Carleton University

The Review of Bill C-91: Pharmaceutical Policy Development under a Majority Liberal Government

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Abstract

This thesis tells the story of the Liberal government's 1997 review of Bill C-91, a bill to enact the *Patent Act Amendment Act, 1992*. Bill C-91 included provisions for eliminating compulsory licensing of pharmaceuticals and creating regulations—the Linkage Regulations—that delayed the entry of generic drugs onto the market. Both of these developments were harmful to the generic industry while beneficial to the brand name industry. The general focus of the review was the extent to which the current pharmaceutical policy should be modified, if at all. This thesis examines factors influencing the Liberal government's decision-making process, strategies employed by stakeholders to the review and competition between government branches with competing policy interests. It argues that the Liberal government used its powers to manage the review to create conditions which allowed it to maintain the current policy.

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Glossary of Terms and Acronyms

ACTN – Advisory Committee on Trade Negotiations – A private sector trade advisory board to the US Government.

Bill C-102 – A bill passed in 1969 by the Trudeau government which allowed generic manufacturers to import either the active ingredients of domestically patented pharmaceuticals, or the finished product. The provisions of this Bill led to the creation of a healthy, Canadian generic drug industry.

Bill C-22 – A bill passed in 1987 by the Mulroney government which curtailed the use of compulsory licensing for pharmaceutical patents.

Bill C-91 – A bill passed in 1993 by the Mulroney government which effectively eliminated the use of compulsory licensing for pharmaceutical patents.

Bolar Provisions – A set of exemptions to patent infringement which were created by the *Manufacturing and Storage of Patented Medicines Regulations* in March 1993. These exemptions included an early working provision and a stockpiling provision and were designed to facilitate the entry of generic drugs onto the market immediately after the expiration of a patent.

BQ – Bloc Québécois

CCA – Department of Consumer and Corporate Affairs

CDMA – Canadian Drug Manufacturer's Association – The trade association for Canada's generic pharmaceutical industry. The CDMA membership was comprised of only domestic companies. It later changed its name to the Canadian Generic Pharmaceutical Association.

CHC – Canadian Health Coalition – A not-for-profit, non-partisan organization dedicated to protecting and expanding Canada's public health system for the benefit of all Canadians.

Compulsory Licensing – A license through which a corporation that owns the exclusive rights (patent) to manufacture and market a product is forced by the state to allow another to produce and market that product, in exchange for a royalty; usually a small percentage of the sale price.

CUFTA – Canada-US Free Trade Agreement – A trade agreement between Canada and the US which was signed in 1987 and came into force in 1988.

Dunkel Text – A draft text compiled in 1991 by Arthur Dunkel, the director-general of the GATT, which would serve as the basis for the final agreement which launched the WTO. When Dunkel compiled the Text, negotiations for the Uruguay Round of the GATT had stalled and the deadline for agreement had passed. The Dunkel Text outlined progress to date on the negotiations and was used as a basis for further bargaining.

Early Working Exception – An exemption to patent provision provided by the Patent Act, which stipulated that a generic company could manufacture and use a patented product to obtain regulatory approval for a generic drug.

Evergreening – A process whereby a brand name pharmaceutical company extends one of its patents beyond the standard patent term.

Food and Drugs Act – The primary piece of legislation governing the production, import, export, transport across provinces and sale of food, drugs, contraceptive devices and cosmetics in Canada.

GATT – General Agreement on Tariffs and Trade – Formed in 1947, the GATT was an international treaty whose main objective was the reduction of barriers to international trade. The GATT was superseded by the WTO in 1995.

Horizontal policy issue – A policy issue that concerns, or is the responsibility of, more than one government branch.

IBAC – Industrial Biotechnology Association of Canada – The trade association representing the Canadian biopharmaceutical industry.

Interlocutory Injunction – In patent law, a court directive ordering one company to cease manufacturing a product which might be infringing on the patent rights of another company.

IP – Intellectual Property – Intangible property that is the result of creativity (such as patents or trademarks or copyrights).

Linkage Regulations – Formally known as the *Patented Medicine (Notice of Compliance) Regulations*, the Linkage Regulations were created in March 1993 with the ostensible purpose of protecting pharmaceutical patents from infringement. Under the Linkage framework, regulatory approval of generic drugs could not be granted until the generic company could show—in a court of law—that the drug was not infringing on any active patents.

LPC – Liberal Party of Canada

Me-too Drug – A drug whose development requires little if any innovation, while offering no additional therapeutic benefit over comparative products already on the market. Me-too drugs are essentially copies of existing drugs.

MRC – Medical Research Council of Canada – The branch within the Government of Canada which is responsible for funding health research.

NAFTA – North American Free Trade Agreement – A free trade agreement between Canada, Mexico and the US which was signed in 1992 and came into force in early 1994.

NDP – New Democratic Party of Canada

NFH – National Forum on Health - The National Forum on Health was an advisory body established by the Prime Minister of Canada in October 1994 to advise the federal government on innovative ways to improve Canada's health system and the health of Canadians. The Forum's final report was released in 1997.

NOA – Notice of Allegation – A notification, from a generic drug company to a brand name drug company, indicating that a product that the generic company wishes to manufacture is not infringing on any of the active patents of the brand name company. An NOA is part of the process laid out in the Linkage Regulations.

NOC – Notice of Compliance – A notification, issued to a drug manufacturer indicating that they have complied the appropriate safety and efficacy requirements. Only after an NOC has been issued is a manufacturer free to market their drug.

OAG – Office of the Auditor General of Canada

Patent Act – The primary piece of legislation governing patent law in Canada.

PC – Progressive Conservative Party of Canada

PhRMA – Pharmaceutical Research and Manufacturers of America – The trade association for US brand name pharmaceutical companies.

PMO – Prime Minister's Office

PMAC – Pharmaceutical Manufacturers of Canada – The trade association for Canada's brand name pharmaceutical industry. PMAC represented mostly subsidiary companies of multinational corporations. It changed its name to Canada's Research-based Pharmaceutical Companies (Rx&D) in 1999.

PMPRB – Patented Medicines Prices Review Board – Established in 1987, the Board was an "independent", quasi-judicial body, charged with regulating the prices of patented medicines, as well as monitoring and reporting on R&D investments made by the brand name industry.

PMPI – Patented Medicines Price Index – The PMPRB's index for measuring pricing trends of patented medicines.

Process Patent – In the case of drugs, a patent on a particular component of a drug manufacturing process.

Product Patent – In the case of drugs, a patent on the drug product itself.

PQ – Parti Québécois

PTR – Patent Term Restoration – The extension of patent periods to compensate companies for shorter periods of exclusivity resulting from regulatory delays.

R&D – Research and Development

Rx&D – Canada's Research-Based Pharmaceutical Companies – The new name adopted (formerly PMAC) by the trade association for the brand name pharmaceutical industry in 1999.

Stockpiling Exception – An exemption to patent provision provided by the Patent Act, which stipulated that a generic company could begin manufacturing and stockpiling product—beginning six months prior to the expiration of the pertinent patent— of a generic drug it was planning to bring to market.

TRIPS – Agreement on Trade-Related Aspects of Intellectual Property – A WTO side agreement setting out minimum standards for the protection of IP.

USR – Unequal Structures of Representation

USTR (Office of the United States Trade Representative) – The US government agency responsible for developing and recommending United States trade policy to the President of the United States, conducting trade negotiations at bilateral and multilateral levels, and coordinating trade policy within the Government.

WTO – World Trade Organization – Inaugurated in 1995, it is an international organization designed to supervise and liberalize international trade. The WTO replaced the GATT to deal with the regulation of trade between participating countries, provide a framework for negotiating and formalizing trade agreements, and resolve disputes to ensure the adherence of members to WTO agreements.

CHAPTER 1 – Introduction

Introduction

In February 1993, Brian Mulroney's Progressive Conservative (PC) government used its majority position to pass Bill C-91, a bill to enact the *Patent Act Amendment Act, 1992*.[1] Bill C-91 completed Mulroney's plan for a shift in Canadian pharmaceutical policy, which elevated investment concerns above those of pricing and access. Only six years earlier, the Mulroney government had passed Bill C-22, which had placed significant restrictions on the issuing of compulsory licensing,[2] thereby providing brand name companies with longer monopoly periods for their drugs. Bill C-91 eliminated compulsory licensing altogether, while also providing for a new regulatory framework giving brand name pharmaceutical companies greater powers to limit the introduction of generic drugs (Smith, 2000).

Critics charged that Bill C-91 was designed to benefit the brand name pharmaceutical industry by decreasing competition, thereby allowing brand name companies to keep drug prices higher for longer periods of time. In addition to generic companies having to wait longer to bring their products to market, it was feared higher drug prices would negatively impact consumers and provincial governments, which are responsible for providing drugs to targeted populations.

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[1] The *Patent Act Amendment Act, 1992* modified the *Patent Act.*

[2] A compulsory license is one in which a corporation that owns the exclusive rights (patent) to manufacture and market a product is forced by the state to allow another to produce and market that product in exchange for a royalty; usually a small percentage of the sale price. The intention behind compulsory licensing is to encourage several companies to market the same product and to engage in "competitive pricing", thereby providing consumers with savings in relation to what they would have paid under monopoly conditions (Lexchin, 1997).

As the Official Opposition at the time, the Liberal Party of Canada (LPC) positioned itself as the protector of consumer interests by arguing strongly against the Bill (Campbell & Pal, 1994). During parliamentary procedures, the Liberals were "successful" in obtaining the inclusion of a clause mandating a statutory review of Bill C-91, to be held no later than four years from the Act coming into force (T. Macerollo, interview, July 17, 2008).

Less than a year after the enactment of Bill C-91, the LPC formed a majority government. The new Liberal government found itself in the difficult position of trying to negotiate the demands of competing pharmaceutical industries, mediate a conflicted bureaucracy and reconcile the Party's earlier stance on patent protection with its desire to create a business-friendly investment climate. Due to the political controversy surrounding pharmaceutical patent protection, the Liberals attempted to delay a decision regarding a review of Bill C-91 for as long as possible (T. Macerollo, interview, July 17, 2008). Unsatisfied with the Government's stance regarding a prospective review, the brand name industry elevated the review's status to an issue of national unity by instigating a public discussion in Quebec around patent protection and the federal government's lack of concern for the wellbeing of Quebec. These developments placed effective limits on the Government's policy options, while precipitating regional discord within the federal caucus (T. Macerollo, August 22, 2008).

This thesis recounts events surrounding the 1997 review of Bill C-91. It examines the strategies employed by stakeholders as well as the structures that

regulate policy development under a majority government. In focusing on this particular case, several factors of policy making are elucidated, including the competition between foreign and domestic capitals, the antagonism between competing policy objectives and the competing interests of different geographic regions. Although the review of Bill C-91 occurred more than ten years ago, many of the considerations that informed its outcome—economic, cultural and political—are still present today.

This chapter presents the thesis statement followed by a theoretical framework and then proceeds to develop the thesis in two ways. First, it outlines research methods used to collect data. Second, it presents a brief reading of the trade associations for the brand name and generic pharmaceutical sectors—the two primary industrial stakeholders to the review. This information serves to contextualize the positions, behaviours and strategies of the two competing sectors during several episodes in the evolution of pharmaceutical patent law outlined in subsequent chapters, in particular the review of Bill C-91.

Thesis Statement

There were two basic positions regarding the review of Bill C-91: support for Canada's then-current pharmaceutical policy and opposition to it. Within the pharmaceutical industry, the brand name sector called for maintenance of the policy while the generic sector lobbied for changes. The brand name sector's position was supported by Industry Canada and the Montréal Liberal caucus, while the generic industry's position was backed by Health Canada and the

Toronto Liberal caucus. Support for the brand name position by Montréal Liberals was related to local economic development and, to a lesser extent, political donations. Support for the generic position by Toronto Liberals was primarily related to political donations. Prior to the Industry Committee's hearings on Bill C-91, the Chrétien government decided to maintain the policy. This decision was influenced by the brand name industry's financial support of the LPC, as well as concerns—articulated by Industry Canada and the Montréal caucus—for the economic and political fallout that might result from action taken by the brand name sector in retaliation to decreased patent protection. To gain support for their respective positions regarding pharmaceutical policy, stakeholders employed rhetorical strategies before, and throughout, the review. To create conditions which would allow it to maintain the policy, the Chrétien government influenced the review process using the powers available to it by virtue of its majority position. The achievement of the brand name sector in securing a policy outcome that reflected its interests was largely related to its superior resource capacity and its ability to target its resources effectively.

Less than a year after winning a majority in the 1993 federal election, the Chrétien government was forced to clarify its intentions with regard to a review of Bill C-91. While the domestic generic pharmaceutical industry called for amendments to accelerate the marketability of generic products, the multinational brand name industry lobbied for the maintenance of the then-current policy.

To pressure the Government into maintaining the policy, the brand name industry exploited Quebec's political situation and the regional character of the

LPC, by establishing a connection between the industry's financial interests and the economic interests of Quebec. As part of this strategy, the brand name industry threatened to halt planned investments and decrease future investments in the Montréal area if its demands on patent protection were unmet. The Liberal government decided to maintain the policy, a decision arrived at privately some time prior to the review. There were a number of factors shaping this decision, most of them political.

First, the Chrétien government was worried about the impact of federal policy changes in Quebec. The province of Quebec—especially the island of Montréal—was an important constituency for the LPC. With the recent emergence of the Bloc Québécois (BQ)—which supported the maintenance of the Government's prevailing pharmaceutical policy—as a major force in Quebec federal politics, the Liberals could ill afford to risk alienating prospective Quebec voters over the review. To a lesser degree, these worries were motivated by a concern for inciting nationalist sentiments, at a time—shortly after the 1995 Referendum—when the LPC was actively trying to promote federalism and improve the perception of the federal government in Quebec.

Second, the Government was influenced by the demands of the Montréal caucus—an organized and powerful faction of the LPC. There were divisions within the Party regarding the review of Bill C-91, including a significant rift between the Montréal and Toronto caucuses. Members of the Montréal caucus were strongly supportive of maintaining the then-current policy, a position related, on the one hand, to political donations from brand name companies. More

significant were their concerns for regional economic development, as Montréal Liberals feared that the brand name industry would follow through on its threats to reduce investments in retaliation for decreased patent protection. Conversely, many members of the Toronto caucus lobbied for changes to the policy that would weaken patent protection, a position motivated primarily by political donations from generic companies.

Third, the Government's decision was influenced by the financial support provided to the LPC by the brand name industry. The brand name industry was a significant contributor to the LPC throughout Chrétien's first term, especially in the two years (1996 and 1997) preceding its decision regarding Bill C-91. A desire to maintain a high level of support from the brand name industry helped to shape the Government's decision.

Fourth, within the federal bureaucracy there was a belief that effective patent protection was needed to attract pharmaceutical investments in R&D and that Bill C-91's amendments had been a positive step in this direction. While this was the dominant perspective, it was not shared by all departments. The main advocate for stronger patent protection and the maintenance of the then-current policy was Industry Canada, which had a specific mandate to foster innovation, create investment and increase Canada's share of global trade. In contrast, Health Canada opposed the policy, demanding changes to accelerate the marketability of generic drugs which would lead to greater price competition, lower drug costs and improved access to medicines. Health's perspective was informed by its mandate to help Canadians maintain and improve their health;

pressure from the provinces for changes to reduce provincial formulary costs; and an institutional aversion to its role in enforcing regulations associated with the *Patent Act*. Ultimately, the perspective of Industry prevailed.

Leading up to, and throughout, the review of Bill C-91, stakeholders employed strategies to support their particular proposals for pharmaceutical patent policy. These strategies included a combination of public relations, advertising, lobbying and rhetorical techniques. In the end, the brand name sector prevailed, securing a policy outcome that, on balance, addressed its primary interests. This success was largely related to its superior resource capacity and its ability to target its resources effectively. Other stakeholders—including the generic sector and the Canadian Health Coalition (CHC)—lacked comparable resource bases, contributing to their inability to persuade the Government to address their interests.

While the Government had a general idea of how it wanted to proceed, there was a risk that the review could present political difficulties. To mitigate these risks, the Government influenced the review process using several of the powers available to it by virtue of its majority position. These powers included the ability to (1) appoint the Standing Committee on Industry—rather than Health—to manage the review; (2) appoint particular Liberals to the Committee to ensure that a majority of Committee members supported Bill C-91; (3) influence Liberal Committee members, including the Chair; (4) manipulate the drafting of the Committee's final report; and, (5) amend the Committee membership to ensure passage of the Government-approved final report. By taking these steps,

the Government helped to create conditions which allowed it to refrain from making significant changes to its pharmaceutical policy. This outcome was particularly favourable to the financial interests of the brand name sector and the political interests of the LPC.

Theoretical Framework

This section outlines a theoretical framework for examining the events surrounding the review of Bill C-91. The issues surrounding the review are complicated, necessitating a multifaceted theoretical approach. Accordingly, this theoretical framework draws on a number of sources and focuses on: (1) the types of rhetorical strategies employed by different stakeholders to a public policy process; (2) the LPC's general approach to policy development with a focus on policies concerning Quebec; and, (3) the outcome of a policy process dealing with a horizontal issue (i.e. those affecting more than one branch) involving government branches with competing priorities.

Stone's Policy Paradox

Stone (2002) outlines a set of rhetorical devices, or strategies, used by stakeholders to a policy development process that is useful for examining the tactics employed during the review of Bill C-91. These strategies—called "languages" by Stone—are used to persuade decision-makers to accept a particular interpretation of a policy problem, as well as solutions to deal with that

problem. Included in the list of Stone's "languages" are a set of strategies that are specifically relevant to the review of Bill C-91, namely narrative stories; ambiguity; numbers and measures; interests; and solutions.

Narrative stories are told in an attempt to shape the way that policy problems are perceived. Stakeholders use narrative stories to try and persuade others to associate a problem with a particular storyline—some commonly recognized structure or sequence of events—that has a familiar outcome (Stone, 2002). The power of narrative stories comes from their familiarity; they take a situation or issue with a contested origin or significance and give it meaning by representing it in terms that are familiar and predictable. Using narrative stories to convince others of the eventual outcome of a policy problem paves the way for stakeholders to propose solutions that serve particular financial and/or political interests. Stone (2002) outlines three common narrative stories used in policy problem definition that are particularly applicable to the review.

The first is the *story of decline*, which suggests a breakdown of a particular phenomenon and proposes solutions to prevent a complete collapse. The story of decline usually adheres to the following structure: "In the beginning, things were pretty good. But they got worse. In fact, right now, they are nearly intolerable. Something must be done" (Stone, 2002, p. 138). With this particular narrative, proposals usually touch on the implementation of new policies.

The second narrative story is a variation of the first, and is called the *story of stymied progress*. This story suggests the presence of an impediment to the advancement of a particular phenomenon or sector and proposes solutions to

remove the obstacle. The story of stymied progress goes as follows: "In the beginning things were terrible. Then things got better, thanks to a certain someone [or something]. But now somebody or something is interfering with our hero [or improvement], so things are going to get terrible again" (Stone, 2002, p. 139). With this particular narrative story, stakeholder proposals focus on maintaining threatened policies, restoring the effectiveness of current systems, or instituting further changes.

The third narrative story is the *story of helplessness and control.* This story suggests that there are feasible solutions to a particular problem that was once thought to be uncontrollable. The story of helplessness and control adheres to the following pattern: "The situation is bad. We have always believed that the situation was out of our control, something we had to accept but could not influence. Now, however, let me show you that in fact we can control things" (Stone, 2002, p. 142). With this narrative story, stakeholders challenge previously held assumptions and propose the implementation of new policies. A common variety of the story of helplessness and control is the *conspiracy.* The conspiracy twist introduces malice and oppression into the storyline, by suggesting that the powerful groups have caused deliberate harm while benefiting from the suppression of knowledge. A conspiracy's focus on moral considerations is designed to incite feelings of anger and betrayal, usually to support one group's attempt to wrest control from another (Stone, 2002).

Another symbolic device used by stakeholders to a policy process is ambiguity. Ambiguity is a powerful tool for building broad support for an idea,

because it allows stakeholders to construct proposals that can mean different things to different groups. By omitting details and masking context, ambiguity conceals the true motivation or intent of ideas and/or policies. In this way, ambiguity serves to promote multiple meanings from the same idea, allowing stakeholders to gain the support of many people/groups with varying—sometimes competing—interests. Ambiguity can also lead to unification and alliance building, as groups with different agendas coalesce around ideas for different reasons. In all of these ways, ambiguity serves to move proposals forward (Stone, 2002).

Along with the concealment of information, ambiguity can be a useful tool for those wanting to avoid the consequences inherent in making important—and often controversial—decisions or statements, which could then be used to challenge one's position at a later date. In both cases, ambiguity allows parties to benefit from the appearance of being forthright and/or responsible, while avoiding the potential consequences associated with concrete specifications.

One of the most common and effective ways of defining problems is through the use of numbers and measures. In defining and interpreting a policy issue, several different measures can usually be employed. Accordingly, much of the debate involving numbers in policy development is based on which particular measures are the most relevant, and what constitutes a valid construction of those measures. Stone (2002) maintains that the origin of many political issues is categorization—the contested question of what counts and what doesn't—as stratification necessarily results in the benefit of some and the

exclusion of others. Logically, the interests of stakeholders to a policy issue will motivate them to try and persuade others that their preferred measures, as well as the specific definitions of those measures, are the most relevant and effective for defining the essence of a particular policy problem.

Stone (2002) warns decision-makers against taking for granted the accuracy of measures provided by stakeholders, as the tendency for reactivity can be high. Furthermore, numbers and statistics provided by 'independent' measurers—such as government regulatory bodies—should also be scrutinized, as public agencies working closely with industry are vulnerable to influential mechanisms, including selective disclosure, pleading, or even outright bribery. At a minimum, regulators desire cordial working relations with those whom they are monitoring and might not want to jeopardize that by persistent questioning or digging for details.

Another effective rhetorical device used to gain the support of others in a policy process is impact. Here, stakeholders outline which different people/groups will be targeted by their proposal, as well as the nature and degree of the impact. In spelling out whose interests will benefit from a proposed policy, stakeholders aim to gain support for their proposal from those who profit, as well as their allies (Stone, 2002). While an appeal to the direct material interests of would-be supporters can be an effective strategy in many circumstances, electoral politics places a premium on proposals which can be shown to be in the public's best interest. In these cases, stakeholders must first compete with one another to define what actually constitutes the public interest in

the particular context. Once the public interest has been more or less determined, stakeholders can turn their attention to trying to persuade others that the public interest will be best served by their proposals (Stone, 2002).

To make a persuasive case with broad-based appeal, policies will often be couched in terms of enduring societal objectives such as equity, efficiency, liberty or security. Moreover, whether or not the public interest is actually served by a proposal is not that important. What matters is the perceived effect on the public interest, which provides a basis for politicians to make a reasonable argument to their constituents (Stone, 2002).

The final strategy of Stone's considered here is the manner in which prospective solutions are addressed. In particular, Stone (2002) outlines two strategies used by stakeholders to address competing proposals, as they attempt to leverage their own preferred solutions. First, stakeholders will attempt to discredit competing proposals by labeling them as infeasible. By demonstrating the reasons for which a particular proposal cannot work, stakeholders try to narrow the field of possible solutions that will be considered in a policy decision. Along those lines, stakeholders will also attempt to conceal possible solutions that run counter to their interests (Stone, 2002). Second, in addressing competing proposals, stakeholders will try to keep the focus on the specific impacts—costs or benefits—that make a competing solution appear unfavourable relative to their own. In cases where there are more than two competing proposals, the focus can shift in accordance with the relative strengths and weaknesses of the proposals being contrasted.

While Stone (2002) conceptualizes some of the rhetorical devices employed by stakeholders to a policy process, her theory does not account for other political factors influencing policy development within the LPC, or the ability of Industry Canada to have its interests reflected in policy outcomes ahead of Health. Accordingly, Stone's theory is supplemented with some conceptualization around the LPC's pragmatic approach to policy development and the impact of the unequal distribution of power between government departments on the policy process.

Liberal Pragmatism

In constructing a theoretical framework to account for the strategy and politics of the LPC in regards to the review of Bill C-91, it was necessary to draw information from a number of scholars including Reg Whitaker, Stephen Clarkson, and Christina McCall-Newman. The result is an eclectic conception of the LPC defined ultimately by pragmatism, an understanding which is explained, in general, using the theory of public choice. Public choice theory helps to clarify the behaviour and strategy of the Liberal government during the review of Bill C-91 through a consideration of the electoral importance of Quebec, a rationalization of the LPC's pro-federalist stance to secure electoral support in Quebec and an overview of Chrétien's Quebec strategy following the 1995 Referendum.

Public choice theory can be used to conceptualize certain political phenomena, including the behaviour of politicians, actions taken by political

parties and polices adopted by governments (Dyck, 2000). Basically, public choice theory postulates that political actors will adopt an approach that increases their probability of being elected—in the case of politicians—or taking power—in the case of political parties (Dyck, 2000). This can include a host of strategies or actions, including the adoption of policies that address the needs of financial supporters; the adoption of policies to maintain party unity; attempting to conceal, or obfuscate, potentially unpopular policies and behaviours; and focusing political efforts on strategic areas where party allegiances are volatile and "swing-voters" more abundant.

The concept of public choice can be applied to the actions and policies of the LPC, which has shown itself to be—on balance—ideologically flexible and willing to adopt policies from across the political spectrum to achieve and then maintain power (Clarkson, 2005). This pragmatic approach to politics of the LPC has its roots in the Party's early beginnings, when it was only able to achieve power after abandoning its traditional radical positions for a moderate tone, accompanied by policies agreeable to the business community (Clarkson, 2005; Whitaker, 1977). More recently, the LPC has gained a reputation for adopting policies that it had once opposed, as well as "campaigning from the left" of the political spectrum followed by "governing from the right" (Clarkson, 2005; McCall-Newman, 1982). It is this hallmark of Liberalism—prioritizing pragmatism over principle—that is revealed in the strategies and motivation behind policy making on matters related to Quebec.

Historically, the election of the LPC has depended to a large degree on the support of the Quebec electorate (Clarkson, 2005). The LPC's strong Quebec base has its roots in controversial incidents surrounding the Conservative Party in the late nineteenth and early twentieth century. These incidents—the Conservative government's decision to hang Louis Riel, Conservative divisions over the Manitoba Schools Question and the Conservative government's decision to implement conscription during the First World War—were strongly opposed by French Quebeckers, who responded by shutting out the Party for the better part of the next 75 years (Clarkson, 2005; McCall-Newman, 1982). With its broad contingent of Quebec candidates and by virtue of it being the only other national party with a realistic chance of forming government, the LPC took advantage of the Conservative Party's demise to become Quebec's most popular federal party. To maintain this advantage, the LPC has employed a general strategy of prioritizing Quebec's concerns in matters of policy and concealing Party disputes between French and English caucus members (McCall-Newman, 1982).

The electoral fortunes of the LPC in Quebec have been magnified by Canada's voting system. With concentrated support in many areas, the LPC has benefited from the unevenness of Canada's first-past-the-post system, which often results in a disparity between the percentage of seats and the percentage of votes (Clarkson, 2005). This "winner's premium" has been especially significant in Quebec, where the Liberals have historically received 50 to 60% of the votes, while making off with approximately 70% of the seats. Considering the

large proportion of total electoral seats in Quebec, success in Quebec has played a large part in the success of the LPC (Clarkson, 2005).

Historically, the LPC has operated under the banner of a federalist party; however, the type of federalism practiced has varied, informed by the standpoint of the Party's leadership and the politics of the day. Within this spectrum, decentralizing tendencies have ranged from the amicable periods of classical federalism under Laurier and King, to the antagonistic federal-provincial relations of the Trudeau era (Dyck, 2000). While the character of federalism practiced by the LPC has varied, so too have the motivations for the Party's promotion of federalism vis-à-vis Quebec. These primary motivations range from an authentic belief in the purpose and effectiveness of Canadian federalism, to the exploitation of the concept of federalism as a means for political gain (R. Whitaker, personal communication, July 5, 2009).

The first motivation derives from a genuine concern for securing a united Canada, engendered by a sense of pride for, and identification with, the shared history of Canada and Quebec. This brand of federalism rests on the belief that the political, economic and cultural security of Quebec is better served within the Canadian federation. Indeed, this was the position of Trudeau, who, in response to the sharp rise in French Canadian nationalism during the 1960's, decided to join the LPC in order to promote a federalist program in Quebec (McCall-Newman, 1982).

The political motivation for the LPC's federalist standpoint is twofold. On the one hand, the LPC have been able to profit in Quebec by presenting

themselves as the only truly federalist party[3] with a reasonable chance of forming a government. This perception has helped the LPC to secure a large percentage of the federalist vote in Quebec (R. Whitaker, personal communication, July 5, 2009). However, as a result, the prospects of the LPC have become closely linked to levels of support for federalism in Quebec, a position challenged more recently by the rise in support for sovereignty followed by the emergence of the BQ (C. Belanger, personal communication, July 6, 2009). Accordingly, electoral pressures related to federalist sentiments have forced the LPC to focus its efforts on the promotion of federalism in Quebec.

Another way in which the LPC has profited from its federalist label is its ability to exploit the national unity issue to justify actions whose genuine inspirations emanate from elsewhere. Due to its supremacy, the national unity cause has worked as an effective pretext for introducing controversial legislation and carrying out unpopular polices, while shielding the Party from the fallout of revealing actual political motivations (S. Clarkson, personal communication, July 7, 2009).

When Chrétien's Liberals came to power in 1993, the BQ was the Official Opposition and support for Quebec sovereignty was relatively high. Mulroney had recently failed—for the second time—to use proposed decentralization and the designation of distinct status to bring Quebec into a new constitutional fold. These factors, along with Chrétien's low approval ratings in French Quebec, helped to persuade the Liberal government to avoid constitutional issues early in

[3] Historically, the PC's and the Conservatives have opted for a strong program of decentralization when in power (Dyck, 2000).

Chrétien's first term (Whitaker, 2006). However, following the disastrous results of the 1995 Referendum, the Liberals were forced to deal with the sovereignty issue to reassert the Party's standing in French Quebec and the rest of Canada. In so doing, Chrétien opted for a new approach which entailed two simultaneous strategies—Plan A and Plan B (Whitaker, 2006).

Plan A measures were designed to address some of the demands of Quebec while boosting the perception of Canada and the federal government among Quebeckers. Some of these measures were in direct response to promises made by Chrétien in the final weeks of the Referendum campaign, including the Government's passing of a resolution recognizing Quebec as a distinct society, increased powers for Quebec—and other provinces—to prevent constitutional amendments and the transfer of federal control for labour market training to Quebec. Plan A measures were essentially the "carrots" designed to appease Quebeckers who held a negative view of the federal government and included the now infamous sponsorship program (Young, 2006). In contrast, Plan B included measures to counter the arguments of Quebec secessionists, and to clearly define—with the guidance of the Supreme Court—the requirements and procedures for Quebec's separation from Canada. Plan B measures were the "sticks", and would eventually culminate in the passing of the Clarity Act in 1999 (Young, 2006).

Unequal Structures of Representation

Mahon (1984) provides insight into how particular policy decisions can be traced to the relative power of different government branches and the institutional perspectives that they hold. According to Mahon (1984), the Marxian concept of unequal structures of representation (USR) helps to explain how the state's composition affects its policy response to particular issues in a capitalist society. In this framework, the organization of the state is seen as historically specific and reflective of the prevailing distribution of power in society; both within and between classes. Consequently, the state structure is comprised of different branches which act as the representatives of particular social forces within society. Just as the power of these social forces in society is unequal, so it is for their corresponding representatives within the state (Mahon, 1984).

According to USR, compromises between different social forces are negotiated and then implemented through public policy. Furthermore, it dictates that, in general, the policy preferences of government branches (e.g. finance, industry, trade) representing stronger social classes and fractions will prevail over the policy preferences of those branches (e.g. health, labour, environment) representing subordinate forces. Put another way, there is an imbalance of power between government branches within the federal government, with stronger branches having greater influence on policy development than weaker branches. Applying the concept of USR suggests that a powerful department like Industry Canada would have more influence over policy issues than a weaker branch like Health Canada. While Mahon's (1984) concept is helpful in providing

insight into the inequalities between government branches and the values they represent, this thesis does not accept its assumption of deeper links to class and intra-class relations.

Consolidated Theoretical Framework

By drawing on the ideas outlined above, a consolidated theory is advanced to frame the events addressed in this thesis, in particular, federal policy development by a Liberal majority government on a controversial issue affecting Quebec, dividing the bureaucracy and splitting the Liberal caucus along regional-linguistic lines. In regards to issues affecting Quebec, a Liberal majority government will use its powers to create conditions which allow it to develop policies that address Quebec's concerns. This course of action is informed by an application of public choice theory to the LPC's electoral strategy vis-à-vis Quebec in the post-Referendum period, which suggests that the LPC advance policies to appease the Quebec electorate. This strategy was consistent with the LPC's immediate concern for increasing its electoral seat count in Quebec, the maintenance of its lucrative financial relationship with the brand name industry, its desire to preserve Party unity and the Plan A measures of the Government's post-Referendum strategy.

Furthermore, stakeholders to a policy development process will use rhetorical devices to try and persuade decision-makers that their interpretation of a problem is correct and their proposals be adopted. Symbolic strategies employed by stakeholders include using narrative stories to define problems;

using ambiguous language to present nuanced proposals; using selective numbers and measures to define problems; specifying whose interests will benefit from particular proposals; and undermining the solutions of competing stakeholders (Stone, 2002). Finally, the concept of USR states that the power of different government branches to influence public policy is unequal (Mahon, 1984). Consequently, in regards to horizontal issues where branches hold competing views, the concerns of the more powerful branch(es) (e.g. Industry Canada) will be reflected in the policy solution ahead of those of subordinate departments (e.g. Health Canada).

Research Methods

Evidence was collected from secondary sources (scholarly journals and books), archival data (newspaper articles and government/parliamentary reports) and interviews. In addition to background information, data were collected for three time periods, including the following: (1) the pre-review period between the beginning of the election campaign in September 1993 and the beginning of the review of Bill C-91 in February 1997; (2) the actual review period including the two months between February and April 1997; and, (3) the post-review period lasting from the end of the review in April 1997 up until September 1998, when the Office of the Auditor General (OAG) reported on an audit of the Patented Medicine Prices Review Board (PMPRB).

While helpful, documentary sources do not provide a comprehensive account of the review and related issues. Moreover, while the minutes of the

Standing Committee on Industry's hearings were helpful in analyzing the actual review period, there was a relative lack of documentary evidence focused on the politics pertaining to the periods leading up to and immediately following the review. To address these gaps, and to help clarify other issues raised in the documentary evidence, interviews were conducted with persons identified as possessing direct knowledge of the review and related topics.

Initial interview subjects were identified through a preliminary search of primary and secondary sources. One particularly helpful source for identifying interview subjects was the 1996 -1997 Federal Government Directory (Canada, 1996), which included all federal government employees identified by branch and office. Former political staffers were preferred over public servants as interview candidates, as they were deemed to be less constrained by the organizational imperatives common to the Canadian federal bureaucracy. Subsequent interview subjects were identified through information gathered from preliminary interviews. Interviews were conducted with Tony Macerollo, Chief of Staff for the Minister of Industry (John Manley); Marjory Loveys, a policy analyst at the Prime Minister's Office (PMO); David Walker, a Liberal MP and Chair of the Standing Committee on Industry; and John Solomon, an NDP associate member of the Standing Committee on Industry with a critical view of Bill C-91. In addition, interviews were conducted with anonymous sources, including Liberal political staffers and federal bureaucrats.[4]

It was important to speak to representatives from the PMO (Loveys) and Industry Canada (Macerollo) to provide a perspective on the politics and the

[4] Each of the participants held their listed position during the time of the review of Bill C-91.

Government's strategy with regard to the review. Moreover, due to his important role in managing the Committee hearings—as well as his close relationship with the Minister of Industry during the review—information provided by the Industry Committee's Chair (Walker) was considered essential. Last, it was important to interview a non-Government MP with a critical view of Bill C-91 (Solomon) to supplement the data collected on the review. Interviews were tape recorded with the permission of the participants and then transcribed immediately after each interview was complete. Interviews included targeted questions, but were semi-structured to allow participants to discuss issues openly and freely, or to raise and explore other issues they felt were relevant to the review. Interviews generated information that was helpful to understanding the Government's major political concerns regarding the review, Cabinet and Committee processes and the relationship between the Government and the Industry Committee.

In addition to the interviews conducted, several interview requests were either denied, or went unanswered. Interview requests were not accepted by the Minister of Industry (Manley); the Minister of Health (David Dingwall); the Director of Policy at the PMO (Chaviva Hosek); representatives from brand name pharmaceutical companies (Chris Ward, Richard Williams and Paul Lucas); a representative from the generic pharmaceutical industry (Jeff Connell); the Chair of the PMPRB (Robert Elgie); and a Liberal member of the Standing Committee on Industry (Joe Volpe).[5] In addition, contact information could not be located for other individuals whose input would have been valuable to this study.

[5] Each of these people held the position that is listed at the time of the review of Bill C-91.

While data was gathered from interviews, the majority of information was generated by the testimony from the Standing Committee on Industry's hearings on Bill C-91. Analyzing Committee discourses helped to clarify the interests of participants; the strategies employed to advance these interests; the presence of shared interests and alliances; and the relative positions of power from which each participant was operating from.

These hearings involved testimony from over 140 witnesses and dealt with a vast number of issues related to pharmaceutical policy. Due to the scope of this master's thesis, it was not practical to evaluate the testimony from all witnesses, nor was it useful to focus on all the issues covered. Accordingly, decisions were made to focus on a limited number of witnesses representing the key stakeholders.

Due to their stake in the outcome of the review, the following were identified as key stakeholders at the hearings: (1) the Pharmaceutical Manufacturers Association of Canada (PMAC), representing the Canadian brand name pharmaceutical industry; (2) the Canadian Drug Manufacturers Association (CDMA), representing the Canadian generic pharmaceutical industry; (3) the Industrial Biotechnology Association of Canada (IBAC), representing the Canadian biopharmaceutical industry; (4) the CHC, representing Canadian citizens/consumers; (5) Industry Canada and Health Canada, representing the federal government; (6) provincial health ministers from British Columbia, Saskatchewan and Manitoba, representing their respective provincial health ministries; and, (7) the PMPRB, representing itself.

Each key stakeholder focused on a core group of issues—those that held the greatest significance for the interests of their constituents. However, some issues appeared more important than others, as indicated by the number of parties who addressed them, or by the amount of time specific parties spent on them. A summary and analysis of these particular issues—identified as primary issues—is outlined in Chapter 3. Questions and comments from Committee members are included to help clarify their positions on the issues, while providing context to the dynamics of the hearings. The primary issues from the hearings outlined in Chapter 3 include: the retroactivity of Bill C-91; the Bolar Provisions (early-working and stockpiling exceptions); the Linkage Regulations; patented medicine price regulation; patent term restoration (PTR); pharmaceutical research and development (R&D) investments; exporting restrictions on generic copies of Canadian patented drugs; pharmaceutical research in Canada; the appearance of generic drugs; and compulsory licensing and a national pharmacare strategy.

While the data provided by the sources above were useful, caution in using material provided by them was exercised for a couple of reasons. First, the material presented in some documents—especially government documents—may have been biased by the source's consideration for the way in which the public will perceive the material, especially in a political context (Palys, 1997). Consequently, consideration was given to the possible reactivity of documentary evidence when considering the veracity of its content. Similarly, the selectivity of documentary evidence was also taken into account, as it can impact the kinds of

information made available, as well as which sources are accessible for public consumption. In sum, one must be mindful of the "context of production" in evaluating documents (Palys, 1997).

Second, caution was exercised in the evaluation of information collected from interview sources. A number of factors—protecting reputations, protecting interests, poor recollection, and a lack of knowledge of broader issues—can affect the quality of data resulting from interviews (Palys, 1997). While triangulation was employed to verify information gathered from interviews and other sources when possible, the accuracy of the data was limited by the number of people interviewed. Clearly, the validity of the data collected, as well as the conclusions drawn from it, would have been strengthened had input from more sources with knowledge of the issues been available.

The Canadian Pharmaceutical Industry

A general reading of the two primary industrial actors involved with the review of Bill C-91 is essential to the development of this thesis. At the time of the review, the main industry battle-lines were drawn between the brand name pharmaceutical sector—represented by PMAC—and the generic pharmaceutical sector—represented by the CDMA.

Pharmaceutical Manufacturers Association of Canada

PMAC[6] was the trade association representing Canadian subsidiaries of multinational brand name pharmaceutical companies.[7] The organization was established in Toronto in 1914, but moved its headquarters to Ottawa in 1967[8] to lobby the federal government. Around the time of the review, PMAC firms dominated the prescription drug market in Canada (Industry Canada, 1997) and made a sizeable contribution to the economy and job creation[9] (Rx&D, n.d.). As of the late 1980s, PMAC represented 65 pharmaceutical firms, almost all of which were multinational, patent-holding corporations (Atkinson & Coleman, 1989). Generally speaking, Quebec—the Greater Montréal area to be specific—has been the geographical centre of Canada's brand name pharmaceutical industry. The profitability of brand name pharmaceutical companies rests on their ability to "discover" and patent new drugs and then sell these drugs in markets which provide long periods of market exclusivity for their products. Market exclusivity shields brand name companies from competition, allowing them to keep their products priced higher for longer periods. Although PMAC companies carry out research that leads to the discovery of new drugs, they also

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[6] PMAC was originally established in 1914 under the name the Canadian Association of Manufacturers of Medicinals and Toilet Products, but changed its name to the Canadian Pharmaceutical Manufacturers Association (CPMA) one year later. It adopted the PMAC title in 1965 (Lexchin, 1984) and then changed its name again in 1999 to Canada's Research-Based Pharmaceutical Companies (Rx&D), to highlight the research component of its operations.

[7] In its early beginnings, PMAC also represented some Canadian-owned brand name companies which were eventually taken over, or merged, with foreign companies (Lang, 1974).

[8] Lang (1974) reports that PMAC moved its operations to Ottawa in anticipation of significant changes to pharmaceutical patent policy as the federal government had been taking a greater interest in the industry. This decision to move headquarters to Ottawa has proven successful (Lexchin, 1984).

[9] According to Rx&D (n.d.), the brand name pharmaceutical industry employed approximately 21,000 people in Canada in the late 1990s. In addition, it the brand name industry accounted for approximately 80% of Canadian prescription drug sales (Industry Canada, 1997).

partner with universities and biopharmaceutical companies to develop and market products discovered by others.

At the time of the review, the brand name pharmaceutical industry had become one of the most lucrative and powerful industries in the world (Robinson, 2001). In 1995 alone, estimated worldwide sales for the pharmaceutical industry stood at $340 billion (PMPRB, 1996). In that same year, the pharmaceutical industry was awarded the *Fortune 500* "triple crown" for being ranked number one in return on revenues (16.4%), return on assets (12.7%), and return on equity (31.2%) (Morgan, 1996).

In addition to financial strength, the Canadian brand name pharmaceutical industry boasted a number of other assets. For one, PMAC operated a highly structured organization, including a full-time professional staff since 1958 (Atkinson & Coleman, 1989). Since moving to Ottawa in 1967, PMAC had built up an elaborate committee structure and effective networks with like-minded organizations, earning itself a reputation within the public and private sector as a serious and focused association.

At the time of the review, PMAC maintained an institutionalized relationship with the federal bureaucracy through its connections with the Therapeutic Products Directorate[10] (TPD) of the Health Products and Food Branch[11] of Health Canada. Owing to its organizational proficiency and the federal government's lack of expertise and capacity in the area of pharmaceuticals, PMAC had become an active participant in the design of

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[10] The TPD was formerly the Drugs Directorate.
[11] The Health Products and Food Branch was formerly the Health Protection Branch.

policies and regulations regarding pharmaceutical safety and efficacy. This included a significant advisory role in the development of policy through a joint working committee between PMAC the civil servants from the TPD (Lexchin, 2001).

In recent decades, PMAC has benefited tremendously from personnel interchange with government. Through interchange, former pharmaceutical employees[12] have taken the perspective of the sector to their new roles in government, while former public officials and civil servants have provided the sector with influential connections and invaluable knowledge of government operations (Campbell & Pal, 1989). One particularly important transfer was that of Judy Erola to the presidency of PMAC in the mid-1980's. Only months before joining PMAC, Erola had been Trudeau's Minister of Consumer and Corporate Affairs (CCA)—one of the principal federal departments responsible for drug policy (Campbell & Pal, 1994). By virtue of its financial strength, PMAC has also been in a position to hire some of the most effective and connected lobbyists in Ottawa (Campbell & Pal, 1989). PMAC spent millions of dollars on lobbyists during the debates around Bill C-22[13] and Bill C-91,[14] to ensure that its message

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[12] For example, Martin O'Connell—former Cabinet minister in the Trudeau government—had worked for Eli Lilly and PMAC before becoming a consultant on patent law revision for the Department of Consumer and Corporate Affairs (CCA) in the mid-80s, just before the Mulroney government introduced Bill C-22. During the time that Bill C-22 was being debated in the House of Commons, John Turner was the leader of the Liberal Opposition. Previous to that, Turner had been on the Board of Directors of Sandoz—a multinational drug company with operations in Quebec—during the 1970s (Campbell & Pal, 1989).

[13] During the debates around Bill C-22, PMAC spent millions of dollars on Government Consultants Incorporated (GCI). GCI was founded by Garry Ouellet—a very good friend of Mulroney—and Gerald Doucet—the brother of Mulroney's chief of staff, Fred Doucet. Doucet led the effort to organize PMAC's public relations campaign for Bill C-22 and was instrumental in organizing meetings between PMAC and the Minister of CCA, Michel Cote (Campbell & Pal, 1989). In 1988, GCI went on to recruit Cote, after he had decided not to run for re-election. In addition to Ouellet and Doucet, GCI boasted a number of ex-politicians and senior bureaucrats with extensive contacts in the federal government (Campbell & Pal, 1989).

reached powerful and influential people within government. Leading up to, and during the review of Bill C-91, PMAC continued it pattern of extensive lobbying. In addition to officials in the PMO and Manley's Office (T. Macerollo, interview, July 17, 2008), members of the Standing Committee on Industry were targeted, specifically the Chair, David Walker ("Getting a pole position", 1997).[15]

The Canadian brand name industry has also tried to influence policy through political donations, having contributed over $1 million to individual LPC candidates between 1993 and 2002 (Clarke, 2004). In addition to domestic donations, billions of dollars in political contributions in other jurisdictions—primarily the US—by the parent firms of Canadian subsidiaries, has been used to lobby foreign governments to defend the interests of the brand name industry through diplomatic channels.[16] This sort of "diplomacy" was most apparent in US demands regarding Bill C-22, an event that is discussed in more detail in Chapter 2.

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[14] When Bill C-91 was being debated in 1993, PMAC engaged in a multi-faceted, all-fronts lobby effort, with massive amounts of advertising—both print and broadcast—and a heavy use of direct mail (Cameron, 1992). For Bill C-91, PMAC hired almost every available major lobbying and public relations firm that was active in Ottawa. Some of these firms include GCI; Frank Doucet Consulting International; Hill and Knowlton; the law firm Gowling, Strathy, and Henderic; the public relations firm Gervais, Gagnon, and Frenette; Earnscliffe Strategy Group; and Marian May and Associates (Campbell & Pal, 1994).

[15] In fact, it has been reported that Walker's staff actually solicited donations from the brand name sector by advertising his chairmanship of the Standing Committee on Industry and his prospective role in the upcoming hearings on Bill C-91 (Cameron, 1997).

[16] For example, during the 2000 election campaign alone, the US brand name industry employed over 600 federal lobbyists and spent a total of $262 million on lobbying, advertising and campaign contributions (Public Citizens, 2001).

The Canadian Drug Manufacturers Association

In contrast to PMAC, members of the CDMA were primarily in the business of manufacturing copies of drugs already on the market, drugs conventionally referred to as generics.[17] The profitability of generic firms rests on the speed with which they can market a product created by another (usually brand name) company. Consequently, the CDMA's fundamental concern has been with decreasing the period of market exclusivity afforded to patented medicines, thereby shortening the waiting time before their companies can copy and market pharmaceutical drugs.

The CDMA was founded in Toronto in 1967 with a mandate to represent the collective interests of Canadian-owned generic pharmaceutical companies. As of the late 1980s, the CDMA represented approximately 20 firms, although membership has rarely been stable[18] (Atkinson & Coleman, 1989). Most CDMA members have their facilities located in Ontario, with a large concentration in the Greater Toronto area. While generics only accounted for 17% of Canadian prescription drug sales at the time of the review, their two largest members—Apotex Inc. and Novopharm Ltd.—were ranked 3rd and 8th respectively in total drug sales (Industry Canada, 1997). At the time of the review, the CDMA's impact on job creation and the Canadian economy was minor relative to PMAC, but not insignificant. Over 5,000 employees worked in the generic drug sector in Canada, of which 80% worked for CDMA member companies (Canada, 1997d).

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[17] Some companies (e.g. Apotex) that had started out producing only generic drugs were now also in the business of R&D, manufacturing fine chemicals and patenting drugs (Canada, 1997d).

[18] This instability has been related to the intense competition resulting from the small number of firms (Atkinson & Coleman, 1989)

Save for its previous relationship with the now defunct CCA[19] (Campbell & Pal, 1994), the CDMA has never been considered a respected sectoral association within the federal government. On the contrary, its lack of a permanent staff in the past and ad hoc organizational structure has earned it a reputation within government as a "fledgling interest group" (Atkinson & Coleman, 1989). Similar to PMAC, the CDMA has used lobbying to try and advance its position on pharmaceutical policy within the federal government. However, the CDMA's relatively weak financial position and lack of organizational capacity[20] has hampered its ability to benefit from the type of effective lobbying enjoyed by PMAC. This financial disparity was especially evident during the Bill C-22 and Bill C-91 debates.[21] Moreover, while the CDMA and its member companies have employed several influential people[22] with experience in the federal government, their combined knowledge and influence pales in comparison to that of a former CCA Minister, like Erola. As CDMA members have not been able to benefit from the kind of financial wealth enjoyed by their brand name counterparts, they have placed greater importance of using political

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[19] The CCA was dismantled in 1993 and its responsibilities were broken up and delegated to other branches of the federal government.

[20] Of course, the fact that the CDMA—unlike PMAC—was always arguing against the preferred policy of the Government has also factored in on its lack of success.

[21] During the debates around Bill C-91, while PMAC hired numerous lobbying and public relations firms, the CDMA was only able to hire Government Policy Consultants, the law firm McIlroy and McIlroy, and Canlac Corporation (Campbell & Pal, 1994).

[22] Some examples of former government employees who went on to work for the CDMA include Ivan Fleishman, Skip Wallis and Jim Keon. Fleishman, the former executive assistant to Liberal Minister John Roberts, came to work for CDMA as a consultant in the early 1980's (Campbell & Pal, 1989). Wallis, a former campaign manager for the PC's in the early-1980's, was hired on as a consultant by the CDMA in 1985 (Campbell & Pal, 1989). Keon was hired on as the vice president of research and international affairs for the CDMA in 1994, and brought extensive knowledge and experience to the Association. During his 17 years working as a federal civil servant, Keon had worked as a director of IP for the CCA and as a key member of Canada's trade bargaining team (Jenish, 2003).

donations to gain political influence. For instance, during the 1997 election, both Apotex and Novopharm made numerous contributions in excess of $1,000—mostly towards incumbent Toronto Liberal MPs (Elections Canada, 2008a).

CHAPTER 2 – The Evolution of Canadian and Global Pharmaceutical Patent Law

Introduction

While the focus of this thesis is the review of Bill C-91, it was only one episode in the evolution of pharmaceutical patent law in Canada. Rather than look at the review as a static, stand-alone event, it must be considered in the context of decades of highly contested policy development where different stakeholders have benefited during different periods. Due to the involvement of multinational corporations and because of the globalizing effect of trade agreements in the recent past, a basic understanding of international pharmaceutical politics is also necessary to understand the Canadian situation. Accordingly, this chapter outlines major events—both domestic and foreign—which have affected the evolution of Canada pharmaceutical patent policy up to, and including, the passage of Bill C-91 in 1993.

Bill C-102 – Compulsory Licensing Expanded

Compulsory licensing of pharmaceuticals was first legalized in Canada in 1923; however, very few manufacturers applied for licenses because prevailing laws required that active ingredients be manufactured in Canada (Smith, 1993). At the time, few Canadian generic companies had the capacity, or the resources, to manufacture fine chemicals. Consequently, very few[23] licenses were issued

[23] In total only 49 applications were submitted and 22 licenses issued (Lexchin, 1997). As Campbell and Pal (1989) explain, the reason that there were so few licenses applied for during this period was that

between 1923 and 1969.[24] During the 1960's, several high profile reports[25] concluded that the Canadian patent system was responsible for Canada having some of the highest drug prices in the world. In 1967, Pearson's government responded to these findings by introducing Bill C-190, which included provisions allowing for the issuance of compulsory licenses to import medicines. Although the Bill died in adjournment, it was reintroduced by the Trudeau government in 1968 as Bill C-102.

Despite PMAC's multimillion dollar lobbying effort[26] to challenge changes to the *Patent Act*, Bill C-102 passed and came into force in 1969 (Campbell & Pal, 1989). The changes to the *Patent Act* provoked by Bill C-102 allowed generic manufacturers to import either the active ingredients of domestically patented pharmaceuticals, or the finished product (Campbell & Pal, 1989). In exchange for the granting of compulsory licenses, generic companies were obliged to pay royalty rates to the patent owner equal to 4% of the generic net selling price (Ogilvy Renault LLP, 2002).

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compulsory licenses only provided the licensee the right to use the process to manufacture the product, but did not include a right for the generic company to import the active chemical ingredient. Without the legal right to import the active chemical ingredient—whose only source short of manufacturing it in-house was foreign—compulsory licenses were ineffective policy tools because they were essentially useless to the generic companies.

[24] Not surprisingly, these few licenses had little effect on the prices being charged by brand name pharmaceutical companies who were still able to take advantage of their monopoly situations (Smith, 1993).

[25] A number of government reports addressed the issue of high drug prices in the 1950s and 1960s. These reports included D.H.W. Henry's 'Green Book' Report; The Restrictive Trade Practices Commission's Report Concerning the Manufacture, Distribution and Sale of Drugs; The Isley Commission's Report on Patents, Copyrights, and Industrial Design; The Hall Commission's Report on Health Services; and, The House of Commons Special Committee's Report on Drug Costs and Prices (Campbell and Pal, 1989).

[26] PMAC officials contacted hundreds of CEOs from Canadian businesses in an effort to convince them that Bill C-102 was generally bad for Canadian business. At the Committee stage, PMAC supplied opposition MPs with generous amounts of information to use against anti-industry witnesses (Lexchin, 2001). Lang (1974) maintains that it was the determination of the federal civil service and the marginal position of the brand name industry in the Canadian economy at that time that weakened its opposition against Bill C-102.

The Bill C-102 amendments ushered in a new era in the Canadian pharmaceutical industry, one that saw the development of a healthy Canadian-owned generic drug industry, leading to greater competition and lower drug prices.[27] Furthermore, the decrease in drug prices made it possible for the expansion of provincial drug programs, which subsidized drug payments for the elderly and unemployed (Lexchin, 1997).

US Bilateral Strategy – Strengthening Foreign Patent Rights by Coercion

Beginning in the mid-1970s, the US Government began using private sector advisory committees to assist legislators on matters involving trade. In the early 1980s, Ed Pratt—then CEO of the brand name pharmaceutical company Pfizer—was the chairperson of one of the most powerful of these advisory groups—the Advisory Committee on Trade Negotiations (ACTN) (Braithwaite & Drahos, 2000). At this time, the US brand name pharmaceutical industry was becoming increasingly concerned with a number of factors negatively impacting its profitability.[28] Using Pratt's influential position within the ACTN, the brand name industry was able to effect a realignment of trade priorities and practices within the US Government, to pressure foreign countries to increase protection for US intellectual property (IP) abroad (Braithwaite & Drahos, 2000).

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[27] From 1969 to 1985, 765 applications for compulsory licenses were filed of which approximately 400 were issued. Most of these licenses were for the importation of active ingredients or finished drug products to Canada (Ogilvy Renault LLP, 2002).

[28] Some of these factors included government promotion of generic drugs as a cost-containment measure, lax foreign IP laws resulting in piracy, the establishment of foreign compulsory licensing regimes, and the impending expiration of patents for blockbuster drugs (Braithwaite & Drahos, 2000).

To force other states to change their domestic patent laws, the ACTN advised the US Government to institute a coercive policy linking IP protection with access to US markets (Braithwaite & Drahos, 2000). In response, the US Congress passed successive laws giving the Office of the US Trade Representative (USTR) far-reaching powers to sanction[29] trading partners deemed to be providing inadequate protection to US IP interests.[30] In defining inadequate protection of US IP rights, the USTR took a very broad and strategic view that included not only foreign policies and legislation, but all state action (and inaction) judged as damaging to the US's broader IP goals.[31]

The short-term strategy of the ACTN's efforts was to shape new bilateral trade agreements and enhance US IP rights abroad. However, the ultimate, long-term goal was the placement of strong, enforceable IP protection into the multilateral trade agreement, something eventually realized with the establishment of the World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property and Services (TRIPS).[32]

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[29] Some examples of sanctions include the withdrawal of trade benefits and the imposition of import restrictions on goods. To some developing countries, exclusion from a lucrative market like the US had a catastrophic impact (Braithwaite & Drahos, 2000)

[30] The process of identifying problem countries and then imposing sanctions is called the "Special 301 Process".

[31] One striking example of this type of strong-arming was during the Uruguay Round of trade negotiations were sanctions were imposed against countries that did not support the US in its aims to establish broad, enforceable IP standards in a multilateral forum (Harrison, 2004). See Harrison (2004) for more examples of how the US used sanctions to pressure developing countries such as Argentina, Brazil, Thailand and India to amend their policies on IP.

[32] Harrison (2004) argues that the US brand name industry embarked on this strategy because of its weakening position in the domestic policy arena vis-à-vis the generic drug industry and consumer groups. By shifting the focus away from domestic drug prices and towards the foreign rights of US innovators, the US brand name industry was able to evade the political power of domestic interest groups by pursuing their interests through foreign policy changes. With the enactment of NAFTA and later TRIPS, Harrison (2004) believes the US brand name industry was able to use international trade agreements to realize its domestic political aspirations.

Bill C-22 – Restricting Compulsory Licensing

After more than a decade of compulsory licensing, the early 1980's saw the reemergence of drug patenting as a major political issue in Canada. The reasons behind this are multifaceted and include ideology, concern about the political fallout from pharmaceutical plant closures in Quebec, concerns about low levels of investment by high-tech industries, pressure from the brand name pharmaceutical industry and trade pressure from the United States (Campbell & Pal, 1989).

In 1983, the Trudeau government responded to growing pressure from the brand name industry by asking Dr. Harry Eastman[33] to carry out a commission of inquiry into the Canadian pharmaceutical industry. In 1985,[34] the Commission reported that Canada's brand name pharmaceutical industry was very profitable and had lost only 3% of its market share despite the proliferation of compulsory licensing (Canada, 1985). The Commission also reported that generic drugs were substantially cheaper[35] than brand name drugs and that their presence in the market had forced brand name companies to reduce the prices of their own products. According to the Commission, the presence of generic drugs in the marketplace had saved Canadians $211 million in 1983 alone (Canada, 1985). The Commission concluded that compulsory licensing had greatly benefited consumers while having a negligible impact on the brand name industry's bottom line. Nevertheless, the Commission did propose some changes to Canada's

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[33] Eastman was an esteemed economics professor from the University of Toronto.
[34] By the time the Eastman Commission reported in 1985, the PCs had formed a government led by Brian Mulroney (Campbell & Pal, 1989).
[35] On average, generic drugs were approximately 51% cheaper than their brand name equivalents (Canada, 1985).

pharmaceutical patent policy; in particular, provisions for four years of patent protection from compulsory licensing and a new formula for calculating drug royalties (Canada, 1985). To stimulate basic R&D by the Canadian brand name pharmaceutical industry, Eastman proposed depositing royalties into a special fund to be disbursed to firms in accordance with their level of participation in basic R&D[36] (Smith, 1993).

In late 1986, the Mulroney government introduced Bill C-22—an Act to amend the *Patent Act*. Bill C-22 proposed several amendments to the *Patent Act*, most importantly, the restriction of compulsory licensing. Along the lines of Eastman's recommendations, Bill C-22 provided brand name products protection from compulsory licensing for a set number of years determined by a system called "deferred compulsory licensing" (Ogilvy Renault LLP, 2002). Under this system, brand name companies would be given ten years of protection against generic companies receiving compulsory licenses to import and seven years of protection against compulsory licenses to manufacture the active ingredients in Canada (Smith, 2000).[37]

In addition to restricting compulsory licensing, Bill C-22 increased the standard pharmaceutical patent period,[38] while permitting the issuance of patents

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[36] Under the Commission's suggested plan, royalties from this fund would be disbursed to brand name companies based on a combination of (1) their firm's share of Canadian R&D; and, (2) the sales of their products that had been licensed to generic companies (Smith, 1993).

[37] Compulsory licenses to import were essentially licenses that allowed generic firms to import either the finished drug product or the active ingredient (which would of course be used to manufacture the product in Canada). Compulsory licenses to manufacture were issued to generic firm only in cases where they intended to manufacture the active ingredient in Canada (Smith, 2000).

[38] The patent period was changed from seventeen years from the date the patent was issued to twenty years from the date the patent was filed (Smith, 1993).

for products.[39] Furthermore, Bill C-22 provided for the creation of the PMPRB, an "independent",[40] quasi-judicial body, charged with regulating the prices of patented medicines, as well as monitoring and reporting on R&D investments made by the brand name industry (Campbell & Pal, 1989).

The PMPRB was created to address concerns that restrictions to compulsory licensing would lead to a rise in prescription drug costs. In addition, the PMPRB was responsible for monitoring and reporting on annual pricing trends in the Canadian pharmaceutical industry and reporting on the ratios of R&D expenditures to sales for brand name companies. The Board's mandate to monitor R&D to sales ratios stemmed from PMAC's commitment to increase Canadian R&D[41] in exchange for the enactment of Bill C-22 (Smith, 1993; Ogilvy Renault LLP, 2002).

To control patented medicine prices, the Board employed a two-stage strategy. These stages included the establishment of guidelines to set the introductory price of a new drug, followed by the monitoring of that price to ensure that it did not rise above the level of inflation. To set new prices, the Board considered the level of improvement of the new drug as well as its price in other jurisdictions[42] (Smith, 1996).

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[39] Previously, patents were available only for manufacturing processes which left them open to a certain level of risk if a "new process" (which didn't have to be extensively novel) were devised to manufacture the product. Under Bill C-22, process patents were eliminated and patents were now issued on products. This change effectively increased the exclusivity rights of patentees (Smith, 1993).

[40] Although it claims to be independent, positions at the PMPRB are appointed by Cabinet which suggests that there is a risk of political influence in the Board's operations.

[41] PMAC members pledged to increase their R&D spending to 10% of domestic sales by 1996 (Campbell & Pal, 1994).

[42] The PMPRB publishes guidelines on the pricing of drugs, which are initially categorized into existing and new treatments. Existing drugs were priced according to established benchmarks. New drugs were further categorized into 3 groups. Category 1 is generally comprised of existing drugs at new strengths.

Bill C-22 provided the Board with a number of powers to help it enforce its guidelines. For one, the Board's authority was set at that of a Superior Court with respect to the production and inspection of documents, the examination of witnesses and the enforcement of orders (Ogilvy & Renault LLP, 2002). Furthermore, to compel brand name companies to reduce excessive prices, the Board was given the power to grant compulsory licenses against any of a company's patented products (Marusyk & Swain, 1993; Ogilvy and Renault LLP, 2002).

Despite its majority position, the Mulroney government was unable to steer Bill C-22 smoothly through the legislative process. The Bill faced tough opposition from consumer groups, as well as the LPC—now the Official Opposition. To try and push the Bill forward, the Mulroney government invoked closure during several legislative proceedings.[43] On a number of occasions, the Bill was amended by the Liberal-dominated Senate and sent back the House for further debate (Campbell & Pal, 1989). While the Mulroney government had its own appetite for extending patent protection, there is also evidence suggesting that the US government pressured Canada to eliminate compulsory licensing as a condition for the former's acceptance of the Canada-US Free Trade Agreement (CUFTA) being negotiated at that time (Auerbach, 1987; McDonald, 1995).

Category 2 consists of "breakthrough" drugs which are designated as significant therapeutic improvements over existing treatments. Category 3 includes new drugs, or new strengths of existing drugs, that provide moderate or no improvement on existing treatments. Category 2 drugs ("breakthrough" treatments) could not be priced higher than the median price of the same drug from a fixed "basket" of seven industrialized countries comprised of the US, UK, Switzerland, Sweden, Germany, Italy and France. As a safeguard, Canada's price could never be higher than all of the countries to which it was being compared. To control the product's price after an initial price was set the Board did not permit annual price changes to rise faster than the rate of inflation (Smith, 1996).

[43] The Government used closure during all three readings of the Bill as well as in some of the Committee proceedings (Campbell & Pal, 1989).

The issue of US infringement on Canadian sovereignty has always been politically sensitive, even more so in light of the controversial free trade negotiations unfolding at that time. The Mulroney government thus denied any link between Bill C-22 and CUFTA (O'Donnell, 1987). To deflect charges of "selling out" to the Americans over patent protection, the Mulroney government attempted to reframe Bill C-22 as a "Made in Canada" project, designed to attract and maintain much needed high-tech investment—especially in Quebec (Campbell & Pal, 1989). The recession of the early 1980's, along with the general perception that Quebec's pharmaceutical industry was in decline, provided the rationale and opportunity for Mulroney to exploit Quebec's political situation.

Indeed, since the late 1970's, several companies previously located in the Greater Montréal area had expanded to Ontario, while a few others had relocated their entire operations outside of Quebec.[44] By focusing the debate on Bill C-22's impact on Quebec's economy, the Government was able to fend off its critics by labeling opponents of Bill C-22 as anti-Quebec; a charge that the LPC was eager to distance itself from, owing to the festering national unity issue[45] and its low popularity[46] in Quebec at that time. Furthermore, Liberal MPs were

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[44] The Eastman Commission argued that these relocations could be characterized as part of the "general westward movement" of companies, probably induced by language requirements and high levels of taxation in Quebec (Canada, 1985). Some of the companies that moved their Quebec offices include Hoffman-La Roche, SmithKline & French, Bristol-Myers and Ayerst, McKenna Laboratories (Atkinson & Coleman, 1989). The closure and transfer to New York State of the Montréal plant of Ayerst, McKenna Laboratories in 1982 was exceptionally damaging to the local economy, as it had resulted in the loss of almost three hundred high-value research jobs (Pazderka, 1985).

[45] Sovereignty had gained momentum in Quebec during the past decade, culminating in the Quebec Referendum on Sovereignty in 1980.

[46] The LPC had fared extremely poorly in Quebec during the most recent (1984) federal election, winning only seventeen seats compared to the fifty-eight for the PCs.

divided by the regional character of the Bill, with Montréal Liberals in full support. With a few Quebec Liberals having already broken ranks, the Party opposition to the Bill presented a significant threat to maintaining unity within the LPC (Campbell & Pal, 1989). In an attempt to bolster the Government's position during debate over the Bill, PMAC announced its intention to hold off on the creation of 1,300 new jobs and $700 million in planned investment—most of which was targeted for Quebec—until the legislation had passed.[47]

In addition to consumer groups and the LPC, the Mulroney government faced stiff opposition from most of the provinces, whose formulary costs stood to increase under Bill C-22. The only province that supported the Bill was Quebec, which was weary of the economic and political fallout from plant closures and eager to capitalize on the new investments announced by the brand name industry. Indeed, investment in the life sciences sector—especially pharmaceuticals—was a fundamental aspect of Quebec's new economic "cluster strategy" (T. Macerollo, interview, July 17, 2008). In support of its strategy to attract pharmaceutical investment, the Government of Quebec had implemented a generous package of tax-based incentives.[48] As an additional inducement, Quebec had also increased its use of expensive brand name drugs on public formularies, despite the existence of cheaper, generic substitutes.[49]

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[47] Projects by as Rhone-Poulenc, Mallinckrodt, Burroughs-Welcome, Johnson and Johnson, and Ayerst, McKenna Laboratories were all put on hold (Canada, 1985).

[48] This included corporate tax breaks and loopholes, a 20% refundable tax credit on salaries of R&D personnel working at recognized research centres, as well as a two-year provincial income tax break for any foreign researcher working for a multinational pharmaceutical firm or academic institution (Brady, 1998).

[49] Quebec was the only province that did not require publicly-funded drug programs to utilize lower cost generic drugs, but rather promoted the higher-priced brand name options (McGovern, 1995). This policy of favouring brand name products has led to the lowest usage rate of generic drugs in the entire country (Thompson, 1997).

Furthermore, Quebec ensured that its drug approval system accepted more brand named drugs than any other province, while providing regulatory approval times that were second to none (McGovern, 1999).

In an attempt to appease the cost concerns of the other provinces—signifying just how important the Bill was to the Government—$100 million was pledged to the provinces to assist them in dealing with the financial impacts of Bill C-22 (Campbell & Pal, 1989). In the end, the Government was able to pass Bill C-22 through a combination of Liberal anxiety over alienating Quebec voters, provincial deference resulting from the generous transfers and the shrewd manipulation of Parliamentary rules.

US Multilateral Strategy – Broad Patent Rights in NAFTA and the GATT

In the years immediately preceding the finalization of the WTO and TRIPS, the US negotiated approximately 40 bilateral and multilateral trade agreements. According to Harrison (2004), the completion of these agreements leading up to, and during, the Uruguay Round of negotiations for the General Agreement on Tariffs and Trade (GATT), was a major component of the US strategy to increase the standard of IP protection leading up to the final negotiations to improve its bargaining position.

One example of this strategy is the IP section of North American Free Trade Agreement (NAFTA),[50] whose text was finalized in 1992 (Braithwaite and

[50] Chapter 17 is NAFTA's section on IP rights.

Drahos, 2000). NAFTA's Chapter 17 includes some of the strongest provisions for IP up to that point in time,[51] while providing the industry with a powerful precedent to support its controversial multilateral IP proposal for TRIPS. NAFTA provided a particularly suitable model for TRIPS, not only because of its high IP standards, but also because of the nature of the countries involved in the agreement. Speaking to a legal audience in the late 1990's, the former President of the Pharmaceutical Research Manufacturer's Association[52] (PhRMA), Gerald Mossinghoff (1999, as quoted in Kuyek, 2002), summed up the brand name industry's position on NAFTA by saying that it was:

> [a]n important breakthrough in IP rights.... What NAFTA did was to affirm that (1) IP is a proper subject for trade agreements; and, (2) IP standards should be set at a very high level. These developments in NAFTA occurred just before the agreement known as Trade-Related Aspects of Intellectual Property (TRIPS), which was being negotiated by GATT at the same time. The TRIPS provisions are very similar to NAFTA provisions because the three NAFTA countries were representative of countries at different stages of development and thus were quite influential during the negotiations about TRIPS. The US pushed for TRIPS, while Mexico and Canada were able to draw the support of developing and smaller emerging countries (p. 28).

In Mossinghof's view, the NAFTA precedent was instrumental in moving the US proposal for a high standard of IP protection in TRIPS forward.

When the final TRIPS text was agreed upon in 1994, it became the most binding global IP regime in history (Abdelgafar, 2006). Under

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[51] For summary information detailing the IP provisions of NAFTA see Smith (1997a). For detailed information of the IP provisions of NAFTA see OAS (2007).

[52] The PhRMA is the trade association representing the collective interests of brand name pharmaceutical companies in the US (equivalent of PMAC in Canada, although most members of PMAC are subsidiaries of members in PhRMA)

TRIPS, member nations were required to provide national treatment[53] and most-favoured nation[54] (MFN) status to the nationals of all member states. Furthermore, TRIPS mandated the harmonization of the domestic IP policies for member countries to a new minimum standard, roughly in line with US norms (Abdelgafar, 2006). Process and product patents for pharmaceuticals had to be issued for no less than 20 years from the time a patent was filed, and compulsory licensing—a tool used by several countries to provide their populations with affordable medicines—was severely curtailed in theory and nearly impossible in practice. Finally, a dispute-resolution framework was put in to place to deal with disagreements that could not be solved bilaterally, in which countries could retaliate against one another in any sector covered by the WTO. This particular provision was especially threatening for vulnerable "lesser-developed countries" (Abdelgafar, 2006).

Bill C-91 – The Elimination of Compulsory Licensing

In June 1992, the Mulroney government moved to further increase domestic patent protection by introducing Bill C-91, the *Patent Act Amendment Act* (Harrison, 2004). The justification for the introduction of Bill C-91 was to ensure that Canada complied with its international IP obligations,[55] although

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[53] In international trade terms, national treatment is basically equal treatment for the products and services of foreign companies and domestic companies.
[54] In international trade terms, MFN is essentially equal treatment for the products and services for all foreign companies regardless of their country of origin.
[55] Canada's new international obligations referred to the IP provisions of NAFTA and TRIPS.

ulterior motives—considered below—may provide a more plausible explanation (Campbell & Pal, 1994). Bill C-91 amended the *Patent Act* by eliminating compulsory licensing, approving limited exceptions to patent infringement and establishing a framework for Cabinet to create regulations to govern the entry of generic drugs onto the market (Smith, 1993). Furthermore, in an effort to allay fears regarding the Bill's impact on drug prices, Bill C-91 provided the PMPRB with "greater powers" to monitor drug prices and enforce its pricing standards (Ogilvy Renault LLP, 2002).

Arguably its most significant amendment, Bill C-91 eliminated the practice of compulsory licensing for pharmaceuticals. Recall that prior to the enactment of Bill C-91, compulsory licensing—although limited—was available under a system of "deferred compulsory licensing". Under Bill C-91, brand name drugs would enjoy complete market exclusivity from the time regulators approved the drug for sale, up to the end of the patent period (Campbell & Pal, 1994). Without worry of competition from generic companies, the only limitation on the prices of new patented medicines would be the enforcement of pricing guidelines by the PMPRB (Campbell & Pal, 1994). At the time Bill C-91 was introduced, Canada's compulsory licensing regime was considered rather exceptional among comparable, industrialized countries (Campbell & Pal, 1994).

Bill C-91 also created two specific exceptions to patent infringement permitting generic companies to legally manufacture patented medicines before

a patent had expired. Known as the Bolar Provisions,[56] these two exceptions included an "early working" provision and a "stockpiling" provision (Smith, 1997b). The early working exception stipulated that a generic company could manufacture and use a patented product to obtain regulatory approval for a generic drug. The stockpiling exception specified that generic companies could—beginning six months prior to the expiration of the pertinent patent—manufacture and store a generic drug it was planning to bring to market (Smith, 1997b).

Both of these exceptions were intended to confer an advantage to generic companies[57] by providing them with an opportunity to gain regulatory approval and manufacture product before a patent had expired. Without these exceptions, generic companies would have been required to wait an additional five to seven years after the expiration of a patent, before they would have been able to gain regulatory approval and manufacture product. As a result of the Bolar Provisions, generic companies could be ready to market their products the day after a patent had expired (Canada, 1997d).

Also included in Bill C-91 was a provision authorizing Cabinet to establish new regulations to govern the approval of generic drugs. Under this authority, the Government established the Patented Medicine (Notice of Compliance) Regulations. According to the Government at that time, these Regulations were

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[56] The label "Bolar Provisions" comes from the landmark patent infringement case involving Bolar Pharmaceuticals. This case eventually led to the US Congress passing the Hatch-Waxman Act which included a provision for an early working exception (Ashurst, 2005).

[57] The Bolar Provisions were also beneficial to consumers and provincial health ministries as they brought down the costs of prescription drugs by introducing competition to the market sooner.

necessary to prevent generic companies from engaging in patent infringement (Ogilvy Renault LLP, 2002).

The Notice of Compliance Regulations—or Linkage Regulations, as they are usually referred—were introduced at the request of the brand name industry without consulting other stakeholders; in particular, the generic industry (Canada, 1997d). The brand name industry maintained that the Linkage Regulations were an essential countermeasure to the new Bolar Provisions, which had increased the likelihood of patent infringement on the part of generic companies (Ogilvy Renault LLP, 2002). The brand name industry argued that US-style injunctive relief[58] was not readily available in the Canadian court system to deal with infringement cases and that the Canadian standard of awarding monetary damages was insufficient to address their fundamental market concerns. They maintained that the Linkage Regulations were an appropriate substitute measure that could supply the brand name companies with the injunctive power that the courts refused to provide[59] (Canada, 1997f).

Under the Linkage framework, generic companies could not receive regulatory approval[60] without first notifying the appropriate brand name company that they intended to copy and manufacture its product; within the Regulations,

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[58] Basically, in the pharmaceutical industry, an interlocutory injunction is a court order preventing a generic company from marketing a product.

[59] The justification for the Linkage Regulations stemmed from differences between Canada and the US with respect to the availability of interlocutory injunctive relief. The US had an entire court dedicated to litigation around patent law, which gave companies greater access to an interlocutory injunction. On the other hand, Canada lacked a comparable patent court and had no tradition of extensive interlocutory provisions. By convention, Canada granted injunctive relief only in cases where the losses were deemed unquantifiable. In Canada, issues of patent infringement arising from the pharmaceutical industry had normally been interpreted as 'quantifiable' by the Canadian court system, whereby the losses incurred by the brand name company as a result of patent infringement could be estimated and then awarded by looking at the resultant sales of the generic company (T. Macerollo, interview, July 17, 2008).

[60] In Canada, regulatory approval is granted by the issuance of a notice of compliance (NOC), which basically certifies that a drug had passed the necessary safety and efficacy tests.

this particular action is called a notice of allegation (NOA). Essentially, the NOA was a legal claim on behalf of the generic company declaring that there were no active patents connected to the particular product they intended to copy. After being served an NOA, brand name companies could then exercise their right under the Linkage framework to block the regulatory approval of that generic drug, simply by alleging that the generic company was infringing one of its patents listed on the Minister of National Health and Welfare's (now the Minister of Health's) patent list.[61]

Interestingly, in making an allegation of patent infringement, brand name companies were under no legal obligation to provide evidence in support of the charge. Moreover, the automatic stay—or injunction—imposed on the approval of a generic product as a result of an allegation of infringement would remain active for a maximum of 30 months, unless the matter was settled privately by the parties or through the courts (Smith, 1997b). While the brand name industry maintained that the Linkage framework was essential to protecting their patents from infringement, critics have charged that the system has resulted in a de facto extra 30 months of patent protection for brand name drugs—a boon in the case of "blockbuster drugs"[62] (Canada, 1997d).

Although the overall mandate of the PMPRB was left unchanged by Bill C-91, the legislation did alter its powers to deal with brand name companies charged with violating price guidelines. While Bill C-22 had provided the Board with the authority to issue compulsory licenses when brand name companies had

[61] The "linking" of the patent list to regulatory approval is where the label Linkage Regulations derives from.

[62] A blockbuster drug is one that generates annual revenues of over $1 billion (Angell, 2004b).

refused to comply with its directives, Bill C-91's abolition of compulsory licensing eliminated this option. Consequently, Bill C-91 provided the Board with new remedial powers to assist it in controlling prices and offsetting revenue gains owing to excessive prices. These powers included the authority to:

1. Order patentees to further reduce prices (below what the Board considered reasonable) for a set period of time;
2. Order patentees to reduce the price of another patented product other than the product being priced excessively;
3. Order patentees to pay a fine directly to the Government, up to twice the amount of revenue generated by the excessive price.

Furthermore, failure to comply with the reporting requirements of the Board or the above orders was punishable by (corporate) fine as well as individual imprisonment (Smith, 1995; Mills, 2001).

The politics surrounding Bill C-91 were quite different from what the Mulroney government had faced with Bill C-22, when the concept of globalization was just beginning to emerge and the importance of attracting foreign investment had yet to take hold. When Bill C-91 was introduced in 1992, trade agreements had become commonplace, the imperative for attracting investment was the norm and the buzz of "globalization" dominated economic discourse. Consequently, in the new globalizing economy, the Mulroney government was able to point to Canada's impending trade obligations—which would ensue from NAFTA and TRIPS—as justification for the elimination of compulsory licensing through Bill C-91.

While the LPC opposed Bill C-91, its opposition was tempered relative to its stance regarding Bill C-22. This change was likely informed by the inevitability of the Bill's passage—owing to Mulroney's majority—and concern for alienating Quebec voters[63] in the upcoming election. During the Bill C-91 debates, opposition from Liberal MPs was measured.[64] In fact, it has been reported that throughout the Bill C-91 debates, Chrétien never spoke to the issue of drug patents during Question Period (Campbell & Pal, 1994).

In addition to Canada's international commitments, the Mulroney government pointed to the pharmaceutical investment that would be attracted by Bill C-91. The notion that increased patent protection induces higher levels of pharmaceutical R&D is known as "patent theory". Contrary to the Mulroney government's assertions, there is little evidence to support patent theory (Abdelgafar, 2006). When applied to the global pharmaceutical industry in particular, available evidence suggests that patent theory is flawed, as multinational pharmaceutical companies prefer to carry out basic R&D in their home country regardless of the geographical distribution of patent protection.[65]

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[63] Much like Bill C-22, Bill C-91 was seen as a prospective boost to the Quebec economy.

[64] One exception was the Liberal health critic, Ron MacDonald. Chrétien and the Party leadership had a difficult time reigning in MacDonald who was vocal during the debates around Bill C-91. In fact, MacDonald was probably the person most responsible for getting the statutory four-year review included into its final version (T. Macerollo, interview, July 17, 2008).

[65] The pattern is the result of the distribution of the costs of producing prescription drugs, a process that can basically be separated into two stages: (1) the discovery and synthesis of new chemical entities and, (2) safety and efficacy testing for regulatory approval followed by the production (mixing of chemicals), marketing and distribution of the final product. Generally speaking, the first stage requires large financial investments and a high degree of skill and expertise. To take advantage of economies of scale and to ensure greater external and internal control of the research process, companies prefer to concentrate research from this first stage in a centralized location, usually the country where their headquarters is located (e.g. United States, Switzerland and Germany). On the other hand, production in the second stage requires far less R&D and can be decentralized to local markets, while the safety and efficacy testing required for domestic regulatory approval must be carried out in the respective country where market approval is being sought (Atkinson & Coleman, 1989).

This had been the conclusion drawn earlier by the Eastman Commission, to justify its opinion that Canada was not well placed to become a leader in pharmaceutical R&D (Canada, 1985).

Nevertheless, the Mulroney government still pointed to increased investment and employment following the passage of Bill C-22 as evidence in support of patent theory and their decision to introduce Bill C-91. While conceding that investment and employment did rise following Bill C-22, critics argued that these increases were more likely the result of Canada's share of the general expansion experienced by the global pharmaceutical industry during that period (Lexchin, 2005). This conclusion was also supported by internal Government studies leading up to Bill C-91. Certainly, the Mulroney government would have been apprised of the findings of the Eastman Commission and its own studies in deciding whether to proceed with Bill C-91.

In response to the claim that the timing of Bill C-91 related to Canada's new obligations under NAFTA and TRIPS, there are discrepancies. At the time Bill C-91 was introduced to Parliament, it was far from certain that either agreement—NAFTA or TRIPS—would be ratified by the necessary bodies, or that the high standards in the IP sections would remain in the final texts.[66] Consequently, the international IP obligations used to justify Bill C-91 were, up to that point, non-existent. Indeed, this irregularity was the one of the issues

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[66] NAFTA had yet to be ratified by the US Congress, and there were indications that Congress was leaning towards rejecting it. Furthermore, the Chrétien Liberals were generally opposed to NAFTA, and eventually campaigned on repealing it, or at least amending it. With regard to TRIPS, a final text was still years away from being completed. The TRIPS basis for Bill C-91 was a draft agreement called the Dunkel Text. Furthermore, there was no guarantee that the Canadian Parliament would ratify the WTO agreement in the event that it was ever completed.

focused on by the Liberal opposition at the time (T. Macerollo, interview, July 17, 2008). The inaccuracies of the Mulroney government's claims suggest that there might be alternative justifications for the Bill's timing.

One reason for introducing Bill C-91 prior to the ratification of NAFTA and TRIPS could be that the Mulroney government had been set on increasing patent protection regardless of Canada's international obligations. If this were true, then Mulroney could have been using these agreements as an economic pretext for a political decision to strengthen Canadian patent laws. If that were the case, then it was important to introduce Bill C-91—or a bill like it—before the NAFTA and TRIPS processes concluded, to avoid the possibility of changes to the agreements or the agreements not coming to fruition.

A second reason might have been the financial benefit that this decision accrued to the brand name industry. The Mulroney government brought Bill C-91 into force retroactively to the date that Canada had agreed to the Dunkel Text, a full year before Bill C-91 actually came into law[67] (Robinson, 2001). This action had the effect of canceling several compulsory licenses issued between December 1991 and January 1993, as well as all applications being processed at that time[68] (Canada, 1997d). Bringing Bill C-91 into force as of late 1991 provided an extra two years of patent protection prior to the ratification of NAFTA[69] and three years prior to the ratification of the WTO and TRIPS.[70]

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[67] The Dunkel Text was signed on December 20, 1991 and Bill C-91 became law on February 4, 1993.

[68] Apotex—the largest Canadian generic company—claims that the December 20, 1991 date was specifically selected by the Government to block them from continuing with a compulsory license they had received on December 21 for their generic version of Merck Frosst's profitable drug *enalapril* (Robinson, 2001; Jenish, 2003).

[69] NAFTA was ratified by the Canadian Parliament in June of 1993 (the day before Mulroney stepped down as leader) and by the US Congress and Senate in November of 1993.

Undoubtedly, the retroactive nature of the Bill was a costly development for the generic industry and a financial boon to the brand name industry.

A third reason may have been pressure from the US and its brand name drug industry to eliminate Canada's compulsory licensing regime because of the "damaging" model it provided to countries looking for ways to cut health costs (Duncan & Blaker, n.d., as cited in Campbell & Pal, 1994). Recent President-elect Bill Clinton had campaigned on health reforms (Diebel, 1993), inciting concern within the brand name industry that new radical drug policies—along the lines of compulsory licensing—might be implemented to deal with soaring US drug prices (Harrison, 2004; Campbell & Pal, 1994). Considering the size and importance of the US market, as well as its global role as a standard-setting economy, any form of compulsory licensing in the US would have been disastrous for the brand name pharmaceutical industry. Likewise, the existence of Canada's compulsory licensing regime could have only been harmful for the US strategy to include strong patent protection in TRIPS. Canada's decision to move forward with Bill C-91 in the midst of TRIPS negotiations eliminated this optics issue, while providing support to the US position on multilateral patent protection.

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[70] Parliament agreed to permit Canada to join the WTO in December of 1994.

CHAPTER 3 – The Review of Bill C-91

Introduction

This chapter analyzes events pertaining to the review of Bill C-91, which was carried out by the Standing Committee on Industry from February to April 1997. The analysis is organized into three sections covering the periods leading up to, during and shortly after the Industry Committee's public hearings. This chapter develops the thesis in two ways. First, it provides a thorough overview of the pertinent events and issues surrounding the review of Bill C-91. Second, it presents evidence in support of the main argument: the brand name industry's strategy to exploit the political environment in Quebec, the Government's concern with the impact of the industry's strategy, the rhetorical strategies employed by stakeholders to the review, the Government's ability to influence the review and the Government's policy response to the review.

During the1993 election campaign, some quarters—most importantly, the CDMA—believed that a Liberal government would revisit, and probably repeal, Bill C-91. Indeed, this would have been consistent with Liberal opposition to Bill C-22 and Bill C-91 (T. Macerollo, interview, July 17, 2008). However, once in power, the Liberals had to reckon with the difficult realities of pharmaceutical policy making in Canada, including international trade commitments, investment concerns and Quebec politics.

Weathering the Storm – 1993 to 1997

In October 1993, the Chrétien Liberals were elected with a majority government. Chrétien's first Cabinet included John Manley[71] as Minister of Industry and Diane Marleau[72] as Minister of Health. Both Industry Canada and Health Canada had an association with the *Patent Act*; Industry by virtue of its responsibility for IP and Health through its responsibility for the Linkage Regulations and the PMPRB (T. Macerollo, interview, July 17, 2008). Not long after coming to power, the Liberals were pressed to clarify their intentions regarding Bill C-91 and the *Patent Act*. While the generic companies favoured immediate repeal, the brand name industry sought the maintenance of the status quo. At a minimum, both desired some level of certainty on the issue (T. Macerollo, interview, July 17, 2008).

Aware of the controversy, the Government attempted to ignore Bill C-91 for as long as it could (T. Macerollo, interview, July 17, 2008). In the meantime, significant international developments placed limits on its room to manoeuvre with respect to patent protection. In December 1993, the US Congress and Senate ratified NAFTA, solidifying Canada's international commitment to the stronger patent protection outlined in Bill C-91[73] (Vienneau, 1993). Shortly thereafter, the Liberal government agreed to join the newly formed WTO, thereby accepting the provisions for global patent protection contained within the accompanying TRIPS agreement[74] ("Trade deal", 1994). If anything, these

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[71] Manley represented a riding in Ottawa and had practiced law before entering federal politics.
[72] Marleau represented a riding in Sudbury where she was mayor before entering federal politics.
[73] The Canadian Parliament had already ratified NAFTA in June of 1993.
[74] Canada's membership in the WTO would be later be ratified by Parliament in December 1994.

agreements placed political—if not legal—limits on the kinds of changes that would be feasible under a review Bill C-91. Both NAFTA and TRIPS mandated 20-year patent periods and both appeared inflexible with regard to the circumstances upon which compulsory licenses could be issued (Abdelgafar, 2006).

Despite mounting pressure from both pharmaceutical sectors, the Liberal government was able to conceal its intentions with regard to the nature and timing of a review of Bill C-91 for a short period.[75] By keeping this information secret, the Government was attempting to shield itself from the political fallout from a decision, while trying to extract further investments from PMAC members (T. Macerollo, interview, July 17, 2008). Finally, in April 1994, Manley announced that the Bill would be reviewed (McCarthy, 1994). Days later, the brand name industry threatened to cancel pending investments in the Montréal area. Testifying to a parliamentary committee for the Quebec National Assembly, Quebec's Minister of Industry and Commerce, Gerald Tremblay,[76] disclosed that a representative of a brand name company had warned him that the imminent review of Bill C-91 would lead to the postponement of a local investment project valued at $50 million (T. Macerollo, interview, July 17, 2008). By threatening to halt such a lucrative investment, the brand name industry reminded the Liberals—and Quebeckers—of the potential economic and political costs surrounding pharmaceutical patent decisions. Under pressure from the

[75] There was a lot of discussion in Government about what sort of process might constitute a review (T. Macerollo, interview, July 17, 2008).
[76] Tremblay was a member of the Quebec Liberal Party.

Parti Québécois (PQ),[77] Tremblay accused his federal counterparts of "creating economic instability" by planning to carry out a review of Bill C-91 (McCarthy, 1994).

In addition to discord between federal and provincial Liberals, the federal government had to deal with bureaucratic divisions between Industry Canada and Health Canada. Industry Canada was concerned with maintaining an attractive investment climate through the provision of strong patent protection. Industry understood that there was a direct political connection between investment and patent protection; only jurisdictions that provided strong patent protection were rewarded with valuable investments (T. Macerollo, interview, August 22, 2008).

Health Canada opposed Bill C-91 for three reasons. First, Health felt that patents were strictly an industrial issue and its administration of the *Patent Act* through the Linkage Regulations was inappropriate and burdensome. Second, Health had to deal with pressure from the provinces, which called on the federal government to take measures to decrease provincial health costs, of which drugs made up a significant portion. Third, as the department responsible for the health and wellbeing of Canadians, Health possessed an interest in decreasing the costs of prescription drugs (T. Macerollo, interview, August 22, 2008).

Aware of these bureaucratic divisions and the importance of the issue to Quebec's life sciences community, the BQ—the Official Opposition at the time and strong supporters of the brand name industry—led the attack on the Chrétien

[77] The PQ was the Official Opposition in the Quebec National Assembly at that time. The PQ were strong supporters of Bill C-91and the brand name pharmaceutical industry in general (T. Macerollo, interview, July 17, 2008).

government (Canada, Parliament, House of Commons, 1994c). Manley responded to the Bloc's challenge by assuming the position of chief spokesperson for the Government, often intercepting questions aimed at his fellow Ministers—in particular Marleau—regarding patent protection and the pharmaceutical industry. In this way, Manley was able to use his political skills to present a united Government position on Bill C-91 (Canada, Parliament, House of Commons, 1994a). This position was that the Government intended to carry out a review sometime within the statutory four-year period; however, it was still undecided as to how soon that would be.[78] Under pressure from the PMO, Manley eventually announced that a review would not result in reopening of the *Patent Act* and that the outcome of the review process would not deter Canada from honouring all of its international commitments[79] (T. Macerollo, interview, July 17, 2008). This last point was reinforced when the Minister of Foreign Affairs[80] informed the press that significant changes to the *Patent Act* would be almost impossible due to the restrictions of NAFTA and TRIPS (Sanger, 1994). These comments suggested to the interested parties that the Liberals intended to limit the nature of the changes emanating from a review.

The Joint Committee on the Scrutiny of Regulations is a committee charged with vetting regulations created by Cabinet. The Joint Committee serves to counterbalance the power of Cabinet to construct and impose regulations; a process that falls outside of the regular scrutiny of the legislative

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[78] The Government hinted that the timing of the review might be influenced by PMAC's ability to live up to its previous investment commitments (Canada, Parliament, House of Commons, 1994b).
[79] Not opening up the *Patent Act* and honouring "international commitments" were basically code for declaring that the 20-year patent period would not be modified.
[80] Andre Ouellet was the Minister of Foreign Affairs at this time.

process (T. Macerollo, interview, July 17, 2008). The Linkage Regulations were brought before the Joint Committee in October of 1994, where some MPs argued that they were unfair and should be struck down. While the original debate was framed to limit a discussion of the Regulations to the fairness of its retroactivity clause, a group of members opposed to the Regulations were successful in expanding the examination to include consideration of outright repeal (Canada. Parliament. Senate / House of Commons. Joint Committee for the Scrutiny of Regulations, 1994).

Opponents argued that the Regulations had been brought into effect without proper consultation, placing generic companies at an unfair disadvantage. Moreover, opponents argued that the Canadian court system along with the *Patent Act* was sufficient to deal with cases of alleged patent infringement. When brought to a vote, the opponents were narrowly defeated.[81] (Canada. Parliament. Senate / House of Commons. Joint Committee for the Scrutiny of Regulations, 1994).

After the Joint Committee's decision, pharmaceutical patents took a back seat to more pressing parliamentary issues (i.e. the 1995 Quebec Referendum) until February 1997, when the review of Bill C-91 was set to begin. Leading up to the review, the LPC caucus was divided over the Bill and there was little hope that the presentation of new information in the course of a review would change

[81] Opponents of the Regulations were defeated 4-3. Among those opponents of the Linkage Regulations on the Joint Committee were Dan McTeague and Tom Wappel; both Liberal MPs representing Toronto, and Ted White, a Reform MP representing Vancouver. Against repealing the regulations were Phillip Derek Lewis, a Liberal Senator representing Newfoundland and Labrador; Derek Lee, a Liberal MP representing Toronto; Gilbert Fillion, a BQ MP representing Chicoutimi (standing in for Gaston Leroux, a BQ MP representing Southeastern Quebec); and Peter Milliken, a Liberal MP representing Kingston (Canada. Parliament. Senate / House of Commons. Joint Committee for the Scrutiny of Regulations, 1994).

anybody's position (T. Macerollo, interview, July 17, 2008). On one side of the issue were a combination of MPs from Montréal and those supporting Industry's position on patent protection and Canada's international obligations. On the other side were MPs—many from Toronto—expressing concern about the impact of Bill C-91 on health costs and access to medicines.

Support for the brand name industry's position by Montréal MPs can be connected primarily to regional economic concerns, and to a lesser extent, campaign contributions. With a concentration of brand name companies in the Montréal area, Montréal Liberals had a significant stake in the local pharmaceutical industry and the related life sciences sector. An outcome favourable to the brand name industry might be rewarded with new investment in the region, while a decrease in patent protection might lead to the cancellation of planned investments—as it had been threatened to Tremblay (see pg. 59)—and fewer investments in the future. The economic impact of such retaliatory action might have damaged the electoral prospects of Montréal Liberal candidates.

While few Montréal Liberal candidates received large contributions from the brand name industry for the 1993 election campaign (see Table 3.1), the prospect of future contributions might have played a role in their support for the then-current policy. In fact, campaign contributions to Montréal Liberal candidates did increase significantly for the 1997 election campaign. While Nick Discepola had been the only Montréal Liberal candidate to receive significant support ($2,300) from the brand name industry in 1993, several—including Bernard Patry ($9,200), Paul Martin, ($5,500), Discepola ($2,700), Lucienne

Robillard ($1,500) and Clifford Lincoln ($1,500)—received large contributions in 1997[82] (see Table 3.2). The brand name industry's political donations during the 1997 election are considered in greater detail in Chapter 4.

Table 3.1 – Liberal Candidates Receiving Political Donations in Excess of $500 from the Brand Name Industry during the 1993 Election Campaign.

Candidate	Riding	Area	Amount
Nick Discepola	Vaudreuil	Montréal	$2,300
Jag Bhaduria	Markham – Whitchurch - Stouffville	Toronto	$1,000
Clifford Lincoln	Lachine – Lac-Saint-Louis	Montréal	$800
Roy MacLaren	Etobicoke North	Toronto	$800

Source: Elections Canada.

Table 3.2 – Liberal Candidates Receiving Political Donations in Excess of $500 from the Brand Name Industry during the 1997 Election Campaign.

Candidate	Riding	General Area	Amount
Bernard Patry	Pierrefonds – Dollards	Montreal	$9,200
Carolyn Parrish	Mississauga West	Toronto	$5,600
Paul Martin	LaSalle – Émard	Montreal	$5,500
Nick Discepola	Vaudreuil	Montreal	$2,700
Marcel Massé	Hull – Aylmer	Gatineau	$1,936
Lucienne Robillard	Westmount – Ville-Marie	Montreal	$1,500
Clifford Lincoln	Lachine – Lac-Saint-Louis	Montreal	$1,500
Jim Peterson	Willowdale	Toronto	$1,200
Martin Cauchon	Outremont	Montreal	$1,068
Paddy Torsney	Burlington	Toronto	$1,000
Pierre Pettigrew	Papineau – St. Denis	Montreal	$700
Ian Murray	Lanark – Carleton	Ottawa	$700

Source: Elections Canada.

Support for the generic industry's position by Toronto Liberal candidates appears to have been related to campaign contributions rather than local riding

[82] For the purposes of the analysis regarding campaign financing to candidates in both 1993 and 1997, campaign support in excess of $500 from a respective industry was considered large.

concerns. While the concentration of generic firms in the Toronto area might suggest that support from Toronto Liberals was linked to economic development, this wasn't the case. There were also a large number of brand name firms located in the Toronto area, whose local economic impact was greater than that of the generic industry (T. Macerollo, interview, July 17, 2008).

The generic industry provided large contributions to several Toronto MPs, including Volpe ($1,961), Art Eggleton ($1,000), Barry Campbell ($1,000), Maurizio Bevilacqua ($1,000) and Jim Peterson ($750) (see Table 3.3). Targeting these MPs may have reflected personal ties[83] or perhaps the perceived standing of Toronto Liberals within the Party structure. Another reason might be the impression created by Toronto candidates during the campaign, that a Liberal government would repeal Bill C-91 (T. Macerollo, interview, July 17, 2008).

Table 3.3 – Liberal Candidates Receiving Political Donations in Excess of $500 from the Generic Industry during the 1993 Election Campaign

Candidate	Riding	Area	Amount
Herb Gray	Windsor West	Windsor	$5,000
Lloyd Axeworthy	Winnipeg South Centre	Winnipeg	$3,000
Ron MacDonald	Dartmouth	Nova Scotia	$2,500
Reg Alcock	Winnipeg South	Winnipeg	$2,000
Joe Volpe	Eglinton –Lawrence	Toronto	$1,961
David Walker	Winnipeg North Centre	Winnipeg	$1,500
Andre Ouellet	Papineau – St-Michel	Montréal	$1,000
Art Eggleton	York Centre	Toronto	$1,000
Barry Campbell	St. Paul's	Toronto	$1,000
Maurizio Bevilacqua	York North	Toronto	$1,000
Paul Martin	LaSalle – Emard	Montréal	$750
Jim Peterson	Willowdale	Toronto	$750

Source: Elections Canada.

[83] The CEO of Apotex, Barry Sherman, was very close to many of the Toronto Liberals (T. Macerollo, interview, July 17, 2008).

In addition to Toronto candidates, the generic industry targeted other Liberals who were either influential within the LPC or running in areas where generic manufacturing facilities were located. For instance, Winnipeg was the site of an Apotex fermentation plant, which might account for contributions to Lloyd Axeworthy ($3,000), Reg Alcock ($2,000) and Walker ($1,500). Other Liberal candidates receiving significant contributions from the generic industry were Herb Gray ($5,000) and Ron MacDonald ($2,500). Gray was a longtime Liberal and former Cabinet minister with personal ties to individuals in the generic industry (T. Macerollo, interview, July 17, 2008). As the Liberal health critic in opposition, MacDonald had been a vocal opponent of Bill C-91 and was largely responsible for the addition of the clause mandating the four-year review (T. Macerollo, interview, July 17, 2008).

Despite a smaller pool of financial resources to draw from, the generic industry appears to have provided more financial support to individual Liberal candidates than the brand name industry for the 1993 election campaign[84] (see Table 3.1 and Table 3.3). The brand name industry might have targeted PC candidates, considering their momentum at the beginning of the campaign and their strong support for patent protection. This was, however, not the case, as PC candidates received fewer total donations from the brand name industry, as well as fewer large donations (Elections Canada, 2008a). A more suitable explanation might be that the generic industry hoped that a Liberal government would consider repealing Bill C-91 and so it donated all it could to gain influence with individual Liberal candidates.

[84] Here, large contributions (greater than $500) are used as a proxy for financial support.

More important perhaps than contributions to individual Liberal candidates, were donations to the Party itself. During Chrétien's first term, the brand name industry was a major contributor to the LPC. While the generic industry donated more to the LPC in 1993 (similar to the contribution profiles for individual candidates), the brand name industry's contributions were significantly greater in the years that followed (see Table 3.4). In 1996—the year leading up to the review—the brand name industry donated approximately $116,000 to the LPC, while the generic industry contributed approximately $38,000.[85] One explanation for the increase in support from the brand name industry is that it was trying to influence the Government's decision regarding the review.

Table 3.4 – Total of Single Contributions in Excess of $900 from Pharmaceutical Industries to the LPC for 1993 to 1997.

Year	Generic Contributions	Brand Name Contributions
1993	$89,144	$63,416
1994	$18,523	$64,150
1995	$21,548	$24,115
1996	$38,246	$116,305
1997	$64,887	$114,843

Source: Elections Canada.

Prior to the review, the Government came to a decision regarding which aspects of its pharmaceutical patent policy it would consider modifying. According to Macerollo, the Government decided it would not modify the 20-year patent period outlined in the *Patent Act*, but would only consider the Linkage Regulations:

[85] All of these contribution totals to the LPC are estimates, which only include company donations in excess of $900.

> At that point we had pretty much confirmed amongst ourselves (Cabinet) that we weren't going to open up the Act; we now had [international] obligations that we had to fulfill. Cabinet ministers concluded at the time that the issue was with the Linkage Regulations and not with the Act itself (T. Macerollo, interview, July 17, 2008).

The fact that the Government decided months prior to the review to limit its policy solutions—regardless of what information came to light during the hearings—emphasizes the political nature of the process.

After determining the parameters of the review, the issue of organizing and managing the review process still needed to be addressed. Since both Industry Canada and Health Canada were linked to the *Patent Act*, a decision had to be made as to which department's committee would lead the review. The decision in favour of the Standing Committee on Industry reflected a partial victory for the brand name pharmaceutical sector ("Getting a pole position", 1997). Indeed, with Manley and Industry leading the way, the Government could be more confident that the review would unfold in a manner that didn't pose a significant threat to its preferred policy direction.

While it was important for the Government to have Industry leading the review, it was not politically feasible to exclude Health or other opponents of Bill C-91 all together. Accordingly, Manley directed Walker—appointed Chair of the Industry Committee—to modify the Committee's membership to include members from the Standing Committee on Health, as well as others;[86] in order to

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[86] A notable addition to the Industry Committee was Toronto Liberal MP, Joe Volpe. In addition to being the parliamentary secretary (PS) for Health, Volpe had received financial donations from generic companies and was a strong supporter of the generic industry. Another interesting addition was Carolyn Parrish (Mississauga), who ended up being an ardent supporter of the brand name industry's position

"accommodate both individual and political requirements, as well as to have some heavyweights there discussing the issues" (T. Macerollo, interview, July 17, 2008). With regard to the structure of the Committee, Macerollo described the Government's strategy to maintain Party unity as follows:

> The design of the Committee was astute to ensure that the political constituencies felt that they were getting represented through their advocates on the Committee. Part of the parliamentary process requires that alienated constituents get an airing; they don't necessarily get their way, but they have to *believe* that they've had an airing; and that's particularly important when you've got a majority, or you'll push alienated MPs [...] into voting with an opposition party (T. Macerollo, interview, July 17, 2008, emphasis added).

In addition to these medium-term changes, the membership of the Committee was fluid and fluctuated from day-to-day during the review process (T. Macerollo, interview, July 17, 2008).

The Standing Committee on Industry Hearings

Televised hearings of the review of Bill C-91 took place over the course of two months beginning on February 17, 1997. Walker recalled the tense atmosphere leading up to the hearings and the cut-throat politics they entailed:

> Nobody was particularly looking forward to this review, including myself. It came at a very intense period in my personal life and I could recall the early battles over patent legislation from when I was an opposition MP. It was a tremendously pressure-filled situation, one with very little protection [unlike my recent experiences working in Finance]; this was like really being out there. People would say and do things; they would go to great lengths to discredit one another. It was one of the only times in my life where I felt my

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during the hearings; a stance that she was rewarded for in campaign contributions for the following election.

> political reputation was really at stake (D. Walker, interview, July 23, 2008).

The ability to construct the Committee and interact with Liberal members helped the Government to address the intra-party politics surrounding the review. For his part, Manley cultivated personal rapport with the Liberal Committee members on both sides of the issue. He regularly invited them for supper to discuss the issues and to get their opinions. Manley and his staff attempted to pressure uncooperative Liberal members by reminding them of the impact of the Committee's decisions on the broader political fortunes of the Party and their own political ambitions[87] (T. Macerollo, interview, July 17, 2008).

The structure of the Committee also influenced the balance of questioning from members on both sides of the issue. Despite the addition to the Committee of Liberal MPs opposed to Bill C-91, those in support—including BQ and Reform MPs—still made up a sizable majority. During federal committee hearings, the time permitted to question witnesses was allocated by member—five minutes per witness.[88] By virtue of their decided majority, the group supporting Bill C-91 was clearly overrepresented in the questioning of witnesses, which impacted the direction of the hearings and the overall tone of the testimony.

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[87] Here, Manley would be referring to the LPC's popularity with Quebec voters; its reputation with big business; and its reputation with the international trading community. Manley advised them that any move to limit patent protection would be damaging on these fronts (T. Macerollo, interview, July 17, 2008).

[88] In general, the federal committee process was not conducive to providing MPs with a fair opportunity to explore issues. Due to the sheer size of committees, as well as the many issues that each was responsible for, it was impractical to provide each member an adequate amount of time to question witnesses. In the case of Bill C-91, five minutes was not nearly long enough for members to adequately pursue the complicated topics at issue (J. Solomon, interview, August 1, 2008).

In total, the Committee heard testimony from over 140 witnesses, representing dozens of interests and backgrounds.[89] This section summarizes the testimony and the positions taken by the following key stakeholders:

- Industry Canada
- Health Canada
- The PMPRB
- The CHC
- PMAC
- The CDMA
- IBAC
- Provincial health ministries (from BC, Manitoba and Saskatchewan)

The primary issues covered during the hearings include the following:

- The retroactivity of Bill C-91
- The Bolar Provisions (early-working and stockpiling exceptions)
- The Linkage Regulations
- Patented medicine price regulation
- Patent term restoration (PTR)
- Pharmaceutical R&D investments
- Exporting restrictions on drugs patented in Canada
- Pharmaceutical research in Canada
- Appearance of generic drugs
- Compulsory licensing and a national pharmacare program

The remainder of this section is organized around these preceding issues, and includes the perspectives of each of the stakeholders—where applicable—as well as particular questions raised by Committee members.

Retroactivity of Bill C-91

When Bill C-91 was passed in February 1993, it included provisions to amend the *Patent Act*. The Government brought these amendments into force

[89] Witnesses included, among others, pharmaceutical companies and trade associations, insurance companies, health advocacy groups, business councils, federal and provincial health ministries, research organizations, and faith-based groups to name a few.

retroactively to December 21, 1991, the day following Canada's endorsement of the Dunkel Text. This move nullified active applications for compulsory licenses as well compulsory licenses granted after December 20, 1991 (Jenish, 2003). Essentially, the impact of retroactivity was a significant delay in the regulatory approval of additional generic products.

The CDMA called on the Committee to reverse the retroactivity of Bill C-91 and argued that its members should be permitted to market affected products (Canada, 1997d). It testified that the retroactivity of Bill C-91 was clearly punitive, as it did not give consideration to the significant investments already made with the understanding that the former regime would remain in place.[90] Moreover, the CDMA argued that retroactivity amounted to a financial windfall for brand name companies at the expense of generic companies, the provinces and especially the public, all of whom would end up bearing the increased costs associated with limited competition.[91] The CDMA maintained that both NAFTA and TRIPS were ambiguous with regard to the date when compulsory licenses had to be eliminated and that the Mulroney government had been under no obligation to bring the Act into force retroactively. In essence, the CDMA charged that the decision to make Bill C-91 retroactive was motivated by political, rather than legal, interests.

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[90] This included investments that had gone into thirty-six products for which compulsory licenses had already been granted, as well as the work that had been done on dozens of products for which license applications had been submitted to Industry Canada (Canada, 1997d).

[91] The CDMA cited a study by Stephen Schondelmeyer (pharmacoeconomics professor at Queen's University) which stated that the retroactivity of Bill C-91 had resulted in sales gains of $750 million for brand name companies while costing the Canadian health care system an additional $198 million, and the generic industry sales losses of $552 million (Canada, 1997d).

The Bolar Provisions – Exceptions to Patent Infringement

There were several concerns at issue regarding the Bolar Provisions, including the extent to which they increased the risk of patent infringement, their acceptability in light of international IP standards, whether they served the public interest, and ultimately, whether or not they should be maintained.

Not surprisingly, the CDMA argued strongly that the Bolar Provisions should be preserved, as they ensured that generic products were ready to sell immediately after the expiration of a patent. According to the CDMA, the absence of the Bolar Provisions would provide brand name companies with an extra five to seven years of market exclusivity, owing to the additional time generic companies would spend dealing with regulatory and manufacturing processes following the expiration of a patent (Canada, 1997d). The CDMA stressed that the elimination of the Bolar Provisions would be costly for Canadians, who benefited from cheaper drugs becoming available more quickly. The CDMA also pointed out that the elimination of the Bolar Provisions would hurt the international competitiveness of the Canadian generic industry, which might compel some companies to move their research facilities out of the country. Despite claims made by the Government and PMAC, the CDMA denied any knowledge of a plausible link between the Bolar Provisions and the risk of patent infringement (Canada, 1997d).

In contrast, PMAC argued that the Bolar Provisions needed to be eliminated because they were a veiled form of patent infringement (Canada, 1997f). According to PMAC, by allowing generic manufacturers to bring products

straight to market after a patent had expired, the Government had created a significant gap between Canada and other developed nations with regard to "effective patent protection". PMAC maintained that Canada's use of the stockpiling provision was unique within international pharmaceutical regulation and that only one other country[92] provided an early working exception (Canada, 1997f).

The Linkage Regulations

Undoubtedly, the most contentious change brought about by Bill C-91 was the implementation of the Linkage Regulations, which had the effect of increasing patent terms by providing brand name companies with a tool to delay the entry of generic drugs onto the market (Canada, 1997d). The primary issues discussed at the hearings with regard to the Linkage framework were the manner in which the Regulations were implemented; the financial impact of the Regulations on various stakeholders; the suitability and effectiveness of the Regulations; exploitation of the Regulations on behalf of PMAC members; whether or not the Regulations should be repealed or modified; and whether or not the provisions of the Regulations should be included directly into the *Patent Act*.

Both Manley and Dingwall were interested to hear what the Committee had to say about the Linkage Regulations. Manley told the Committee that the Regulations had been devised as a counterbalance to the Bolar Provisions

[92] This other country was the US. This is interesting considering that the US was headquarters for many of the brand name companies and was considered by many as having some of the toughest patent laws in the world (Canada, 1997f).

which, in his opinion, had increased the risk of patent infringement.[93] Nevertheless, Manley was aware of the extra litigation brought about by the Regulations and was apprised of the possibility that brand name companies had been exploiting them to keep generic products off the market (Canada, 1997a).

Dingwall was more enthusiastic about changes to the Regulations and the Committee's forthcoming recommendations on the subject. He stressed his unease with the lack of effective consultation (with the generic industry) regarding the Regulations and the secrecy surrounding their implementation. In acknowledging the argument that the Regulations provided a de facto 30-month injunction, he challenged the Committee to consider ways in which the Regulations could be modified to make them more effective and more amenable to all stakeholders (Canada, 1997b).

For its part, the CDMA argued forcefully that the Linkage Regulations had resulted in the abuse of patent protection while serving no purpose other than to extend the monopoly periods of brand name companies (Canada, 1997d). The CDMA maintained that the relief provided by the Regulations was unnecessary as the ordinary remedies of the Canadian court system were sufficient to prevent infringement. They argued that the financial risks involved in patent infringement were already sufficiently prohibitive, which made the ostensible justification for the Regulations redundant.[94] In their view, the Linkage framework introduced

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[93] There is no available evidence that the introduction of the Bolar Provisions increased the risk of patent infringement, calling into question the overall rationale for the implementation of the Linkage Regulations (Canada, 1997d; T. Macerollo, interview, July 17, 2008).

[94] If a case was eventually decided in favour of the patentee, the generic company would be enjoined, required to pay damages, forced to give up for destruction all of its remaining inventory of the product, and have to pay legal costs for itself as well as the patentee (Canada, 1997d).

new powers for patentees to bring suit to generic companies at any time and the ability to keep generic products off the market for an extra two and a half years (Canada, 1997d).

According to the CDMA, brand name companies systematically abused the Regulations. Because they could keep their competitors off the market for an additional 30 months—without even having to produce evidence at a hearing—brand name companies would take every opportunity to block a generic manufacturer from receiving an NOC (Canada, 1997d). The CDMA claimed that up until the time of the review, there had been over one hundred cases of brand name companies blocking generic companies from receiving an NOC. Moreover, the CDMA argued that the Regulations' targeting of pharmaceuticals was prejudicial to this particular field of technology, in ways that were inconsistent with the principles of NAFTA and TRIPS.[95]

According to the CDMA, brand name companies abused the Linkage Regulations in a number of ways, including: the listing of irrelevant patents;[96] the routine baseless initiation of applications for orders of prohibition against generic companies; the systematic delay of court proceedings to ensure that cases were never heard promptly; and the evergreening of monopoly periods by continually adding new patents to the Minister of Health's list[97] (Canada, 1997d). In support

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[95] This was ironic considering that the entire basis for eliminating compulsory licensing of pharmaceuticals was that such a system was exclusive to pharmaceuticals and therefore incompatible with NAFTA and TRIPS. These agreements stipulated that IP rights must be without prejudice to a particular field of technology (Canada, 1997d).

[96] Some of the irrelevant patents listed by the brand name companies as "patents for drugs" included patents for a compact disc storage container, a bicycle, a mobile crane, and a lens for a cathode ray tube (Canada, 1997d).

[97] There are a number of drug attributes that can be patented allowing brand name companies to stagger new patents so that they can continue to allege infringement as each injunction period elapses.

of their position on the Regulations, the CDMA demonstrated several examples of government officials and public servants who had disagreed with the Linkage framework. Among these were a former PC Minister of CCA Pierre Blais;[98] Health Canada officials[99] and a member of the Canadian judiciary[100] (Canada, 1997d).

According to Apotex—the largest company represented by the CDMA—the financial impact of the Regulations had been devastating for several reasons. First, the Regulations caused Apotex to be constantly tied up by legal proceedings resulting in millions of dollars of legal costs, all of which would not be reimbursed in the event of a favourable ruling.[101] Second, there was no revenue from the disputed products forcing Apotex to carry "hundreds of millions of dollars of investments" without any returns. These monies, Apotex argued, were desperately needed to assist them with the ongoing litigation and to invest in new opportunities and discoveries. Furthermore, because of the limited lifetime of pharmaceutical products resulting from innovation and imitation, these investments would be worth considerably less by the time the delayed products finally made it to market[102] (Canada, 1997d).

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[98] In a 1992 letter, Blais had informed the brand name company Burroughs Wellcome that there was no justification for something akin to the Linkage Regulations because Canada's legal remedies to patent infringement were sufficient. Strangely enough, it was only a few months later that the PC Government introduced the Linkage Regulations (Canada, 1997d).

[99] The CDMA had obtained an internal Health Canada study acquired by access to information, acknowledging that the Regulations were being abused by the brand name industry instead of working in the manner originally intended (Canada, 1997d).

[100] The CDMA brought to the attention of the Committee a recent judgment from the Federal Court in which the judge stated that the Linkage Regulations had been harnessed to protect the financial wealth of the drug patentees (Canada, 1997d).

[101] The Linkage Regulations, in their original form, did not provide for damages to the generic companies (Canada, 1997d).

[102] New products were continually replacing old products, sometimes because the former provided genuine improvements, but usually because of successful marketing by the brand name company (Angell, 2004b).

It appeared from the tone of questioning, as well as some of the comments made by Committee members, that there was sympathy for the position of the CDMA with regards to the Regulations. Both Ron MacDonald[103] and Real Menard[104] agreed that something should be done to introduce some balance into the framework. In response to questioning from Morris Bodnar[105] as to whether they would consider modifications to the Regulations short of outright repeal, the CDMA was agreeable, but skeptical. In their view, the entire process was fundamentally flawed. Even if they were awarded damages in the event of a favourable decision—an idea suggested by Bodnar—their revenue stream would still stagnate for a significant period and their investments would still depreciate while they waited for the courts.[106] Moreover, the CDMA argued, they had never been granted an adequate explanation for the necessity of the Linkage framework in the first place (Canada, 1997d).

In contrast, PMAC insisted that the Linkage Regulations were essential to providing "effective patent protection" and argued that their rules should be incorporated directly into the *Patent Act*. In its view, the necessity of the Regulations resulted from a clear gap in Canadian law making it difficult for patentees to obtain recourse to interlocutory injunctions when patents were being infringed upon (Canada, 1997f). PMAC argued that within regular Canadian law, interlocutory injunctive relief was granted only if a patentee could prove that

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[103] MacDonald was a Liberal MP representing Dartmouth, NS.
[104] Menard was a BQ MP representing Montréal. Menard's sympathy for the CDMA position on the Linkage Regulations is surprising because of the Bloc's steadfast support for Bill C-91.
[105] Bodnar was a Liberal MP from Saskatoon and also Manley's PS (for Industry).
[106] Apotex claimed that they had 50 products tied-up in the NOC court proceedings at the time of the hearings (Canada, 1997d).

permanent harm would result without the aid of an injunction. In PMAC's view, it was almost impossible to prove that irreparable harm would ensue in patent infringement cases. It believed that a shift in the burden of proof to the generic industry had helped Canada to achieve the global IP standard, while demonstrating its commitment to IP rights and "protecting" innovative investments (Canada, 1997f).

PMAC questioned whether the Regulations actually delayed the marketability of generic products. In its view, Health Canada's processing occurred simultaneously with the court proceedings, thus resulting in very few delays. According to PMAC data, NOC applications for generic products took an average of 32 months, a full 2 months longer than the maximum delay that could be imposed through the Linkage framework (Canada, 1997f). To support their claim that the Regulations were having a negligible impact on generic approval times, PMAC presented evidence to the Committee that only four out of the 58 court cases that had been settled through the Linkage framework had run longer than the normal approval process resulting in a genuine delay of the generic product coming to market. From its point of view, PMAC felt that this was a very small proportion of products, especially when compared to all the cases of patent infringement that had been prevented[107] (Canada, 1997f).

Not surprisingly, PMAC faced some difficult questioning by Committee members opposed to Bill C-91, in particular Joe Volpe.[108] Volpe attempted to

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[107] An official with Health Canada suggested that the process was actually much more complicated than PMAC's interpretation and that despite the statistics offered by PMAC the Linkage Regulations often delayed the introduction of generic products onto the market (Anonymous, interview).

[108] Volpe was a Liberal MP representing Toronto.

demonstrate the frivolousness with which the brand name companies had utilized the Regulations, charges that PMAC was unable—for the most part—to address.[109] PMAC cautiously endorsed suggestions by the Bloc to modify the Regulations to address the heavy amount of litigation, while keeping the essential framework of the system intact (Canada, 1997f).

Representing Canada's biopharmaceutical industry, IBAC told the Committee that a weakening of patent protection in Canada would jeopardize their efforts to develop life-saving medicines (Canada, 1997e). IBAC argued that patent protection was especially important to their member companies, most of which were still too small to be able to engage in the lengthy litigation characterized by patent cases. From that perspective, IBAC supported PMAC's call for the continuation of the Linkage Regulations and the enactment of its "principle"[110] into law. However, in recognition of the litigious nature of the Regulations alluded to by Committee members, IBAC did accept that minor modifications might be necessary to decrease the amount of time stakeholders were spending in the courts (Canada, 1997e).

Each of the three provincial health ministries testifying at the hearing[111] was very critical of the Linkage Regulations. They argued that the Regulations kept cheaper generic drugs off of the market for longer than necessary, which

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[109] PMAC claimed that the high number of withdrawals stemmed from the fact that it rarely had enough available information when it was first served a NOA from a generic company. In these cases, PMAC argued that it was important for brand name companies to protect themselves by blocking NOC applications as a matter of course and then withdrawing their protest after coming across information that demonstrated that their patent was not being infringed upon. In some of the cases PMAC had withdrawn from proceedings involving process patents after the courts had clarified that they should not be on the patent list (Canada, 1997f).

[110] This principle was that the awarding of a NOC would be linked to the patent list and that the burden of proof with regard to infringement would remain with generic companies (Canada, 1997e).

[111] This included BC, Saskatchewan and Manitoba.

increased their health costs. All three provinces called for the replacement of the Regulations with a simpler, fairer system, one that balanced the interests of all of the pharmaceutical industries[112] along with provinces and consumers (Canada, 1997g; Canada, 1997h). Manitoba suggested that many of the prevailing legal delays might be addressed by eliminating process patents and allowing only product patents (Canada, 1997g). For its part, BC called for limitations on the practice of "evergreening", a strategy, it argued, that the brand name industry employed to exploit the Regulations (Canada, 1997h).

Regulation of Patented Medicine Prices

The regulation of the prices of patented medicines was the responsibility of the PMPRB. Recall that as a result of the elimination of compulsory licensing through Bill C-91, the enforcement mechanisms available to the Board had changed. In place of the threat of compulsory licensing, Bill C-91 had provided the Board with new powers to induce brand name companies to comply with pricing guidelines and recover revenues accrued from excess pricing. With regard to the pricing of patented medicines, the Committee heard testimony with respect to the PMPRB's ability to control the prices of patented medicines; the close working relationship between the PMPRB and PMAC members; the methodology used by the PMPRB to establish pricing guidelines; and the cost of R&D involved in discovering and manufacturing new drugs.

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[112] Saskatchewan was adamant that any changes made to the Linkage Regulations must not damage the local biopharmaceutical industry which was generously supported by both the federal and provincial governments (Canada, 1997h).

Representing the PMPRB at the Committee hearings were the Board's Chairperson, Robert Elgie and its Executive Director, Wayne Critchley. In the opinion of Elgie and Critchley, the Board had been successful at keeping the prices of patented medicines within its guidelines. They maintained that the Board's work had made a significant contribution to the decline in the growth rate of Canada's patented medicine prices, which were rising slower than the pre-1987 Canadian rate and rates in comparable countries (Canada, 1997b). The PMRPB also boasted about its ability to obtain price reductions and compensation from patentees when prices had been deemed excessive by the Board's guidelines. According to the PMPRB, in over 100 undertakings to recover costs from excessive pricing, the Board had collected $107 million and was forced only once to resort to public hearings[113] (Canada, 1997b).

In his testimony to the Committee, Elgie painted the picture of a very familiar and amicable relationship between the PMPRB and the brand name industry. Indeed, Elgie admitted that the Board had to work very closely with brand name companies and rely on their "goodwill" to help with the establishment of guidelines for the introductory pricing of new patented medicines in Canada. Elgie confirmed that the Board did not possess the means to obtain adequate pricing information from foreign jurisdictions on its own (Canada, 1997b).

In general, the Committee's questioning of Elgie and Critchley did not appear very difficult or probing. However, three of the Committee's members—

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[113] In this case a company called ICN Canada Ltd. had engaged in a policy of selling the drug *virazole* at an excessive price (Canada, 1997b).

John Solomon,[114] Volpe and MacDonald—did challenge the Board on certain issues, in particular, introductory price setting for new patented medicines (Canada, 1997b). Volpe took issue with the Board's inability to consider R&D and manufacturing costs when deciding on a price for a "breakthrough drug". According to Volpe, it was too risky to rely on the median price of a group of countries as a reference point, because Canada had no means of determining its suitability. From his point of view, the cost of researching and/or manufacturing the drug needed to play a role in determining the price (Canada, 1997b).

For his part, MacDonald was skeptical of the use of only seven countries to compare introductory prices of "breakthrough drugs", rather than all 24 countries of the OECD (Canada, 1997b). In response, Elgie stated that the basket of seven countries had not been selected by the Board, but rather by the Mulroney government in 1987. He went on to state that in 1993, the decision to use this particular basket of countries had been reaffirmed by a task force consisting of representatives of provincial health ministries, the federal government, pharmaceutical industry representatives, consumer representatives and pharmacist groups (Canada, 1997b).

Solomon probed the Board's representatives about the consistency of the types of prices compared between Canada and the other seven countries (Canada, 1997b). His main concern was that the PMPRB used the "transaction price"—the price paid by the consumer—as the comparator price in Canada, but often used the "list price"[115] as the comparator price for the other seven

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[114] Solomon was a NDP MP from Regina.

[115] The list price is sometimes referred to as the "catalogue price".

countries. In general, the list price is higher than the transaction price because it does not take into account the effect of bulk sales, discounts or donations. Solomon believed that comparisons could be only accurate if the Board compared the same types of prices. He argued that by comparing Canada's transaction price with the list price from other countries, the Board was inserting a structural bias into its methodology that would tend to inflate the allowable cost for a particular drug in Canada. In response, Elgie argued that the Board only had limited resources to research price information—much of which was unavailable anyway—and that it therefore had to rely on the companies themselves to provide the data (Canada, 1997b).

Both Manley and Dingwall accepted the PMPRB's figures which demonstrated that the prices of patented medicines had been effectively controlled. In general they were pleased with the Board's ability to keep the rate of increase of patented medicine prices below the rate of inflation (Canada 1997a; Canada 1997b). In response to concerns raised by MacDonald[116] regarding the applicability of the basket of seven countries, Dingwall acknowledged the importance of setting the entry-level price correctly and the effect that it would have on drug prices for years to come. Furthermore, as the Minister responsible for the PMPRB, Dingwall informed the Committee that the Board had the power to select any basket that it wished and that the makeup of the basket was not fixed. In his view, the Government was very interested in the

[116] As the Liberal opposition's critic for CCA during the Mulroney government, MacDonald had been the Liberals' most vocal opponent of Bill C-91when it had been originally introduced. Macerollo believed that MacDonald's harsh criticism of the Bill during the review process was influenced, in part, by a desire to reconcile with his earlier critiques (T. Macerollo, interview, July 17, 2008).

Committee's opinion as to whether or not the basket was adequate as it stood (Canada, 1997b).

Speaking for the CHC, Lexchin took issue with several of the points made by Elgie and the Board, especially with respect to the impact of patented medicines prices in Canada over the previous decade. First, Lexchin pointed out the bias inherent in the methodology used by the Board to set its guidelines for introductory Canadian prices of breakthrough drugs. Lexchin criticized the Board for the composition of its list of seven comparator countries, which included countries (e.g. US, United Kingdom, Sweden and Switzerland) with some of the highest drug prices in the world (Canada, 1997c). The selection of these countries appeared arbitrary, and the Coalition believed that it was more sensible to compare Canadian prices with those from all OECD countries. According to Lexchin, using prices from all OECD countries to set introductory prices for new Canadian patented medicines would result in an average price decrease of 10% to 15%. In his opinion, the Board's ability to restrict the rate of increase of patented medicines below the rate of inflation—an achievement it had boasted about—mattered very little in terms of consumer savings when products were being excessively priced to begin with (Canada, 1997c).

Lexchin also argued that the *cost* of prescription drugs had been increasing significantly since changes to the *Patent Act* brought about by Bills C-22 and C-91. While the Board may have been somewhat effective at controlling the rise in price of new patented medicines, Lexchin argued that this did not equate to controlling costs. Trends on pricing—like those provided by the

PMPRB—did not communicate information about what people were *spending* on prescriptions—which was actually important. To make this point, Lexchin stated:

> That's what counts, that's what matters to people. It's not what the manufacturers charge for the drug, it's what people have to pay when they go to buy a prescription. If a drug costs $50 but I never get it, I'm never prescribed it, then I don't care whether or not it's $50. But if I have to go out and buy it, then I certainly do care if it's $50 (Canada, 1997c).

Referring to a 1992 study done by Green Shield Services, Lexchin claimed that the average cost of a prescription in Ontario had risen by almost 100% from 1987 (the year of the Board's inception) to 1993. Furthermore, the Green Shield report stated that over half of these increases were due to new drugs, specifically patented medicines whose costs had risen at almost double the annual rate of generic prescriptions (Canada, 1997c).

Although they made little mention of the introductory pricing during their opening statements, PMAC representatives were forced to defend the PMPRB's rationale for pricing guidelines in questioning by MacDonald and Walt Lastewka.[117] Two particular issues that appeared to bother MacDonald and Lastewka included: (1) the dramatic reduction in price and loss of market share (90%) for brand name products when generic competition entered the market; and, (2) the lack of a relationship between the costs involved in R&D and the introductory price of new patented medicines. Rather than an indication of a previously overpriced product, PMAC rationalized their loss of market share as a result of the immediate inclusion of generic products on provincial formularies. They pointed out that in many Canadian jurisdictions, hospitals and other health

[117] Lastewka was a Liberal MP from St. Catherines.

institutes were mandated to buy the cheaper, generic products as soon as they found their way onto provincial formularies, resulting in a substantial loss of business for brand name companies. When asked about their opinion on the possible reconsideration of the PMPRB's basket of seven countries for the full set of 24 OECD countries, PMAC disagreed, suggesting that the guidelines had already been thoroughly vetted by a "diverse" panel of stakeholders (Canada, 1997f).

One of the most exciting—and informative—exchanges of the entire Committee proceedings occurred between MacDonald and PMAC representatives regarding the derivation of introductory prices and their relationship to R&D costs. MacDonald was not satisfied with the PMPRB's use of the basket of seven countries and argued that the system was inadequate because of Canada's inability to ensure that the prices from these other countries were reasonable. Rather than simply dictating that Canadian prices had to be less than some "unproven" median price, he felt the Board should have been linking the introductory price to the actual cost of developing the drug (Canada, 1997f). In a heated argument with representatives of PMAC, MacDonald challenged them to demonstrate why they could not produce figures to the PMPRB—in confidence—outlining the actual R&D costs associated with a new drug. Unwilling (or unable) to provide a straight answer, PMAC attempted to confuse the issue by giving answers to questions that had not been asked. Fortunately for PMAC, the hearings were concluded before the issue came to a head (Canada, 1997f).

Each of the three provinces appearing before the Committee was skeptical of the PMPRB's ability to keep drug costs down and critical of its approach to setting introductory prices. They argued that while annual price increases for patented medicine were being controlled, the introductory prices were too high to begin with, leading to a sizeable increase in the average, and overall, cost of a prescriptions.[118] Accordingly, the provinces echoed calls for an increase in the number of countries used by the Board to set Canadian introductory prices and demanded that the PMPRB change its methodology to take into account the benefit of bulk buying in comparator countries (Canada, 1997g; Canada, 1997h).

BC questioned the rationale of providing "me-too drugs"[119] and "line extensions"[120] with patent protection equivalent to that which was being offered to "breakthroughs". It argued that brand name companies engaged in an extensive marketing strategy to influence physicians to switch their patients from drugs with expiring patents to newer, more expensive me-too drugs, despite a lack of improvement in therapeutic benefit. This practice had lead to an increase in BC's health costs as it prevented them from taking advantage of cheaper generic drugs coming onto the market due to doctors switching their patients to the newer—but not necessarily better—drugs. In BC's opinion, the initial prices of me-too drugs and line extensions needed to be reduced (Canada, 1997h).

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[118] This was similar to the experience of Ontario as reported in the Green Shield Services Inc. (1992) study.
[119] Me-too drugs are products whose development required little if any innovation while offering no additional therapeutic benefit over comparative products already on the market; they are essentially copies of existing drugs. Line extensions are "new drugs" that result from minor modifications to "older drugs" (Angell, 2004a).
[120] Line extensions include modifications such as new forms of administration, colours, minor modification in chemical make-up, or new dosing regime.

Patent Term Restoration

When compared to patents from other fields of technology, pharmaceuticals are unique in certain respects. One important difference is the extra regulation around drug products related to safety and efficacy. Due to the heavy competition involved in patenting compounds for drug manufacturing, companies cannot afford to wait for products to be approved, or even tested, before they are patented. Consequently, the actual time left in the life of a patent when a drug finally comes to market is relatively less when compared to patents from other fields of technology. PTR refers to the granting of an extra period of market exclusivity to compensate pharmaceutical producers for lengthy process of obtaining regulatory approval (Lexchin, 1997). Before the Standing Committee met to discuss Bill C-91, Canada had no provisions for offering PTR.

Since the objective of PTR was to extend the period of market exclusivity for brand name companies, the CDMA was unequivocally opposed to it. To demonstrate that Canada's effective patent protection was already competitive with other comparable jurisdictions, the CDMA provided data from a Queen's University health policy research group[121] demonstrating that the effective patent life of pharmaceuticals in Canada was between 12 and 14 years. This figure was significantly longer than the 10 years being claimed by PMAC and longer even than the average U.S. monopoly period of 11.7 years[122] (Canada, 1997d). The CDMA claimed that longer monopoly periods in Canada could be accounted for by the increase in the evergreening of patents; a strategy that had been

[121] The Queen's University study was funded by the CDMA (Canada, 1997d).
[122] This estimate was provided by Gerald Mossinghoff, the previous president of PhRMA (Canada, 1997d).

reinforced by the introduction of the Linkage Regulations. They argued that through the repeated filing of new patents for a single product,[123] brand name companies were able to persist in challenging the issuances of NOCs to generic companies, each time invoking a new 30-month injunction (Canada, 1997d).

PTR was a major priority for PMAC as it was the one item through which the brand name industry could gain additional patent protection. In making its case for PTR, PMAC argued that Canada's provision of effective patent protection lagged behind its trading partners.[124] Citing the substantial risks and investments[125] involved in discovering and developing new drugs, PMAC argued that the industry needed longer monopoly periods to help it recoup its investments and losses (Canada, 1997f). PMAC maintained that it took an average of 10 years to conduct research and acquire regulatory approval for a pharmaceutical product in Canada, leaving only 10 years of genuine market exclusivity. PMAC representatives pointed out that other countries offered up to an additional five years of patent protection to compensate patentees for the extra time involved in clinical testing and acquiring regulatory approval. In their view, Canada needed to provide some form of PTR—if only on a case-by-case basis—to bring itself up to the global standard of IP protection and maintain its reputation as a good place to invest (Canada, 1997f).

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[123] The CDMA claimed that patents were listed for new formulations, new uses, new crystal forms, or sometimes for nothing pertinent at all (Canada, 1997d).

[124] Specifically, PMAC compared Canada to the United States, Japan and the EU. Judging from PMAC's testimony, these jurisdictions offered the global standard in "effective" patent protection (Canada, 1997f).

[125] PMAC cited $500 million as representative of the cost of discovering and developing a new product (Canada, 1997f). In other settings PMAC has claimed a figure as high as $800 million; however, these figures are highly disputed (Lexchin, 1997).

It was difficult for the Committee to obtain from PMAC a concrete representation of what effective patent protection should look like in Canada. Volpe challenged PMAC representatives to reconcile their increased investment over the past several years with their attacks on Canada's apparently weak protection of IP. In response, PMAC was unable to provide a clear justification for this apparent irony (Canada, 1997f). In reply to PMAC's call for PTR, one Reform MP noted that there were actually several ways[126] to increase monopoly periods and that what the Committee really needed to know was how long patentees required market exclusivity in order for them to recoup their investments. Rather than provide a hard figure—for fear, perhaps, that it might weaken their future bargaining position—PMAC was non-committal and simply declared that it desired that Canada attain the international standard. In response to what could only be characterized as ambiguous posturing, MacDonald pressed PMAC to disclose whether or not it was the goal of their industry to obtain PTR as the new international standard. Again, PMAC was vague and evasive (Canada, 1997f).

Citing longer than average R&D and regulatory approval periods for their industry,[127] IBAC echoed PMAC's calls for some form of PTR. IBAC also agreed with PMAC's position that provisions for PTR should be competitive with what was being offered by Canada's major trading partners. However, when challenged by Committee members IBAC conceded that PTR need not be made

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[126] An extension of market exclusivity could be attained by many different measures including increasing the patent term, eliminating the Bolar Provisions, increasing regulatory approval rates, or providing PTR (Canada, 1997f).

[127] IBAC representatives cited one example where a product had been under review for 6 years (Canada, 1997e).

available for all cases, but rather only in extreme instances where regulatory approval was unusually long (Canada, 1997e).

Pharmaceutical R&D Investments

While Bill C-91 was being debated in Parliament in 1992-1993, PMAC committed to providing the Medical Research Council of Canada (MRC) with contributions of $200 million over 5 years (Lexchin, 1997). These commitments were in addition to a promise made by PMAC prior to the passage of Bill C-22, committing its members to increasing their average research to sales ratio to 10% by 1996 (Canada, 1997b). While the Bill C-91 commitments to the MRC were to be used specifically for basic research—as determined by the MRC—PMAC's Bill C-22 commitments did not distinguish between basic and applied research.[128] The PMPRB was responsible for monitoring and reporting on the R&D investments made by PMAC and its individual member companies.

There were several issues related to pharmaceutical R&D explored during the Committee's hearings, including the reliability of R&D information supplied by PMAC companies to the PMPRB; the impact of Bill C-91 on pharmaceutical R&D; the extent to which PMAC had lived up to its R&D commitments; R&D contributions by the generic and biopharmaceutical sectors; discrepancies between basic and applied research; the relationship between multinational brand name companies and smaller, Canadian-based biopharmaceutical

[128] According to Elgie, basic research generally involved chemical and biologic studies to discover new compounds and organisms with practical medical uses, while applied research generally involved clinical trials, post-market studies and research into manufacturing processes (Canada, 1997c).

companies; the commercialization of Canada's health research agenda; and mechanisms to ensure equitable distribution of pharmaceutical R&D among provinces.

The PMPRB reported that, on average,[129] PMAC had surpassed its Bill C-22 commitment to raise its ratio of R&D to sales to 10% by 1996 (Canada, 1997c). Some Committee members questioned the accuracy of these figures, which had been provided by the companies themselves, with little to no verification by the Board. Elgie testified that the PMPRB had to rely on the brand name companies to voluntarily supply information about their own R&D activities and that budget restrictions limited the Board to engaging in validation audits only from "time-to-time". This de facto honour system had developed as a result of the Board's limited means for independently verifying price information and research declarations. In addition to concerns around the reliability of R&D claims, also at issue was whether or not claims were for genuine R&D activity. According to Elgie, for activity to qualify for an acceptable R&D submission, the Board's only stipulation was that it met the definition supplied by the Scientific Research and Experimental Development program of the Canada Income Tax Act[130] (Canada, 1997c).

Both Manley and Dingwall lauded the increased investment of the brand name sector following the passage of Bill C-22 and Bill C-91. Dingwall felt that Canada had increased its competitiveness for attracting multinational investment

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[129] The key here is that PMAC members had fulfilled their commitment only by using the average as a measure. Some patentees were doing no R&D while others were doing much more than 10%. The PMPRB reported that 46 patentees were doing less than 10% (Canada, 1997c).

[130] Under the Scientific Research and Experimental Development program, investors were able to file for a tax credit for expenses that were related to R&D (Madore, 1998).

as a result of the changes it had made to patent protection (Canada, 1997b). In response to questioning from a Reform member regarding job losses within the Canadian brand name sector, Manley blamed international restructuring in the global industry and argued that the jobs that had been gained were "high value-added jobs" which were as good and as important, as three to four "regular jobs"[131] (Canada, 1997b). Under questioning from Lastewka, Manley admitted that PMAC had not kept up with its Bill C-91 commitments to fund the MRC. In light of these shortfalls, Manley stated that the Government had the capability to induce PMAC to comply. Among the measures available were changes to the Linkage Regulations, maintenance of the Bolar Provisions and rejection of PTR (Canada, 1997a).

The CDMA attempted to highlight its investment contributions, as well as its recent performance in job creation. Moreover, with some of its companies expanding the scope of their operations to the production and discovery of fine chemical entities, the CDMA claimed that its larger members were now engaging in high levels of R&D, with plans for further expansion[132] (Canada, 1997d). The CDMA pointed out that its companies employed around 4,000 people in Canada—almost half of whom were in Quebec—with many of those jobs in high-tech R&D positions with more to come. According to their data, job creation and investment had continued to grow among member companies, while it had stagnated and had begun declining in the brand name sector (Canada, 1997d).

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[131] Macerollo stressed the importance of R&D jobs because, unlike production jobs, they were not so easily transferred to other locales (i.e. they were more secure). He argued that in an age in which capital flight had become so pronounced, such jobs were at a premium (T. Macerollo, interview, July 17, 2008).

[132] The CDMA claimed that its companies had spent $128 million on R&D in 1995 and that their R&D to sales ratio was 16.3% (Canada, 1997d).

PMAC highlighted its achievements in living up to its Bill C-22 commitments on R&D[133] (Canada, 1997f). In addition to emphasizing sector-wide achievements, representatives from some of PMAC's leading member companies—including GlaxoWellcome and Merck Frosst Canada—were present to apprise the Committee of their individual companies' accomplishments, including high employment levels; multi-million dollar investments in the Toronto and Montréal areas; financial support for Canadian biotech companies; and financial partnerships with provincial governments. In an attempt to pacify the R&D concerns of the Committee, PMAC committed to maintaining the 10% ratio of R&D to sales if the provisions of Bill C-91 remained in place following the review (Canada, 1997f).

On the issue of R&D, Committee members were aggressive in their questioning of PMAC, especially in regard to declining levels of basic research and their lack of funding—to date—of the MRC program. In response, PMAC argued that its basic-to-applied research ratio was competitive with the international standard and that it intended to make good on its five-year funding promise to the MRC in time to fulfill its commitment (Canada, 1997f).

Bloc members were very assertive in their questioning of PMAC representatives. They argued that PMAC should raise its level of R&D to the global standard if it expected the Committee to recommend new initiatives to further strengthen the protection of their patents in Canada (Canada, 1997f). Rather than give a formal commitment, PMAC tried to convince Bloc members that investments would naturally flow to any jurisdiction offering a high standard

[133] According to the PMPRB, PMAC had fulfilled this commitment (Canada, 1997b).

of patent protection. All committee members—the Bloc included—were unimpressed with PMAC's assurances, counter-arguing that PMAC had nothing to lose by formalizing their assurances if the connection between patent protection and increased investment was so certain. Despite these efforts, no firm commitments from PMAC were obtained (Canada, 1997f).

IBAC identified the extension of patent protection as the most important factor[134] in the recent growth of Canada's nascent biopharmaceutical industry. According to IBAC, the majority of Canadian biopharmaceutical companies were recent start-ups, with a significant proportion of their growth occurring since the passing of Bill C-91. At the time of the review, there were approximately 132 biopharmaceutical companies in Canada—double the number from 1993—with the industry forecasting sustained growth including a 50% increase in jobs by the year 2000 (Canada, 1997e).

During its presentation, IBAC outlined the partnerships between its members and the multinational brand name industry. According to IBAC, the strength of the biopharmaceutical industry was its proficiency in conducting basic, innovative research and applying biotechnology to drug production (Canada, 1997e). For its part, traditional brand name pharmaceutical companies—by virtue of the size and experience of its companies—provided financing and expertise in the areas of drug development, manufacturing and foreign marketing. Through these partnerships, biopharmaceutical firms were

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[134] Other factors IBAC credited with contributing to growth and investment in the domestic biopharmaceutical sector included Canada's generous research tax credits, its sound regulatory approval system, its high standard of living, its strong health and education systems and its strong, mature scientific and research communities (Canada, 1997e).

able to license their discoveries to larger multinational pharmaceutical companies in exchange for royalty payments. In general, such partnerships were the basis for the prosperity and survival of biopharmaceutical companies (Canada, 1997e).

Although Committee members were generally supportive of the biopharmaceutical industry, they appeared suspicious of the close relationship between IBAC and PMAC firms. Indeed, some biopharmaceutical companies represented by IBAC were also members of PMAC[135] and it was not uncommon for multinational brand name pharmaceutical companies to own shares of Canadian biopharmaceutical companies (Canada, 1997e). There was also uncertainty among Committee members with regard to the actual impact of Bill C-91 on the biopharmaceutical industry. Internationally, the biopharmaceutical industry had experienced significant growth in the 1990's, leading some Committee members to question whether the success of Canadian biopharmaceutical companies was a function of greater domestic patent protection—as claimed by IBAC—or simply part of the broader expansion of the global industry (Canada, 1997e).

Speaking for the Coalition, Lexchin took a critical view on the R&D accomplishments of the brand name industry while providing suggestions on how future investments might be better used. He argued that R&D investments with the greatest economic value were those derived from basic, rather than applied research. Lexchin expressed concern that a sizeable majority of the research

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[135] Approximately 18% of IBAC members were PMAC members. Although this percentage may appear insignificant, the biopharmaceutical industry itself only made up a portion of the IBAC and so the percentage of biopharmaceutical firms represented by PMAC at the time would have been greater (Canada, 1997e).

being done by PMAC members was applied and that the ratio of basic-to-applied research had been declining. Furthermore, Lexchin maintained that 40% of PMAC "investments" were being written off due to Canada's generous research tax deductions, leading him to suggest that the true economic impact of R&D was substantially lower than the raw numbers suggested (Canada, 1997c).

Lexchin also pointed out that the extra patent protection offered through Bills C-22 and C-91 was, in effect, an indirect subsidy to the industry. However, the Canadian brand name industry engaged in primarily applied research, including the duplication of research being conducted elsewhere by other companies—so called "me-too research"—or research that would have been done regardless for Canadian regulatory purposes. In the view of the Coalition, the R&D benefits to Canada of extended patent protection had been overestimated and had not been sufficient considering the level of subsidy provided by the Canadian government (Canada, 1997c).

The Coalition also took issue with the perception that levels of patent protection in Canada played a role in determining whether or not a drug was manufactured and—more importantly—whether or not it was manufactured in Canada. In two heated exchanges with the Bloc members, Lexchin explained that the brand name pharmaceutical industry's primary use for Canada was as a market, and not a very large one at that. Lexchin maintained that the only markets that actually influenced investment decisions by the multinational industry were the largest, including the US, European Union and Japan. For its part, Canada had a negligible influence on R&D decisions, because it only

represented 2% of the industry's global sales. However, when pressed by the Bloc members, Lexchin did concede that patent protection could influence which country a company chooses to invest its money, but that this was more of a political decision rather than a natural economic relationship (Canada, 1997c).

Lastly, the Coalition endorsed a recent recommendation by the National Forum on Health (NFH), which called for an industry-financed, but publicly administered, program to fund health research in Canada. The Coalition's support for the NFH proposal stemmed from its concern about the increasing role played by the pharmaceutical industry in setting medical research priorities in Canada. As the single greatest direct funder of medical research in Canada, the pharmaceutical industry's commercial imperatives played a far greater role in steering the medical research agenda than it had in the past. The Coalition believed that a public research organization such as the MRC was a possible candidate for the administration of such a program (Canada, 1997c).

All three provinces appearing before the Committee were unsatisfied with the proportion of Canada's pharmaceutical R&D investment that had been apportioned to their jurisdiction. The provinces demanded a more equitable share, arguing that while they had been forced to endure all of the costs associated with Bill C-91, each of them had benefited only marginally from the promised investments. Recommendations were made for the creation of an enforcement mechanism to persuade PMAC to make-up for the regional disparity in its R&D investments (Canada, 1997g; Canada 1997h). Moreover, the provinces charged that similar disparities existed in federal funding programs

from the MRC and that action to ensure a more equitable allocation of these monies was also required. The decline in basic research since the passage of Bill C-91 was also criticized by the provinces, which lent their support to the NFH's proposal for a health research program free from industry influence (Canada, 1997g; Canada 1997h).

Exporting Restrictions on Drugs Patented in Canada

As a result of the changes contained within Bill C-91, generic producers were no longer authorized to manufacture drugs patented in Canada for the purposes of exporting to countries where the same drug was off-patent. This measure appeared to be in anticipation of future provisions of multilateral agreements that might include "cross-filed patents".[136] The primary issue was the attempt to balance the international IP rights of Canadian patent holders with the foreign investment rights of Canadian generic companies (CDMA, n.d.)

The CDMA argued that the restriction on exporting patented medicines should be lifted. They maintained that the impact of Bill C-91 on exporting restrictions was actually unintended[137] and that its continued enforcement was hurting the international competitiveness of the Canadian generic industry. The export restrictions prevented generic companies from taking advantage of export

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[136] A cross-filed patent is one which must be respected in any country that belongs to a particular treaty and not just the country in which it is filed (Doern & Sharaput, 2000).

[137] The CDMA claimed that Michael Wilson—Minister of Industry when Bill C-91 was introduced—had admitted that the export restrictions in Bill C-91 were an unfortunate mistake that occurred only because Canadian officials were unaware that different countries had different patent expiry dates (Canada, 1997d). Although this may be true, it is doubtful that Wilson would not have known that export restrictions, or the cross-filing of patents, would become a reality in the post-TRIPS world.

opportunities in foreign markets—such at the US—so long as the drugs were manufactured in Canada[138] (Canada, 1997d). Consequently, the export restrictions had actually forced some CDMA members to relocate manufacturing facilities and jobs outside of Canada, including the US. Reminding the Committee of Canada's lopsided trade deficit with the US—$1.6 billion and rising—the CDMA urged the Committee to take action on this issue (Canada, 1997d).

Little attention was given to the issue of export restrictions of patented medicines by PMAC, although it did state its objection to changes that would permit exports (Canada, 1997f).

Appearance of Generic Drugs

Leading up to the review of Bill C-91, there were a significant number of patent infringement cases ongoing in the Canadian courts. One particular issue being debated in several of these cases was the appearance—size, shape and colour—of generic pharmaceuticals. The primary concern regarding the appearance of generic pharmaceuticals was the extent to which they imitated brand name products (Canada, 1997d).

The CDMA argued that food and drug regulations and the Trade-marks Act should both be amended to *require* that all generic drugs be similar in appearance to their brand name equivalents. Without providing much in the way of evidence, the CDMA contended that the marketing of generic drugs that were

[138] For example, patents for pharmaceuticals were often filed earlier (by around one year) in the US than in Canada, and so these same products usually came off patent earlier in the US (Canada, 1997d).

similar in appearance to the brand name equivalent was a long-standing practice in Canada which helped to reduce confusion among consumers. The CDMA argued that such a practice had widespread support among health care stakeholders and consumers, especially the elderly and those who took several pills many times a day (Canada, 1997d).

In seeking a requirement for generic products to have similar size, shape and colour to their brand name counterparts, the CDMA was attempting to undermine the brand name industry's efforts to stall generic companies in the courts by alleging patent infringement on the basis of appearance. Interestingly, PMAC did not respond to the issue of generic drug appearance during their testimony (Canada, 1997d).

Compulsory Licensing and a National Pharmacare Program

According to the Mulroney government, the primary reason for Bill C-91 had been the elimination of compulsory licensing, in order to bring Canada into compliance with expected changes to international standards of patent protection. The elimination of compulsory licensing had resulted in a full 20 years of market exclusivity for patented medicines (Campbell & Pal, 1994). After coming to power, the Liberal government maintained that it could never go back to a regime that allowed compulsory licensing, as it would violate Canada's obligations under international trade agreements (T. Macerollo, interview, July 17, 2008).

Despite the position of the Liberal government, both NAFTA and TRIPS contained limited exceptions to patent infringement that permitted governments to override patents under specific circumstances. Consumer groups like the CHC argued that these exceptions provided the legal justification to reinstate compulsory licensing, so long as generic drugs were distributed through a national pharmacare program. From the perspective of the CHC, a national pharmacare program was a necessary step to increasing access to medicines and improving the health of Canadians (CHC, 1997; Canada, 1997j).

The CHC called on the Committee to seriously consider the NFH's recommendation to establish a publicly-funded, universal drug plan, or national pharmacare program. Lexchin estimated that between 12% and 15% of Canadians—mostly the working poor—were without any drug coverage, a statistic which placed Canada among the worst OECD countries. In addition to ensuring greater access to medicines, Lexchin argued that a national pharmacare program would save Canadians money by taking advantage of the bulk-purchasing power of provinces and the increased efficiency of a single public insurance provider (Canada, 1997c).

Speaking for the Coalition, John Dillon argued that the Government was within its legal rights to issue compulsory licenses, so long as the licenses were used to produce drugs provided through a public program. Drugs distributed under this kind of a program could be considered as 'public goods' rather than commodities, which would exempt them from the patent protection standards of Canada's trade agreements. Indeed, Lexchin cautioned that a national

pharmacare program could be affordable only if the government were able to take advantage of the lower prices resulting from compulsory licensing.

In defending this proposal, Barry Appleton—an international trade lawyer speaking on behalf of the Coalition—disagreed sharply with Manley's declarations that Canada had no options at its disposal regarding the 20-year patent period and compulsory licensing. Both NAFTA and TRIPS permitted Canada to except certain items from patentability by claiming that it was acting to protect *ordre public*; a broad term used in international law referring to a government's right to take measures for the general public benefit or the national interest. According to Appleton, a publicly-funded universal drug plan would fall under the category of *ordre public*, which would qualify pharmaceuticals as candidates for exceptions to patentability, or compulsory licensing (Canada, 1997c).

Each of the three provinces appearing before the Committee supported the NFH's call for a national pharmacare program, concurring with the assertion that the success of such an initiative would depend on the federal government's ability to reign in drug costs through compulsory licensing (Canada, 1997g; Canada, 1997h). Representing some of the stronger provincial drug programs[139] in the country, these provinces argued that any federally-led initiative could not have a regressive impact on their own programs, but should raise the standard of service that they were already providing (Canada, 1997g).

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[139] BC's reference-based pricing program stipulated that the Province would fund only the least expensive drug in a therapeutic class. This program saved BC approximately $74 million in the two years leading up the review of Bill C-91, money that was directed back into its drug program. Saskatchewan also had a similar program whereby only the least expensive drug was covered (Canada, 1997h).

CHAPTER 4 – Outcomes of the Review

Introduction

This chapter recounts the aftermath of the review of Bill C-91 to develop the thesis in several ways. First, the influence of the Government on the Committee process is demonstrated through an assessment of the Industry Committee's recommendations and an examination of the drafting of the Committee's final report. Second, the Government's policy response to the review is outlined demonstrating the Government's support for the brand name industry. Third, an analysis of the political donation profiles of the brand name and generic industries is provided, which suggests some relationship between the influence of, or the role played by, certain Liberals candidates and donations. Finally, a synopsis of an OAG audit report into the PMPRB is provided, demonstrating the Board's bias towards the brand name industry thereby reinforcing the claim that the Government's policy decisions were based on politics rather than principle.

The Industry Committee's Report

On April 23, just one month before the 1997 federal election, the Industry Committee voted to adopt a report to Parliament on the review of Bill C-91. Included in the report was a request that the Government (i.e. the Ministers of Industry and Health) table a response to the following recommendations within 150 days:

1) Following on the proposals made by the NFH, steps should be taken to investigate the feasibility of a national pharmacare program. The BQ affirmed that in the event that national pharmacare program was established, the federal government should transfer equivalent tax points to provinces—like Quebec—where such programs already existed.

2) The mandate of the PMPRB should be reviewed and strengthened and the OAG should perform an audit of the Board. Furthermore, the Government should take steps to allow greater public access to non-proprietary information held by the Board.

3) Canada should live up to its international obligations and maintain its 20-year patent period.

4) The Government should revisit the Linkage Regulations to address the concerns raised by the various stakeholders. Two options proposed by the BQ for amending the Regulations include (1) the clarification of the patent list along with the establishment of parallel time frames for the NOC and court processes; or, (2) the creation of a system based on the American model where the usual court procedures of injunction and significant civil damages apply.

5) The Government should initiate negotiations with the pharmaceutical industry to establish a program to foster basic health research, similar in design to the MRC-PMAC Health Program which was scheduled to conclude in 1998. The Committee proposed that both the generic and brand name industry be given the option of voluntarily participating in the program, together with the MRC, or pay an annual levy of 1% of sales. In the view of the Committee, such a program should be administered by the MRC through its regular peer review procedures.

6) The PMPRB should consult with stakeholders to establish what other useful information it could provide to the public (Canada, 1997i).

In addition to the above recommendations, the Committee reported that it did not believe that generic producers should be allowed to manufacture and export patented medicines to countries where the medicines were off-patent. According to the Committee, it was not clear that exporting patented drugs would be within

Canada's international legal rights as defined by NAFTA and TRIPS (Canada, 1997i).

Also included in the report was a minority opinion drafted by Reform Party members, which opposed some of the report's recommendations while attempting to add direction and clarity to others. For instance, in contrast to the rather neutral language contained in the report's recommendations regarding the PMPRB, Reform members called for an audit of the Board's pricing methodologies, while also suggesting that the number of comparator countries be raised (Canada, 1997i). With regard to a national pharmacare program, Reform members "cautioned" that Canadians should have "choice in health care", while emphasizing that provincial jurisdiction should be respected. In addition to these recommendations, Reform members emphasized their displeasure over the inadequate time given to Committee members to study the draft recommendations (Canada, 1997i).

One interesting aspect of the Committee's recommendations was the reluctance to direct the Government to take a specific course of action. In most cases the Committee outlined issues that it felt the Government needed to consider or address, but provided little guidance on what the final outcome of these processes should be. For instance, instead of directing the Government to implement a national pharmacare program, the Committee recommended that "steps should be taken to *investigate the feasibility* of a national pharmacare program" (Canada, 1997i, emphasis added). With regard to the PMPRB's methodology, rather than instructing the Government to increase the number of

comparator countries, or mandate the use of similar prices for inter-country comparisons, the Committee simply recommended that "[t]he mandate of the PMPRB should be *reviewed* and *strengthened*" (Canada, 1997i, emphasis added).

Indeed, language is vital in politics and considering the controversy surrouding the review one cannot overlook the significance of the phrasing in the Committee's report. The ambiguous nature of its recommendations suggests that they may have been designed to include enough substance to give the appearance of meaningful reflection, while providing ample flexibility for the Government to proceed in its preferred direction. According to Macerollo (interview, August 22, 2008), the formulation of "harmless" recommendations for controversial issues was not an unusual practice in federal committee work, as it gave the impression that thoughtful work was being done without painting the government into a corner.

Political Donations – 1997 Election Campaign

The federal election campaign began shortly after the passing of the Industry Committee's report. To curry favour with the government that would decide on changes to Canada's pharmaceutical patent policy, both industries provided financial support to individual Liberal candidates and the LPC. The brand name industry donated approximately $115,000 to the LPC in 1997; a significant amount considering the high stakes in an election year. For its part, the generic industry only donated $65,000 (see Table 3.4). This disparity in

contributions between the two industries was similar to the previous year and might be indicative of an attempt by the brand name industry to influence the next government to maintain the then-current policy.

In regards to individual Liberal candidates, the generic industry's contributions (see Table 4.1) were similar to the 1993 election, while the brand name sector significantly increased the number of Liberal candidates targeted, as well as the value of its contributions (see Table 3.2).

Table 4.1 – Liberal Candidates Receiving Political Donations in Excess of $500 from the Generic Industry during the 1997 Election Campaign.

Candidate	Riding	General Area	Amount
Elinor Caplan	Thornhill	Toronto	$3,200
Sergio Marchio	York West	Toronto	$3,000
Herb Gray	Windsor West	Windsor	$3,000
Martin Cauchon	Outremont	Montréal	$2,434
Jean Chrétien	Saint-Maurice	Shawinigan	$2,000
Bonnie Brown	Oakville	Toronto	$1,735
Art Eggleton	York Centre	Toronto	$1,500
Joe Volpe	Eglinton –Lawrence	Toronto	$1,000
Lucienne Robillard	Westmount – Ville-Marie	Montréal	$1,000
Pierre Pettigrew	Papineau – St-Denis	Montréal	$1,000
Janko Peric	Cambridge	Toronto	$800
Roy Cullen	Etobicoke North	Toronto	$620

Source: Elections Canada.

In general, the pharmaceutical donation profiles seemed to reflect the level of influence of Liberal recipients, or the positions taken by Liberal MPs in regard to the review. A number of Liberal candidates from the Montréal area received large contributions from the brand name industry, including Patry ($9,200), Martin ($5,500) and Discepola ($2,700). Both Patry and Discepola had been members of the Industry Committee, while other beneficiaries had been

Cabinet ministers during Chrétien's first term. The total amount donated to Patry is noteworthy in itself, but even more so considering that he was not a Cabinet minister, nor had he received much support from the brand name industry in the 1993 election ($300). It may be that Patry was a key figure supporting the brand name sector on the Industry Committee and within the LPC in general.

Another Industry Committee member receiving significant support from the brand name industry was Parrish ($5,650), who had backed its position during the review. Parrish—a Toronto-area MP with a reputation of being a maverick—was not a member of either the Industry or Health Committee prior to the review, but had found her way onto the Industry Committee shortly after the hearings began. Like Patry, Parrish's significant support from the brand name industry is interesting, as she appeared to be marginal member of caucus. It might be indicative of her work on the Committee, where she stood out as particularly combative with witnesses challenging the position of the brand name industry.

During the 1997 election campaign, the generic industry once again supported Toronto MPs, including Caplan ($3,200), Marchi ($3,000), Brown ($1,735), Eggleton ($1,500) and Volpe ($1,000) (see Table 4.1). Both Brown and Volpe were key figures in the Industry Committee's review, where they had supported the generic industry's position. For their part, Marchi and Eggleton had been Cabinet ministers during Chrétien's first term. While Caplan had not been on the Industry Committee or in Chrétien's Cabinet, she had been Minister of Health in a previous Ontario Liberal government and was slated for a Cabinet

position.[140] Other Liberal candidates receiving significant support from the generic industry were Cauchon—a rising star in the LPC who would go on to become a Minister in Chrétien's second government;[141] Gray ($3,000); and Chrétien ($2,000).

After the Election – Policy Amendments

On June 2, 1997, Canadians returned the Liberals to power with a second consecutive majority government. Manley retained his Ottawa seat, while Dingwall was defeated in Cape Breton. During the election campaign, Manley was subjected to various smear campaigns,[142] allegedly orchestrated by the Chairman and CEO of Apotex, Barry Sherman. These tactics, in response to the Liberal's inaction on the patent file, did not sit well with the PM or fellow Liberals (Anonymous, interview).

Manley was returned to his post as Minister of Industry[143] while Allan Rock—a Toronto MP and former Minister of Justice—was appointed the new Minister of Health. Recall that the Government had decided prior to the Industry Committee hearings to uphold the 20-year patent period, while remaining open to changes to the Linkage Regulations. Deliberations regarding the fate of the Regulations commenced shortly after the election and an important meeting was

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[140] Caplan would go on to become a Cabinet minister during Chrétien's second term.
[141] Along with fellow Montreal Liberal candidates Robillard and Pettigrew, Cauchon's pharmaceutical contributions came from Rogier Inc., one of the few Montreal-based generic companies.
[142] Posters were put up outside John Manley's campaign office stating that he was the enemy of healthcare (Anonymous, interview)
[143] Speculation was that Manley's ability to handle the sensitive patent file greatly impacted Chrétien's decision to return him to his post at Industry (Eggertson, 1997c).

set for Cabinet Committee, where Manley and Rock had agreed to collaborate on a presentation regarding minor amendments to the Regulations;[144] however, things did not go as planned (T. Macerollo, interview, July 17, 2008).

The night before this meeting was to take place, the PMO and Privy Council Office learned that Rock had decided not to participate in a scheduled joint presentation with Manley, calling for moderate changes to the Regulations. Instead, Rock decided to deliver his own presentation in an attempt to persuade other Ministers to support his proposal for repealing the Linkage framework. At the end of the presentations, the Ministers supported Manley.[145] At this point, Chrétien handed the patent file to Manley, permitting his office to decide the fate of the Linkage Regulations without input from Health.[146] Shortly after, Manley made the decision to maintain the existing Linkage framework, while proposing minor amendments which are outlined below.

First, amendments granted the Minister of Health the authority to audit the active patent list to remove irrelevant patents. In the past, brand name companies had included inappropriate patents on the Minister's list, while challenging the Minister's authority to audit that list. These amendments clarified the Minister's powers (Smith, 1998).

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[144] Discussions at Cabinet Committee were conventionally used to form consensus—do the 'heavy lifting'—on issues before they were taken to full Cabinet (T. Macerollo, interview, July 17, 2008).

[145] There was speculation that the other Cabinet ministers had voted against Rock despite being sympathetic to his position. In the view of one official close to the proceedings, the other ministers were weary of Rock's individualistic, "freelancing" style, and had voted against him to convey their disapproval of his tactics and their unease with surprises at the Cabinet table (Anonymous, interview).

[146] In regard to the PM's decision, an anonymous Liberal official close to the proceedings stated that there was little doubt in his/her mind, that it was a combination of Sherman's actions and Rock's decision to go on his own that persuaded Chrétien to go forward with one clear leader—Manley—on the file (Anonymous, interview).

Second, amendments required generic companies to provide greater detail in their NOA submissions. In particular, when making a claim that their proposed drug would not infringe on existing patents, generic companies were now required to explicitly list the dosage form, strength and route of administration (Smith, 1998).

Third, amendments obliged generic companies to disclose information from their NOC applications in situations where such information was deemed pertinent to an infringement case. Furthermore, amendments shifted the burden of proof onto generic companies in situations where they wished to manufacture a version of a brand name product, while alleging non-infringement of a process patent (Smith, 1998).

Fourth, amendments provided the courts with broader powers to dismiss cases involving irrelevant patents or frivolous charges. In addition, judges were now authorized to award damages to generic companies under certain circumstances (Smith, 1998).

Finally, amendments decreased the maximum stay period from 30 to 24 months. Moreover, provisions were included to provide judges with the power to modify the stay period in conjunction with the level of cooperation exhibited by the respective parties to the case (Smith, 1998).

Maintenance of the basic Linkage framework was consistent with Industry Canada's position from the outset, as it had supported PMAC's claim that the Regulations did not delay generic companies from brining their products to

market.[147] The decision to propose a decrease to the maximum stay period was a reflection of the Government's belief that the average period for a NOC approval had decreased. Therefore, from the perspective of the Government, the maximum stay period needed to be reduced to align it with the time involved in an NOC application process. The Government maintained that these amendments were an attempt to try and improve the fairness of the process, while discouraging both industries from trying to take advantage of the system. (T. Macerollo, interview, July 17, 2008).

These proposed amendments were published in the Canada Gazette, Part I, on January 24, 1998 and approved by Cabinet on March 12, 1998. Essentially, these amendments had been decided upon immediately after the 1997 election—following Rock's miscalculation—and kept quiet by the Government for the better part of a year (T. Macerollo, interview, July 17, 2008). The above changes to the Linkage Regulations would represent the Chrétien government's total response to the Committee's final report. Despite the Industry Committee's recommendations, no apparent action was taken by the Government to explore the possibilities for a national pharmacare program, increase public access to the PMPRB's information, or negotiate with the pharmaceutical industry for a health research funding program. Furthermore, despite the Committee's explicit request in the final report, no official response was tabled to Parliament by the Minister of Industry or the Minister of Health. It should be noted that in response to one of the recommendations, the OAG—an agency that operated

[147] The government took this position on the basis that they believed that the injunction process ran parallel to the NOC application process (T. Macerollo, interview, July 17, 2008).

independently of the executive branch—did institute an full audit of the PMPRB in 1998, the findings of which are explored in detail below.

The "Draft" Committee Report

In September of 1997, the CHC obtained[148] a copy of a "draft report" from the Industry Committee's work. Unlike the final report appearing on the Parliamentary website (Canada, 1997i), this "draft report" included several recommendations that would have had a negative impact on brand name companies. At the time, Mike McBane—co-coordinator of the CHC—insisted that the changes to this "draft report" were the result of political interference by Manley's office (Russell, 1997). McBane charged that the Government had intervened to change the Liberal membership of the Industry Committee to ensure that numbers were sufficient to pass Manley's preferred version of the Report (Russell, 1997). Some of the recommendations appearing in the Committee's "draft report" include:

1) Legislative amendments should be made to the Income Tax Act to allow Revenue Canada to audit patentees in regards to their R&D tax deductions;

2) The PMPRB should provide a detailed report to Parliament on its methodologies for setting introductory prices for new, breakthrough patented medicines;

3) The Government should ask the WTO to reevaluate its minimum 20-year patent period;

4) Legislative changes should be made to allow generic drug companies to copy the size, shape and colour of brand name drugs;

[148] The report was obtained for CHC by Ottawa researcher Ken Rubin under an access to information request.

5) An exemption should be granted to generic companies, to allow them to manufacture medicines patented in Canada for export to countries where the drug is off-patent; and,

6) The Linkage Regulations should be repealed (Russell, 1997).

Interestingly, every single recommendation from the "draft report" would have been either beneficial to the generic industry, or detrimental to the brand name industry. There are two explanations provided for the "draft report".

The first comes from McBane: the Committee formulated a pro-generic report that was subsequently undermined by Industry Canada. According to McBane, a "draft report" favourable to the generic industry and satisfactory to the majority of the Committee's membership was drafted by the Committee Clerk.[149] Walker altered the report on orders from Manley's office, because it would have presented the Government with significant political difficulties. The Government then changed the Committee membership to ensure support for the amended report, which was subsequently passed (Russell, 1997).

This was not denied by Liberals[150] close to the proceedings. According to Walker, the composition of federal committees was very fluid in general and a reshuffling of the Committee would not have been unusual considering the political magnitude of the report on the eve of a federal election. Walker did remember that at least one Ontario Liberal was dropped from the Committee for refusing to support the Government's position (D. Walker, interview, August 20, 2008).

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[149] The Committee's final report identifies Susan Baldwin as the Committee Clerk (Canada, 1997i).
[150] Neither Walker (interview, August 20, 2008) nor Macerollo (interview, August 22, 2008) denied the reshuffling of the Committee, but neither confirmed it either.

Although he also had difficulty remembering, Macerollo offered a second explanation of what may have happened. Macerollo argued that the "draft report" was probably not something that had been agreed upon by the Committee, but rather an initial draft by the Committee Clerk to serve as a starting point for discussions by the members. According to Macerollo, it was the job of the Committee Clerk to consider the testimony from the hearings to come up with a summary report, which may or may not include recommendations (T. Macerollo, interview, August 22, 2008).

This version is somewhat corroborated by Walker. He agreed that in all likelihood, the Clerk would have drafted her own report with input from the parliamentary research officers. However, while this report may have been representative of the overall tone of the hearings and the general perspectives of the Committee members, its contents would not have reflected the political priorities of the Government (D. Walker, interview, August 20, 2008). This may account for the existence of two reports arriving at opposite conclusions. Regardless of which version of events is correct, it is interesting that the Clerk felt that the Committee's overall response was so favourable to the CHC and CDMA. Furthermore, these accounts are suggestive of the Government's overwhelming influence on the contents of the recommendations.

The Office of the Auditor General's 1997 Report on the PMPRB

In response to one of the recommendations in the Industry Committee's final report, the OAG carried out a preliminary audit of the PMPRB in early 1998.

Following its preliminary work, the OAG decided to proceed with a "full-value-for-money audit" of the Board to evaluate the Board's interpretation of pertinent legislation, its methodology for regulating patented medicine prices and the accuracy of the Board's analysis of the impact of federal regulation on patented medicine prices (Canada, 1998). In September 1998, the OAG issued an audit report that was critical of the Board's practices. Owing to the credibility of the OAG and its stature within the federal government, its findings are important and are outlined below in some detail. In addition, clarification—where necessary—that demonstrates the OAG's rationale for arriving at conclusions and proposing recommendations is also provided.

Recommendation #1 – Measuring Other Factors

In the view of the OAG, the Board needed to do a better job of measuring its own effectiveness by reporting on all factors impacting patented drug prices, and not just federal pricing regulation. The Board had estimated that its activities had saved the Canadian health care system between $2.9 billion and $4.2 billion. The OAG felt, however, that this overestimated the Board's impact, as it failed to consider the effect of provincial cost-containment strategies,[151] increased market penetration by patented drug producers and the influence of private health insurance programs. In the opinion of the OAG, taking these other factors into account was feasible considering available methodologies (Canada, 1998).

[151] One particularly effective example of provincial regulation of prices is BC's referenced-based pricing system, in which only the least expensive drug was covered where there is a lack of evidence that more expensive therapies are more effective (Canada, 1998).

Recommendation #2 – Review Pricing Methodologies

Not satisfied with the price-setting methodologies outlined in the actual Patented Medicine Regulations, the OAG recommended that the Board consult with the Government on the need to review legislation and regulations relating to the pricing of new "breakthrough" patented medicines. In particular, the OAG felt that the Regulations needed to be amended to require the Board to use foreign transaction prices in helping to set Canadian transaction prices. As it stood, the Board was only required to use foreign list prices, which inflated Canadian transaction prices by not factoring in foreign discounts and rebates (Canada, 1998).

The OAG was also skeptical of the Board's use of the basket of seven comparator countries. The OAG felt that these comparator countries were poor candidates for comparison, as they all had different price regulation systems than Canada.[152] Furthermore, the OAG found that in 20% of all cases, the only other country selling a particular drug was the US, which had the highest prices of all seven comparator countries. In those cases, the only restriction on a new Canadian price was that it could not be more expensive than the corresponding US price. Consequently, high US prices were leading to high new Canadian prices in a significant number of cases (Canada, 1998).

Recommendation #3 – Rigorous Application of Guidelines

The OAG's third recommondation was that the Board apply its own guidelines more rigorously and ensure that the reasons for, and the impacts of,

[152] The exception was the US, which had no system at all (Canada, 1998).

its decisions are transparent when exceptions are made. The OAG outlined a number of cases in which the Board failed to meet this standard (Canada, 1998). For instance, in 1997, 15% of patented medicines had exceeded the allowable price, but approximately 13% of those cases were not pursued by the Board. The Board justified this lack of follow-up on the grounds that excess revenues accrued were too small to warrant investigation. However, by the OAG's calculations, high prices for these products had resultd in excess revenues of approximately $1.2 million in 1997. In reporting to Parliament, the Board had misled MPs claiming that these drugs were priced within the guidelines. Furthermore, there was little reason to believe that the Board's approach had been any different in previous years, which suggests that a signficant amount of money may not have been collected over that time (Canada, 1998). In addition to allowing prices to rise too quickly, the Board was also guilty of ignoring its guidelines with respect to introductory pricing. In allowing the initial price of one particular new drug to be above all of the comparator countries, the Board allowed one company to reap almost $5 million in excess revenues between 1993 and 1997 (Canada, 1998).

Recommendation #4 – Verifying Price Information

The OAG's fourth recommendation was that the Board identify cost-effective means to verify price information provided by brand name companies. The OAG was surprised by the extent to which the Board relied on brand name companies to provide pricing data—both foreign and domestic—and expressed

concern regarding the quality of these data.[153] While acknowledging the Board's lack of resource capacity, the OAG noted that very few audits had been carried out to verify the accuracy of industry-supplied pricing data. These concerns were validated by a 1997 external review of industry-supplied pricing information, which concluded that foreign prices submitted to the Board were, on average, higher than the actual prices (Canada, 1998).

Recommendation #5 – Increased Collaboration with Statistics Canada

The OAG's final recommendation was that the Board work more closely with Statistics Canada to improve the accuracy of its reporting on drug pricing trends. While the Board had devised its own index—the Patented Medicines Price Index (PMPI)—to measure and report on pricing trends for patented medicines, the OAG discovered disparities between the PMPI and Statistics Canada indices. These discrepancies raised concerns about the reliability of the Board's measures, suggesting a need for greater collaboration (Canada, 1998).

In summary, the OAG identified many areas where the Board needed to improve, some of which required government intervention. In particular, the OAG felt that the Board required more resources and a greater level of expertise to verify industry pricing information. Moreover, the OAG recommended that changes be made to the Patented Medicine Regulations that would enable the Board to set fair prices for new patented medicines. Furthermore, the OAG felt

[153] This skepticism was fueled by the impact that this pricing information had on the profitability of brand name companies (Canada, 1998).

that the Board needed to operate in a more consistent and accountable fashion, especially in regard to its reporting requirements and application of pricing guidelines.

These findings support many of the concerns raised by Lexchin and some Committee members during the hearings. Furthemore, the conclusions of the OAG corroborate charges leveled at the Board by former employee Arthur Jenkinson. In an interview with the CHC in the Summer of 1997, Jenkinson was critical of the Board's practices and organizational culture. Similar to the OAG's findings, Jenkinson alleged that the Board rarely verified pricing data provided by brand name firms, pricing data was usually provided for only two or three of the highest priced countries, the Board's price comparisons resulted from comparing different—list and transaction—prices[154] and the Board had misled Parliament on the subject of pricing trends[155] (CHC, 1997).

In addition to these charges, Jenkinson claimed that the Board operated in a secretive and unaccountable manner, while holding a significantly biased view favouring PMAC and its members. In fact, Jenkinson went so far as to allege that this bias was so ingrained that any data or employee found challenging PMAC or its members was discarded or dismissed by the Board's leadership (CHC, 1997). While problems identified by Jenkinson and corroborated by the OAG were serious enough to warrant immediate attention, one could argue that the allegations of systemic bias and secrecy—if true—are at least as crucial.

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[154] In Jenkinson's opinion, ignoring the differences between list and transaction prices probably lead to average price increases of up to 50% (CHC, 1997).

[155] Jenkinson charged that the Board omitted excessively priced drugs from its pricing index, resulting in "flawed data" and "skewed comparisons" with the rate of inflation. According to Jenkinson, these omissions allowed drug prices to rise higher than their guidelines permitted (CHC, 1997).

Moreover, Jenkinson's credibility in light of the OAG report and its findings suggests that these other charges could be legitimate and deserving of thorough investigation.

CHAPTER 5 – Main Findings and Conclusions

Introduction

This chapter begins with a review of the main findings of the thesis. These findings are organized into seven sections, each addressing a particular component of the thesis statement. The chapter concludes with an outline of the thesis' contributions, a brief commentary on the role of agency in policy development, a list of the thesis' limitations, and finally, some suggestions for future study.

Main Findings

The main findings of the thesis are outlined below and are organized into sections to address the following issues: (1) PMAC's exploitation of Quebec politics and the Liberal governments response to this strategy; (2) regional-linguistic divisions within the LPC, which were linked to economic development and political donations; (3) the significant financial support provided by the brand name industry to the LPC; (4) divisions between Industry Canada and Health Canada over the review; (5) the rhetorical strategies employed by the different stakeholders to the review; (6) the different ways in which the Government influenced the review; (7) the Government's policy decision following the review, which favoured the brand name industry; and, (8) the resource capacity strength of the brand name industry, which helped it secure a favourable policy outcome.

PMAC's Exploitation of Quebec Politics

The concentration of brand name pharmaceutical companies in the Montréal area, along with the important economic role played by the industry in Quebec, left Quebec's pharmaceutical industry vulnerable to exploitation by the brand name industry. Indeed, the political situation in Quebec had factored in the debates around previous Bills targeted at the pharmaceutical industry. In these cases, concern for alienating Quebec voters helped to mute Liberal opposition to strengthening patent protection (Campbell & Pal, 1994).

Quebec's role in recent debates suggests that exploitation of its political situation remains fruitful for the brand name industry. In this case, PMAC informed a Minister of the Liberal Quebec government (Tremblay) that a local, multi-million dollar investment would be stalled if the federal government chose to conduct an immediate review of Bill C-91. Subsequently, the Minister went public with this information, along with his opposition to a review. In revealing these threats, Tremblay publicized the issue and elevated it to a serious matter of federal-provincial concern.

As a result of Tremblay's comments, the Liberals faced a barrage of questioning from the BQ regarding the review of Bill C-91. Sensing the Government's vulnerability, the Bloc attempted to damage the Liberals by accusing them of indifference to the economic wellbeing of Quebeckers. In the end, PMAC's intervention was successful at reminding the Government of the brand name industry's power to exploit the Quebec political situation, while also

persuading the Government to announce that a review was not imminent and would not impact the 20-year patent period.

The Liberal government's concern for political fallout in Quebec was related to three primary issues: support for federalism in Quebec, a decline in Quebec voter support (primarily in Montréal) and the risk of regional divisions within the Party. The first two issues are closely related, as the LPC's electoral success in Quebec is linked to Quebeckers' support for federalism, especially with the recent rise of BQ—a viable sovereigntist option.

Recall that the review was conducted only 16 months following the narrow federalist victory in the 1995 Quebec Referendum. During the period in which the review was carried out, the federal government had embarked on a number of post-Referendum manoeuvers designed to pacify separatist sentiments, improve the federal government's image in Quebec and strengthen Quebecker's identification with Canada. These initiatives were in addition to steps taken by the LPC to fulfill promises made during the Referendum campaign, including passage of a resolution recognizing Quebec as a distinct society, increasing Quebec's power—and the power of other provinces—to prevent constitutional amendments and the transfer of control for labour market training to Quebec. These tactics are often referred to as the Plan A measures of the federal government's response to its narrow victory in the Referendum, employed to try and shore up support for federalism and position itself for the upcoming election (T. Macerollo, interview, August 22, 2008).

Historically, the Liberals had been the preferred federalist option in Quebec, relying on a strong electoral performance in the province to bring them to power. In Quebec, the Liberals had benefited disproportionately from Canada's first-past-the-post system, often taking a greater percentage of seats than its share of the popular vote. Despite finishing a distant second to the BQ in Quebec in 1993, the Liberals had been able to form a majority by virtue of the absence of a viable national alternative, the fragmentation of the political right and the emergence of regional parties (Carty et al., 2000). While the Party hoped to improve upon its 1993 performance in Quebec, holding its advantage in the Montréal area—a predominantly Anglophone region and traditional bastion of LPC support—was a priority.

Outside of Montréal, the BQ had limited the Liberals to only four seats in the 1993 election. Holding Montréal and increasing its seat count in the rest of Quebec—if only by a few—would likely dispose the BQ from its status as the Official Opposition, a position it had used to hammer the Liberals on issues related to Quebec.[156] Freeing themselves from the daily wrath of the Bloc would have been a positive development for the Liberals, who were keen to avoid political problems in an important electoral province like Quebec.

Indeed, considering the "damage control" mode that the Liberals were in following the Referendum, it's easy to understand how the politics surrounding the review would motivate them to side with the brand name industry and

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[156] In effect, this is what ended up happening. The Liberals increased their Quebec seat count from 19 to 26, while the BQ fell from 54 to 44. The Quebec seats that were not picked up by the Liberals were won by the PC's. This change in Quebec coupled with the increase in seats won by the Reform Party helped Reform to replace the BQ as the Official Opposition.

maintain the pharmaceutical policy; which, according to Macerollo (interview, August 22, 2008), is precisely what happened. Cognizant of the shortcomings and bias of the Linkage Regulations, the Government recognized that it could have presented a reasonable argument for repeal, especially in light of the of the irregular cross-departmental (Industry and Health) linkages. However, the Government believed that this course of action would have provoked a significant backlash from the brand name industry, one which would have likely targeted Quebec:

> If the Regulations had been repealed [...] the brand name companies would have been forced to go through the courts to try and prove irreparable harm had been done to them [through patent infringement]. The headquarters for many of the brand name companies would likely have decided that [Canada] simply wasn't a good place to do business. It is realistic to assume that a couple of decisions to locate facilities in Montréal would have been cancelled (T. Macerollo, interview, August 22, 2008).

Such a development would have been damaging to the Quebec economy, as well as the political fortunes of the LPC in Quebec—specifically in Montréal. Stalled investments or the relocation of facilities outside of Montréal would have negatively affected the regional economy. In all likelihood, this would have precipitated a decline in voter support for the Liberals in the upcoming federal election and perhaps the level of brand name donations to Montréal Liberal candidates.

Since the brand name industry has always benefited from changes to Canadian patent policy, it is difficult to gauge Macerollo's assessment of their reaction. Indeed, one might question whether an extreme response by the industry made good business sense, considering the benefits of doing

pharmaceutical research in Canada.[157] However, the Government believed that Canada's unique position as a precedent-setting country in the global pharmaceutical industry would have ultimately conditioned the industry's response to unfavourable policies emanating from the review:

> They would have carried out their threats [to decrease investment], because of the precedent [Canada's policy] would have set. In Canada, we have a tendency to want to have our way, every which way. One of our [attributes] or the reasons we've been successful at this, has been a function of the fact that we are not a precedent-setting example for jurisdictions around the world. [In] this sector though, [Canada] had the potential to be precedent-setting, [and because of this], the response from the brand name industry would have been serious. [For example], a company like Merck likely would have said that we cannot live with the situation in Canada, because if we let that happen, it has the potential to replicate itself in many other jurisdictions. So, we've got to be clear that we're not going to invest in jurisdictions where there is no effective patent protection (T. Macerollo, interview, August 22, 2008).

Due to Canada's precedent-setting role in pharmaceutical policy, there appears to have been a reasonable business case for divestment had there been a decrease in patent protection. Furthermore, for maximum impact, it seems sensible to assume that retaliatory action by the industry would have focused on their investments in Quebec; a damaging prospect for the Government's Plan A strategy and its electoral aspirations.

Regional Divisions – The Montréal and Toronto Caucuses

Recall that the LPC caucus was divided on the issue of pharmaceutical patent protection, with the main lines of division drawn between MPs from the

[157] Some advantages of doing business in Canada include low tax rates for businesses, an educated workforce, publicly-funded healthcare, a stable political situation and a strong scientific community.

Montréal and Toronto areas. This regional split in the LPC caucus was derived on the one hand from the geographical distribution of the Canadian pharmaceutical industry, and on the other, from political donation profiles.

Montréal Liberal MPs supported the position of the brand name companies, many of which were located in their region. This support was primarily related to local economic concerns, and to a lesser extent, political donations from brand name companies. Concern for the local economy derived from fear that that brand name industry would reduce its investments in Quebec in retaliation to government polices that ran counter to its interests. Montréal Liberal candidates worried about the potential political fallout—decreased voter support—from the economic impact that might result from such action.

Some Montréal Liberal candidates benefited from the financial support of the brand name industry. During the 1993 election campaign, several Montréal Liberal candidates received modest donations from the brand name industry (Elections Canada, 2008a), while a few received significant contributions. During the 1997 election campaign, the brand name industry increased its support for Montréal Liberal candidates, targeting several large donations at former Industry Committee members and those slated for positions in Chrétien's next Cabinet.

The generic industry enjoyed the vocal support of several Liberal MPs from the Toronto area. However, rather than local economic concerns, it's more likely that this support was linked primarily to political donations, as the brand name industry had a similar, if not greater, economic impact on the regional economy of Toronto. The targeting of political donations at Toronto Liberal

candidates during the 1993 election campaign may have been linked to assurances by some Toronto candidates that a Liberal government would repeal Bill C-91. While Toronto Liberal candidates benefited from several modest donations from the generic industry during the 1993 campaign (Elections Canada, 2008a), a few received significant contributions. During the 1997 election campaign, Toronto Liberal candidates were once again supported by the generic industry, including several large donations to former Industry Committee members as well as those lined up for Cabinet positions in the next government. It appears that both the brand name and generic industries targeted their support at Liberal candidates who had either shown support for their respective interests, or were slated for influential positions in an upcoming government.

The discord between Montréal (primarily French) and Toronto (English) Liberals over the review was a potential political problem for the LPC, as the Party wished to present a united front on the patent issue, avoid publicity of French-English divisions within the Party and avoid defections by Montréal members. It has been suggested that on many issues—including this one—the Montréal caucus was more organized and strategic compared to the Toronto caucus, a factor that may have influenced the Government's eventual decisions regarding the review (T. Macerollo, interview, July 17, 2008; Clarkson, personal communication, July 7, 2009). After coming to a decision at Cabinet regarding the limited parameters of a review, the Government took steps to try to maintain Party unity and avoid alienating MPs from the Toronto caucus. This included a compromise to modify the Liberal membership of the Industry Committee to

include more Liberals opposed to Bill C-91 (T. Macerollo, interview, July 17, 2008). Despite these modifications, the Industry Committee's membership remained biased in favour of the brand name industry's position.

Brand Name Industry's Political Contributions to the LPC

The brand name industry was a major contributor to the LPC throughout Chrétien's first term. Brand name contributions to the Party peaked in 1996 and 1997—the two years prior to its decision to maintain the then-current policy—with approximate totals of $114,000 and $116,000, respectively. In those same two years, the generic industry's contributions were approximately $64,000 and $38,000, respectively. According to these figures, the financial support provided by the brand name industry to the LPC was significantly greater than that of the generic industry during the period when the Government was deciding how to manage and then respond to the review.

Before Chrétien reformed Canada's political financing rules in 2003, the LPC was largely dependent on corporate donations for both its day-to-day operations and election campaigning. The dependence of the LPC on corporate donations and the discrepancy in the financial support provided by the two industries might suggest that the Government's decision to maintain its pharmaceutical policy was influenced, to an extent, by the financial support provided by the brand name industry and the Party's desire to continue receiving such support in the future.

Bureaucratic Divisions – Health Canada and Industry Canada

Industry Canada and Health Canada held competing perspectives on a preferred direction for pharmaceutical patent policy. Industry's support for the then-current policy emanated from its responsibility for creating a business climate conducive to attracting foreign investment to Canada. Health's opposition was linked to its mandate to help Canadians maintain and improve their health; pressure from the provinces to bring down drug costs; and an institutional aversion to administering the *Patent Act* via the Linkage framework (T. Macerollo, interview, July 17, 2008). A rift between Industry and Health regarding the patent file emerged early on in Chrétien's first mandate, forcing the Government to seek a compromise. Despite great effort on the part of the PMO and Ministerial staff, neither department demonstrated much flexibility (M. Loveys, interview, July 7, 2008).

The difference in perspectives on patent protection between the two departments was exhibited by statements made by their respective Ministers. In comments made to the House of Commons and the press, Manley was unequivocal regarding Industry's support for patent protection and his confidence in the important role it played in securing greater investments in Canada. While more nuanced than Manley, Health's opposition to the policy was revealed through comments made by Marleau in Question Period (Canada, Parliament, House of Commons, 1994d) and to the press ("Marleau refuses", 1994). As a result of her dissention, Marleau was eventually replaced by Dingwall (Fuller, n.d.) who, while supportive of consumers and the generic industry, was careful to

temper his criticisms of the Government's pharmaceutical policy in public (Geddes, 1996).

Dingwall's tacit opposition to the Government's pharmaceutical policy continued during the Industry Committee's review, as the Government had banned caucus members from speaking out against Bill C-91 (Eggertson, 1997b). In remarks to the Committee and press, Dingwall expressed resigned support for the Government's position on patent protection (Eggertson, 1997a); however, while the review was ongoing, Dingwall attempted to shore up Cabinet support for changes to the Linkage framework and the PMPRB (T. Macerollo, interview, July 17, 2008). His desire to secure these changes was evident from several comments to Committee members during his testimony. Also representing Health's position during the Committee hearings was Volpe, who acted as Dingwall's PS. Unlike Dingwall, Volpe was free from the more rigorous constraints of Cabinet and was among the group of Committee members who were the most aggressive in their questioning of witnesses supporting greater patent protection.

Following Dingwall's defeat in the 1997 election, Rock—the new Minister of Health—continued the defense of Health's position at Cabinet. In the end, however, Rock's proposal for an elimination of the Linkage framework was rejected by Cabinet and Manley was permitted to make the final decision regarding the Linkage Regulations without input from Health. Predictably, Manley's decision—the essential maintenance of the basic Linkage framework—largely reflected the interests of Industry while ignoring those of Health.

Stakeholder Strategies – Revisiting Stone's "Languages"

Throughout the period surrounding the review of Bill C-91, each of the stakeholders employed a set of tactics to try and to protect, or realize, their particular interests. This section considers the different techniques and "languages" outlined by Stone (2002) to analyze the strategies of each of the stakeholders, including the Government, PMAC, the CDMA, the CHC, the PMPRB, IBAC and the three provinces appearing before the Committee.

Prior to the hearings into Bill C-91, the Government's main strategy was to avoid commitment and controversy by remaining *ambiguous* regarding its intentions on a review of Bill C-91. To this end, the 1993 Red Book—which had served as the Liberal's platform—had been purposefully vague about patent protection (T. Macerollo, interview, July 17, 2008). After coming to power, the Government was pressured by both the brand name and generic industries to reveal its plans for a review. In response, the Government continued to *conceal* important information to avoid the political consequences, while giving itself flexibility to react to changing circumstances. Moreover, by waiting to make its intentions on a review public, the Government sought to induce the brand name industry to pledge further R&D commitments in exchange for maintenance of the then-current policy. This pattern of *evasion* continued until late April 1994 when Manley finally announced that a review would be held within the required four-year period.

During the Committee's hearings, Manley and Dingwall made statements designed to express to stakeholders and Committee members the Government's

general perspective on the issues and to indicate what types of *decisions* the Government considered realistic. These statements helped to place practical limits on the types of solutions proposed and discussed during the hearings, as clearly there was little point in wasting time on options the Government had already labeled as infeasible, or undesirable.

Manley praised the impact of Bill C-91 on Canadian investment and declared—as he had before the review—that the Government intended to honour the 20-year patent period outlined in NAFTA and TRIPS. Moreover, he stated that the Government did not feel that PTR was appropriate for Canada.[158] For his part, Dingwall informed the Committee that the Government would consider changes to the Linkage Regulations as well as the methodology for setting Canada's introductory prices for new patented medicines. Privately, Manley was in constant contact with Liberal Committee members where he expressed to them which *decisions* were politically feasible for the LPC. In response to these constraints, Walker designed the Committee's final report to include *ambiguous* recommendations, leaving the Government plenty of wiggle room to proceed in its preferred direction.

PMAC argued that the public *interest* was best served by providing strong patent protection to research-based companies such as brand name pharmaceutical firms. It argued that the global nature of the pharmaceutical industry meant that R&D investment dollars—leading to jobs and increased economic activity—would flow to the jurisdictions with the most effective patent protection. Although PMAC explicitly focused on the public interest during its

[158] This did not stop PMAC from presenting a case for PTR.

testimony, the implicit message was that strong patent protection would also serve the LPC's political interests by shoring up electoral support in Montréal.

Throughout its testimony, PMAC attempted to frame the situation in terms of Stone's *narrative of stymied progress*. PMAC maintained that its members—as well as Canadians—had benefited from the recent changes to patent protection, but that the industry was being held back by resistance to those changes and new measures to bring Canada's policies in line with its trading partners.

There was much disagreement among stakeholders as to whether or not the Linkage Regulations were hindering generic companies from attaining NOC's in a timely fashion. To support its position that the Regulations were having minimal impact, PMAC focused on the small number of cases (four out of 58) that had gone through the court process and outlasted the average NOC approval time. By emphasizing this particular *measure*, PMAC was able to ignore essential details by focusing on a small slice of information from a very complicated process.

To demonstrate that the brand name industry had lived up to its R&D commitments, PMAC focused on its members' average R&D investments according to the definition supplied by the Scientific Research and Experimental Development program of the Canada Income Tax Act. Concentrating on this particular *measure* allowed PMAC to argue that it had lived up to its commitments. However, this particular statistic ignores the details and

controversy surrounding the important differences between basic and applied research and the flexibility of the Income Tax definition.

Throughout the proceedings, PMAC and its representatives were often *evasive* and *ambiguous*. Committee members attempted to gain clarity from PMAC on various items, including whether PMAC would commit to attaining the international standard on R&D in Canada and what PMAC considered to be an acceptable period of market exclusivity in the context of effective patent protection. PMAC was also vague when asked why they could not provide information regarding the actual R&D costs for drugs to be used as a basis for setting introductory prices for new patented medicines. In most of these cases, it appeared as if PMAC was attempting to avoid making commitments that would limit its future bargaining position, while trying to keep information secret that could negatively impact the profitability of its members.

As a result of the shared interests among generic manufacturers and consumers, the CDMA was able to emphasize the extent to which its proposals served the public *interest*. While consumers and CDMA members were both negatively impacted by Bill C-91 amendments, the CDMA argued that its proposals would save consumers money and have a positive effect on the accessibility of pharmaceuticals. The CDMA's calls for lifting of the export ban and the creation of a law mandating similar appearances of generic and brand name drugs were also advanced in the name of the public *interest*.

In making its case to the Committee, the CDMA relied on a selective group of *measures* that placed the activity of its members in a favourable light,

while disparaging the activity of brand name companies. With regard to the Linkage Regulations, the CDMA focused on the *number* of frivolous lawsuits brought forward by PMAC, while presenting statistics that demonstrated the financial impact of these lawsuits. Another *measure* highlighted by the CDMA was the recent growth in R&D investments by its members. Certainly, much had been made before and during the hearings about the importance of attracting R&D investment from PMAC members. By presenting statistics to the Committee that demonstrated that generic firms could also be significant contributors to the economy, the CDMA was attempting to bolster its position on this important front.

As a not-for-profit organization with a mandate to protect and expand Canada's public health system, the CHC was able to present its arguments for lowering drug costs free from the perception of any financial conflict of interest. If any stakeholder could genuinely claim to be acting in public's *interest*, it was probably the CHC. The Coalition presented *measures* demonstrating the negative impact that Bill C-91 had on the cost of medicines to Canadians. In presenting their case, the CHC countered several of the arguments advanced by the Government, the PMPRB and PMAC. Using selective statistics, the CHC demonstrated the ineffectiveness of the PMPRB, the extent to which prescription drug costs had been rising and the exaggerated character of PMAC claims regarding the significance of its members' R&D investments. Moreover, the CHC took issue with the Mulroney government's *decision* to—ostensibly—pursue greater R&D investments by providing stronger patent protection. According to

the CHC, beyond pure politics, no such association between patent protection and investment existed.

The CHC reminded Committee members of the recommendations made by the Prime Minister's NFH, specifically its call for a national pharmacare strategy and an industry-funded health research body. The CHC was the only stakeholder to present an argument for either of these proposals, both of which were designed to benefit Canadian citizens rather than industry. In recalling and then stressing these proposals to the Committee, the Coalition tried to make the case that these were legitimate and feasible *solutions,* which needed to be considered.

In calling for an independent body to steer health research in a direction that served the public *interest*, the CHC evoked Stone's (2002) *narrative of decline and control.* The decline and control storyline suggested that while health research had once been pursued largely for the advancement of knowledge and the benefit of society, it was now organized around profitability and other imperatives of industry. The CHC argued that the public needed to reclaim control of the health research agenda and that an organization such as the MRC was one mechanism by which to do so.

While arguing forcefully that a *decision* by the Government to implement a national pharmacare strategy was feasible, the Coalition cautioned that the affordability of such an initiative would depend on a return to some form of compulsory licensing. The CHC presented a legal opinion that Canada was within its trading rights to make use of compulsory licensing so long as the drugs

produced were targeted at a government initiative, such as a universal drug program. This claim by the CHC followed Stone's (2002) *narrative of control*, which suggested that we—Canadian citizens and our government—could do something about the situation, despite being told that it is impossible and out of our hands. By claiming that compulsory licensing was still possible despite NAFTA and TRIPS, the Coalition disputed the Government's stated opinion. In challenging the Government's assertion regarding the feasibility of compulsory licensing, the CHC seemed to be suggesting that the Government was engaged in a *conspiracy* to keep drug prices artificially high.

In presenting its perspective on Bill C-91, the PMPRB presented several *measures* which indicated the compliance of PMAC members on pricing and meeting its R&D commitments, as well as the effectiveness of the Board at regulating patented medicine prices and enforcing its own guidelines. While other stakeholders explored the details behind the Board's pricing methodologies and the brand name industry's R&D claims, the PMPRB chose instead to provide basic statistics without context or critical analysis.

During the hearings, the Board outlined a close working relationship between its staff and PMAC members, one in which the Board was dependent on PMAC members for pricing and investment information. Owing to the Board's mandate to ensure compliance with its pricing guidelines, there is a concern that *reactivity* may have played a part in any one of several stages of data collection, analysis, or presentation. Furthermore, because of the political importance of the Board's work and the huge sums of money involved in drug pricing, there was

also the genuine risk that PMAC members may have used any number of inducements to *influence* the reporting of Board members.

From the perspective of the biopharmaceutical firms—represented by IBAC—the important issue surrounding Bill C-91 was its impact on the growth of its relatively young industry. IBAC claimed that its members depended on the Linkage Regulations to protect their patents, because most had yet to reach a stage of financial maturity permitting them to operate normally while simultaneously dealing with patent cases in the courts. IBAC outlined the general partnership between its members and those of PMAC, suggesting that the growth and prosperity of its sector was dependent on the financial strength of the brand name industry. The primary issues facing biopharmaceutical companies were portrayed by IBAC using Stone's (2002) *narrative of stymied progress*. According to this storyline, the biopharmaceutical industry had shown tremendous growth thanks to the provisions of Bill C-91; however, the prospect of weakened patent protection in Canada threatened to stagnate or even devastate a successful, Canadian high-tech industry.

The primary goal of each of the three provinces appearing before the Committee was to induce changes to bring down the costs of prescription drugs thereby lowering their provincial formularies costs. Their conception of the public *interest* was bringing health costs under control and improving access to medicines. The provinces argued that the Linkage Regulations needed to be scrapped because they were keeping drug costs unnecessarily high. Furthermore, the provinces supported the CHC's proposal for a national

pharmacare program as they felt it would be a helpful initiative for bringing down drug costs. The provinces also presented *measures* that called into question the effectiveness of the PMPRB's methods for setting introductory prices and called on the Government to implement a fairer system that used more comparator countries and compared similar prices.

Government Influence on the Review

This thesis argues that the Government exerted its influence on the review process to try and avoid the political difficulties that would have arisen had the Committee's recommendations been inconsistent with the Government's strategy. The Government's influence was largely derived from the selection of the Industry Committee to conduct the review and the resultant access to the Committee this provided Manley and Industry Canada.

To begin with, the decision to select Industry Canada to conduct the hearings helped to frame the review as a matter of industrial, rather than health policy. This action suggested that investment concerns—rather than access to medicines—would be the chief criteria for assessment. The framing of the review as a matter of industrial policy was an advantage for the brand name industry, and by association, the Government.

Due to the supervisory role of Industry Canada during the review, the Government was able to influence the Committee process through Manley's communication and contact with Committee members. These interactions took place both publicly—during Manley's testimony—and privately—through

meetings with Liberal Committee members. During his testimony, Manley stressed the Government's intention to maintain the 20-year patent period. In clarifying the Government's position on this matter, Manley sought to deter meaningful discourse concerning a decrease in the patent term through compulsory licensing.

In private, Manley promoted the Party's interests through conversations with Liberal Committee members—which made up a majority of the Committee membership—where he reinforced the political significance of the review's outcome and its potential impact on the broader fortunes of the LPC (and the political careers of Committee members, potentially). In particular, the importance of the Linkage framework to prospective investments in the Quebec region was reinforced (D. Walker, interview, August 22, 2008). Moreover, throughout the review, Manley kept in close contact and communication with Walker, who, as Chair, played a significant role in the Committee process. In this way Manley was able to keep apprised of the impressions of Committee members, while working with Walker to advance the Government's agenda (D. Walker, interview, July 23, 2008).

While the exact course of events is contested by interested actors, the fact that the Government influenced the drafting of the Committee's final report to ensure that recommendations were politically expedient is undisputed. There are two versions of how the Government influenced the drafting of the report. The first is an allegation by the CHC that Manley's office intervened to reshape a "draft report" that included recommendations unfavourable to the brand name

industry. The second is that Walker prepared the Committee report on his own—without input from the Committee Clerk regarding Committee evidence or the opinions of Committee members—to ensure that its tone and recommendations were congruent with the Government's political interests. Furthermore, it was also alleged that the Government amended the Liberal membership of the Committee at the last minute to ensure passage of the Government-approved report. This reshuffling of the Committee was not denied by Walker, who recalled the dismissal of at least one dissident Ontario member. Moreover, Walker stated that there was would have been nothing extraordinary about the Government taking these steps to ensure passage of the Government's preferred report, especially on the eve of an election (D. Walker, interview, August 22, 2008).

Policy Decisions Favoured the Brand Name Industry

To demonstrate that the outcomes emanating from the review of Bill C-91 were, on the balance, favourable to the brand name industry, this section outlines the policy preferences of the primary stakeholders to the review—PMAC, the CDMA, IBAC, CHC and the three provinces—and compares them to the actual outcome.

During the review process, stakeholders articulated their policy preferences in accordance with the material interests of their constituents. Some stakeholders shared mutual interests and alliances were forged. In general, the line of division was drawn between those favouring measures for greater patent

protection—PMAC and IBAC—and those favouring a reduction in patent protection—the CDMA, the CHC and the three provinces.

PMAC desired the maintenance of the then-current policy, especially the 20-year patent period and the Linkage framework. Together, these two provisions were principally responsible for the long periods of market exclusivity, upon which the profitability of PMAC companies rested. Moreover, PMAC sought changes to the prevailing policy to increase the period of market exclusivity through the implementation of PTR and the elimination of the Bolar Provisions. By virtue of its members' dependence on PMAC companies, IBAC echoed most of PMAC's position and proposals during testimony to the Committee. For instance, IBAC endorse PMAC's appeal for the maintenance of the policy, specifically the 20-year patent period and the Linkage framework. With regard to amendments to the policy, IBAC supported PMAC's request for PTR.

While there existed a confluence of interests on several items considered during the hearings, the focus and motivation of the CDMA, CHC and the three provinces varied. The CDMA sought several changes to the prevailing policy as a means of decreasing the period of market exclusivity so that generic products could come to market more quickly. Similar to PMAC, the motivation of the CDMA was market share and the profitability of its member companies. To that end, the principal demands made by the CDMA were the elimination of the Linkage Regulations, a repeal of the retroactivity clause of Bill C-91 and maintenance of the Bolar Provisions. Furthermore, the CDMA sought policy

changes to increase their profitability in other ways, including new legislation around the appearance of generic drugs and the elimination of export restrictions on drugs that were off-patent in foreign jurisdictions.

While the CHC generally supported the CDMA's proposals to decrease patent protection, it had little concern for the profitability of generic companies. Rather, the CHC's prime motivation for requesting shorter periods of market exclusivity was to decrease the cost of drugs in the hopes of increasing access to medicines. To those ends, the CHC also called for changes to the PMPRB's pricing methodologies, a new health research program and the implementation of a national pharmacare program based on compulsory licensing.

The three provinces appearing before the Committee supported the CDMA's and the CHC's proposals which would bring down the cost of providing drugs through their provincial formularies. With this objective in mind, the provinces were strongly supportive of significant changes to the Linkage framework, changes to the PMPRB's pricing methodologies and the implementation of national pharmacare program.

Following the review, the Government implemented minor changes to its pharmaceutical patent policy, which basically amounted to a fine-tuning of the Linkage framework. Amendments included a decrease in the maximum stay period from 30 to 24 months, increased reporting requirements for generic companies and broader, refined powers for authorities—the Minister of Health and judges—to deal with irrelevant patents and frivolous lawsuits. Despite minor modifications, the Linkage framework remained in place, permitting brand name

companies to continue blocking the approval of generic drugs and evergreening their patents.

In addition, the Government maintained the 20-year patent period, thereby rejecting the CHC's proposal for a national pharmacare program based on compulsory licensing. This was not unexpected, in light of comments made by Government representatives both before and during the review. Moreover, the Government passed on other amendments that could have increased the period of market exclusivity, such as the elimination of the Bolar Provisions and the implementation of PTR. Furthermore, the timing of the Government's response was too early to consider the OAG's recommendations for changes at the PMPRB, which could have impacted the pricing of new patented medicines. On balance, the policy response of the Government—the essential maintenance of the prevailing policy—was beneficial to the PMAC-IBAC alliance and served to uphold the brand name industry's dominant position in the Canadian pharmaceutical industry

The Brand Name Sector's Resource Capacity Strength

The brand name industry's success at securing a favourable policy outcome following the review derived from its financial support of the LPC, its exploitation of Quebec politics and its ability to articulate a position regarding the value of pharmaceutical investment to the Canadian economy. The success of this strategy was due, in large part, to the superior resource base from which the brand name industry operated. In contrast, the failure of other stakeholders—in

particular, the generic industry—to have their interests reflected in the policy outcome was related to their relatively weaker resource capacities.

To begin with, the Canadian brand name industry was significantly more profitable than the generic industry, especially when the wealth of parent companies was taken into account.[159] Obviously, greater financial resources provide more frequent and effective access to public and political influence through lobbying, marketing and political donations. Furthermore, PMAC's organizational strength and the experience gained from past campaigns would have provided it with the knowledge to effectively target its financial resources. During the battles over Bills C-22 and C-91, the CDMA had been significantly outmatched by PMAC in all of the preceding categories.

Brand name donations to the LPC and individual Liberal candidates during the period—1996 to 1997—when the Government was deciding whether to maintain its pharmaceutical policy, were significantly greater than those of CDMA members and more strategically targeted. This included large donations to members of the influential Montréal caucus, who already had a shared interest in the welfare of the brand name industry. While the financial resources devoted by the two associations to lobbying and marketing for the review was not ascertained, PMAC's financial strength, as well as patterns established during earlier debates on patent protection, suggest that more money was spent by PMAC.

In addition to the connections and expertise of lobbyists, PMAC would have benefited from the connections and insider knowledge of government

[159] Recall that PMAC's members were subsidiaries of multinationals.

decision-making possessed by former officials, especially Erola. Other stakeholders lacked a comparable profile of organization or expertise. PMAC members also benefited from a close working relationship with the PMPRB—the agency charged with monitoring it—and profited from the Board's biased view of the industry and its dependence for information on pricing and R&D (CHC 1997; Canada, 1998). PMAC's position of influence and friendly relations with members of the PMPRB, appear to have compromised the Board in its dealings with, and reporting on, the activities of brand name companies (CHC 1997; Canada, 1998). Owing to the perception of the PMPRB as an independent government regulator, the relationship between the Board and PMAC companies was a valuable resource for the brand name industry during the review.

Last, but perhaps most important, was the geographic location of many brand name facilities and the prevailing importance of attracting investment to Canada. Having its industry's operations concentrated in the Montréal area, allowed the industry to exploit the LPC's vulnerability in regards the Quebec political situation, while taking advantage of the strong position of Montréal Liberals within caucus. Furthermore, the perception that brand name companies were—or had the potential to be—important investors in Canadian R&D, helped to leverage PMAC's position during a period marked by free-flowing capital and the imperatives of globalization. Again, none of the other stakeholders could present political arguments to match the persuasiveness of those advanced by PMAC and the brand name industry.

Conclusions

The thesis concludes with some general inferences about the role of agency in public policy development; an outline of the thesis' empirical, theoretical and social contributions; a list of the thesis' limitations; and suggestions for future study.

The Role of Agency in Policy Development

In addition to elucidating some of the motivating factors around government policy making, this thesis demonstrates the parallel role of ideas and personality. Indeed, none of the events were predetermined as a result of the (unequal) structures of decision-making and priority-setting within the state. In spite of these mediating properties, it seems that there was room for personal agency.

With respect to the review and surrounding events, a case can be made that the actions—or inactions—of certain individuals were instrumental in the eventual outcome. For instance, one wonders what might have happened had one more member from the Joint Committee voted down the Linkage Regulations in October 1994 (i.e. a vote of 4-3 for repeal instead of 4-3 against). Such a vote might have led to repeal of the Linkage Regulations—one of the most contentious aspects of Bill C-91—years before the review even took place.

Furthermore, what might have transpired had Rock shown better political judgment to win the confidence and support of the rest of Cabinet shortly after the 1997 election? Would he, or Dingwall for that matter, have had an easier

time if Manley had not demonstrated such political astuteness in his careful handling of the patent file? Would things have turned out differently for the generic industry if Sherman had resisted the urge to embarrass Manley and the Liberals during the 1997 election campaign? One can only speculate on the answers.

Certainly, the outcome of the review was, to a great extent, shaped by the structures of parliamentary government, the motivations of the LPC and the advantages of majority government. However, within this framework of political decision-making, it seems that there were in fact openings and opportunities, for the ideas and strengths of individuals to influence the eventual outcome of events.

Empirical Contribution

The primary contribution of this thesis is empirical. Development of the thesis involved marshaling evidence from a number of primary sources, including parliamentary committee testimony and key informant interviews. These data—previously unavailable or obscured by their location—help to shed light on the direction of Government activity and decision-making surrounding the review, specifically the importance of the Quebec political situation and inter-Party politics. Moreover, through an examination of this particular case, much can be learned about the general motivations, structures and processes for decision-making within a Liberal majority government.

Indeed, politics and government decision-making are rarely transparent affairs. What is witnessed on television or read in newspapers provides only a fraction of the story. The nature of much of the evidence collected and presented in this thesis—especially from interviews with people close to these proceedings—is not readily available. It is hoped that its inclusion here might be helpful to others in future research on pharmaceutical and/or public policy issues.

There is a growing body of research focusing on the regulation of the pharmaceutical industry in Canada and elsewhere, with increased attention being paid to the implications of trade agreements such as NAFTA and TRIPS. Although scholarly work focusing on Bill C-91 existed prior to this thesis (see Campbell & Pal, 1994), there was a research gap with respect to the 1997 review; this thesis helps to address that gap.

Theoretical Contribution

While the primary contribution of this thesis is empirical, it also makes a theoretical contribution by proposing a framework for analyzing government policy development under a majority Liberal government and then demonstrating how the events of the review correspond. This thesis proposes an eclectic theory which combines insights on stakeholder strategies to a policy development process, historical-based reflections on the tactics of federal Liberal governments and the tendency for the policy preferences of more powerful government branches to prevail.

Specifically, a framework is advanced which suggests that a Liberal government will attempt to address the interests of Quebec in a policy development process to secure electoral support from within that province. Moreover, respective stakeholders will employ rhetorical strategies throughout the policy process, with the objective of gaining support for their proposals and obtaining a policy outcome that reflects their preferences. Furthermore, in situations where the particular policy being developed is horizontal, the concerns of the more powerful government branches will be addressed ahead of others.

The utility of this framework is its focus on some of the central factors of the policy development process—the tactical approaches of private stakeholders; electoral considerations of MPs and political parties; and power struggles within the federal bureaucracy. Moreover, while this thesis specifically addresses pharmaceutical policy concerning Quebec, the theory can be extended to other situations concerning policy development under a federal Liberal government. Regardless of the issue or jurisdiction under consideration, the central principle remains: a federal Liberal government will generally—to the extent that obfuscation and ambiguity permit—behave in a pragmatic fashion, by attempting to create conditions that will give it the best possible chance of winning the next election.

Social Contribution

In telling the story of the review of Bill C-91 and bringing to light some of the factors affecting the policy process within the Canadian State, this thesis

provides a critical explanation of important historical events in the field of Canadian pharmaceutical policy development. A greater awareness of the political factors impacting the policy process may assist reformers in strategically focusing their efforts, while preparing them for probable responses from the State and competing stakeholders.

In addition to supporting further research in policy analysis, these data can be used by activists advocating for change, specifically in the area of pharmaceutical policy. Indeed, many of the issues that were front and centre during the review remain unresolved to this day. Despite the recommendations of the NFH and numerous other Commissions,[160] Canadians are still without a national pharmacare program (Armstrong & Armstrong, 2008) and evergreening practices continue to prolong the monopoly periods of brand name pharmaceutical companies (Valiquet, 2006). Furthermore, owing to the sustained high costs of brand name drugs, the feasibility of a national pharmacare program is likely still contingent on cost-containment measures such as compulsory licensing.

The election of Barrack Obama as the new US President might provide an opening to revisit some of the ideas for reducing the cost of drugs. Obama has signaled that a reworking of NAFTA may be on the horizon, opening the door to the possibility of changes in the field of IP protection (Polaris Institute, n.d.). Furthermore Obama has declared that health reform will be a priority for his first administration (Sack, 2008), raising the possibility that the US could potentially pave the way for reforms in the way that pharmaceutical pricing is regulated.

[160] For example, the Hall Commission and the Romanow Commission.

Indeed, significant international reforms to pharmaceutical patent protection may be necessary to counterbalance resistance to domestic changes on the part of Canada's two governing parties and Canada's brand name pharmaceutical industry.

Nevertheless, to contribute to meaningful social change, reformers and activists must look back at what has already happened and strive to understand the "present as history" (Sweezy, 1953); this much is certain. Indeed, only after we obtain a thorough understanding of the ideas, past events and processes that have brought us to where we are today, will we be in a position to articulate effective arguments, efficiently target limited resources and avoid the mistakes of past struggles. In a genuinely political policy competition, such knowledge is indispensable. It is hoped that this thesis, in some small but meaningful way, might be of some assistance.

Limitations of the Thesis

While the author believes that the thesis is adequately developed, there are some limitations that should be pointed out. First, the small number of interviewees resulted in gaps in the data. While the information provided by interviewees—in particular Macerollo and Walker—was helpful in gaining an understanding of the politics and processes surrounding the review, the perspectives of other stakeholders would have provided a greater breadth of information, as well as a means of substantiating or rejecting their accounts. In

particular, information from the perspective of Health Canada and the two pharmaceutical industries would have been useful.

Furthermore, there are a small number of claims made in the thesis which might have been corroborated by data collected from additional interviews. These include assertions that the economic impact of the brand name industry in the Toronto area was greater than that of the generic industry, and that the Montréal caucus was more powerful and organized than the Toronto caucus. Furthermore, interviews with more members of the LPC, as well as industry representatives, might have revealed: (1) the extent to which regional economic development and political donations influenced the action of Liberal MPs and the Party leadership; and, (2) the amount of employee interchange that had occurred—historically—between government and the two pharmaceutical industries.

Next, while the scope of the thesis was limited by time constraints, the analysis might have benefited by considering testimony from more stakeholders. While it was assumed that focusing on the primary stakeholders would provide a thorough reading of those factors having the greatest influence on the Government's decision making, this resulted in the omission of a number of important perspectives. Some of these stakeholders include academic researchers, policy institutes, citizen's groups, insurance companies, trade unions, health boards, business groups and many others.

Suggestions for Future Study

There are a number of issues addressed in the thesis that might be candidates for future study. First, there was much debate during the Committee hearings regarding the Linkage Regulations and the extent to which they actually delayed the issuance of NOCs to generic firms. While the CDMA maintained that NOCs were delayed, PMAC and the Government argued the contrary. Macerollo (interview, July 17, 2008) maintains that the Government's belief that the NOC and Linkage processes ran parallel influenced its decision to maintain the Regulations while shortening the stay period. An anonymous official at Health Canada did not support this claim. Accordingly, there is a research opportunity to examine the history of court cases arising from the Linkage framework. Such an analysis could be useful in assessing the legitimacy of injunctions brought about by brand name companies and evaluating the extent to which generic firms have had their regulatory approval delayed. Furthermore, one might also consider the extent to which amendments brought about by the review affected the amount, and nature, of litigation around pharmaceutical patents, as well as other effects of these amendments on both the brand name and generic sectors.

Second, there were a number of recommendations made by the OAG in its September 1998 audit report on the PMPRB. These recommendations are interesting because they originate from an independent body within the federal bureaucracy, relatively free from the political considerations of the executive branch. However, implementation of the OAG's recommendations falls under the purview of the executive level and is thus influenced by the party politics and—to

the extent that changes would impact industrial interests—the power of the brand name pharmaceutical industry. Future research could assess progress on the implementation of the OAG's recommendations and the impact of such changes.

Finally, there is an opportunity to use the results from this thesis to conduct comparative research into Canadian pharmaceutical policy development. Passed by Parliament in 2004, Bill C-9 was a Liberal initiative responding to recent changes at the WTO designed to make it easier for generic companies to export patented drugs to "lesser-developed countries". Similar to the review of Bill C-91, the review of Bill C-9 involved patent rights, the financial interests of both pharmaceutical sectors and consideration of drug prices and access to medicines. However, despite these commonalities, there were also a number of important differences. For instance, the review of Bill C-9 was carried out by a Conservative, rather than a Liberal government; it took place in a minority situation, instead of a majority; it was conducted by the Minister of Industry, rather than the Standing Committee on Industry; and it focused on drug access for impoverished foreigners, instead of Canadians. Comparison of the two reviews would be interesting and may contribute to a better understanding of the extent to which the variables outlined above affect pharmaceutical policy development in Canada.

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