

**The Politics of Drug Patenting in Canada
1965-2005**

**A Thesis Submitted to the
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In the Department of Political Studies
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ABSTRACT

The central objective of this study is to examine the factors that have influenced the evolution of the drug patenting regulatory framework in Canada from 1965 to 2005. The principal focus is on the extent to which in formulating that regulatory framework the Canadian federal government has been influenced by domestic and international interests and forces. In examining the domestic interests and forces attention is devoted to the financial interests of the two sectoral associations representing the patented and generic drug manufacturers and the economic and political interests of the governing and opposition parties. In examining the international interests and forces the focus is both on the emergence of international institutions and agreements and on the interests of various countries and drug companies located therein which wanted to ensure that Canada's regulatory framework would not have an adverse effect on them.

This study reveals that there was three relatively distinct phases in the evolution of Canada's drug patenting regulatory framework and that each was influenced primarily by different sets of factors. The first phase which lasted from 1965 to 1991 was influenced entirely by domestic interests and forces produced by a highly charged political debate over reduced patent protection and drug price restrictions on the one hand, and increased patent protection and economic development on the other. The second phase, which lasted from 1992 to 2001, consisted largely of international forces. This included the emergence of new international institutions and agreements such as the World Trade Organization and the North American Free Trade Agreement, which created new intellectual property obligations for Canada and provided for even longer periods of patent protection than what had already existed. The third phase which began 2002 and continues to the present day, consists of a combination of domestic and international forces which attempt to reconcile domestic issues such as price restriction and economic development with international issues such as allowing Third World countries an opportunity to import drugs at reasonable prices. The Government of Canada's response to all of these pressures has predominantly reflected the objectives of patented drug manufacturers.

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CHAPTER 1

INTRODUCTION

[1.1] Background

Intellectual property (IP) rights create a public policy dilemma for governments. On the one hand, governments enact legislation to promote and protect creations or inventions of the mind, while on the other hand governments ensure that such legislation is limited so that society can enjoy the benefits of these sorts of creations and inventions. One way governments achieve this is by granting inventors a specified period for patent protection, so they have a period of market exclusivity to recoup the research and development costs associated with bringing the invention to market. Once the period of patent protection has expired, governments then allow others to use the patented product to create a competitive product. Thus, as Bruce Doern and Markus Sharaput have written, “intellectual property policy and institutions in Canada and elsewhere are...centered on a crucial trade-off between protecting IP and disseminating IP.”¹ The difficulty lies in determining at which point the trade-off should occur. For some industries, say in the manufacturing of bicycles, the point may occur later because the dissemination of IP may not be all that beneficial or important either to the public as a whole or to the public interest. However, for others, the point may be sooner, as the benefit may be more important either to the public or to the public interest.

In Canada, the pharmaceutical industry has created this public policy conundrum for government. One reason is that the research and development required to produce a

¹ G. Bruce Doern and Markus Sharaput, *Canadian Intellectual Property: The Politics of Innovating Institutions and Interests* (Toronto: University of Toronto Press, 2000) 3.

new drug is enormous, both in terms of time and money. According to Canada's research-based pharmaceutical companies (Rx&D) it takes anywhere between 10 and 15 years to get a drug approved for sale in Canada.² In addition, the association suggests that the cost of developing a single, brand name drug in Canada is roughly \$1.3 billion.³ Therefore, in an attempt to capture the costs of producing its drugs, Rx&D and its members companies encourage government to provide adequate and uninterrupted periods of patent protection. However, because pharmaceutical drugs have an impact on Canada's health care system, special rules have been created to allow for the early approval of cheaper generic alternatives. As a result, the Canadian Generic Pharmaceutical Association (CGPA) has encouraged the federal government to restrict patent protection so that they can enter the drug market earlier rather than later, thereby reducing the prices of pharmaceuticals.⁴

In 1969, for instance, the Government of Canada, created a system of full compulsory licensing that allowed the generic manufacturer to copy and sell its own version of a patented medicine, prior to the expiry of the patent. To the patented manufacturers, such legislation restricted their ability to conduct research and development in Canada, as they were not receiving the accompanying protection for their

² Rx&D: Canada's Research-Based Pharmaceutical Companies, "Towards Increasing Research and Development in Canada: A New Innovative Pharmaceutical Strategy," (November, 2003) 10. Obtained from <http://www.canadapharma.org>. Rx&D is the sectoral association that represents 52 of Canada's patented pharmaceutical and biotechnology companies. For an overview of the companies that make up this association see Appendix 1, "Current Members Canada's Research Based Pharmaceutical Companies (Rx&D)."

³ This refers to Canadian dollars see *ibid*. There is some debate about what the actual cost of producing a patented pharmaceutical drug. Some reports indicate that it is between \$ 600 and 800 million. See for example, <http://www.innovation.gc.ca/gol/innovation/site.nsf/en/in02241.html>.

⁴ The CGPA represents 20 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. For an overview of companies that make up this association, see Appendix 2, "Current Members of the Canadian Generic Pharmaceutical Association (CGPA)." For more information see, http://www.cdma-acfpp.org/en/about/who_we_are

inventions. What the compulsory licensing scheme did accomplish was the creation of a robust generic drug industry in Canada and launched a political salvo that would see the patented and generic manufacturers engage in intense lobbying efforts to encourage government to enact additional legislation to protect their respective sectors of the industry.

What emerged in the years following compulsory licensing in 1969 was the recognition by successive federal governments—Liberal and Conservative—that it was imperative to strike a balance between offering sufficient patent protection on the one hand and inducing generic competition to restrict prices on the other. Certain political pressures emerged both domestically and internationally, which saw the government enact legislation that tilted the balance away from price restrictions and towards patent protection. In other words, economic development, in the form of pharmaceutical research and development triumphed over policies of shorter patent terms and price restrictions. Domestically, for instance, pharmaceutical research and development began to decline. Internationally, new agreements emerged, largely crafted by the objectives of the United States,⁵ to cause Canada to undertake further changes to the practice of drug patenting. In recent years, domestic and international pressures converged on the government and gave way to further policy initiatives that would see the federal government attempt to undertake additional changes that would attempt to re-align the balance between patent protection and price restriction. What remained consistent through all these legislative and policy changes was that the debate between government

⁵ See, Sylvia Ostry, *The Post-Cold War Trading System: Who's on First?* (Chicago: University of Chicago Press, 1997). In the book, Ostry makes the point that the intellectual property rules that were adopted by the WTO and TRIPS were a replication of the United States regime and its allies of the OECD countries.

and industry stakeholders and among industry stakeholders themselves changed very little.

This thesis tells the story of that debate over time. The story is primarily about the politics of drug patenting in Canada during the past four decades. It is the story of the politics surrounding and driving important changes to drug patenting laws that, in one way or another, have affected the daily lives of Canadians and have created significant tensions between government and industry in finding that elusive intersection between protection and dissemination of IP products.

[1.2] Focus, Objectives, and Research Questions

The focus of this thesis is on the political evolution of Canada's statutory and regulatory frameworks for drug patenting policy from 1965-2005. The purpose is to determine the nature and extent to which industry stakeholders, specifically the sectoral associations representing patented and generic manufacturers, have been able to influence government in making changes (or not making changes) to Canada's patent laws and regulations. The primary objective of this study is to analyze the ongoing debate among government, Parliament and the sectoral associations representing the pharmaceutical industry in establishing a balanced regulatory regime for pharmaceutical drugs in Canada.⁶ It argues that because of their membership, amount of resources, and their contribution to the Canadian economy, patented drug manufacturers have been able to exert a greater degree of influence than the generic drug manufacturers over the statutory and regulatory framework pertaining to drug patenting in Canada. One notable feature emerging from this study is that the policy making process pertaining to pharmaceuticals

⁶ For a comparative profile of these associations see Appendix 3, "Profile of the Umbrella Organizations Representing the Patented and Generic Drug Manufacturers in Canada."

is a very closed process, largely influenced by vested interests and lacking in public input and participation.

In keeping with that objective, this thesis seeks to address the following research questions:

1. How do certain stakeholders (associations) influence the policy objectives and policy outcomes of government?
2. Has the resulting statutory and regulatory framework for pharmaceuticals in Canada been effective in producing a balance between the competing policy objectives of offering sufficient patent protection and greater public access for pharmaceutical drugs?
3. How have domestic and international pressures contributed to the development of the statutory and regulatory framework for drug patenting in Canada?

While a number of other important issues have emerged within the broader context of the Canadian pharmaceutical industry, this study is only concerned with the legislative changes and policy decisions related to drug patenting in Canada. Therefore, it is beyond the scope of this study to address the statutory and regulatory changes as they relate to other important issues such as drug risk, safety, and efficacy, drug pricing, internet pharmacies, and the role of provincial formularies in determining the types of drugs that are available to consumers in a particular province.

Moreover, this thesis does not examine the influence of other important stakeholders from the analysis; namely, medical professionals, consumer groups, and provincial governments. Although this may limit the scope of this thesis, as important as these groups are the debate with respect to drug patenting in Canada has primarily

involved the patented and generic manufacturers, again demonstrating the extent to which policy making in this area is a limited process. However, because consumer groups are advocates of cheaper drugs, it is reasonable to assume that their position mirrors that of the generic producers. In fact, the Consumers Association of Canada (CAC) was part of the group—supported, but not joined by, the CGPA—that launched a review with the Competition Bureau of Canada to look into the practices of the patented manufacturers, with respect to adding additional patents to its product.⁷

[1.3] Analytical Framework: Policy Communities/ Policy Networks

How do industry stakeholders, or sectoral associations, influence the regulatory framework for pharmaceuticals in Canada?⁸ How does this framework operate within the scope of the political, administrative, and legal constraints that are placed upon it? For analytical purposes this study relies on the models and theories embodied in the policy network and policy community literature. The value of this literature is that it provides useful models and theories to explain the pattern of relationships among institutions and actors within a particular policy sector and the effects they have on policy development, implementation, and evaluation.⁹ More specifically, in the case of the pharmaceutical industry, the literature directs attention to the interplay of government, Parliament and industry stakeholders. It achieves this task by explaining how interests are organized within a particular policy sector and the influence that these stakeholders have on the types of policy decisions that governments make or do not make.

⁷ See chapter four of this thesis for an overview of the issues.

⁸ For the purposes of this thesis, I use the term industry stakeholders to refer to the umbrella organizations that represent patented drug manufacturers and generic drug manufacturers. Namely, Rx&D (or PMAC) for the patented drug manufacturers and the CGPA (or CDMA) for the generic drug manufacturers.

⁹ For an overview of the contributions on the literature, see Leslie A. Pal, *Beyond Policy Analysis: Public Issue Management in Turbulent Times*, 2nd edition. (Toronto: Nelson Canada, 2001) 244.

For example, William D. Coleman and Grace Skogstad place the emphasis on the roles that sectoral associations play in developing public policy.¹⁰ They reveal that such organizations are both advocates and participants in the policy process. As advocates, these groups act as lobbyists to influence the purpose and intent of public policy. However, “successful advocacy depends on the group’s capacity,” suggest Coleman and Skogstad, “to develop a knowledge of the policy making process, to generate information...to mobilize support for its policy proposals, and to maintain internal member cohesion.”¹¹ As participants, associations must possess the capacity to create a distinctive identity as an organization and have the ability to speak beyond very narrow interests. Otherwise, political support would dissipate, as major political actors would ignore the association’s policy objectives.

There are also important distinctions to be made between the policy communities and policy network concepts. Policy communities, refer “to all actors or potential actors who share a common interest or a common policy focus and who over time succeed in shaping policy.”¹² In contrast, according to Michael Atkinson and William Coleman, “political scientists have used the term policy network more loosely to refer to dependency relationships that emerge between both organizations and individuals who are in frequent contact with one another in particular policy areas.”¹³ In a more recent

¹⁰ William D. Coleman and Grace Skogstad eds., *Policy Communities and Public Policy in Canada: A Structural Approach*. (Mississauga: Copp Clark Pitman Ltd. 1990) 20.

¹¹ *Ibid.*

¹² *Ibid.*, 197.

¹³ Michael Atkinson and William Coleman, “Policy Networks, Policy Communities, and the Problems of Governance” in Laurent Dobuzinskis, Michael Howlett, and David Laycock, eds., *Policy Studies in Canada: The State of the Art* (Toronto: University of Toronto Press, 1996) 196.

paper, Skogstad refers to policy networks as capturing "...the structural or power relationship between the actors..."¹⁴

[1.3.1] Policy Communities

According to Skogstad, policy communities list a set of actors who share at least some common identity, but who may be opposed to a policy direction.¹⁵ This is particularly true of the pharmaceutical industry. Because the industry has two main producers, patentees and generics, the actors share a common identity. However, each producer seeks to protect their interests become opposed to one another over policy direction, with one group advocating greater patent protection and the other less.

Paul Pross has defined policy communities as "groupings of government agencies, pressure groups, media people, and individuals including academics, who, for various reasons, have an interest in a particular policy field and attempt to influence it."¹⁶ However, Pross' definition does not travel particularly well across policy fields because some policy sectors are influenced by government agencies and professional organizations to a larger degree than others. Another problem with this definition is that, in the context of this study, it includes a broad grouping of stakeholders, such as academics, individuals and the media, who have only minimal influence on policy decisions made by government. As this thesis will show, the changes made to the statutory and regulatory framework for drug patenting in Canada were influenced by a

¹⁴ Grace Skogstad, "Policy Networks and Policy Communities: Conceptual Evolution and Governing Realities," Prepared for the Workshop on "Canada's Contribution to Comparative Theorizing," Annual Meeting of the Canadian Political Science Association, University of Western Ontario, London, Ontario, June 2, 2005, 3.

¹⁵ *Ibid.*

¹⁶ As quoted in Pal, 242.

very narrow group of stakeholders who were directly involved as producers in the industry.

[1.3.2] Policy Networks

Policy networks identify the interactions and relationships and the consequences these relationships have on the development and delivery of public policy.¹⁷ Network analysis is deemed to utilize a structural approach because it focuses on “patterns of relations among actors, patterns that can be mapped and are to some degree distinct from the beliefs or ideas that the actors themselves carry into the policy process.”¹⁸ The advantage of the policy network concept is that it captures variation across policy fields. More importantly, it identifies different types and characteristics of networks that have come to influence government decision-making. Typically, a highly mobilized association will have a greater ability to influence the policy agenda of government. For example, Atkinson and Coleman have identified six important features of highly mobilized business groups that serve as effective policy networks.¹⁹ They are: (a) separate associations representing different products; (b) one association that speaks for the sector as a whole; (c) a high proportion of firms in a particular sector are represented by the association compared to those who are not; (d) large firms that demonstrate leadership in the sector; (e) in-house capacity to generate information; and (f) the sector has associations that can strike deals with government and make members abide by such deals.

¹⁷ Pal, 244.

¹⁸ *Ibid.*

¹⁹ See M.M. Atkinson and William D. Coleman, *The state, business, and industrial change in Canada*. (Toronto: University of Toronto Press, 1989) 82-3.

With respect to the pharmaceutical industry itself, the above conditions set out by Atkinson and Coleman are a good fit. For instance, there are two major groups of associations within this sector, namely brand-name (patented) and generic producers' associations. One association represents each group within this sector. Each association speaks for the sector representing different products. Such an association represents almost all firms. The larger firms demonstrate a greater degree of leadership in the sector. Finally, both groups in the sector have the ability to generate in-house information and have the ability to make deals with government. Does that mean that each sectoral association is an equal player in determining the policy decisions of government? Not necessarily.

The type of network and the characteristics it possesses is important. For example, Pal lists a number of different types of networks ranging from a pressure pluralist network, at the top, to a state directed network, at the bottom.²⁰ At the top end of the spectrum, the state agency is autonomous and the associations are weak. Many groups are involved, but they are advocates rather than participants. At the bottom end of the spectrum, the state is the dominant player. Associations are weak, dispersed, and do not play much of a role in policy development. However, in the middle of the spectrum a power balance is struck between the state and the associations. Pal refers to this network as the 'corporatist network.'²¹ In a corporatist network, the state agency is strong and the associational system includes few large and powerful groups, with both the state and association participating in policy formulation and implementation. More precisely, as Skogstad points out, it is a network where there is "a more equitable balance between

²⁰ *Ibid.*, 246, see figure 6.3

²¹ *Ibid.*

state and economic actors.”²² However, because the associations are few and typically represent different sectors of the same industry, one association will have a greater impact on policy outcomes, mainly due to organizational features, such as size (in terms of representation) financial resources, and its ability to appeal to the broader goals and objectives of government.

Pal argues that the community/network concept is important because it encompasses important changes that have contributed to a shift in governance.²³ The shift has resulted from the ever-increasing complexity of government and society, whereby a greater emphasis is placed on information and expert knowledge from both governmental and nongovernmental agencies and actors. Perhaps more indicative of what the policy community and policy network literature attempts to explain, especially in terms of policy analysis, is who participates and who wields power.²⁴ But what happens when the participant/power relationship extends beyond national borders and encompasses the broader international community?

[1.3.3] Policy Communities, Policy Networks, and the Structure of Global Power

Predominantly, the policy communities and policy networks literature attempts to determine the relationship key stakeholders have on the development of public policy at the domestic level, but often pay little attention to international influences. Criticism of the policy network approach suggests that network analysts pay “insufficient attention to the broader context of macro political, ideological, and economic structures within which

²² Skogstad, 4.

²³ Pal, 241.

²⁴ Atkinson and Coleman, in *Policy Studies in Canada*, 197. It should be noted that there is a limitation to this model. It is more descriptive than prescriptive in the sense that it fails to adequately capture the causal relationship among key variables.

policy networks themselves are situated.”²⁵ The critics have a point. For instance, the liberalization of trade rules in the early 1990s has broadened the scope of domestic economic and industrial policies in Canada. As a result, many of these policies have become shaped by the emergence of globalization and thus more reliant on international agreements. International agreements, in turn, have created an additional set of obligations that have, consequently, reduced the ability of domestic political actors to craft economic and industrial policies that genuinely reflect the needs and desires of their constituents.

In her book, *States and Markets*, Susan Strange attributes this to the notion of structural power. Structural power, in her view, “shapes and determines the structures of the global political economy within which other states, their political institutions, [and] their economic enterprises...have to operate.”²⁶ This has become more evident with the emergence of the World Trade Organization (WTO) and its authority to impose sanctions on states that do not conform to its declarations. As a result, “structural power,” argues Strange, “confers the power to decide how things shall be done, the power to shape frameworks within which states relate to each other, relate to people, or relate to corporate enterprises.”²⁷

The key point for Strange is that structural power has a reach far greater than the borders of a sovereign state. However, that is only part of the issue. States enter into bargains with other states, “but those bargains,” posits Strange, “...depend heavily on some internal, domestic bargains, especially in the most structurally powerful states.”²⁸

²⁵ Skogstad, 6.

²⁶ Susan Strange, *States and Markets*, 2nd edition. (London, New York: Continuum, 1994) 24-5.

²⁷ *Ibid.*

²⁸ *Ibid.*, 40.

Often these bargains emerge between political parties or government and industry. As chapter two will reveal, a bargain was made between the Government of Canada and the brand-name pharmaceutical industry through the adoption of *Bill C-91*, which would give the patented pharmaceutical companies greater patent protection if they would increase their research and development investment in Canada. Once the bargain is secured at the domestic level, multi-lateral bargains emerged with other countries. For Strange, the adoption of WTO and North American Free Trade Agreement (NAFTA) would suggest that a bargain was made between signatory states and in the process, witnessed even greater patent protection for pharmaceutical products in Canada.

By integrating Strange's hypothesis into the policy community/policy network framework a more accurate analysis can be developed to explain the influences of major sectoral associations in shaping and determining the evolution of the statutory and regulatory framework for drug patenting in Canada. The corporatist network will be able to identify the debate and policy outcomes that emerged as a result of domestic pressures, particularly those which emerged over the period of 1965 to 1991. The structural power model will be able to articulate the debate and identify the policy outcomes as it pertains to international pressures, which emerged over the period of 1992-2001. Both models will be useful in explaining the policy outcomes as a result of a convergence of both domestic and international pressures, such as which occurred between 2002 and 2005. This blending of the models, therefore, will help to "integrate micro level explanations of...behaviour with macro level accounts of the state and the political economy."²⁹ In other words, the inclusion of both models in the analytical framework will help to explain how and why the Government of Canada responded the way it did to various domestic

²⁹ Skogstad, 7.

and international pressures pertaining to the statutory and regulatory framework for drug patenting.

Previous studies on the pharmaceutical industry in Canada have used different analytical approaches to determine the influence of stakeholders on government. One approach, used by Lexchin, is the clientele pluralism model.³⁰ This model is useful when the relationship focuses on one particular government department or agency. Another approach, used by Wiktorowicz, focuses on institutions and interests. In her study on the regulation of pharmaceuticals in France, Britain, the United States, and Canada, Wiktorowicz utilizes a theoretical perspective that offers a neo-institutional approach.³¹ This approach suggests that “organizations are shaped by the culmination of historical forces upon them and embody a distinctive set of structures, ideologies and values.”³² Again, this perspective is useful when focusing on a particular agency, and in conducting a comparative study on institutions.

[1.4] Methodology

In an attempt to understand the politics of drug patenting in Canada, this study focuses on the political debate between government, parliament, and industry stakeholders and the response by those institutions to that debate. Toward that end, this study entails two major analytical tasks. The first is to trace the major developments in intellectual property policy in Canada as it pertains to the changes in statutory and

³⁰ See Joel Lexchin, “Profits First, The Pharmaceutical Industry in Canada,” in B. Singh Bolaria and Harley D. Dickinson, eds., *Health, Illness, and Health Care in Canada, 3rd edition*, (Scarborough, ON: Nelson, 2002) 394-5. Here Lexchin focuses on the Health Protection Branch of Health Canada to suggest that the state has a high degree of concentration of power in one agency (HPB) but a low degree of autonomy. The result is that some power has been relinquished to the drug manufacturers, especially as it pertains to information, such as in the case of clinical trials.

³¹ Mary E. Wiktorowicz, “Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain, and France,” *Journal of Health Politics, Policy, and Law*, Vol. 28 No. 4, August 2003 (Raleigh, NC: Duke University Press, 2003) 615-58.

³² *Ibid.*, 618.

regulatory frameworks for the pharmaceutical industry from 1965 to 2005. The second is to identify the conflicting objectives among industry stakeholders to determine the degree of influence that each of them had in producing statutory and regulatory frameworks that would benefit the companies comprising their organizations.

To accomplish the above tasks, this study utilizes a qualitative approach. In doing so, it focuses on primary sources such as, legislative debates, committee hearings, and government documents. However, in providing a more complete analysis, this study also includes secondary and tertiary sources, such as books, journal articles, newspaper articles, as well as industry and trade publications. It is hoped that with the inclusion of such materials this study is able to offer a nuanced understanding of the politics of drug patenting in Canada.

In obtaining the above primary, secondary, tertiary sources for utilization in this study, the Internet (or World Wide Web) was of vital importance. Because government institutions, associations, scholarly journals, and newspapers have published many documents and proceedings on the Internet a wealth of information was readily available. However, with respect to historical materials, such as Parliamentary committee hearings conducted before the 35th Parliament, and published books, the resources available through the University of Saskatchewan Library were crucial to the development of this thesis. In addition, personal contacts both inside and outside of the University directed attention to key sources that would benefit the analysis from a thematic, analytical, and organizational perspective. Once the materials were collected, they were grouped into key topic areas, so that the researcher could determine the effectiveness and usefulness of the collected sources in advancing the major objectives and argument of this thesis.

[1.5] Organization of Thesis

In examining the political dynamics and influences that produced changes to Canada's statutory and regulatory framework for drug patenting, the remainder of this thesis is organized into four chapters. The objective of chapter two is to provide an overview of the key domestic pressures that emerged to cause the federal government to make a number of statutory and regulatory changes, from 1965 to 1991 to the treatment of pharmaceutical drugs in Canada. The chapter chronicles the major political and policy developments that contributed to a significant shift in government policy from restricting drug prices with the adoption of compulsory licensing, to encouraging increased investment in pharmaceutical research and development by providing increased patent protection.

The objective of chapter three is to trace the evolution of the drug patenting policy from 1992-2001. It chronicles how major international agreements, such as NAFTA and Trade Related-Aspects of Intellectual Property-Rights (TRIPS) were negotiated and adopted to strengthen patent protection for the multinational drug companies. The purpose is to demonstrate that significant international pressures developed which caused the federal government to undertake another set of statutory and regulatory changes concerning the treatment of pharmaceuticals in Canada. During this period, patented manufacturers were able to use international organizations and agreements as leverage in encouraging the Government of Canada to offer even greater patent protection.

The objective of chapter four is to show that between 2002 and 2005 a convergence of both domestic and international pressures emerged to cause the Government of Canada to implement another set of amendments to its patent laws.

Domestically, the release of the *Final Report* of the Commission on the Future of Health Care in Canada (Romanow Report) put pressure on Ottawa to review various practices of the pharmaceutical industry that were restricting the entrance to the market of generic drugs. Internationally, major health problems in the third world and the subsequent suspension of the WTO to suspend certain TRIPS articles resulted in Parliament passing *Bill C-9*, known as the Jean Chretien Pledge to Africa Act, to give generic drug manufacturers an opportunity to export the products to these countries, with the approval of patented drug manufacturers. Despite the convergence of these pressures, chapter four reveals that although there were attempts to shift the statutory and regulatory frameworks away from the patented drug manufacturers and towards the generic drug manufacturers that, in the end, the patented drug manufacturers once again emerged victorious.

The objective of the fifth and concluding chapter is fourfold. First, it provides an overview of the thesis objectives to determine how industry stakeholders have come to influence the outcome of statutory and regulatory changes to Canada's drug patenting laws. Second, it summarizes the major findings of this study to show that government policy has shifted over time to the benefit of patented manufacturers. Third, it offers some concluding observations with respect to the politics of drug patenting in Canada. Finally, it provides recommendations for further research to examine how politics have become intertwined in all facets of the pharmaceutical industry in Canada.

CHAPTER 2

THE POLITICS OF DRUG PATENTING IN CANADA, 1965 – 1991:

THE EMERGENCE OF DOMESTIC PRESSURES

[2.1] Introduction

While the issue of drug patenting in Canada does not immediately produce images of high political drama, a review of the political dynamics involving amendments to the *Patent Act* indicates otherwise. The history of patent protection for pharmaceutical drugs has involved both change and controversy. While the change has come in the form of numerous legislative amendments, the controversy stems from the competing objectives of government to restrict drug prices on the one hand, and to encourage more private sector investment and innovation, on the other. Contributing to this debate was the shifting foundations of Canada's political ideology: more precisely, the shift from the post-war Keynesian welfare state to a less interventionist neo-conservative agenda that was already operating in countries like the United States and Great Britain. This change in ideology was the catalyst for bringing a number of changes to Canada's economic and political landscape and, encompassed within it, Canada's drug patenting laws.

It therefore becomes important for this study to trace the evolution of Canada's drug patenting policies for two reasons: (a) to determine the major political shifts in pharmaceutical regulation and intellectual property protection; and (b) to determine the influence of key industry stakeholders in influencing this shift. In tracing the evolution, this section chronicles the major developments in Canada's pharmaceutical patent regime to determine the ongoing shift in government policy as it pertains to the regulation of pharmaceutical patents in Canada. Particular attention is devoted to the Pharmaceutical

Manufacturing Association of Canada's (PMAC) development in becoming a highly mobilized association. Throughout most of the debate, PMAC was the only sectoral association representing the pharmaceutical industry, as its generic equivalent, the Canadian Drug Manufacturers Association (CDMA) was not established until 1984. As a result of the CDMA becoming engaged in the process, the pharmaceutical industry was no longer influenced by one association. By the time Ottawa enacted *Bill C-22*, the interplay between government, parliament and the pharmaceutical industry now included two sectoral associations, each wanting to obtain special rules from government to gain additional market share. According to the policy communities and policy network literature the interplay of government and two main sectoral associations, create a corporatist network. However, within this type of network, power and influence is not shared equally. Instead, as this chapter reveals, only one association emerges victorious by obtaining concessions from government.

This chapter begins by providing an overview of the early system for patented medicines in Canada: a system that can be described as a response to domestic pressures. The first section explores how the changes evolved to include a regulatory regime referred to as compulsory licensing. Because the compulsory licensing regime was deemed to be an ineffective mechanism for patent protection, the Canadian government decided to launch a major inquiry into the pharmaceutical industry in 1984. Thus, the second section reviews the contributions of the *Commission of Inquiry on the Pharmaceutical Industry*, or better known as the Eastman Commission. The newly elected Progressive Conservative government largely rejected the Report of the Eastman Commission both because the previous Liberal government appointed it and, more

importantly, because the new government did not agree with Eastman's conclusions. However, regardless of what Eastman would recommend, the Mulroney government made a major commitment to multinational pharmaceutical companies, indicating that it would amend the *Patent Act* once in office. Thus, the final section of this chapter reviews the adoption and passage of *Bill C-22*, which proved to be a politically explosive piece of legislation. It marked a change in Canadian political ideology and witnessed a shift in government policies that explicitly favoured patented manufacturers.

[2.2] Responding to Domestic Pressures: Price Restriction vs. Private Investment?

The nature of intellectual property policy specific to the pharmaceutical industry has varied over time. For Canada, the policy direction was largely influenced by the changes undertaken in the United Kingdom (UK). In 1919, the UK amended its patent legislation and restricted the term of patent protection for food and drugs strictly to either processes or product by processes, but not the product itself. The British Government also enacted a system of compulsory licensing, which was intended to permit the entry of new firms into the market. These changes occurred because the British government wanted to create a domestically owned pharmaceutical industry.³³ As a result, this amendment was copied in other countries of the British Empire, including Canada.

In 1923, the Canadian Government amended its patent legislation pertaining to pharmaceuticals by introducing provisions that provided for inventions relating to substances prepared or produced by chemical processes and intended for food or medicine. The legislation required that, in order to receive adequate patent protection, the active ingredient must be manufactured in Canada. Such provisions (similar to the British

³³ For a brief overview of the evolution see, Harry C. Eastman, *Report of the Commission of Inquiry on the Pharmaceutical Industry*. (Ottawa: Minister of Supply and Services, 1985) xxiv.

legislation) permitted the patentees to obtain patent protection for a chemical process used to produce the drug, but not for the product itself. Canada did not recognize product patents for pharmaceuticals at the time because they were deemed to be a creation of nature and therefore, could not be created through research and development.

The changes to Canada's patent law also created a system of compulsory licensing, which was restricted to the use of an "invention for the purposes of preparation or production of food or medicine, but not otherwise."³⁴ Under the amendment, a licensee could receive a compulsory license for the purposes of manufacturing a drug product in Canada, but was not permitted to import it. In exchange for the granting of a compulsory license, the licensee would pay a pre-determined royalty to the patentee. However, the limitations placed on the granting of a compulsory license to develop the domestic market had very little impact on the industry, as just 22 compulsory licenses were issued between the period of 1923 and 1969, despite the popularity of major drugs such as Inderal, Valium, and Anturan.³⁵

Nonetheless, in the years following the amendments public attitudes and government policies toward the pharmaceutical industry changed. According to one study, the changes were brought about by the publicity surrounding the negative consequences that a particular drug (Thalidomide) had on the children whose mothers consumed it during pregnancy between 1955 and 1961, and by the Senate Subcommittee (Kefauver Committee) hearings on Antitrust and Monopoly, which was reviewing the practices of the pharmaceutical industry in the United States.³⁶ The

³⁴ For a legal overview of the evolution of Canadian legislation, see Ogilvy Renault, "Evolution of Canadian Legislation Affecting Innovative Drug Patents." (Montreal, November 22, 2002) 1.

³⁵ *Ibid.*

³⁶ Eastman, xxxiv.

negative publicity that emerged from these events encouraged the Government of Canada to undertake more significant legislative changes.

[2.3] Initiating Change: The Expansion of Compulsory Licensing

In the late 1950s and early 1960s the federal government commissioned a number of expert studies pertaining to patents and Canada's health care system. For example, the *Restrictive Trade Practices Commission*, commissioned in 1958, issued a report in 1963 indicating that because Canadian drug prices were the highest in the world, "the abolition of patents relating to drugs is the only effective remedy for the undesirable consequences arising out of the control of drugs in Canada."³⁷ Similarly, in 1960, the *Royal Commission on Patents, Copyrights, and Industrial Designs* reported that drug prices and corporate profits were too high and recommended the adoption of an enhanced compulsory licensing provision.³⁸ Subsequently, the *Royal Commission on Health Services* (the Hall Commission) echoed the sentiments of the previous studies and suggested that the compulsory licensing provision be expanded to provide for importation.³⁹ Finally, the House of Commons Special Committee on Drug Costs and Prices, set up in 1967, endorsed the concept of compulsory licensing to import drug compounds for the purposes of reducing drug costs and to encourage industry competition.⁴⁰

Taken together, these studies recommended reducing the length of patent protection for pharmaceutical drugs in order to maintain drug costs. At the time, patent protection was given a term of 17 years from the date of application, but with the

³⁷ Restrictive Trade Practices Commission, *Report Concerning the Manufacture, Distribution, and Sale of Drugs* (Ottawa: January, 1963).

³⁸ Royal Commission on Patents, Copyrights, and Industrial Designs, *Report* (Ottawa: 1960).

³⁹ Royal Commission on Health Services, *Final Report*, (Ottawa, 1964) 40.

⁴⁰ House of Commons Special Committee on Drug Costs and Prices, *Final Report* (Ottawa, 1967).

granting of a compulsory license and the operation of the regulatory system, the exclusive period was reduced to four years.⁴¹ Following these studies, and in particular the Hall Commission, Canada adopted a publicly-funded, universal health care system, which involved at least some drug costs for hospitals and public clinics. This meant that regulating pharmaceutical prices would help to manage some portion of the overall public health expenditures.

Sensing the impending magnitude of the costs of patented medicines on a publicly-funded health care system and acting on the recommendations from the expert studies, the federal Liberal government amended the *Patent Act* in 1967, by introducing *Bill C-190*, under then minister of the newly formed Department of Consumer and Corporate Affairs, John Turner. The objective of the bill was to permit the granting of compulsory licenses for the purposes of importing drugs into Canada. However, *Bill C-190* died as the result of an adjournment and was subsequently re-introduced in 1968, this time as *Bill C-102*.

Bill C-102 extended the authority of the Commissioner of Patents to grant compulsory licenses for what was referred to as third parties, for the purposes of: (a) importing the patented invention; (b) making the patented medicine; (c) using the patented medicine to produce medicine; and (d) selling the patented invention abroad in bulk dosage form. In other words, the amendment allowed generic drug manufacturers to obtain a compulsory license for the purpose of importing patented medicines to copy, manufacture, and then sell in Canada and abroad. Because sales of pharmaceuticals in Canada were still relatively small in the years prior to 1969, generic drug makers rarely attempted to obtain a compulsory license for the products manufactured in Canada.

⁴¹ Eastman, xxxiv.

However, the ability to import more popular drugs from outside Canada provided generic drug manufacturers a greater incentive to enter the market. These amendments resulted in an explosion of compulsory licenses and resulted in the creation of a modern generic drug industry.⁴² For example, during the period between 1969 and 1985, over 700 compulsory licensing applications were applied for and approximately 400 compulsory licenses were issued in Canada.⁴³

In attempts to ensure that a balance between patent protection and generic competition was maintained, the amendments provided discretionary powers to the Commissioner of Patents to either grant or refuse the application. Moreover, the amendments also permitted the Commissioner to apply a royalty rate of 4% on the net selling price of the drug, to the patentee, upon the issuance of a compulsory license. However, PMAC, the umbrella organization representing patented pharmaceutical companies, vehemently opposed the legislation and mounted an aggressive campaign against it. Nonetheless, the campaign did not sway the government's objective of encouraging generic competition. In his article, "Pharmaceuticals: Politics and Policy," Dr. Joel Lexchin recognizes that PMAC had little influence on the Liberal government's industrial policy because of "...the relatively marginal position of the pharmaceutical industry in Canadian economy: there were no multinationals pharmaceutical companies based in Canada, and employment in the pharmaceutical industry was low, as was the overall value of production by the industry."⁴⁴ He goes on to reveal that; "...it was relatively easy for the government to pass a bill antithetical to the drug companies since

⁴² Ogilvy Renault, 2.

⁴³ Eastman, xx.

⁴⁴ Joel Lexchin, *Pharmaceuticals: Politics and Policy*, in Pat Armstrong, Hugh Armstrong, and David Coburn eds., *Unhealthy Times: Political Economy Perspectives on Health Care*. (Oxford; New York: Oxford University Press, 2001) 32.

the political consequences were minimal.”⁴⁵ Moreover, Leslie Pal and Robert Campbell suggest that PMAC was unsuccessful in its lobby because their claims were perceived to be illegitimate and because the expert studies “created a solid public perception of high drug prices and profits generated by a foreign dominated sector.”⁴⁶ The net result was that *Bill C-102* received significant support from the public as it was deemed to be an effective instrument in keeping drug prices low. One important observation about the enactment of *Bill C-102* is that it was not adopted because of the lobby of the generic drug sector, but because of the influence that the expert studies had on government. However, with the changing nature of the Canadian economy and the greater relevance placed on intellectual property rights, the influence of the pharmaceutical industry on Canadian public policy was about to grow.

[2.4] In Search of a Strategy: *Commission of Inquiry on the Pharmaceutical Industry*

Because of the displeasure with the 1969 amendments voiced by PMAC and the emergence of intellectual property rights in industrial policy both in Canada and, in particular, the United States, the Trudeau government was considering a review of the compulsory licensing provision, or more specifically section 41(4) of the *Patent Act*. These pressures, combined with actions of some of the multinational pharmaceutical firms (e.g., Ayerst) in pulling their operations and research facilities out of Canada, created a further tension for the government. Because many of the patented pharmaceutical companies were located in Quebec and half of the Liberal caucus was from that province, this created nothing short of a political storm for the federal Liberals,

⁴⁵ Ibid.

⁴⁶ For an excellent overview of the history of drug patenting in Canada, see Robert M. Campbell and Leslie Pal, “The Long and Winding Road: Bill C-22 and The Politics of Drug Patents,” in *The Real Worlds of Canadian Politics: Cases in Process and Policy*, 1st edition (Peterborough, ON, Broadview Press, 1989) 62.

as the government became concerned with the low level of investment in the pharmaceutical sector, especially as it concerned Quebec.⁴⁷ The powerful Quebec caucus encouraged the government to act immediately to change its policy with respect to the industry, and in particular compulsory licensing. For example, Minister of Consumer and Corporate Affairs and political minister for Quebec, Andre Ouellette, argued that the government needed to shift its focus from pharmaceutical price control to “...create a better a climate for investment and research in Canda.”⁴⁸ As a result, the Liberal government changed its position, signalling it would be willing to scrap the compulsory licensing provision if patented pharmaceutical companies would agree to increase their commitment of research and development in Canada.

Unsure of how to proceed on the matter because of the apparent change in government policy, newly appointed Minister of Consumer and Corporate Affairs, Judy Erola, established the *Commission of Inquiry on the Pharmaceutical Industry*.⁴⁹ Headed by University of Toronto economics professor, Dr. Harry Eastman, the Commission was to “provide an analysis of the operation of the pharmaceutical industry in Canada, noting the differences among generic and patent holding firms and the operation of the international and domestic pharmaceutical market...”⁵⁰ Even though the Quebec Liberal caucus attempted to block the move, Prime Minister Trudeau overruled it and approved the commission.

The Eastman Commission heard from 41 witnesses and received 146 briefs, with the bulk of these submissions communicating a “sense of urgency...respecting the need

⁴⁷ *Ibid.*, 63.

⁴⁸ *Ibid.*, 67.

⁴⁹ The Order in Council was originally issued on April 17, 1984 and amended again on December 20, 1984, to extend the mandate of the commission from December 1984 to February, 1985.

⁵⁰ Eastman, xiv.

for change in the compulsory licensing provisions of the Patent Act.”⁵¹ The sense of urgency was largely due to the notion that, in spite of the generic drug makers inducing competition into the market, there were concerns over installing an appropriate mechanism for patent protection and encouraging further investment in Canada. After all, the generics only comprised three percent of the drug market in Canada at the time.

During the course of the Commission’s mandate several important political events transpired to constrain Eastman’s work. First, Prime Minister Trudeau resigned and the federal Liberals selected John Turner on 30 June 1984 to lead the party and become Prime Minister. Second, Prime Minister Turner dissolved Parliament and called an election to be held on 4 September of that same year, only to go down to defeat to Brian Mulroney and the Progressive Conservatives. The election of the Mulroney government, with the largest majority in Canadian history, led to a major shift of government policy, from one that favoured price restrictions and the development of the generic sector, to one that encouraged investment and a more favourable regime for patent protection.

However, the change in government did not dissuade Dr. Eastman from continuing his work. The Eastman Commission made a number of recommendations in its final report, delivered in May 1985. Among the recommendations, the commission suggested that a defined period of market exclusivity should be awarded to the patentee: “to protect innovating firms from the very early issuance of a compulsory license, Canadian policy should provide a short period of market exclusivity to patent holders...four years would be appropriate.”⁵² For the commission, the granting of four years of market exclusivity would result when a newly patented drug had been issued a

⁵¹ *Ibid.*, xv.

⁵² *Ibid.*, xx.

Notice of Compliance to authorize its sale. The trade off for this limited market exclusivity would see the patentee's receive a royalty of 14% of generic sales, as opposed to the existing 4% of sales.

As noted earlier, the *Patent Act* limited pharmaceutical patents to processes, or products by processes, but not to a product itself. The commission believed that such a restriction was a waste of resources and recommended, "...limitations on product patents for pharmaceutical products in the *Patent Act* be removed."⁵³ Ultimately, this recommendation was designed to encourage innovating drug companies to undertake further research and development.

At the time, the *Patent Act* also included a provision of reverse onus, whereby the generic manufacturer was required to provide proof to allegations that their activities were not infringing upon the patent process itself. The rationale underlying this provision was that the alleged infringer was in a better position to determine whether he or she was infringing a patent than the patent holder, and, therefore, would be required to prove that no infringement occurred. As a result, the Commission recommended that with the ability of patentees to produce product patents, the reverse onus provision should be removed to reduce the burden of proof for generics to comply with the legislation.⁵⁴

While the above recommendations dealt with the most technical aspects of Canada's existing patent regime, Eastman made several other pronouncements that did not sit well with either PMAC or the government. The commission revealed that, "compulsory licensing is an effective component of patent policy for the pharmaceutical industry...without compulsory licensing, the high prices and profits of such drugs would

⁵³ *Ibid.*, xxiii.

⁵⁴ *Ibid.*, xxiii.

induce other patent holding firms to engage in research to imitate a new drug....⁵⁵ In Eastman's view, a repeal of compulsory licensing would create higher prices, less competition, and more product differentiation among the top-selling and most profitable drugs among patent holders. This led the commission to conclude: "Canada is not well placed to become a major world center for pharmaceutical research or for the production of active chemical ingredients."⁵⁶

[2.5] A Fundamental Shift in Government Policy: The Adoption of *Bill C-22*

Following the release of the Eastman Report, the Mulroney Government introduced *Bill C-22* as an amendment to the *Patent Act*. In their study of the passage of this Bill, Campbell and Pal conclude that it was "one of the most bizarre political incidents in recent Canadian history."⁵⁷ Why? Because the bill had to be passed three times by the House of Commons before it became law, as the Senate became the de-facto opposition to the bill. Many of the old political operatives of the 1960s and 1970s made their way to the Liberal benches in the Senate, and as a result, attempted to thwart the government's legislative agenda. On a grander scale, the passage of *Bill C-22* was encompassed by larger symbolic issues such as free trade, the Meech Lake Accord, and the regional cleavages that had percolated to the top of the political discourse between Quebec and the rest of Canada. More revealing, however, was the ability of PMAC to organize itself to become an effective lobby to a sympathetic government, a stark contrast to its inability earlier to influence the outcome of *Bill C-102*. One major reason why PMAC became a more effective lobby was because it hired former Minister Erola to

⁵⁵ *Ibid.*, xix.

⁵⁶ *Ibid.*, xxvii.

⁵⁷ Campbell and Pal, 53.

become the association's president. Almost immediately, this strengthened the ability of PMAC to have its voice heard.⁵⁸

Bill C-22 was introduced into the House of Commons in June 1986. The general objective of the bill was to provide patented manufacturers greater protection for their products and to encourage multinational drug companies to invest more money in research and development in Canada. More specifically, the *Bill* amended the *Patent Act* by permitting innovative drug manufacturers to obtain product patents for the discovery of new compounds. It also deferred the issuance of a compulsory license anywhere from 7 to 20 years, depending upon when a Notice of Compliance had been issued to a patentee. Finally, it created the Patented Medicines Prices Review Board (PMPRB), to be chaired by Dr. Eastman, to limit the prices of new drugs in Canada and to report on the amount of research and development expenditures provided by patented drug manufacturers. One additional component of the *Bill* was that the Act and its regulations were to be reviewed by Cabinet four years after its passage and by Parliament ten years after. However, the bill proved to be politically divisive on a number of fronts.

Bill C-22 represented a fundamental change in government policy with respect to the treatment of patented medicines. It became apparent that generic drugs would no longer be supported by government policy. This outraged the CDMA and, as might be expected, they fiercely lobbied against the Bill, much the way PMAC did prior to the enactment of *Bill C-102*. However, the government did not have much sympathy for the CDMA's concerns because it wanted to revive investment in the sector, regardless of what Eastman had recommended or what the CDMA proposed.

⁵⁸ *Ibid.*, 54.

Because of the political acrimony surrounding the passage of *Bill C-22*, the government invoked closure to limit debate on second reading. The *Bill* headed to committee, for the first time, on 11 December 1986. Five days later, on 16 December, the Committee heard testimony from then Minister of Consumer and Corporate Affairs, Harvie Andre. Andre revealed that the government was concerned about how its existing patent legislation was being viewed amongst its major trading partners. According to the Minister, there was the need to “modernize Canadian patent law and make it more consistent with our European trading partners.”⁵⁹ Concerns were raised by European governments, which suggested that Canada’s existing patent legislation did not correspond to the protection offered by other industrialized nations.⁶⁰ In Europe, for example, patent protection, at that time, was for an uninterrupted period of 17 years from the date of granting or 20 years from the date of application.

In exchange for this increased patent protection, PMAC members agreed to devote up to 10% of their sales by 1996 to undertake further research and development in Canada. Opposition members were critical of the proposal because there was no mechanism contained in the text of *Bill C-22* to ensure that these targets would be met. One NDP member of the committee asked the Minister: “why does your legislation not call for commitments on each company on a specific basis that would be measurable and enforceable?”⁶¹ To which the minister replied, “we do not think they are necessary. We prefer carrots to whips. If it turns out that the donkey will not go with the carrot then

⁵⁹ Parliament of Canada, 33:2, *Minutes of Proceedings and Evidence* of the Legislative Committee on Bill C-22. December 16, 1982, 1:11, 1530.

⁶⁰ *Ibid.*, 1535.

⁶¹ *Ibid.*, 1625.

maybe you will have to use the whip.”⁶² The minister viewed PMAC as an important organization in assisting the government reach its objective of providing greater private investment in Canada. The association’s verbal assurances to commit more investment dollars in Canada seemed to satisfy the government. However, the minister later surmised that if the association failed to meet these targets, they could lose the patent protection offered by the *Bill*.

The Committee did not sit again until 20 January 1987 because of the Christmas break. This time representatives from the CDMA appeared before the committee. In its presentation, the CDMA asserted that, “unless this Bill is amended...we can easily predict a gloomy future for the pharmaceutical industry in Canada and for Canadians.”⁶³ The CDMA held the view that *Bill C-22* went too far in providing patent protection to patented pharmaceuticals and that the compulsory licensing system was needed to protect its part of the industry.

Later that same day, the committee heard from the representatives of PMAC. PMAC gave *Bill C-22* a glowing endorsement: “this bill is more than just a change to benefit brand name drug manufacturers and to bring Canada’s patent law into conformity with other western industrialized countries. This bill directly benefits all Canadians.”⁶⁴ However, opposition members on the committee were skeptical of PMAC’s commitment to increasing research and development in Canada if the bill was passed. In his questioning of PMAC members, Liberal member David Dingwall, asked, “would you be able to provide...the breakdown of the dollar amounts on a yearly basis, the companies

⁶² *Ibid.*, 1545.

⁶³ Parliament of Canada, 33:2, *Minutes of Proceedings and Evidence of the Legislative Committee on Bill C-22*, January 20, 1987, 1125.

⁶⁴ *Ibid.*, 1545.

who are making those actual commitments...exactly where the money is going to go?”⁶⁵

While PMAC did not provide specifics of the amount each company would spend on R&D, its verbal assurances were sufficient for government members of the committee.

Bill C-22 sat in committee for the next three months, with stakeholders representing several groups and associations, ranging from consumer groups and medical professionals, to provincial governments, providing testimony for or against the Bill. However, in mid-March the committee sent the Bill back to the House of Commons, virtually unchanged. Debate at third reading resulted in partisan bickering as the Opposition introduced a number of motions to amend the legislation. Again, the government invoked closure on debate and the House of Commons passed the bill on 6 May 1987.

Bill C-22 now headed to the Senate where it would be in the hands of a Liberal majority who opposed the Bill. Because there was little opposition to the government in the House of Commons, the Liberal controlled Senate felt it was their duty to provide “sober second thought” on the legislation. As a result, the House of Commons had to send *Bill C-22* back to the Senate on three occasions before it could become law. According to Campbell and Pal, “this was the longest parliamentary standoff between the two chambers in 40 years.”⁶⁶ However, because of the tactics by the Senate, some disaffected Quebec Liberals jumped ship to the Conservatives, as the delay of *Bill C-22* was straining the Quebec economy. Finally, on 19 November 1987, after making minor technical amendments, the Senate passed *Bill C-22*. Its passage created a sense a relief for

⁶⁵ *Ibid.*, 1700.

⁶⁶ Campbell and Pal, 82.

the government, as one minister called the process “antiquated and just a little bit weird.”⁶⁷

[2.6] Conclusion

A review of the early system of drug patenting in Canada, suggests that political forces greatly contributed to producing major changes to Canada’s drug patenting system. In the early 1920s the Government of Canada amended the *Patent Act* for purposes of creating a home-grown industry, much like that in Britain. While the intent of the amendment was to encourage more drug development, it did little to achieve this objective because of the relatively small Canadian market. Multinational drug companies greatly controlled the market and the unfettered patent protection they received permitted them to achieve high profits. Because the government was receiving conflicting evidence about the costs of patented medicines, it commissioned a number of expert studies over the course of the 1950s and 1960s to confirm or refute the suspicions. The expert studies all agreed that drug prices were too high and something had to be done. Much to the consternation of PMAC, the government expanded the system of compulsory licensing in 1969 to allow generic manufacturers to import drug compounds to manufacture its own version of patented medicine. This amendment to the *Patent Act* precipitated the establishment of Canada’s generic drug industry and is credited with producing a downward trend in drug prices.⁶⁸

However, the implications of the amendment created a political controversy for the government, as PMAC retaliated by reducing their investments in Canada. The federal Liberals ultimately decided to reconsider their industrial policy, as investment

⁶⁷ *Ibid.*, 87.

⁶⁸ Eastman, xxv.

was on the decline. In the final months of the Trudeau government, the Quebec caucus started to revolt and even attempted to block the appointment of a royal commission that might have sustained the current system. The prime minister proceeded nonetheless and the commission ultimately concluded that compulsory licensing was an effective policy in restricting drug prices (albeit after a change of government). The commission's report to the new government, whose campaign platform revealed that it would review the Patent Act "to allow innovating companies to profit from the investment made in research and development," did not conform to the government's policy agenda and would ultimately be ignored.⁶⁹ Following the release of the Eastman Report, the government forged ahead with its commitment to review the *Patent Act* and unveiled *Bill C-22*, which could be characterized as a political pact between the government and PMAC. PMAC, having been on the political outs with the federal Liberals prior to and following the adoption of compulsory licensing, took the opportunity of a new, pro-business government to coordinate their interests to influence the policy agenda of the new government.

Campbell and Pal suggest that the tactics of PMAC represented lobbying overkill because the government was intent on changing the rules in any event.⁷⁰ Rather than focusing on a game of numbers, where one side would argue the costs are X and the other the costs are Y, PMAC focused its attention on matters of great political consequence. Because there was a large concentration of PMAC member companies in Quebec as opposed to their CDMA counterparts, it was able to play upon the economic development interests of Quebec. This was politically important, because around the same time, the

⁶⁹ Campbell and Pal, 68.

⁷⁰ *Ibid.*, 71.

Meech Lake Accord was being devised to formally bring Quebec into the constitution. Moreover, it also played to the government's broader economic agenda in attracting more private sector investment by overhauling Canada's industrial policy. Perhaps, just as significant, however, was PMAC's decision to hire, as the Association's president, a former minister of the Crown who had a key understanding of the issues. This permitted the organization to focus its position on political matters, as opposed to strictly economic ones, in contrast to their ineffectual interventions on *Bill C-102*, which enabled them to become a highly mobilized and influential organization.

The major theme of this chapter is that Canada's drug patenting initiatives were a response to domestic pressures. Pressures, such as developing a domestic drug market, the regulation of drug prices, Quebec interests, and a better investment climate for research and development were key factors underlying a number of legislative changes regarding the treatment of pharmaceuticals in Canada. While *Bill C-22* was ultimately a Canadian response to domestic political and economic pressures, it was also greatly influenced by PMAC and the multinational drug companies it represented. However, because PMAC members were entirely foreign the issue did not end at Canada's borders. The passage of *Bill C-22* coincided with the conclusion of the Canada-United States Free Trade Agreement and the commencement of the Uruguay Round of negotiations under the aegis of the General Agreement on Tariffs and Trade, which would eventually have an impact on Canada's intellectual property policy. Canada again had to respond, but this time to international forces regarding its treatment of pharmaceutical drugs. As a result, a number of further legislative and policy changes were needed to bring Canada's IP regime in line with its major trading partners. The next chapter, therefore, reviews the

evolution of the legislative changes to Canada's pharmaceutical industry that were spawned by a number of international agreements and treaties.

CHAPTER 3:

THE EVOLUTION OF DRUG PATENTING IN CANADA 1992-2001:

THE EMERGENCE OF INTERNATIONAL PRESSURES

[3.1] Introduction

Chapter two suggested that changes to Canada's patent laws regarding the treatment of pharmaceuticals were the result of the Government of Canada responding to a variety of domestic pressures. The last significant response came in 1987 when the federal government enacted *Bill C-22*. Although the Canada-United States Free Trade negotiations and the changes undertaken by the European Union exerted some influence on the Canadian government to offer greater patent protection for pharmaceutical products, the major impetus of *Bill C-22* was to revive an industry that had been restricted by Canada's domestic laws. However, with the advent of the 1990s and the inevitable emergence of global political and market forces, Canada was forced to dismantle some of the protections offered to its domestic pharmaceutical industry and had to amend its legislation in order to conform to the influences of the international community. The commitment, for example, to the Canada-United States Free Trade Agreement, the North American Free Trade Agreement (NAFTA), the General Agreement on Tariffs and Trade (GATT) and its re-emergence as the World Trade Organization (WTO), along with Trade Related Aspects of Intellectual Property Agreement (TRIPS), resulted in new international obligations for Canada in terms of pharmaceutical patent protection. Did these global obligations force the government's hand in enacting legislation that would offer even greater patent protection for

multinational drug companies? Or did it just confirm what Canada wanted to do for domestic purposes?

As a result of these international agreements, Canada's pharmaceutical industry would witness a full-scale shift, away from offering certain advantages to generic drug manufacturers, toward adopting a regime that was significantly more favourable to patented drug manufacturers. Subsequent legislative amendments to the *Patent Act*, such as *Bill C-91* and *Bill S-17*, were directly influenced by international political factors, but were couched in terms that Canada had no choice but to satisfy its global commitments. Consequently, generic manufacturers would face a number of legislative setbacks that would reduce their collective ability to be an equal player in the market.

The purpose of this chapter is to describe the major legislative changes to Canada's drug patenting regime undertaken by the Government of Canada as the result of international agreements. This chapter offers an overview of what can be characterized as the "modern system" for pharmaceutical products in Canada and the federal government's response to international pressures. Here, the emergence of the structural power model becomes important in describing the changes made as a result of international agreements. Because structural power determines the structure of the global political economy in which sovereign states have to operate, this chapter demonstrates how Canada's intellectual property regime had to conform to this power structure. Indeed a bargain was struck not only between GATT participants, but also with government and PMAC, in exchanging greater patent protection for increased research and development investment.

The response to the emergence of international forces began in 1992, with the Government of Canada agreeing to GATT provisions, which offered greater patent protection to pharmaceutical products. Thus, the chapter begins by providing a descriptive overview of the most relevant articles of TRIPS and NAFTA to determine why it was necessary for Canada to amend the Patent Act and extend patent protection beyond what was provided in *Bill C-22*. Next, this chapter provides an overview of the political discourse surrounding the passage of *Bill C-91*, the 1993 amendments to the Patent Act. The objective of the amendment was to bring Canada's intellectual property regime for pharmaceutical products in line with the international obligations provided under NAFTA and the WTO.

This chapter then reviews the political showdown that occurred with respect to the Parliamentary Review of *Bill C-91*, which was conducted in 1997. The purpose is to show that it was not the change of government in Ottawa which influenced the direction of drug patenting in Canada, but the global community exercised even greater influence over Canada's pharmaceutical policies. Finally, to further demonstrate the influence of international pressures, this chapter addresses the amendments made to the *Patent Act* by the enactment of *Bill S-17*. The Bill was adopted by Parliament because of a ruling by the WTO that Canada's patent regime was inconsistent with the protection required by the TRIPS agreement.

[3.2] The Emergence of Global Forces in the 1990s: The Changing Nature of IP

The adoption of GATT created an international agreement towards reducing trade restrictions between member countries. While the agreement was aimed at reaching a consensus on a host of trading issues, the most important, for the purpose of this study, were those pertaining to IP rights. It all began with the Uruguay Round of negotiations, which commenced on 15 September 1986, and dealt primarily with establishing minimum international standards for intellectual property protection. The inclusion of intellectual property came at the request of the United States because it was concerned that many countries were infringing upon its IP rights due to the lack of protection offered elsewhere in the world.⁷¹ The influence of the United States in the negotiations of the Uruguay Round resulted in the establishment of: (a) minimum IP standards to be observed by member countries; (b) uniform enforcement procedures; and (c) a mechanism that would resolve disputes among member countries. The conclusion of the Uruguay Round, which occurred on 15 December 1993, saw the formation of the WTO and the TRIPS agreement.⁷² The agreement was deemed to be a victory for the United States. More importantly, it was also a major victory for multinational drug companies who had operations in Canada, but who were largely headquartered in the United States and Europe.

Simultaneously, the negotiations surrounding NAFTA also focused on adding greater IP protection provisions. Thus, Chapter 17 of NAFTA established minimum standards concerning the recognition and protection of IP rights in North America. Taken

⁷¹ This is often referred to as the ‘free-rider’ problem, where other countries can take advantage of discoveries in certain countries with sufficient patent protection.

⁷² The TRIPS agreement was attached as annex to the establishment of the WTO and came into force in Canada on 1 January 1996.

together, the articles comprising TRIPS and NAFTA committed the Canadian government to offer greater patent protection for patented pharmaceuticals—an obligation that would come at the expense of generic drugs. For example, both TRIPS and NAFTA stipulate that each member country shall reciprocally respect IP rights of individuals and companies from fellow member states. In addition, both agreements indicate that member countries are obliged to offer non-discriminatory patent protection regardless of the technology. This meant that Canada would have to abolish compulsory licensing because it was only applicable to pharmaceuticals and not any other sector. Finally, both agreements permitted the deferral of generic drug approval. The deferral occurs when a generic manufacturer, in its submission for regulatory approval, relies on pre-clinical and clinical data confidentially submitted by a patented manufacturer, so it can proceed to produce its copied version of the drug. As a result of TRIPS and NAFTA, Canada was forced to amend its legislation to reflect the major changes brought about by these agreements.

[3.3] The Passage of Bill C-91: A Further Capitulation?

Like its predecessor *Bill C-22*, *Bill C-91*, provided further protection to multinational drug manufacturers. This time however, the Bill did not provide as much political acrimony as *Bill C-22* had, because the Mulroney government had already won the debate, as the opposition—the Senate and many others who were involved in the battle over *Bill C-22*—viewed the emergence of global forces as inevitable.⁷³ Moreover, in their extensive study on the passage of *Bill C-91*, Robert Campbell and Leslie Pal have written that, “the contrast in legislative proposals exposed many critical dimensions of

⁷³ . Robert M. Campbell and Leslie A. Pal, *The Real Worlds of Canadian Politics: Cases in Process and Policy*, 3rd edition. (Peterborough, ON: Broadview Press, 1994) 27.

the political system, especially how ideas such as globalization have increased the external influences on domestic policy.”⁷⁴ Canada, more than ever, now had to respond to the pressures created by the global community as the result of being a signatory to various trade agreements.

Canada made its commitment to GATT in January 1992, at which time International Trade Minister Michael Wilson announced that Canada agreed to endorse the GATT proposals to further enhance patent protection for pharmaceutical products. As noted above, the Uruguay Round of GATT negotiations contained provisions that would give pharmaceutical patent holders in Canada the same amount of exclusive protection offered in other GATT countries (i.e., twenty years from the date of filing). According to Minister Wilson, stronger patent protection would create a more favourable investment climate in Canada.⁷⁵ Predictably, the patented pharmaceuticals applauded the move, while the generic manufacturers complained that the agreement would destroy its industry.

Shortly after the announcement by Minister Wilson, PMAC members made good on their earlier promise to increase investment in Canada provided the government offered greater patent protection. Thus, in the weeks ahead of the legislative debate, the patented manufacturers made announcement after announcement of plans to invest an initial \$325 million in research and development.⁷⁶ With this incentive, there was little doubt that the government would proceed with the legislation. Moreover, because CDMA had little to offer in terms of matching this investment commitment they mounted a

⁷⁴ For an overview of the enactment of *Bill C-91*, see *ibid.*, 27.

⁷⁵ Government of Canada, *News Release*, “GATT Intellectually Property Measures Endorsed, Ottawa, January 14, 1992.

⁷⁶ These figures were obtained from Campbell and Pal, 49.

defensive campaign based on the assertion that the sovereignty of Canadians was imperilled by the GATT agreement and that the Government of Canada had succumbed to American pressures.⁷⁷ However, this tactic failed to drum up enough support for the CDMA case.

As a result of the commitment made to GATT and subsequently, NAFTA, combined with the announcements by PMAC, the Mulroney government forged ahead and introduced *Bill C-91* in the House of Commons on 23 June 1992. This time the government was not prepared to allow the Bill to become tied up in committee, the House of Commons, or the Senate, as was the case with *Bill C-22*. To ensure its passage, the government had limited debate at each stage of the process. Campbell and Pal report that it was “the first time a Canadian government had limited debate at every stage of the legislative process.”⁷⁸ But perhaps more indicative as to why the *Bill* would proceed was a further commitment made by PMAC members of an additional \$171 million for research and development. This combined with the \$325 million promised earlier, assured that the government would pass the legislation PMAC promised those investments because they wanted guaranteed patent protection. In the words of a PMAC spokesperson, “we’re not counting our chickens before they hatch,”⁷⁹ but the conditions to ensure that would hatch were set.

Bill C-91 proposed to amend the *Patent Act* in a number of fundamental ways. First, the *Bill* abolished the compulsory licensing provisions that were enacted by the Liberal government in 1969. As described in the previous chapter, *Bill C-22* deferred the practice of compulsory licensing and now its abolishment was at hand. Second, as a trade

⁷⁷ *Ibid.*, 50.

⁷⁸ *Ibid.*, 28.

⁷⁹ Allan Swift, “Patent Protection Ensures Drug Research,” *Toronto Star*. (Toronto, ON.: July 7, 1992) D.6.

off for the abolition of compulsory licensing, the *Bill* permitted generic drug manufacturers to early work the patented drug and to stockpile a generic version of the drug six months prior to the expiry of the manufacturer's patent. This meant that the generics could come to market immediately when the manufacturer's patent expired. Third, *Bill C-91* strengthened the powers of the PMPRB. It was suggested by many in opposition that earlier legislation did little to provide the agency with so-called teeth to issue remedies. Thus, *Bill C-91* provided the agency with the authority to order the patentee to reduce the price of its medicine if it was found to be excessive or, in some cases, to refund the excess revenues. If the patentee failed to do so, the Board could impose fines or seek imprisonment of the guilty party.

Fourth, and perhaps the most contentious provision arising from *Bill C-91*, was the adoption of the *Patented Medicines Notice of Compliance Regulations*. The purpose of the regulations, which is described in more detail in the subsequent chapter (and Appendix 4), was to prevent the granting of a Notice of Compliance (NOC) to a generic manufacturer until it had addressed any or all patents that were placed on the drug, a practice occasioned by the adoption of TRIPS.⁸⁰ Finally, like *Bill C-22*, *Bill C-91* also contained the provision (s.14) that the *Patent Act* and its regulations were to be reviewed by Parliament four years after its passage and, again, ten years thereafter. However, with the introduction of *Bill C-91*, the government bypassed the review of *Bill C-22* altogether, rationalizing that it had to amend the *Patent Act* due to its international obligations.

Reaction to the bill was sharp and strikingly familiar. Headlines in the national newspapers indicated that it was a battle between Quebec and the rest of Canada, a

⁸⁰ Ogilvy Renault, 4.

weakening of Canadian sovereignty, and consequently, a capitulation to the interests of multinational drug companies.⁸¹ Nonetheless, the government was committed to ensuring that the Bill would be passed according to its legislative time frame. As a result, second reading began on 16 November 1992—in the aftermath of the failure of the Charlottetown Accord—where the government limited debate to just three hours.⁸²

In committee, which first met on 23 November 1992, *Bill C-91* did not get the same opportunity to undergo similar scrutiny as *Bill C-22*. This was partly because committee members were engaged in a series of procedural battles with the Committee Chair, Rene Soetens, who presumably had instructions from the government to ensure that *Bill C-91* would receive timely passage. In fact, the government cut a deal with the opposition not to hold up the Bill in committee in exchange for sending it back to the House of Commons for further debate.⁸³ Another reason was that opposition to the Bill had not been as vociferous as it was with *Bill C-22*. In fact, Opposition leader, Jean Chretien, did not utter a word in the debate, neither for nor against, for fear of alienating the business community and potential supporters in Quebec and other provinces who derive much economic development from pharmaceutical research and development in the face of an impending federal election.⁸⁴

As a result, the committee hearings proceeded at breakneck speed with the usual combatants, particularly PMAC and the CDMA and their supporters, lining up in favour of or against the Bill. In sharp contrast to the hearings involving *Bill C-22*, which took three months, the committee dealt with *Bill C-91* for a total of seven days. It was returned

⁸¹ See for example, Joan Bryden, “Patent drug bill pits rest of nation against Quebec,” *The Toronto Star*, (June 19, 1992) and Susan Delacourt, “Does Ottawa Want Out?” *Globe and Mail*, (June 19, 1992).

⁸² Campbell and Pal, (1994) 57.

⁸³ *Ibid.*, 59

⁸⁴ *Ibid.*, 57.

to the House of Commons on 3 December and passed by 10 December at which time it headed for the Senate.

However, this time, the Senate was a much more cooperative chamber for the Mulroney Government's legislative agenda. Earlier battles over *Bill C-22*, Free Trade, and the passage of the Goods and Services Tax saw a very activist Senate supplant the weak parliamentary opposition as the de-facto opposition to the government. But because the Progressive Conservative Party now held a majority in the Chamber—as the result of the prime minister invoking section 26 of the Constitution Act, 1867, which permitted the appointment of 'eight additional senators'—all but guaranteeing the passage of *Bill C-91*. Despite the obstacles, Liberal Senator Michael Kirby, declared his party's intention was to amend the legislation or, failing that, to stop it.⁸⁵ In spite of the declaration by Senator Kirby, the numbers were simply not there, as the Senate, without amendment, passed *Bill C-91* on 3 February 1993. As a result of the Bill's passage, the multinational drug companies announced even further investments, while Apotex, the largest generic drug manufacturer in Canada, suggested that its plans for building an additional plant in Canada would be put on hold.⁸⁶

[3.4] The 1997 Parliamentary Review: New Government, Same Story?

In February of 1997, the House of Commons Standing Committee on Industry conducted a review of *Bill C-91* as instructed by Section 14 of the 1993 amendment to the *Patent Act*. This time the, however, the political dynamics had changed: the Liberal Party was back in power, under Prime Minister Jean Chretien; the Progressive

⁸⁵ David Scanlan, "Senate takes aim at Tory Drug Bill," *Southam News and Calgary Herald* (Calgary: January 19, 1993) A10.

⁸⁶ Shawn McCarthy, "\$50 million plant cancelled in wake of drug patent bill," *Toronto Star*, (Toronto: February 23, 1993) C4.

Conservative party was reduced to a paltry two seats; the Bloc Quebecois became the official opposition; the Reform Party of Canada of Canada emerged as the new voice on the right; and the NDP lost its official party status. These dynamics suggested that the generic companies were at a significant disadvantage to have their concerns not only heard but acted upon by the government, or to gain the ear of sympathetic opposition parties, as its main supporter, the NDP had lost its official party status.

The committee, chaired by Liberal Member of Parliament, David Walker, was to review every facet of *Bill C-91* and then report its findings to the House of Commons for further consideration. The committee sat from February to April and heard from over 140 witnesses. In a summary of the recommendations, the committee wrote: “it will come as no surprise to hear that we found this policy area to be one of the most contentious and difficult ones facing the Canadian government...our recommendations are grounded in the belief that we must address the wide range of problems that came to light during our hearings.”⁸⁷ The problems that the report referred to centered, again, on the issues of patent protection, drug prices, and the *PM(NOC) Regulations*, which the committee recognized as being at the heart of the debate.⁸⁸

Appearing before the committee, Health Minister, David Dingwall, who in opposition was a vehement critic of *Bills C-22* and *C-91* and the changes brought about by the WTO and NAFTA, had a change of heart: “I don’t think Canada can walk away from the World Trade Organization...and NAFTA. The regime we do have is one we’re

⁸⁷ House of Commons, Standing Committee on Industry, *Report, Summary of Recommendations* (Ottawa: 1997) 1.

⁸⁸ *Ibid.*

going to have to live with and we're going to have to work with.”⁸⁹ Industry Minister John Manley echoed these same sentiments: “we have chosen as a trading nation to enter into NAFTA and the WTO agreements and have benefited immensely from them.”⁹⁰ Thus, it was becoming increasingly obvious that the government was of the view that no significant changes to *Bill C-91* were needed.

Following the appearances by Ministers Dingwall and Manley, the CDMA appeared before the committee and encouraged the committee to correct the imbalances and unfairness created by *Bill C-91*. This time, the CDMA called for the repeal of the PM(NOC) regulations and re-enactment of the compulsory licensing system that was so instrumental in creating the industry. The generic association also acknowledged that it was in agreement with Canada's international obligations with respect to IP rights concerning pharmaceuticals, but argued that “there is flexibility in those agreements” and changes should be made to *Bill C-91* because it “is threatening the future of this industry....”⁹¹

In contrast, PMAC saw *Bill C-91* as necessary for their members to have substantial patent protection for their products. While not totally satisfied with the Bill itself, PMAC encouraged committee members to recommend changes that would bolster patent protection. Speaking before the committee, Judy Erola, then president of PMAC, affirmed, “as long as *Bill C-91* remains in place we are committed to maintaining the

⁸⁹ House of Commons, Standing Committee on Industry, *Proceedings*, Parliamentary Review of Bill C-91 (Ottawa: March 4, 1997) 1600.

⁹⁰ House of Commons, Standing Committee on Industry, *Proceedings*, Parliamentary Review of Bill C-91 (Ottawa: February 17, 1997) 1915.

⁹¹ House of Commons, Standing Committee on Industry, *Proceedings*, Parliamentary Review of Bill C-91 (Ottawa: March 5, 1997) 1600-1605.

present ratio of R and D to sales.”⁹² She continued, asserting that, “current levels and standards of patent protection must, at a minimum, be maintained, [preferably] “...the patent early working provisions should be revoked to make Canadian patent laws consistent with most of our international competitors.”⁹³

In the end, the Committee made six recommendations, agreeable to all parties except for the NDP, which effectively supported maintaining the status quo. The most significant of those was recommendation three which stated, “the Committee believes that Canada should remain committed to our international trade obligations. The Committee accepts the 20-year patent period.”⁹⁴ As for the *PM(NOC) Regulations*, the report only suggested that the “government re-visit the regulatory regime associated with *Bill C-91*, given the concerns that have been raised by stakeholders.”⁹⁵ However, allegations were made, primarily by the NDP, that the committee’s recommendations had been watered down and some discarded. A report in the *Montreal Gazette* alleged that a draft report by the committee was “gutted, removing more than a dozen proposed changes to the Patent Act....”⁹⁶ NDP member of the committee, John Solomon, characterized the final report as a “whitewash.”⁹⁷ As in the past, politics played an important role. The committee drafted its final report on 23 April and three days later, Prime Minister Chretien called an election to be held in June of that year. Again, it would not have been politically savvy for the Liberal dominated committee to recommend major changes to the *Patent Act*, just prior to entering an election campaign. Although the

⁹² House of Commons, Standing Committee on Industry, *Proceedings*, Parliamentary Review of Bill C-91 (Ottawa: March 6, 1997) 1540.

⁹³ *Ibid.*

⁹⁴ Standing Committee on Industry, *Report, Summary of Recommendations*, 3.

⁹⁵ *Ibid.*

⁹⁶ Brad Evenson, “Drug Patent reform plan was gutted: Decision could cost Canadians billions,” *Montreal Gazette*, (Montreal: August 27, 1997) A8.

⁹⁷ *Ibid.*

government had changed since the passage of *Bill C-91*, the concern about investments in research and development, and the sensitive nature of the issue in Quebec politics still remained, in spite of the influences of global forces. Nonetheless, the committee work resulted in very minor technical changes to the regulations.⁹⁸

[3.5] Bill S-17: The WTO Strikes Again

On 20 February 2001, Government Leader, Sharon Carstairs, introduced *Bill S-17* in the Senate of Canada. The purpose of the Bill was to amend the *Patent Act* as occasioned by recent WTO rulings. First, the European Union launched a challenge to the WTO indicating that the early working and stockpiling exceptions permitted under Canada's *Patent Act* was a violation of Articles 28.1 and 33 of the TRIPS Agreement. Article 28.1 of TRIPS reveals: "a patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling or importing for these purposes of that product."⁹⁹ Article 33 indicates that, "the term of patent protection shall not end before the expiration of a period of twenty years counted from the filing date."¹⁰⁰ The EU argued that section 55.2(1) of the *Patent Act* was a clear violation of Article 28.1, because the provision allowed for a generic manufacturer to use a patented invention while the patent was still in force to receive regulatory approval for sale of a similar product once the patent had expired. Moreover, the EU further maintained that by treating pharmaceutical patent holders differently (i.e., by providing

⁹⁸ Government of Canada, "New Drug Patent Regulations Come into Force," (Ottawa: Industry Canada, March 13, 1998) obtained from, <http://innovationstrategy.gc.ca/cmb>, on April 24, 2005.

⁹⁹ *Trade Related-Aspects of Intellectual Property Agreement*, Article 28.1. Subsection (b) of the article establishes the same test, but refers to process patents instead of product patents.

¹⁰⁰ *Ibid*, Article 33.

NOC provisions exclusively to pharmaceuticals) than those in other technologies, Canada was in violation of Article 27.1 of TRIPS—as was described earlier.

Canada countered the EU challenge by maintaining that Section 55.2(1) conformed to TRIPS because: (a) it was a limited exception as occasioned by Article 30 of TRIPS; and (b) the *Patent Act* does not discriminate against the technology nor reduce the minimum patent term.¹⁰¹ The WTO ultimately ruled that although the early working exception of the *Patent Act* was consistent with Canada’s TRIPS obligations, it concluded that the stockpiling exception was not. In the wake of this decision, Canada implemented the ruling and revoked the *Manufacturing and Storage of Patented Medicines Regulations*.

Second, like the EU, the U.S. also launched a challenge to the WTO against Canada’s *Patent Act*. The U.S. challenge alleged that Canada’s term of patent protection for patents issued pertaining to applications filed before 1 October 1989, was inconsistent under TRIPS.¹⁰² The inconsistency, according to the U.S., came from patents based on applications filed before 1 October 1989, where the term was 17 years from the date the patent was issued and not the 20 years from filing established by TRIPS.¹⁰³ However, Canada contended that patents issued under the Old Act had virtually the same protection as those issued under the New Act. The genesis of Canadian argument was that this form of term protection did not apply to patents issued prior to TRIPS came into force. Despite Canada’s contention, the WTO ruled in favour of the U.S. indicating that “the term for

¹⁰¹ Margaret Smith, “Bill S-17: An Act To Amend the Patent Act,” *Parliamentary Research Branch, Library of Parliament*, LS-390E (Ottawa: March 1, 2001) 3.

¹⁰² Government of Canada, *News Release*, “Government of Canada brings Patent Act into conformity with obligations under the World Trade Organization,” (Ottawa: July 12, 2001).

¹⁰³ Patents filed prior to 1 October 1989 were considered as ‘Old Act’ Patents, because they were in place prior to TRIPS and were under the authority of *Bill C-22*. Patents filed after that date were considered to be ‘New Act’ Patents because they were under the authority of *Bill C-91*.

patent protection for Old Act patents is inconsistent with the TRIPS agreement in situations where the patents were granted within three years from the date the patent application was filed.”¹⁰⁴ Clearly, the purpose of these challenges launched by the U.S. and EU were to protect the interests of patented drug manufacturers in markets, such as Canada, that were deemed to offer greater incentives to generic drug manufacturers.

Nevertheless, the outcome of the WTO decisions did not create much anxiety, politically, within the federal government. Speaking before the Senate Standing Committee on Banking, Trade, and Commerce, Industry Minister Brian Tobin surmised that, “*Bill S-17* has one purpose...to bring Canada's Patent Act into compliance with two rulings of the World Trade Organization. The amendments to the act...are straightforward and do not undermine the structure of our patent regime”¹⁰⁵ Capitalizing on the politics of Mr. Tobin’s remarks, Conservative Senator John Lynch Staunton retorted, “I just want to know why the assurances you are giving today are more credible than the same assurances which we gave when we were in government.”¹⁰⁶

As to be expected, Canada’s research based pharmaceutical companies (Rx&D) also supported the amendment. In the words the association’s president: “Let us state at the outset that Rx&D fully supports the will of the Government of Canada to respect its international obligations by rapidly taking steps to correct the so-called "17/20" and stock-piling issues.”¹⁰⁷ It should be noted that in 1999, PMAC changed its name to Rx&D to reflect the evolution of the pharmaceutical industry in Canada.¹⁰⁸ The

¹⁰⁴ Smith, 4.

¹⁰⁵ Senate of Canada, *Proceedings*, Standing Committee on Banking, Trade and Commerce, (Ottawa, March 21, 2001) 1545.

¹⁰⁶ *Ibid.*

¹⁰⁷ *Ibid.*, 1615.

¹⁰⁸ For more information on the history of Rx&D and PMAC see http://www.canadapharma.org/About_Rx&D.

association heaped further praise on its once political nemesis, the Liberal Party of Canada, by stating in adopting *Bill S-17*, "...Canada will comply with its international treaty obligations. This is not only the right thing to do...but it is also, the first step in advancing the government's innovation agenda."¹⁰⁹

However, the CDMA viewed *Bill S-17* as a further legal stifling of its ability to produce drugs. In testimony before the Senate Standing Committee, Jim Keon, President of the CDMA, gave a stern warning to Senators that the Bill will impact its industry: "we cannot support this legislation in its current form...*Bill S-17* contributes to the steadily worsening legal and regulatory environment for generic drugs in Canada."¹¹⁰ Despite the warning, the Senate passed the Bill on 1 May and it was subsequently introduced into the House of Commons on 3 May. *Bill S-17* went through the legislative process in the House in a relatively short period of time, and was passed on 7 June 2001. *Bill S-17* became law on 14 June 2001, bringing Canada into conformity with its international obligations under the WTO.

[3.6] Conclusion

The primary objective of this chapter was to demonstrate how international agreements influenced the pharmaceutical industry in Canada. The purpose was to show how agreements like TRIPS and NAFTA effectively mandated the Government of Canada to undertake legislative changes that would bind its domestic priorities with meeting its international obligations. In other words, the international arrangements simply confirmed changes made before the agreements and tipped much of the balance in favour of the patented manufacturers. The WTO and the TRIPS Agreement constrained

¹⁰⁹ *Ibid.*

¹¹⁰ *Ibid.*, March 21, 2001, 1100.

domestic government's ability to simply enact IP legislation that met the needs of its domestic constituents; it now had to conform to the wishes of the larger international community. The adoption of NAFTA all but confirmed the fact that Canada could no longer provide special treatment to generic manufacturers even if those cheaper drugs would reduce financial strain on Canada's publicly funded health care system.

If, as the previous chapter pointed out, *Bill C-22* was Canada's last major response to domestic pressures concerning the protection of pharmaceutical drugs, then, *Bill C-91* was its first major response to international pressures. In their comprehensive study, Campbell and Pal write: "*Bill C-91* was presented as a logical, necessary policy, precisely because of its association with NAFTA and GATT arrangements, Canada's strategic regional and international responses to globalization."¹¹¹ However, when *Bill C-91* was first introduced, the GATT arrangement was simply a draft, and no government had yet signed it. Moreover, NAFTA had not yet been ratified. Indeed, Canada used these agreements as necessary mechanisms to provide further statutory and regulatory advantages to the patented drug manufacturers.

One of the key foundations of the policy communities and policy network literature is that the better a sectoral association is able to organize itself, the greater the influence it will have on government policy. More specifically, the utilization of the corporatist network, where two competing business associations exert pressure on government to enact legislation favourable to their particular association, reveals that one association emerges victorious in having many or all of its objectives met. It would be naïve not to think that PMAC was able to organize itself as an effective lobby, to a sympathetic government, to have its interests protected. Thus, *Bill C-91* could be seen as

¹¹¹ Campbell and Pal, 63.

a major victory for PMAC members: it offered greater patent protection, abolished compulsory licensing, and created the *PM(NOC) Regulations* to ensure that the generics did not infringe upon the patent. However, PMAC members followed up on their commitment to increase their ratio of research and development investment to sales, and this commitment would be difficult for any government to overlook.

Even with a change in government, from Progressive Conservative to Liberal, in the 1993 federal election did not change how patented pharmaceuticals would be regulated in Canada. In opposition, the federal Liberals were major supporters of the generics, but once in office, the support seemed to dissipate. The 1997 parliamentary review of *Bill C-91* all but confirmed this, as the Liberal-dominated House of Commons Industry Committee did not see fit to instruct Parliament to undertake major changes to Canada's patent law. Despite the allegations made by the CDMA that *Bill C-91* was destroying its industry, the Liberal government could not find enough political currency to accept the allegations and undertake major changes. They were of the opinion that the law already treated the generics fairly and the legislation was not hurting generic manufacturers in spite of their testimony. In fact, Minister Manley made the comment to the committee that "the generic industry remains vibrant today, four years after *Bill C-91*."¹¹²

Nevertheless, four years after the review of *Bill C-91*, Canada had to make further amendments to the *Patent Act* as the result of two WTO rulings. Thus, Canada enacted *Bill S-17*, which gave greater patent protection to patented drugs and abolished the regulations allowing for generic manufacturers to stockpile their own versions of the patented drug, prior to the expiration of the patent. The challenges made to the WTO by

¹¹² House of Commons Standing Committee on Industry, *Summary of Proceedings*, 20-21.

first the EU, and second, the United States with respect to Canada's patent law demonstrates the extent to which international agreements, supported by the interests of multinational drug companies can influence the outcome of Canadian government policy. Consequently, Canada's pharmaceutical industry was influenced less by domestic issues and more by international issues spawned by the advent of globalization. The structural power model, as described in chapter one, indicates that international agreements have come to develop a different set of frameworks that define various state and corporate relationships. Indeed, there has been reluctance by government to pursue policies that act contrary to international agreements like TRIPS and NAFTA. Because of the power structures and the bargains that have emerged from these agreements, multinational drug companies gain a greater regulatory advantage from domestic policy makers. Given these developments and the resulting amendments to the *Patent Act*, the next chapter examines how a convergence of both domestic and international pressures has exacerbated the politics of drug patenting in Canada.

CHAPTER 4

THE POLITICS OF DRUG PATENTING IN CANADA, 2002-2005:

A CONVERGENCE OF DOMESTIC AND INTERNATIONAL PRESSURES

[4.1] Introduction

The major objective of both chapters two and three was to identify how the statutory and regulatory framework for drug patenting in Canada has evolved over time. Through that review, this study has revealed that the various policy outcomes were the result of Canada responding to a variety of domestic and international pressures. Moreover, it has attempted to show that the amendments to the *Patent Act* have been greatly influenced by the ability of patented drug manufacturers to lobby the federal government effectively in changing its IP policy. However, because the issue of drug patenting is nestled within the larger domains of industrial policy and health policy, government will always have to consider domestic issues regardless of the pressures that the international community may impose. Ideally, governments must strive to strike a balance between offering sufficient patent protection and controlling health expenditures. In other words, should Canada's pharmaceutical policies favour economic development by offering greater patent protection? Or should Canada's pharmaceutical policy favour the sustainability of Canada's health care system and allow for early entry of generic competition?

To answer those questions and in keeping with the overall objective of this thesis, which is to analyze the evolution of drug patenting in Canada, the objective in this chapter is to provide an overview of how the Government of Canada has responded when faced with a convergence of domestic and international issues related to the practice of

drug patenting. More specifically, the purpose of this chapter is to provide an overview and analysis of particular initiatives that have taken place since the passage of *Bill S-17* in 2001 until 2005. During this period, various domestic and international pressures emerged or re-emerged to cause the federal government to proceed with more changes to its patent laws. The analysis will show that government and industry stakeholders have had to "put some water in their wine" in producing a regulatory framework in which various public and private interests were balanced, but ultimately, that patented drug manufacturers were able to maintain their influence over the framework.

As was pointed out in the earlier chapters the relationship between government and industry within a corporatist network resulted in several changes to the statutory and regulatory framework for drug patenting in Canada. However, when these changes did not go far enough in terms of offering patented drug manufactures the protection they required, the network was eclipsed by international power structures and political bargains that resulted in further changes to Canada's statutory and regulatory framework for drug patenting. In this chapter, because of the focus on a convergence of domestic and international pressures, the corporatist network and the structural power model come together to help explain the further changes to the statutory and regulatory framework.

This chapter is divided into two main sections. The first section focuses on political factors that emerged during this recent period. It begins by providing an overview of the recommendations contained in the Romanow report with respect to drug patenting practices. This chapter reveals that as a result of a key recommendation in Romanow report the federal government decided to act in this policy area. The House of Commons Industry Committee conducted four days of hearings into the automatic

injunction provisions of the *PM(NOC) Regulations*. While the committee was conducting its hearings, the Competition Bureau announced that it was conducting an investigation into the practices of patented manufacturers with respect to the regulations. This section will review the findings of the Bureau to determine what, if any, implications its decision had on the system.

The second section addresses the major changes made to the statutory and regulatory framework between 2002 and 2005. More specifically, this section chronicles the changes made to the Patent Act and the Patented Medicines Notice of Compliance Regulations by focusing on *Bill C-9*, the *Jean Chretien Pledge to Africa Act* and the amendments to the *PM(NOC) Regulations*, which were announced by the federal government on 11 December 2004. Whereas *Bill C-9* was passed by Parliament on 14 May 2004, the amendments to the regulations have yet to come in to force.

[4.2] A Convergence of Domestic and International Pressures:

The Political Component

[4.2.1] The Romanow Report: Renewing the Domestic Debate

In November 2002, after much anticipation, the Royal Commission on the Future of Health Care in Canada (the Romanow Report) released its final report, providing a number of recommendations that would potentially fix Canada's ailing health care system. The Report included an entire chapter devoted to the growing importance of prescription drugs on Canada's health care system.¹¹³ Acknowledging this, Romanow declared: "when medicare was first introduced prescription drugs played a limited role in

¹¹³ It should be noted that the Senate Standing Committee on Social Affairs, Science, and Technology, chaired by Senator Michael Kirby, released its report, *The Health of Canadians: The Federal Role*, in October 2002, but it did not have any recommendations pertaining to the drug patenting system in Canada. Rather, the committee focused on changes to prescription drug coverage plans.

the health care system...today they are a fact of life for many Canadians.”¹¹⁴ This so-called ‘fact of life’ was revealed by the fact that in 1980 prescription drugs accounted for 5.8% of total health expenditures, but by 2001 they accounted for 12% of total health expenditures.¹¹⁵ Critics would argue that the increase in expenditures was the result of offering greater patent protection to patented manufacturer’s, while proponents would argue that the increased expenditure was the result of the extra patent protection allowing for an increase in research and development, and therefore, more effective products. However, to the chagrin of the critics, the Romanow report indicated that there is no empirical evidence to indicate that Canada’s patent laws are responsible for the increase in drug prices.¹¹⁶

Nevertheless, Romanow called upon the federal government to review certain aspects of patent protection. Recommendation 41 of the report stated: “The federal government should immediately review the pharmaceutical industry practices related to patent protection, specifically the practice of evergreening and the notice of compliance regulations.”¹¹⁷ The concept of evergreening refers to a process whereby patented drug manufacturers add additional patents to a particular drug (e.g., for changes in composition or dosage) thereby triggering an automatic injunction, which keeps a generic drug manufacturer from entering the market with a copied version of the original patented drug until it has addressed all patents (even the new ones) listed for the drug.¹¹⁸

¹¹⁴ Commission on the future of Health Care in Canada, *Final Report*, “Building on Values,” (Ottawa, 2002) 189.

¹¹⁵ *Ibid.*, 196-7.

¹¹⁶ *Ibid.*, 209.

¹¹⁷ *Ibid.*, 208.

¹¹⁸ For more on this concept see *ibid.*, or Appendix 4 of this thesis, “Features of the Drug Approval Process.”

It was soon obvious that the Romanow report re-engaged the domestic debate over the treatment of pharmaceuticals in Canada.

In the House of Commons, some Liberal backbenchers and NDP opposition members encouraged the government to adopt the recommendation and immediately undertake another review of the industry. The Canadian Generic Pharmaceutical Association (CGPA) praised the report and immediately lobbied the government to follow up on the recommendation.¹¹⁹ In a news release following the release of the Report CGPA president, Jim Keon, suggested that, “abuse of drug patent laws that delay Canadians’ access to lower-cost generic drugs even after original 20-year patents expire is too expensive to be allowed to continue.”¹²⁰ However, the patented manufacturers disagreed with that recommendation. In an opinion-editorial piece submitted to the national media, Rx& D was critical of the Romanow report in calling on the government to review patent protection: “Why aren't Canadian researchers worthy of the same acknowledgment of their work as their colleagues in the United States or Europe? These recommendations may lead to Canada losing its best researchers and depriving patients of the best solutions for treatment.”¹²¹ Thus, the Romanow report served as a political springboard to renew the domestic debate over the practices of Canada’s pharmaceutical industry. Once reaction to the report had died down, the House of Commons Standing Committee on Industry, Science, and Technology voted to conduct hearings into the

¹¹⁹ The formerly the CDMA, the organization changed its name to the CGPA in 2002, to be more reflective of what the association does. For more information see, <http://www.canadiangenerics.ca>

¹²⁰ Canadian Generic Pharmaceutical Association, “Government Must Act Now to Implement Romanow Recommendations on Drug Patent Laws: Generic Industry,” (November 28, 2002) obtained from http://www.cdma-acfpp.org/en/news%5Cnov_28_02.shtml.

¹²¹ Jean Francoise Leprince and Andre Macharette, “An Ounce of Prevention is worth a Pound of Cure,” (January 13, 2003) obtained from, www.canadapharma.org/Media_Centre/News_Releases/2003/Jan13-03-Oped_e.html.

automatic injunction provisions of the *PM(NOC) Regulations* as recommended by the report.

[4.2.2] Committee Hearings into The PM(NOC) Regulations: A Perpetual Issue

On 2 June 2003, a very divided Industry committee commenced hearings into the *PM(NOC) Regulations*, focusing on the automatic injunction provisions. The committee had to wait until June because earlier attempts to conduct the hearings in April, which were made by some Liberal and NDP members, were voted down by other Liberal members of the committee—primarily those from Quebec, along with members of the Canadian Alliance, Progressive Conservative Party and Bloc Quebecois. The delay caused Liberal member of the Committee, Dan McTeague, to denounce his colleagues and angrily retort: “obviously they don’t care about what Roy Romanow said...Canadian consumers are being fleeced because delays in getting generics to market keep drug prices high.”¹²²

The hearings began with officials from both Industry Canada and Health Canada providing committee members with a technical overview of how the process for drug patenting and drug approval works in Canada.¹²³ In questioning officials, it became clear that some committee members were attempting to find solutions, while others wanted to just get rid of regulations altogether. In determining a possible trade-off to changing the regulations, James Rajotte of the Canadian Alliance Party (CA) asked senior deputy minister of Industry, Mr. Andrei Sulzenko: “if this committee does decide to amend, in any way, the NOC regulations that we would have to look at early working in

¹²² Glenn McGregor, “Victory for Big Drug Makers,” *Ottawa Citizen* (Ottawa: April 1, 2003) A3.

¹²³ For an overview and comments relating to this system see Appendix 4 of this thesis.

conjunction because they are flip sides of the same coin.”¹²⁴ To which Mr. Sulzenko replied: I did say it was part of a balanced package...[if] we get rid of the regulations entirely...[then] the other balancing feature of early working couldn’t stand alone.”¹²⁵ To Industry Canada, the regulations are essential to striking a balance. However, Brain Masse of the NDP expressed outward disdain for the regulations, referring to them as a “complete dog’s breakfast.”¹²⁶

Some committee members pointed to the idea that the regulations unfairly favour patented drug manufacturers. Again, Dan McTeague, sticking to script, indicated that the system favours intellectual property. However, it was revealed during the testimony that Canada is the only industrialized country to have adopted the early working exception without having adopted a patent extension system. It was this advantage that made one Liberal member from Quebec comment, “the premature license to produce gives generic drug manufacturers an absolutely extraordinary advantage.”¹²⁷

On the following day, CGPA representatives appeared before the committee. Their presentation was similar to what was given in the past; namely, that the regulations are restricting their ability to produce drugs and create an unfair advantage for patented manufacturers. President and Chief Executive Officer of Ratiopharm, Jean Guy Goulet, opined: “It is clear that the regulations are not saving the interests of Canadians. In our view, the regulations must be scrapped to end the abuse of the drug patent laws. We strongly encourage this committee to recommend the regulations be eliminated.”¹²⁸

¹²⁴ House of Commons Standing Committee on Industry Science and Technology, *Evidence of Proceedings*, June 2, 2003, 1625.

¹²⁵ *Ibid.*

¹²⁶ *Ibid.*, 1705.

¹²⁷ *Ibid.*, 1655.

¹²⁸ House of Commons Standing Committee on Industry, Science and Technology 37(2) *Evidence of Proceedings*, Tuesday, June 3, 2003, 1605.

However, in questioning the generic representatives, Paul Crete of the Bloc Quebecois, countered, "...do you automatically accept the idea that the current practice of patent infringement that allows generic drugs to be prepared in advance would be abolished? There is a balance in this legislation."¹²⁹ In response, the generic representatives indicated that they were against the creation of special rules for the pharmaceutical industry.

Having said that, Serge Marcil of the Liberal Party asked: "So what more needs to be done to satisfy the generic industry...?"¹³⁰ In responding, the generic representatives gave little in the way of solutions other than recommending a repeal of the regulations. One representative proposed a solution that was being looked at in the United States, wherein the patented manufacturer could only invoke the automatic injunction one time before permitting generic entry. However, the CGPA were not going to compromise on their position of doing away with the automatic injunction provision. Jim Keon reported to the committee, "I think it is important to understand what we are suggesting. We are suggesting the elimination of the automatic injunction..."¹³¹ From the testimony given by the CGPA, it was clear they were unwilling to accept any changes other than outright repeal. However, a majority of committee members were unwilling to proceed in such a fashion.

On 4 June 2003, representatives from Rx&D appeared before the committee. It was clear from previous testimony that the organization was in favour of the regulations and their testimony before the committee this time did not deviate from that position. Paul Lucas, President and CEO of GlaxoSmithKline, suggested that the regulations needed to be maintained for the following reasons: "One, they ensure balance within

¹²⁹ *Ibid.*, 1625.

¹³⁰ *Ibid.*, 1630.

¹³¹ *Ibid.*, 1635.

Canada's patent regime. Two, they help us meet our international obligations. Three, they help our economy prosper. Four, they encourage innovation into new therapies....¹³²

While these reasons may overstate the importance of the regulations, the patentees maintain that they are essential to the functioning of their operations in Canada. Thus, the regulations are an important enforcement mechanism against patent infringement. To Mr. Lucas, the regulations are working well: "We respectfully request that you support the current system and recommend that you do not repeal or weaken the linkage regulations."¹³³

During the testimony, it was pointed out that, in spite of the allegations being made by the generics that the regulations extends patents beyond 20 years, patents have a defined period and cannot be extended beyond the 20 year-term. Over the course of the testimony the example of the drug Losec (produced by Astra Zeneca) was brought up to demonstrate that the drug had more than one patent (eleven) and thus, was clearly abusing the regulations. However, to the satisfaction of some committee members, Rx&D representatives explained that the original compound, which the patent expired in 1999, was of no value because it decayed in the stomach. As a result, the manufacturer was forced to develop a new coating, which required the additional patents to make the compound more valuable to consumers. According to Rx&D, patented drug manufacturers should be offered protection for advances in medicine regardless of whether it is a new compound or a change in process.

Similar to the questions posed to the CGPA, Rx&D representatives were asked by Yukon Liberal, Larry Bagnell, to try and think of a compromise that would permit 20-

¹³² House of Commons Standing Committee on Industry, Science and Technology, 37(2) *Evidence of Proceedings*, Wednesday June 4, 2003, 1530.

¹³³ *Ibid.*, 1540.

year ironclad protection followed by easy access for the generics.¹³⁴ Murray Elston, a former minister of Health in Ontario under David Peterson's Liberals, now President of Rx&D replied, "...if there were sufficient changes made in the environment here in Canada...and we were sure we could be competitive with others, we could see ourselves moving to two and three times the investment that currently is made in this country."¹³⁵ However it was Mr. Elston's contention that nothing should be done to weaken patent protection. It is Rx&D's position, much to the disagreement of many, especially the generics, that generic manufacturers have a greater opportunity in Canada than elsewhere. Paul Lucas suggested to the committee that Canada has a weaker patent regime than Europe, the United States, and Japan because, "they have patent term restoration; we don't. They have data protection, which we should get under TRIPS but don't."¹³⁶ It is those features, according to Rx&D, that gives generic manufacturers a greater advantage in Canada.

On a similar line of questioning Mr. Masse asked: "Can you not suggest anything that would improve the current situation so that consumers aren't basically funding lawyers through a system here where we have rising drug costs...?"¹³⁷ To which Mr. Lucas replied, "...we do not want to spend our money on lawyers. If the generic industry were not engaging in strategic patent busting and waited until our patents expired, we wouldn't have to spend that money [on litigation]."¹³⁸ Obviously, the divisions within the committee were clear. The line of questioning demonstrates that certain committee members, regardless of evidence, were either for or against the CGPA position or for or

¹³⁴ *Ibid.*, 1550.

¹³⁵ *Ibid.*

¹³⁶ *Ibid.*, 1555.

¹³⁷ *Ibid.*, 1625.

¹³⁸ *Ibid.*,

against the Rx&D position, with few, if any, in the middle. But the divisions were also a product of members of parliament representing constituents. Andre Bachand, then a Quebec member of the Progressive Conservative Party, invited committee colleagues “...to take highway 20 to my riding. That would give you an idea of the investment being made in research and development in Quebec and elsewhere in Canada.”¹³⁹

On the final day of testimony, 9 June 2004, the committee heard again from officials representing Industry Canada and Health Canada. Although nothing new came from the testimony, other than a clarification of earlier testimony, there were heated exchanges between Members of Parliament who believed the regulations were treating the generics unfairly and Industry Canada officials, who were accused of protecting the brand name manufacturers.¹⁴⁰ Because of the major divisions within the committee, coupled with the fact that Parliament was to be prorogued, it failed to offer a report with respect to undertaking amendments to the regulations. However, the controversy did not end in committee. The issue was sent before the Competition Bureau of Canada for further study.

[4.3.3] The Competition Bureau: Investigating the Patented Drug Manufacturers

On 9 June 2003, on the final day of hearings into the automatic injunction provisions by the Industry Committee, Canada’s Competition Bureau announced that it was conducting an inquiry into the alleged misuse of the *PM(NOC) Regulations* by patented drug manufacturers. The inquiry began because of a complaint filed with the Bureau by the National Union of Public and General Employees and other organizations

¹³⁹ *Ibid.*, 1610. Mr. Bachand represented the constituency of Richmond-Arthabaska, located in southern Quebec, near Sherbrooke. The constituency serves as Canadian headquarters to a number of patented manufacturers.

¹⁴⁰ House of Commons Standing Committee on Industry, Science and Technology, *Evidence of Proceedings* 37(2) Monday June 9, 2003, 1610-1630.

representing seniors, pensioners, health care activists and consumer groups, all supporters of a greater role for generic drug manufacturers. According to section 9 of the *Competition Act*, an inquiry is commenced following a six-resident application alleging an industrial offence.¹⁴¹ The complaint, which became public on 14 May 2003, alleged that the patented drug manufacturers were routinely engaging in the practice of evergreening.

On 27 February 2004, the Competition Bureau concluded its hearings. Among its findings, the Bureau pointed out that while it recognizes that the regulations may delay the entry of a generic drug, brand name patent holders are acting “within the purpose and intent” of the regulations when seeking a prohibition to block a notice of compliance being issued to a generic manufacturer.¹⁴² Moreover, the Bureau indicated that the regulations contain specific provisions to address and balance the competitive interests of the patent holder and the generic manufacturer. While, the Bureau alluded to the problems within the regulations, it also recognized that they appropriately strike a competitive balance. As a result, the Bureau reported that, “the *Competition Act* is not the appropriate vehicle to address the allegations raised in the complaint.”¹⁴³ It seemed as if the generic manufacturers were about to receive another setback. However, the Bureau suggested that, “the Government may wish to review the current rules to ensure that an appropriate balance is maintained between protecting intellectual policy rights and facilitating a competitive supply of pharmaceutical products for Canadian consumers.”¹⁴⁴

Reaction to the Bureau’s decision was mixed. Dan McTeague called the decision

¹⁴¹ Government of Canada, *Competition Act, R.S., 1985* (Ottawa).

¹⁴² Government of Canada, *Competition Bureau*, “Competition Bureau Responds to Complaint Over Alleged Misuse of Canada’s Drug Patent Rules,” (Ottawa: February 27, 2004).

¹⁴³ *Ibid.*

¹⁴⁴ *Ibid.*

courageous, while a spokesperson for Rx & D said the Bureau did the right thing by sending the issue back to the lawmakers.¹⁴⁵

[4.3] A Convergence of Domestic and International Pressures:

The Policy Component

[4.3.1] Bill C-9 (The Jean Chrétien Pledge to Africa Act): A Return of International Pressures

In August 2003, negotiations among WTO member states resulted in a decision by the organization to waive certain provisions of the TRIPS agreement in an attempt to provide nations of the Third World with the opportunity to import less expensive pharmaceutical products. At issue was a commitment to provide Third World countries with access to pharmaceuticals that would help combat the growing problem of HIV/AIDS and other public health problems in these countries. However, at the time of negotiations, Article 31(f) of the TRIPS agreement prevents WTO member states that manufacture generic drugs from exporting those drugs to other countries. More specifically, the decision stipulates that the agreement must be used to deal with public health problems and not to satisfy industrial or commercial objectives and to ensure that “these products are not diverted from their intended beneficiaries.”¹⁴⁶ The decision came on the heels of the 2001 Doha Declaration, where WTO member states recognized the gravity of public health problems, such as AIDS, affecting the least developed countries of the world. Following Doha, Canadian Prime Minister Chrétien urged fellow WTO states to join Canada in providing these countries access to less expensive pharmaceutical products.

¹⁴⁵ _____ “Drug Law costing billions,” *Regina Leader Post* (Regina: February 28, 2004) A10.

¹⁴⁶ Government of Canada, *News Release*, “The Jean Chretien Pledge to Africa Act Approved by Parliament,” (Ottawa: May 13, 2004). Obtained from <http://www.ic.gc.ca>, on April 26, 2005.

Thus in November 2003, the Chrétien government introduced *Bill C-56* to meet its declared obligations as a result of Doha. The Bill passed second reading, but died on the order paper because of Prime Minister Chrétien's retirement and because Parliament was prorogued. However, the Bill was re-introduced by the Martin government under the title *Bill C-9*, or the *Jean Chrétien Pledge to Africa Act*,¹⁴⁷ and was immediately sent to the House of Commons Standing Committee in Industry Science and Technology for further study. Prior to reaching the committee, *Bill C-9* amended both the *Patent Act* and the *Food and Drugs Act* to permit Canada to “authorize someone other than the patent holder to manufacture a lower cost version of the patented medicine in order to export it to a developing country with insufficient or no pharmaceutical manufacturing capacity.”¹⁴⁸ In other words, the Bill would allow a generic manufacturer to obtain a compulsory license to manufacture and export its own version of a patented medicine to developing countries, provided the patentee agreed. As a trade off, the patentee was given the right of first refusal, which would give the patentee thirty days to take over any contract negotiated by the generics.

In reviewing the legislation the committee heard from a number of stakeholders, including the patented and generic drug manufacturers. During the proceedings, representatives from Rx&D declared their support for the intent of the legislation: “The research-based pharmaceutical community has proactively offered its continued support to officials being tasked with developing this crucial piece of legislation.”¹⁴⁹ That being said, however, Rx&D proposed a number of technical recommendations to the

¹⁴⁷ The bill was given the name to recognize the former Prime Minister's commitment to the issue of helping Third World countries tackle several health related problems. For more information see, *ibid.*

¹⁴⁸ *Ibid.*

¹⁴⁹ House of Commons Standing Committee on Industry Science and Technology 37:3, *Evidence of Proceedings* (February 26, 2004) 0930.

committee, which included anti-diversionary strategies and forcing generic manufacturers to first obtain a voluntary license from the patentee prior to obtaining a compulsory license to manufacture and export the drug, before it would give its full endorsement.¹⁵⁰

The CGPA also supported the intent of the amendment. Speaking before the committee, Jim Keon declared “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.”¹⁵¹ However, the organization did not believe that the amendments went far enough and was primarily concerned that the patentees had the right of first refusal, which would restrict generics from negotiating with the country to which it was to export. Thus, Keon urged the committee to “eliminate the right of first refusal,” because in his words, it would “act as a disincentive.”¹⁵²

As a result of the testimony, the Committee made a number of technical amendments to the legislation that was reflected in the passage of the Bill on 14 May 2004. However, much to the dismay of the generic manufacturers *Bill C-9* did not do away with the right of first refusal and gave the patentee the legal right to challenge an authorization for the generic manufacturers to export where it can be established that the purpose of the export is for commercial purposes and not for humanitarian purposes.¹⁵³

¹⁵⁰ *Ibid.*, 0935.

¹⁵¹ *Ibid.*, 0940.

¹⁵² *Ibid.*, 0945.

¹⁵³ Gowlings, Lafleur, Henderson, “New Regime for Compulsory Licensing of Pharmaceuticals,” *Pharmacapsules, Bulletin Edition, no 7* (Ottawa: May 24, 2005).

[4.3.2] *Amendments to the PM(NOC) Regulations: Token response or actual change?*

Shortly after the passage of *Bill C-9*, the federal government announced that it was making changes to the *PM(NOC) Regulations*.¹⁵⁴ The changes came on the heels of testimony provided to the Industry committee and the emergence of recent jurisprudence strengthening the ability of patented manufacturers to enforce new patents on old products, resulting in additional litigation, and thereby, delaying generic competition. On 11 December 2004, Ottawa pre-published the proposed amendments in the *Canada Gazette*, indicating that the purpose of the amendments were to restore the policy balance that was originally intended when the *PM(NOC) Regulations* came into force in 1993. As a result of the proposed changes, concerned stakeholders would have an opportunity to submit comments regarding the amendments, as the government announced it would engage in a 75-day consultation period. This period has now elapsed and no changes to the proposed amendments have been made as of June 2005.

The intention of the changes was to clarify the rules pertaining to the listing of patents and when those listed patents must be addressed. According to Industry Minister, David Emerson, “the government’s actions will cut down on unnecessary litigation and clarify the rules, which...work to benefit both innovative and generic drug companies.”¹⁵⁵ The amendments would benefit both the generic and innovative sectors by allowing generic drugs to enter the market once a patent has expired, while providing the patent holder with greater data protection measures, governed under the *Food and Drugs Act*. Under the amendment, new, brand name drugs would receive an internationally

¹⁵⁴ The amendments also included changes to the *Food and Drugs Act*.

¹⁵⁵ Government of Canada, “Government of Canada Proposes Amendments to Intellectual Property Rules for Pharmaceuticals.” (Ottawa: December 12, 2004). Obtained from <http://www.gc.ca/news>. (Accessed January 7, 2005).

competitive, minimum period of market exclusivity of eight years for the data obtained through clinical trials.¹⁵⁶ Data protection has been an issue for which the brand name manufacturers wanted to see greater enforcement. Currently, the *Food and Drug Regulations* permit a generic manufacturer to utilize clinical data obtained by brand name manufacturers, when the generic attempts to seek bioequivalence, and thus an NOC, for the drug it intends to copy.

While, the changes seek to find the necessary balance between sufficient patent protection and early generic entry, the regulations have yet to come into force. In this give a little, take a little, no clear-cut winner emerges in the debate. The assumption is, however, that nothing short of repeal of the regulations would satisfy the generics. For the patentees, the changes provide a small victory, but indeed, do not go far enough in providing the iron-clad patent protection they seek for their products. Nevertheless, as it stands today, the current practice will undoubtedly continue until Cabinet finds the political courage to proceed.

[4.4] Conclusion: Has Canada Found the Balance?

The major objective of this chapter was to suggest that between 2002 and 2005 a third wave of debate about drug patenting had emerged in Canada. No longer was the wave simply confined to a host of domestic influences or a myriad of international commitments; this wave consisted of both domestic and international pressures. The convergence of these forces immediately caused the Government of Canada to act in undertaking changes to its IP regime. In one sense the political activities that occurred early on in this period largely mirror those that were chronicled in chapter two. For example, the recommendations contained in the Romanow report had the same effect on

¹⁵⁶ *Ibid.*

government that the Restrictive Trade Practices Commission and the Hall Commission had earlier; it sent the message that something had to be done. The Romanow report did not call for changes to the statutory or regulatory framework, but called on the federal government to at least look into the practices of the pharmaceutical industry in Canada.

Although there was reluctance to delve into the issue on the part of the House of Commons Industry Committee, it nonetheless conducted a very divisive four day investigation into the workings of the automatic injunction provisions of the *PM(NOC) Regulations*. The outcome of the Committee's investigation produced very little in the way of changes and ultimately upheld the status quo. This was deemed to be a clear victory on the part of Rx&D.

Fearing that the Committee would do very little in terms of changing the regulations, organizations in support of the generic drug manufacturers undertook the initiative to have the Competition Bureau launch an investigation into the practices of the patented drug manufacturers with respect to the *PM(NOC) Regulations* and the practice of evergreening. Although the Bureau acknowledged some problems with the regulations, it ultimately concluded that the practices of the pharmaceutical industry in Canada were beyond its jurisdiction. Because the Bureau failed to recommend any substantive changes the decision was viewed as another victory for the patented manufacturers, regardless of how supporters of the CGPA, such as Liberal M.P. McTeague, may have interpreted the outcome.

As chapter three pointed out, international pressures also influenced changes to Canada's IP regime. During this period, however, the changes did not result in greater patent protection, but gave generic manufacturers the opportunity to export their products

to Third World countries. *Bill C-9* was the result of WTO countries agreeing to relax certain provision of TRIPS to allow specific third world countries greater access to pharmaceutical products. The agreement allowed generic manufacturers to obtain a compulsory license, a practice that was done away with due to *Bill C-91*, for the purpose of satisfying the commitment. While initially, the adoption of *Bill C-9* may have been viewed as victory for the generic manufacturers, once the bill was in front of the Parliamentary committee, Rx&D was able to influence a number of changes that would give them a greater say in which drugs and which manufacturers may obtain a compulsory license. Again, the patented drug manufacturers emerged victorious because they were able to effectively lobby Parliament to ensure that their products received the necessary protections.

Finally, the Government announced it was undertaking amendments to the *PM(NOC) Regulations* that would strike the so-called balance in regulating the practices of patented and generic drug manufacturers. While the changes saw both of the major sectoral associations receive some incentives, the amendments to the regulations have yet to be approved by Cabinet. Although the amendments provide a greater opportunity for generics drugs to come to market once an original patent has expired they also provide patented drug manufacturers a greater enforcement mechanism with respect to data protection. The formal adoption of these amendments may be the next step in finding that ever-elusive balance between access and protection. However, one former federal cabinet minister is not so sure. Speaking in 2002, then Industry Minister Allan Rock asked: “are we ever going to get agreement between generics and brand names on what the right

balance is between patent protection and competition. Are we ever going to get unanimity on whether the NOC regulations are right or should be adjusted more? I think not.”¹⁵⁷

Changes to Canada’s IP regime with respect to pharmaceuticals, whether major or minor, have tended to favour the objectives of Rx&D. While questions are continuously raised regarding industry practices, it seems that there is reluctance on the part of government to shift the balance toward the centre and to give generics a greater role in the industry. However, one important point needs to be made. Rx&D represents approximately 52 innovative pharmaceutical and biotechnology firms, with about half located in the Province of Quebec and half in the Province of Ontario.¹⁵⁸ According to Rx&D, member companies spend over \$800 million annually on research development. In contrast the CGPA, represents approximately 20 generic manufacturers and distributors, with only three firms in the Province of Quebec and the rest in Ontario and Manitoba. According to the CGPA, member firms spend \$250 million annually on research and development. What does this mean? It means that government, in pursuing public policy objectives, would be ill advised to ignore these figures. Therefore, public policy outcomes, according to the policy community and policy network literature, are largely reflective of the priorities advanced by the influences of powerful industry stakeholders, or associations. As a result, Rx&D, because of who they represent, where they are located, and what they contribute in terms of dollars to the economy will always have greater influence on government, unless government’s main objective is to restrict prices and neglect investment, as happened in 1969 with the passage of *Bill C-102*.

¹⁵⁷ Jack Aubry, “Drug Patent Rules defended by Industry Minister,” *Ottawa Citizen*, (Ottawa: May 8. 2002) A4.

¹⁵⁸ See appendixes 1, 2, and 3 for a profile and overview of the sectoral associations representing patented and generic drug manufacturers.

However, given the current circumstances this will unlikely occur and the outcome will remain largely the same.

CHAPTER 5

CONCLUSIONS

[5.1] Introduction

The objective of the concluding chapter is fourfold. First, it provides an overview of the thesis objectives to determine how industry stakeholders—more precisely, sectoral associations—have been able to influence the outcome of statutory and regulatory changes to Canada’s drug patent laws. Second, it summarizes the major findings of this study to demonstrate that three waves of pressures developed over time to cause the Government of Canada to shift its policies in favour of providing greater patent protection for patented medicines. Third, the chapter offers some observations regarding key features of the politics of drug patenting in Canada. Finally, the chapter concludes by providing some recommendations for further research to examine how politics has become intertwined with various components of the pharmaceutical industry in Canada.

[5.2] The Influence of Industry Stakeholders

The focus of this thesis was to provide an overview of the political evolution of Canada’s statutory and regulatory framework regarding drug patenting policy from 1965 to 2005. Within that context, the primary objective of this study was to analyze the ongoing debate between government, Parliament and the sectoral associations representing the patented and generic sectors of the Canadian pharmaceutical industry in their attempts to construct a balanced statutory and regulatory framework for the protection and dissemination of IP pertaining to pharmaceuticals. Throughout this period various Canadian governments have amended Canada’s patent legislation in a number of

ways either to restrict or expand patent protection. Initially, the goal for government was to develop a Canadian drug market. Government created incentives, such as enacting a compulsory licensing scheme, to restrict patent protection and generate this underdeveloped portion of the industry. However, Rx&D (PMAC) members became highly mobilized in their efforts to fight this restriction, and utilized both domestic and international avenues to cause the government of Canada to remove the restriction and expand patent protection.

Domestically, Rx&D found a sympathetic government who was willing to offer greater patent protection in exchange for additional investment into pharmaceutical research and development. Internationally, the parent companies of Rx&D members, primarily located in the United States and Europe (see appendix two for a listing of headquarters), lobbied their governments to develop international standards, through GATT and the WTO, which would establish a uniform patent term for all member countries. The result was that member countries of the WTO, and signatories to the TRIPS agreement, for example, were required to ensure that domestic IP legislation reflected the letter and intent of the agreement. Of course, the Government of Canada, if it had the political will to provide generic manufactures with greater legislative incentives, could have rejected TRIPS (and NAFTA) and forged ahead nonetheless. Nevertheless, subsequent changes to Canada's patent laws and regulations pertaining to pharmaceuticals were couched in terms of satisfying the federal government's international commitments. Perhaps full participation in TRIPS and NAFTA gave the government a way out, as it realized that it could not withstand the influence of PMAC or forgo the contributions this sector makes to the Canadian economy. Today, several

factors account for why the Government of Canada would be reluctant to upset the Rx&D ‘apple cart.’

In 2004, for example, the 52 companies represented by Rx&D generated \$12.91 billion in sales—with one company, Pfizer, accounting for \$2.2 billion in sales—spent \$1.17 billion on research and development, and employed approximately 23,000 people in Canada.¹⁵⁹ In contrast, the CGPA represents 20 companies associated with the production of generic drugs—five of which are controlled by one company (Apotex). These companies posted \$2.51 billion in sales—with Apotex accounting for \$785 million of this amount—spent \$250 million on research and development, and employed approximately 10,000 persons in Canada.¹⁶⁰ Given that economic and financial imbalance, it is relatively obvious why, in recent years, the Government of Canada has been reluctant to pursue policies that act contrary to the objectives of PMAC/Rx&D.

Even with its most recent attempts to amend the *PM(NOC) Regulations* in 2004 to reduce the amount of litigation involving patent infringement, the federal government provided other protections to Rx&D companies, such as more stringent provisions regarding data protection, as a trade off to ensure that it satisfied some, not all, of Rx&D’s policy objectives. Moreover, with the adoption of *Bill C-9*, which gave generic manufacturers a greater role in providing third world countries with cheaper drugs to fight a variety of public health problems, the Government of Canada gave patented manufacturers the right to refuse any contract and take over negotiations as it deems desirable.

¹⁵⁹ See for example, Parliament of Canada, Patented Medicines Prices Review Board, *Annual Report, 2004* (Ottawa, June 15, 2005) and IMS Health Canada, “Retail Prescriptions grow 5.6% in 2004, down from 7.9% in 2003,” (obtained from http://www.imshealthcanada.com/htmen/1_0_16.htm, June 18, 2005).

¹⁶⁰ See *Ibid* and <http://www.canadiangenerics.ca/aboutus>.

To explain the degree of influence of various sector associations, this thesis put forward an analytical framework that was drawn from the policy community and policy network literature. The value of that literature is that it directs attention to the interplay between governing institutions and industry stakeholders. Occasionally, however, the focus of the literature is too narrow as it is most interested in the type of relationship a particular government agency or department has with stakeholders. In addition, the model is limited to providing a descriptive analysis rather than a causal relationship among the variables involved. In many cases there are a variety of stakeholders (pluralist network) while in others there is simply one (state directed network). In terms of defining the relationship between government (i.e., cabinet), parliament (i.e., MP's and committee's), and industry stakeholders (i.e., sectoral associations) on the one hand, and among industry stakeholders on the other the literature is important in determining how sectoral associations serve as effective policy network actors. The six conditions identified by Atkinson and Coleman in chapter one provide the basis for a highly mobilized sector, which in turn strengthens its ability to influence government. The key indicator in determining how effective a sectoral association is, however, depends upon what concessions it receives from government in terms of regulatory protections. In this case, the sectoral association's interests in protecting drug patents were clearly most influential over time.

In terms of the focus of this particular study, the purpose was to identify how sectoral associations, representing the brand-name and generic manufacturers lobbied Parliament and the Government of Canada to change, or not to change, the statutory and regulatory framework pertaining to drug patenting. Because of the state's reliance on

only two stakeholders in the policy process, one type of policy network (i.e., the corporatist network) is best-suited to explain how the influence of industry stakeholders, who pursue competing objectives, have affected the policy objectives and outcomes of government. As described in chapter one, a corporatist network emerges where the state is strong and the associational system includes few large and powerful groups. In this type of network the state and the associational actors participate in policy formulation and implementation. Because the state often lacks the political will or resources to satisfy all groups involved, one group (or stakeholder) will have a greater influence on the policy outcomes of the state. Such influence is attributed primarily to the association's organizational features, including representation, leadership and financial importance for the economy.

With respect to the evolution of the statutory and regulatory framework for drug patenting in Canada, Rx & D has had a far greater influence on Canada's drug patent policy than its generic counterparts. Several factors such as the number of firms it represents, the leadership it possess (as a result of hiring former ministers of federal and provincial governments, or members of provincial legislatures to lead the organization since 1985) and the financial resources it contributes to the Canadian economy demonstrates the extent of the association's influence on government. Although a large portion of CGPA members are Canadian-owned firms, compared to only a few Rx&D members, this has mattered very little in terms of influencing the existing statutory and regulatory climate for drug patenting in Canada. In fact, various Canadian governments have enacted legislation that is more beneficial to Rx&D members. However, the policy network literature only helps to tell part of the story involving domestic government

institutions. What happens when the organizations or institutions are no longer domestic in nature and have come to include foreign governments and international trading bodies such as the WTO?

To shed light on the international actors and factors, this thesis has incorporated international political economy literature to explain the influence of international agreements on domestic markets. In particular, the structural power model is useful in determining how sovereign states, including their political institutions and corporate entities, operate within the structure of the global political economy. The emergence of NAFTA and the WTO has created new economic power structures that require greater conformity among member states. As chapter three pointed out, amendments to Canada's patent laws was the result of the Government of Canada conforming to TRIPS and NAFTA. What this suggests, therefore, is that if Canada is going to play the game then it must play by the rules. The rules, because they are political in nature, are the result of a bargain being reached among participatory states. The bargain initially begins at home, usually between government and industry and extends beyond domestic borders. Such bargains come to shape the global economic power structure that dictates how certain economic activities, such as patent protection, are to be governed. Indeed, it would be reasonable to assume that without the emergence of the global power structure and the bargains that underpin it, the regulatory framework for drug patenting in Canada would have a radically different character than it does today. For example, prior to the adoption of Bill C-91, the generic drug sector witnessed unprecedented growth because certain statutory mechanisms were in place to restrict patent protection for pharmaceuticals. However, once IP protection was included in international agreements, brand-name drug

manufacturers benefited greatly. As a consequence, the Canadian government was forced to shift its priorities.

[5.3] Shifting Priorities: Government's Response to the Three Waves of Pressures

One idea that has remained clear throughout this study is that the evolution of drug patenting in Canada has created a major public policy dilemma for the federal government: should it restrict the patent term of a brand name drug so that a generic version can enter the market in a timely fashion, induce competition and thus reduce drug prices? Or, should it strengthen the patent term for a brand name drug so that innovative pharmaceutical companies can conduct additional research and development, recoup the costs associated with production, and increase investment in Canada resulting in greater highly-skilled and high paying-jobs? In other words, how does government address two of its major responsibilities, (a) providing health benefits through greater access to pharmaceuticals and (b) encouraging economic growth, by extending patent protections? This dilemma has created a number of pressures that caused the Government of Canada to undertake a number of statutory and regulatory amendments concerning the practice of drug patenting.

Initially, the Government of Canada had to respond to a myriad of domestic pressures. As chapter two has pointed out, the first wave of pressures occurred from 1965 to 1991. First, the federal government was interested in creating a Canadian-owned pharmaceutical industry since the industry was entirely comprised of multi-national drug companies. It relied on the legitimacy of expert studies, rather than industry lobby, to enact legislation that restricted patent protection. Second, because of this restriction, the

multi-national drug companies retaliated by pulling their operations out of Canada. This had dire consequences in the Province of Quebec. At the time 11 of the 21 largest patented drug manufacturers, belonging to PMAC, were located in the Province of Quebec. Some of these firms decided to restrict operations. Consequently, investment in pharmaceutical research and development began to decline, sending the Quebec economy into a tailspin. Third, because of the mounting pressures in Quebec, the Trudeau government established a Commission of Inquiry on the Pharmaceutical Industry in Canada. The Eastman Commission recommended upholding the status quo, but the report was rejected largely because a new government was elected to office. Finally, the Mulroney government, which was intent on reviving the pharmaceutical industry by encouraging more investment in research and development, enacted *Bill C-22* at the urging of PMAC members. This shift in policy toward greater protection for IP proved to be politically divisive, but it did precipitate a revival of pharmaceutical research and development and greater economic development in Quebec.

As chapter three pointed out, a second wave of pressures developed over the course of 1992 to 2001. However, these pressures were the result of a new international order that had developed with respect to the treatment of IP. No longer could patent legislation simply satisfy domestic objectives; now it had to conform to broader international standards. This caused the Government of Canada to act in a number of ways.

First, because Ottawa announced it was agreeing to the Dunkel Draft concerning GATT and the adoption of the WTO and TRIPS, along with agreeing to NAFTA and its additional IP protections, it had to once again amend the *Patent Act* to bring it in line with

its international commitments. This decision gave greater patent protection to brand-name drug manufacturers. The added protection ultimately tipped the statutory balance in favour of the protection of intellectual property, as it completely abolished compulsory licensing. Second, following the adoption of *Bill C-22*, Canada elected to create special rules to strike a balance between offering patented drug manufacturers greater patent protection and generic drug manufacturers the ability to early work and stockpile their copied versions of brand name drugs. Canada also provided that patents filed before 1989 receive 17 years protection as opposed to the 20 years protection as dictated by NAFTA and TRIPS. Because of these practices, challenges were launched to the WTO by the European Union and United States to dismantle this balance. The WTO ruled that the practice of stockpiling violated TRIPS and that all patents must receive the 20-year protection. As a result Canada was forced to comply and once again amend its legislation.

In addition to these developments, chapter four pointed out that from 2002 to 2005 a few important domestic and international factors converged on Canada's statutory and regulatory framework for drug patenting. First, reminiscent of the events in chapter two, the role of expert studies re-emerged to encourage the federal government to review the practices of the pharmaceutical industry. Second, an investigation was launched by a federal quasi-judicial body, at the request of groups in support of the CGPA, into the practice of brand-name drug manufacturers with respect to the *PM(NOC) Regulations*. Third, a parliamentary committee undertook a study into certain provisions of the regulations, but because of the political divisions it did not make any recommendations, upholding the status quo. Finally, the WTO agreed to suspend certain articles of TRIPS to permit generic drug manufacturers to export drugs to Third World Countries. As a result

of this decision Canada enacted legislation to permit this practice, but gave the brand-name manufacturers the final say in determining the term of the contract and the types of drugs that can be permitted for export.

The evolution of Canada's drug patenting framework reveals that government has shifted its priorities from restriction to expansion. During this shift the influence of the brand-name pharmaceutical sector has been too significant to ignore. Although royal commissions, federal organizations, and parliamentarians have encouraged the Canadian government to re-establish the balance between patent protection and patent restriction, the federal government has been reluctant to do so for a variety of reasons related to political and economic interests at the domestic and international levels. However because the statutory and regulatory balance concerning drug patenting in Canada has been shifted towards the brand-name sector, the public policy dilemma that has resulted over the protection and dissemination of IP will continue.

[5.4] Key Observations: What do the Changes Mean?

The ongoing debate between government, Parliament, and industry stakeholders on the one hand, and among industry stakeholders on the other regarding the statutory and regulatory framework for drug patenting in Canada continuously ebbs and flows. Although this study has focused on the interplay of Canada's governing institutions and the sectoral associations representing industry stakeholders, Ottawa's decisions regarding changes to the statutory and regulatory framework for drug patenting also have implications for other groups. Provincial governments and consumers are greatly affected by decisions that alter this framework. Extended patent terms result in increased costs to provincial drug plans and to consumers. In the debates leading up to the adoption of the

two major bills resulting in extended patent protection, *Bill C-22* and *Bill C-91*, all but one provincial government (i.e., Quebec) opposed their adoption. As a result, one key observation is that the CGPA has a wide range of support, particularly outside the province of Quebec. However, this support has done little in the way of providing the generic drug sector with greater opportunities to sell generic drugs sooner by limiting the time frame for patent protection.

Throughout this study little explicit attention was paid to the fact that regardless of what sector the drug companies belong to—brand name or generic—they are all profit-maximizing businesses, accountable to shareholders, with the primary purpose of creating wealth. The debate between Rx&D and the CGPA is not about which sector offers better products, but rather, it is about market share: lack of market share results in lack of sales and indeed, lack of profits. Extended patent protection prevents generic drug manufacturers from gaining access to the market for a fixed period of time, thereby permitting the patentee to maintain a monopoly. Reduced patent protection increases the ability of generic drug manufacturers to enter the market and gain market share earlier. But because the market is inefficient in correcting the imbalance, government intervention is required to strike a balance between these competing objectives. In an attempt to find a balance that works well for all stakeholders and for the public interest, government intervention in Canada since 1969 has consistently tilted the balance towards extending patent protection as opposed to reducing it.

This study has shown how from 1965 to 2005 government has intervened to regulate the practice of drug patenting. Today, while the system has its imperfections, the statutory and regulatory framework for drug patenting in Canada is a reflection of

sectoral influences, international power structures, and domestic political bargains. Critics argue that the system gives special treatment to the brand-name manufacturers, while proponents counter that the system is appropriate for recognizing the innovative character of the extensive research and development undertaken by patented drug manufacturers. If the past is any indication, as long as Canadians continue to elect Liberal and Conservative administrations to govern the country, there is unlikely to be a change in this statutory and regulatory framework. Barring the collapse of the WTO or the end of its protection of IP, it is unlikely that the Government of Canada would act contrary to this international order. As a result of these factors, it seems that the debate over the statutory and regulatory framework for drug patenting will continue into perpetuity. Moreover, with the recent Supreme Court of Canada ruling in *Chaoulli v. Quebec*,¹⁶¹ which resulted in a greater role for private health insurance in Canada, a reasonable assumption can be made that the brand-name drug sector may now have an even greater influence in encouraging further changes to Canada's drug patenting framework.¹⁶²

[5.5] Pharma-Politics—Recommendations for Further Research

Although the focus of this study is the political evolution of drug patenting in Canada, several emerging issues have come to place additional pressures on government and the Canadian pharmaceutical industry. Within this study an entire chapter was devoted to the emergence of international agreements and how they created additional pressures for the Government of Canada's drug patenting policy. A more complete analysis of how the globalization of intellectual property rights—especially as it concerns

¹⁶¹ For the decision see, Supreme Court of Canada, *Chaoulli v. Quebec (Attorney General)*, <http://www.lexum.umontreal.ca/cscscc/en/rec/html/2005scc035.wpd.html>.

¹⁶² Although the assumption could be made that private insurance companies may align themselves with the generic sector in order to protect their bottom line when offering policies that insure prescription drug costs.

pharmaceutical patents—has restricted the ability of domestic political actors to make public policy that encompasses its domestic needs is essential to a further understanding of just how important the brand name pharmaceutical industry has become in setting international standards.¹⁶³

Because Canada has a regulatory body responsible for regulating the price of patented pharmaceuticals in Canada (i.e., the Patented Medicines Prices Review Board) further research could be conducted to see how effective the Board has been in regulating prices. Such research may reveal that an expansion of the Board's mandate may be in order to regulate the price of generic drugs in Canada and to impose greater sanctions on those companies that violate the established pricing standards set out by the board.

The recent controversy surrounding the negative side effects associated with pharmaceuticals in the Cox-inhibitor class, such as Vioxx and Celebrex, has raised questions regarding the drug approval process in Canada and similarly, the so-called benefit of IP. Because Health Canada is reliant on the data produced by patented drug manufacturers in conducting clinical trials, some questions have been raised about Health Canada's independence in reviewing the data and approving the drug. But if serious side effects result from consuming patented medicines should certain remedies not be in place to perhaps negate the patent term. After all, the intent behind pharmaceutical patent protection is to give manufacturers sufficient periods of time to develop new and innovative products. Presumably, this includes reducing the side effects to consumers of taking drugs, such as Vioxx and Celebrex.

¹⁶³ As a starting point, especially with respect to the changes brought about by Bill C-9, see Laura C. Esmail, "An Analysis of Bill C-9: An Act to amend the Patent Act and the Food and Drugs Act, the Right of Refusal and Alternative Mechanisms, http://www.law.utoronto.ca/healthlaw/docs/student_Esmail.pdf (obtained on June 15, 2005)

Recently, Ottawa has undertaken several initiatives to strengthen the review process, but it is difficult to determine how effective these measures will be.¹⁶⁴ Thus, a study on the politics of risk, safety and efficacy in the drug approval process would determine how independent Health Canada is in approving drugs. Similarly, linking IP into the fold could determine the extent to which expanded IP protection has produced safe and efficacious drugs. Perhaps a national drug agency, as alluded to in the Romanow report, and akin to the Food and Drug Administration in the United States, may be a necessary step for Canada.

In addition, the provinces have a role in regulating pharmaceuticals in terms of determining what products are available to consumers under provincial drug formularies. As a consequence, a national patchwork quilt of drug coverage schemes has emerged in Canada, resulting in a variety of products being available to consumers in different jurisdictions. Perhaps the adoption of a national drug formulary may be an option for Ottawa and the provinces to pursue. However, this would mean that the provinces would have to give up some power to Ottawa in terms of delivering the program, a situation unlikely given the disparate views some provinces have over the delivery of health care programs in Canada.

From various testimonies provided to parliamentary committees by senior officials from Industry Canada and Health Canada, there appears to be a degree of fragmentation in the entire system. Several political, economic, and medical factors contribute to the regulation of pharmaceutical drugs in Canada. Industry Canada and Health Canada are the primary government departments responsible for regulating the

¹⁶⁴ See for example, Government of Canada, “Draft Guidance for Industry: Reconsideration of Final Decisions Issued for Human Drug Submissions, *Report*, Health Canada (Ottawa, February 15, 2005).

pharmaceutical industry. For example, Industry Canada is responsible for regulations pertaining to the PMPRB and the *PM(NOC) Regulations* and through the Canadian Intellectual Property Office (CIPO) the granting of patents, while Health Canada is responsible for the administration of the PMPRB and the *PM(NOC) Regulations*, and also for approving drugs on the basis of risk, safety, and efficacy. A study to determine the nature and degree of fragmentation between these two departments would likely determine how effective the system is in regulating all components of the pharmaceutical industry. Perhaps alternative structures may be suitable to end the continuous controversy that surrounds the practice of adding additional patents to a brand-name drug and the drug approval process. However, what will remain, regardless of any alternative, is that the regulation of pharmaceutical products is a highly political undertaking and changes to the statutory or institutional frameworks will largely reflect that fact.

Finally, Canada's pharmaceutical policy has been used as a mechanism to satisfy several objectives: innovation, economic development, affordable health care and regional cleavages, and globalization. As a result of these sometimes competing and complementary objectives, further research utilizing other frameworks for analysis may be conducted to determine the extent to which these objectives influence policy making and policy outcomes in this area. The policy communities and policy networks literature limits itself to the relationships between the state and key stakeholders. However, other models such as the Triple Helix, which proposes that there is an expanding role of the knowledge sector as it pertains to the political and economic objectives of society may help to explain how the pharmaceutical industry and its relationship with government and

university has emerged over time.¹⁶⁵ Perhaps this may determine the extent to which this relationship has altered the policy making process, particularly in areas that utilize scientific discoveries, from an open, transparent, and accessible exercise, to one that has become closed, undemocratic, and inaccessible focussing primarily on experts and industry stakeholders.

¹⁶⁵ For an overview of this model, see Loet Leydesdorff and Henry Etzkowitz, "Emergence of a Triple Helix of University-Industry-Government Relations, in *Science and Public Policy*, Vol. 25, No.6 (London: Beech Tree Publishing, February, 1998)

APPENDIX 1

Current Members of Canada's Research Based Pharmaceutical Companies (Rx&D):

Member Company:	Canadian Headquarters:	Worldwide Headquarters
Abbott Laboratories Ltd. (1931)	Saint Laurent, Quebec	Chicago, Illinois
Actelion Pharamceutics Canada (2001)	Laval, Quebec	Basel, Switzerland
AEterna Zenatris Inc. (1991)	Quebec City, Quebec	Quebec City Quebec
Altana Pharma (1996)	Oakville, Ontario	Konstanz, Germany
Amgen Canada Inc. (1991)	Mississauga, Ontario	Thousand Oaks, California
Astellas Pharma Canada, Inc. (2005)	Markham, Ontario	Tokyo, Japan
Astra Zeneca Canada Inc. (1954)	Mississauga, Ontario	London, England
Aventis Pharma (Sanofi-Aventis) (1947)	Laval, Quebec	Paris, France
Axcan Pharma Inc. (1982)	Mont St-Hilaire, Quebec	Mont St-Hilaire, Quebec
Bayer Inc. (1936)	Etobicoke, Ontario	Leverkusen, Germany
Berlex Canada Inc. (1960)	Pointe-Claire, Quebec	Berlin, Germany
Boehringer Ingelheim, Canada (1972)	Burlington, Ontario	Ingelheim, Germany
Bristol-Meyers Squibb Canada (1925)	Montreal, Quebec	Princeton, New Jersey
Celmed BioSciences Inc. (2001)	Saint Laurent, Quebec	Saint Laurent, Quebec
CTBR Bio-Research Inc. (1965)	Senneville, Quebec	Tranent, Scotland
E-Z-EM Canada Ltd. (1968)	Anjou, Quebec	Lake Success, New York
Eli Lilly Canada Inc. (1938)	Toronto, Ontario	Indianapolis, Indiana
Fournier Pharma Inc. (1986)	Montreal, Quebec	Dijon, France
Genome Canada (2000)	Ottawa, Ontario	Ottawa, Ontario
GlaxoSmithKline (1902)	Mississauga, Ontario	Brentford-Middlesex, England
Hoffman-La Roche Ltd. (1931)	Mississauga, Ontario	Basel, Switzerland
Innovus Research Inc. (1984)	Burlington, Ontario	Medford, Massachussets
Janssen-Ortho (Johnson & Johnson) (1941)	North York, Ontario	New Brunswick, New Jersey
Leo Pharma Inc. (1983)	Thornhill, Ontario	Ballerup, Denmark
Lorus Therapeutics Inc. (1986)	Toronto, Ontario	Toronto, Ontario
Lundbeck Canada (1994)	Montreal, Quebec	Copenhagen, Denmark
Merck Frosst Canada & Co. (1899)	Kirkland, Quebec	White House Station, New Jersey
Neurochem, Inc. (1993)	Laval, Quebec	Laval, Quebec
Novartis Pharmaceuticals Inc. (1927)	Dorval, Quebec	Basel, Switzerland
Nucro-Technics Incorporated (1970)	Scarborough, Ontario	Scarborough, Ontario
OSG Ivers-Lee Inc. (1959)	Brampton, Ontario	Brampton, Ontario
Organon Canada (Akzo Nobel) (1939)	Scarborough, Ontario	Oss, the Netherlands
Paladin Labs Inc. (1996)	Montreal, Quebec	Montreal, Quebec
Patheon Inc. (1974)	Mississauga, Ontario	Mississauga, Ontario
Pfizer Canada, Inc. (1951)	Kirkland, Quebec	New York City, New York
Procter & Gamble Pharmaceuticals (1944)	Toronto, Ontario	Cincinnati, Ohio
Purdue Pharma (1956)	Pickering, Ontario	New York City, New York
Quintiles Canada, Inc. (1996)	Saint Laurent, Quebec	Durham, North Carolina

Ropack Inc. (1976)	Montreal, Quebec	Montreal, Quebec
SFBC New Drug Services Canada (1994)	London, Ontario	Miami, Florida
SGS Pharmaceutical Laboratories (1984)	Mississauga, Ontario	Geneva, Switzerland
Schering Canada, Inc. (1926)	Pointe-Claire, Quebec	Kenilworth, New Jersey
Servier Canada Inc. (1978)	Laval, Quebec	Cedex, France
Shire Bio Chem Inc. (1986)	Ville Saint-Laurent, Quebec	Chineham, England
Solvay Pharma Inc. (1982)	Markham, Ontario	Brussels, Belgium
Theratechnologies, Inc. (1993)	Saint Laurent, Quebec	Saint Laurent, Quebec
Tm Bioscience Corporation (1993)	Toronto, Ontario	Toronto, Ontario
Ventana Clinical Research Corporation (1997)	Toronto, Ontario	Toronto, Ontario
Wyeth (1883)	Markham, Ontario	Madison, New Jersey

APPENDIX 2

Current Members of the Canadian Generic Pharmaceutical Association (CGPA):

Member Company:	Canadian Headquarters:	World Headquarters
Dosage Manufacturers		
Apotex, Inc. (1974)	Toronto, Ontario	Toronto, Ontario
Apotex Fermentation, Inc. (1974)	Winnipeg, Manitoba	Toronto, Ontario
Cangene Coporation (Apotex) (1991)	Winnipeg, Manitoba	Toronto, Ontario
Cobalt Pharmaceuticals (Arrow) (2000)	Mississauga, Ontario	Roseberry, Australia
Novopharm Limited (Teva) (1965)	Toronto, Ontario	Petach Tikva, Israel
Nu-Pharm (Apotex) (2000)	Richmond Hill, Ontario	Toronto, Ontario
Orbus Pharma Inc. (2000)	Markham, Ontario	Markham, Ontario
Pharamascience, Inc. (1983)	Montreal, Quebec	Montreal, Quebec
Pro Doc Ltee (1955)	Laval, Quebec	Laval, Quebec
Ratiopharm (Ratiopharm GmbH) (1974)	Toronto, Ontario	Ulm, Germany
Rhoxalpharma (Hexal AG) (1997)	St. Laurent, Quebec	Holzkirchen, Germany
Taro Phramaceuticals (1984)	Brampton, Ontario	Hawthorne, New York
Industry Suppliers		
ACIC (1974)	Brantford, Ontario	Brantford, Ontario
Debro Pharmaceuticals (1968)	Brampton, Ontario	London, England
Pdi-Pharmaceuticals, Inc. (1978)	Richmond Hill, Ontario	Richmond Hill, Ontario
Active Ingredient Manufacturers		
Apotex Pharamachem Inc. (1974)	Brantford, Onatrio	Toronto, Ontario
Contract Research Organizations		
Algorithme Pharma Inc. (1972)	Laval, Quebec	Laval, Quebec
SFBC Anapharm (1994)	Quebec City, Quebec	Miami, Florida
Biovail Contract Research (1975)	Toronto, Ontario	Toronto, Ontario
MDS Pharma Services (1986)	Saint-Laurent, Quebec	Toronto, Ontario

APPENDIX 3

Profile of the Umbrella Organizations Representing Patented and Generic Drug Manufacturers in Canada

FEATURES	ORGANIZATIONS:	
	Rx& D (formerly PMAC)	CGPA (formerly CDMA)
Mission	To improve the quality of life of all Canadians and enhance our health care system by fostering the discovery, development and availability of new medicines.	To represent a dynamic group of companies that specialize in the production of high quality, affordable generic drugs and fine chemicals and in conducting the clinical trials required for government approval of generic drugs.
Founded (year)	1914	1984
President of Organization	Russell Williams, Former Liberal MNA, Province of Quebec.	Jim Keon, Former senior civil servant, Government of Canada
Number of Companies	52	20
Amount of Sales (2004)	\$12.92 billion (C\$)	2.51 billion (C\$)
Amount of Research and Development (2004)	\$1.17 billion (C\$)	\$250 million (C\$)
Number of Persons Employed	Approximately 23,000	Approxiametly 10,000
Largest Producer (Sales \$)	Pfizer (\$2.2 billion)	Apotex (\$785 million)

APPENDIX 4

Features of the Drug Approval Process in Canada

Both Industry Canada and Health Canada are the key government institutions that are responsible for approving both patented and non-patented medicines in Canada. At first glance, one may wonder why regulations pertaining to patents involve Health Canada. The reason is that *PM(NOC) Regulations* link patent protection to the federal drug review process.¹⁶⁶ Industry Canada, through the Canadian Intellectual Property Office (CIPO) and the Commissioner of Patents, is responsible for granting (or refusing) a patent, while Health Canada, through the Therapeutics Product Directorate (TPD) of the Health Protection Branch, must determine the safety and efficacy of a drug, based on the data obtained through closely-monitored clinical trials.¹⁶⁷

From a statutory perspective, however, the *Patent Act, and the Food and Drugs Act* set out specific requirements for the drug approval process in Canada. For example, the *Patent Act* lays out the requirements for obtaining a patent, which are general requirements applicable to any industry. According to section 27(1) of the *Patent Act*: “The Commissioner shall grant a patent for an invention to the inventor or the inventor's legal representative if an application for the patent in Canada is filed in accordance with this Act and all other requirements for the issuance of a patent under this Act are met.”¹⁶⁸ However, the invention cannot be a mere scientific principle or abstract theorem. Rather,

¹⁶⁶ House of Commons Standing Committee on Industry, Science and Technology, 37(2) *Evidence of Proceedings*, June 2, 2003, 1555.

¹⁶⁷ In this process, Industry Canada plays a limited role, subject to only patented drugs, whereas, Health Canada has a more expansive role in approving patented medicines, changes to the patented drug, and generic drugs.

¹⁶⁸ Government of Canada, *The Patent Act, R.S. c4*.

an invention must be “any new and useful art, process, machine, manufacture, or composition of matter, or any new useful improvement in any art, process, machine, manufacture or composition of matter.”¹⁶⁹ In addition, the *Act* specifies that a patent will only be granted where: (a) the invention and its operation or use is fully described; (b) the application sets out the various steps in the process or the method of making or constructing a compound; and (c) for a process, explain the necessary sequence so as to distinguish it from other inventions.¹⁷⁰ In other words, the innovation must be new, novel, useful and non obvious.

While the *Patent Act* is general in nature and makes no explicit mention of pharmaceuticals (except for addressing the role of the PMPRB) the *Food and Drugs Act* and its regulations deal more specifically with pharmaceutical products. Before a drug can be sold in Canada, the *Food and Drugs Act* and the *Food and Drug Regulations* requires that a drug submission be filed with Health Canada for approval. Once Health Canada approves the submission, a Notice of Compliance (NOC) is issued to the drug manufacturer (patented and generic). The NOC indicates that the manufacturer has complied with, or met, the drug approval standards adopted by Health Canada.

In Canada, there are three distinguishable types of drug submissions: a new drug submission (NDS); a supplemental new drug submission (SNDS); and an abbreviated new drug submission (ANDS). As the name suggests, the NDS is a submission that is filed in order to seek approval for the sale of a new drug in Canada. It is the largest type of all drug submissions and is typically filed by patented manufacturers, although generic drug manufacturers are permitted to file such a submission, but seldom do so because of

¹⁶⁹ *Ibid.*

¹⁷⁰ *Ibid.*, section 27.3.

the cost and the extensive clinical trials that are required to demonstrate that the drug is safe and efficacious.¹⁷¹ However, once it has been established that the drug filed under the NDS is safe, efficacious, and of high quality Health Canada will then grant a NOC, indicating that the company may begin to sell the drug in Canada.

The SNDS is a submission filed for the purpose of making significant changes or a minor change to a new drug. Again, the SNDS must also demonstrate that the drug is safe, efficacious and of high quality before it receives a NOC in approving changes to the drug. However, the SNDS is the most controversial of all submissions because it is an alteration to the original NDS and provides the product with an additional period of protection. Typically, a SNDS is filed when a manufacturer changes the physical characteristics of the drug, say, from tablet to liquid form, or the medicinal properties of the drug, so that it strengthens or weakens the dosage. This does not mean that NOC will result in an additional 20-year patent term, but that before a generic manufacturer can copy the original drug, it must also address any changes made by way of the SNDS. For example, before a generic manufacturer could copy the active ingredient found in the drug Losec, it had to address eleven patents before receiving an NOC. By triggering the automatic injunction, the manufacturer of Losec could keep the generic version from entering the market for an additional 22 years because it would have to address the additional patents through the courts. In fact, there is currently no limit to the number of SNDS's that an original drug can have in Canada.

Finally, the ANDS is a submission that is available to generic drug companies who want to copy and manufacture a brand-name drug. Rather than having to conduct

¹⁷¹ House of Commons Standing Committee on Industry Science and Technology, 37(2) *Evidence of Proceedings*, June 2, 2003, 1555.

costly and extensive clinical trials, generic drug companies may demonstrate that their version of the drug is safe and efficacious on a comparative basis.¹⁷² This means that the generic drug company, when filing an ANDS, must compare their drug to something called the ‘Canadian Reference Product.’¹⁷³ Next, the generic manufacturer must demonstrate what is termed bioequivalence, meaning that the formulation of the generic drug achieves the same levels in the blood as the reference drug. Once bioequivalence is established, Health Canada then issues a NOC for the generic drug, permitting its sale in Canada.

In testimony given to the Standing Committee on Industry, Science, and Technology in 2003, Director General of the TPD, Robert Peterson, acknowledged that the purpose of the drug submission’s structure “was to designed to support drug review. It was not designed with the aim of safeguarding intellectual property rights.”¹⁷⁴ While this is true, Dr. Peterson also pointed out that: “this in our view is one reason why the linkage aspects of the patented medicines NOC regulations are so hard to grapple with....”¹⁷⁵ So how does the linkage work?

The PM(NOC) Regulations indicate that the Minister of Health must maintain a register for all patents listed. Section 4(1) of the PM(NOC) regulations states that: “a person who files or has filed a submission for, or has been issued a NOC in respect of a drug that contains a medicine may submit to the Minister a patent list...in respect of that

¹⁷² *Ibid.*, 1600.

¹⁷³ The Canadian Reference Product is contained in Division 6 of the *Food and Drugs Act* and lists the medicinal properties of a particular type of drug. The generic drug, therefore, must be pharmaceutically equivalent to the patented drug it is copying.

¹⁷⁴ Standing Committee, *Evidence of Proceedings*, June 2, 2003, 1600.

¹⁷⁵ *Ibid.*

drug.”¹⁷⁶ Basically, the list serves to identify the patents, which protect various brand name drugs as occasioned by the notice of compliance issued for the NDS and SNDS. In particular, the patent list reveals a number of characteristics of a brand name drug: (a) strength and dosage; (b) the patent holder; and (c) the date when each patent will expire. The list must be submitted at the same time the company files for a drug submission. Before the drug can be listed, and receive a NOC, the patented manufacturer must file for a patent—or patents—with CIPO, within 30 days of filing the drug submission. If it fails to do so in the allotted time, the patent will not be accepted for listing in connection with the NDS. In the case of an SNDS, the same situation applies, but according to Dr. Peterson, “this opportunity is not overtly stated in the regulations, and has led to some challenges....”¹⁷⁷ However, there is one caveat: to be listed on the register, the patent must make a claim for the medicine itself or a claim for the use of a medicine. In other words, not just any patent can be listed on the register.¹⁷⁸

According to 2003 data, the register, comprising a total of 705 patents, identified 390 different medicines.¹⁷⁹ Of that number, 230 medicines had one patent listed, while 84 had two patents listed, and one particular medicine had 11 patents listed to protect it. Because of these listing rules, the regulations have led to significant litigation before the courts. From 1999 to 2003 a total of 34 judicial review applications have been filed before the courts, with 27 being dismissed or withdrawn on allegations of a frivolous

¹⁷⁶ *Patented Medicines (Notice of Compliance) Regulations*.

¹⁷⁷ House of Commons Standing Committee on Industry, Science and Technology, *Evidence of Proceedings*, June 2, 2003, 1605.

¹⁷⁸ *Ibid.*

¹⁷⁹ *Ibid.*

patent.¹⁸⁰ This additional litigation has led to a number of problems for Health Canada as a regulator and according to the TPD, “the patented medicines NOC regulations impose a series of extra steps and requirements in the course of carrying out our daily work, which is ensuring that each new drug is safe, efficacious, and of high quality prior to being sold in Canada.”¹⁸¹ This would seem to suggest that Health Canada is not particularly fond of the regulations, especially as they pertain to the listing requirements. Because Industry Canada is responsible of the drafting of the regulations and Health Canada with the administration, there is a perceived lack of consensus as to what constitutes a listing on the register.

Section 55.2(4) of the *Patent Act*, permits the Governor in Council to make regulations that prevent the infringement of a patent, and provides the patentee with an injunctive relief that restricts the ability of a generic manufacturer to receive an NOC. Basically, that is the main objective of the *PM(NOC) Regulations*. For instance, when a generic manufacturer elects to a copy a brand name drug that is listed on the register, it must address any or all patents listed on it before receiving a notice of compliance from Health Canada. If the generic manufacturer fails to do so, the patentee can commence a court proceeding that triggers an automatic interim injunction for a period of 24 months or longer. The injunction prevents Health Canada from granting a NOC to the generic manufacturer, which effectively keeps it off the market. This is often referred to as the practice of evergreening because it allows the patented manufacturer to add additional improvements to the original compound (or patent), thereby restricting market entry of a generic drug.

¹⁸⁰ *Ibid.*, 1610.

¹⁸¹ *Ibid.*, 1600.

Therefore, according to section 5(1) of the PM (NOC) Regulations a generic manufacturer may not receive a notice of compliance unless it can maintain that the patent is: (a) frivolous; (b) has expired; (c) is not valid; or (d) vexatious. If a generic manufacturer can substantiate any of these claims it then files a Notice of Allegation (NOA) against the patentee, which alleges that by seeking a NOC, it is not infringing upon the patent or patents. Upon receiving the (NOA), the patentee has 45 days to apply for a court order prohibiting the minister from granting a NOC to the generic manufacturer, until the generic manufacturer can satisfy the courts that the allegation it is making is valid. Once it makes the application, the patentee automatically triggers an injunction and the generic manufacturer is automatically restricted from receiving an NOC for a period of not less than 24 months. In addition, upon making such an allegation, the generic manufacturer must prove (the reverse onus clause) that it is not infringing on the patent. The patentee, therefore, does not have to demonstrate that the patent is valid.

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