determined in license application.</td>
</tr>
<tr>
<td>Information provided in compulsory license application</td>
<td>No comment.</td>
<td>No comment.</td>
<td>Generic and CIPO should post detailed information about contract and shipment on its websites.</td>
</tr>
<tr>
<td>Profit limits</td>
<td>No comment.</td>
<td>Generic firms may need profit incentive to participate.</td>
<td>Patent-holders can challenge license if average price of product is 25% or more than the Canadian equivalent.</td>
</tr>
<tr>
<td>Health Canada approval of generic products</td>
<td>No comment.</td>
<td>No comment.</td>
<td>Health Canada approval required; flexibility permitted for drugs without a reference product in Canada.</td>
</tr>
<tr>
<td>Royalty rates</td>
<td>Cap the royalty rate.</td>
<td>Cap royalty rate at 4%.</td>
<td>Royalty rate formula based upon importing country's status on UN Human Dev Index, with a cap of 2%.</td>
</tr>
<tr>
<td>Diversion</td>
<td>Strong anti-diversion measures should be incorporated.</td>
<td>Anti-diversion measures may be too onerous.</td>
<td>Proactive tracking, special packaging/colouring/shape; criminal penalties; pre-export inspections.</td>
</tr>
<tr>
<td>Who can procure medicines</td>
<td>NGOs should not be freely permitted to procure medicines.</td>
<td>NGOs should be eligible to procure medicines.</td>
<td>NGOs must receive permission from the importing country government to procure medicines.</td>
</tr>
</tbody>
</table>
Tables 1-6 presents the content analysis results by describing the frequency with which stakeholders discussed the four goals and listed themes. This quantitative presentation provides the foundation for the qualitative summaries that follow. Tables 7, 8 and 9 present the specific policy design decisions that were up for debate during the 2004 consultations, the corresponding stakeholder positions and the final policy decision.

The remainder of this chapter is divided by stakeholder group. The summary of each stakeholder's comments illustrates how each stakeholder framed the themes and issues. Chapter 7 combines these analyses to determine how framing interacted with institutions and interests to influence the design of CAMR.
Qualitative Summary – 2004

The qualitative summary is presented for each stakeholder group and contains a summary of the themes resulting from the content analysis of the Standing Committee Hearings on Industry Science and Technology on Bill C-9, An Act to Amend the Patent Act and Food and Drugs Act, from February 24, 2004 to April 22, 2004.115

Research-Based Industry

Equity

The research-based industry appeared to be making an equity argument but their argument was largely based upon their discourse on aid (aid, 41%) and the equal opportunity to supply (equal opportunity to supply, 22%). The research-based industry's description of their philanthropic programs drove their emphasis on aid, which they associated with drug affordability.

"…in almost each and every country of Africa, there is at least one program that is undertaken by pharmaceutical companies. To be more specific, I have here a series of numbers. I don't like to throw numbers on the floor; this is only a reflection of what we are doing. Abbott committed $100 million to global core-care initiatives. Aventis is a partner with WHO on sleeping sickness…Most of the money I was alluding to was in reference to infrastructure support, and that does not include the supply of the drugs. Those are usually supplied free of charge within those programs."

They framed CAMR as aid, as being complementary to the WHO initiative called "3 by 5", which aims to get 3 million people on antiretroviral treatment by 2005. The industry argued that this goal would have to be achieved in partnership, with research-based, generic and NGOs working together. They also discussed the increased availability of

funds worldwide through government donations and private organizations, which are required to help finance the building of the health systems necessary to deliver drugs.

"We know that what we are discussing now, which is the availability of drugs to those countries, is necessary but not sufficient. You need to have reasonably efficiently working health care systems. In those countries, one of the ways to achieve this is to fund the systems. I think the major difference today is there are many more private or government funds available."

The remaining portion of their equity argument consisted of their proposal, the equal opportunity to supply (equal opportunity to supply, 22%). This proposal was their alternative to the contentious 'right of refusal'.

"...the process is intended to work such that if a country posts a request on the intended WTO website that they are in need of an order, both the research-based and the generic have an opportunity to negotiate with the country based on their terms and conditions. If the generic wins the contract, all they have to do is notify the commissioner of patents, notify us, and negotiate, if possible, a voluntary licence, because that will be the quickest way to get the drugs available. But failing that--which takes 30 days, by the way--they are free to apply for a compulsory licence."

The industry framed the 'equal opportunity to supply' in terms of equity but also in terms of efficiency and liberty. They argued that their proposal would facilitate an equal process because it provides both the patent-holder and the interested generic manufacturer an opportunity to bid and compete on potential developing country contracts and supply the medicines.

"We want to make sure that there's a process involved, though, that when those contracts come to Canada we're notified, and as the process is moving forward to apply for a voluntary licence, we have an opportunity to compete on that contract as well."
Second, the research-based industry argued that the equal opportunity to supply is efficient in that it: 1) reduces the time required to make the medicines available; 2) avoids the generic industry the sunk costs associated with contract negotiation; and 3) "increases the competition and the likelihood that you're going to get more affordable medications in the world".

"I believe that the goal of research-based pharmaceutical companies, with our proposal this morning that we are calling opportunity of equal supply, is to find a solution to the access problem. We want to reduce the waiting time for patients that need these medicines, so that their wait is as short as possible."

Finally, the research-based industry framed the equal opportunity to supply in terms of liberty, as it ensures that the patent-holder's property is not used without their knowledge and they are notified of all potential developing country contracts.

"Given that the WTO decision does not mandate an open bidding process for every contract, we believe that the “equal opportunities to supply” option is a good alternative to the right of first refusal. It allows for contracts to be finalized directly between an importing country and a generic company without the patentee ever being aware that its patent was in question or having an opportunity to supply."

_Liberty_

Discussion of the equal opportunity to supply involved many liberty issues, given the references to notifying the patentee, ensuring voluntary license negotiations and what is required by the TRIPS Agreement. Overall, the research-based industry's focus on liberty (liberty, 37%) was comprised of references to intellectual property issues (intellectual property, 23%), WTO or TRIPS references (WTO or TRIPS, 21%) and the right of refusal (right of refusal, 10%). Notably, they did not comment on the impact of patent protection on prices or market competition and did not issue any support for compulsory licensing. Instead, most of the discussion of intellectual property issues pertained to the
application process and the terms for a compulsory license under the regime. Overall, they supported voluntary license negotiations prior to compulsory license application, notification of potential developing country contracts, and they were opposed to a fixed 2% royalty rate.

"…we do not believe, as opposed to TRIPS, in a fixed royalty. We believe, for orders going, it should be based on the value of the contract in the importing country."

They were particularly concerned about potential generic firm contracts with higher income developing countries "where the contracts might be more valuable" as opposed to least-developing countries where they anticipated few to no royalties. Later, Mr. Jean-Francois Leprince appeared to contradict this statement by suggesting that a fixed royalty rate could lead to a potential trade challenge under the WTO Dispute Settlement Mechanism.

"…the royalty rate, as Mr. McCool has explained, is part of the TRIPS agreements that come under the World Trade Organization, and I would remind committee members that the Canadian government needs to adhere very closely to the WTO agreements, even more so because of this initiative, where Canada is creating a precedent and has to set an example through exemplary practices…it would be very unfortunate if we ended up with a trade challenge from another country because of provisions dealing with royalty rates."

The research-based industry's references to WTO or TRIPS (WTO or TRIPS, 21%) were made in support of their recommendations including the royalty rate, the equal opportunity to supply and anti-diversion measures.

Efficiency
Diversion was another key issue for the research-based industry (diversion, 13%), "…that is the potential for illegal diversion of product to countries other than those intended…". They were concerned about the need to prevent and flag diversion when it happens and
advocated strong anti-diversion measures such as packaging, marking, labeling and changing the shape of products. They framed these anti-diversion measures as creating "certainty and stability" and "transparency".

They framed the issue of diversion as efficiency and security, arguing that diversion could impede drug access by the intended beneficiaries of the legislation.

"The diversion measures are extremely important. If not done properly it would be the one thing that would prevent access to medicines long term. If you have diversion you're actually diverting it away from patients of need and countries of need. So the stronger the language is and the more protection you have, the more you can ensure and the better tracking you have that the product is actually being delivered and it is being used appropriately on-site. So we feel very strongly about that. We've asked for a penalty only if a company knowingly knows that diversion is taking place and continues to support it. But the diversion is extremely important."

The equal opportunity to supply was the exclusive subject of their references to procurement (procurement, 15%) and market competition (market competition, 4%). Their discussion of procurement referred to ensuring the patent-holder an opportunity to negotiate with the potential importing country and bid on potential contracts. Their discussion of market competition was focused on ensuring that the brand name company can compete against a potential generic manufacturer.

In relation to profits or ROI (profits or ROI, 3%), the research-based industry emphasized the "humanitarian and non-commercial" nature of the Paragraph 6 Decision.

"You have to remember the intent of the system is humanitarian and non-commercial."
Security

The research-based industry referred often to drug affordability (affordability, 12%); however, they did not refer to a role for generic competition or compulsory licensing and did not suggest that prices or patents were barriers.

"…we want to reaffirm our commitment to achieving the basic objective that brings us together around this table this morning: the efficient and timely distribution of affordable medication to countries and patients who need it."

The research-based industry also mentioned the issues related to development (development, 8%), which includes issues of corruption, infrastructure, poverty and lack of financing, inadequate health systems and lack of human resources. In discussing these development issues, they argued that the problem is not drug affordability; it is health system infrastructure and human resources.

"…I want to say that offering access to affordable medicines is but one element in providing relief to the developing world. We must address the issues of access to physicians, proper diagnosis, and creation of a sustainable infrastructure."

The research-based industry briefly mentioned the theme of innovation (innovation, 2%).

"While we will continue implementing international aid programs, we also believe that our role in helping the developing world is finding cures to such terrible diseases as HIV/AIDS. We are proud of companies like GlaxoSmithKline and Merck & Co., who at present each have HIV/AIDS vaccines at human clinical trial phases and are hopeful they will succeed. Our goal is to continue research for the next generation of drugs to treat diseases affecting patients around the world."

They also mentioned their donation of drugs in relation to sleeping sickness, a neglected disease. Their only comment regarding quality and safety (quality and safety, 3%) was in
relation to the reference product for bioequivalence testing. They did not want Health Canada to refer to products in other countries, stating that they would like to see comparison to those products already approved by Health Canada.

The research-based industry was silent on the issues of human rights and the Canadian domestic economy.

Generic Pharmaceutical Industry

Liberty

Much of the generic industry's references to liberty (liberty, 58%) contained underlying arguments of efficiency.

First, they rejected the research-based industry's originally proposed "right of refusal" (right of refusal, 8%), arguing that patent holders were free to drop their prices or donate their products at any time and that this right did not need to be incorporated into the legislation.

"It is our view that the brand-name drug companies already have, and will continue to have, a de facto right of first refusal, as they are the patent holders of the products covered under this legislation. They can make and sell, or donate, the medicines at any time to anyone they wish. This legislation in no way affects that right."

The generic industry also framed the right of refusal as inefficient: the possibility of losing negotiated contracts to patent-holders would discourage generic firms from even entering the negotiating process. Furthermore, the generic industry needed to recoup any sunk costs associated with developing a drug under the regime.

"The right of first refusal erodes the incentive for generic drug makers to enter into the lengthy development process, or to seek out and set up deals for less developed countries. The generic company cannot remove productive resources
from other activities and invest time and money in developing medicines protected by patents in Canada, if it has to hand negotiated contracts over to a third party—the brand-name drug companies."

In relation to their discussion of intellectual property (intellectual property, 44%), the generic industry primarily advocated notifying the patent-holders at an early stage of their intent to enter negotiations with a potential importing country then voluntary license negotiations, and failing that, automatic right to apply for a compulsory license.

"On page 4 of our brief we actually have recommended that the generic company inform the patent holder of any tendering process it intends to enter into."

"…we would rather see negotiations, and if possible…a voluntary license could be given. If not, then in our view there should be an automatic right to apply to the commissioner for the license."

The other main strand of their argument reflected a desire to limit the royalty payments to patent-holders. They wanted a capped royalty rate at 2%, which they framed in terms of liberty and security. First, they reasoned that patent holders deserve some kind of remuneration.

"I think it was agreed by our industry that 2%, while it added to the costs of developing the product, was a recognition that these products are under patent and that some royalties should go back to the patent owner."

Second, they argued that a capped rate would keep the drugs affordable.

"…we believe a cap on the royalty rate is absolutely necessary to ensure that the products are made and are able to be distributed at reasonable prices."
Less mentioned was the link between patents and drug affordability. They did suggest that patents prevent access to Canadian drugs, through the "extraterritorial application of patent law" beyond Canada's borders to countries where patents do not exist. They argued that the removal of this clause was TRIPS compliant and would allow the Canadian government to better achieve its goal of increasing affordable access to medicines in developing countries.

"A more general problem for our companies is that current Canadian patent law extends domestic patent protection to all markets in developing countries even if they don't have patents. This unfairly denies persons in countries without patents the ability to access Canadian goods. It also unfairly prevents Canadian manufacturers from competing on an equal basis with manufacturers in other countries in which there is no patent."

Other domestic issues mentioned briefly included concern over evergreening and the NOC regulations.

The other main strain of their liberty arguments were focused on TRIPS (WTO or TRIPS, 13%). Arguing that market competition was required to bring drug prices down, they framed the purpose of the Doha Declaration, the Paragraph 6 Decision and even the WHO three by five initiative as increasing the number of pharmaceutical suppliers.

"..the purpose of the Doha initiative, which this legislation is intended to implement, is to increase the number of manufacturers around the world of the medicines needed on the international scene. More manufacturers mean more supplies and lower prices. If there weren't a need for more manufacturers and more suppliers, and if there were enough medicines on the world market at reduced prices for the developing world, there would have been no need for the November 2001 Doha declaration, no need for the August 30, 2003 WTO decision on access to medicines, and no need for Bill C-9."
The removal of the list of medicines and the extraterritorial application of patent law were justified as TRIPS compliant.

**Efficiency**

As stated above, the generic industry reiterated their view that the purpose of the Doha initiative was to generate global market competition (market competition, 13%).

The generic industry explained the costly and lengthy process of researching and developing a drug and the importance of being able to recoup their costs (profits and ROI, 7%).

"What we're suggesting is that the companies need certainty, legal certainty that in fact they can actually develop and sell these products, because remember, here we're talking about, largely, the anti-retroviral drugs, and when we look at the patents in Canada, many of them are going to exist to 2012 or 2016. So you need legal certainty, if you're going to undertake these humanitarian functions, that in fact you're actually going to be able to make and sell the product or donate the product abroad and that you're not going to later find yourself in difficulty."

Regarding the question of allowing NGOs to contract directly with a Canadian generic manufacturer (eligible importers, 14%), the generic industry saw the restriction as problematic and framed it as an issue of the efficient delivery of medicines.

"These are the people who are on the ground, working with patients, working with doctors and hospitals in these countries. I think as we try to build this legislation to cover everything from the point of making it in Canada to its arriving on the ground to its administration to a patient, I'm not quite sure that in terms of the spirit of the legislation, it's really all that possible."

References to procurement (procurement, 6%) were references to the early stage notification of intended negotiations with developing country purchasers, a liberty issue.
Security
They cited drug affordability often (drug affordability, 19%) and, as stated above, linked it to market competition. Generic drugs were framed as being affordable. In this vein, they framed Bill C-9 as an initiative to increase access to Canadian generic drugs.

"Let me begin my comments on the bill by saying that the Canadian Generic Pharmaceutical Association is strongly supportive of the government's desire to make Canadian generic pharmaceuticals available for export to developing countries in times of health crisis. The CGPA and its member companies have been encouraging the government to take meaningful action to help developing nations gain access to affordable medicines since the Doha declaration of November 2001."

They issued clear support of obtaining Health Canada approval (quality and safety, 9%) and they spoke briefly of the importance of their sector's contribution to the Canadian domestic economy (domestic economy, 4%).

Equity
The generic industry framed themselves as philanthropic, describing their commitment to increasing drug access through aid initiatives (aid, 25%).

"Our member companies donate millions of dollars' worth of generic drugs annually to the developing world. In most cases, these drugs are donated to non-governmental organizations who administer the drugs directly to people in the developing world who need them."

They also spent a considerable portion of their "aid" time, in arguing the importance of NGO contracting with generics. In terms of the legislation's contents, they supported the elimination of the list of medicines (list of medicines, 4%), arguing that the WTO Agreement did not indicate any need for it.
Civil Society

Liberty

Most representatives framed patent protection (intellectual property, 25%), as stipulated by the WTO TRIPS Agreement, as the cause of high drug prices. One representative quoted the U.K. Commission on Intellectual Property Rights and Development:

"As intellectual property rights are strengthened globally, the cost of medicines in developing countries is likely to increase, unless effective steps are taken to facilitate their availability at lower cost. [...]"

Among these statements, NGOs briefly yet forcefully linked India's impending compliance with the TRIPS agreement to the diminishing of affordable generic medicine supply. Civil society clearly defended the use of compulsory licensing as a tool to increase market competition and drug affordability.

"After January 1, 2005, the source for affordable generic versions of essential medicines will dry up. The only reason that we now have access to $140 a year triple therapy is because countries like India do not grant product patents yet. This soon will no longer be the case. Unless producing countries make regular and widespread use of compulsory licensing, including for exports, drug prices will continue to increase."

Dr. Fred Abbott, an academic witness, argued that no prior voluntary license negotiations were required under the TRIPS agreement and that by inserting them into the Canadian legislation, they were adding additional, unnecessary restrictions.

"The critical thing is, HIV/AIDS is universally recognized as a global public health emergency, and addressing it by compulsory licensing requires no prior negotiation with the patent holder. Bill C-9 does not account for this very obvious and incontrovertible fact."
Instead, he recommended that no prior negotiations were required and that the generic producer automatically applies for a compulsory license to the federal government.

References to WTO and TRIPS (WTO or TRIPS, 27%) mainly reflected the language that they were using: what was and wasn't required by TRIPS; the interpretation of TRIPS. They framed the goals of the Paragraph 6 Decision as generating generic competition.

"The foremost objective of the decision on paragraph 6 was to facilitate the low-priced supply of medicines by making the market more competitive for the benefit of countries with insufficient or no manufacturing capacity in the pharmaceutical sector. The way to create a competitive market in pharmaceuticals is to encourage generic producers."

NGOs viewed the right of refusal (right of refusal, 16%) as anti-competitive and not required by the TRIPS agreement. By giving patent holders an opportunity to 'scoop' contracts, it was the 'fatal flaw' in the legislation that would ultimately dissuade generic holders from participating in the regime.

"The measures in the proposed bill enabling patent holders the right to take over contracts negotiated by a generic company, even after the patent holder has turned down the request to provide a voluntary licence, are not acceptable—not because they favour one company over another, but because they kill the basis for commercial interest in competition from the generic drug industry. It is only this competition that can guarantee sustained lower prices of drugs over the long term, and there is ample empirical evidence to substantiate this claim."

"A careful study of the TRIPS clause, article 31, the Doha declaration, and the August 30, 2003, WTO general council decision shows there's no requirement
that patent holders be given an opportunity to take over contracts negotiated between importers and generic producers."

In contrast, HPIC argued that it would generate competition between the patent-holding drug manufacturer and the generic drug manufacturer.

"I believe the provision was put there in an attempt by the drafters of the bill to ensure that generic producers really do offer the best prices possible to developing countries. By giving patent holders an opportunity to take over contracts negotiated by generic producers, perhaps the intention was to ensure that generic competitors would be honest in their negotiations and genuinely offer low prices with the threat of competition over their shoulders."

Dr. Abbott challenged this interpretation and suggested that generic producers would never 'behave so irrationally as to continue to pursue fruitless negotiating" given the fact that patent-holders would have an incentive to pick up their contracts.

"Imagine that in the basic Canadian market you have a dominant supplier in the market, an exclusive supplier that has its own purchasers, and you have a much weaker, much smaller potential competitor that wants to get into the business and tries to talk to prospective customers that are currently dealing with the dominant supplier. But when it goes to deal with those customers it sends a letter to the dominant supplier saying: “Dear dominant supplier, I'm going to talk with your customer next Tuesday. I want to make sure you know about that just in case you think I might get a deal that will take away your market. You'll be in the room there with me and can make the counter proposal to the prospective purchaser and make sure that I can't outbid you on this particular business.”

Civil society was the only group to mention developing country pressure (developing country pressure, 2%). Dr. Abbott stated that pharmaceutical companies ask governments in developed countries to pressure developing countries not to purchase generic drugs.
"What it also does, and I want to address the reality, is create a situation where the patent holder then goes to its home country government--let's call it the United States, or Great Britain, or Germany--and says “You know, I have some generic producers here talking with X government in Africa and I'm really disturbed about that; I don't want them to buy generic. I want you to send the ambassador to talk to the public procurement authority." I regret that I've been involved in so many of these situations. I think you need to provide the generic producer with the right to conduct business without that kind of intervention, and that is very important."

One witness argued that the brand name industry uses pressure tactics in cooperation with powerful countries to prevent countries from using compulsory licensing and other TRIPS flexibilities.

"A public health safeguard was written into the TRIPS agreement that ought to have provided the flexibility for countries to manufacture or import affordable generic drugs. However, due to effective lobbying by the brand name pharmaceutical companies and bullying tactics by certain large countries, no country was able to make use of that safeguard…"

**Efficiency**

All NGOs viewed increased market competition (market competition, 11%) as the most effective way to reduce drug prices. The strength of CAMR was to encourage compulsory licensing regimes in other countries, ultimately expanding the competitive market for generic drugs.

"Oxfam's research and that of other non-governmental organizations show clearly that prices of medicines fall dramatically when generic companies are allowed to compete. Canada's legislation to implement the August 30 agreement is essential, because it will help bring competition back to the marketplace."
NGOs discussion of procurement was mainly in relation to debunking the right of refusal, which they argued is a 'global multi-source bidding process, using a WTO website-based system.' (procurement, 4%). Dr. Abbott explained that the bidding process in pharmaceutical procurement was separate from the WTO notification requirement.

"I'm afraid there's a bit of a misunderstanding on your part on what that website is. That website is the website provided for in the decision on implementation of paragraph 6, under which a country notifies that it is an eligible importing country and intends to make use of the system. It is a one-time notification that does not in any way involve any kind of negotiation or bidding process. It's merely a declaration of eligibility, and that in fact is specifically provided for in the draft of Bill C-9. The notion of a WTO tender-based bidding system website absolutely does not exist."

Dr. Abbott argued that the other weakness of the industry proposal was that this global bidding process did not take into account the global pharmaceutical suppliers such as India, Argentina or Brazil.

"Even assuming this hurdle was overcome some time in the next several years, the industry proposal hypothesizes a global bidding process, but then refers only to the Commissioner of Patents of Canada for making licensing decisions, yet Canadian companies would not be involved in the results of much of the foreseeable bidding…the winning bidder is most likely to be an Indian, Argentinian, or Brazilian patent producer who has no nexus or relationship with Canada. The Canadian Commissioner of Patents has nothing to do with that."

NGOs unanimously supported the idea of permitting generic companies to contract directly with an NGO (eligible importers, 6%).
"The second flaw is that MSF cannot clear the drugs. MSF is an independent humanitarian organization. We could never be an agent of government. The very nature of our mandate—to provide humanitarian assistance to countries—is possible because of our independence from government. So we could never, and will never, become an agent of government, because then we could not serve the people who have needs…"

Civil society hardly mentioned diversion (diversion, 2%), partly because they did not think it was a major issue.

"While there may be a concern about possible diversion, I think we need to be careful not to overstate the concern and let it become an excuse not to act."

Discussion over profits was mixed (profits and ROI, 4%). One NGO argued that CAMR provided the opportunity to rise above profits and commercial interests. Another NGO mentioned that the research-based industry makes no profits from the developing countries, as mentioned earlier. Some comments suggested that they actually thought that generic companies could have commercial incentives within the regime.

"Resource-limited settings do not today represent a sales market that is able to contribute to revenues needed for research and development and corporate shareholder profits. This may represent, however, a significant opportunity for various generic companies in Canada, provided they are able to manufacture and distribute drugs at a cheaper price than generic manufacturers from other countries, such as India and Brazil, while still covering their costs and turning profits for their shareholders."

_Equity_
Civil society spoke the most about aid (aid, 17%), which included prevention, care, and treatment programs and capacity-building through training and infrastructure support.
"When we began the project we made a plan for providing everything, and I mean every-thing: the medicines, the training, the lab equipment, the transport, the lot. We worked with communities, we worked with health workers, we worked with their supervisors. There were clinics that had no medicine, and some of those health workers had no salaries, so they weren't very motivated to do what they did."

"The treatment action that's being set up by WHO obviously requires setting up an infrastructure and doing the training that's needed in order to deliver the drugs, but the actual resources that are needed at the country level need to come through institutions like the Global Fund."

"We would always argue that you need to have a development assistance program, which includes health education and everything else. The millennium development goals call for about $10 billion per year as a target for development assistance, particularly in health. Current contributions worldwide are less than half of that."

Much of their discussion on aid covered the issue of financial assistance, donations, support and funding that is currently being done in the field. Overall, there's a general sense that there is an inadequate level of global funding, including that coming from the Government of Canada.

"Canada's contribution of $25 million U.S. per year is well below our share of the global cost of fighting these three diseases, and in fact is less than the Gates Foundation's contribution."

They acknowledged the benefits of aid but they stressed that aid programs were not a sustainable solution to the access crisis and that lowering the cost of medicines was critical.
"I should note that the substantial donations that were mentioned this morning of medicines are important, but they are no solution. Health ministers from poor countries frequently have to grovel before powerful companies to beg for donations. It is not a sustainable way to run a health program. It is not sustainable when developing countries have to depend on the whims of companies as to when they decide to give and what they decide to give. We need to have a sustainable source of medicines that they can purchase in the marketplace, and that will come through generic competition."

Most NGOs disputed the creation of a list of eligible medicines (list of medicines, 12%). They stated that it was not required by the TRIPS agreement and that developing countries had already fought a long battle to prevent a list of diseases during WTO negotiations. The list impinged on the sovereignty of countries to determine what their public health needs are and contested it on the basis of inefficiency, that it would inevitably create delays and obstacles.

"….we believe there shouldn't be a list, because developing countries at the Doha talks on the 30th of August fought very hard for there not to be a list of scheduled diseases, for there not to be a list of medicines. Including this list flies in the face of all the work that was done at these international negotiations, all the discussions saying that we're not to have any lists of this sort, because there doesn't need to be a list. It infringes on the sovereignty of a country in saying what their own public health problems are."

In contrast, HPIC supported allowing the list of medicines to initially guide the regime.

Disagreements over the list of eligible countries (list of countries, 7%) were fewer but forceful. NGOs were against the list and wanted it removed given the absence in the TRIPS Agreement of such provision. NGOs praised the government for extending the benefits to least-developed countries; however, they argued that many countries fell between the cracks including East Timor, Iraq, and Venezuela.
Security

The theme of development (development, 17%) related mainly to the issue of perceived barriers, problems and deficiencies in developing countries. There was a lot of discussion of these topics by NGOs but much of it was in response to questions posed by the Standing Committee on existing barriers to drug access and whether making cheap drugs available would really do anything to address the problem. The content of the development node is overwhelmingly about the issue of health care infrastructure in developing countries.

"I just wanted to address this infrastructure point. I think it's very true that we do need to have good infrastructure in order to provide medicine, and it is very challenging, but I think this is not something that needs to be traded off against access to essential medicines. That's my point. This is something that needs to be dealt with as well. In MSF we face those issues in the field; it is an issue, but we can overcome it. I just wouldn't like that to be used as a reason we shouldn't be able to change things. This issue is about providing access to low-cost medicines for people in developing countries, and just because an infrastructure is not there is not a reason to say we shouldn't provide low-priced drugs. The two things are not mutually exclusive; both have to be worked on."

Many NGOs also emphasized that this is where they play an important supportive role, and help roll out necessary programs providing support in resource-limited settings. One NGO in particular (CARE) appeared to suggest that these issues while present, could be overcome through the help of the NGO community:

"As part of that, we are, as with the TB project in Zambia, sometimes able to reach places that the overstretched government systems cannot reach. In other places, where political favouritism and interference is an issue, the potential for direct provision with Canadian generics by organizations such as ours, by UN organizations, is even more essential. I know that there are concerns being
expressed today, and were previously on Tuesday, about the infrastructural or technical capacity to monitor and administer life-saving medicine. Now these challenges—and that's what they are, they're challenges—are things that we need to overcome, and they can be overcome."

Other barriers discussed included other development issues such as access to clean water, roads and transportation, security and peace, access to nutrition. The lack of financial resources of developing countries and the issue of poverty was mentioned less so. Even less was the issue of institutional capacity and political stability in these countries to either provide health care services or actually implement the legislation itself. HPIC suggested that the lack of institutional capacity in developing countries is a major problem.

"I would think one of the real issues is that the focus countries Canada is going to be interested in have some form of capacity and have the therapies in place to deal with ARVs. I think that's probably one of the primary points that really needs to be considered."

They linked it to the issues of substandard quality as well as diversion:

"They must have in place a basic system for the monitoring and checking of essential drugs, both to make them available and also—I believe this is important—to ensure quality. I spent 15 years in Africa and in every region of the continent I saw drugs that were of poor quality, that were long passed their expiry date or that were exported from Europe to African markets."

Civil society affirmed the importance of increasing drug affordability (drug affordability, 15%), maintaining that high prices are a major barrier to drug access and the Paragraph 6 Decision and CAMR as part of the solution.
With respect to drug innovation (innovation, 2%), they underscored the fact that the majority of the developing world makes a negligible contribution to the costs of research and development.

"Very briefly, it's true that the companies actually have stopped doing research on many of the diseases that afflict poor people, because there's no profit in it for them. It's also true that they get a very minimal amount of their profits, practically negligible profits, from the poor countries that we're talking about; 1% of the global pharmaceutical profits come from the whole continent of Africa. There isn't money in this for them, which is why the drugs aren't being provided. I think this is why the measure is coming about."

Civil society was almost the only stakeholder to mention human rights (human rights, 4%). To them, CAMR was about realizing the human right to health, which was required by treaties that Canada was signatory to. NGOs linked achieving this right to health as a development and foreign policy goal. One NGO explicitly stated that the human right to health supercedes Canada's trade obligations to protect intellectual property rights:

"The current bill ensures that countries that are unable to benefit from compulsory licensing, those with insufficient pharmaceutical manufacturing capabilities, can improve their access to medicines. There is no question that, in terms of international rights, our obligations to protect intellectual property rights are secondary to respecting fundamental rights such as the right to health. Our actions must reflect our international commitments."

**Liberal Government**

*Liberty*

The bulk of the government's discourse on intellectual property (intellectual property, 41%) was the use of the language of IP and patents in describing the amendments to the Patent Act, the requirements and the how the regime worked itself.
Balance was a key theme in the government's discourse on intellectual property, arguing that this balance between intellectual property rights and ensuring access to medicines could be attained.

"Ultimately, the government was confronted with the need to ensure that these amendments maintain the integrity of Canada's intellectual property regime for pharmaceuticals, while at the same time facilitating the flow of low-cost medicines to countries in need."

"On the one hand, we want to make sure that there is a quick and additional supply or demand of drugs for countries who need them. On the other hand, we want to make sure that the intellectual property system will continue to create necessary incentives for the development of new products in Canada, and that it will continue to attract necessary investment in order to offer products to Canadians as well as to beneficiaries in other countries."

They discussed the compulsory licensing process and its terms under the legislation. The government viewed prior voluntary license negotiations as a key TRIPS obligation under Article 31(b).

"One particular obligation that proved challenging in this respect was article 31(b) of TRIPS, which stipulates that before a licence may be granted, its applicant must have made efforts to obtain a voluntary licence from the patentee on reasonable commercial terms. The manner in which this obligation has been implemented provides the patent owner with a right of first refusal. In essence, it requires that an applicant for a compulsory licence first disclose the terms of its agreement with an important country to the patentee, who then has the option of pre-empting the grant of a licence if it is prepared to supply the needed medicines on terms no less favourable."

They considered a compulsory license of two years to be compliant with TRIPS.
"When it came time to determine the duration of a compulsory licence, that was based on article 31(c) of TRIPS, which provides that the duration of the licence must be limited to the purpose for which it was authorized. In this context, the two-year period was considered reasonable to meet the needs of a so-called standard drug supply contract, given that drugs have a limited shelf life and that at that point in time, one of the things that people wanted to ensure was that the exported drugs would not be expired."

The government did not talk about the issue of patents and its impact on pricing and did not frame compulsory licensing as generic competition or reduced drug prices. No discussion occurred regarding the effectiveness of the intellectual property system in stimulating innovation. Also, the government did not discuss the issue of developing country intimidation in relation to attempts to use compulsory licensing.

The government's discourse over compulsory licensing was mainly in relation to interpreting and complying with the WTO TRIPS Agreement and the WTO Paragraph 6 Decision (WTO or TRIPS, 22%). They did not mention the Doha Declaration, in relation to their interpretation of the agreement or waiver.

"…the August 30 decision constitutes a waiver of only two of the 12 TRIPS obligations pertaining to compulsory licensing, some of which are nominally at odds with the humanitarian nature of this initiative. We were thus required to tread a very fine line between maximizing compliance with TRIPS and devising an effective and functional regime."

Foreshadowing the right of refusal, one Liberal government cabinet minister argued that the goal of Bill C-9 is to allow the Canadian industry to benefit from intellectual property flexibilities, which would then address the drug access gap.
"…you have to understand that what we are trying to do is to let Canadian industry be the first to take advantage of the fact that we have lifted certain international intellectual property obligations. That's what we are trying to do here….So we want Canadian industry, whether it's the patent industry or the generic drug industry—as a government we are neutral—to be able to benefit from the lifting of these international obligations. Through CIDA and Health Canada, we are going to do the best job possible to get these drugs to the right people on time."

As mentioned above, the government argued that the right of refusal (right of refusal, 7%) was their way of complying with Article 31(b) of the TRIPS Agreement; however, they justified its inclusion based upon four additional grounds: 1) efficiency and expediency, 2) procedural fairness, 3) sending a positive international signal to the international community and 4) ensuring the participation of both industries.

"There are three basic reasons we have chosen the mechanism outlined in the bill. First, given that a generic drug can take from two to five years to develop and prove, encouraging the provision of medicines from their most immediate source (the patentee) was viewed as consistent with the underlying policy objective of getting medicines to those in need as quickly as possible. Second, it ensures that the patentee has proper notice of a country's intention to import. This is an essential component of procedural fairness which is not clearly provided for under the decision. Finally, it was seen as sending a positive signal to the international community that humanitarian initiatives in this area can be effective and yet have due regard for the property rights of patentees."

"…I think, the work of your committee is going to be very important in order to see, not only with the generic drug industry but also with the brand name industry how we could arrive at a balance that would allow the participation of both industries."
These arguments are similar to that from the research-based industry's submissions the following month.\textsuperscript{116}

\textit{Equity}

The government's initial justification for the list of medicines (list of medicines, 18\%) was the vagueness of the WTO Decision.

"The first challenge stems from the very language of the August 30 decision itself, which is somewhat vague. As a result, certain provisions are open to wide and differing interpretation. Even a question as fundamental as the nature and scope of drugs covered by the decision remains a subject of considerable debate. Some contend that it is limited to those needed to treat HIV/AIDS, tuberculosis, and malaria only, while others insist that no restrictions whatsoever apply. With no precedent upon which to rely, the government was left to make a reasoned judgment, and we believe that we have chosen the most appropriate course of action."

They did not refer to the negotiations on the scope of diseases at the WTO. Instead, they argued that their solution was a compromise between stakeholder requests for a narrow definition of medicines and no definition at all. They used the WHO Essential Medicines List as a 'starting point' because it "provides a sound guide to the most efficacious, safe and cost-effective medicines for priority conditions in a basic health care system".

To assuage concerns over the scope of the list, the government emphasized that the schedule can be 'readily amended' to include drugs not on the list through the Governor in Council, implying flexibility. They committed to creating an expert advisory committee to advise the government on the need for amendments to the schedule. Furthermore, the government provided examples of medicines to be added to the list, which NGOs recommended. Four drugs, all for the treatment of HIV/AIDS, were on the WHO Essential Medicines List but were not listed in the Canadian bill.

During the clause by clause, a representative from the Therapeutics Product Directorate discussed some proposed additions to the medicines list by the NDP. Notably, they rejected the addition of tenofovir because it had just been released onto the domestic market, so they would have to wait for more post-market surveillance information on the product before they would be capable of following an abbreviated new drug submission. Possibly more importantly, a new reason for the existence of the list emerged.

"I believe schedule 1 constitutes a guidance to industry that allows for them to understand which products Health Canada has knowledge and experience on in order to allow them to negotiate a contract and submit an abbreviated new drug submission. The Minister of Health must advise the patents commissioner on whether the product meets Canadian regulatory requirements. We can only do so in a facilitated process, using an abbreviated new drug submission, if those products have been regulated in Canada as a brand or in another format. So the list itself is essential in order for companies to bring that type of facilitated application to us."

On the list of countries, the government argued that because the TRIPS Agreement applied to WTO member countries only, that the benefits of Bill C-9 must be restricted to WTO members. Their inclusion of some non-WTO member countries was framed as going beyond what was required by the TRIPS Agreement. The government's inclusion of least-developed countries as recognized by the United Nations was justified based upon Canadian foreign development policy. Schedule 3 lists countries that are WTO members but 'self-identified' as agreeing only to use the legislation in cases of "national emergency or extreme urgency". For those countries that did not fall under any listed schedules, the government identified other means through which they could provide assistance. Furthermore, the Governor in Council could always amend the list, if any of these countries were either identified as a least-developed country or acceded to the WTO.
"As my colleague from the international trade department has pointed out, we have already gone beyond the agreement, which is fundamentally a WTO agreement, through a waiver. So we have already gone beyond it in the case of a number of LDCs, as Minister Robillard mentioned. There are 18, I believe. There is a balance here in terms of countries to include or not include. The one point that I think is worth reinforcing is that CIDA is working in a number of these developing countries that are in the ranks above the least developed."

During the clause by clause analysis, they discussed the process that would be required to add or remove countries from the list and discussed the NDP's list of suggested countries, stating that they were all admissible.

The majority of the government's emphasis on equity focused on aid (aid, 13%). Most of their comments described CIDA's aid and development programs, which mainly provide a range of health system assistance such as: prevention, treatment, drug distribution, health education, addressing stigma and/or care.

The government clearly rejected any suggestions to tie CIDA's aid to CAMR in any way. The committee questioned the amount of resources the government committed to ensuring CAMR works but the government responded by emphasizing CIDA's existing involvement in capacity building, financial contributions and donations to development and/or health programs.

The government framed their foreign development assistance as financial support to facilitate Bill C-9, which covered a range of aspects including capacity building and financing drug procurement. CAMR was a fundamental component of their larger development agenda.

They made a clear link between Bill C-9 and the World Health Organization's 3 by 5 initiative, which aimed to get 3 million people on treatment by 2005. The government suggested that Bill C-9 would contribute to attaining this goal.
"As I said, we are participating in this initiative for the 3 million cases we anticipate treating by 2005. We are working with NGOs, Doctors Without Borders, and other very serious and dedicated people. Naturally, CIDA also has very good contacts in the field. So we are going to be very vigilant on that score. It doesn't necessarily require a huge budget, what's most important is the determination to succeed."

The government also framed Bill C-9 as a way to increase donor purchasing power across the entire world, resulting in the most efficient use of resources. Throughout the debate, the government also encouraged other countries with manufacturing capacity to implement the Paragraph 6 Decision.

"As I've already explained, CIDA is already spending significantly. So, for us, the best possible result to be gained from this initiative, this bill, would be, for instance, for other countries that already have the capacity to manufacture these products to follow suit. And so, over time, the price of these essential drugs on the ground would be greatly reduced. As I've already stated, what we hope is that our funding, our aid and our efforts will lead to better health results and help in the fight against these diseases. We are already involved in this fight; it's about using our resources as efficiently as possible."

Efficiency

All government statements identified diversion (diversion, 10%) as a critical issue that must be addressed.117 Their discourse focused on the incorporation of anti-diversion measures to ensure that drugs do not seep back into developed country markets. From this perspective, diversion was framed as a liberty issue in that they would protect patent-

117 Rx&D dedicated 3.5 pages of 11 pages of suggested amendments on diversion. They listed many examples of diversion and then argued in favor of taking "all reasonable measures" to prevent diversion to ensure compliance with the Paragraph 6 Decision, as an "imperative from the perspective of the patentee's rights, and for safety reasons." Canada's Research-Based Pharmaceutical Companies. February 2004. "Providing Affordable Medicines to Patients in the Developing World: a Submission to the House of Commons Standing Committee on Industry, Science and Technology regarding Bill C-9."
holders' profitable markets from the reimportation of cheaper generic copies. However, in the opening remarks, the government clearly framed the legislation as having to strike a balance between anti-diversion measures and ensuring an efficient process for getting the drugs out to developing countries.

"Thus, while measures must exist to ensure that the regime is not abused by unscrupulous parties who would divert licensed medicines to more profitable markets for personal gain, they must not be so burdensome as to frustrate the efforts of those whose intentions are truly in keeping with the humanitarian aim of this initiative."

The government framed diversion as "abusive" practice, "illegal" activity, and made reference to "horror stories".

Much of the discussion focused on Health Canada's regulations to prevent diversion, such as labeling and marking of drugs to ensure that they are traceable and distinguishable, which they stated were prescribed by the WTO General Council. They stated that Health Canada would provide pre-export and periodic inspection to ensure shipments of drugs are meeting these requirements. Furthermore, the government linked issues of patent infringement to failure to comply with anti-diversion measures. If there is no longer compliance with Food and Drug Regulations, Health Canada can notify the Commissioner of Patents, which can trigger the end of the license.

Lastly, anti-diversion measures were framed as a function of transparency, which, as they stated, was prescribed by the WTO Decision.

"One of the things that was felt to be instrumental in ensuring that diversion is limited was the whole public disclosure element of the August 30 decision. The world will know when products are about to be exported under compulsory licence, what that product is, where it is intended to go, and what it looks like, so that the world can see or can expect that if they find that product in their market,
they can signal that to the patentee and immediately the compulsory licence can be terminated."

Discussion of litigation (litigation, 7%) was about the terms under which the patent-holder can challenge a license, which included the royalty rate and the so-called "good faith clause".

"We've provided for a right for patentees if they disagree with the outcome of the formula...[t]hey make an application to the Federal Court seeking an order varying the royalty rate as calculated by the formula. The court, in considering that application, must take into account the humanitarian reasons underlying the issuance of the authorization, the licence, and the economic value of the contract to the importing member. Those two requirements basically track the language in TRIPS."

"If the average price is 25% or higher than the average price for the equivalent brand-name product in Canada, based on a number of formulary listings, both public and private, the patentee can make an application to the Federal Court for a number of different remedies, on the grounds that the agreement to which the licence relates is commercial in nature."

They discussed the potential for criminal penalties for any known false representation of information by the generic company of any information provided in the license. They also wanted to avoid delays due to litigation by reducing the discretion of the Commissioner of Patents.

Most discourse about profits (profits or ROI, 6%) was in relation to capping the price at which generic firms could sell their products, to ensure that the regime is not used for 'commercial purposes'. They set the threshold for price at 25% of the brand name equivalent in Canada.
"Well, 25% of the brand-name price is a pretty generous threshold; I think most people in the industry would recognize that."

The remaining discourse included references to negotiations with the patent holder on "reasonable commercial terms", which refers to the royalty rate.

The government amended the regime to permit NGOs to contract directly with generic firms (eligible importers, 3%).

"The amendment was based on testimony from the various NGOs who were concerned that the bill did not include any role for them, because the word “agent” was used before. So, we simply removed the word “agent” to address the NGOs' fears that they would not be able to keep their role in procuring drugs. In this case, an NGO operating in a developing country could buy drugs under the Canadian regime if the government in that country took various measures."

**Security**

The government emphasized the devastating toll of HIV/AIDS the developing world, framing Bill C-9 as one tool to curb the pandemic (development, 5%). Some officials mentioned of the lack of capacity of developing countries to do their own drug quality and safety assessment, suggesting that the Canadian government's safety review could assist. They acknowledged the lack of institutional capacity to use the legislation in some countries, hoping that NGOs could assist with the legal aspects of drug importation under Bill C-9. Neither technology transfer nor the local production of medicines in developing countries was mentioned.

The government amended the Food and Drugs Act to incorporate a health and safety review of the drugs produced and exported under compulsory license (quality and safety, 5%). The government wanted these drugs to meet the same standards as those for the domestic market so as not to hold developing countries up to a lower standard of medicines. Health Canada's approval also compensated for the lack of regulatory capacity
in developing countries to conduct their own drug reviews. The government did not mention WHO prequalification, a common standard that poor countries use in lieu of their own regulatory regimes.

The little that the government said about affordability (drug affordability, 2%) was in relation to Bill C-9's role in achieving price reductions.

"Ultimately, the government was confronted with the need to ensure that these amendments maintain the integrity of Canada's intellectual property regime for pharmaceuticals, while at the same time facilitating the flow of low-cost medicines to countries in need."

It is notable that the government neither explicitly linked generic competition nor compulsory licensing to achieving affordability. They also did not mention the role of preferential pricing of patented drugs. They did mention that price was not the only barrier to drug access.

"In our international efforts to address epidemics such as HIV/AIDS, Canada will need to work on more than just bringing down the price of medicines. We are well aware that price is not the only barrier to increased access to treatment."

As mentioned earlier, the government emphasized Bill C-9's role in leveraging donor resources and hoping that other governments would pass similar legislation to offer more supplies at an affordable price.

The Liberal government did not say much about innovation (innovation, 4%) but when they did, they spoke mainly of the importance of incentives and rewards to encourage innovation and to ensure financial investment in R&D.

"We must be true to the humanitarian nature of this initiative. At the same time, we must never forget the importance of intellectual property rights, such as those
embodied in patents. After all, such protection supports the continued advancements in medical science upon which we all depend."

"The government's objective has always been to draft legislation that is responsible. It attempts to achieve the goal of true assistance without, of course, undermining the advance of research to develop new medicines that are so critical to combating such diseases."

The government reiterated the goal of striking "a balance between the government's goals for the system". One of these goals was to ensure that the intellectual property system continued to provide incentives for drug development to benefit Canadians and people around the world. The question of the value of current pharmaceutical innovation with respect to neglected diseases or 'me-too' drugs did not arise. The government did not discuss the impact of compulsory licensing for export to developing countries on the research-based industry's R&D budgets.

**Intellectual Property Institute of Canada**

*Liberty*

Most of IPIC's focus on intellectual property (intellectual property, 63%) was aimed at ensuring that the Commissioner of Patents receives some discretion on whether or not to issue a particular compulsory license. They argued in favor of this discretion to ensure that 'interested parties' have the opportunity to present the commissioner with concerns on whether or not a particular license or contract may not be appropriate or whether limitations on the license should be issued. IPIC characterized inappropriate cases as those countries which have potential for diversion or where the supplier does not have the capacity to fulfill the contract. This discretion would ensure compliance with the TRIPS agreement and is in line with Canada's historical implementation. To strike a balance between the timely delivery of medicines and providing commissioner discretion, they proposed issuing an interim authorization prior to opening the process up to challenge.
"The proposal we put forward was to have a two-stage process. The first is an interim authorization. That's essentially something that's granted almost as a right. For example, are all the documents in place? It's something that's similar to what's in the legislation right now. That ensures that the drugs can be provided in a timely fashion. The second, though, is that parties who are interested, be it the patentee, the applicant for the authorization, or other interested parties, should be able to make submissions to the commissioner of patents as to whether the authorization is appropriate or whether limitations should be placed on the authorization. The commissioner of patents should have some discretion as to what controls are appropriate for that particular authorization or whether in fact the authorization should be granted at all…"

"In my submission, what you don't want to have happen--and it reminds me of that old Esso commercial about the mechanics, where they say “pay me now or pay me later”--is you don't want to have somebody challenge this and find out that you're not compliant with TRIPS at some point in the future because you didn't provide discretion to the commissioner of patents or someone else. Article 31, in certain circumstances, requires consideration to be given on applications on a case-by-case basis. Keeping that in mind, what's wrong with giving the commissioner a little bit of discretion? Other tribunals of Parliament have that discretion."

They also wanted more opportunity for interested parties to make submissions regarding the termination of compulsory licenses.

Concern was issued about a fixed royalty rate and the IPIC suggested that this was in contravention of TRIPS. The IPIC suggested that commissioner discretion should again be exercised here, to ensure that royalty rates are not too high and not too low either.

"Canada must still comply with provisions of article 31. With respect to royalty rates, paragraphs 31(a) and 31(h)…of TRIPS… require that authorizations be
looked at with respect to the individual merits of a particular authorization… rather than set a fixed royalty rate, the committee thought the discretion of the commissioner should once again be exercised."

All the discourse on right of refusal (right of refusal, 18%) relates to their proposed alternative to the right of refusal, which is primarily based upon efficiency: Their remedy to some criticisms of the right of refusal was a mechanism that incorporates competition into the legislation between the patent-holder and the generic company. They argued that patentees should not only be allowed to take over generic company contracts but that they should have to bid on the contract and beat the generic companies' price. IPIC viewed the Canadian generic market as an oligopoly with a limited number of generic companies. Having these provisions in the legislation would result in the best price possible.

"…what the committee doesn't want to have happen is a situation where there's no competition for price, namely where there's a limited number of market suppliers that put forward proposals as to the contracts and prices they are going to charge and where there isn't effective competition in terms of incentives being offered for other people to beat that price. That's the worst thing that can happen, because you're not going to get the inexpensive drugs…"

IPIC recommended that generic companies be compensated for any costs they may have incurred in negotiating the contract with a potential developing country importer ("a finder's fee"). This amendment would remove the disincentive that the right of refusal arguably posed to generic companies.

"I think what we're looking at there is that you don't want to punish somebody for finding a contract. You want to make sure they're compensated for their out-of-pocket expenses with respect to obtaining that contract."
Efficiency
IPIC commented on the threat of diversion (diversion, 9%) and argued that ensuring Commissioner discretion was one way of preventing these drugs from being diverted.

"...what happens if a particular country has a website, but all the drugs being provided to the country from other countries or companies are going on the website for sale elsewhere and diversion is inevitable? Is that something the commissioner should be made aware of in determining whether to grant the overall licence?"

Comments on profits (profits or ROI, 4%) were mainly underscoring the need to ensure that the regime is used for non-commercial purposes.

As mentioned above, references to market competition (market competition, 11%) were discussed under the right of refusal.

Security
IPIC avoided framing Bill C-9 as facilitating the export of either brand name or generic drugs to developing countries. Instead, they framed the bill's purpose as facilitating the export of the most affordable drugs (drug affordability, 19%).

"...our committee looked at this for our submission, and it wasn't about an opportunity to get a brand-name company into a certain country. It wasn't about an opportunity to get generics into the market. The policy or the objective sought by the committee was to try to come up with a mechanism that would provide safe and inexpensive medication where it was needed, no matter who supplied it."

Liberal MPs
Liberty
Among the liberty issues cited (liberty, 50%), intellectual property (intellectual property, 36%) was the most common. Most of this discussion focused on the requirements and
procedure of compulsory license application and the terms of the license. Overall, their comments reflected a commitment to protecting intellectual property.

"… you consider that the control measures included in clause 31 of the TRIPS are sufficient to protect the interests of pharmaceutical research and development companies. In your opinion, then, they will be able to protect their rights sufficiently, and to justify the fact that they invest a lot before developing a drug…"

Liberal MPs proposed several amendments to Bill C-9 that were accepted. First, they insisted on voluntary license negotiations prior to application for a compulsory license, suggesting that a compulsory license was the last resort.

"I think that this is a humanitarian issue and that it is good that the bill allows or calls on the generic companies to enter into discussions on a voluntary licence, rather than claim that it is impossible. Mandatory licences are always a last resort."

They spent a considerable portion of the debate discussing the grounds under which to terminate a compulsory license. Grounds for termination proposed and accepted by the Liberals included: 1) when the compulsory license was deemed 'commercial in nature'; 2) when any inaccurate information in the compulsory license application was provided; and 3) when the drugs were exported or found in a country other than the one identified in the authorization.

To address these latter concerns, the Liberals advocated strong anti-diversion measures (diversion, 7%), including identification of every known point in the pharmaceutical distribution chain from Canada to the final importing country. In addition, several measures to ensure "transparency" were included in the legislation, including requirements by the generic firm to disseminate information on the terms of the agreement, establish a website, and notify the patent holder, importing country and purchaser of its shipment 15 days prior to its exportation.
The Liberals advocated a two-year limit on compulsory licenses with a one time renewal of two years, as opposed to the requests of civil society to remove such limits.

There was some discussion over the amount of discretion that should be given to the Commissioner of Patents in terminating or issuing the license. Most Liberal MPs agreed that giving the Commissioner of Patents too much discretion would create delays in drug exports through license challenges or litigation from patent-holding companies. Instead, they supported explicit terms for issuing the compulsory license in regulations, to try to minimize litigation and ensure the quick delivery of medicines.

Liberal MPs supported the legislation of a 30-day limit on voluntary license negotiations between the generic firm and the patent-holder before compulsory license application was allowed.

Regarding the right of refusal (right of refusal, 10%), Liberal MPs acknowledged civil society's and generic firms' concerns. They did not want to discourage generic drug makers from participating in the legislation. That said, they were significantly preoccupied with incorporating a mechanism to notify patent-holders of potential generic company contracts.118

"I wonder whether it would be better for the generic manufacturers if they had a mechanism to notify proprietary manufacturers earlier in the process. For example, a generic manufacturer might respond to a request by a certain country and perhaps intend to begin negotiations, but would be required to inform the commissioner, for example. Proprietary manufacturers with licences would then have the opportunity to say whether they were interested."

Only one Liberal (David Collenette) framed the Right of Refusal as anti-competitive.

118 As described by Rx&D, notification was required for several reasons. Rx&D. Supplementary Briefing Note for Bill C-9. March 11, 2004. Access to Information Act.
"I can't understand how this bill got to this stage the way it's written with respect to the right of first refusal….The fact is we have a cartel when it comes to the research-based drug companies in the world….Generic brands, once they have been freed from their patent restrictions, are significantly cheaper than the brand models."

By the end of the hearings, the Liberals supported the removal of the right of refusal, eliminating any requirement for notification of generic firm contracts with developing countries.

"I think representatives of the generic industry maintained that the ability of a patentee to execute the terms of a contract negotiated by a generic company meant that generic companies would be acting as unpaid business agents for their brand-name counterparts. In turn, representatives of various NGOs described the right of first refusal as a fundamental flaw. And we've heard, we've listened…"

MPs did not discuss the role of patents in innovation and most did not express a view on the relationship between patents and drug prices. Only one Liberal MP (David Collenette) expressed explicit support of compulsory licensing, citing it as the reason that Canadians currently have access to cheap generic drugs.

"Thankfully, because of what Mr. Trudeau did in 1969, in bringing in compulsory licensing—unfortunately reversed by the Conservative government, by Mr. Mulroney, in Bill C-22, in 1988 or 1987, somewhere around there—the fact is that we have developed a generic industry that has provided low-cost alternatives to Canadians, and those drugs can be available in this instance."

Finally, reference to the WTO TRIPS Agreement was frequent (WTO or TRIPS, 15%), illustrating the terms under which the Liberals framed their arguments. Overall, their questions and discussion was concerned with ensuring TRIPS compliance.


*Equity*

Liberal MPs spent considerable time debating whether or not the Paragraph 6 Decision applied only to WTO members (list of countries, 18%).

"The question I'm asking is, does the agreement of WTO, TRIPS, Doha, etc.—all of the components—say it should be opened up to every single developing country? When I read some of the articles, they say, “eligible members” of WTO. That's why I'm asking. Is there some piece that I've missed?"

After Dr. Fred Abbott's testimony, they acknowledged the idea that nothing in the TRIPS Agreement requires this clause.

"So in your expert opinion, in terms of the developing countries, the requirement that they be WTO members is not in fact something we have to stick with. That is something we can change, and doing so would make sense in terms of reaching out to these developing countries."

They agreed on a compromise solution that would add non-WTO countries to the schedules through authority granted to the Governor in Council, who could either add or remove countries to any of the lists. The Liberals recommended Myanmar be added to the list but were resistant to the NDP's attempts to add individual countries given the authority granted to the Governor in Council.

"We've already made provisions in this bill that other countries could be added, if they desired, by formally, diplomatically, asking Canada to be added. Surely to God we can appreciate the sovereignty of another country by saying if it wants to be added all it has to do is ask through diplomatic channels."

They did eventually support the NDP's recommendation that East Timor be added to the lists.
The Liberals also delineated additional requirements that non-WTO member countries declare that they will not use the product for commercial purposes and adhere to the anti-diversion measures as indicated by the WTO Decision. The Governor in Council could remove any of these countries from the list if they failed to honor these terms.

Regarding the list of medicines (list of medicines, 12%), Liberal MPs rejected civil society's request to remove the list based upon two main reasons, the first being accountability.

"What the list issue comes down to, as far as I'm concerned, is accountability. As someone who has been on the other side of the table, I believe we have to be very, very careful to ensure that government remains accountable and that any drugs prescribed are prescribed in the proper way, authorized by the WHO or by Health Canada."

During the clause by clause analysis, MPs rejected the NDP's request to remove the list based upon the government's reasoning that it was required to ensure that the drug was patented and approved for marketing by Health Canada. Basically, the list was essential to the process of waiving patent rights altogether.

"You must have a list. That is why we have patented drugs. It's not as if, without a list...why then go through this exercise of waiving patent rights that the brand companies have to do? So it's only because we have patented drugs in this country that in fact we can waive as per a TRIPS agreement."

Instead, they incorporated a mechanism to amend the list by the Governor in Council. They viewed this compromise as offering considerable flexibility and downplayed suggestions that the process was vulnerable to political pressure.
"Yes, it's theoretically possible, Mr. Dillon, that someone could go off on some wild tangent for days and days and days when there's a health emergency breaking out. I think we saw with the anthrax threat that we were able pretty quickly to break patents. I'm not sure that's really feasible when there is an identifiable need. So let's be clear that a governor in council change takes minutes."

Liberal MPs amended the list to include some anti-retroviral drugs recommended by civil society.

MPs acknowledged and praised the philanthropic activities of both brand name and generic pharmaceutical companies (aid, 3%).

"I hope this does not turn into the typical war between the generics and the brand companies, because I think both of them are doing some wonderful things in the world now. We have brand companies supplying some countries with free medicine. You have generics, some of the best--and the Canadian solution is always to have a balance between the brands and the generics--also doing some very good things."

Efficiency
As mentioned above, anti-diversion measures (diversion, 7%) were taken very seriously by the Liberals. Most anti-diversion measures proposed by committee members were supported by the Liberals. Some of these included: full transparency at each stage in the compulsory licensing application and approval process and dissemination of the terms of the agreement, quantity and destination of the shipment, including all known points in the distribution chain.

"I think it's also in keeping with what BQ-2 said in regard to the logistical chain, making sure the drugs actually get to where they are intended to go and in terms
of the people we know, everybody connected with the chain. We would have no objection, obviously, to clarifying the intent of this section."

Liberals' discussion of profits (profits and ROI, 7%) mainly referred to restrictions on profit by generic companies using the legislation. They wanted to ensure that the legislation would not be used for profit and only 'humanitarian and non-commercial purposes', as indicated by the WTO Decision. The Liberals supported a price cap on drugs that would be produced under the legislation.

"The object of this legislation is to ensure that it has humanitarian and compassionate objectives. It's to ensure that developing countries, least developing countries, are in a position, if they so wish, to address public health emergencies, life-threatening epidemics, etc., and to try to grapple with the health problems within their countries….So I completely agree with the government when it says, in regard to the authorization, that the average price of the product should be actually equal to or less than 25%...."

To provide an enforcement mechanism, they incorporated the right of the patentee to challenge a licence in Federal Court on the grounds that the agreement it relates to is commercial in nature (litigation 1%), with the burden of proof placed on the patent-holder.

In contrast, David Collenette was the only MP that raised questions about the profits of the research-based industry.

"I would ask colleagues to look at the rate of return of research-based drug companies and see that it's a pretty good business to be in. It requires more international regulation."

Most Liberal MPs agreed that market competition (market competition, 4%) would lower prices. Throughout most of the debates, the Liberals viewed market competition as that
between the patent-holder and a Canadian generic company prior to the issuance of compulsory license as opposed to competition between multiple generic firms in the global marketplace.

"Don't we want to make sure that both generic and brand get an opportunity to bid in order to make sure the price is as low as possible? If you don't have the brand companies bidding, what makes you think the generics are going to drive the cost down?"

"...you continue to say that it is important to get generic drugs to the people who need them. Is the point not that we get the lowest-cost drugs to the people, whether they're brand name or generic? Why do you keep saying generic drugs?"

Eventually, Liberal MPs viewed this limited definition of market competition as facilitated through the Right of Refusal, as anti-competitive.

"…the right of refusal. It's an indirect way to stop the competition. In one way, brand-name companies that want to start up need a country, and in other ways, they don't want any competition. How do you justify that?"

Liberal MPs were weary of the option to allow NGOs to contract directly with a generic company in Canada (eligible importers, 3%). Their criticisms ranged from NGOs' inability to procure in bulk, their unreliable resources and, most of all, the lack of accountability of NGOs.

"I do have concerns with the notion that somehow NGOs have direct access to drugs without necessarily them having been prescribed, in this case by Canada. NGOs are not accountable to the people of Canada. They do great jobs. They are volunteer organizations and the like. But the government, which sanctions what drugs can be used, is accountable to the public and therefore must follow prescribed procedures."
During the clause by clause analysis, Liberal MP Marlene Jennings succeeded in incorporating an amendment that required any NGO wishing to procure drugs under the legislation as having to receive authorization by the importing government.

"…the purpose of this amendment is to clarify the question of the person or entity who is authorized to obtain a license. It's a matter of ensuring that the party is a representative of the government or an entity of the government, a physical person or an entity authorized by the government of the importing country. It's simply a matter of ensuring that persons or entities who apply for a license and who wish to enter into a contract with a pharmaceutical company to obtain a license and import pharmaceutical products into a country are authorized to do so."

**Security**

Liberal MPs spoke of their commitment to ensuring Bill C-9 achieved the lowest possible price (drug affordability 6%); however as illustrated above, most references were in reference to lowering prices through competition between brand name companies and generic companies.

Liberal MP David Collenette suggested patent protection is partly to blame for high drug prices.

References to development reflected Liberals' concern about whether or not the drugs were actually going to get into patients' hands given the health system and broader infrastructure barriers existing in these countries (development 2%). One MP suggested that these barriers could lead to diversion and inappropriate use of medicines. Another MP acknowledged these concerns but emphasized that the legislation was an incredibly important step internationally. Overall, Liberals implored the government to take into account all steps of drug delivery but did not suggest a trade-off exists between addressing these infrastructure issues.
"Let's be realistic here. We've got a list of countries that in fact don't even have governments, don't have civil societies, and don't have the social infrastructure to deliver the very complicated drugs we're talking about. ….So I'm just wondering, within the five departments that are going to be involved, is there a plan to make sure that once Canada is delivering the drugs that we're going to be satisfied that the governments, the NGOs, or the whole infrastructure, including the brand company or the generic, is going to do everything possible to make sure that the drug is actually getting to the very people who need it?"

Liberal MPs did not mention technology transfer or the local production of medicines.

Liberals did not refer to innovation much (innovation, 2%) aside from referring to patented inventions. They did not elaborate on the role of patents in stimulating innovation or the direction of innovation.

**Conservative MPs**

*Equity*

Conservative MPs appeared to assume that the list of medicines (list of medicines, 14%) and the list of countries (list of countries, 14%) were necessary. They considered removal of the lists as a threat to pharmaceutical innovation.

"I think we do have to keep in mind the fact that it is the patented drug companies that are creating these drugs in the first place. My concern, and what I don't want to see, is if we just provide patented drugs at cost to almost any nation and open up these schedules, the brand-name companies say “You know what? There's nothing in it for us to develop these drugs. We're not going to do it any more. We're simply going to focus on other drugs from which we can actually make a living.”
They viewed the process of amending the list of medicines through the Governor in Council as acceptable.

"…in terms of schedule 1, it can be amended “by adding the name of any patented product that may be used to address public health problems...if the Governor in Council considers it appropriate to do so”. Maybe I'm misreading this, but this seems to me to be a fairly simple way to add medicines."

They also wanted to ensure that the process of adding countries or medicines was speedy and efficient, by adding the word "timely" to the section referring to orders of the Governor in Council.

"the purpose of this amendment falls in line with some of the other amendments by the government, and it is to basically ensure that additions to the list are made in a timely manner. Many of the witnesses testified to concerns about the timeliness of adding either nations or medicines."

They also wanted to ensure that any accepted additions to the list of medicines were in line with WHO recommendations.

"Are these drugs, with the dosage and everything, suitable to the WHO rules and regulations and everything?"

Some Conservative MPs showed concern that certain countries, such as Vietnam and East Timor, were not on the list of countries.

"…why aren't certain countries such as Vietnam and East Timor not there, and how can we rectify that?"

In relation to adding drugs or countries, they wanted to ensure that parliamentarians would have a role in additions or removals from the lists.
"…it would be nice to have Parliament play some sort of role here, aside from just… I mean, if these pass, we parliamentarians have no role in adding to the list of medicines or the list of nations."

Conservative MPs praised the brand name pharmaceutical companies' aid (aid, 8%) efforts in addressing problems in developing countries.

"I would like to start off by asking Mr. McCool and Mr. Leprince about what the pharmaceuticals are doing already to provide drugs to people in need in countries this bill will apply to. There is a perception that the pharmaceutical companies are doing very little at this point. Their generic colleagues outlined a few things. Could you tell us some of the specifics?"

Conservative MPs also demanded the Liberal government clarify how much money and resources they were dedicating through various departments to ensure that the drugs actually get to the people who need them.

"I guess what I'm referring to is more the infrastructure side of the program that was alluded to by Mr. Rajotte and others. How are we going to make sure these drugs get to the people who need them? Are we going to be directly involved in establishing those programs? What is the cost of those programs? Are there going to be accountability measures to make sure the program is reaching its goals?"

*Liberty*

Conservative MPs made virtually no comments about patents (intellectual property, 22%) and their relationship with pricing or competition, although one MP framed patents as a critical means to innovation (see above). They stressed that patents were not the only barrier to drug access.
"…we can change the Patent Act and we can change the Food and Drugs Act, but there's so much more that actually has to be done in order to get medicines to people who need them."

They also expressed concern over how much latitude should be given to the Commissioner of Patents in issuing a compulsory licensing and procedure of license termination.

Conservative MPs viewed a fixed royalty rate as problematic and sought to find an alternative that would be more TRIPS compliant (WTO or TRIPS, 5%).

"This bill suggests a fixed royalty rate of 2%, and she said brand name companies say this is inconsistent with TRIPS. Could you explain why? Is this consistent with TRIPS? Is it not? Is there another way perhaps to address this that would be more consistent with TRIPS?"

They responded positively to proposals of a variable royalty rate.

Conservative MPs showed clear interest in addressing the "right of refusal" (right of refusal, 9%) and directed questions at the presented alternatives to this regime. Again, concern was making sure amendments were TRIPS compliant.

"Are there any other ways, any alternatives this committee should be looking at in order to ensure that Canada does comply with paragraph 31.(2)(b), beyond the right of first refusal, or is this, in your view, the only or the best way that Canada can comply with that section?"

Efficiency
Conservative MPs showed much concern over the potential for diversion (diversion, 5%) of Canadian-made medicines into other jurisdictions for profit. They wanted specific
measures to prevent diversion, a tracking or "policing" system and also asked about penalties and criminal procedures if diversion were to occur.

"Now, aside from increasing inspections, can you describe specific measures that are going to be put into place to ensure that Canadian-made drugs are not siphoned off to inappropriate markets for profit?....What will be the penalties if the drugs are indeed found in other countries that are not on the list?"

Conservative MPs also questioned why NGOs would not be able to place drug distribution order (eligible importers, 4%) and whether it was wise to open up the process to a range of NGOs that may or may not be reputable.

"Doctors Without Borders has an excellent reputation, but I don't know every NGO out there. So would you limit it to certain NGOs that have these excellent reputations, or would you have it wide open?"

Litigation concerns (litigation, 4%) included the potential for Commissioner of Patents discretion to create opportunities for litigation, which would then hold up the shipment process. They also wanted to know what terms the patent-holders could appeal, including the royalty rate.

Security
Conservative MPs said little about drug affordability (drug affordability, 1%) aside from the argument that it was only one part of the solution.

"I think the first issue I want to touch upon is the whole issue of it being one thing to export cheap drugs or to get cheap drugs to try to address this problem, but it's a completely different matter to ensure that the drugs get to the people who need them, that the people who need them have the proper nutrition, have clean water, have physicians or nurses or a medical infrastructure in place so they can properly take these, so that we are actually addressing the problem."
They focused mostly on development-related barriers (development, 5%), issuing concern about the lack of health system infrastructure and broader development issues such as access to clean water and proper nutrition. Questions focused on what the Canadian government was going to do to address these infrastructure issues to ensure that drugs exported under this initiative were indeed going to make it out to the people who need them.

"I guess what I'm referring to is more the infrastructure side of the program that was alluded to by Mr. Rajotte and others. How are we going to make sure these drugs get to the people who need them? Are we going to be directly involved in establishing those programs? What is the cost of those programs? Are there going to be accountability measures to make sure the program is reaching its goals?"

No comments were made about technology transfer.

As described above under "equity", one Conservative MP emphasized the brand name industry's contribution to drug innovation (innovation, 3%), suggesting that the elimination of the schedule of drugs and countries would discourage future innovation.

Their final concern under security referred to whether a drug could be eligible even though it did not have a comparative reference product in Canada (quality and safety 1%).

"In the bill it says that by adding the name of any patented product that may be used to address public health problems. I'd like to know whether or not any patented product would include products that have not received Health Canada approval. Do you have a product that has been patented that is not allowed to be used in Canada yet, but perhaps is eligible to be on this schedule?"
New Democratic Party (NDP) MPs

*Liberty*

The NDP MPs discourse on intellectual property (intellectual property, 25%) was substantially different than that by all other MPs. They issued explicit support of compulsory licensing and proposed adding language in the bill to this effect.

"I think the motion, adding “other epidemics, by enabling countries with insufficient or no manufacturing capacities in the pharmaceutical sector to make effective use of compulsory licensing”, better represents than the government language today what the WTO adopted—and as well, the intent of the bill. We believe the restrictions that could ensue and on top of that the problems of adding potential solutions to countries with emerging problems would further complicate it."

This amendment was negated under Liberal MP Jennings' argument that the proposed language would make the regime more restrictive than that proposed by TRIPS, arguing that the source of the drugs – generic or brand – was irrelevant and that mandatory licenses were always a last resort.

They emphasized the issue of royalties and advocated a cap on the royalty rate of 4%, regardless of the formula employed based upon the premise of keeping the drugs affordable. They also advocated eliminating the two-year limit on compulsory licenses arguing that it would empower developing countries and NGOs rolling out these drugs to decide what's best to ensure the treatment of their patients.

"We have this because we're empowering the NGOs and those developing countries that want to enter into agreements with the generics to make their decisions. They will have the opportunity and the sovereignty to decide exactly what relationship they want to have and the best way to actually roll out the programs necessary to treat the people they're responsible for."
The NDP also issued concern that the proposed anti-diversion measure of identifying everyone in distribution chain could be too onerous and provide additional barriers to the legislation.

Finally, they proposed a 30-day cap on the voluntary license negotiations prior to allowing a generic firm to apply for a compulsory license, which was agreed to.

The NDP spoke strongly against the right of refusal (right of refusal, 8%) suggesting that patent-holders already had the opportunity to supply drugs without having to incorporate it into the legislation.

"The pharmaceutical companies really already have a first right of refusal, because they are the patent holders. If they wanted to provide these medications abroad at a lower cost, they could do so already without this legislation. Is that not correct? There's nothing stopping them from having a two percent mark-up and providing the drugs immediately, as opposed to waiting for this legislation, then putting them on the market."

Lastly, their proposed amendments and arguments were framed in terms of how to interpret TRIPS and the Paragraph 6 Decision and what would be TRIPS compliant (WTO or TRIPS, 10%).

Equity
The NDP challenged the need of even having a list of medicines (list of medicines, 16%), suggesting that it was never contained or contemplated in the TRIPS Agreement or Doha Declaration. They proposed removing the list altogether.

"The purpose of this amendment is to include a full definition of pharmaceutical product that more closely resembles the definitions included in the ministerial decision on November 1 and the general counsel decision on August 3...Limiting our
definition to schedule 1 limits the scope of the bill and the purpose behind those international agreements."

They argued that additions made to the list have the potential to be vulnerable to political pressure and interference.

"….having to go to political masters to get a drug on a list, as opposed to taking it out of that realm altogether and basing it on human health and need and processing it that way rather than coming back to political masters."

The NDP proposed several drugs be added to the list, some of which were approved during the clause by clause analysis.

The NDP also did not think a list of countries (list of countries, 11%) was necessary under the legislation suggesting it was not required by the TRIPS Agreement or the Doha Declaration. They proposed several amendments to add individual countries to the list during the clause by clause analysis (along with the Bloc Quebecois), which were all voted down by the committee. Among these included East Timor, the only country they were able to get on the list.

"I think East Timor is a good example of the problems we have. This nation has historical problems and a number of different issues. I think it's almost unconscionable that East Timor is not included in this list. There was genocide in East Timor, it's a developing country, and it could specifically be helped with its malaria problem. We know we have a lot of different agencies involved in East Timor, and I think it needs to be added to the list."

The NDP addressed the lack of overseas development assistance committed by the Canadian government and acknowledged the importance of NGOs in ensuring that drugs are delivered appropriately to patients in resource poor settings (aid, 6%).
Efficiency
They also suggested that the brand name industry must be regulated to ensure good marketing practices among the affluent populations in developing countries (procurement, 4%).

"Will there be any monitoring of advertising, packaging, and safety issues, and whether these companies are going to expand other markets in the area? There will be affluent people in these markets who will also be able to purchase drugs, as opposed to those who are too poor to afford their own treatment right now."

The NDP issued concern about how a generic firm's contract would be deemed "commercial in nature" (profits and ROI, 3%). They also suggested that generic firms would need financial incentives to participate in this initiative. In response to IPIC's alternative to the right of refusal, which would compensate generic firms for out of pocket costs lost in negotiating a contract.

"Are you talking about compensating them for expenses? Are they going to then be able to apply for a profit? Second, if it doesn't lead to generics getting into the market, have we been successful at all if they're not encouraged to flourish in this environment so people will be able to receive drugs across the board?"

The NDP supported the idea of NGOs being able to contract directly with a generic company to procure drugs under the legislation (eligible importers, 3%).

Security
The NDP emphasized the urgency of ensuring the legislation facilitates affordable medicines to the developing world (drug affordability, 7%) but blamed the Liberal government for introducing a flawed legislation that favored the brand name industry's interests.
"What this is about is getting the legislation the way it needs to be, to access those drugs on an affordable basis with an appropriate sense of urgency. For that reason, I think the fact that deeply flawed legislation was introduced was very problematic. There are 5,000 to 6,000 people a day dying of HIV/AIDS, which means that the 30-day delay that's already transpired has left a half a million people dying."

The NDP did not talk about the relationship between prices and patent protection, market competition or philanthropy.

Most of their focus on development-related barriers (development, 4%) was on health sector infrastructure, acknowledging a need to put more resources into its development but also that the lack of infrastructure is not an excuse to abandon the legislation.

"What is very distressing is to hear the amount of lobbying going on to try to persuade the government not to proceed with the legislation as it needs to be, using the excuse that the health infrastructure isn't there anyway, so why bother. I wonder if I could ask for your response on this, and to ask Médecins Sans Frontières to comment further, because I think it's very important for the point to be made that this isn't a trade-off."

**Bloc Quebecois (BQ) MPs**

*Efficiency*

The most cited issue under efficiency was diversion (diversion, 14%). The Bloc MPs emphasized the problem of diversion and favored strong anti-diversion measures.

"…would it not be relevant to be able to identify all the known stakeholders in the logistical chain between Canada and the importing country, so as to be certain, when we authorize the export of a certain quantity of product, that we know exactly which routing the product will take, to ensure that we do not lose it along the way? In other words, this would be to ensure that it will not be easy to set up a smuggling operation because we were not demanding enough in this regard?"
They also recommended amendments to change the colour of products to protect against "smuggling".

The Bloc was concerned about the terms under which NGOs would receive contracts to distribute drugs in a country and what kind of clearance they needed to have from the country in which they were working in (eligible importers, 11%). They were concerned about NGOs imposing their own priorities onto developing country governments and of adopting a 'paternalistic' attitude towards the countries in question.

"How can we ensure that the priorities of the countries concerned are met, and how can we avoid creating a certain type of paternalism? In Canada, we would not like it if people came in and started spending money, in all good faith, without consulting our government."

They also issued concerns about the potential for litigation from patent-holders (litigation, 7%) to hold up the licensing process and the shipment of drugs.

"…I am personally really worried that the potential to object to the generics notice of intent to supply as in the case of interim relief, could cause legal paralysis. Is this fear warranted?"

*Liberty*

MPs said nothing about the effect of patents on pricing or innovation and nor did they issue a position on compulsory licensing (intellectual property, 20%). Most of their discourse on intellectual property was in concern to preventing NGOs as eligible importers and preventing litigation as described above. Other concerns included ensuring that the royalty rate was capped to ensure affordability and the potential for disagreements on the royalty rate to hold up drug shipments.
Bloc MPs showed reservations regarding the right of refusal (right of refusal, 2%) and openly explored options presented by the witnesses including the brand name industry's equal opportunity to supply.

As with other stakeholders, there was some concern issued about certain clauses complying with or going beyond the TRIPS agreement (WTO or TRIPS, 8%), in particular the list of medicines and list of countries.

**Equity**
Bloc MPs did not show a clear position on the list of countries (list of countries, 10%) although they did emphasize the importance of complying with the TRIPS Agreement. In conjunction with the NDP, they proposed to add several countries to the existing lists, especially in cases where countries did not have the institutional capacity to request to be added at a later date. They framed these additions as achieving efficiency.

"The purpose of the legislation is to ensure that pharmaceutical products are available as soon as possible in designated countries, in accordance with the legislation. Bearing that in mind, if we include the list of countries right away, we're speeding up the process…We should be able to append a list to the bill right now, which would spare many countries that are rather disorganized, administratively speaking, from having to go through useless procedures."

Bloc MPs questioned the need to have the list of medicines (list of medicines, 8%) but their primary concern was compliance with the TRIPS agreement. They sided towards keeping the list especially if civil society recommendations on list additions could be addressed.

"…we have to know whether we are talking about one, two, three, five or ten medicines that might be added, or whether some that are being developed could become available in the short term. We will have to be given this information, because without it, the arguments against the list are weakened."
The Bloc MPs emphasized the importance of ensuring additional aid (aid, 6%) accompanied this legislation to address infrastructure and other development-related issues.

"Would you go so far as to say that just passing the bill without putting up any extra funding would be basically a wasted effort?"

They posed questions to many witnesses, asking them whether the equal opportunity to supply (equal opportunity to supply, 6%) was a feasible alternative to the right of refusal.

*Security*

The Bloc Quebecois did not mention any security issues aside from development issues (development, 4%) in relation to the need for aid as mentioned above.
Chapter 7: Discussion of 2004 Debates

Summary

This chapter argues that stakeholder framing is ultimately determined by the way the government defined the problem and the nature and structure of the institutions involved in the debates. By using the statistics present in Chapter 6, this chapter seeks to answer two questions:

1. What explains how participants framed access to medicines in the 2004 CAMR debates?
2. Why did some frames win, while others lost in the final design decisions of CAMR?

These questions will be answered by applying the theoretical framework of framing, interests, and institutions to the observed framing results. What appears evident in the 2004 debates is that the fundamental conflict during the policy debates centered around protecting intellectual property versus promoting generic competition.

The codebook outlined the major themes that arise during policy debates about access to medicines in developing countries. These themes were categorized according to Stone's four policy goal framework: equity, security, liberty and efficiency. Equity issues, defined as issues relating to fairness of distribution, include aid to developing countries, the research-based industry's proposed equal opportunity to supply, and Bill C-9's list of medicines and list of countries. Security issues, defined as basic needs, included development, drug affordability, drug quality and safety, human rights, domestic economic issues and innovation. Liberty issues, defined as freedom or exemption from restraint, included intellectual property, the WTO TRIPS Agreement, the right of refusal and developing country pressure. Efficiency issues, defined as obtaining the most output
for a certain input, included diversion, litigation, market competition, procurement issues, profits, eligible importers and CAMR output and uptake.

Chapter 6 presented the findings of the content analysis results of the 2004 Standing Committee Hearings on Bill C-9. These findings illustrated that the debates were primarily focused on issues related to liberty (47%) and equity (34%). More specifically, the participants in the 2004 debates appeared to be mainly arguing over: 1) where to draw the line with respect to protecting intellectual property (31.8%); and, 2) how to interpret the various clauses of the WTO TRIPS Agreement (18.5%). Participants' focus on equity (34%) was mainly about: 1) what the benefits of the regime should entail (List of Medicines, 12.4%); 2) who would be eligible for these benefits (10.6%); and, 3) the role of aid in increasing access to medicines (11.5%). Issues that were less frequently discussed related to efficiency (23%) and security (19%). More specifically, these underrepresented issues included market competition (5.1%), procurement practices and protocols (3.1%), litigation (2.5%), innovation (2.0%), human rights (1.4%) and Canadian domestic economic issues (0.1%). To the extent that these issues were deemphasized, they were not what participants argued about during the debates.

Overall, these statistics serve as the foundation of the three main findings outlined in this chapter. First, the combination of participants' focus on intellectual property and TRIPS along with the institutional context in which this debate took place led the discourse in a certain direction. By framing the initiative as the implementation of the Paragraph 6 Decision, the Liberal government immediately channeled the debate into the domestic institutions that had authority over pharmaceutical patent law, along with their policy legacy, preferences, norms, and rules. Since the venue largely dictates how an issue will be framed (Baumgartner & Jones, 1993) and can influence how actors perceive and articulate their interests (Howlett et al., 2009), intellectual property and the WTO TRIPS Agreement became the terms of debate for most stakeholders. Given that the goal of protecting intellectual property, as promoted by the research-based industry, was entrenched in the bureaucracy, Canada's economic structure, international trade rules and electoral considerations of the most politicians on the SCIST (except for the NDP), these
goals ended up taking priority over most other considerations, including the goals of drug affordability (8.3%) through market competition (5.1%). These institutional factors appeared to have the largest impact on what the final design of CAMR would look like.

Second, the goals or issues that received less attention during these debates were later identified in 2007 as major barriers to the use of the legislation by civil society and the generic industry. These include CAMR's lack of congruence with developing country procurement practices (3.1%), the threat of litigation against participating generic companies (2.5%) and political or economic pressure placed on developing countries by more powerful countries to avoid using TRIPS flexibilities altogether (developing country pressure, 0.5%).

Finally, this chapter examines the issues which were hardly discussed, and as a result, were not considered. These issues include innovation (2.0%), human rights (1.4%) and the Canadian domestic economy (0.1%). As this chapter will argue, the initial problem definition played a role in deemphasizing these issues; however, the receptivity of the leading institutions to these frames also affected the scope of issues up for debate. In particular, three relationships were largely overlooked during these debates: 1) the relationship between intellectual property protection, TRIPS and innovation; 2) the impact of CAMR on the Canadian domestic economy; and, 3) the relationship of human rights in relation to drug access, patents and TRIPS. For example, the virtually negligible role that human rights played throughout these hearings, points to the lack of receptivity of the policy venue to that policy goal. While the liberal government infused their political rhetoric with references to human rights (Graham, 2003; Martin, 2004), once the policy process was underway, there was little substance behind these claims.

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121 The barriers to CAMR's success are largely dependent upon whose perspective is assumed, which is one of the findings of this study. For the purposes of this introduction, I have used civil society and the generic industry's concerns as a reference point for the barriers to CAMR's use based upon the premise that they are the key stakeholders in the implementation of the regime. These barriers were based on their positions during the 2007 hearings, and triangulated by information from their 2007 consultation submissions and the Standing Committee's final report to the Government.

122 Other barriers that civil society and the generic industry identified but are evident in the qualitative findings (and will be discussed Chapters 8 and 9) include delays associated with voluntary license negotiations, restrictions on the duration, quantity and number of countries per compulsory license, and perhaps most importantly, the requirements of the WTO Paragraph 6 Decision itself.
Outline

This chapter proceeds as follows: first, I discuss the frequency statistics from a macro-level perspective to answer: why were these issues discussed instead of others? This section explains how institutional factors may have influenced the overall framing observed. The international institutional constraints related to Canada's position during the 2001 Doha Negotiations and Canada's relationship with the United States on trade-related issues played key influencing roles, which structured the content of the standing committee hearings by presenting debate participants with the menu of policy battles from which to choose. This led participants to devote considerable time debating over how and to what extent intellectual property rights should be curtailed as opposed to focusing on the other equally legitimate issues including those "upstream implementation issues" that the generic industry and civil society later identified as fundamental barriers to the regime's success.

Second, by examining actors' interests and uncovering their underlying policy goals, I aim to answer the question of: why did actors frame access to medicines the way they did? This section argues that the interpretation of TRIPS that the government and politicians endorsed, more often than not, favored that explicitly backed by the research-based industry as opposed to that of civil society or the generic industry. The NDP, with only one vote on the committee, was the only party that largely supported civil society's and the generic industry's interests. This section is divided by stakeholder group.

The next section discusses why some issues were under-emphasized in the debates, otherwise known as the "dogs that didn't bark". Lastly, this chapter concludes with a summary of the findings and conclusions for this chapter.

Overview of Stakeholder Framing in the 2004 Debates

The most frequently cited policy goal during the standing committee hearings was liberty (47.5%) and within this category, the most cited references were intellectual property
(31.8%) and the WTO TRIPS Agreement (18.5%). The emphasis on these issues appears to be related to how the problem of access to medicines was defined and by association, the institutions that led the legislative process.

By framing the initiative as the implementation of the Paragraph 6 Decision, the Liberal government immediately channeled the debate into the domestic institutions that had authority over pharmaceutical patent law, along with their policy legacy, preferences norms, and rules. As mentioned earlier, the Departments of Industry Canada and International Trade took the lead on the legislative process. Industry Canada's mandate is to encourage and support innovation to ensure a strong, competitive, knowledge-based economy and protecting intellectual property is one of their primary policy instruments to achieve this goal (Government of Canada, 2010). Compliance with international trade agreements and treaties is under the aegis of the Department of International Trade (Government of Canada, 2009). Since the venue largely dictates how an issue will be framed (Baumgartner & Jones, 1993) and may have influenced how actors perceived and articulated their interests (Howlett et al., 2009), intellectual property (31.8%) and the WTO TRIPS Agreement (18.5%) became the terms of debate. Participants appeared to spend most of their time debating over how and to what extent intellectual property rights should be curtailed as opposed to focusing on the other equally legitimate issues including those upstream implementation issues that the generic industry, civil society and some government bureaucrats later identified as fundamental barriers to the regime's success.

More importantly, the institutional constraints related to Canada's position during the 2001 Doha Negotiations (Abbott, 2005; Elliott, 2003b)and Canada's relationship with the United States on trade-related issues (Doern & Sharaput, 2000) may have influenced the draft legislation but may have also influenced how actors behaved and framed their own interests. As discussed earlier, the Paragraph 6 Decision was preceded by prolonged and controversial negotiations with countries sharply divided on three key aspects of the Decision: the eligible diseases, the eligible countries and the article of the TRIPS Agreement that would be addressed by the solution (Abbott, 2005). Negotiations
concluded with resolution on all three issues: the Decision did not specify any list of
diseases, certain countries agreed to opt out of the arrangement and Article 31(f) was the
solution. Despite apparent resolution at the international level, the Liberal Government
revived all three issues in the domestic context: first, it created a list of eligible
medicines; second, it created a list of eligible countries, and; third, it interpreted Article
31(b) to provide the patent-holder an opportunity to take over any supply contract that a
generic company had negotiated with an eligible purchaser.123 These issues then became
the focus of controversial debates between societal interests, politicians and government.

Bill C-9 structured the content of the standing committee hearings by presenting debate
participants with the menu of policy battles from which to choose (Schattschneider,
1964). As Stone says, "an alternative is judged by the company it keeps" (Stone, 2002).
Societal interests and political parties were forced to choose what issues mattered to them
more, at the expense of other equally valid issues.

For debate participants, one of the more important issues was the so-called "right of
refusal" (All Actors, 10.7%) clause. Civil society held this issue front and center of their
campaign (right of refusal, 15.7%). As will be discussed in the subsequent section, the
government's inclusion of the right of refusal may have had a significant effect on the
content of the policy debates. Since "the enemy of what you want less, is what you want
more," (Kellow, 1988) it is possible that civil society and the generic industry's fight to
remove the right of refusal came at a cost of lobbying for other changes to the legislation.
In this sense, the last minute amendment to Bill C-56 to include the right of refusal may
have restricted their choice of conflicts even further.

The reinsertion of the lists of medicines (12.4%) and countries (10.6%) are a large part of
why equity issues (34%) received so much attention as well. These were two contentious
issues that civil society (12.4% and 7.07%, respectively) contested and to which
politicians (7.7-16.4% and 9.1-18.1%, respectively) and the Government (17.8% and
10.7%, respectively) debated extensively. In this sense, the focus on equity was partly a

123 Bill C-56, §21.04 (6)-(7); Bill C-9, §21.04(6)-7.
debate over the distribution of benefits within this regime: what countries were eligible to benefit from the regime and what pharmaceuticals could they have access to?

The issue of aid (All Actors, 11.5%) received considerable debate as well, discussed mainly by the research-based industry (41.4%), the generic industry (25.2%), civil society (16.7%) and the Government (13.4%). The contents and direction of this discourse will be discussed in the next section.

Issues categorized as efficiency (All Actors, 23%) and security (All Actors, 19%) appeared to take a back seat to liberty and equity issues in this debate. No one issue appeared to dominate the discussion within these policy goals although there were some trends. Issues relating to the diversion (6.1%) of medicines were mentioned most frequently. The WTO Paragraph 6 Decision's Chairperson's Statement (World Trade Organization, 2003a) makes explicit statements regarding the importer and exporters obligations to prevent diversion of medicines. This appears to have been taken quite seriously by the research-based industry (13.2%), IPIC (9.4%), the government (9.9%) and most politicians (1-14.3%). Market competition (All Actors, 5.1%) was another efficiency issue that received some attention. The generic industry (13.3%), civil society (10.9%) and IPIC (10.8%) emphasizing it most among societal interests while all politicians, aside from the Liberals (4.2%) hardly mentioned it at all (0-0.6%).

References to drug affordability (8.3%) and development issues (7.5%) were the most frequently cited security goals. Frequent references to affordability are not surprising, as the initiative was framed by the Government and many other societal interests as aiming to facilitate affordable medicines to countries in need (L. C. Esmail, Phillips, Kuek, Cosio, & Kohler, 2010). Still, drug affordability was mainly referred to by societal interests (12.3-19.3%) while the government (2.2%) and politicians (0-6.0%) mentioned it much less. As will be discussed in the next section, the lack of emphasis on affordability by the government and politicians suggests one or more of the following: 1) there was little disagreement about attaining this goal or 2) drug affordability was less of a priority than other competing goals.
References to development-related drug access issues (7.5%) were also raised frequently by participants but most by civil society (16.7%) and the research-based industry (7.9%). While some of these references involved participants framing the legislation as a way to achieve development,124 others referred to more systemic problems in developing countries. As will be discussed later, the research-based industry argued that development barriers were the fundamental problem and in doing so, tried to reframe the problem of drug access to one of infrastructure, poverty and financing for drugs and corruption; while acknowledging the development-related barriers (in particular infrastructure and poverty and financing) civil society countered this argument to say that NGOs can assist with health care delivery in resource poor settings and more importantly that implementing the Paragraph 6 Decision and addressing these development-related issues were not pitted against one another as a trade-off.

The following sections examine the discourse of each stakeholder group in order to determine what their underlying policy goals might have been. What this section argues is that the major competing frames among societal interests during the 2004 debates can be viewed as a conflict between protecting intellectual property versus encouraging generic competition. For civil society, their primary goal appeared to be achieving a compulsory licensing regime that would encourage global generic competition and provide an additional source of cheap generic medicines for the developing world. For the research-based industry, it was about protecting their patent rights and potential developing country markets. While the generic industry appeared to support the regime, their discourse suggests that their underlying goal was to ensure that their participation in the regime would not result in any loss of investment or resources.

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Framing, Interests and Institutions: What Explains Stakeholders' Discourse?

Liberal Government and Liberal MPs

The story of the Liberal Government and Liberal MPs is one of compromise and balancing stakeholder interests. The Government's initial rhetoric prioritizing the importance of global health and human rights over the protection of intellectual property (Graham, 2003) and explicitly framing the goal of Bill C-56 to allow the generic production of drugs were not emphasized in the Liberals' discourse over the design of the regime. Upon analysis of the Government's and Liberal MPs' testimony, it becomes apparent that the interpretation of TRIPS that the Liberal Government endorsed, more often than not, favored an interpretation explicitly backed by the research-based industry as opposed to that of civil society.

Most Government and Liberal MPs references to liberty goals (Liberty: Government, 53%; Liberal MPs, 50%) reflected a frame that ultimately favored the protection of patent-holder rights over that of encouraging the generic production of affordable drugs. In their references to intellectual property (Intellectual Property: Government, 41.2%; Liberal MPs, 36.5%), they advocated a balance between access to medicines and intellectual property rights but this balance contrasted dramatically with that of civil society and the generic industry. Specifically, the Government and Liberal MPs did not explicitly endorse compulsory licensing as a tool to achieve drug affordability and this oversight appears to have been deliberate, as it foreshadowed the right of refusal clause.

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126 Of course, the Government needs to abide by international laws, however the Paragraph 6 Decision can be implemented in a variety of ways. See Ng and Kohler for a comparison of CAMR to other regimes including (but not exhaustive) India's, Norway's, the Netherlands, the EU's, and Korea's. For example, Norway's legislation does not have a list of eligible medicines instead defining "pharmaceutical products" as those "covered by paragraph 1(a) of the General Council Decision". Furthermore, the EU's legislation waives prior voluntary license negotiations with the patent-holder in "situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement."
Initially, the Government (Right of refusal: Government, 7.4%) defended the right of refusal as their way of implementing Article 31(b). They framed it as achieving "procedural fairness" in that it gave the patentee "proper notice of a country's intention to import". But what this really showed is that the Liberal Government held a fundamentally different objective than civil society or the generic industry:

"First, given that a generic drug can take from two to five years to develop and prove, encouraging the provision of medicines from their most immediate source was viewed as consistent with the underlying policy objective of getting medicines to those in need as quickly as possible."128

The Liberal Government, backed by the Liberal MPs, framed the objective of the legislation as achieving the goal of lower prices, even if the drugs were supplied by the patent-holder. By encouraging competition (Market competition: Liberal Government, 0.6%; Liberal MPs, 4.2%) between an interested Canadian generic manufacturer and the patent-holder(s), Bill C-9 would act as a stick to the research-based industry in encouraging them to sell their drugs at an affordable price (Affordability: Liberal Government, 2.2%; Liberal MPs, 6%) to developing countries in need. This vision was in line with that of the research-based industry's equal opportunity to supply (which will be outlined next) and contrasted markedly with civil society's ultimate goal of generating global competition through the production of Canadian generic drugs. The right of refusal clause was the Liberals' way of remaining "neutral" in the debate, not favoring either the brand name or generic industry.

Liberal MPs acknowledged civil society's and the generic industry's concerns about the right of refusal (Right of refusal: Liberal MPs, 9.9%); however, they focused most of their time debating alternatives that incorporated a mechanism to first notify patent-holders of potential generic company contracts. Again, the concept of prior notification

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was proposed by the research-based industry through their proposed "equal opportunity to supply" and in their written submission to government (Canada's Research-Based Pharmaceutical Companies, 2004).

The Liberals' promotion of the right of refusal and early notification was a clear sign of support for the research-based industry, which was likely related to the Liberals' interests in maintaining domestic research-based industry's R&D investment. The day after the Liberals announced the initiative, the International Federation for Pharmaceutical Manufacturers slammed the Liberal Government, saying that their initiative would be a "negative black-eye for investment in Canada" (Chase & Fagan, 2003). Even though the research-based industry eventually voiced support for the regime (Canada's Research-Based Pharmaceutical Companies, 2003), it is likely that they did not want Canada to set any kind of precedent for using compulsory licensing. By supporting the right of refusal, the Liberal Government found a way to permit compulsory licensing while still protecting the research-based industry's intellectual property. As one Government bureaucrat said, the right of refusal sent "…a positive signal to the international community that humanitarian initiatives in this area can be effective and yet have due regard for the property rights of patentees." The way in which the Liberal Government respected these rights, however, made the use of the regime, in the eyes of civil society and the generic industry, difficult and defeated the purpose of the initiative.

After much opposition from civil society and a late-stage intervention by the Prime Minister's Office, the Liberals backed the removal of the right of refusal and did not incorporate any notification mechanism (Elliott, 2004). Civil society's campaign was largely focused on the removal of the right of refusal and early notification clauses (Elliott, 2003b). They did so by relying heavily on the media and, perhaps most importantly, by involving celebrity rock star Bono. Bono previously endorsed Paul Martin's Liberal leadership given his commitment to development issues (Laghi, 2003).

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On March 20th, 2004, Bono's aid group DATA\textsuperscript{130} issued a press release accusing the Martin Government of letting down the international community, urging him to remove the right of refusal and any other prior notification clauses (Agence France-Presse, 2004). In the context of an upcoming election later that year, the Prime Minister's Office responded to Bono's call by giving orders to the bureaucracy and Liberal Party to support the removal of the controversial clauses (The Toronto Star, 2004).

Still, the legislation retained other intellectual property protections that seemed to favor the research-based industry, including a two-year limit on compulsory licenses and a requirement for prior voluntary license negotiations despite some civil society protests.\textsuperscript{131} The Liberals also focused extensively on defining the grounds under which compulsory licenses should be terminated. Grounds for termination proposed and accepted by the Liberals included: 1) when the compulsory license was deemed 'commercial in nature'; 2) when any inaccurate information in the compulsory license application was provided; and 3) when the drugs were exported or found in a country other than the one identified in the authorization.

Some MPs chose to stray a little from the Liberal party line. In defense of the research-based industry, Liberal MP Marlene Jennings introduced a number of individual-member amendments including advocating for stronger anti-diversion measures and requiring NGOs to obtain the authorization from the country of import to purchase the medicines. She was firm in her view that compulsory licenses were the least preferred route.\textsuperscript{132} On the other side, Liberal MP David Collenette was more outspoken against the research-based industry, instead framing the right of refusal as an anti-competitive mechanism and explicitly supporting compulsory licensing as a successful mechanism to facilitate access to affordable drugs.\textsuperscript{133}

\textsuperscript{130} DATA stands for "Debt AIDS Trade Africa".
\textsuperscript{132} Marlene Jennings' riding is located in Notre Dame de Grace, which is located nearby a number of research-based industry headquarters.
\textsuperscript{133} David Collenette's riding was Don Valley East, which was near the only two Canadian generic manufacturers' headquarters, Apotex and Novopharm.
Contributing to the emphasis on liberty issues were references to the WTO TRIPS Agreement (WTO or TRIPS: Liberal Government, 22.1%; Liberal MPs, 15.3%) as the Liberals framed their policy design proposals in relation to TRIPS compliance. It is no surprise that the Liberals were concerned about TRIPS compliance; for WTO members, the decision to comply or shirk with TRIPS is by and large, a non-decision (Bachrach & Baratz, 1963). What is possibly more relevant here is the interpretation of TRIPS that would ultimately guide their proposed legislation.

The threat of U.S. trade sanctions was a constant factor influencing the Liberals legislative design decisions, a possibility that the research-based industry clearly voiced. In their testimony, the research-based industry issued a warning against potential trade challenges if Bill C-9 retained the capped royalty rate.134 On March 29, 2004, the Pharmaceutical Research-based Manufacturers or America (PhRMA) requested that Canada be designated a Priority Foreign Country under the USTR's Special 301 Watch List based upon four complaints, one of which included unknown clauses of Bill C-9.135 The “Special 301” Report is an annual review of the global state of intellectual property rights (IPR) protection and enforcement, conducted by the Office of the United States Trade Representative (USTR).136 Priority foreign countries are those on the Special 301 Watch list that "have the most onerous and egregious acts, policies and practices which have the greatest adverse impact (actual or potential) on the relevant U.S. products; and [do] not engage in good faith negotiations or making significant progress in negotiations to address these problems."137 The USTR may investigate these priority foreign countries' acts, policies and practices. Given the multiple pharmaceutical patent issues that Canada

135 PhRMA claimed that Canada provided inadequate intellectual property protection for pharmaceuticals due to the following issues: 1) the Patented Medicines (NOC) Regulations; 2) data protection; 3) the Patented Medicines Prices Review Board (PMPRB); and 4) the Jean Chrétien Pledge to Africa Act. From: Memo to the Honourable Lucienne Robillard, from Jean-Claude Villard, Subject: Meeting with Canada's Research-based Pharmaceutical Companies (Rx&D), March 29, 2004. Obtained from Access to Information Act.
136 See USTR's 2009 Special 301 report, available at: http://keionline.org/ustr/special301
was juggling at the time, Canada had to achieve a fine balance between crafting a workable regime and implementing the Paragraph 6 Decision in a way that would be acceptable to the research-based industry and, by association, to the U.S. government.

Liberals' focus on equity issues (Equity: Liberal Government 40%, Liberal MPs, 31%) also illustrated the expression of U.S. preferences. As mentioned earlier, the United States took fundamental concern over two particular aspects of the Paragraph 6 Decision at the WTO: the scope of diseases and the scope of countries. The Liberals' defended their inclusion of the list of medicines (List of Medicines: Liberal Government, 17.8%; Liberal MPs, 11.7%) and lists of countries (List of Countries: Liberal Government, 10.7%; Liberal MPs, 18.1%) on a number of grounds, including the vagueness of the Paragraph 6 Decision and providing mechanism for accountability. They did, however, make compromises to accommodate civil society interests through making additions to the lists, particularly in the area of antiretroviral drugs, and incorporating a process to make additions to the lists through the Governor in Council.

While the Liberal Government didn't move on most of the major demands of civil society, these compromises appeared to be their attempt to facilitate what they saw as a similar end result but through a different procedure. But in the eyes of civil society and the generic industry, these compromises only meant a heavier administrative burden on generic industry and most importantly, on resource-strapped developing country governments.

In comparison to liberty and equity issues, the Liberals made fewer arguments in terms of efficiency (Efficiency: Liberal Government, 24%; Liberal MPs, 20%) and when they did, they appeared to primarily frame efficiency in similar terms to the research-based industry (Canada's Research-Based Pharmaceutical Companies, 2004). With respect to diversion (Diversion: Liberal Government, 9.9%; Liberal MPs, 7.2%), the Liberals focused on ensuring that the legislation did not threaten the research-based industry's profitable markets. With respect to profits (Profits: Liberal Government, 6.5%, Liberal

138 In particular, the list of medicines, lists of countries and eligible importers.
MPs, 6.6%), the Liberals aimed to ensure that the generic industry would not use the regime for commercial purposes. When placed against the demands of civil society, the Liberals' interpretation of efficiency was less about achieving efficiency through open market competition (Market Competition: Liberal MPs, 4.2%; Liberal Government, 0.6%) and more about protecting the research-based industry's exclusive market access and any profits therein. As mentioned earlier, even when the Liberals discussed market competition, they framed it as competition between the patent-holder and the generic firm.

The Liberals' lack of emphasis on security issues (Security: Liberal Government, 15%; Liberal MPs, 11%) can partly be explained by their emphasis on other policy goals; naturally, discussion of certain issues comes at the expense of others (Kellow, 1988). As Schon and Rein argue, it is virtually impossible to consider all of the aspects of a certain problem or situation (Schön & Rein, 1994). In the case of CAMR, the debate over drug access narrowed down to an issue of liberty and equity, mainly, at the expense of consideration of security goals.

Overall, most of the Liberals' discussion of security goals, again, weighed largely in favor of the research-based industry. The Liberal Government's few references to affordability (2.2%) were framed almost identically to that of the research-based industry: first, affordability was about facilitating the export of low-priced medicines through encouraging competition between the brand name and generic industries; second, they stated that affordability was not the only barrier to drug access. Affordability was not about compulsory licensing or encouraging the export of generic drugs. Although Liberal MPs spoke about affordability more often than the government (Affordability, 6.0%), the only deviation from the Liberal Government's position came from David Collenette, as described above. The Liberal Government (Development: Liberal Government, 5.1%) seemed to be responding to concerns over whether development-related barriers would impede the distribution and delivery of drugs under Bill C-9. Among these concerned were Liberal MPs (Liberal MPs, 2.3%). By outlining CIDA's programming and recent injections of cash into the Global Fund, the Liberal Government attempted to deflect the
competing argument that other barriers such as infrastructure, corruption, human resources, poverty and financing, might block the success of Bill C-9 or be more urgent barriers than the patent issue. Liberals' and other MPs' concern over distributional and delivery barriers to the success of Bill C-9 appeared to overshadow the real barriers experienced in the Apotex case, which were scarcely mentioned by the Liberal Government and Liberal MPs: the administrative and institutional barriers on the developing country government side.

Despite concessions made to the research-based industry, the Liberal Government also made compromises for the generic industry and civil society. Making it a primary component of their foreign policy platform (Martin, 2004), the Martin Government had a clear incentive to ensure that the final version of the legislation would actually work. The endorsement and participation of both the generic industry and civil society would be necessary in achieving that goal.

Instead of eliminating the list of medicines or the lists of countries, the Liberal Government incorporated a process to amend the lists through the Governor in Council. The Liberal Government proposed and supported the addition of several medicines, many of which were antiretroviral drugs recommended by civil society. They only added East Timor to the List of Countries, suggesting that they wanted to respect the sovereignty of countries in whether or not they wanted to be considered for the legislation. The Liberals found a compromise solution for the royalty rates, which removed the cap but incorporated a formula based upon the standing of the country on the UN's human development index. While the Liberal Government attempted to incorporate language that would authorize generic companies to contract directly with NGOs, Liberal MP Marlene Jennings blocked this attempt by incorporating a clause that required NGOs to receive authorization from the importing country prior to entering any contract. The degree of discretion granted to the Commissioner of Patents was not an issue raised by civil society; however, the Liberal Government made an explicit attempt to limit this discretion so that the regime would not get held up by litigation (Litigation: Liberal Government, 6.7%, Liberal MPs, 1.2%). Finally, the Liberals supported the NDP
proposal to limit voluntary license negotiations to 30 days prior to compulsory license application.

The Influence of Institutions on the Liberal Government's Policy Goals

Overall, the Liberals' discourse during the 2004 debates reflected the reality of Canadian pharmaceutical intellectual property policy, which has moved towards a position that leaves less and less room for patent flexibilities as a tool towards pursuing drug affordability. As mentioned earlier, Canada has become a policy-taker from the United States on issues related to intellectual property (Doern & Sharaput, 2000). Canada's bureaucracy and institutions have been implementing a patent policy that has effectively removed compulsory licensing from its arsenal since 1987 (Lexchin, 1997).

That said, Canada's policy seems equally affected by the demands of having to comply with TRIPS (Jordan, 2005). In the context of Putnam's two-level game, the Liberal Government had to carefully balance their obligations at the WTO with their domestic interests of crafting a functional compulsory licensing policy. Cohen makes the case that in developing states, the cost of honoring and shirking the TRIPS Agreement are both high (J. C. Cohen, 2001). In the case of developed states, like Canada, the cost of shirking certain commitments under TRIPS may be much higher, given Canada's reliance on the United States as a trading partner (Abel, Bernanke, & Kneebone, 2008). In the case of Canada's Access to Medicines Regime in particular, it appears as though the Liberal Government believed that an interpretation of the Paragraph 6 Decision supportive of civil society interests was much more costly than abiding by the stance that they promoted at WTO. After losing two consecutive WTO Disputes between the EU and the US on their domestic pharmaceutical patent policies, the trepidation of the Liberal Government in pursuing more liberal pharmaceutical patent policies is not surprising.

139 Nearly 80% of Canadian exports are directed to the U.S. and one job out of three in Canada relies on the U.S. economy.
The threat of trade challenges was mentioned more than once by the research-based industry.140 141

Nevertheless, Liberal politicians still appeared to see some policy space left for the use of compulsory licensing, as proven by their actions during the Anthrax scare.142 As mentioned in Chapter 4, at the WHO, the Canadian Government's statements appeared to leave some policy space for developing countries as well (Velasquez et al., 2004) but given their statements at the WTO, the extent of this space seemed small. During the Paragraph 6 Decision negotiations, Canada colluded with a group of developed countries led by the US (Japan, Switzerland, European countries and Australia) to restrict the scope of the Paragraph 6 Decision (Elliott, 2003b). Their main demands were restrictions on the scope of diseases that would eligible under the Decision and the scope of countries that could use it.

Perhaps, the most influential factor is the WTO Decision, which itself, was framed largely in favor of the interests of the research-based industry (Médecins sans Frontières et al., 2003). Given Bill C-9's starting point, and the institutional and political priorities of the Government and the majority of politicians in Canada, Bill C-9 was formed to be a regime that, in the words of Liberal MP Marlene Jennings, truly made compulsory licensing "a last resort".143

**The Research-Based Industry**

The research-based industry's discourse throughout the debates suggests that their priority was to maintain existing protections on their intellectual property and exclusive marketing rights. While they expressed support for Bill C-9 and issued a variety of recommendations for the policy, the research-based industry clearly did not support the

142 Need reference.
less restrictive compulsory licensing regime advocated by civil society. Statements two years prior by the IFPMA referred to compulsory licensing as a "threat to public health" (Bale, 2001). They aggressively opposed the Doha Declaration and the Paragraph 6 Decision (Abbott, 2002). It appears as though CAMR was a policy battle that they had to engage in. Their discourse throughout the debates emphasized trying to resolve the issue through voluntary measures and cooperation and they continue to reframe the problem of drug access as an issue of health systems infrastructure and capacity, which should be addressed through aid programs.

The research-based industry's most frequently cited category was equity (61%) and within this category they discussed the issue of aid (41.4%) the most. The research-based industry was clearly interested in improving the health of the poor in developing countries given their commitment to the developing world through their philanthropic programs. But in the past, the research-based industry has promoted their philanthropic programs in lieu of supporting measures to curtail their patent rights (Henry & Lexchin, 2002). During the Bill C-9 debates, the research-based industry suggested that CAMR's design might ultimately affect their philanthropic programs. Such responses create a perceived trade-off between addressing patents as a way to improve drug access and allowing the option for industry aid.

These actions may put developing country governments in the position of having to choose between these two options. Developing country governments have spoken out against such trade-offs, suggesting that they are unfair and that they should be allowed to pursue multiple solutions given the gravity of their public health needs. The Liberal Government did issue some concern that CAMR would affect industry aid programs; however, to date no evidence to this effect has been reported.

145 During the 2001 WTO TRIPS Council debates, the Zimbabwean representative (representing an African coalition of countries) stressed that "… such arrangements [TRIPS flexibilities] must not prejudice the rights of Members under the TRIPS Agreement."
While the research-based industry's emphasis on their philanthropic activities is a clear sign of corporate social responsibility, it can also be viewed as an effort to shift the approach to improving drug access away from the issues of affordability and patents. Throughout their references to security goals (27%), the problem was not framed as an issue related to patents and prices; instead it was the systemic problems of development (7.9%) such as corruption, infrastructure, poverty and lack of financing that is evoked. These attempts by the research-based industry to reframe the problem are not new and suggest again, that the government must choose between either addressing development-related issues or curtailing patent rights to address drug affordability, a claim aggressively denied by civil society.\(^{146}\) Such arguments funnel the debate towards voluntary policy alternatives, which include aid programs. They framed their support for facilitating access to affordable medicines (12.34%) in relation to their participation in the regime but they did not suggest that patents or prices were barriers to access and said nothing about the role of generic competition.

The research-based industry also referred to equity (61%) in terms of what a fair bidding process should look like. Their proposed "equal opportunity to supply" (22.2%) gave patent-holders the opportunity to compete against generic manufacturers on developing country contracts, which they framed as "fair process".\(^{147}\) As Stone describes, the degree to which a "process view" of equity is fair depends upon what standard is used and since no standard is independent, there is always room for debate and disagreement (Stone, 2002). From the research-based industry's perspective, providing equal opportunities to both patent-holders and generic companies to bid on developing country contracts is fair competition for potential developing country markets, something they also framed as "allowing the participation of both industries".\(^{148}\) As will be described in the following section, civil society attempted to reframe this proposal as unfair competition, since the patent-holder is the dominant market actor it would outbid a generic manufacturer who


has yet to obtain a license, establish the process to manufacture the drug and gain entry into any market. Ultimately, the government chose civil society's definition of fair competition but as will be described in detail later, this proved to be a difficult battle for civil society to win.

The research-based industry's references to liberty goals (37%) ensured the protection of their intellectual property (23.5%), either through ensuring prior voluntary license negotiations or through ensuring that the patent holder was notified of incoming contracts under the legislation. The research-based industry preferred voluntary measures, which gives them the authority to define the terms under which their intellectual property would be licensed. This approach has been criticized by civil society advocates as being more restrictive than what could be realized through government-issued licenses and ultimately not a sustainable solution given its piecemeal approach (t'Hoen, 2009).

Royalties (8.3%) were also a significant concern for the research-based industry, arguing that a fixed royalty rate was not compliant with TRIPS Article 31, a position also held by the Intellectual Property Institute of Canada (IPIC). The industry's concern appeared linked to potentially higher income countries, where a rate higher than 2% might be justified. The assumption underlying TRIPS Article 31 is that the patent-holder has the right to remuneration from the third-party use of their invention. The royalty rate may have consequences on the extent to which affordable drugs are available under compulsory licensing. In the past, there has been a wide variation in the ways governments and courts have determined the amount of compensation for patent-holders under compulsory licensing (Scherer & Watal, 2002). Arguably, if Bill C-9 imposed high royalty payments, no price reduction would result. In contrast, if a lower rate were employed, there may be fears that this would encourage widespread compulsory licensing.

150 Correa states that the variance in royalties under government use in the U.S. ranges from 4-16% but rarely exceed 10% (Reichman and Hasenzahl 2003). UK royalty rates paid for "licenses of right" varied from 23-31% (Correa, p 249, "Can TRIPS Foster Technology Transfer to Developing Countries?" in Maskus and Reichman 2005).
as was the case in Canada. It is likely that both the research-based industry and IPIC advocated a variable royalty rate as a protective measure, under the event that compulsory licensing becomes more frequently used or if the scope of compulsory licensing were to expand to include more lucrative markets. It is possible that the research-based industry felt especially vulnerable with the question of royalty rates, as they suggested the potential for a trade challenge if the Canadian government did not address a fixed royalty rate. As mentioned earlier, avoiding a potential trade challenge from the United States or EU appears to have been a significant influencing factor in the government's design decisions of Bill C-9.

The research-based industry framed efficiency (28%) mainly in terms of preventing diversion (15.0%) and procurement (13.2%). Under procurement (13.2%), the industry only discussed their desire to be able to bid for developing country contracts obtained by generic companies, as opposed to discussing other issues further up in the procurement process such as international bidding protocols, an issue that in 2007, was identified as a major oversight of the regime. The research-based industry defined market competition (4%) as that between the patent-holder and the generic company in Canada, something that civil society deemed as fundamentally anti-competitive, if viewed from the perspective of a global marketplace.

Protecting intellectual property is the foundation of the research-based industry's business model. It finances research and development and serves an incentive function to spur pharmaceutical innovation (DiMasi & Grabowski, 2007). As will be discussed later, civil society tried to highlight the negligible contribution that the relevant developing country markets currently make towards these functions but this point got lost in the debate.

Although the research-based industry issued clear support for Bill C-9, their vested interests appear to have been largely out of line with the proposed legislation. It is likely that the research-based industry preferred to be at the table, with a say in how the

151 Under Canada's compulsory licensing regime for pharmaceuticals, a rate of 4.0% against the licensee's price was applied almost uniformly, and it has been argued that this royalty rate aided the widespread use of compulsory licensing in Canada (Scherer and Watal 2002).
legislation would work, as opposed to aggressively opposing it and allowing other interests to shape the final outcome.

**Civil Society**

Throughout the 2004 debates, civil society's goal centered on achieving the most liberal compulsory licensing policy possible within the constraints of the Paragraph 6 Decision, with the ultimate objective to maximize developing countries' access to affordable generic drugs. CAMR was viewed as a tool to promote the production and export of Canadian generic drugs with the hope of also spurring global generic competition and further driving prices down.

Civil society lobbied for this by making an argument primarily based on liberty (48%) but their framing largely overlapped with security (33%), equity (37%) and efficiency (24%) goals as well. From their perspective, patents (intellectual property, 24.8%) were the problem, blocking market competition (11%), which was key to making drugs more affordable (affordability, 15%). In their view, the entire purpose of the Paragraph 6 Decision (TRIPS, 27.2%) was to generate global generic competition through compulsory licensing.

Their rationale behind compulsory licensing was based upon evidence that increased generic competition results in price reductions that can rarely be achieved through the research-based industry's price reductions alone (Médecins sans Frontières, 2009). Given India's role as major supplier of affordable generic antiretroviral drugs to the developing world, and their requirement to comply with TRIPS by 2005, civil society saw the "pharmacy of the poor" in jeopardy (Médecins sans Frontières, 2007). It is unlikely that civil society saw the Canadian generic industry as capable of replacing India's role, but Canada was a window of opportunity within a scope of dwindling policy options. As Richard Elliott, of the Canadian HIV/AIDS Legal Network argued (Elliott, 2003a), NGOs sought to make an imperfect WTO Decision work. Furthermore, civil society
likely had a political aim as well.\textsuperscript{152} As the Prime Minister Chrétien noted, the hope was that Canada would encourage other countries to implement the Paragraph 6 Decision.\textsuperscript{153}

What appears to have been the biggest obstacle to civil society's goal of creating an efficient and functional regime was the Right of Refusal (15.7%). Content analysis results (Chapter 6) showed that civil society spent a large proportion of their time (15.7% of debates) lobbying against the right of refusal. While the research-based industry argued that their proposed "equal opportunity to supply" would increase competition, civil society rejected this claim, arguing that it was fundamentally anticompetitive (market competition, 11%), and a disincentive to generic company participation as it would "kill the basis for commercial interest in competition from the generic drug industry." What civil society failed to emphasize in their discourse was that even without the right of refusal, there would be virtually no commercial incentive for the generic industry to participate. As observed during CAMR's implementation, the only obvious incentive for Apotex's participation was based upon a moral imperative and possibly improving their company image and brand.

Civil society groups fought long and hard against the right of refusal and they also used the media to a large extent (L. C. Esmail et al., 2010). In the end civil society was able to overcome this hurdle with what appeared to be good timing, a little luck and strategic thinking.\textsuperscript{154} The Liberal Government's move to remove the right of refusal and any notification or bidding clause was a huge victory for civil society, but not without its costs. As Kellow states, "the enemy of what you want less, is what you want more," (Kellow, 1988). Arguably, the Right of Refusal clause forced civil society to focus less

\textsuperscript{152} This is the main argument of Morin and Gold (2009), who propose that civil society was primarily motivated by political goals as opposed to concretely increasing access to medicines through use of the Canadian regime.

\textsuperscript{153} "Canada will be the first country to introduce legislation to implement the WTO agreement. We hope that our quick response will encourage other countries to follow our example." From: Canada. Parliament. House of Commons. Debates. 37th Parliament, 2nd Session, Vol. 138 (November 4, 2003) pp9145.

\textsuperscript{154} As argued earlier in this chapter, civil society appeared to take advantage of Bono's endorsement of Paul Martin during the 2004 election campaign.
on other aspects of the legislation, which later proved to be formidable barriers to its use by developing countries.

Civil society spent considerable time during their debates trying to reframe the idea of market competition (11%). While the Liberal Government, Liberal MPs, research-based industry and the Intellectual Property Institute of Canada (IPIC) framed it as competition between the patent-holder and a potentially interested Canadian generic company, civil society and the generic industry framed it as global generic competition. The debate was so consumed by this discussion that there was hardly any room to discuss the ability of the Canadian generic industry to compete against lower cost centres in emerging markets, which would be required by international bidding protocols (procurement, 4%). The implications of this oversight will be discussed in more detail in the final section.

Aid (17%) was a major theme as well and civil society discussed the issue with two apparent objectives. First, they sought to counter the perception that corporate philanthropy, while a valuable contribution to addressing the problem of drug access, was not sustainable and left developing countries entirely dependent upon the good will of private entities. Henry and Lexchin argue that corporate philanthropy and drug donations are a mechanism for keeping global drug prices high while being seen as assisting the most disadvantaged groups (Henry & Lexchin, 2002). Along these lines, civil society insists that the development of generic drugs is a more sustainable and reliable solution.

The research-based pharmaceutical companies are for-profit entities (as are generic pharmaceutical companies) and as such, they need to ensure adequate profit margins are incorporated into the sales of their drugs, with high-income countries are their key profitable markets. The research-based industry may be attempting to hit a balance between their policy objectives of making profits for their shareholders and staying competitive while trying to accommodate the needs of low-income countries. Still, even though compulsory licensing in low-income markets may not hurt their bottom line, it is clearly a policy alternative that they find too risky and a threat to their future profitability.
Civil society also framed aid in relation to their role as aid providers. They argued that the success of this regime required that NGOs be allowed to purchase medicines (Eligible Importers, 6%). Moreover, the presence of NGOs in resource poor settings countered the research-based industry's argument that the real problem was development (17%). Given NGOs presence and capacity to safely and effectively deliver medicines in resource-poor settings, setting up the infrastructure did not have to come before reducing drug prices. While investments in improving health systems infrastructure, addressing poverty and increased financial aid were important, improving infrastructure was not a trade-off with improving drug affordability.

In trying to maximize developing countries' access to affordable generic medicines, civil society's references to equity were aimed at making the regime expansive in scope. To this effect, they argued for the elimination of the lists of medicines (12%) and list of countries (7%). They accused the Liberal Government of reintroducing debates that were already resolved at the WTO. Civil society's fundamental belief was that each country should have the autonomy to determine what their drug needs were. In essence, they considered the list of medicines as paternalistic in that it prioritized what diseases and drugs they could have affordable access to. Stone states that questions of equity often require defining who should be permitted to receive the benefits and what these benefits should be. Since no objective standard exists, any definition can be challenged.

While the Liberal Government argued the rationale behind using the WHO Essential List of Medicines as their starting point, civil society rejected this standard. The WHO Essential List of Medicines was established to help guide countries in devising national formularies (World Health Organization, 2009). Moreover, since cost-effectiveness is a major criterion for inclusion on the list, many of WHO Essential Medicines are off-patent (L. C. Esmail, 2007). Civil society argued that the WTO Decision covers all medicines, referring only to "pharmaceutical products".155

155 Canada. Parliament. House of Commons. Standing Committee on Industry, Science and Technology. Evidence. (February 24, 2004) 37th Parliament, 3rd Session. As stated earlier, the IFPMA opposed this position during the negotiations leading up to the WTO Paragraph 6 Decision on the basis that imitator industries in India, Brazil and Argentina would take advantage of the Decision to reap profits from more lucrative pharmaceutical markets such as Viagra or newer cardiovascular disease drugs.
The debate over the list of medicines is essentially a continuation of the conflict at the international level. As described earlier, Abbott reports that a group of countries led by the United States attempted to limit the Decision to a list of diseases (HIV, TB, malaria), apparently to protect the research-based industry's more lucrative markets, especially in treating chronic disease. In the end, civil society succeeded in listing several new antiretroviral medicines but the Liberal Government retained the list, on the basis of accountability, and procedural necessity. Given this outcome, the research-based industry was able to limit the impact that compulsory licensing would have on their more lucrative chronic disease markets.

At the end of the day, the battle for a functional and usable compulsory licensing regime was fought only by civil society backed by an NDP, with only one vote on the standing committee. Civil society won a major battle with the removal of the right of refusal but the rest of the design decisions appear to favor the preferences of the research-based industry. These design decisions appear to have already been locked in at the international level. Canada's position at the WTO is largely in line with the alternatives they advocated in the structure of the regime. Given the terms of the debate (TRIPS, 27.2%), civil society was fighting an uphill battle.

The Generic Industry

The generic industry was the first societal interest group to publicly request that the Government implement the WTO Paragraph 6 Decision and throughout the debates, they were fully supportive of Bill C-9. Still, the generic industry had virtually no business interest in the regime. After the WTO reached its August 30th Decision, even the Indian Generic Manufacturers association, an association representing emerging market producers who generally have low input costs, said that their companies would unlikely participate given the commercial restrictions on the regime (Shah, 2003). Most likely, the Canadian generic industry participated in the debate over Bill C-9 for a public relations outcome; taking a lead in a high profile humanitarian venture would bolster their image and provide visibility to the Canadian generic industry. Overall, the generic industry's
statements and positions were mostly in line with civil society; however, the generic industry's business interests ultimately prevailed.

The generic industry made primarily a liberty argument (58%), driven by references to intellectual property (44.4%) and to a lesser extent, TRIPS (12.8%), royalties (11.9%), and the right of refusal (8.0%). By and large, the content of their statements on intellectual property were in line with civil society. They explicitly framed patents as a fundamental barrier to the developing world's access to affordable Canadian generic products, they were fervently opposed to the right of refusal, and they advocated a capped royalty at 2%. Despite these goals, the generic industry's position on the alternative to the right of refusal – the equal opportunity to supply – starkly contrasted with that of civil society. In essence, the generic industry advocated a measure that would invite the patent-holder to compete against them for developing country contracts. Their particular concern with the right of refusal appears to have been the potential loss on investments they may have made in negotiating a contract with a developing country purchaser as well as investing in the manufacturing process (Profits, 7.4%). This suggests that the generic industry may have been less interested in actually supplying the drugs and more interested in protecting their profitability and competitiveness.

Along these lines, efficiency (41%) was another highly emphasized theme by the generic industry. Again, most of these statements were largely in line with civil society. By framing the goal of the initiative as generating market competition (13.3%), the generic industry clearly advocated for their participation in the regime. Their support for having NGOs be allowed to be eligible importers (14.2%) likely reflects both the lack of infrastructure within their industry to assist with the roll out of medicines and also the recognition that the developing country governments would require technical assistance from the NGO community to use compulsory licensing, as has been done in the past. Finally, profits and return on investment (7.4%) appears to have been a major concern.

since the industry did not want to invest in making a drug without the guarantee that they would be able to sell it, as is the current situation of Apotex. Unless Apotex receives another license to produce and export drugs, their investment in R&D and manufacturing will not yield any returns until the relevant patents expire in Canada. Still, generic companies may find incentive in establishing their manufacturing capacity for a drug, which would allow them to enter the market sooner once the patents expire.

Least emphasized were equity (30%) and security (30%) but these statements still reflected a position in line with civil society. They framed aid (25.2%) as requiring NGO support for rollout. They supported the removal of the list of medicines (4%). Security goals were about affordability (19.2%), mainly there to frame the regime to increase access to affordable Canadian generic drugs. Finally, their emphasis on quality and safety (9.1%) reflected their desire to obtain Health Canada approval, likely on the basis of speeding up market entry in Canada and elsewhere when the patent finally expires.

Overall, it appears as though the generic industry wanted to encourage global generic competition; however, their hopes of achieving it through affordable generic production in Canada were low. Their advocacy on this issue was likely more for the purposes of increasing their visibility on a humanitarian policy that resonated with the Canadian public; and it fell in line with their past policy positions. Had providing affordable generic medicines to developing countries really been a top priority for the generic industry, it is unlikely that they would have supported, let alone advocated, an anticompetitive mechanism similar to the equal opportunity to supply. Taken in context of the generic industry's emphasis on Canadian-generic market access and recouping their investments, their discourse suggests that providing affordable drugs to poor countries was not their primary goal. Most likely, they did not anticipate much profitability or business advantage. Instead, the generic industry appeared to be more concerned with supporting a licensing regime that would create minimal procedural burdens for them and would allow them to recoup any costs or investments made.
The for-profit nature of the private generic industry appears to have been the prevailing interest, as they would not be willing to absorb losses simply to participate in a humanitarian venture. This would particularly prove to be the case with CAMR, as in 2007 we saw that Apotex exposed itself to the threat of litigation and significant sunk costs. In summary, the generic industry supported the regime in theory but to the extent that their industry was willing to sacrifice their profitability, their support for the regime can be seen as unsubstantiated rhetoric.

The Intellectual Property Institute of Canada (IPIC)

The Intellectual Property Institute of Canada (IPIC) advocated the interests of the research-based industry through their emphasis on liberty goals (85%) throughout their testimony. IPIC is explicit about their role in representing the interests of "Canadian intellectual property practitioners" and do so by "protect[ing] and promot[ing] intellectual property in the Canadian economy." In the Bill C-9 policy debates, they fulfilled this role by promoting policy alternatives that protected the research-based industry's intellectual property rights (63%).

First, IPIC advocated for increased discretion by the Canadian Commissioner of Patents to issue, limit or terminate compulsory licenses (intellectual property, 63%). Along with increased Commissioner discretion, they argued that patent-holders should be allowed to challenge licenses on the basis of the potential for diversion (9.4%) or where quality and safety (4.2%) might be an issue. These arguments mirror those made by Rx&D in their February submission, which were made on the basis of accountability and transparency (Canada's Research-Based Pharmaceutical Companies, 2004).

In protecting their potential market share, the incentive exists for the research-based industry to challenge compulsory licenses, particularly when promising market shares are

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158 See IPIC's website at: [http://www.ipic.ca/english/general/about.cfm](http://www.ipic.ca/english/general/about.cfm) [Date accessed 12 February 2010].
159 See IPIC's website at: [http://www.ipic.ca/english/general/about.cfm](http://www.ipic.ca/english/general/about.cfm) [Date accessed 12 February 2010].
160 Rx&D proposed the "right to make representations" if a country has a history of diversion, if the quantity is deemed excessive, if the royalty rate is deemed inappropriate, and in relation to the duration of the license.
at stake. Such challenges could delay licenses from being issued and the practice could be subject to abuse. These potentially detrimental effects of increasing Commissioner’s discretion were noted by the Government and Liberal MPs during later stages of the debates. Citing heavy litigation between the research-based and generic drug industries, the Government was reluctant to give any discretion to the Commissioner of Patents. As will be discussed and explained later on, this was one particular policy battle that IPIC and the research-based industry subsequently lost.

Royalties (20%) were also a significant concern for IPIC, as it argued that a fixed royalty rate was not compliant with TRIPS Article 31, a position shared by the research-based industry. As the research-based industry stated in their testimony, their concern appeared linked to potentially higher income countries, where a rate higher than 2% might be justified. TRIPS Article 31(h) stipulates that "adequate remuneration" must be given to the patent holder. The assumption behind this clause is that the patent-holder has the right to remuneration from the third-party use of their invention. Obviously, the royalty rate has consequences on the extent to which affordable drugs are available under compulsory licensing (Scherer & Watal, 2002). It is plausible that if Bill C-9 would impose high royalty payments, there would be no price reduction at all. In contrast, under Canada's compulsory licensing regime for pharmaceuticals, a rate of 4.0% against the licensee's price was applied almost uniformly, and it has been argued that this royalty rate aided the widespread use of compulsory licensing in Canada (Scherer & Watal, 2002).

It is likely that both IPIC and the research-based industry advocated a variable royalty rate as a protective measure, under the event that compulsory licensing becomes more frequently used or if the scope of compulsory licensing were to expand to include more lucrative markets. As with the question of eligible countries, not all developing countries have access to all pharmaceutical products (Abbott, 2005) and if the country list were to

ever expand, it is possible that higher income countries could become the beneficiary of the Canadian regime.

The IPIC's frequent references to the right of refusal (18%) originate from what they saw as its premise: they viewed the right of refusal as a mechanism to generate competition (market competition, 10.8%) and avoid the oligopoly of the Canadian generic industry. By encouraging competition between the patent-holder(s) and generic companies, and ensuring that the patent-holder beat the price of the generic firm, the right of refusal would lead to the best price possible (affordability, 19.3%). To mitigate the complaints around generic companies' potential sunk costs in negotiating contracts, they proposed compensation by the research-based firm through a "finder's fee".

IPIC's proposal hardly differs from that of the research-based industry's proposed "equal opportunity to supply". As civil society representatives argued during the hearings, the proposal invites a dominant market actor into negotiations with a generic company who has a clear disadvantage since it does not yet have a license or a market share.\textsuperscript{164} IPIC's proposal defends intellectual property rights by providing the patent-holder(s) the opportunity to block generic competition for the potential developing country contract.

As discussed in Chapter 4, any form of compulsory licensing is against the interests of patent-holders as it interferes with their intellectual property rights. The IPIC's and research-based industry's fundamental goal throughout these negotiations appeared to be directed towards limiting the amount of government intervention into their exclusive market access.

\textbf{Conservative MPs}

The Conservative Party primarily referenced liberty (30%) and equity (31%) issues throughout the testimony. Traditionally, the Conservatives support more free-market and pro-business positions, which explicitly includes the protection of property rights.

Conservative Party of Canada, 2008). As illustrated in Chapter 4, the Conservative Party's rhetoric during parliamentary debates resembled that of the research-based industry by supporting the aid efforts of the industry, and voluntary licensing, and emphasizing that drugs are only one part of the solution. The Conservative Party appears to have largely favored the research-based industry's interests by advocating the protection of their intellectual property rights.

First, the Conservative Party avoided any rhetoric linking patents (intellectual property, 11%) with pricing or competition. Instead, like the research-based industry, they stressed that patents were not the only barrier to access, citing the problem development-related barriers (5%) such as lack of infrastructure (5.4%), corruption (3%), lack of trained health professionals (1%) and poverty and lack of financing (2.1%). As mentioned earlier, the global research-based industry has used the argument of development-related barriers to shift the issue of drug access away from patents. The Conservative Party's framing of patents and development-related barriers suggests that they may have preferred other solutions to the drug access as opposed to curtailing intellectual property rights.

The Conservative Party was opaque with respect to their position on the right of refusal (9%). While they appeared concerned about the amount of opposition to the clause, they framed the problem as ensuring compliance with Article 31(b) that requires prior negotiations with the patent holder, despite civil society's insistence that Article 31(b) did not require any form of notification or right of refusal to the patent-holder. In the end, the Conservative Party supported its removal.

Among other issues that indicate their position, they issued concerned over a fixed royalty rate (6.6%) suggesting that it was not TRIPS compliant, in line with the research-based industry's position. In contrast with the research-based industry but in line with the

Liberal Government, the Conservatives issued concern with the potential for litigation that might result from an increase in Commissioner’s discretion.

The Conservative Party’s main concerns under equity were to maintain both the lists of medicines (14%) and the lists of countries (14%). By framing the removal of the lists as a threat to innovation (3.5%), Conservatives were making a link between developing country markets and contributions to the research and development budgets of the research-based industry. Only civil society discussed the relationship between developing country markets and the R&D budgets of the research-based industry (innovation, 2.1%). As will be discussed later, this relationship and more importantly, the impact that Bill C-9 might have on these budgets was a topic largely ignored. This suggests that most actors argued in defense of intellectual property rights as an end in itself. Finally, the Conservatives praised the research-based industry's aid (8%) efforts. In the context of their rhetoric, this suggests that the Conservatives support of voluntary industry aid as a preferred policy tool.

What becomes apparent from analyzing the Conservative Party's rhetoric in the case of Bill C-9 is that their support of the legislation is similar in nature to the research-based industry: they support the legislation as increasing access to affordable medicines; however, because they value intellectual property rights, they wish to pursue this goal through other measures such as aid and philanthropy, addressing infrastructure and other broader barriers, and if patents must be addressed, they would prefer to pursue it through voluntary licensing measures.

**Bloc Quebecois (BQ)**

The Bloc appeared to shift from a nuanced position that balanced civil society and research-based industry concerns to a position that mostly favored the research-based industry's interpretation of the Decision. During the 2003 parliamentary debates, the BQ presented a divided position on the implementation of the regime. While they supported the pro-industry anti-diversion measures and the need to ensure it was not used for commercial purposes, they clearly identified patent flexibilities as a useful policy tool to
address drug access, they opposed the lists of medicines and countries and they opposed the right of refusal. What is notable in these statements is their mention of Oxfam, one of the key NGOs involved in advocacy on the regime. Oxfam-Quebec has a highly active membership in Quebec\textsuperscript{166} so their lobbying campaign may have been successful in affecting the Bloc's position on Bill C-9. That said, the Bloc's position appeared to shift to favor the research-based industry's interests once the standing committee hearings began.

The Bloc appeared reluctant to allow NGOs to contract directly with a generic firm (eligible importers, 11%), framing it as "paternalism" towards developing countries and ultimately interfering with the sovereignty of country governments in determining what their priorities are. They appeared to join sides with Liberal MPs Marlene Jennings and the Conservative Party on this issue, suggesting that the NGOs should have to receive some clearance from the importing country if they were to use it. And yet, from civil society's perspective, this was yet another administrative obstacle that could delay or prevent generic drugs from reaching patients in need, particularly given the problems of institutional capacity in these countries.

They advocated strong anti-diversion measures (14%) and promoted the equal opportunity to supply (6%) as a viable alternative to the right of refusal (1.9%), both key alternatives proposed by the research-based industry.

The Bloc's opposition on the List of Medicines (7.7%) seemed to wane during the hearings, suggesting that if the required medicines could be added "the arguments against the list are weakened." The same could be said for the List of Countries (9.1%), as they did not cite opposition during the hearings; however, the BQ proposed to add several countries to the list during the hearings that might not have the administrative capacity to go through the process of requesting addition in the future. These two moves suggest that the BQ appears to have tried to hit a compromise to the NGO's demands to drop the lists and what they framed as TRIPS compliance (8.1%) but ultimately favored the limited

\textsuperscript{166} Oxfam-Quebec has 5 campus groups, 77 employees, 400 volunteers, 10,786 members and 15,000 donors in Quebec alone. \url{http://oxfam.qc.ca/fr/nos-gens} [date accessed 2 January 2010]
interpretation of the Paragraph 6 Decision, which the research-based industry supported (Abbott, 2005).

The only two issues that appeared to be in line with civil society and the generic industry's frames were a capped royalty (2.8%) rate at 2% and concern about increased Commissioner discretion holding up the process through litigation (7%).

The Bloc Quebecois' position favoring the research-based industry's interpretation of the Decision is likely due to the heavy presence of the research-based industry in Quebec (Investissement Quebec, 2009). Thirty international companies house their head offices in Quebec (patented, generic and custom-manufacturers) among which include: Abbott, BMS, Merck Frosst, Sanofi Aventis, AstraZeneca, GSK Bio, Novartis, Servier, BI, Johnson and Johnson, Pfizer and Wyeth. Nearly half of the Canadian biopharmaceutical industry is based in Quebec, and the bulk of basic and clinical research in Canada is conducted in Montreal, employing close to 1,000 researchers (AstraZeneca, BI, GSK Bio, Merck Frosst, Wyeth). Some research centres exist throughout the province as well including Quebec City, Laval and Sherbrooke.

Despite the advocacy of Oxfam-Quebec, it is likely that the Bloc found themselves in a position where they had to compromise their original opposition to certain aspects of Bill C-9. This left civil society in a position with only one party's support: the NDP.

New Democratic Party (NDP)

It is clear that the NDP was the most receptive to civil society interests. All of the content of their debates somehow represented civil society's position on the policy alternatives being proposed. Given the NDP's party platform and their statements about CAMR during House of Commons proceedings, their alliance with civil society comes as no surprise. The NDP is rooted in a social democratic ideology, which believes that "the production and distribution of goods and services [should] be directed to meeting the
social and individual needs of people…and not to the making of profit…”167 (New Democratic Party of Canada, 2001) Towards these ends, the NDP actively supported curtailing intellectual property rights if that would ensure access to affordable medicines in developing countries. Upon introduction of Bill C-56 in parliament, the NDP explicitly framed patents as a barrier to drug access and affordability. The NDP lambasted the Liberal Government for incorporating the right of refusal clause, calling it a "giveaway to big pharma" and they were crucial in helping move Bill C-56 to committee (Elliott, 2004), framing NGOs as "heroes" in their efforts to try and secure affordable drugs for Africa. That said, the NDP does not have to govern the country, nor is it likely that they will be governing anytime soon.

The content of the NDP's policy debates were no different. Their statements throughout the hearings reflected the end goal of facilitating compulsory licensing so that generic companies could produce and export affordable drugs. They were the only political party that explicitly advocated compulsory licensing (15%) and they proposed adding language to give this effect in the legislation but the committee voted down this proposal. They advocated a capped royalty (8.2%) rate at 4% to ensure drug affordability. Most importantly, they were fiercely opposed to the inclusion of the right of refusal (7.7%) or any kind of notification, arguing that the research-based companies already had the opportunity to sell their drugs to poor countries at an affordable price. They consistently framed their arguments in terms of what was TRIPS compliant (10.2%) but therein lies one of the fundamental determinants of this case: what was and wasn't TRIPS compliant were the terms of the debate and the venue of Industry Canada and International Trade interpreted this in a manner which favored the research-based industry more than it did civil society or the generic industry.

The NDP wanted the lists of medicines (16.4%) and countries (11.7%) removed on the basis that it limited the scope and the spirit of the Decision and the Doha Declaration. Furthermore, the process of adding to the list of medicines could be vulnerable to

167 It goes on to state“…to modify and control the operations of the monopolistic productive and distributive organization through economic and social planning. Towards these ends and where necessary the extension of the principle of social ownership.” (New Democratic Party of Canada, 2001)
political pressure, a proposition rejected by committee members but only weeks later proven in the case of Bayer and moxifloxacillin (McGregor, 2004). All members of the committee rejected the proposal to remove the lists; however, the NDP proposed several medicines to be added to the list, many of which were accepted by the committee with the technical guidance of the Therapeutics Products Directorate. The NDP also proposed that several countries to be added to the lists of countries, all of but one which were denied. Liberal MPs backed the inclusion of East Timor; with the devastation from the tsunami still fresh in the public's mind, denying access of this country to the regime would have likely caused the Liberals political embarrassment.

While they took the opportunity to criticize the government's failure in meeting the goal of 0.7% of GDP for official development assistance (aid, 6.2%), the NDP also advocated the inclusion of NGOs as eligible purchasers of medicines based upon their role in health care delivery in resource poor settings. The Liberal Government was receptive to this proposal and amended the legislation accordingly until Marlene Jennings, a Liberal MP representing a Montreal riding geographically situated near some research-based industry headquarters, effectively negated this clause.

Overall, the NDP was able to push through a number of minor amendments to the legislation, including additions to the list of medicines and minor changes in wording; however, on civil society's major demands - the removal of the lists, allowing NGOs to purchase medicines, and the right of refusal - the NDP's single vote on the committee did not get them very far. As will be described later, the largest victory for civil society –the removal of the right of refusal – was likely due to the involvement of the Prime Minister. Ultimately, civil society faced an uphill battle in getting their major amendments through the committee given the support that the research-based industry had from the majority of the politicians on the committee.

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168 Her riding is featured on her MP website: marlenejennings.liberal.ca/en/our-community
The Dogs that Didn't Bark

As mentioned at the beginning of this chapter, the content analysis codebook searched for a number of different themes in the 2004 and 2007 policy debates; some of these concepts were barely discussed and some didn't get mentioned at all. These issues included technology transfer and technological development, procurement practices in developing countries, potential delays with voluntary license negotiations, developing country pressure and country notification and the limits of the Paragraph 6 Decision itself. Also, discussions over the domestic economy, innovation and human rights showed up infrequently.

Institutional factors and scope of conflict theory (Schattschneider, 1964) can help explain the absence of some of these issues in the 2004 policy debates. This section discusses the under-emphasis of three major policy goals related to drug access: innovation, domestic economy and human rights. The remaining issues, which were later identified as barriers in 2007, will be discussed in Chapter 9.

Human Rights

Civil society was the only societal interest group that mentioned the goal of protecting human rights, aside from a brief reference made by one Liberal MP.169 As mentioned before, the right to health is recognized by many international and regional treaties, including the International Covenant on Economic, Social and Cultural Rights (ICESCR) which provides the grounds for states legal obligations towards the right to health (Hogerzeil, Samson, Casanovas, & Rahmani-Ocora, 2006; Office of the United Nations High Commissioner for Human Rights, 1966). Article 12.2 extends this right to access to medicines.170

169 One Liberal MP stated “…if we ever wanted to tackle the issue of the right to health as being a fundamental right, Canada might have to consider projects to help apply the legislation in developing countries and least developed countries." See: Canada. Parliament. House of Commons. Standing Committee on Industry, Science and Technology. Evidence. (March 10, 2004) 37th Parliament, 3rd Session.

170 General Comment 14 of May 2000 explicitly links Article 12.2(d) to the provision of essential drugs.
From civil society's perspective, operationalizing the right to health meant crafting a legislation that reflects states' obligation to promote access to affordable medicines for all (2004). For the one Liberal MP, the right to health could be promoted through a proactive implementation of CAMR, which involved helping countries actually use the legislation to this effect. These interpretations of human rights imply a level of responsibility on the Government of Canada to ensure that CAMR is both designed and implemented to achieve more affordable drug access for all. Based upon the design of the regime itself, the Government's professed commitment to protecting human rights as reported by the media (Graham, 2003) did not materialize, suggesting that institutional factors played an important role.

Forman argues that the power of rights discourse in achieving improved access to medicines is dependent upon the political and economic context (Forman, 2007). Focusing on the persuasive power of the human right to medicines, she argues that in cases of entrenched political or economic interests, coercive tools such as litigation are necessary in order to realize this right. In the case of CAMR, Canada's political and economic interests appeared to diminish the use of the right to health as a persuasive argument, which played out in how CAMR ended up being designed.

**The Canadian Domestic Economy**

The generic industry was the only stakeholder to discuss Canadian domestic economic issues, citing their industry's contributions to the domestic economy. However, little to no domestic economic argument could have been made for the establishment and use of CAMR. According to the WTO Chairperson's statement, Paragraph 6 could not be used for commercial purposes (World Trade Organization, 2003a). Furthermore, early on in the legislative process, the CGPA stated that they never expected to make any money from the regime to begin with (L. C. Esmail et al., 2010). Even the Director-General of the Indian Generic Pharmaceutical Alliance stated that they thought Paragraph 6 was

171 Mr. Paul Hunt, UN Special Rapporteur on the Right to Health stated that "The procedures for implementing the new legislation should facilitate the goal of improving access to drugs and promoting public health in developing countries." (Canadian HIV/AIDS Legal Network, 2004).
unworkable as it provided no commercial incentives for the generic industry to participate (Shah, 2003). If a low-cost centre like India finds little incentive to participate in the Paragraph 6 regime, then it is unlikely that a high-cost centre like Canada would find it either. Apotex's participation in the regime appears to be an isolated event.

Despite the research-based industry's silence on this issue during the debates, they frequently referred to their contributions to Canadian employment and domestic investment in research and development in their press releases.172 Given the IFPMA's comment upon the Government's announcement of its intention to implement the Paragraph 6 Decision173, the threat of reduced investment from the research-based industry was likely always present. Still, the research-based industry's low level of domestic investment on basic research (see Chapter 4) raises the question of the quality of the investment that Canada is receiving in exchange for protecting patent-holders' rights.

The real domestic economic issue, which hardly received attention during the debates, appears to have been the potential consequences of U.S.-led trade challenge under the WTO. As mentioned earlier, almost 80% of Canadian exports are directed to the U.S. and one job out of three in Canada relies on the U.S. economy (Abel et al., 2008). Given the U.S.'s promotion of the research-based industry's intellectual property interests abroad and given Canada's history in WTO challenges on pharmaceutical patent law (See Chapter 4), it appears as though the Government did not want to risk Canada's domestic economic interests for a humanitarian initiative.

**Pharmaceutical Innovation**

Most participants did not examine the relationship between innovation and the protection of intellectual property. While civil society's arguments severed the link between the

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172 The IFPMA's initial statements regarding Canada's intention to implement the Paragraph 6 Decision, explicitly linked the initiative to the reduction of the industry's R&D investment in Canada (Chase, 2003).

173 As mentioned in Chapter 4, Harvey Bale, the Director-General of the International Federation for Pharmaceutical Manufacturers Association (IFPMA) stated that it would be "a negative black eye that would very well affect the research investment in Canada."
budgets for R&D research and sales in poor countries, no other stakeholder suggested this was the case. Instead, all politicians' discourse regarding innovation showed a fundamental assumption that protection was needed, even in developing countries, to uphold the incentive for future innovation.

No consensus exists regarding how to structure an intellectual property regime to best encourage innovation. Stiglitz argues that there is a fundamental inefficiency created by patents, some of the reasons which include high administrative costs and reducing the welfare of society by preventing the timely access to more affordable, generic medicines (Stiglitz, 2007). Furthermore, he argues that a poorly-designed intellectual property regime can actually impede innovation. Based upon recent research at the WHO, the contribution that eligible countries would make to the industry's research and development budgets is negligible. In 2006, The WHO Commission on Intellectual Property and Public Health (CIPIH) produced an independent report, which concluded that one important problem in drug access is the lack of economic demand for pharmaceuticals in developing country markets (Commission on Intellectual Property Rights, Innovation and Public Health, 2006). This lack of economic demand makes patents ineffective at promoting drug development for the poor because “…patents only work where profitable markets exist,” (Correa, 2006). This evidence detracts from the Government's arguments to uphold the system of pharmaceutical innovation and reaffirms the likelihood that TRIPS compliance was their primary concern. Moreover, it illustrates how effectively TRIPS links the issues of intellectual property protection and trade thereby muting the debate over the relationship between innovation and patent protection, at least in the policy venue of the WTO.

**Conclusions**

Despite a similar rhetoric across stakeholder, framing differences show that not all of them supported the same version of a drug access initiative. While both civil society and the generic industry framed the purpose of the Paragraph 6 Decision as generating generic competition to reduce drug prices, the research-based industry, the Intellectual Property Institute of Canada and the Canadian Liberal Government framed the goal of
Paragraph 6 and Bill C-9 as aiming to facilitate the flow of affordable medicines. The research-based industry did not explicitly disagree with the idea of CAMR; however, their arguments taken in the context of their past policy positions shows that they were ultimately not interested in seeing a functional regime. The Liberal government may have supported a functional regime but did not place generating generic competition as a priority.

The Liberal Government's decision to favor intellectual property protection and the limited use of compulsory licensing seemed related to three factors that are linked to one another: 1) how the problem was first defined; 2) the policy venue in which the debate took place; and 3) the demands of having to comply with TRIPS. By framing the initiative as the implementation of the Paragraph 6 Decision, the Liberal Government immediately channeled the debate into the institutions that deal with trade and intellectual property; namely, the Departments of Industry Canada and International Trade, along with their mandates, policy legacy and interests. Since Canadian intellectual property policy have been moving in a direction that leaves less and less room for patent flexibilities as a tool towards drug affordability (Doern & Sharaput, 2000; Lexchin, 1997), a debate over re-introducing compulsory licensing is working within limited policy space to start with. Canada's policy decisions seem equally affected by the demands of having to comply with TRIPS. With the threat of U.S. trade sanctions always on the horizon, it is not surprising that the Liberals crafted a regime that conformed to many of the research-based industry's demands.

The combination of this policy context and a debate focused largely on issues related to patents and TRIPS is that a number of issues pertinent to drug access were not raised, or if they were, they were not taken up by the political system. These under-represented themes included innovation, domestic economy and human rights. Again, institutional factors are partly responsible for this outcome. First, the protection of human rights is not under the mandate of Industry Canada or International Trade. Although the Liberal

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Government framed CAMR early on as a tool to pursue human rights (Graham, 2003), these goals clearly did not get prioritized in the policy development process. Secondly, the lack of emphasis on innovation and Canadian domestic economic interests suggest that these goals and their relationships to TRIPS and intellectual property protection were assumed.

Overall, it appears as though the Liberal government's underlying goal in 2004 was to pass legislation to give effect to the Paragraph 6 Decision while ensuring that intellectual property rights were adequately protected. The way in which they did this created a regime that permitted compulsory licensing under a set of circumstances, which both the Canadian generic industry and civil society viewed as restrictive and unworkable. The issues that took up most space in the debates focused on whether to give patent-holders an opportunity to preempt generic company contracts as opposed to the issues that surfaced in its implementation in 2007, which will be discussed next.
Chapter 8: Content Analysis Results of Policy Debates 2007

Outline

An overview of the major issues and actors involved in policy debates about access to medicines in developing countries and intellectual property protection was outlined in Chapter 4. These issues were then incorporated into the codebook and categorized according to Stone's four-goal framework, as outlined in Chapter 5. This section presents the results of the 2007 content analysis.175

The content analysis systematically analyzed the Parliamentary Standing Committee hearings, which reviewed Canada's Access to Medicines Regime (CAMR) three years after it was passed. This legislative review was a mandatory component of CAMR legislation, as it was incorporated into the legislation when it was passed in 2004. The goal of this analysis was to determine the framing content of these hearings to determine how stakeholders framed access to medicines in the case of CAMR.

The first section of this chapter provides a context for the Standing Committee hearings on CAMR in 2007. The subsequent section presents tables describing frequency with which stakeholders discussed certain themes and issues. This quantitative presentation provides a picture of the policy goals and themes that drove the debate. The remainder of the chapter provides a qualitative summary of each stakeholder's comments is presented to illustrate how each stakeholder framed the themes and issues. The combination of these results provide the foundation for Chapter 9, which analyzes these statistics and qualitative framing contents in the theoretical framework of ideas, interests and institutions to determine how framing, interests and institutions interacted and influenced the final policy product.

175 See Chapter 3 for an explanation of the analysis.
Introduction

Chapter 3 describes the methods by which the codebook was created and it can be found in Appendix 1. The codebook is organized according to Stone's four policy goal framework: equity, security, liberty and efficiency. Equity issues, defined as issues relating to fairness of distribution, included the following themes: aid to developing countries, the research-based industry's proposed equal opportunity to supply, and Bill C-9's list of medicines and list of countries. Security issues, defined as basic needs, included development\textsuperscript{176}, drug affordability, drug quality and safety, human rights, domestic economic issues and innovation. Liberty issues, defined as freedom or exemption from restraint, included intellectual property, the WTO TRIPS Agreement, the right of refusal and developing country pressure. Efficiency issues, defined as obtaining the most output for a certain input, included diversion, litigation, market competition, procurement issues, profits, eligible importers and CAMR output and uptake.

In 2007, a larger scope of actors, from international and domestic organizations, submitted written consultations compared with the 2004 debates (Appendix 3). The legislative review was well-publicized and facilitated through a website where the government posted a consultation paper listing specific questions regarding the regime. Any public individual or group was invited to make a written submission in response to the consultation paper.

Consultations were held over three days between April 16, 2007 and April 23, 2007. Government Bureaucrats from the Departments of Industry Canada, Health Canada, Foreign Affairs and International Trade and the Canadian International Development Agency testified on April 16, 2007. Representatives from civil society organizations testified on April 18, 2007 including: representatives from Médecins Sans Frontières, the Canadian HIV/AIDS Legal Network, Oxfam Canada, Interagency Coalition on AIDS and Development, the International Human Rights Program at the Faculty of Law (University of Toronto), Health Partners International of Canada and Mr. Stephen Lewis (Former

\textsuperscript{176} The Development theme encompasses issues such as poverty, financing, clean water, nutrition, infrastructure, technological development and technology transfer. See Chapter 3, Methods.)
United Nations Special Envoy for HIV/AIDS in Africa, Stephen Lewis Foundation). The stakeholder groups below represent all of the witnesses who testified. Representatives from both generic and research-based industries testified on April 23, 2009, including: Mr. Jim Keon (President, Canadian Generic Pharmaceutical Association), Mr. Jack Kay (President and Chief Executive Officer, Apotex Inc.; Canadian Generic Pharmaceutical Association), Mr. Gregg Alton (Senior Vice-President and General Counsel, Gilead Sciences Inc.), Mr. Russell Williams (President, Canada's Research-Based Pharmaceutical Companies (Rx&D)), Mr. Terry McCool (Vice-President, Corporate Affairs, Eli Lilly Canada Inc.; Canada's Research-Based Pharmaceutical Companies (Rx&D)).

The frequency statistics presented at the beginning of this chapter represents how often each stakeholder group mentioned a concept or policy issue. The unit of analysis is a complete session of hearings, which in the case of 2007, includes 3 hearings. It is important to note that the consultation paper was specifically framed around a set of questions on whether various aspects of the regime were adequate or needed to be changed which likely influenced the content of the policy debates. That said, witnesses were each given time to present their views prior to being questioned by MPs.

The next section presents the results describing frequency with which stakeholders discussed certain themes and issues. This quantitative presentation provides a picture of the policy goals and themes that drove the debate (Tables 10-15). Subsequently, a list of specific policy design issues along with stakeholders', politicians' and Government's positions on the issues are listed in Tables 16-17. Lastly, a qualitative summary of each stakeholder's comments is presented to illustrate how each stakeholder framed the themes and issues.
**Content Analysis Results (Tables) - 2007**

Table 10: Proportion of Debates Coded by Policy Goal (2007)

<table>
<thead>
<tr>
<th></th>
<th>Total Words</th>
<th>Total %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity</td>
<td>15964</td>
<td>29%</td>
</tr>
<tr>
<td>Security</td>
<td>15213</td>
<td>27%</td>
</tr>
<tr>
<td>Liberty</td>
<td>20777</td>
<td>37%</td>
</tr>
<tr>
<td>Efficiency</td>
<td>19421</td>
<td>35%</td>
</tr>
</tbody>
</table>

1 The denominator = 55530 words (i.e. total number of words in ALL 2007 debates)
2 Percentages aggregate all stakeholder groups and political parties. Percentages represent proportion of text where specified themes were found. Paragraphs often made reference to more than one concept; therefore paragraphs were often coded for multiple themes.

Table 11: Proportion of Debates Coded by Policy Goal by Stakeholder (2007)

<table>
<thead>
<tr>
<th></th>
<th>Research-based (n=3622)</th>
<th>Generic (n=2938)</th>
<th>Civil Society (n=31610)</th>
<th>Government (n=19956)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity</td>
<td>31%</td>
<td>14%</td>
<td>32%</td>
<td>35%</td>
</tr>
<tr>
<td>Security</td>
<td>39%</td>
<td>32%</td>
<td>29%</td>
<td>29%</td>
</tr>
<tr>
<td>Liberty</td>
<td>37%</td>
<td>47%</td>
<td>41%</td>
<td>48%</td>
</tr>
<tr>
<td>Efficiency</td>
<td>13%</td>
<td>20%</td>
<td>24%</td>
<td>12%</td>
</tr>
</tbody>
</table>

1 n = total number of words per testimony of stakeholder group. Unit of analysis = stakeholder-testimony.
2 Percentages represent proportion of text where specified themes were found. Paragraphs often made reference to more than one concept; therefore paragraphs were often coded for multiple themes.

Table 12: Proportion of Debates Coded by Policy Goal by Political Party (2007)

<table>
<thead>
<tr>
<th></th>
<th>Liberals (n=25593)</th>
<th>Conservatives (n=7864)</th>
<th>Bloc Quebecois (n=5467)</th>
<th>NDP (n=8159)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity</td>
<td>31%</td>
<td>14%</td>
<td>32%</td>
<td>35%</td>
</tr>
<tr>
<td>Security</td>
<td>39%</td>
<td>32%</td>
<td>29%</td>
<td>29%</td>
</tr>
<tr>
<td>Liberty</td>
<td>37%</td>
<td>47%</td>
<td>41%</td>
<td>48%</td>
</tr>
<tr>
<td>Efficiency</td>
<td>13%</td>
<td>20%</td>
<td>24%</td>
<td>12%</td>
</tr>
</tbody>
</table>

1 n = total number of words per testimony of stakeholder group. Unit of analysis = stakeholder-testimony.
2 Percentages represent proportion of text where specified themes were found. Paragraphs often made reference to more than one concept; therefore paragraphs were often coded for multiple themes.
Table 13: Proportion of Debates Coded by Theme (2007) ¹, ²

<table>
<thead>
<tr>
<th>Theme</th>
<th>Total</th>
<th>Total %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aid</td>
<td>12818</td>
<td>23.10%</td>
</tr>
<tr>
<td>List of Countries</td>
<td>967</td>
<td>1.70%</td>
</tr>
<tr>
<td>List of Medicines</td>
<td>2781</td>
<td>5.00%</td>
</tr>
<tr>
<td>Equal Opportunity to Supply</td>
<td>154</td>
<td>0.30%</td>
</tr>
<tr>
<td><strong>Security</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Affordability</td>
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<tr>
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<tr>
<td>Human Rights</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Quality and Safety</td>
<td>1965</td>
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<tr>
<td><strong>Liberty</strong></td>
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<td></td>
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<tr>
<td>Intellectual Property</td>
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<tr>
<td>WTO or TRIPS</td>
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<tr>
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</tr>
<tr>
<td>Diversion</td>
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</tr>
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</tr>
<tr>
<td>Market Competition</td>
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<tr>
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<td>2937</td>
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<td>Profit and ROI</td>
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<tr>
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</tr>
<tr>
<td>CAMR Outcomes and Uptake</td>
<td>11642</td>
<td>21.00%</td>
</tr>
</tbody>
</table>

¹ The denominator = 55530 words (i.e. total number of words in ALL 2007 debates)
² Percentages aggregate all stakeholder groups and political parties. Percentages represent proportion of text where specified themes were found. Paragraphs often made reference to more than one concept; therefore paragraphs were often coded for multiple themes.
<table>
<thead>
<tr>
<th></th>
<th>Research Industry (n=8785)</th>
<th>Generic Industry (n=4146)</th>
<th>Civil Society (n=14327)</th>
<th>Government (n=11330)</th>
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</thead>
<tbody>
<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aid</td>
<td>29%</td>
<td>12%</td>
<td>25%</td>
<td>29%</td>
</tr>
<tr>
<td>List of Countries</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>6%</td>
</tr>
<tr>
<td>List of Medicines</td>
<td>3%</td>
<td>2%</td>
<td>8%</td>
<td>3%</td>
</tr>
<tr>
<td>Equal Opportunity to Supply</td>
<td>0%</td>
<td>0%</td>
<td>1%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Security</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug affordability</td>
<td>17%</td>
<td>21%</td>
<td>17%</td>
<td>7%</td>
</tr>
<tr>
<td>Development</td>
<td>19%</td>
<td>2%</td>
<td>11%</td>
<td>12%</td>
</tr>
<tr>
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<td>4%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Human Rights</td>
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<td>0%</td>
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<td>1%</td>
</tr>
<tr>
<td>Innovation</td>
<td>2%</td>
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<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Neglected Diseases</td>
<td>0%</td>
<td>0%</td>
<td>1%</td>
<td>0%</td>
</tr>
<tr>
<td>Quality and Safety</td>
<td>2%</td>
<td>4%</td>
<td>3%</td>
<td>10%</td>
</tr>
<tr>
<td><strong>Liberty</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>5%</td>
<td>0%</td>
</tr>
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<td>Right of Refusal</td>
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<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>WTO or TRIPS</td>
<td>12%</td>
<td>7%</td>
<td>23%</td>
<td>21%</td>
</tr>
<tr>
<td><strong>Efficiency</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diversion</td>
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<td>3%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Litigation</td>
<td>0%</td>
<td>1%</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Market Competition</td>
<td>1%</td>
<td>11%</td>
<td>4%</td>
<td>1%</td>
</tr>
<tr>
<td>Procurement</td>
<td>5%</td>
<td>3%</td>
<td>10%</td>
<td>3%</td>
</tr>
<tr>
<td>Profit and ROI</td>
<td>4%</td>
<td>6%</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Eligible Importers</td>
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<td>0%</td>
</tr>
<tr>
<td>CAMR Outcomes and Uptake</td>
<td>18%</td>
<td>13%</td>
<td>14%</td>
<td>24%</td>
</tr>
</tbody>
</table>

1 n = total number of words per testimony of stakeholder group. Unit of analysis = stakeholder-testimony.  
2 Percentages represent proportion of text where specified themes were found. Paragraphs often made reference to more than one concept; therefore paragraphs were often coded for multiple themes.
Table 15: Proportion of Debates Coded by Theme by Political Party (2007) ¹, ²

<table>
<thead>
<tr>
<th></th>
<th>Liberals (n=5474)</th>
<th>Conservatives (n=4935)</th>
<th>Bloc Quebecois (n=2013)</th>
<th>NDP (n=3168)</th>
<th>Independent MP (n=1352)</th>
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</thead>
<tbody>
<tr>
<td>Equity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aid</td>
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<td>22%</td>
<td>2%</td>
<td>9%</td>
</tr>
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<td>2%</td>
<td>0%</td>
<td>3%</td>
<td>0%</td>
</tr>
<tr>
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<td>7%</td>
<td>19%</td>
<td>4%</td>
<td>0%</td>
</tr>
<tr>
<td>Equal Opportunity to Supply</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Security</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug affordability</td>
<td>11%</td>
<td>2%</td>
<td>10%</td>
<td>6%</td>
<td>0%</td>
</tr>
<tr>
<td>Development</td>
<td>6%</td>
<td>9%</td>
<td>24%</td>
<td>7%</td>
<td>24%</td>
</tr>
<tr>
<td>Domestic Economy</td>
<td>0%</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Human Rights</td>
<td>0%</td>
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<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Innovation</td>
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<td>2%</td>
<td>0%</td>
<td>0%</td>
<td>4%</td>
</tr>
<tr>
<td>Quality and Safety</td>
<td>0%</td>
<td>2%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Liberty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>17%</td>
<td>29%</td>
<td>20%</td>
<td>11%</td>
<td>7%</td>
</tr>
<tr>
<td>Developing Country Pressure</td>
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<td>0%</td>
<td>4%</td>
<td>0%</td>
</tr>
<tr>
<td>Right of Refusal</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>WTO or TRIPS</td>
<td>11%</td>
<td>2%</td>
<td>6%</td>
<td>4%</td>
<td>20%</td>
</tr>
<tr>
<td>Efficiency</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diversion</td>
<td>1%</td>
<td>0%</td>
<td>10%</td>
<td>0%</td>
<td>14%</td>
</tr>
<tr>
<td>Litigation</td>
<td>1%</td>
<td>3%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Market Competition</td>
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<td>5%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Procurement</td>
<td>8%</td>
<td>0%</td>
<td>5%</td>
<td>0%</td>
<td>3%</td>
</tr>
<tr>
<td>Profit and ROI</td>
<td>5%</td>
<td>6%</td>
<td>2%</td>
<td>4%</td>
<td>0%</td>
</tr>
<tr>
<td>Eligible Importers</td>
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<td>1%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>CAMR Outcomes and Uptake</td>
<td>21%</td>
<td>16%</td>
<td>33%</td>
<td>49%</td>
<td>41%</td>
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</tbody>
</table>

¹ n = total number of words per testimony of stakeholder group. Unit of analysis = stakeholder-testimony.
² Percentages represent proportion of text where specified themes were found. Paragraphs often made reference to more than one concept; therefore paragraphs were often coded for multiple themes.
<table>
<thead>
<tr>
<th>Design Decisions</th>
<th>Research-Based Industry</th>
<th>Generic Industry</th>
<th>Civil Society</th>
<th>Government Bureaucrats</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profit Limits/Litigation</td>
<td>Maintain litigation rights relating to commercial use.</td>
<td>Remove litigation rights relating to commercial use.</td>
<td>Remove litigation rights relating to commercial use.</td>
<td>Profit limits appear to discourage generic industry participation.</td>
</tr>
<tr>
<td>Who can procure the medicines</td>
<td>Maintain restrictions on eligibility to state actors.</td>
<td>NGOs should be allowed to procure medicines.</td>
<td>NGOs should be allowed to procure medicines.</td>
<td>No comment.</td>
</tr>
<tr>
<td>Country notification</td>
<td>Maintain country notification requirements.</td>
<td>Eliminate country notification requirement.</td>
<td>Eliminate country notification requirement.</td>
<td>Maintain country notification requirements.</td>
</tr>
<tr>
<td>Procurement within regional trade groups</td>
<td>No comment</td>
<td>Permit export to groups of countries to permit economies of scale.</td>
<td>Permit export to groups of countries to permit economies of scale.</td>
<td>No comment.</td>
</tr>
<tr>
<td>Voluntary license negotiations</td>
<td>Maintain requirement to seek voluntary license first.</td>
<td>Remove or shorten period for voluntary license negotiations.</td>
<td>Remove or shorten period for voluntary license negotiations.</td>
<td>Voluntary license negotiations appear to cause delays.</td>
</tr>
<tr>
<td>Quantity exported under license</td>
<td>Maintain quantity forecasting requirement but allow for some flexibility.</td>
<td>Remove quantity forecasting requirement.</td>
<td>Remove quantity forecasting requirement.</td>
<td>No comment.</td>
</tr>
<tr>
<td>WTO Paragraph 6 Decision</td>
<td>The Decision should not be amended.</td>
<td>The problem is with the WTO Decision itself.</td>
<td>Canada must act at WTO to remedy the constraints of the Decision.</td>
<td>No comment.</td>
</tr>
</tbody>
</table>
Table 17: Politician Positions on Policy Design (2007)

<table>
<thead>
<tr>
<th>Design Decisions</th>
<th>Liberal MPs</th>
<th>Conservatives</th>
<th>Bloc Quebecois</th>
<th>NDP</th>
<th>Independent</th>
</tr>
</thead>
<tbody>
<tr>
<td>The list of medicines</td>
<td>No comment</td>
<td>No comment</td>
<td>Eliminate list of eligible products.</td>
<td>Eliminate list of eligible products.</td>
<td>No comment</td>
</tr>
<tr>
<td>Termination of compulsory license</td>
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<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
</tr>
<tr>
<td>Profit Limits/Litigation</td>
<td>Profit limits appear to discourage generic industry participation.</td>
<td>Profit limits appear to discourage generic industry participation.</td>
<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
</tr>
<tr>
<td>Health Canada's Drug Review</td>
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<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
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<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
</tr>
<tr>
<td>Diversion</td>
<td>No comment</td>
<td>No comment</td>
<td>Maintain anti-diversionary measures.</td>
<td>No comment</td>
<td>No comment</td>
</tr>
<tr>
<td>Who can procure the medicines</td>
<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
</tr>
<tr>
<td>Country notification</td>
<td>Country notification appears to be a major barrier.</td>
<td>Country notification appears to be a major barrier.</td>
<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
</tr>
<tr>
<td>Procurement within regional trade groups</td>
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<td>No comment</td>
<td>No comment</td>
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<td>No comment</td>
</tr>
<tr>
<td>Voluntary license negotiations</td>
<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
<td>Voluntary license negotiations appear to cause delays.</td>
<td>No comment</td>
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<tr>
<td>Duration of license</td>
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<td>No comment</td>
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<td>No comment</td>
</tr>
<tr>
<td>WTO Paragraph 6 Decision</td>
<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
</tr>
</tbody>
</table>
Qualitative Summary – 2007

The qualitative summary is presented for each stakeholder group and contains a summary of the themes resulting from the content analysis of the Standing Committee Hearings on Industry Science and Technology on Canada's Access to Medicines Regime, from April 16, 2007 to April 23, 2007.177

Research-Based Industry

Security

Russell Williams, the President of Canada's Rx&D, and Gregg Alton, representing Gilead, presented at the testimony. They declared their commitment to addressing the global needs of patients with HIV, which they defined as drug innovation (innovation, 2%) and drug affordability (drug affordability, 17%). The industry clearly favored voluntary price reductions as a primary mechanism for achieving equitable drug access through non-profit pricing to low-income countries and tiered pricing to middle-income countries.

"We're committed to meeting the needs of patients living with HIV throughout the world. We do this through scientific research and development programs, where we invent new medicines that give patients important new treatment options. In addition, we have developed a comprehensive access program that addresses the impact of poverty on the ability of those living in the world to afford our medicine. In nearly 100 least-developed countries—this includes all of Africa—our access program makes our HIV products available at our cost. There is not one penny of profit in our program. We have also worked closely with middle-income countries, countries that have financial capabilities well above sub-Saharan Africa, and have pricing tiers offering substantial discounts to countries like Thailand, Mexico, and Brazil. We've worked very closely with these countries. We have a very close relationship. And they are very comfortable with our pricing strategies."

The brand industry maintained that despite these price reductions, they expect developed countries to pay full price. They acknowledged a role for Indian generic companies to provide affordable medicines, which involved voluntary license agreements with the brand name industry. In this context, they framed CAMR as a well-designed policy that may have a role if Indian generics are no longer affordable or if the brand name industry could not address the need itself.

"CAMR is an important, comprehensive, and well-designed regime that balances the rights of patients in the developing world with the rights of the R and D industry. While CAMR has not been used to date, it could be an important vehicle for access if patents prevent least-developed countries from accessing affordable medicine. This will be particularly important if, as India begins to enforce patents, generic or low-cost branded products are not available in these countries."

Furthermore, they suggested that developing countries did not yet use CAMR because their pricing programs and Indian generics are already meeting existing needs.

"When you talk about CAMR and the fact that it hasn't been used to date, I think part of the reason is not that it's a failure, but that a lot of the programs in place are actually doing the types of things that Gilead is doing."

Development (development, 19%) was a major focus in the industry's testimony, as they argued that drug affordability was not the primary concern. Instead, they called for a comprehensive solution that addressed a range of issues including health care infrastructure, human resources for health, nutrition, and corruption. They also emphasized the impact of HIV on development.

"The problem is weak health care infrastructure. The problem is too few health care professionals and a lack of political will to make HIV care a priority in these countries. According to the latest World Health Report, for every 50,000 people
in Canada, there were 500 nurses; in Uganda there were 31 nurses and in Ethiopia there were 11 nurses for every 50,000 people. How are we going to provide access to people if they don't have people to take care of them? Until these barriers are addressed, actions by Canada, NGOs, the generic industry, and companies like Gilead are going to meet limited success in their programs."

**Equity**

In this sense, they emphasized their aid programs (aid, 29%), much of which addressed these development issues but encompassed their reduced pricing strategies. Technology transfer was one way they addressed both development and affordability needs.

"All of our agreements include a full technology transfer to enable our partners to quickly ramp up production of active pharmaceutical ingredients and tablets. Our partners are free to establish pricing for their products—we impose no restrictions on the pricing—and they pay us a 5% royalty on the price that they set. They said more money from donors were needed to purchase affordable drugs despite the reduced prices because countries even at low prices, don't have the money."

**Liberty**

With respect to intellectual property (intellectual property, 34%), they clearly articulated that compulsory licensing should be avoided. They equated compulsory licensing with "breaking patents" and claimed that CAMR should not be about "overriding patents".

"The goal should not be to break patents. The goal should not be to use CAMR. The goal should not be to use the flexibilities in TRIPS. The goal should be for the research and development industry to have responsible pricing mechanisms that allow access to their products by the developing world."

They also argued that most governments do not want to issue compulsory licenses and accused NGOs of waging a campaign to break patents.
"One thing we need to understand is that a lot of times these governments actually do not want a compulsory licence. They would rather work things out. The NGO community has had a very vocal public campaign to break intellectual property rights throughout the world. They want to do that. They claim victory when a government threatens a compulsory licence, and they claim failure when it doesn't do so. This may be a situation where the NGO is actually trying to encourage a compulsory licence, trying to encourage the use of CAMR, when the government itself is not in a position where it wants to do that."

The industry wanted WTO notification of countries' intent to use the Paragraph 6 mechanisms (WTO or TRIPS, 12%) so that the industry could communicate with the country and to try to meet its needs without the use of compulsory licensing.

"If there were ever a case where there was a need for a legislation-like hammer or the flexibility in TRIPS, I would feel, from Gilead's point of view that we had failed as a company in meeting the needs of these countries throughout the world. We really do think that the requirement to identify the country and have our request come forward is important. Because we'd like to understand if we're not meeting those needs, and we'd like the ability to talk to that government and try to work out an arrangement whereby we can provide our drug to them through our systems, the systems we've put in place."

The industry disputed the idea that intellectual property impeded drug access, arguing that the trade-off between the two was illusory. Instead, they favored voluntary licensing agreements, stating that it reduced production costs through manufacturing efficiencies thereby improving affordability. They favored "responsible pricing mechanisms" or voluntary price reductions to address such issues, framing them as the "responsible use of intellectual property".

"I'm saying that prices and patents are not what is causing these patients to die."
"Safeguarding intellectual property also plays a role in access of pharmaceutical products. People tend to argue that access and intellectual property are mutually exclusive, but I disagree. I would argue that intellectual property creates access because it leads to new medicines. The fact is that intellectual property fosters research and innovation, and that leads to life-saving drugs and vaccines. It is therefore important that we do not put research at risk in this country. Intellectual property regimes exist in developed countries because they create a climate for innovation to treat disease. They do not exist in many parts of the developing world. As such, Canada has a responsibility to create a regime that protects intellectual property and leads to greater access of prescription drugs among poor nations."

**Efficiency**

With respect to the efficiency of CAMR (CAMR outcomes and uptake, 18%), the industry argued that developing country governments were unaware of the legislation and that an accurate evaluation was impossible since it was not 'fully tested yet'. They cautioned the committee against making legislative changes.

"Before altering the legislation, it is our view that the government should give it an opportunity to be tested. Rather than rewriting Canada's Access to Medicines Regime, I would recommend, as a first step, that the government undertake a full-scale education program to inform stakeholders—especially those in developing countries—of the legislation and its mechanisms."

The brand name industry also cited concrete reasons for its apparent lack of efficacy, suggesting that a lack of awareness on the part of developing country decision-makers was partly to blame. They reasoned that the lack of affordability of Canadian generic drugs was also a contributing factor. Lastly, the industry cited the unwillingness of a country to identify itself to the WTO as a barrier and linked it to HIV denialism in some developing countries.
"We're talking about why CAMR is not working. Mr. Kay has come up with an example, where a country that appears to have a substantial need for a product is not even willing to identify itself to avail itself of a low-cost generic. I think it highlights a broader problem, which is the true desire of these countries to deal with HIV. If they're not even willing to be named to deal with their patients and the 300,000 children who are dying, it's a real problem."

They asserted that the legislative process was simple and suggested again that CAMR's underutilization indicated that drug needs of the developing world were currently met.

"I just want to say, you had 146 countries sign the declaration at the WTO. They all agreed to that process. It's very simple. All they have to do is say they need a supply, and then they can come to the Canadian generics to get it if they want. Right now, their needs are being satisfied by either the Indian generics or the brand-name industry through their philanthropy or selling drugs at no cost.

I'd also just point out that to my knowledge there's not one HIV product that is in need in the developing world that cannot be manufactured in India."

**Generic Industry**

*Security*

Jim Keon, the President of the CGPA, and Jack Kay, the COO of Apotex, testified at the hearings. On the issue of drug affordability (drug affordability, 21%), the generic industry blamed the brand name industry's high prices for contributing to the inequity in drug access. They questioned the extent of the brand industry's voluntary price reductions, citing the existence of the Paragraph 6 Decision.

"All I'm saying is if that in fact is correct, that the brand industry is offering these products to the developing countries, there would be no need for our organizations such as the World Health Organization or MSF to come to the generic industry and ask us to provide these products."
"…the brand-name companies own these medicines, they have the patents, now they can go to any country they want and offer the product at any price. Why did the developing countries want the system under the WTO? Why do they support the Canadian legislation? Why would they like to see improvements? It's because they're not getting the product as often as they want at the price they want. They want more competition, they want someone else to bid on their tenders. That brings prices down; that's what they need, and that's what this legislation is intended to do."

As expected, they maintained that generic competition (market competition, 11%) was the only way to achieve significant price reductions and argued that this competition was the intended purpose of CAMR in the first place.

"This legislation is intended to generate competition, because it has been shown time and again that new prices come down when an Indian generic company or someone else has the product and is ready to offer it to a government. That's what makes the price come down."

The generic industry agreed that Indian generics are a key affordable source of generic drugs but insisted that the antiretroviral produced by Apotex was competitively priced.

The generic industry's few words on their contribution to the domestic economy (domestic economy, 4%) were nonetheless poignant, illustrating Apotex's role as larger than that of the entire brand name industry combined.

"Earlier someone mentioned the manufacturing capacity in Canada. Apotex itself--and if Jack wants to speak to this, he can--has more capacity to manufacture medicines in Canada than all of the brand-name industry combined in Canada. We have about eight or nine companies that have major manufacturing facilities on the generic side. That is why Canada wanted to have this legislation, because we do have a robust generic drug industry."
Equity
Again, they described their role in providing aid and drug donations to the developing world they but saw such discussion as a distraction from the main policy issue (aid, 12%).

"….this legislation has nothing to do with generic companies providing medicines abroad that are not covered by patent. This legislation has nothing to do with brand-name companies providing their products, whether it's philanthropically or for sale, abroad. They can do that now. This legislation is intended to allow generic companies to access patented medicines. I think we should stay focused on that. It's all very good that we have donation programs and the brands have donation programs. It has nothing to do with this legislation."

Apotex's involvement in the drug order was described as philanthropy and they referred the innovation of their triple-fixed dose combination product.

Liberty
With respect to intellectual property (intellectual property, 43%), the generic industry acknowledged that India's compliance with the TRIPS agreement threatens the developing world's major supplier of affordable generic drugs suggesting that CAMR may become relevant then.

"India has been called the pharmacy for the poor world because it didn't have patents. Starting in 2005, it now does have patents. If in the future we find, as Jack said, that India and Indian companies are not able to produce these products at low prices and make them available, the Canadian legislation will become very important. It's quite possible that Canadian companies will be interested in making these products and some of the NGOs will be interested in buying them. We haven't needed to do that, but in the future we might."
The generic industry alleged that the brand name industry impeded CAMR and that they ultimately did not want generic companies making copies of their patented products and shipping them abroad. They accused patent-holders of abusing their property rights and argued that compulsory licensing is key to reducing drug prices, even through voluntary price reductions.

"Recently in Thailand, with a drug called Aluvia, an anti-AIDS medicine, the Thai government said it was going to issue a compulsory licence to import the product from India. Abbott, the owner of that patented product, threatened to pull seven other products off the market and put tremendous pressure on that country. Eventually, because of pressure from a lot of the NGOs and political pressure, Abbott backed off and is now making the product available at lower prices. However, without an effective functioning compulsory licensing system and without the threat of generic competition and lower prices, that would never happen."

**Efficiency**

The generic industry viewed CAMR as a poorly designed piece of legislation which contributes nothing to the existing global drug inequity (CAMR outcomes and uptake, 13%).

"This legislation perpetuates the human crisis, without getting anything done."

CAMR was overly complex and ineffective. The problems included the limitation of the license for one country only, the duration of two years, the requirement of the recipient country to be identified up front and the requirement for voluntary license negotiations. In the case of Apotex, they had to negotiate with four different patent-holders for the fixed-dose combination anti-retroviral product and one company refused to issue them a voluntary license. At that stage, Apotex involved their lawyers to apply for a compulsory license for that particular patent.
"As Jack said, there is a real political problem with countries self-identifying. We would like to see that requirement removed, or limited in some way. We would like to make the licence essentially an automatic licence, to remove and limit to the extent possible the need to negotiate with the brands. As well, we would like to remove the requirement that there only be one country at a time, for a maximum amount of product. We need to have the right, if we're going to invest $2 million, to make this product for a long period of time, to ship it wherever it's needed to whoever needs it."

Ultimately, the generic industry wanted an automatic compulsory license issued immediately upon quality and safety approval.

"The entire burden is left on the shoulders of the poor countries, who do not have the expertise or the resources. The legislation is designed for pharmaceutical companies doing business in the industrialized world, not Africa. In conclusion, our recommendation, having experienced the process, is that we need to move to a defined compulsory licence upon regulatory approval. This will speed up the process and limit legal costs, which can be substantial."

The challenge that Apotex described was one of business competitiveness (profits and ROI, 6%).

"It really comes down to the fact that Apotex is in the business of making money for its shareholders. We have decided to do this because the government passed the legislation. We tried to work through the legislation because MSF came to us with a bona fide order for the product. I am not going to tie up my resources, our legal departments, in order to go through the process of trying to get a compulsory licence, because it's just far too complicated. The Government of Canada should facilitate this, because it's the right thing for us to do as Canadians."
The generic industry was clearly frustrated by the brand name industry’s suggestions that the procedure under CAMR was simple.

"I have no comment. It's just too frustrating. They're saying that they're making it easy, go, you have to answer these four questions. But if in fact an organization with the reputation of MSF comes to us and says “We have this country that wants to buy the product, and the price you're prepared to buy at is competitive with the Indian companies, but the difficulty is that the country does not want to identify that it needs a handout from Canada”, it's just frustrating."

Civil Society

Security

Civil society disputed claims that CAMR does not work because drug needs are already being met. They cited the remaining disparity in drug access for patients with HIV/AIDS – three quarters of those with HIV in the developing world still lack access to ARVs – and argued that fixing CAMR was necessary to ensure the continued supply of affordable drugs to the poor (drug affordability, 17%). They argued that drug costs remained a significant barrier to drug access, especially to access to second-line anti-retroviral drugs, which could be 12-50% more expensive than first-line therapy. Brand name drugs remained expensive aside from the occasional program that offered discounted medicines and even then, brand industry could not beat generic prices. India's compliance with the TRIPS Agreement threatened the future of reliable and sustainable supply of affordable and quality medicines for the developing world.

"But first of all, why has the Canadian regime not worked? We know it's not because there is no need for medicines. We heard earlier from Mr. Lewis, and we've seen the UN report that came out earlier this week that said that almost three-quarters of people living with HIV in the developing world are still, despite the progress that has been made in the last couple of years, not getting access to the antiretrovirals they need. There's no question, as we've also heard, that there is still a woeful lack of financing overall for scaling up the response to the global AIDS pandemic."
"There is no question that India is now the source of most of the drugs that are providing antiretroviral treatment around the world, and overwhelmingly the source for drugs in Africa…. [t]hey form the basis for most of the treatment, but it's not endless. They have production limitations, and there is some uncertainty as to the nature of the amendments to the Patent Act in India whether those drugs can continue to be produced in such large quantums." 178

"I think it's worth noting that the brand name pharmaceutical industry cannot begin to compete with the prices that have been negotiated for generic drugs. The brand names, even at best, are between $500 and $800 per person per year. The Clinton Foundation negotiated a price initially of $139 per person per year, and that price is coming down."

One NGO suggested that the affordability of drugs could not be met by Canadian drugs simply because they could not match global market prices.

"What CAMR is doing is affecting the price people are paying for drugs produced in Canada. And because it isn't working, Canadian suppliers are only supplying high-cost drugs to those systems, and as a consequence, they aren't the producers of choice, because there are other countries--Brazil and India, in particular, but others--that are actually meeting the need."

Civil society acknowledged the development related problems (development, 11%) in many of these countries, pointing out the devastation caused by the HIV/AIDS pandemic. Some NGOs highlighted the meager purchasing power of many African governments calling upon an increase in global health financing. They disputed the idea that a trade-off exists between addressing infrastructure and human resource barriers with ensuring a functional compulsory license regime. Moreover, they argued that, as Jeffrey Sachs

178 As mentioned earlier, India began to comply with TRIPS standards in 2005.
notes, that the burden of disease must be addressed first before the developing world's other problems could be addressed.

"There are those who say there are other needs internationally. I say that's absolutely right, but this legislation is designed to address one of the imperative needs, incorporating several of the millennium development goals, and it should not be seen as subordinate to other priorities. For those who say that a large part of the problem is really health systems and health resources, I concede there's some truth in that, but if this legislation ensures the basis for long-term treatment, then Canada, and others, and the African countries themselves will have the confidence to restore the fractured infrastructures."

In contrast, HPIC urged the Canadian government to support the local production of drugs in African countries, arguing that CAMR is a stop gap measure.

"…it's very important to know your costs of inputs, costs of shipping, and costs of distribution. That's why I say this is really a transitional strategy. The African countries need to be encouraged to produce it on their own."

The topic of human rights came up once (human rights, 1%), as MSF argued that rights were not respected under the current regime and that CAMR ultimately favored commercial interests over ensuring affordable, equitable drug access.

"We've tied our regime into so many knots of red tape that our capacity to break through this has in fact been completely stymied. Yet again, the will of Parliament and the will of Canadians has been thwarted by legislation that is far too timid and far too deferential to issues that have nothing to do with humanity, nothing to do with human rights, and nothing to do with getting people access to health care, and everything to do with protecting privilege and protecting profit."
Liberty

Much of civil society's discourse on intellectual property (intellectual property, 23%) reflected their belief that higher standards of intellectual property led to higher drug prices. They argued that the patent-holders' liberties continue to increase, as demonstrated by the United States' bilateral and regional trade agreements that require more intellectual property protection than that required by the TRIPS Agreement (WTO or TRIPS, 23%). These "TRIPS-plus" standards impose "monopoly pricing", which then makes medicines even less affordable. Some NGOs reported that patent-holders misuse their intellectual property rights through intimidation and pressure tactics against developing countries that attempt to make use of their TRIPS flexibilities. They viewed CAMR's country notification requirement as a major barrier in its success, for this precise reason and demanded that the requirement for country identification be dropped.

"Nor have the African countries as yet sought a compulsory licence, largely because I think no African country wants to be the first to go forward if their names are not protected. There is a tendency to retaliation, both threats from, often, the United States and explicit threats from pharmaceutical companies."

"Look at what's happening right now in Thailand. The Thailand government issued a compulsory licence for the production of a generic equivalent of a drug called Kaletra, which is produced by Abbott Laboratories. Abbott engaged in quite an astonishing act of retaliation by saying that it would withdraw all its current drugs or any further drug development from the Thai market. Abbott has received a great deal of criticism because of that, but you can imagine the sense of vulnerability amongst African countries unless there is a regime in place that secures initially their confidence and then the flow of drugs."

For civil society, generic competition (market competition, 4%) was the most effective way to ensure a reliable, sustainable source of affordable and quality medicines for the future. Generic competition meant getting more 'bang' for each donor 'buck' and CAMR
was an important step towards generating that global competition needed to decrease prices. As civil society representatives said:

"The main impact of this legislative change is creating opportunities, for the $8 billion that's out there to buy the drugs, to start their coming from Canada—making the competition happen."

"If we can take a drug that had been $10,000 per person per year and through generic production produce it for $139 per person per year, that should end the discussion. All of our efforts should be around how we ensure that this drug gets to people who are dying without it."

As in 2004, civil society viewed compulsory licensing as a critical mechanism to generate this much-needed generic competition but they found many flaws with CAMR's compulsory licensing mechanism. These flaws included the requirement that each new contract require a new license, which made a license only valid for the production and export of one drug to one country for a pre-determined quantity. Furthermore, licenses were valid for two years with an opportunity for an additional two-year renewal in case of delays in production or export, which they found problematic.

"For every single drug order that a developing country might wish to place for a generic version of a patented drug, it must, as you've heard from Ms. Perkins, negotiate a contract with a generic producer here in Canada. The contract can only be tentative, because there is no licence issued at that point, and the producer must then go through an entire process of first seeking a voluntary licence and trying to negotiate a royalty. At the end of all that, the producer might then actually get a licence that will allow it to supply that particular product, in that quantity, to that particular country. That process must be gone through every single time."
Efficiency

Civil society called for a simple, streamlined mechanism that issued a compulsory license immediately upon Health Canada regulatory approval. They argued that this mechanism would be in line with procurement practices of developing countries (procurement, 10%). Furthermore, it was more efficient by facilitating economies of scale, making the drug even cheaper.

"Our central recommendation…is to simplify this process by letting the generic manufacturer here in Canada get one compulsory licence at the beginning of the process, before there are any particular contracts negotiated with any particular country or countries. With that legal authorization in hand, the generic manufacturer can then bid through transparent international tendering processes that many developing countries will have. They can negotiate with multiple developing countries on the list of eligible countries and achieve a certain degree of economy of scale, because they can actually negotiate larger-sized contracts, which means they can negotiate with suppliers of active pharmaceutical ingredients to get the prices of producing the pill down even further, and they will not be required to go through the process every single time, for every single drug order from each particular country."

Civil society found CAMR inefficient on many other counts (CAMR outcomes and uptake, 14%). The list of medicines (list of medicines, 8%) was unnecessary and dissuaded developing countries and generic companies from engaging in the legislation. The inability of NGOs to contract directly with generic manufacturers prevented a major sector of medicine procurers from using the legislation (eligible importers, 1%). Anti-diversion (diversion, 2%) and commercial limitation clauses (profits and ROI, 3%) encouraged litigation (litigation, 4%) against generic companies. Health Canada approval was unnecessary (quality and safety, 3%) and added an additional delay to the export of much-needed medications and the extra requirements for non-WTO member countries were unfair.
"We should eliminate the additional unnecessary and unjustified double standard that has been imposed for developing countries that do not belong to the WTO in order to import Canadian-made generics. We also need to eliminate the provisions in the Canadian access to medicines regime that create additional opportunities for brand-name companies to go to court and engage in vexatious litigation that will tie things up further."

In contrast to previous statements in the media, NGOs explicitly blamed the WTO Decision itself for many of CAMR's ills. To remedy this, the Canadian HIV/AIDS Legal Network argued that all of their recommendations could be implemented under Article 30 of the TRIPS Agreement.

"The problem is that the WTO decision itself is unnecessarily complicated, time-consuming, and risky. It sets out a process for obtaining a compulsory licence that is unrealistic, is user-unfriendly, and does not speak to the needs and the realities of developing countries and the practical considerations that face generic pharmaceutical manufacturers, which are primarily commercially motivated actors, as we all know, just as the brand name companies are."

"Something needs to change, and if Canada were to set that precedent and actually say, “We're going to use other flexibilities in the WTO rules to legislate a simple, straightforward process with one licence at the beginning and that's it”, that would embolden a number of other countries to re-examine their own regimes and perhaps think about doing something similar. I think that would be a tremendous contribution for Canada to make."

**Equity**

Civil society responded to the government's questions on aid (aid, 25%). Stephen Lewis described at length the initiatives going on globally to address the HIV/AIDS pandemic. Programs such as the Global Fund, the WHO 3 by 5 initiative, the Clinton Foundation's efforts and PEPFAR made important contributions to addressing the pandemic but much
more had to be done. Lewis called for governments to meet their funding commitments expressed at the last G8 meeting and derided the unpredictability and lack of sustainable financing. By addressing a future gap in the supply of affordable medicines, CAMR could be the systemic change that global pharmaceutical markets needed.

"But frankly, it would be a much greater contribution to have a systematic flow of drugs to these countries over the years that are required, because the promise of cutting a cheque varies from administration to administration, and the amounts vary. As I said, our ODA contribution declined between 2005 and 2006 as a percentage of GNP. And it may decline further. So the drug regimen is really, I think, the basis on which to proceed."

NGOs rejected the government's suggestions to provide funds through CIDA to purchase drugs produced under the regime. They clearly favored a compulsory licensing regime over drug donations to address the gap in drug access.

"I would caution, however, that we not run afoul by falling into tied aid; that we don't somehow think that by putting up a bunch of Canadian taxpayers' dollars through CIDA we can somehow buy our way out of the fundamental problems with the Canadian regime and the compulsory licensing process. I think that would be, if one is to be cynical for a moment, almost a way of trying to paper over the more fundamental problem with the compulsory licensing process. You might, as a result of it, grease the wheels enough by subsidizing Canadian companies to maybe get one or two things out of the pipeline. I think the fundamental challenge is to actually make the process work in a more sustainable way, so that compulsory licensing is actually easily done, not just when CIDA might put up enough money tied to purchasing from Canadian suppliers, if in fact there might be a better deal from some other supplier."
Conservative MPs

Efficiency

Overall, Conservative MPs made few statements that indicated their position with respect to CAMR or with respect to the policy goals that they valued. Most discourse focused on CAMR's implementation problems in one way or another (CAMR outcomes and uptake, 16%).

In terms of why CAMR was not working, they probed witnesses from all sectors on what their responsibilities were under the legislation. They asked bureaucrats and industry representatives whether they actively raised awareness about the legislation with developing country governments and why no developing countries indicated interest in using the legislation. They queried the generic companies on how much CAMR's framework was to blame for the lack of outcomes. One MP suggested that some amendments might be called for.

"This question is for the Canadian Generic Pharmaceutical Association. If all the red tape disappeared from the Canadian legislation, would you be able to provide medications from Canada to the less developed countries, and if you could, how?"

"….Do you hear that, Mr. Williams? So this can be done. There may be some changing of the act. Maybe we can just make it a little bit more simple, but it's not inconceivable that licences would be granted."

There was significant concern over Canadian generic companies' ability to compete globally (market competition, 5%), especially against Indian generic manufacturers and the implications this had over the feasibility of the regime.

"So how are we going to be able to manufacture those pills if we're not able to be competitive?"
"I think five companies were producing the product you were talking about. When I look at them—and I can show you this if you want that—Apotex has the highest pricing of the five. In terms of the generic medicines, is that still...even though there's a variation? I think you said you were still price-competitive."

With respect to profits (profits and ROI, 6%), MPs were skeptical that CAMR would work given the profit limitations under the regime and the profit-driven nature of business. One MP expressed compassion towards patent-holding companies, claiming they were unfairly chastised for their achievements in innovation. He suggested that the government should pay the market price for drugs to meet the inequity gap.

"This is interesting. I feel kind of bad for you. I'll tell you why I feel bad. You're being browbeaten because you happen to be companies that make a lot of money doing something right. And if you hadn't done those things right, we'd still be in the quandary we were in 15 to 20 years ago, when AIDS first.... "

"I can understand profit, I really can. It's what drives us. I was just saying to my colleague, it's not fair to suggest that your company has to provide all the answers. If we want to do that as a country, we need to shell out the bucks, to say it very bluntly."

*Liberty*

On the topic of intellectual property (intellectual property, 29%), most questions focused on implementation problems at the voluntary license negotiation and compulsory license application stages of CAMR. Conservative MPs tried to understand what the delays and obstacles were with voluntary license negotiations, the compulsory license applications, and the developing country notification stage. They also showed interest in Gilead's suggestion that the forecasting requirement of CAMR be removed.
"...the NGOs and the generics are opposed to the requirement to first seek voluntary licence...why is this requirement needed? Is it conceivable that a voluntary licence would be granted?"

"I think the generics are arguing that this notification can be met in a much easier and simpler form than what has happened under CAMR now. If there were some form of notification, but if it were simplified, would you be in favour of that, or do you believe the notification in CAMR is the minimum standard?"

They recognized that one of the major obstacles in CAMR was the requirement for country notification and probed whether country notification could be removed or simplified (WTO or TRIPS, 2%). Despite this obstacle, they demonstrated a commitment to exporting affordable drugs to these countries.

"It seems to me that we've hit an impasse where if no country actually wants to be identified, this legislation will never work. What I'm looking for as the chair, and I think what all members are looking for, is a process that will work here."

Only one statement explicitly supported the protection of intellectual property but recognized that implementing patent flexibilities was the goal of this legislation.

"I don't think there is anyone around this table who would not want to make sure we protect intellectual property."

**Security**

Some MPs raised the question of what aspect of developing countries needs Canada should be focusing on. They briefly mentioned issues related to development (development, 9%) and some MPs questioned whether CAMR was the best way to address countries needs.
"I was wondering, let's say you're the health minister of Uganda right now, and you're given a budget of say $10 million for your entire country, and you're sitting around thinking how you are going to spend that. Are you going to be thinking of CAMR at all, or are you going to be thinking of things like clean wells, infrastructure, educating more doctors, educating more nurses, providing infrastructure there?"

"I think you made a good point, that a lot of this does sound somewhat paternalistic--or it does to me. Should we be dictating? Should you be even buying these drugs? Should you be spending it on wells or irrigation systems or feeding your population? I'm not sure."

One MP cited concern over Canada's domestic generic industry (domestic economy, 1%) that companies would move to offshore manufacturing just to remain competitive under the regime.

"With the way it appears to be going, I was just curious about whether this is going to force companies like the generic Canadians to set up shop in India in order to compete with other countries or with other companies that are already there. Are we saying we're going to be moving all our manufacturing offshore now?"

*Equity*

One Conservative MP suggested that achieving the goal of equitable access to affordable drugs could bypass the tension around patents by simply putting out a request for proposals through CIDA or other donors and give both brand name companies and generic companies a chance to bid on the tender (aid, 11%). Such a mechanism would acknowledge the fact that the patent-holders are the inventors and producers of the medicines in the first place.
"It seems to me much simpler to actually say, here's what the Government of Canada is coming to the table with through CIDA, here's perhaps the Gates Foundation, and here's an opportunity for either the brand name or the generic to come forward and supply the medicine. The goal is to get the medicine from here to a person, as Mr. Fox said, so that person's life improves. It's not to get involved in a patent debate in Canada."

Conservative MPs asked what aid programs existed globally and which programs did the best work. They considered Mr. Martin's proposal to have CIDA fund the purchase of drugs under CAMR. MPs also mentioned the conservative government's recent announcement of tax incentives and questioned whether such initiatives would make more impact than CAMR.

"There was a measure where corporations donating medicines can claim a tax deduction equal to the cost of the donated medicine, or half the amount by which the fair market value of the donated medicine exceeds its cost—whichever is less…Do you think this would be a step in the right direction?"

They raised civil society's complaint regarding the medicine list (list of medicines, 7%) and asked witnesses why it was present and whether it should be removed.

"You're correct in the sense that we do not have to have the schedules in the legislation. In fact, I think other countries do not have schedules in their legislation. But when I asked this of the Industry Canada representative, he said that if we don't have schedules in the legislation, it will in fact make the process longer because litigation over the patents will result. So it was Industry Canada's view that if you had the schedules and you had the identified pharmaceuticals, you'd actually make the process simpler. I want to get your response to that statement."
Conservative Government (Bureaucrats only)

Security

The government expressed its support of increasing access to affordable drugs (drug affordability, 7%) but framed CAMR as only one of many other options that is available through aid to developing countries. Purchasing expensive drugs from Canada may not the wisest decision for developing countries seeking to alleviate drug access inequity.

"If you provide funding to these countries, you should enable them to determine where best to source their drugs. If the generic versions of these patented drugs are much cheaper in India, why on earth would you insist on their spending the money that you give them in Canada?"

Bureaucrats acknowledge other pressing needs of developing countries, which also interfered with medicines access. They emphasized health system infrastructure, lack of human resource and inadequate institutional capacity (development, 12%) and stated that CIDA helped countries address these aspects as well.

"As an example, Africa has only 1.3% of the world's human resources for health, yet it carries about 25% of the burden of global disease. If you look at sub-Saharan Africa, it's estimated that only about 30% of the population has access to basic health services. Some of the more specific issues related to access to medicines, issues of capacity in developing countries around procurement and regulatory issues and supply chain, continue to challenge developing countries. These are all things the development community, including CIDA, is working with developing countries to address."

They cited the lack of administrative capacity and institutional framework as a barrier to CAMR's success.

"As I mentioned at the outset, there a number of strict terms and conditions under the waiver that importing countries have to abide by. That includes figuring out
whether the drug is patented in that country and indicating, if it is patented, whether they've issued or can issue a compulsory licence. If they're not a least developed country, they have to indicate that they have insufficient or no manufacturing capacity to produce the drug. It sounds fairly simple to people in developed countries, but to them it does seem to pose a barrier to use."

David Lee, the Health Canada representative, highlighted that developing country governments want technology transfer and do not necessarily want to use CAMR at all.

"At least from my part, from what I've heard.... It's threefold, basically. I've given presentations on the regime to the African group at the TRIPS Council in Geneva and to various African delegations. Initially what I heard was that they're more interested in technology transfer--understandably so. They want to be able to take care of their public health issues themselves in time. That's one thing."

The government cited Canada's human rights obligations (human rights, 1%), contending that ensuring access to medicines for the poor in developing countries was not a legal obligation. Their effort to address drug access through development assistance was, above all, a moral obligation.

"In addition, the right to the highest attainable standard of physical and mental health is outlined in numerous UN human rights instruments, including the United Nations Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights. While that covenant requires each state party to promote the right to health for its own citizens, there is no interstate obligation to protect the right in other countries, and while all international development assistance, including health-related assistance, is a moral and not a legal obligation, Canada has been a major donor to health-related initiatives in the developing world."
The government stated that their Health Canada quality and safety review (quality and safety, 10%) ensured that developing countries were not held to a different standard than Canadians when it came to drugs.

"At Health Canada, we're responsible to make sure that before any drug is exported from here under the patent regime, it's safe, efficacious, and of high quality. So it's the same as a Canadian citizen would get; no double standard."

The government hardly mentioned innovation aside from their description of patents below (innovation, 1%).

**Equity**

In response to questions on whether CIDA funded the purchase of drugs through CAMR (aid, 29%), CIDA bureaucrat Chris Armstrong emphasized that they rarely condition health sector funding in this way and that it was not a current alternative. CAMR could play a role if the aid-receiving country deemed it appropriate and if it was an effective use of donor money.

"It's something we would need to look at carefully with respect to our aid effectiveness principles, our principles of country ownership, allowing the flexibilities of developing countries to access the medicines that are most affordable, most efficacious for them. At the same time, though, we would certainly bring their attention--and have done so on many, many occasions--to the legislation that exists in Canada. We have made them aware that those flexibilities exist in Canada, that our manufacturers do have the ability through this legislation to provide it through compulsory licensing. But it's a question of putting the decision and the country ownership within the hands of the developing country to make those decisions."
At the same time, Industry Canada representative Doug Clark suggested that CAMR could contribute to addressing the drug inequity if it only received more funds from government.

"I do believe the legislation can work. It's premature to conclude otherwise. We're making a sincere effort here to explore possible changes and improvements to the regime. Judging from all of the discussions that we've had to date, not much will happen because of a lack of money. Basically, it boils down to a question of funding."

They described the aid available to these countries in the form of financial, programmatic and political support. The CIDA representative paid significant attention to programs relating to HIV/AIDS, TB and malaria. They presented Canada's financing commitments to global procurement agencies such as the Global Fund and examples of their support of health sector programs aimed to improve development. CIDA highlighted its support of the International Human Rights Program at the University of Toronto, which provided technical assistance to help Ghana use the TRIPS flexibilities to increase access to medicines. Bureaucrats recognized the Conservative government's tax incentive program as well. Despite these efforts, they also acknowledged the desperate need for increasing global funding.

"Canada is committed to assisting developing countries in dealing with health issues and CAMR is just one of the tools used to achieve this objective…At the June 2006 UN high-level meeting on HIV/AIDS, Canada committed, along with other member states, to support efforts to move toward universal access to HIV prevention, care, treatment, and support by the year 2010….The G-8 has also been a consistent and strong supporter of this goal. At the July 2006 St. Petersburg summit, G-8 leaders recognized that improved access to means of prevention, treatment, and care in many countries is essential to curbing infectious diseases. Leaders also noted the possibility for WTO members to use the flexibility set out in the waiver decision."
"Finally, on the last slide, just to give you a quick overview of what we're doing—and again, this is illustrative, not complete—for the fiscal year 2006-07, which has just come to an end, it's estimated that we will have spent about $822 million specifically on health sector support in the developing world. That's approximately 30% of CIDA's overall sectoral spending."

Doug Clark defended the inclusion of Schedule 1 (list of medicines, 3%), which defines what medicines are eligible to produce and export under the regime. He argued that it made the regime more efficient despite the fact that other Paragraph 6 regimes had no similar clause.

"As I said, there are many different ways to skin a cat. The way Canada implemented the waiver is not the only way to implement. That's clear. Other countries have waived certain things. They've waived the voluntary licence requirement in instances of national emergency or extreme emergency. We haven't done that. Other countries don't have pre-approved lists of drugs in eligible importing countries. In my mind, speaking as an expert in the patent field, that's an advantage to our regime, not a disadvantage. Having a pre-approved list makes it a lot easier for the patent authority to figure out whether they can grant a licence or not, and it minimizes the opportunity to litigate that decision."

The issue of equity also came up with respect to the list of countries (list of countries, 6%), where Mr. Clark explained that each country's development status indicates the terms of use of the regime.

*Liberty*

Much of the discussion involving intellectual property, patents, and licensing (intellectual property, 37%) focused on explanation of the WTO TRIPS agreement, the Paragraph 6 Decision, and the corresponding provisions under CAMR. The government protects patents for the functional purpose of encouraging research and development and
promoting the diffusion of knowledge. Canada is legally obligated to protect patents because of its membership to the WTO and because of NAFTA.

"In Canada and in all other WTO-compliant countries, the term of patent protection is 20 years from the date the patent was filed. In certain circumstances, however, governments can override patent protection provided they do so consistent with certain international obligations. They can authorize a third party to make, use, or sell a patented invention."

Overall, their discourse reflected a view that TRIPS defines what Canada's goals are with respect to granting intellectual property rights and under what circumstances these rights could be overridden (WTO or TRIPS, 21%).

"Canada was one of the first countries to announce its intention to implement the waiver. It's not a positive obligation. It's up to individual developed country members whether they want to implement it."

Mr. Clark explained what conditions must be fulfilled by the generic company and importing country, if they wanted to use compulsory licensing under CAMR. The generic company had to provide knowledge of country of importation, the name of the drug and its quantity, and the name of the purchaser if different from the country. The generic company must apply for a voluntary license with the patent-holder 30 days before applying for a compulsory license from the Commissioner of Patents. Mr. Clark declared that these negotiations were required under Article 31b of TRIPS and suggested that this created delays in Apotex's efforts to use the regime.

"There was at least an initial attempt on the part of Apotex to seek voluntary licences. It's a triple-fixed dose so they tried to seek licences from the relative patentees. At that time, there wasn't a country of mention, so there was some discussion on whether that was a bona fide attempt to seek a licence."
Mr. Clark explained that the generic company had to pay a royalty to the patentee based upon a predetermined index. The importing country has several responsibilities including identifying whether or not the drug is patented in the country and if it is, they must issue a compulsory license. The importing country must declare that it has insufficient or no manufacturing capacity in its pharmaceutical sector. Furthermore, the country must notify the WTO, or Canada, of its intention to use the Paragraph 6 mechanism depending upon whether or not it is a WTO member.

"A copy of the importing country's notice, either to the WTO, in the case of a WTO member, or Canada, in the case of a non-WTO member, must be provided."

The compulsory license is valid for two years with a one-time two year renewal allowed. Mr. Clark argued that they capped the duration of the license to avoid locking the country into a price, in case drug prices subsequently drop.

Other comments related to the Paragraph 6 requirement that importing countries had to declare insufficient or no manufacturing capacity in the pharmaceutical sector (WTO or TRIPS, 21%). Also, bureaucrats described the calculation of CAMR's royalty rate, which incorporates the importing country's status on the UN Human Development Index.

Efficiency
Bureaucrats discussed profits (profits and ROI, 3%) in relation to the WTO Paragraph 6 requirement that compulsory licensing cannot be used for commercial purposes and must be used in good faith. They did not view the remuneration requirement, which took into account the level of development of the importing country, as creating a price barrier to the drugs.

"As I explained, royalties can easily be calculated. They are quite reasonable, between .02% and 4%. I don't see this as an insurmountable obstacle."
They explained that CAMR also contains a litigation clause (litigation, 3%) that gives an opportunity for patent-holder to challenge generic if the price of the product is equal to or greater than the average price of the equivalent product sold in Canada by the patentee (profits and ROI, 3%).

"On their engagement in it and whether or not it's viewed as a humanitarian or profit-making issue, certainly the overall intention of the WTO decision was humanitarian. There's no doubt about that. But as Mr. Clark has mentioned, it's facilitating legislation to enable the engagement of our private sector, so it does rely on private sector engagement, and I don't have the answer on how that happens."

Antidiversion measures must be implemented so that the drug is distinguishable from the brand name equivalent (diversion, 2%). Health Canada assumes a role as the pre-export inspector under CAMR, verifying that the drug is distinctive from the brand name drug to ensure diversion can be identified.

Bureaucrats responded to concerns about developing countries' awareness of the legislation, stating that they actively promoted CAMR in several international venues (CAMR outcomes and uptake, 24%).

"We've all had occasion, each one of us here at this table, to interact with those countries. We've actually prepared a list, in addition to the website that we established, and the online users guide and the CD-ROM that we've distributed, of all the outreach activities we've engaged in. It's quite a lengthy one."

Mr. Clark suggested that if countries were not interested in using CAMR, that the efficiency of the regime itself was not ultimately to blame.

"What we're dealing with here is a facilitating regime. It allows the private sector -- we're not talking about a government program -- to take advantage of
opportunities to sell and export at low cost to developing countries patented
generic drugs. Now then, if there are no opportunities, if the countries... That
doesn't affect the means. If the means do not exist, everything else is purely
“academic”, in some respects."

He disputed claims that CAMR was needlessly complicated and saw the lack of
outcomes linked to the lack of funding for the initiative.

"Mention is often made of the regime's regulatory impediments. All of the
obstacles that we've talked about are far more serious than those faced by generic
drug companies when they wish to market a generic version of a patented drug.
Companies manage to overcome these obstacles daily. It really comes down to a
question of incentives and it's not up to Industry Canada to...I don't know what to
tell you. The regime was set up, but it is not being funded."

**Liberal MPs**

*Security*
Liberals identified that CAMR was not efficient even though it removed "roadblocks" in
accessing affordable medicines (drug affordability, 11%). They acknowledged the
affordability of Indian generic medicines and recognized the fact that India had lower
production costs, and had a better business case than Canadian generic manufacturers
under CAMR to provide low cost medicines. Liberal MPs acknowledged the role of
brand name companies in providing discounted medicines to the poor and suggested that
the Canadian government provide financing to purchase brand name drugs at cost.

"Recognizing that the R-and-D-based pharmaceutical industry is providing drugs
at cheaper prices, in certain cases in the developing world, if CIDA were to
approach the pharmaceutical industry and say that these are the drugs we need for
these countries, and agree that we would pay for them, would the R-and-D-based
pharmaceutical firms offer the drugs at cost? If the concern is patent protection, if
the concern is the potential loss of the integrity of the patent system, would the R-
and-D-based industry provide, at cost, drugs to the developing world if CIDA, acting on behalf of the developing world, were to offer to buy them?"

One MP stated that addressing infrastructure and development is key to ensuring the effective roll out of affordable medicines (development, 6%). Also, concern that the lack of administrative and institutional capacity of countries was responsible for the lack of uptake on CAMR.

Equity
Liberal MPs pressed the bureaucrats on what kind of assistance has been offered to developing countries to use this regime (aid, 33%). They wanted to know what department was in charge of running CAMR as a program, whether they provided technical assistance to countries and why they were not providing a funding envelope to ensure the success of this regime.

"But I'm puzzled as to why Canada has not taken the position that we would become a direct first-party provider of these services using the WTO TRIPS waivers, Canada's access to medicines regime, and our own statutory powers. Why doesn't CIDA simply go in, solicit an importing country that has identified an epidemic, and provide the championship on the ground in the host country's own health facilities, and on the ground here in Ottawa, in getting this process through? It seems highly consistent."

Liberal MPs strongly supported the idea of 'tied aid' and suggested that the government run some pilot projects based upon the model to see whether CAMR can work.

"This seems to be what CIDA does. Eighty-five percent of our development assistance envelope is Canadian companies."

Liberal MPs went further to suggest that the Canadian government issues aid for the purchase of brand name drugs at cost, depending upon the needs of developing countries.
The remaining discourse included questions to all witnesses as to what Canada, other countries and other organizations, such as the Clinton Foundation, the Global Fund and the US PEPFAR program, were doing to improve drug access globally.

*Liberty*

Most discourse over intellectual property (intellectual property, 17%) focused on what the implementation problems were and explored potential solutions to the impasse. Several passages spoke to the issue of country notification as an obstacle within the legislation. Liberal MPs questioned whether notification was necessary given the existing protections already incorporated into the regime to prevent abuse.

"But I'm asking the question: is it necessary, in your view? Why would you want to defend having the country name itself if there are existing safeguards to protect abuses, or do you actually believe that without naming the country there will be abuses?"

Liberal MPs tried to find ways to ensure the provision of affordable medicines while protecting intellectual property. One solution was similar to the equal opportunity to supply and permitted generic companies to receive a compulsory license only if they outbid the patent-holding company on a tender funded CIDA. Another solution simply bypassed compulsory or voluntary licensing altogether by allowing CIDA to purchase drugs at cost from the brand name manufacturers.

"If the concern is patent protection, if the concern is the potential loss of the integrity of the patent system, would the R-and-D-based industry provide, at cost, drugs to the developing world if CIDA, acting on behalf of the developing world, were to offer to buy them?"
Efficiency
A significant portion of the Liberals' questions focused on what was wrong with the implementation of CAMR (CAMR outcomes and uptake, 21%). As mentioned earlier, the issues centered on the problem of country notification, whether developing countries were aware of CAMR and the role of the government in actively implementing CAMR to ensure its success.

Liberal MPs acknowledged the lack of profit incentive (profits and ROI, 5%) as another barrier to the success of CAMR while Indian generic companies have a strong business case to get involved in affordable medicines production. They explored methods to 'alter the business case' under CAMR through government subsidization of the regime (tied aid).

"I thought it would be the role of government to actually facilitate, as we have done, because I don't think international development assistance is normally a really high-profit area for most companies."

The discourse on market competition reflects the Liberal's suggestion to allow brand and generic companies to compete on an RFP posted by CIDA.

Bloc Quebecois (BQ) MPs

Security
Issues that covered affordability (drug affordability, 10%) addressed the question of whether the royalty rate affected the level of affordability of the medicines and what the private sector was doing to address the issue of affordability, and also the success of CAMR. Paul Crete, who presided over the 2004 hearings, suggested that brand name drugs were unaffordable.

"If I understood you correctly, Mr. Alton, your pharmaceutical product will cost an average of $240 in disadvantaged countries where the gross per capita income is $825. And we're not even talking about the world's poorest nations. That would
be like someone paying $12,000 for drugs in Canada, on an annual income of $40,000. Can anyone in Africa afford this kind of drug?"

Bloc MPs discussed development-related barriers (development, 24%) such as impact of HIV, lack of infrastructure, transportation, clean water and sanitation, situation in rural areas. One MP asked whether these issues should be addressed before drug access

"We know that there is a huge lack of infrastructures in some African countries. There is a lack of access to clean water and to good sanitation. It may be very well to talk about treating patients but do you not think that we should solve those problems of sanitation before sending drugs? Both could be done in parallel though."

**Equity**

Three different Bloc MPs had a chance to question during the testimony. Questions focused on aid alternatives to CAMR (aid, 22%), including tax incentives for drug donations, increased financial contributions for drug procurement and on a government-sponsored rollout of CAMR.

"Would you be willing to take part in a pilot project in five countries where the government would commit to setting up an advisory committee to inform people about the act and to ensure that it is working well? One project would be carried out in each of the five countries. The impression we have today is that both sides are trying to shift the burden of drug problems onto the backs of the world's poorest. I find that very hard to accept."

Bloc MPs queried witnesses regarding the necessity of the list of medicines (list of medicines, 19%) and suggested that the elimination of the list might remove delays especially in the situation of a pandemic.
Liberty
Bloc MPs focused on why CAMR was not working and the nature of royalty payments (intellectual property, 20%). Generally, there appeared to be acknowledgement that patented medicines were out of reach of developing countries but wondering what all parties were doing to try and remedy the situation.

Efficiency
As with other MPs, the focus on efficiency reflected their interest in finding out what was wrong with the implementation of CAMR (CAMR outcomes and uptake, 33%). A question relating to profit asked about the commercial limitations on the regime (profit and ROI, 2%) and the question on procurement (procurement, 5%) suggested that the lack of developing country contracts makes getting a license irrelevant. Some mentioned the problem of diversion (diversion, 10%) suggesting it is widespread.

"We heard how drug shipments were being diverted. We've seen news reports on this problem and it's easy to understand why it is that in war-torn countries, where even food shipments are diverted, pharmaceuticals are also valuable commodities."

New Democratic Party (NDP) MPs
Efficiency
Brian Masse represented the NDP at the 2007 hearings. He pressed the witnesses to explain what was required to make CAMR work and expressed outrage at the lack of results coming out of CAMR (CAMR outcomes and uptake, 49%). He pressed each witness as to what they were doing specifically to help CAMR work, be it through increasing awareness among developing countries, talking to bureaucrats in other jurisdictions about how better to implement CAMR. He condemned the brand name industry for suggesting that the legislation had not been fully tested yet.

"Right now, if it's still, in your view, premature, how much more time is needed and what needs to change, specifically, for this legislation to be successful? I'd
like to know, because the body count is rising. I think we're actually participating in a wilful genocide of people, because we actually have systems in place and we use excuse after excuse after excuse."

Mr. Masse also suggested that if the brand name industry was willing to take a cut in its profits (profits and ROI, 4%), that they would not need a legislation like CAMR in the first place.

"The fact of the matter is that if a brand name company wanted to take a 0.2% profit--or 1%, or 2%, or 3%, or 4%--on their drugs being shipped out somewhere else, they could do so. We wouldn't even need the legislation."

Equity
Mr. Masse chided the government for not reaching its commitment of 0.7% of GDP towards development assistance and blamed this partly for the failure of the regime (aid, 2%). With respect to the lists of medicines (list of medicines, 4%) and countries (list of countries, 3%). Mr. Masse demanded to know whether these lists should be amended or removed altogether, suggesting they were not necessary in the first place.

"So what I want to know is does this legislation need amendments to make it work? Does it need amendments like in other countries, where they're removing some of the pre-approved lists--lists that we created that we didn't have to?"

Security
Mr. Masse indicated that development-related barriers (development, 7%) were definitely present but he also acknowledged a sophisticated level of capacity in Africa. His comment suggested that the blame for CAMR's failure need not rest on the shoulders of Africa.

"This Perspectives magazine is the African journal on HIV/AIDS. It's a pretty sophisticated African publication on the whole issue and how they're dealing with
the situation. So it's not whether we're dealing with individuals and organizations that don't understand how these things move."

Liberty

On the issue of liberty, Mr. Masse was concerned about the delays in voluntary license negotiations between generic companies and patent holders (intellectual property, 11%). He suggested that the time limit on compulsory licenses was also a significant problem.

"Isn't the two-year time limit a little bit restrictive in terms of going through the process and getting an actual application through? What do you do about the fact that people will be living with HIV and AIDS, on some of the drugs we can provide, much longer than the two years on the prescriptions they have?"

Mr. Masse also mentioned the intimidation that countries face in using compulsory licensing and asked whether a similar situation might be occurring with CAMR (developing country pressure, 4%).

"Can you describe greater the concern about setting a standard or precedent that could then be used against a country later? The repercussions probably go well beyond even just HIV and AIDS medications. There are probably other medications they're concerned about being shut out from their citizens."

Independent MP, André Arthur

Equity

Mr. Arthur suggested that the easiest solution would be for the Canadian government to finance the purchase of drugs coming out of the regime yet indicated CIDA's reluctance to tied aid (aid, 9%).

Security

Mr. Arthur suggested that corruption (development, 24%) was the main reason that countries were not interested in the regime.
"Most of those countries have people who live on $1 a day, but have elites who are very rich and have bank accounts in Switzerland. Is it possible that they will accept all the money we'd send their way but are not interested in asking for our medicines because medicines are much more difficult to send to Switzerland?"

He also suggested that the problem was that governments were ultimately only interested in generating their own production capacity.

"They want our money to build their plants to produce their medicine with our patents or our absence of patents. So at no time will we see a real order with real money for real drugs at a good price. They are not interested."

**Efficiency**

Mr. Arthur linked the issue of corruption to the diversion of medicines (diversion, 14%) suggesting that any initiative to send cheap drugs to poor countries would lead to corrupt behavior.

"That brings me to the fact—and only Madame Brunelle has alluded to it, when she talked about the diversion of medicine—that most of those countries are dirt poor, that most of those countries would accept all Canadian funds that could be sent their way, that they would never say no to money, but yet they say no to medicines."

Regarding CAMR's outcomes (CAMR outcomes and uptake, 41%), Mr. Arthur spoke mainly of the failure of CAMR to achieve its goals. He chided the government and pharmaceutical companies for their failure to facilitate the legislation.

"If I had purchased a bottle of Advil before coming to this meeting and had shipped it to a hospital administrator in Ouagadougou, I would have done more
than what all of you have managed to accomplished with 30 countries in two years."
Chapter 9: Discussion of 2007 Debates

Overview of Stakeholder Framing in 2007

The changes observed in the statistics from 2004 to 2007 serve as the foundation of the story this chapter tells. The largest increase observed is in the frequency of efficiency goals (increase in 12%), represents the amount of time spent discussing CAMR's outcomes, implementation and uptake by developing countries and the Canadian generic industry. This is not surprising as the debates themselves were framed specifically for this purpose: to review the legislation, three years on, to assess whether any amendments had to be made to the regime.

The next change observed is a decrease in references to liberty goals (decrease of 10%). This observation can be explained by the focus of most participants in 2004 on the right of refusal (10.7%), which was no longer an issue in 2007 (0%). Instead, there was a greater emphasis by participants in exploring other ways to improve drug affordability (increase in 3.8%), especially through aid programs (increase in 11.6%). Discussions about aid saw particular increases among the Liberals (increase in 30%), the Conservative Government (increase in 16%) and the Bloc Quebecois (increase in 16%).

As will be shown in the analysis of the qualitative data below, the emphasis on aid signals a shift towards pursuing voluntary policy tools, such as corporate philanthropy and voluntary price reductions, and a movement away from compulsory licensing to pursue affordable drug access.

The qualitative data also shows the stark contrast in how stakeholders frame drug access, intellectual property protection and the WTO Paragraph 6 Decision and TRIPS. On one side, the research-based industry argues that intellectual property protection creates drug access because it encourages the development of new medicines. They believe that the ultimate goal should to avoid the use the TRIPS flexibilities— the WTO Decision and compulsory licensing – and to rely instead on their responsible pricing mechanisms and voluntary licensing arrangements. In the research-based industry's opinion, developing country governments actually do not want to use compulsory licensing despite NGO
efforts and protests. The research-based industry's opposition to compulsory licensing and use of TRIPS flexibilities illustrates their opposition to CAMR, and any amendments thereof, despite their expression of support for the regime.

On the other side, both civil society and the generic industry argue that intellectual property protection impeded drug access through the prevention of generic competition, which reduces drug prices. The goal should be to use TRIPS flexibilities to facilitate compulsory licenses. In fact, civil society advocated amending CAMR under TRIPS Article 30 to pursue a more streamlined compulsory licensing mechanism, and instead, identifying the WTO Decision as fundamentally unworkable. The idea that governments did not want to use compulsory licensing was rejected by civil society and the generic industry, arguing that governments faced potential retaliation from drug companies and political pressure from powerful countries whenever they considered using compulsory licensing. What the research-based industry framed as an opportunity to "...communicate with the country and to try to meet its needs without the use of compulsory licensing" was framed as a fundamental barrier in the eyes of civil society and the generic industry. Country notification caused "a fatal reticence, for countries to actually come forward" out of fear of retaliation. Despite comparable statistics on intellectual property and TRIPS, these two sides held very different policy goals.

Another major point of divergence between stakeholders was how they defined what an efficient regime should look like. Government bureaucrats called CAMR efficient in comparison to the 'regulatory requirements' for introducing a generic product in the domestic market upon patent expiration.179 In other words, CAMR was efficient in comparison with existing Canadian domestic patent law. Civil society and the generic industry defined efficiency as open, generic competition to lower drug prices. Bringing prices to their lowest level means that more patients can be treated with the same amount of money. Civil society argued that the brand name industry's policy of preferential or

179 "We've all heard that criticism of the regime: that it's unduly complicated and difficult to navigate. But anybody who is familiar with patent litigation in the pharmaceutical industry, particularly under the patented medicines notice of compliance regulations, with which some of you are familiar, will find that criticism hard to accept." From: Canada. Parliament. House of Commons. Standing Committee on Industry, Science and Technology. Evidence. (April 16, 2007) 39th Parliament, 1st Session.
non-profit pricing could not beat the prices achieved through open market competition between multiple generic firms. In contrast, the research-based industry viewed CAMR as a "simple" and "well-designed" piece of legislation.\textsuperscript{180} As can be seen, the Government and research-based industry's perspective on efficiency was very much in line.

Most politicians focused on trying to identify what went wrong with implementation (CAMR Outcomes and Uptake: Conservatives: 16%, Liberals: 21%, BQ: 33%, NDP, 49%, Independent: 41%). The policy alternatives that politicians considered suggest that an automatic compulsory license was far from their considered policy alternatives. Country notification was an issue that concerned politicians and bureaucrats (Intellectual Property: Conservatives: 29%, Liberals: 17%, BQ: 20%, NDP: 11%, Independent: 7%). Conservative and Liberal MPs questioned whether country notification was needed but bureaucrats defended the clause as necessary to comply with the WTO Decision and TRIPS. Debating whether or not the government should take an Article 30 approach was not discussed at all during the hearings by other members. Civil society and the generic industry's suggestion that developing country pressure played a role was not discussed by politicians or government and was dismissed in the Minister of Industry's final report as "polemical" (Industry Canada, 2007). The only outspoken political party was the NDP, who gave its support to civil society.

**Who Won, and Why: The Conservative Government's Policy Priorities**

Overall, the most significant factor in the outcome of the 2007 debates appears to be the preference of the Conservative Government to maintain the status quo and leave CAMR unchanged. The Conservative government had little incentive to improve the legislation since it was a Liberal initiative. Moreover, under their new leadership, Canada's foreign policy took on a more aggressive approach with respect to intellectual property protection.\textsuperscript{181} The Department of Foreign Affairs and International Trade (DFAIT)


\textsuperscript{181} Letter from Richard Elliott (Canadian HIV/AIDS Legal Network) to Lesia Stangret, Assistant Deputy Director, Intellectual Property, Information and Technology Trade Policy Division, Department of Foreign
announced in 2007 that it was assessing its interests in protecting intellectual property as it initiated trade agreements in Peru, Colombia and the Dominican Republic. The Government's stated intent was to protect the interests of Canadian firms and intellectual property owners in foreign markets given the increased importance of intellectual property in Canada's knowledge-based economy. This new policy position made the prospects for any amendments to the regime unlikely from the start.

Prior to the 2007 Standing Committee hearings, the Minister of Industry, Maxime Bernier, expressed his Party's commitment to hearing the public's ideas on how to improve the legislation so that it "benefits all of Canada and the entire international community." After the consultation, the Government did not respond for months. They blamed the Liberals for creating a failed policy in the first place and then reassured Parliament that they were doing everything they could to encourage both developing countries and generic companies to use the regime.

Later on that year, the Government finally tabled its report to Parliament. They concluded that the case for making legislative or regulatory changes to CAMR had not yet been made (Industry Canada, 2007). They viewed the compulsory licensing process as simple and decided to maintain its outreach activities to encourage CAMR's use. The report pointed to other initiatives that the Government is taking including a new tax incentive to encourage pharmaceutical donations in the Budget 2007 (Industry Canada, 2007). Given the Government's ultimate authority over the review process, their decision effectively shut down the potential for any of the recommended amendments to get passed by Parliament.


184 They referred to the distribution of a CD-ROM with step-by-step instructions on how to use CAMR, which MSF has criticized as being insensitive to the developing country context (Médecins sans Frontières, 2006).
The Government's report supports the discourse of Conservative MPs during the 2007 debates. Emphasizing efficiency (31%) and liberty (29%), they questioned the witnesses (CAMR Outcomes and Uptake, 16%) and identified the major problems within the initiative, which were related to the lack of profit (profits, 6%) incentives for the regime and also issues associated with intellectual property protection (29%). Specifically, they asked questions about apparent delays in voluntary license negotiations, the compulsory licensing application process, the forecasting requirement, and most importantly, country notification. The Conservatives clearly acknowledged that country notification appeared to be an impeding factor and asked whether it could be removed or simplified. While civil society argued that it could be removed under an Article 30 solution, others argued that it was a requirement under the WTO Decision. As recently as December 2009, in response to NDP Judy Wasylycia-Leis' private member's Bill C-393, the Conservatives expressed opposition to the Bill, in relation to the need to respect "Canada's international trade obligations and maintaining the integrity of Canada's patent system." Clearly given the outcome, the Conservative Government prefers to avoid using Article 30.

The Conservative Government's unwillingness to pursue an Article 30 approach is likely related to two factors. First, Canada lost two trade challenges during the 1990s and early 2000s to the European Union and the United States related to Canada's domestic pharmaceutical patents. Since CAMR is meant to benefit the developing world, it is unlikely that the Government would risk another trade challenge for a non-domestic issue. Second, and more importantly, the Conservative Government's policy priority on protecting intellectual property appears to be the most influencing factor.

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Institutional Factors and Stakeholder Participation

A larger scope of actors, from international and domestic organizations, submitted written consultations broadening the scope of conflict in comparison to the 2004 debates. Scope of conflict theory (Schattschneider, 1964) can help explain why this range of actors participated in the debates. The legislative review was well-publicized and facilitated through a website where the government posted a consultation paper listing specific questions regarding the regime (Government of Canada, 2006). Any public individual or group was invited to make a written submission in response to the consultation paper. Civil society was well-organized and increased the visibility of this consultation through circulating information to various list serves and organizing an expert consultation to facilitate a more wide-ranging participation internationally. This consultation took place immediately prior to the 2007 hearings, at which country representatives from Kenya, Thailand and India attended, representatives from domestic and international organizations attended and the lead Canadian bureaucrats in charge of the legislation from Industry Canada, Health Canada and CIDA attended and participated (L. Esmail et al., 2007). The consultation resulted in a report with specific recommendations issued to the Minister of Industry as part of the review process (but outside of the official consultation).

The consultation paper was specifically framed around a set of questions on whether various aspects of the regime were adequate or needed to be changed (Government of Canada, 2006). From this perspective, the policy alternatives were limited to those questions posed by Industry Canada and Health Canada. Still, the institutional process at the bureaucratic level and within the Parliamentary Committee allowed for a range of diverse views and issues to be heard.
Framing, Interests and Institutions: What Explains Stakeholder Discourse?

The Research-Based Industry

The research-based industry's main goal in the 2007 debates appears to have been to dissuade the Standing Committee from amending CAMR, and shifting the policy debate to alternatives that were in line with their interests. The research-based industry explicitly opposed compulsory licensing and promoted voluntary measures, which included aid programs, non-profit and tiered pricing, as well as voluntary licensing to Indian generic manufacturers in some cases.

The brand name industry described CAMR as a simple and well-designed piece of legislation and warned the committee against rushing into changes as the regime was not fully tested yet (CAMR Outcomes and Uptake, 18%). Whether or not the regime was fully tested yet was the subject of controversial debate, as the generic industry and civil society argued that the process had been stuck in voluntary license negotiations for months despite a legislated 30-day limit.188 Since no standard was available to compare the CAMR implementation process, questions about the progression of the regime could always be challenged. Prior to these consultations, MSF produced a document stating that WTO Paragraph 6 Decision was not an expeditious solution and called upon the WTO to go back to the drawing board. Clearly, it was not in the research-based industry's interest to reopen these debates, as it would open their patent rights up to potentially more government intrusion.

Instead, the research-based industry argued that its lack of effectiveness was due to a lack of awareness on the part of developing country decision-makers and that developing

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188 Apotex was in voluntary license negotiations with three different patent-holders; there was some debate either with the patent-holders or the government as to whether they had acquired all of the relevant information yet, as they did not yet find a country willing to declare publicly its desire to use the Paragraph 6 Decision. This public declaration is referred to as "WTO notification". From: Canada. Parliament. House of Commons. Standing Committee on Industry, Science and Technology. Evidence. (April 16, 2007) 39th Parliament, 1st Session.
countries' needs were likely already being fulfilled through other measures, namely through Indian generic companies and brand name preferential pricing programs.

It was along these lines that the research-based industry made a security (39%) argument. The brand name industry clearly showed their preference for their voluntary measures in achieving drug affordability. They framed affordability (17%) in terms of their "responsible pricing programs" or voluntary price reductions, stating that they issue non-profit pricing to low-income countries, tiered-pricing to middle income countries, while high-income countries still had to pay the full price. Attempting to shift the debate away from the question of affordability, again, they argued that drug prices were not the main problem. Here, they emphasized development issues (19%) more than in the 2004 debates, arguing that solutions must be comprehensive in scope and address issues such as infrastructure, human resources, nutrition, and corruption. Encompassing most of the reference on equity (31%), the research-based industry proceeded to discuss their aid programs (29%) which provided comprehensive treatment, assisted with capacity-building and encompassed their reduced pricing strategies. It is clear that the research-based industry supported equity and security goals of affordability and development; however, they framed these goals in a way that shifted the focus away from their intellectual property rights.

The research-based industry emphasized liberty (37%) and in doing so, they were much more explicit about their position on patents. They clearly stated that patents (intellectual property, 34%) were not a barrier and the trade-off between intellectual property and drug access was illusory. Instead, intellectual property fosters drug access because it leads to new medicines. This picture is the classic frame that ultimately gave rise to the demise of compulsory licensing in Canada during the 1980s and 1990s: health was framed as a long-term issue with its eye on innovation as opposed to the short-term needs of drug affordability. Currently in developing countries, the research-based industry's voluntary price reductions attempt to address the short-term health needs as well. Still, as civil society argued in these debates, voluntary price reductions can be unreliable,
unsustainable and rarely reduce prices to the extent that global generic competition does (t'Hoen, 2009).  

The research-based industry was clearly against the use of compulsory licensing, of TRIPS flexibilities (TRIPS 12%) and of the use of CAMR, framing compulsory licensing as breaking patents. But civil society argues that the WTO TRIPS Agreement clearly gives countries the right to not only use the flexibilities, but to determine the grounds upon which to use them (World Trade Organization, 2001). These counterarguments will be discussed later; however, it is clear that the research-based industry and civil society have two very different policy goals in mind.

The research-based industry tended to frame the WTO notification mechanism as a signaling mechanism: it effectively notified the patent-holder that a country is need of a product, so it could try and negotiate with the developing country. But their underlying goal, which they made explicit, was to avoid a compulsory license and any use of TRIPS flexibilities. As will be explained later, civil society suggests that these negotiations with patent-holders are pressure tactics on a country to avoid purchasing generic products and instead, purchase their own.

From the research-based industry's perspective, TRIPS should effectively guarantee a patent-holder a global market for the entire duration of a patent, even if the market has little to no purchasing power as is often the case in low-income countries. In an ideal world, the research-based industry would exercise their patents globally and would define the terms under which their property would be licensed. To this end, the industry acknowledged a role for Indian generic companies in providing affordable medicines through voluntary licensing agreements. The challenge with this approach, as has been identified by many critics as well as civil society, is that developing country governments become heavily reliant on the good will of the private sector in defining what drugs would be made affordable at what price, for what populations and on what terms. The

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reliability and sustainability of such mechanisms are under fire by civil society and some developing country governments (t'Hoen, 2009).

**Civil Society**

Civil society's ultimate objectives during the 2007 debates were no different than in 2004. They still wanted to achieve an easy-to-use compulsory licensing regime in Canada, to facilitate global generic competition and drive down drug prices. They sought to do this by arguing that specific design issues within CAMR were to blame for its lack of success, highlighting the continued barrier that patent protection poses, and by making an argument based on efficiency that the best way of achieving drug affordability was to encourage open market competition between multiple firms.

Civil society's emphasis on issues coded under liberty (47%) reflects their belief that patents remain a major barrier to drug access. Impeding patent protection in India continued to threaten global, affordable drug supplies (Affordability, 17%). They argued that patent-holders abuse their rights through pressuring developing countries (Developing Country Pressure, 5%) to avoid using measures such as compulsory licensing. It was within this vein that civil society framed the amendment of CAMR as a crucial component of the developing world's future affordable drug supply.

To lobby for the amendment of CAMR, civil society pushed an efficiency (20%) argument. They blamed the mechanics of CAMR for its lack of outcomes (Outcomes and Take Up, 14%). Among these issues, the limitations of the license prevented economies of scale and bulk procurement (procurement, 10%), and the anti-diversion (2%) and non-commercial clauses (3%) discouraged the generic industry's participation through the threat of litigation (4%). Furthermore, the inability of NGOs to procure drugs (Eligible Importers, 1%) prevented a major procurer of drugs worldwide from facilitating the implementation of the regime. Their ultimate goal was to achieve streamlined and simple compulsory licensing regime to facilitate global generic competition (market competition, 4%), which they advocated through a TRIPS Article 30 implementation (TRIPS, 23%).
Civil society cited the lack of congruence of CAMR with developing country procurement laws. Due to the need to post international tenders to achieve the best possible price, developing country governments could not enter into a contract with a Canadian generic manufacturer unless it outbids its global competitors. Civil society argued that CAMR put the generic industry at a disadvantage, as it had to enter into the procurement process without a license to even export the drug, and this did not permit them to be considered a serious bidder in an international tendering process.

Civil society also advocated that licenses should be valid for distribution throughout regional trade groups as per subsection 6(i) of the Paragraph 6 Decision; facilitate economies of scale and bulk purchasing. The Conservative government did acknowledge this as a possible amendment in their report but given their lack of willingness to amend CAMR, this option did not get realized.

Interestingly, civil society argued that one of the major problems with CAMR was the WTO Decision itself (TRIPS, 23%). MSF and Apotex's experience in the implementation of CAMR made it unavoidably clear that an easy-to-use compulsory licensing regime was not possible through an implementation of the Paragraph 6 Decision. As discussed in Chapter 7, civil society avoided this issue during the 2004 standing committee hearings. Some members of global civil society dissented over the decision to advocate for Canada's implementation of the Paragraph 6 Decision but their reasons went beyond the argument that the Paragraph 6 Decision was flawed (Elliott, 2003a); they did not see Canada as being able to compete with Indian and other low cost manufacturers globally (Attaran, 2007; J. C. Cohen & Esmail, 2007). It is likely that the Paragraph 6 Decision was a sliver of hope for civil society in a world where the policy space to use patent flexibilities to address drug affordability needs was quickly disappearing. From this perspective, what might be seen as tinkering on the edges of global pharmaceutical patent policy is really a small step at a larger reform agenda seeking to increase the policy space for the use of TRIPS flexibilities. At the very worst, the Canadian initiative could encourage other countries to amend their own patent laws and the Canadian initiative would provide evidence that the Paragraph 6 Decision needs work. Recent events at the
WTO suggest that the Canadian experience has indeed been used, by emerging market countries like India, to lobby for changes at the WTO (Balasubramaniam, 2009).

Civil society's discourse on equity (14%) and security (32%) mainly focused on disputing arguments regarding the primacy of development-related barriers (development, 11%) to drug access and that increased financing in drug procurement and infrastructure development (aid, 25%) was needed but did not compensate for the lack of an effective regime. They disagreed with the idea that preferential pricing arrangements (affordability 17%) were an adequate solution, as brand name discounts are never as deep as that achieved through global generic competition.

Civil society and the research-based industry both spoke of the goal of technology transfer in 2007 but the means by which such technology would be transferred was a point of divergence. Civil society suggested that CAMR could be used produce active pharmaceutical ingredients to facilitate technology transfer and that the local production of medicines were among the goals in developing countries. The research-based industry prefers voluntary licensing arrangements, which, as the Gilead representative mentioned, allows them to secure royalties of 5%, higher than that provided under CAMR. The desire of developing countries for technology transfer was briefly mentioned by an Industry Canada official as partly why there was a lack of interest in the regime. These preferences did not get incorporated into the final policy decision.

Overall, the differences in discourse between civil society and the research-based industry illustrates the fundamental difference in their approach to pursuing equitable drug access: the research-based industry ascribes to a philosophy of voluntary beneficence and are opposed to government intervention on their intellectual property and their rights to reap the benefits therein. While civil society does not oppose to voluntary measures, they frame this mechanism of achieving equity as unsustainable and unreliable as it leaves the power of equity in the hands of the private sector. Instead, they favor government intervention to limit the research-based industry's rights to allow the free market force of open competition to help achieve drug affordability.
The Generic Industry

In 2007, the generic industry's arguments were quite similar to civil society's, but they could speak more to the details of their experience in implementing CAMR. Most differences are accounted for by the description of Apotex's experience in trying to navigate the compulsory licensing application process of CAMR. Essentially, the generic industry argued for achieving drug affordability through compulsory licensing and generic competition. It appears as though the bulk of the generic industry's testimony was focused on identifying fundamental problems with the regime, as they shied away from discussing any other policy alternatives such as aid programs or addressing development-related barriers.

The generic industry framed security (32%) primarily in terms of affordability (21%). They countered the research-based industry's argument that their voluntary price reductions were enough, instead arguing that the entire rationale behind the WTO Decision and the Doha Declaration is that developing countries are not getting the product as often as they want at the price that they want. They pushed the argument that the only way to achieve significant price reductions was through generic competition (market competition, 11%). Clearly, the generic industry has an interest in propagating this message. Increased generic competition, particularly in lower cost centers, is good for business. In fact, before the Doha Declaration was even passed the IFPMA argued that the real interests underlying this movement towards compulsory licensing were the 'copycat' industries in emerging markets that were only interested in gaining profits (Bale, 2001).

There may be some truth to this claim. India's generic industry flourished because of the lack of product patent protection.(Kanji, 1992; May & Sell, 2006) But, having a humanitarian regime benefit from the incentive of profits may be a more sustainable and reliable mechanism, and it may expand more quickly than corporate philanthropy programs. For example, the Clinton Foundation has been able to negotiate some of the largest price reductions ever seen in antiretroviral medicines simply by organizing and
manipulating market forces (Soni & Magaziner, 2006). Furthermore, they've been able to reach an unprecedented volume of production and uptake by developing countries in need. It is possible that the Canadian generic industry, in particular Apotex, is participating in CAMR with an eye on this high volume, low profit margin production of antiretroviral medication, particularly on products that require more sophisticated manufacturing processes. While it is unlikely that CAMR in its current form could form a piece of this high volume, low-cost system, it is possible that the Canadian generic industry sees potential profits there.

To argue in favor of amending CAMR, the generic industry argued that CAMR was a poorly designed legislation, which was overly complex, and ineffective (CAMR Outcomes and Uptake, 13%). Not surprisingly, many of the inefficiencies that they identified are viewed by the research-based industry as fundamental patent rights (43%): the requirement for prior voluntary license negotiations, license limitations on duration, quantity and country, price controls and limits on profitability. Herein lays the crux of the problem: CAMR appears to be a regime that protects intellectual property more than it facilitates generic drug production. Given these ideological differences, it is no surprise that such a chasm exists between the stakeholders' perceptions of what an efficient regime should look like.

The generic industry also suggested that the research-based industry used their patents as instruments of intimidation with countries who sought to use TRIPS flexibilities or buy generic. They argued that regimes like CAMR and compulsory licensing were critical policy tools to help disincentivize these abuses, and force the industry to reduce its prices. In this sense, the generic industry argued that compulsory licensing regimes were critical policy sticks, without which the voluntary price reductions seen on their part would never take place. Certainly, there appears to be some truth to that claim. T'Hoen (2009) outlines several instances where countries have threatened to use compulsory licensing and then achieved steep price reductions from the research-based company. Cohen and Lybecker discuss similar occurrences in Brazil (J. C. Cohen & Lybecker, 2005). There are two major caveats to this 'policy stick': first, to be a credible threat, a country needs to have
sufficient manufacturing capacity; second, negotiations for price reductions can take a very long time. Moreover, the use of compulsory licensing as a policy stick in countries without sufficient manufacturing capacity, the intended beneficiaries of the WTO Paragraph 6 Decision, may be less effective.

The need to identify the recipient country up front prior to voluntary license negotiations was one of the major obstacles identified by the generic industry (developing country pressure, 4%). As Jim Keon stated, there is a political problem with countries self-identifying to the WTO or Canada as wanting to use the regime. These claims were supported by MSF in their experience with the regime as well (Médecins sans Frontières, 2006). These experiences point to a fundamental barrier that is not only beyond the scope of CAMR, but beyond the scope of the WTO: the political pressure against developing countries in using any of these patent flexibilities. In other words, even if CAMR or the WTO Paragraph 6 Decision were to be amended, it is still possible that developing countries would not be able to use the regime, given existing international norms around the use of compulsory licensing. In the Canadian Minister of Industry's final report to Parliament, the Government dismissed the explanation of intimidation tactics as "polemical" (Industry Canada, 2007). Civil society activists, developing country representatives and some academics claim that the intimidation, threat of WTO Disputes and threats of legal action were among the major driving forces behind the WTO 2001 Doha Declaration (Abbott, 2002).\footnote{See: Comments by Ambassador Boniface Chidyausiku (Zimbabwe) (on behalf of the African Group); Meeting Minutes of the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines. 10 July 2001. IP/C/M/31} Regardless, CAMR appears to be a story of competing stakeholder interests in a context where even if civil society or generic interests won there may not have been widespread use of CAMR given these existing norms.

Overall, it appears as though the interests of the generic industry and civil society were more congruent during these debates. This could be due to the fact that the relationship between civil society and the Canadian generic industry became more cooperative. Representatives of Apotex liaised regularly with MSF to coordinate the drug order and
the generic industry was invited to certain civil society meetings. This dependence appeared to result in a pattern of interest group relations where civil society took on the representation of some of the generic industry's goals. For example, for civil society to successfully pursue the goal of increased generic competition, they needed to advocate the generic companies' goal of profit-maximization or return on investment. The generic industry, on the other hand, had very little apparent incentive to participate in this regime aside from improving their reputation and possibly establishing the manufacturing expertise and capacity for specific drugs in anticipation of patent expiration in Canada and elsewhere. Thus far, the Canadian generic industry's involvement has been isolated to Apotex, as no other Canadian generic companies have shown any interest (Elliott, 2010). Most likely Apotex's interests in participating in CAMR and lobbying for changes relates to the public relations function of propagating a positive public image in Canada.

Conservative Government (Bureaucrats)

The Government's discourse during the 2007 debates appears to continue to underscore the primary policy objective of protecting intellectual property rights through a more restrictive interpretation of the WTO Decision and the TRIPS Agreement, which is in line with the research-based industry's interests. It appears as though they were trying to distance themselves from the regime and its lack of success. What others saw as needless bureaucratic complexity, the Government framed as requirements to comply with the TRIPS Agreement and barriers on the developing country side. In effect, the Conservative Government argued that it was not accountable for CAMR's outcomes.191

In defending the CAMR regime, the Conservative Government made a liberty (48%) argument primarily comprised of references to intellectual property (intellectual property, 37%). Most of this discourse focused on explaining the TRIPS requirements and the

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191 Doug Clark, representative from Industry Canada stated: "What we're dealing with here is a facilitating regime. It allows the private sector -- we're not talking about a government program -- to take advantage of opportunities to sell and export at low cost to developing countries patented generic drugs. Now then, if there are no opportunities, if the countries... That doesn't affect the means. If the means do not exist, everything else is purely “academic”, in some respects." From: Canada. Parliament. House of Commons. Standing Committee on Industry, Science and Technology. Evidence. (April 16, 2007) 39th Parliament, 1st Session.
corresponding provisions of CAMR, many of which were identified by civil society and the generic industry as fundamental problems with the regime, including country notification and voluntary license negotiations. Their discourse makes it is clear that the Conservative Government did not include shirking the TRIPS Agreement or settling for a more liberal interpretation of its clauses among its policy options. Protecting intellectual property was the starting point for their discussion, and drug affordability would have to be achieved with whatever policy tools did not threaten this goal.

Along these lines, they framed the WTO Decision (TRIPS, 21%) as only one procurement option among many which developing country governments had to choose. Disputing claims that CAMR was needlessly complicated, the Industry Canada representative suggested that CAMR was not onerous compared to the regulatory impediments that generic drug companies face when they wish to market a generic version of a patented drug in Canada and in this vein, suggested that the humanitarian nature of the Decision, and the subsequent lack of financial incentives for the generic industry, was one of the main reasons for its lack of success. The profit-limitations of the WTO Decision were well-known immediately after the decision was reached. Criticizing the profit-limitations of the regime would have been against the interests of Liberal Government at the time, given it was their own legislative initiative. Now under a Conservative government, bureaucrats have no interest in defending a legislation that most stakeholders, including civil society and the generic industry, argue is unworkable. Still, Apotex has stated that it would be willing to participate in CAMR again to produce a fixed-dose combination pediatric antiretroviral product, if the regime is amended.

Government bureaucrats described CAMR as an efficient regime (CAMR Outcomes and Uptake, 24%). Disputing claims that CAMR was needlessly complicated, the Industry Canada representative suggested that CAMR was not onerous compared the regulatory impediments that generic drug companies face when they wish to market a generic version of a patented drug in Canada. But this viewpoint is precisely where

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192 "We've all heard that criticism of the regime: that it's unduly complicated and difficult to navigate. But anybody who is familiar with patent litigation in the pharmaceutical industry, particularly under the
stakeholders failed to see eye to eye: civil society and the generic drug industry contended that the developing country context has an entirely different set of needs and should be held to a different standard. The Government did not appear to accept these concerns, arguing that CAMR's policy outcomes were partly due to institutional barriers on the developing country side (Development, 12%) and due to developing countries' desire for technology transfer (Development, 12%).

Inadequate institutional capacity appears to be a legitimate concern but the MSF-Apotex experience suggests that it is a surmountable obstacle. In the case of Apotex, NGOs played a major role in filling this gap. Furthermore, CIDA acknowledged that it would provide technical assistance if a country requested it. As for the desire of developing countries to pursue technology transfer, it is not new. They have been advocating this since the 1950s (Kanji, 1992) but the political context in which they seek technology transfer is much different. TRIPS Article 66.2 it requires developed countries’ governments to provide incentives for their companies to transfer technology to least-developed countries. Whether the use of TRIPS flexibilities such as compulsory licensing trades-off developing countries opportunities for technology transfer is something that the African coalition opposed in 2001 at the WTO.

In discussing CAMR's lack of success (CAMR Outcomes and Uptake, 24%), the Government also stressed that other regimes were not being used either. Calling it a 'facilitating regime', the Conservative Government seemed to distance itself from CAMR's outcomes. Their comments suggested that they were not really accountable for the outcomes. Instead, the Government blamed the failure of the regime on the participating stakeholders, namely developing country governments and the generic industry, which does not have enough financial incentive to overcome the regulatory hurdles (this will be further discussed below). While it is true that none of the other


194 See: Comments by Ambassador Boniface Chidyausiku (Zimbabwe) (on behalf of the African Group); Meeting Minutes of the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines. 10 July 2001. IP/C/M/31
Paragraph 6 implementations have resulted in drug shipments, the question of whether or not the Canadian government is responsible for facilitating the success of this regime is to some extent beyond the scope of this research. Still, by off-loading responsibility for the outcomes of CAMR, the Government was able to uphold the primacy of protecting intellectual property rights. More precisely, it appears as though the Government assumed the primacy of patent protection, with the policy alternatives to achieve drug affordability immediately shifted to less intrusive means.

Along these lines, bureaucrats emphasized an equity (35%) and security (29%) argument. Drug affordability (7%) remained a major goal for the government, but CAMR fit within this goal as only one option available to developing countries. Instead, they emphasized other aid programs (29%) such as development assistance, financing of health sector programs and tax incentives for drug donations. In response to questions on whether CIDA could finance drugs under CAMR, they argued that this wasn't possible due to the principle of country ownership and that it was ultimately up to the country government to decide. As a CIDA representative said, "if the generic versions of these patented drugs are much cheaper in India, why on earth would you insist on their spending the money that you give them in Canada?"\(^{195}\)

When CAMR was designed in 2004, the Canadian government did not consult developing country governments to pursue country ownership of this regime, even though they were to be the beneficiaries. At that point, their apparent goal was to ensure that they complied with TRIPS, in context of their institutional preferences and their positions at the WTO. Theoretically speaking, the move of the government to tie aid to CAMR might provide the much-needed pull mechanism to make the system work. That said, civil society argued against tied aid as well, as they thought the regime would work most efficiently if capitalizing on free market forces such as profit-maximization and perfect competition. Nevertheless, by prioritizing country ownership of aid programs, the government was able to prioritize intellectual property rights. Had the Conservative

Government provided a pull mechanism for a compulsory licensing regime, they would be advocating this policy tool globally, which would not be in their interests.

**Liberal MPs**

While Liberal MPs showed an active interest in trying to address the major problems of the regime, their recommendations seemed to favor upholding current levels of intellectual property protection. As a party, they conveyed mixed messages. Some MPs tried to find ways to make the regime work through artificial "pull" mechanisms, while others appeared to distance themselves from the regime recommending to bypass it altogether. There is no doubt that the Liberals were in a difficult position having to manage the negative perceptions left from their initiative that was now coined by many a public policy failure (Attaran, 2007; Cohen-Kohler et al., 2007; Médecins sans Frontières, 2006). That said, as a whole, the Liberals appeared to be propagating the same message as in 2004: intellectual property could still be protected when crafting an effective compulsory licensing regime.

Although the Liberals stated that CAMR did remove "some roadblocks" to affordable drug access, they acknowledged that it was inefficient (CAMR Outcomes and Uptake, 21%). As with most other MPs, many of their questions were directed at finding out what went wrong during implementation. Among these issues, Liberal MPs acknowledged the lack of profit (5%) incentive as one of the barriers to the success of CAMR and they explored methods to 'alter the business case' under CAMR through government subsidization of the regime, through government aid (33%).

Aid (33%) was the driving theme in their emphasis on equity (35%), which speaks to the policy alternatives they ultimately favored. In particular, their emphasis on aid illustrates their attempts to salvage the success of their initiative. By recommending that CIDA "become a direct first-party provider of these services", some MPs suggested that the Canadian government solicit an importing country and facilitate the successful implementation of the regime, essentially creating the 'business case for CAMR. As mentioned earlier, civil society opposed "tied aid" because they believed that the regime
would be most effective more sustainable and reliable if it harnessed the profit-making incentives of the free market. Given that the WTO Decision does not allow that, doing so would require using another TRIPS clause. Civil society recommended an Article 30 solution but that course of action did not resonate with the Liberals. It is worth noting that the 2004 Liberal Government also did not advocate tied aid when establishing the regime. It is possible that they refrained from doing so for the same reasons as the Conservative Government: financing the success of a compulsory licensing regime in Canada, would take the Liberals' support for this policy tool one step further, which would signal opposition to the research-based industry's interests.

Some Liberal MPs did not see any value in trying to salvage the regime at all. They recommended that CIDA simply put up money to buy brand name drugs at a reduced price (11% affordability), "bypassing the patent issue altogether". In this sense, Liberals seemed to be promoting measures of charity and voluntary price reductions. The range of messages suggest the Liberals still did not hold a clear policy position on whether they favored generic competition or the reduced pricing schemes of the research-based industry.

Liberals' emphasis on liberty (28%) was mainly driven by references to intellectual property (17%) and TRIPS (11%). They were interested in uncovering what the key implementation problems were, many of which involved patent protections such as prior voluntary licensing negotiations, profit limitations and country notification. They questioned whether notification was necessary given the existing protections already incorporated into the regime to prevent abuse. Nevertheless, the Liberal Party continued to revisit solutions that assumed existing levels of patent protection needed to remain in place. For example, one Liberal MP proposed a solution similar to the research-based industry's 2004 proposal, the "equal opportunity to supply", which would grant generic companies a compulsory license only if they outbid the patent-holding company on a tender funded by CIDA. The Liberals discourse made it clear that they were just reluctant as they were in 2004 of curtailing intellectual property rights to improve the regime.
Even though the Liberal Party's discourse differs from the Conservative Party, their underlying policy goals do not appear to be much different: both parties seem to prefer avoiding compulsory licensing as a way of achieving drug affordability. The main difference lies in the Liberal Party's decision in 2004 to pursue the implementation of Paragraph 6 Decision in the first place, but as argued in Chapter 7, the Liberals crafted their regime with the underlying policy goals in mind.

**Bloc Quebecois (BQ)**

Most of the Bloc Quebecois' (BQ) policy positions were in line with the research-based industry's rhetoric, emphasizing efficiency (42%), equity (41%) and security (34%). Their discourse suggests that they aim towards a balance in these 2007 debates: they wanted to encourage the generic production of drugs but did not want to curtail intellectual property rights too much. They did this by picking and choosing various design issues to focus on but at the end of the day, their recommendations appeared cosmetic compared to civil society's and the generic industry's demands.

Some of their discourse reflected mild support for civil society's and the generic industry's positions. As with other MPs, they spent the majority of their question time, querying witnesses about the various impediments of the regime (CAMR Outcomes and Uptake, 33%). Like the Liberals, they encouraged participants to give the regime a chance, by recommending pilot projects to help better assess what was wrong with the regime. They also continued to advocate for the removal of the list of medicines (19%), a policy point that civil society lobbied strongly against during the 2004 debates. Still, these recommendations were far from the demands of civil society and the generic industry.

The rest of their discourse appeared to be more supportive of the research-based industry's interests, which as mentioned in Chapter 7 is likely due to the heavy presence of the research-based industry in Quebec. Even though they identified patented drugs as being unaffordable (10%) even at reduced prices, the BQ pointed towards aid (22%) as a mechanism to address this problem. They emphasized development-related barriers.
(24%), exploring the extent to which they impeded the regime and whether these issues should be dealt with first. As in the 2004 debates, they were highly supportive of the anti-diversion (10%) measures within the regime, suggesting that the problem was widespread.

Overall, it appears as though the Bloc Quebecois, while supportive of Canada's implementation of the Paragraph 6 Decision, and seems somewhat supportive of amendments to the regime that civil society propose, the major amendment – to pursue a simplified compulsory licensing mechanism through an Article 30 implementation—was not explicitly referred to by the BQ. Given their comments during the December 2009 discussion of the NDP's Bill C-393, it seems as though the Bloc supports a limited use of compulsory licensing.

The New Democratic Party (NDP)

The NDP spent the little time it had during the standing committee hearings asking witnesses what specific amendments were needed to fix the regime and blaming the 2004 Liberal Government for creating a regime that was built not to work (CAMR Outcomes and Uptake, 49%). They clearly believed that the problems with the regime were on the Canadian side, in the structure of the regime and in its implementation.

Being the only clear supporter of civil society's position, the NDP was in the minority. In 2004, they attempted over 100 amendments to Bill C-9, most of which did not pass essentially because they did not have the support of the other parties. Given their disadvantage, the NDP's had interests in distancing itself from the outcome of the regime by framing CAMR as a failure of political will by the leading party.

The NDP's discourse throughout the 2007 debates showed continued support of civil society interests. They framed certain patent protections as barriers to the regime; in particular, the delays in voluntary license negotiations, the two-year time limit on

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compulsory licenses and the need for country notification (IP, 11%), sympathizing with developing countries that may face intimidation when trying to use compulsory licensing (developing country pressure, 4%).

Not surprisingly, the NDP's overarching goal appeared to be encouraging the production and export of affordable generic drugs (affordability, 6%) through CAMR. Their lack of concern over defending the patent rights of the research-based industry shows that they were willing to commit to a more liberal interpretation of the TRIPS Agreement to facilitate this goal. Whether or not this interpretation would be challenged and found TRIPS compliant is subject to several legal debates but would ultimately rest upon the ruling of a WTO Appellate Body.

As mentioned in Chapter 7, these policy positions are consistent with the NDP's social democratic tradition of redistributing the benefits of innovation to society as opposed to being directed towards profit (New Democratic Party of Canada, 2001). Still, the fact that the NDP is not the governing party makes it easier for them to sustain such a position. The NDP's loyalty to this cause and their support of civil society in achieving it continued well after the 2007 debates. NDP members of the Senate and Parliament introduced two bills drafted by the Canadian HIV/AIDS Legal Network aimed to amend CAMR under TRIPS Article 30. The outcome remains to be seen at the time of writing.

**Independent MP André Arthur**

André Arthur is a former controversial Quebec radio show host who was voted in as an Independent in the Portneuf-Jacques-Cartier riding near Quebec City. Identifying himself as closest to Conservative values, his statements in the media reflect distrust in government and lack of faith in their ability to provide basic services.  

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In the little time that Mr. Arthur had to question witnesses, his position seemed consistent with the Conservative Government, labeling CAMR a failure and identifying the problems as lying mainly on the developing country side: government corruption and states' desire to build their own local manufacturing capacity. Recently, he voted against moving Bill C-393 (see Chapter 10, Epilogue) to committee for review, likely due to the same reasons. He did hold one position that was somewhat in line with the Liberals and Bloc Quebecois; he suggested that the only thing on the Canadian side that might help with CAMR's success would be for CIDA to finance the purchase of drugs coming out of the regime.

**The Dogs That Finally Barked**

A number of issues were raised during the 2007 debates that were identified as barriers to the regime. This section examines these issues and discusses the factors that may have been responsible for their under-representation in the debates.

**Technology Transfer and Procurement Practices**

In 2004, no one raised the goals of technology transfer or technological development within developing countries. Yet, developing countries' desire to increase their local pharmaceutical manufacturing capacity and technology transfer were among the reasons given by government bureaucrats and civil society representatives for the difficulty in finding a developing country willing to use the regime during the 2007 debates. Furthermore, the procurement protocols and laws that developing country governments are subject to was hardly mentioned during the debate and yet, identified in 2007 as one of the major problems of the regime. These discrepancies in framing can be partly explained by to the nature of the interests involved (Schattschneider, 1957).

198 Vote No. 142: 40th Parliament, 2nd Session - Sitting No. 122 - December 2, 2009
2nd reading of Bill C-393, An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act
Yeas: 143 - Nays: 127 - Total Votes: 270 - Paired: 0. Available at:
http://www2.parl.gc.ca/housebills/BillVotes.aspx?Language=e&Mode=1&Parl=40&Ses=2&Bill=C393
In relation to technology transfer, during the 2001 Doha negotiations, the African coalition of countries clearly framed one of the goals of compulsory licensing as increased technological capacity and development.199 Developing country governments, who might be beneficiaries to this regime, were not at the table during the 2004 debates. This is a function of the large domestic bias of the consultative process that was involved. Very rarely do witnesses from other countries – unless they are experts – come in and testify.

To facilitate access to the committee hearing process, committees have advertised scheduled hearings in the newspapers or on the committee’s website, to permit those interested to either submit a brief or contact the clerk to appear before the committee.200 Witnesses who testify before the standing committee are either invited to appear or request to appear.201 Witnesses may include private individuals, experts, organizational or group representatives, lobbyists, public servants, or cabinet ministers. The criteria committees use to select witnesses vary but "include the type of study and the amount of time available".202 The final decision as to who will be invited to testify rests with the committee.203 Committees may also request witnesses to submit written briefs instead of testifying, if time or other circumstances do not permit. For witnesses that do not reside in the area, it is possible to arrange testimony through video-teleconferencing, or by traveling to regions where the witnesses reside. Arguably, such arrangements could have been possible with policymakers or bureaucrats from beneficiary countries; however, no such arrangements to the author's knowledge were arranged. The only two representatives from developing countries who testified in 2004 included an MSF representative from Guatemala and a local government representative from Brazil.

199 See note regarding comments of Zimbabwean TRIPS ambassador, earlier in this chapter.
200 From: http://www.parl.gc.ca/information/about/process/house/WitnessesGuides/Part2-e.htm#section4
neither of whom spoke from the perspective of a potential beneficiary country government.\textsuperscript{204} Also, Dr. Fred Abbott, a professor of law at the University of Florida was invited to appear by the NDP representative on the committee. The remaining witnesses were from Canada.

Furthermore, a group needs to access whether the costs or benefits of a policy make it worthwhile for them to participate, especially in the context of their interests (Schattschneider, 1957). This factor is particularly relevant to developing countries that significantly lack institutional capacity and often cannot afford to get involved in these peripheral policy debates.

The issues of technology transfer and the local production of medicines did not surface until developing country governments actually tried to get involved in the regime and this only occurred as the result of the active outreach efforts by academics and by government bureaucrats’ in raising awareness and trying to assist developing country governments in using the regime (J. C. Cohen, Gyansa-Lutterodt, Torpey, Esmail, & Kurokawa, 2005; Perkins & de Wit, 2007). Had representatives of beneficiary country governments been more involved during the 2004 consultations, it is possible that these issues may have become more prominently discussed or considered. Moreover, the lack of attention to these issues also illustrates the extent to which concerns over intellectual property took over the debates.

By implementing the Paragraph 6 Decision, the Government appeared to be doing something positive for the developing world. A review of the accolades received by Canada from international organizations and global health leaders would suggest the same. That said, it appear that the Government paid careful attention to the needs and desires of a range of developing country governments when crafting the regime. Documents and debates going back as far as the 1950s show that many developing countries are interested in building their own technological capacity, even though it may

not always make economic sense. Ignoring this reality, among others, led the Government into crafting a regime that developing country governments are now not interested in using. But as will be discussed next, the lack of utility of CAMR ultimately has its roots in the WTO Paragraph 6 Decision itself.

Country Notification, Developing Country Pressure and the Feasibility of the Paragraph 6 Decision

Of all the discourse regarding the WTO TRIPS Agreement and the Paragraph 6 Decision, nowhere in the 2994 public debates was the issue of the actual feasibility of the Decision discussed. Scope of conflict theory (Schattschneider, 1964) can help explain why these issues did not receive the kind of attention in 2004 as they did in 2007. Kellow (Kellow, 1988) states that the enemy of what we want less, is what we want more: in 2004, civil society and the generic industry may have perceived the right of refusal, the lists of medicines and countries and allowing NGOs to purchase the medicines, as priority issues that had to be addressed. It is likely that civil society and the generic industry's fight to remove the right of refusal came at a cost of lobbying for other changes to the legislation. Also, civil society and the generic industry may not have anticipated the extent to which some of these issues would actually impede the regime.

While developing country pressure was mentioned by civil society, it is likely that identifying country notification as a major barrier to the regime in 2004 was not an option. In the early stages of legislative development, civil society tested the waters for an Article 30 solution, a direction that they are now insisting upon.205 They likely realized that this was not a feasible option under the political context and avoided bring it into the debate to avoid sabotaging the introduction of a compulsory licensing regime in Canada altogether. A similar argument can be made for the perceived problems under the Paragraph 6 Decision as well, which include the limits on profits for the generic industry.

These issues may not have been mentioned by either civil society or the generic industry because they wanted to make an imperfect decision work.206

Voluntary Licensing Negotiations

In 2007, the generic industry and civil society viewed the requirement to engage in voluntary license negotiations prior to application for compulsory license as another fundamental barrier. At the time of the hearing, Apotex stated that the process was held up at the voluntary licensing stage, having had to seek licenses from four different patent-holders of the fixed-dose combination product. In 2004, their testimony did not recognize voluntary license negotiations as an issue, likely because the policy alternatives that they were facing at the time were much worse. It appears as though the cost of lobbying against the right of refusal and other undesirable elements in the regime, displaced another issue that proved to be a barrier in the implementation of the regime.

Conclusions

This chapter synthesized the results from the content and qualitative analyses and analyzed them through the framework of framing, interests and institutions. In the case of the 2007 policy review of CAMR, the most significant factor appears to have been the preference of the Conservative Government to maintain the status quo and leave CAMR unchanged, which falls in line with their aggressive approach with respect to intellectual property protection in their foreign policy. These factors outweighed other aspects including the larger scope of actors involved in this debate and civil society's more integrated role with bureaucrats and the policy community. From the perspective of framing, the major point of divergence between stakeholders was their definition of what an efficient regime should look like. The government's definition was similar to that of the research-based industry. Moreover, what the results illustrate is that framing can

206 In his op-ed, Elliott wrote: "The WTO deal is imperfect. It creates too much red tape, too many procedural hoops for countries to jump through. And it sets up too many opportunities for governments beholden to "big pharma" to challenge sovereign developing countries in their attempts to make use of the agreed-upon procedure. But despite its flaws, the deal could, if robustly implemented with a minimum of interference, help countries circumvent patent restrictions and import generic versions of patented medicines if they cannot manufacture them within their own borders." (Elliott, 2003a)
obscure the real trade-offs in a policy debate and this can prevent many innovative policy balances from being achieved.

In 2007, the debate was much different focusing on the question of the efficiency of CAMR and identifying intellectual property protection measures and upstream implementation issues as impeding the participation of both the generic industry and developing country governments. Many of these issues were not the focus of the debates in 2004. This can be partly explained by to the nature of the interests involved (Schattschneider, 1957). Regarding the claims that developing country governments are ultimately interested in technology transfer and the local production of medicines, these did not surface until they actually tried to get involved in the regime. Their involvement only occurred as the result of the active outreach efforts by academics and by government bureaucrats' in raising awareness and trying to assist developing country governments in using the regime. Had representatives of developing country governments been more involved during the 2004 consultations, it is possible that these issues may have become more prominently discussed or considered.

Scope of conflict theory (Schattschneider, 1964) can also help explain why other perceived barriers, including voluntary license negotiations, country notification, and litigation, did not receive the kind of attention in 2004 as they did in 2007. Kellow (Kellow, 1988) states that the enemy of what we want less, is what we want more: in 2004, civil society and the generic industry may have perceived the right of refusal, the lists of medicines and countries and allowing NGOs to purchase the medicines, as priority issues that had to be addressed. It is likely that civil society and the generic industry's fight to remove the right of refusal came at a cost of lobbying for other changes to the legislation. Also, civil society and the generic industry may not have anticipated the extent to which some of these issues would actually impede the regime.

Nevertheless, some of these issues were briefly mentioned during the 2004 debates. For example, developing country pressure was mentioned by civil society but it is likely that identifying country notification as a major barrier to the regime in 2004 was not an
option. In the early legislative stages, civil society recommended an Article 30 solution, a direction that they are now insisting upon. They likely realized that this was not a feasible option under the political context and avoided bringing it into the debate to avoid sabotaging the introduction of a compulsory licensing regime in Canada altogether. A similar argument can be made for the perceived problems under the Paragraph 6 Decision as well, which include the limits on profits for the generic industry. These issues may not have been mentioned by either civil society or the generic industry because they wanted to make an imperfect decision work. Finally, the issue of protracted voluntary license negotiations was hardly raised in 2004, likely because the policy alternatives that they were facing were much worse.

Given these political dynamics, it appears as though the main factors that influenced CAMR's design are associated with framing the problem as the implementation of the WTO Paragraph 6 Decision, institutional context in which the debate took place and Canada's demands to comply with TRIPS in a way that would avoid trade sanctions. Had this debate taken place in an institutional context with greater policy space for other arguments, it is possible that a more expansive regime may have resulted.

The findings also suggest that the interests of the Liberal Government in 2003-4 and the Conservative Government in 2007 are not wide-ranging. Although the Liberal Government's decision to amend patent law to facilitate increased affordable drug access is not in line with the Conservative Government's intellectual property policy or its rhetoric, the Liberal Government's policy choices in designing CAMR weighed in favor of protecting the patent-holders' interests.

That the Conservative Government supported the Paragraph 6 Decision in the first place may be surprising; however, their support may speak more to the role that the implementation of the Paragraph 6 Decision played in constructing the norms around the use of compulsory licensing. Canada's implementation was seen by many as setting a

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precedent given it was the first country to announce its intention to implement the regime and given Canada's generic manufacturing capacity made it a credible producer. By supporting a limited and restrictive implementation of the Paragraph 6 Decision, the Conservatives were able to entrench a narrow role for this policy instrument. Just as the research-based industry participated in the debates to help shape the policy tool, the Conservatives' support of the regime gave them a say in what it would look like in the end.

The impact of framing can obscure the real trade-offs in a policy debates. For the research-based industry and its supporters, compulsory licensing is framed as breaking patents, theft and piracy. Throughout policy debates in many areas, social conservatives' arguments against government intervention share a similar connotation: government intervention is labeled as impinging on individual liberty and as inherently inefficient (Stone 2002). This widely held idea prevents many innovative policy balances from being achieved. Governments who wish to exercise their right to use compulsory licensing to facilitate equitable access to medicines are trading off the liberty of patent-holders; however, the real consequences of such restriction may not have such detrimental impacts on innovation or efficiency. There was no room for such debate in the CAMR policy context.
Chapter 10: Epilogue and Conclusions

Rwanda, Senate Bill S-232 and House of Commons Bill C-393

Weeks after the Conservative Government released its review on CAMR, a developing country publicly announced its intention to use CAMR. Rwanda formally notified the WTO of its desire to import medicines under the WTO Paragraph 6 Decision in July 2007.\(^{208}\) This notification was necessary for Apotex to apply for a compulsory license to manufacture the product legally for export (Elliott, 2008). A few months later, on September 20, 2007, Canada issued the first ever compulsory license under the WTO Paragraph 6 mechanism. Upon receipt of the compulsory licenses, Apotex still had to compete in and win an international bidding competition. Rwanda issued an international tender and almost one year later, on May 7, 2008, Apotex won the bidding process quoting a price of US$0.195 per tablet, at a cost of USD$146 per patient per year, lower than any other known generic manufacturer worldwide (Elliott, 2008). Shortly after, on September 27, 2008, Apotex sent the first of two shipments to Rwanda, which will be enough to treat roughly 21,000 patients for one year. The second and final shipment was exported one year later, and since then, Apotex has publicly stated that it is reluctant to participate in the initiative again unless changes are made to streamline the regime (Apotex, 2008). Nevertheless, Canada's Rx&D reported that all of the companies involved in the Rwandan case issued voluntary licenses to Apotex for continued production and export of the fixed-dose combination antiretroviral product (Canada's Research-Based Pharmaceutical Companies, 2009). To date, there have been no reports of continued production and export under these voluntary licenses.

From a policy perspective, there have been new developments in Canada since CAMR's legislative review in 2007. The Canadian HIV/AIDS Legal Network led a new campaign to introduce legislation in the Senate and Parliament to amend CAMR to facilitate a

streamlined, "one-license solution". Senate Bill C-232, a Private Member's bill, was introduced by outgoing Senator Goldstein on March 31, 2009 and was carried on by Senator Carstairs for a second reading in the Senate on May 14th. The Senate referred Bill C-232 to the Senate Committee on Banking, Trade and Commerce, which held hearings over the legislation in October 2009. Although the Senate Bill died upon the prorogation of Parliament in December 2009, NDP MP Judy Waslycia-Leis introduced a parallel, Private Member's legislative amendment in the House of Commons. Bill C-393 aimed to implement the Canadian HIV/AIDS Legal Network's "one-license solution". The Bill's first reading took place on May 25, 2009 and after the second reading on December 2, 2009, Parliament voted in a narrow majority, to bring the Bill to committee for review.

Politically, the NDP has issued its full support behind the regime; however, the remaining political parties seem somewhat divided. Liberal Industry Critic, Marc Garneau, actively opposes the regime, stating that CAMR's problems do not reside within the legislation and instead are on the developing country end: infrastructure, lack of medical staff, distribution networks, financing and lack of awareness about the regime. Meanwhile, a number of Liberal MPs voted in favor of moving it to committee for review. The Bloc Quebecois's comments during the December 2009 House of Commons debates suggest that although they advocate some amendments to the regime, they still support a fairly limited scope for compulsory licensing. The Conservative Government appears entirely opposed to the regime, aside from a few MPs who voted to forward it to

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209 For a full explanation of this one-license solution, see:
http://www.aidslaw.ca/EN/camr/index.htm#Documents


211 Vote No. 142: 40th Parliament, 2nd Session - Sitting No. 122 - December 2, 2009 2nd reading of Bill C-393, An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act. Yeas: 143 - Nays: 127 - Total Votes: 270 - Paired: 0. Available at:
http://www2.parl.gc.ca/housebills/BillVotes.aspx?Language=e&Mode=1&Parl=40&Ses=2&Bill=C393

committee. The Standing Committee hearings are scheduled for this 3rd Session of the 40th Parliament. At the time of writing, these hearings have not yet taken place.

**Global Drug Policy Developments: Does Paragraph 6 Still Matter?**

From a larger global drug policy perspective, there has been a large increase in international efforts aimed at improving drug access, including the growth of the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM), UNITAID and the Clinton Health Access Initiative (CHAI). The Global Fund was established in 2002 and since then it has generated and provided grants totaling US$19.2 billion dollars, of which US$10 billion was for HIV, tuberculosis (TB) and malaria control efforts. For HIV alone, these funds were responsible for putting 2.5 million people on antiretroviral therapy worldwide. UNITAID, an international financing facility started by Brazil, Chile, France, Norway and the United Kingdom in 2006, has raised as much as US$1.3 billion mainly through airline levies and recently by a huge contribution of support by the Gates Foundation. By 2010, 29 countries have committed to contributing to UNITAID. These funds have been used towards the purchase of medicines and diagnostics and provide long-term funding commitments to facilitate economies of scale to drive prices down. UNITAID has recently started to collaborate with the Clinton Health Access Initiative (CHAI, formerly known as the Clinton HIV/AIDS Initiative). Established in 2002, CHAI has organized the marketplace for pharmaceuticals through "forward pricing": the promise of future sales to pharmaceutical manufacturers, which allows manufacturers to invest in the capacity, achieve economies of scale and dramatically reduce their prices, creating profit margins through bulk production.

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213 For details on the status of Bill C-393, see: http://www2.parl.gc.ca/Sites/LOP/LEGISINFO/index.asp?Language=E&Chamber=N&StartList=A&EndList=Z&Session=23&Type=0&Scope=I&query=5834&List=toc-2
governments who agree up front to the bulk purchase of specific medicines (at the time of writing, CHAI has 70 members in this consortium). CHAI has negotiated price reductions for antiretroviral drugs with 8 suppliers on over 40 products and achieved significant price reductions with 12 suppliers for 16 HIV/AIDS diagnostic tests. Overall, CHAI has reduced the cost of first-line antiretroviral therapy by 50%, pediatric antiretroviral treatment by 90%, and a cumulative reduction of 30% on second-line antiretroviral drugs in low income countries.  

More recently, UNITAID's patent pool initiative is a promising venture that involves cooperation with the research-based industry around the voluntary licensing for certain drugs (ARVs). Recently, the last procedural hurdle was passed under UNITAID, clearing the way for the Patent Pool Foundation to start work. The Medicines Patent Pool Foundation has US$ 4.4 million in funding from UNITAID. It will soon begin negotiations with patent holders to license their patents. UNITAID's patent pool will have its limitations, some of which include the recent development that companies appear to be more interested in older ARVs and they are asking for market segmentation – middle-income countries like Brazil, India, South Africa and China may be prevented from either benefiting or participating in the patent pool. There are two major problems with the proposed market segmentation. First, the majority of people in these middle-income countries still live in poverty. In fact, India recently surpassed Sub-Saharan Africa in the number of people living in poverty, based upon a new UN index. Blocking these countries from benefiting from the low-cost medicines that may be produced under the UNITAID patent pools means that much fewer people in need will be

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able to get the drugs that they desperately need. Second, these countries have the manufacturing capacity and expertise in producing affordable generic drugs, so their participation in the Patent Pool initiative is critical. Another problem inherent in the voluntary patent pool as well as CHAI's negotiated price reductions is the fact that these negotiations can take considerable time, which translates into the delay of affordable medicines supply, which can cost millions of lives.

Current options for second and third line antiretrovirals are still limited. Orsi and d'Almeida report that although first-line therapy has benefited from market competition, second and third line antiretroviral drugs run significantly higher at rates such as US$ 610 and 1660 per patient per year (Orsi & d'Almeida, 2010). Prices in middle-income countries can run significantly two to three times higher (Orsi & d'Almeida, 2010). These second and third line drugs is an issue of keeping treatment programs sustainable and permitting the scaling up of treatment. It is from this perspective that global civil society activists still promote a role for compulsory licensing and the Paragraph 6 Decision, as a stick that country governments could use, to either speed up the process of obtaining these price reductions in needed areas of treatment, or to address those medicines where patent-holders are not willing to cooperate. Earlier this year (March 2010), the WTO held a workshop aimed to examine the Paragraph 6 Decision, given complaints by some developing countries (including India) that the Canadian experience shows that the Decision is not working (Balasubramaniam 2009). Clearly, some developing countries still believe that Paragraph 6 matters but CAMR's potential role in improving global drug access is still unclear. There may be potential for Canada to take advantage of its sophisticated manufacturing capacity through the production and export of active pharmaceutical ingredients or other expensive and difficult to produce products. Given Canada's sophisticated generic manufacturing capacity, CAMR may be able to serve a

222 See also, "Members ask: is the "Par.6" system on intellectual property and health working?" WTO webpage, available at: http://www.wto.org/english/news_e/news10_e/trip_02mar10_e.htm [Accessed 10 July 2010].

specialized role but the overall magnitude of CAMR's contribution to improving global drug access will likely be small.

Conclusions

Through a systematic analysis of the framing of policy debates, stakeholder interests and the relevant institutions, this analysis aimed to determine how stakeholders framed access to medicines in the case of CAMR and how framing, institutions and interests led to the policy product known today as Canada's Access to Medicines Regime. In 2004, policy debates were dominated by two themes overall: intellectual property rights and TRIPS compliance. Promoting the right to health through access to essential medicines and the impact of CAMR on innovation was hardly discussed. With the Departments of Industry Canada and International Trade as the lead institutions, the goals of protecting intellectual property and ensuring good trade relations with the United States appear to have taken priority over encouraging generic competition to achieve drug affordability. The result was a more limited interpretation of patent flexibilities under the WTO Paragraph 6 Decision. Perhaps the most striking finding is the minimal discussion over the potential barriers developing country beneficiaries might face when attempting to use compulsory licensing, including their reluctance to use TRIPS flexibilities, constraints inherent in the WTO Paragraph 6 Decision and reconciling many developing countries' desire to pursue technological development. Instead, these issues were raised in 2007, which can be partly accounted for by a greater representation of the interests of some developing country governments.

The 2004 content analysis results confirm the findings in similar studies looking at TRIPS-related policy debates over access to medicines (Abbott, 2005; Sell & Prakash, 2004; t'Hoen, 2009), to show that intellectual property issues dominated the policy contents. In particular, the focus on protecting intellectual property, complying with the TRIPS Agreement and the right of refusal clause effectively displaced the deliberation of other equally valid policy goals as well as upstream policy implementation issues. Further confirming previous literature, the underlying interests within this debate appeared to be divided into two positions: those who advocated a more limited use of
compulsory licensing and those who wanted a broader, more flexible regime. Not surprisingly, the research-based industry, backed by the Intellectual Property Institute of Canada, was in the first camp and civil society was in the latter. Meanwhile, the generic industry appeared to hold a mixed position throughout the debates. In 2004, they seemed like reluctant participants, given the lack of commercial incentive permitted by the Paragraph 6 Decision. After Apotex got involved in CAMR's implementation, the generic industry may have had more vested interests in the outcome of the 2007 debates, and held a position in line with civil society, advocating for a streamlined and easy-to-use compulsory licensing regime.

Overall, the research-based industry's policy positions were supported by Conservative party politicians, Bloc Quebecois politicians, and even the Liberal politicians, the sponsors of this initiative. As illustrated in Tables 7, 8 and 9, many of the design decisions made in 2004 sided with the research-based industry's requests. Meanwhile, political support for civil society and the generic industry was weak, with their sole support coming from the NDP with only one vote on the Parliamentary Committee. Although civil society won a key policy design battle with the removal of the right of refusal and preventing any early notification or bidding by the patent-holder, the victory was small in comparison to the existing framework they were already operating within.

From this perspective, the 2004 Canadian debates occurred within a limited policy space to start with. By framing the problem as the WTO Paragraph 6 Decision, the Liberal Government already influenced the direction of the policy process. With the Departments of Industry Canada and International Trade as the lead drafters of the legislation, the goals of maintaining a knowledge-based economy by continuing to protect intellectual property rights and ensuring good trade relations with the United States guided their interpretation of the WTO Paragraph 6 Decision. The Liberal Government effectively imported its policy positions from the WTO negotiations, many of which developing countries and civil society protested at the time. In the Canadian context, the result was a legislation that largely favored protecting intellectual property and a more limited interpretation of TRIPS when it comes to permitting patent flexibilities.
Of further importance is the private and non-transparent process by which the first draft of the legislation got designed. The only participants in these private consultations were representatives of the research-based industry, the generic industry and civil society. As Howlett describes, this process itself is quite common as it allows for the Government to control the scope of the policy debate (Howlett et al., 2009); however, it was during this stage that the legislation became quickly grounded in a more restricted interpretation of TRIPS, having reintroduced limitations on the scope of medicines and countries, as well as outlining specific restrictions on the nature of compulsory license under the regime. The public debates that permitted closer scrutiny, were conflicts over what was already a very narrow range of alternatives to choose from.

The qualitative contents of the policy debates in 2007 showed a much larger range of issues up for discussion when compared with 2004. Debates focused largely on the efficiency of CAMR, identifying intellectual property protection and upstream implementation issues as impeding the participation of both the generic industry and developing country governments. The framing differences observed can partly be explained by the nature of the policy process: the focus on one issue naturally comes at the expense of another (Kellow, 1988). It appears as though in 2004, civil society and the generic industry's focus on the right of refusal, the lists of medicines, the list of countries and allowing NGOs to be eligible purchasers under the regime, came at a cost of lobbying for other changes to the legislation.

One barrier received significant attention in the 2007 debates but failed to resonate when briefly mentioned in 2004. In particular, developing country pressure was mentioned by civil society in 2004 but it did not have resonance in the policy debate until most stakeholders and politicians acknowledged that country notification was a major impediment to CAMR's success.

Neither civil society nor the generic industry raised issue with country notification, profit limits and delays in voluntary license negotiations in the 2004. Their silence was likely
because the policy alternatives they were facing were much worse; however, that these issues are rooted in the WTO Paragraph 6 Decision itself leads to the obvious question of why civil society and the generic industry lobbied for the implementation of the Paragraph 6 Decision in Canada, despite their opinion that the Decision was flawed (Elliott, 2003a). It is possible that they have an incremental policy approach in mind (Howlett et al., 2009), as they are now calling on more fundamental changes to CAMR and the WTO system in general.

The framing differences observed between 2007 and 2004 can also be partly attributed to the fact that during implementation, new information about the nature of the problem and solution arises. More importantly, the framing differences can be accounted for by a greater representation of the interests of developing country governments. While the range of stakeholders involved in the 2007 legislative review remained similar to 2004, civil society, the generic industry, government bureaucrats and even the research-based industry, had more interaction with beneficiary country representatives which was specific to CAMR, yielding new and more relevant information. On civil society's end, groups from the University of Toronto attempted to facilitate the use of CAMR with Ghana. On the Government bureaucracy's side, outreach efforts were directed to developing country governments spreading awareness about CAMR. Apotex was actively involved with civil society attempting to find a country willing to use CAMR. Even the research-based industry stated that it was involved in outreach regarding CAMR towards developing country governments. Finally, civil society's organized expert consultation involved representatives from developing country governments, international organizations, the generic industry and civil society. Hence, a much larger range of issues came to the fore. Had representatives of developing country governments been more involved during the 2004 consultations, it is possible that these issues may have become more prominently discussed or considered.

Both sets of debates saw a number of issues pertinent to drug access not raised, or if they were, they were not taken up by the political system. These under-represented themes included innovation, the domestic economy and human rights. The silence on these issues
speaks to a larger question of the assumptions underlying policy debates on access to medicines and intellectual property and policy alternatives that were not explored.

Focusing on human rights in particular, it appears as though both civil society and the Liberal Government mentioned the issue of human rights but it did not have much resonance within the political system. Civil society's silence on the issue of human rights within the debates is particularly surprising, given their emphasis on this issue in previous policy debates. Most likely, they realized the lack of emphasis of the government and other politicians on this policy goal, so they strategically framed their discourse to suit the Standing Committee's needs.\(^{224}\) Perhaps more striking is the contrast between the Liberal and Conservative Government's rhetoric on human rights, which appear to be rooted in a very different conception of the realization of the right to health. The Liberal government framed CAMR early on as a tool to pursue human rights (Graham, 2003) and a Liberal MP further suggested that Canada's responsibility includes running projects to help implement CAMR in other countries. These goals did not get incorporated into the final policy design. In contrast, the Conservative Government did not view their responsibilities as extending to the promotion of the right to health for those in other countries.\(^{225}\) Whether or not this legal argument would hold in the courts is beyond this thesis; however, it illustrates their stark opposition to civil society's interpretation of Canada's human rights obligations in the case of CAMR. Furthermore, it leads to a much broader question, which is: what are states' obligations to ensuring access to medicines in other countries and how does this relate to the WTO Paragraph 6 Decision.

The impact of CAMR on global drug policy is beyond the scope of this thesis; however, the research findings point towards some possibilities. The Canadian initiative may have encouraged other countries to implement similar legislation, given the fact that Canada

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\(^{224}\) For example, an entire section of the Canadian HIV/AIDS Legal Network's written submission to the Standing Committee framed a less restrictive interpretation of the WTO Paragraph 6 Decision in terms of Canada's international human rights obligations.

\(^{225}\) The Conservative Government stated, "...While that covenant [the International Covenant on Economic, Social and Cultural Rights] requires each state party to promote the right to health for its own citizens, there is no interstate obligation to protect the right in other countries, and while all international development assistance, including health-related assistance, is a moral and not a legal obligation, Canada has been a major donor to health-related initiatives in the developing world."
was the first country to announce its intention to implement the WTO Decision. Indeed, many other jurisdictions including Norway, India, the EU, and South Korea, to name a few, implemented the Paragraph 6 Decision but none of them have resulted in any exports. More broadly, however, it appears as though CAMR may have further entrenched a limited scope for compulsory licensing in the context of the WTO Paragraph 6 Decision. At best, CAMR provides evidence that better solutions are needed to address drug affordability (Médecins sans Frontières, 2006).

From the perspective of the public policy process, the case study and analysis presented in this thesis shows that framing can obscure the real trade-offs in a policy debates. For the research-based industry and its supporters, compulsory licensing is framed as breaking patents, theft and piracy. Throughout policy debates in many areas, social conservatives' arguments against government intervention share a similar connotation: government intervention is labeled as impinging on individual liberty and as inherently inefficient (Stone, 2002). This widely held idea prevents many innovative policy balances from being achieved. Evidence suggests that the use of compulsory licensing in countries where there is negligible pharmaceutical purchasing power will not be detrimental to pharmaceutical innovation (Commission on Intellectual Property Rights, Innovation and Public Health, 2006). But those strongly opposed to the use of compulsory licensing in developing countries appear to be more concerned about a slippery slope; a fear that compulsory licensing would become a more widely used policy tool and eventually cut into the markets and R&D budgets of the research-based industry. As a consequence, the gradual decline of compulsory licensing as a legitimate policy tool to address drug access removes one more policy tool from governments' arsenals to address the problem of high drug costs.

Still, different institutions value these policy goals differently. In the courts, human rights claims towards affordable drug access trump claims over intellectual property rights. For example, Hogerzeil et al found that in 59 of 71 court cases across 12 countries, access to medicines as the fulfillment of the right to health was legally enforced (Hogerzeil et al., 2006). Given the increased receptivity of the courts to the right to health, it is possible
that Canada's interpretation of the Paragraph 6 Decision could be challenged within a domestic legal context and is a proposition worth further exploration.

At the World Health Organization, the relationship between innovation and intellectual property protection is being examined and reframed towards the goal of redirecting industry research towards the disease burden of the developing world (Commission on Intellectual Property Rights, Innovation and Public Health, 2006). Developing state governments with enough political and economic capacity have also stepped up and used compulsory licensing in stark opposition to threats of trade sanctions or removal of drugs from the market. Brazil has been using the threat of compulsory licensing for over a decade towards obtaining discounts in patented medicines or towards the local production of medicines (J. C. Cohen & Lybecker, 2005). Most recently, Brazil announced that it would impose compulsory licensing measures for US-made pharmaceuticals in response to a WTO ruling, which ruled that U.S. cotton-farmer subsidies were unlawful, and the WTO approved Brazil's use of compulsory licensing as an appropriate response. In this context, compulsory licensing can be framed as a legitimate trade sanction against the United States. In 2007, Thailand issued compulsory licenses, despite protests by the multinational research-based industry, who argued that this would harm innovation and potentially result in trade sanctions (L. Esmail et al., 2007). More recently, Ecuador issued a decree permitting the use of compulsory licenses for diseases considered to be the country's public health priorities. These are just some of the examples of other political contexts that involve a different set of actors, consider a different array of arguments and ultimately have different priorities.

Nevertheless, the opposing positions on the use of compulsory licensing towards drug affordability speak to a larger ideological divide in global drug policy: one based on the principles of the efficiency of market competition and another which relies on voluntary price reductions. These ideas represent an overarching trend, especially in the United States, where government intervention in pharmaceutical markets is viewed as inherently

inefficient and the goals of cost-containment and affordable drug access should be pursued in cooperation with the research-based industry. Moreover, by framing voluntary price reductions in the developing world as a philanthropic activity, the research-based industry and its supporters appear to be framing affordable drug access as an issue of charity as opposed to a fundamental human right.

A similar connotation was present throughout the CAMR debates. The Paragraph 6 Decision and CAMR itself was consistently framed as a humanitarian initiative; however, nowhere in the text of the Paragraph 6 Decision is this theme ever mentioned (World Trade Organization, 2003b). Viewing compulsory licensing as a humanitarian venture may obscure the stated end-goals of many developing country governments towards the pursuit of broader social and economic goals, including technological development. Moreover, permitting or facilitating compulsory licensing as an act of charity seems to obscure the fact that it is a right, further pointing towards the utility of human rights law towards improving drug access, and other social and economic goals. As Kofi Annan states:

"…a rights-based approach to development describes situations not simply in terms of human needs, or developmental requirements, but in terms of society's obligations to respond to the inalienable rights of individuals; empowers people to demand justice as a right, not as charity; and gives communities a moral basis from which to claim international assistance when needed." (Hogerzeil et al., 2006)

It is possible that framing the drug access dilemma as one between humanitarian and commercial goals actually favors the interests of the research-based industry. Instead, framing the conflict as one between human rights and intellectual property rights may

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228 For example, the Obama administration negotiated with PhRMA to obtain cost reductions of $80 billion USD for drugs purchased under the Medicare Prescription Drug Benefit Plan D. In exchange, the Obama administration has proposed that it will not use its purchasing power to negotiate drug prices.

229 Besides, compulsory licensing is precisely how the United States, Canada, India, Brazil and many other countries achieved such vibrant pharmaceutical industries, either generic or innovative. See May and Sell (2006).
better respect developing countries broader and more long-term social and economic goals. Such frames would likely be given more priority in the courts.

Along these lines, future research may consider further examination of the policy consequences of the use of humanitarian rhetoric on initiatives to improve drug access. For example, humanitarianism is often linked to not-for-profit initiatives (L. C. Esmail et al., 2010), a relationship that was apparent in CAMR and deserves deeper investigation. Such studies could better assess how these frames affect the way policy-makers and stakeholders view the policy alternatives available, the mechanisms to achieve drug access and help uncover how stakeholders view their responsibilities in facilitating access to medicines for all.

Furthermore, more research appears to be needed on the content of policy debates on access to medicines and the evaluation of their impact on global health policy in general. MacIntosh and Koivusalo have recently pointed towards the potential unintended consequences of the access to medicines debates on the direction of health policy (Koivusalo & Mackintosh, 2009). They argue that while civil society's goals of improving access to antiretrovirals is laudable and that their actions succeeded in getting access to medicines on the agenda, they have been less successful in influencing policy solutions. One of the consequences of this has been the shift of global health policy towards the "commercialization of global public action", leading to an increased focus on technology as a solution to global public health disparities. Furthermore, the focus on HIV/AIDS, while important, has entrenched a vertical disease-based focus on health, which has dominated global policy debates and evidence suggests it has had negative impacts on the integrity of health systems in developing countries (Grepin, 2009). While this argument is consistent with criticisms as early as 1970s, it remains relevant today since framing influences the policy alternatives that decision-makers consider. A broader analysis of global health policy debates including those on drug access and intellectual property may contribute to the understanding of what policy alternatives have been taken off the agenda and the institutional mechanisms that keep them off. Such analysis would
help contribute to a more comprehensive understanding of the direction of global health policy and the policy alternatives available.

**Limitations**

The limitations of this research are discussed in relation to the case selected and the methodology employed. First, CAMR as a case study on the topic of drug access in developing countries will be discussed. Within the range of policies that exist to address access to medicines, the case of CAMR is a narrow and specific one. The case is limited to the implementation of the WTO Paragraph 6 Decision and the range of actors and the debate contents are only one sample from a broad range of actors, issues and values that are involved in tackling the issue of drug access in developing countries. For example, debates at a multilateral institution, such the WHO, include a broad range of state actors and sometimes civil society and industry representatives. A broader case study could provide more information on the range of possible policy alternatives that are available to pursue drug access and to better assess, as Koivusalo and MacIntosh (2010) ask, how institutions and interests favor some policy alternatives over others. This case was chosen, however, due to its urgency as a policy dilemma: the goal of affordable drug access often conflicts with the goal of protecting intellectual property, and too often, policy initiatives in this area uphold the rights of patent-holders at the expense of patent law reform that would better promote fast, low-cost, generic production to improve global drug access.

A case study of CAMR provided a detailed and rigorous account of a critical global drug policy question: what political factors influence policies that aim to reduce drug prices through the use of patent flexibilities? Furthermore, given CAMR's relevance to the global Paragraph 6 debate—Canada remains the only country to have produced and exported under the Paragraph 6 mechanism—the findings from this research have global drug policy significance. Specifically, CAMR has important lessons to pass on to civil society advocates and policy-makers worldwide about the conditions under which such flexibilities may or may not be politically feasible. In the case of CAMR, strong economic and political interests in protecting intellectual property were entrenched in
Canada's political and institutional structures, which effectively led to a regime where compulsory licensing was meant to be a last resort measure. The findings from this study can inform advocates' and policy-makers' framing strategies, their use of institutions and scope of conflict, to inform future policy initiatives in this area.

Ideally, a comparative case study between CAMR and other state's implementation of the Paragraph 6 Decision may have elucidated more information on how different institutional structures and contexts and a different set of interests impact the outcome of such legislation. For example, India's implementation of the Paragraph 6 Decision appears to have been the broadest interpretation, as it did not include restrictions such as limiting the Decision to a list of diseases, countries and did not put explicit limits on the profitability of generic manufacturers who would use the regime (Ng & Kohler, 2008). Still, the range of possible outcomes from Paragraph 6 remains limited, so the utility of such findings may be limited.

From a methodological perspective, case studies impose some challenges in the generalizability of the findings. Unlike quantitative analyses that provide the statistical foundations to apply findings to other contexts, case studies require the extraction of important factors and lessons learned that can then be applied to other policy contexts. Still, the range of industry and civil society actors involved in CAMR resembles that across other case studies of the global access to medicines campaign and stakeholders' arguments and values appeared to mimick those frames that have been used throughout the debates over intellectual property and drug access since the start of the global civil society campaign in 1999 (Sell and Prakash 2004; Barnard 2002; Abbott, 2002; Abbott, 2005). These similarities facilitate the applicability of these findings to other cases where the goal of drug affordability conflicts with intellectual property rights.

The mixed method content analysis technique imposed its own limitations on the research but these limits are highly related to the heterogeneity of the literature in which this study is based. This thesis research appears to be the only rigorous, comprehensive analysis of

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230 See Ng and Kohler 2008 for a comparison of CAMR with other countries' regimes.
policy contents in the area of drug access and intellectual property. The use of a codebook in this study was required to ensure reliability and validity of the findings. That said, the codebook is unique therefore the transferability of the quantitative content analysis results are limited to the themes searched for. However, the qualitative summaries of the themes provide sufficient information to the reader who may be seek a different perspective on how stakeholders framed the issues.

Lastly, the content analysis was limited to the standing committee hearing transcripts. These data boundaries were drawn in relation to ensuring a representative cross-section of the debates were used and also out of respect of the resource and time limitations of the research itself. Of course, a wider swath of data over a larger period of time likely would have covered more themes and more actors. Nevertheless, the case boundaries were defined much more broadly, with the literature review covering documents prior to the WTO Paragraph 6 Decision and up until the 2007 debates. Furthermore, the thesis included discussion of issues up until mid-2010 in relation to the developments around CAMR, Paragraph 6, and developments globally on drug access. This context helped triangulate the findings of the content analysis and provided additional data to ensure a complete picture of CAMR's political development was presented.
Appendix 1: Codebook for Content Analysis

**Equity Goals**

**Aid:** discussion of any form of assistance or help given to developing countries towards improving their country, quality of life, and increasing drug access. Aid can come from countries, organizations, companies/corporations or individuals. Includes technical assistance and cooperation and 'support'.

**List of Medicines:** discussion regarding the scope of drugs eligible under this legislation. "scope of drugs covered by the decision remains a subject of considerable debate…" "on the question of the scope of eligible drugs…"

**List of Countries:** discussion about the list of eligible countries, otherwise known as Schedules 2, 3 and 4. These schedules restrict the eligible countries to those who are members of the WTO or are considered least-developed countries according to the UN Development Index.

**Equal Opportunity to Supply:** discussion and debate about brand-name companies' counterproposal to the Right of Refusal.

**Security Goals**

**Drug Affordability:** Discussion of drug costs, expensive or cheap drug prices, or pricing policies. Keywords: low/cheap prices, expensive, costs, afford.

**Development:** discussion of development-related issues which are important areas that need to be addressed, or problems, barriers, or deficiencies. Development-related issues are basic facilities, services and installations needed for the functioning of a community or a society. For example: roads, schools, buildings, clean water, education. Includes technology transfer.

**Canada's Domestic Economy:** references to the relevance or implications of the pharmaceutical industry to the domestic economy of Canada. Examples include jobs, employment, investment.

**Innovation:** Innovation in general or specific to the health field, which includes discovery, research and development (R&D) of new pharmaceuticals and other medical technologies.

**Human Rights:** code for discussion of human rights. As it relates to medicines, human rights may be referred to in relation to international covenants, treaties or laws.

**Quality and Safety:** discussion of drug quality, safety and the drug approval process. This includes references to existing global and national standards and processes.

**Liberty Goals**

**Intellectual Property Protection:** discussion of the protection of intellectual property. Specifically focused on patents and IP as opposed to the policy tools that use/manipulate IP such as VL/CL.
**Right of Refusal:** discussion and debate regarding the Right of Refusal.

**Developing country pressure:** references to pressure put on developing countries from other countries or institutions.

**WTO TRIPS Agreement:** references to the TRIPS Agreement, the Paragraph 6 Decision, the Doha Declaration and any requirements or related clauses.

**Efficiency Concepts**

**Market competition:** discussion of competition in a market between firms. Often used in reference to generic competition to lower prices.

**Litigation:** discussion about threats or taking legal action either against pharmaceutical companies or originating from the companies.

**Profits:** discussion of profit, defined as financial gain after all investments and costs are taken into account; discussion of return on investment. Keywords: profit, "make money" "return on investment"231.

**Diversion:** discussion about diversion, the situation in which pharmaceuticals that are intended for a specific market are illegally diverted to a different market and sold at a higher price. Includes reimportation and discussion of mechanisms to prevent diversion (anti-diversion) including marking and labeling.

**Procurement:** discussion of pharmaceutical procurement practices, rules or laws.

**Eligible Importers:** discussions of the possibility of having NGOs import the medicines, contracting directly with or purchasing the medicines directly from Canadian generic companies.

**CAMR Outcomes and Uptake:** discussion about why CAMR isn't resulting in outcomes or being taken up by developing countries or the generic industry.

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231 This means profit according to: [wordnet.princeton.edu/perl/webwn](http://wordnet.princeton.edu/perl/webwn)
Appendix 2: List of Witnesses and Submissions (2004)

Witnesses (2004)

The following lists the witnesses who testified before the Standing Committee on Industry, Science and Technology on Bill C-9 (otherwise known as CAMR).

Canadian Federal Government
Department of Industry:
  • Rob Sutherland-Brown, Senior Counsel, Legal Services, Justice Canada; Marie-Josée Thivierge, Director General, Marketplace Framework Policy Branch.
Department of Health:
  • David K. Lee, Director, Office of Patented Medicines and Liaison, Therapeutic Products Directorate, Health Products and Food Branch.
Canadian International Development Agency:
  • David Maloney, Vice-President, Policy Branch; Sandra Black, Director, Social Development Policies.
Department of Foreign Affairs:
  • Marie Gervais-Vidricaire, Director General, Global Issues Bureau.
Department of International Trade:
  • Suzanne Vinet, Director General, Trade Policy, Services, Investment and Intellectual Property Bureau

Industry Representatives
Canada's Research-Based Pharmaceutical Companies (Rx&D):
  • Jean-François Leprince, President, Aventis Pharma; Terry McCool, Vice-President, Corporate Affairs, Eli Lilly Canada Inc.
Canadian Generic Pharmaceutical Association:
  • Jim Keon, President;
Novopharm Limited.
  • David Windross, Vice-President, Government and Professional Affairs,
Intellectual Property Institute of Canada:
  • Carol Hitchman, President; Patrick Smith, Chair, Patent Legislation Committee.

Civil Society Organizations and Individuals
Canada-Africa Community Health Alliance:
  • Don Kilby, Chairman.
Canada-Africa Partnership on AIDS
  • Kevin Perkins, Executive Director.
Canadian Council for International Cooperation:
  • Gauri Sreenivasan, Policy Coordinator.
Canadian HIV/AIDS Legal Network:
  • Richard Elliott, Director, Policy and Legal Research.
CARE Canada:
Michelle Munro, Policy and Programs Advisor, HIV/AIDS and Health.
Oxfam Canada:
  - Mark Fried, Communications and Advocacy Coordinator.
Health Partners International of Canada:
  - John P. Kelsall, President.
Interagency Coalition on AIDS and Development:
  - Michael O’Connor, Executive Director.
KAIROS (Global Economic Justice Program)
  - John R. Dillon, Coordinator
McGill International Health Initiative:
  - Srinivas Murthy, General Executive, Students Against Global AIDS.
Médecins Sans Frontières:
  - Rachel Kiddell-Monroe, Coordinator (Canada) Access to Essential Medicines Campaign; Virginia Gularte, Medical Doctor, MSF Guatemala.
North-South Institute:
  - Chantal Blouin, Researcher, Trade and Development.
Rights and Democracy
  - Jean-Louis Roy, President.
United Church of Canada:
  - Jim Sinclair, General Secretary
World Vision Canada
  - Dave Toycen, President.

Individuals
  - Frederick M. Abbott, Edward Ball Eminent Scholar, Professor of International Law, Florida State University College of Law.
  - Anivaldo Padilha, Secretary of Planning and Cooperation, Koinonia, Brazil.

Written Submissions (2004 policy consultations)

Civil Society Organizations and Individuals
  - Canadian HIV/AIDS Legal Network:
    o 5 submissions from February 26, 2004 to April 19, 2004
  - Jillian Cohen, Assistant Professor, Leslie Dan Faculty of Pharmacy, University of Toronto (February 2004)
  - Tom Cochrane, Musician (March 10, 2004)
  - John Courtney (unknown affiliation, unknown date)
  - Joel Lexchin, Associate Professor, School of Health Policy and Management, York University (February 23, 2004)
  - McGill International Health Initiative (MIHI) (March 9, 2004)
  - Médecins Sans Frontières
    o 1 submission on March 10, 2004
  - TRT-5 (French AIDS Treatment Coalition, Paris, France)
    o 1 submission on March 7, 2004
  - World Vision
30 submissions on March 5 and March 11, 2004

Industry Representatives
- Canadian Generic Pharmaceutical Association (CGPA)
  o 2 submissions on February 26, 2004 and March 2004
- Canada's Research-Based Pharmaceutical Companies (Rx&D)
  o 2 submissions on February 26, 2004 and March 2004
- Intellectual Property Institute of Canada (IPIC)
  o 1 submission on March 9, 2004

Other Special Interest Groups
- Canadian Union of Public Employees (CUPE):
  o 2 submissions on March 15, 2004 and April 2, 2004
Appendix 3: List of Witnesses and Submissions (2007)

Witnesses (2007)

The following lists the witnesses who testified before the Standing Committee on Industry, Science and Technology on Canada's Access to Medicines to Regime (CAMR).

Department of Health:
- Mr. David Lee, Director, Office of Patented Medicines and Liaison, Therapeutic Products Directorate, Health Products and Food Branch.

Department of Foreign Affairs and International Trade:
- Mr. Douglas George, Director, Intellectual Property, Information and Technology Trade Policy Division
- Mr. Robert Fry, Senior Departmental Coordinator, Pandemic Preparedness, Human Security and Human Rights Bureau.

Canadian International Development Agency
- Mr. Christopher Armstrong, Team Leader, HIV/AIDS.

Department of Industry
- Mr. Douglas Clark, Director, Patent Policy.

Research-Based Industry Representatives
Canadian's Research-Based Pharmaceutical Companies
- Mr. Russell Williams, President.

Gilead Sciences Inc.
- Mr. Gregg Alton, Senior Vice-President and General Counsel.

Eli Lilly Canada Inc.
- Mr. Terry McCool, Vice-President, Corporate Affairs

Generic Industry Representatives
Canadian Generic Pharmaceutical Association
- Mr. Jim Keon, President

Apotex Inc.
- Mr. Jack Kay, President and CEO

Civil Society Organizations and Individuals
Canadian HIV/AIDS Legal Network
- Mr. Richard Elliott

Health Partners International of Canada
- Mr. John Kelsall, President

Interagency Coalition on AIDS and Development
- Mr. Michael O'Connor, Executive Director.

International Human Rights Program, Faculty of Law, University of Toronto
- Sarah Perkins

Médecins Sans Frontières
• Carol Devine, Adviser, Campaign for Access to Essential Medicines..
The Stephen Lewis Foundation
• Mr. Stephen Lewis, Chair, The Stephen Lewis Foundation, Former UN Special
  Envoy for HIV/AIDS in Africa
Oxfam Canada
• Mr. Robert Fox, Executive Director.

**Written Submissions (2007)**

The following lists all of the stakeholder groups that submitted a response to the consultation paper by January 23, 2007.

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<tr>
<th>Research-Based Industry</th>
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<td>Research-Based Industry</td>
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<td>Research-Based Industry</td>
<td>BMS</td>
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<td>Research-Based Industry</td>
<td>Eli Lilly</td>
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<td>Roche</td>
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<td>Research-Based Industry</td>
<td>Rx&amp;D</td>
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<td>Research-Based Industry</td>
<td>Wyeth</td>
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<td>Research-Based Industry</td>
<td>BiotecCanada</td>
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<td>Research-Based Industry</td>
<td>EFPIA (European Federation of Pharmaceutical Industries and Associations)</td>
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<tr>
<td>Research-Based Industry</td>
<td>IFPMA</td>
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<tr>
<td>Research-Based Industry</td>
<td>IPHA (Irish Pharmaceutical Health Care Association)</td>
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<tr>
<td>Interest Group</td>
<td>CCC (Cdn Cham Comm)</td>
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<tr>
<td>Generic Industry</td>
<td>Apotex</td>
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<tr>
<td>Generic Industry</td>
<td>CGPA</td>
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<tr>
<td>Politician</td>
<td>J. Peterson (MP)</td>
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<td>Politician</td>
<td>Keith Martin (MP)</td>
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<tr>
<td>Politician</td>
<td>N.S. Bains (MP)</td>
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<td>Civil Society</td>
<td>NGOs, academics, leaders</td>
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<td>UofT ADI</td>
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<td>Civil Society</td>
<td>Aidslaw</td>
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<td>Civil Society</td>
<td>CCI (Canadian Crossroads Int'l)</td>
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<td>Civil Society</td>
<td>HPIC</td>
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<td>Civil Society</td>
<td>McGill (HRWG)</td>
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<td>Civil Society</td>
<td>MSF</td>
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<td>Civil Society</td>
<td>Oxfam</td>
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<tr>
<td>Civil Society</td>
<td>UNICEF, World Vision, Save the Children, Plan Canada</td>
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Appendix 4: Glossary of Participating Stakeholder Groups

Key Departments in CAMR's Policy Development

Canadian International Development Agency (CIDA)
The Canadian International Development Agency (CIDA) is Canada's federal international development agency. Its mandate is "to manage Canada's support and resources effectively and accountably to achieve meaningful, sustainable results and engage in policy development in Canada and internationally, enabling Canada's effort to realize its development objectives." CIDA is overseen by the Minister for International Cooperation. It is responsible for administering Canada's international development assistance and partners with a range of domestic and international actors including NGOs, industry, international organizations, and country governments to achieve its goals.

Department of Foreign Affairs and International Trade (DFAIT)
The Department of Foreign Affairs and International Trade (DFAIT) is a federal department whose mandate is three fold: "ensuring that Canada's foreign policy reflects true Canadian values and advances Canada's national interests; strengthening rules-based trading arrangements and to expand free and fair market access at bilateral, regional and global levels; and, working with a range of partners inside and outside government to achieve increased economic opportunity and enhanced security for Canada and for Canadians at home and abroad." Prior to the 2007 CAMR debates, DFAIT was split into two departments, with two divided mandates: the Department of Foreign Affairs, and the Department of International Trade.

Health Canada
"Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health." It's main roles are to assist with the administration of the Canada Health Act, financing through providing policy support to the federal government for the Canada Health Transfer, protecting Canadians from harm and facilitating their health through the regulation and approval of health and other products, a service provider in environmental health and protection and an information provider of research and surveillance.

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232 In alphabetical order.
Industry Canada
Industry Canada is a federal department whose mission is "to foster a growing, competitive, knowledge-based Canadian economy." Its mandate is "to help make Canadian industry more productive and competitive in the global economy, thus improving the economic and social well-being of Canadians." Industry Canada oversees a number of tasks including the development of industrial and technological capacity, fostering scientific research, crafting telecommunications policy, promoting trade and investment, promoting small business development and tourism, and outlining the rules and the services that promote effective operation of the marketplace. Several branches are under Industry Canada including the Canadian Intellectual Property Office (CIPO), which is responsible for granting intellectual property rights and for the overall administration of the Patent Act, among other relevant laws.

Participating Industry Groups
Canada's Research-Based Pharmaceutical Companies (Canada's Rx&D)
Canada's Rx&D "is the national association representing over 15,000 men and women who work for 50 research-based pharmaceutical companies in Canada." Since 2004, their President has been Russell Williams. Headquarters is located in Ottawa and regional staff work across Canada. Their mission is to: "[a]dvocate for policies that will bring the best innovative medicines and vaccines to Canadians in a timely and appropriate manner; improve Canada's global competitiveness; and make Canada a world leader in attracting pharmaceutical and biotechnology investments, which are key components of the knowledge-based economy."

Canadian Generic Pharmaceutical Association (CGPA)
The Canadian Generic Pharmaceutical Association (CGPA) is the association that represents "…manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry." Jim Keon is the President of the CGPA. Its member companies include finished dosage manufacturers, industry suppliers/active ingredient manufacturers, and contract research organizations.

Intellectual Property Institute of Canada (IPIC)
The Intellectual Property Institute of Canada (IPIC) is a professional association in Canada that represents the interests of intellectual property practitioners. Their objectives are to: "represent the interests of Canadian intellectual property practitioners; influence the development of intellectual property laws to the extent they impact intellectual

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238 In alphabetical order.
239 See: "Canada's Research-Based Pharmaceutical Companies (Canada's Rx&D): About Rx&D". Available at: [https://www.canadapharma.org/en/about/CorporateInformation.aspx](https://www.canadapharma.org/en/about/CorporateInformation.aspx) [Date Accessed 11 July 2010].
240 See the "Canadian Generic Pharmaceutical Association: About CGPA". Available at: [http://www.canadiangenerics.ca/en/about/who_we_are.asp](http://www.canadiangenerics.ca/en/about/who_we_are.asp) [Date Accessed 11 July 2010].
property matters in Canada; be the recognized and visible authority on Canadian intellectual property law and practice; ensure high levels of knowledge, training, and ethics in Canadian intellectual property practitioners; and, increase the level of intellectual property business in the Canadian economy. 241

**Participating Civil Society Organizations** 242

**Canada-Africa Community Health Alliance**
The Canada Africa Community Health Alliance (CACHA) is a humanitarian foundation that provides basic health care to isolated African villages, assists in the fight against HIV/AIDS, and assists with the developing the human resource capacity in Canada, Gabon, Bénin, Tanzania and Uganda. 243

**Canada-Africa Partnership on AIDS (CAP AIDS)**
The Canada African Partnership on AIDS (CAP AIDS) is a Canadian charity, which focuses on providing resources to other community-based organizations working against HIV/AIDS in Africa. 244

**Canadian Council for International Cooperation**
The Canadian Council for International Cooperation is a coalition of Canadian volunteer organizations that work to achieve sustainable human development globally. They seek "to end global poverty, and to promote social justice and human dignity for all." 245 To achieve these goals, the CCIC monitors and analyzes the Canadian government's policies on issues including foreign affairs, aid, trade, debt and defence." It disseminates information and facilitates links with other similarly positioned Canadian organizations.

**Canadian HIV/AIDS Legal Network**
The Canadian HIV/AIDS Legal Network is a Canadian-based non-profit organization which "...promotes the human rights of people living with and vulnerable to HIV/AIDS, in Canada and internationally. [They] accomplish this through research, legal and policy analysis, education, advocacy, and community mobilization." 246 Their work focuses on the following areas: aboriginal communities, criminal law, discrimination, drug policy and harm reduction, HIV testing, immigration and travel, income security, microbicides and vaccines, prisons, privacy, sex work, sexual orientation and gender identity.

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241 See "Intellectual Property Institute of Canada (IPIC). About IPIC." Available at: [http://www.ipic.ca/english/general/about.cfm](http://www.ipic.ca/english/general/about.cfm) [Date Accessed 11 July 2010].

242 In alphabetical order.

243 See: "The Canadian African Community Health Alliance (CACHA), The "What" of CACHA." Available at: [http://cacha.ca/whatcacha](http://cacha.ca/whatcacha) [Date Accessed 13 July 2010].

244 See: "The Canada-Africa Partnership on AIDS (CAP AIDS), About CAP AIDS." Available at: [http://www.capaids.org/about.html](http://www.capaids.org/about.html) [Date Accessed 13 July 2010].

245 See "the Canadian Council for International Cooperation (CCIC), About Us." Available at: [http://www.ccic.ca/about/index_e.php](http://www.ccic.ca/about/index_e.php) [Date Accessed 11 July 2010].

treatment (Global Treatment Access Group, GTAG, and Canada's Access to Medicines Regime), and Women's Rights.

**CARE Canada**
CARE Canada is a non-profit organization, one of many CARE organizations around the world, whose mission is "to serve individuals and families in the poorest communities in the world." They work in communities to improve the health and well being of the poor and they also delivers emergency aid to survivors of war and natural disasters.

**Global Economic Justice Program, KAIROS**
KAIROS is a faith-based ecumenical organization, focused on social change through advocacy, education and research programs in the areas of ecological justice, economic justice, energy and extraction, human rights, just and sustainable livelihoods, and indigenous peoples. They partner with 21 other organizations across Africa, Asia, Latin America, and the Middle East and 80 local groups across Canada.

**Health Partners International of Canada**
Health Partners International of Canada (HPIC) is a non-profit organization that aims to increase access to medicine and improve health in the developing world. HPIC works through partnerships with healthcare companies who donate products, "…governments and bilateral agencies that cooperate in capacity-building, the Canadian and local NGOs and healthcare professionals who administer the medical aid and advance community development, and the donors who provide the funding..."

**Interagency Coalition on AIDS and Development (ICAD)**
The Interagency Coalition on AIDS and Development is Canadian-based coalition of more than 120 AIDS service organizations (ASOs), non-governmental organizations (NGOs), faith-based organizations, educational institutions and labour unions. "ICAD's mission is to lessen the spread and impact of HIV/AIDS in resource-poor communities and countries by providing leadership, and actively contributing to the Canadian and international response."

**International Human Rights Program, Faculty of Law, University of Toronto**
The International Human Rights Program (IHRP) of the University of Toronto, Faculty of Law is promotes global human rights through legal education, research and advocacy. Their mission "…is to mobilize lawyers to address international human rights issues and

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249 See "Health Partners International Canada (HPIC)". Available at: [http://www.hpicanada.ca/about.cfm](http://www.hpicanada.ca/about.cfm) [Date Accessed 11 July 2010].
to develop the capacity of students and program participants to establish human rights norms in domestic and international contexts.”

McGill International Health Initiative (Students Against Global AIDS). Now known as the McGill Global AIDS Coalition, this group is a student-led HIV/AIDS advocacy group "dedicated to the eradication of HIV/AIDS and to the realization, worldwide, of the right to health." They help foster and develop a student advocacy network in Canada and educate the McGill and Montreal community on global health issues.

Médecins Sans Frontières, Campaign for Access to Essential Medicines (MSF) The Access Campaign was set up by Médecins Sans Frontières in 1999 "to improve access to existing medical tools (medicines, diagnostics, vaccines) and to stimulate the development of urgently needed better tools for people in countries where MSF works." The Campaign also advocates for continued improvements in medical practice, supports efforts to reshape the funding of medical R&D so that innovation is not just market-driven but serves those most in need. MSF has a Canadian branch located in Montreal, Quebec.

North-South Institute (NSI) The North-South Institute is a non-governmental, non-partisan research institute in Canada focused on international development. They are dedicated to eliminating global poverty and enhancing social justice, through providing "research and analysis on foreign policy and international development issues for policy-makers, educators, business, the media and the general public."

Oxfam Canada Oxfam Canada is part of Oxfam International, which is a confederation of 14 national Oxfam agencies around the global. Their mission is to fight "poverty and related injustice around the world." Oxfam Canada supports long-term development, advocacy and emergency programs in 28 countries around the world. Their core programs are located in the Americas, the Horn of Africa, Southern Africa, South Asia and in Canada.

Rights and Democracy Rights & Democracy (International Centre for Human Rights and Democratic Development), is a non-partisan organization that aims "to encourage and support the

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251 See: International Human Rights Program, Faculty of Law, University of Toronto. Available at: http://www.law.utoronto.ca/students_content.asp?itemPath=2/8/0/0/0&contentId=375 [Date Accessed: 13 July 2010].
252 See: McGill Global AIDS Coalition, About MGAC. Available at: http://treatthepeople.com/mgac/ [Date Accessed 13 July 2010].
253 See "MSF Campaign for Access to Essential Medicines". Available at: http://www.msfaccess.org/about-us/ [Date Accessed 11 July 2010].
254 See: North-South Institute, Overview. Available at: http://www.nsi-ins.ca/english/about/default.asp [Date accessed: 11 July 2010].
universal values of human rights and the promotion of democratic institutions and practices around the world." It works with individuals, organizations and governments in Canada and abroad to promote the human and democratic rights defined in the United Nations' International Bill of Human Rights.256

**Stephen Lewis Foundation**
The Stephen Lewis Foundation (SLF) is a non-profit organization that supports community-based organizations that are working to battle HIV/AIDS in Africa. Stephen Lewis, the former UN Special Envoy for HIV/AIDS in Africa is the Chair of the Board. SLF provides care to women who are ill, assists orphans and other AIDS affected children, supports grandmothers who care for their orphan grandchildren and sustains associations of people living with HIV and AIDS.257

**United Church of Canada**
The United Church of Canada is Canada's largest protestant denomination. Among their missions, they are dedicated to social justice and are active politically in Canada. They testified during the 2004 CAMR debates.258

**World Vision Canada**
World Vision is a Christian relief, development and advocacy organization, which works with children, families and communities around the world with the goal of overcoming poverty and injustice. Their work ranges from infrastructure and capacity building of schools and health clinics to responding to humanitarian crises and engaging in political advocacy.259

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256 See "Rights and Democracy: Who We Are". Available at: [http://www.ichrdd.ca/site/who_we_are/index.php?lang=en](http://www.ichrdd.ca/site/who_we_are/index.php?lang=en) [Date accessed: 11 July 2010].

257 See "The Stephen Lewis Foundation (SLF), Who We Are". Available at: [http://www.stephenlewisfoundation.org/about_who.htm](http://www.stephenlewisfoundation.org/about_who.htm) [Date Accessed: 13 July 2010].


259 See: "World Vision Canada: About Us". Available at: [http://www.worldvision.ca/About-Us/Pages/AboutUs.aspx](http://www.worldvision.ca/About-Us/Pages/AboutUs.aspx) [Date Accessed 13 July 2010].
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