

**Determinants of Canadian Policy:  
An Analysis of Bill C-9: The Jean Chrétien Pledge to Africa Act**

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**Determinants of Canadian Foreign Policy:  
An Analysis of Bill C-9: The Jean Chrétien Pledge to Africa Act**

**“It might not usher them into the kingdom of heaven, but they’d be further removed from the inferno”**

- Stephen Lewis commenting on the Canadian government’s announced intention to amend patent laws to allow for the export of generic medicine

### Abstract

On 14 May 2004, Bill C-9, which amended the Patent Act and the Food and Drugs Act, to allow for the export of generic medicines was given royal assent. Using Bill C-9, entitled “The Jean Chrétien Pledge to Africa Act,” as a case study, this thesis will examine how Canadian policy is formulated. Three different theoretical perspectives will be used to examine C-9. The neo-Marxist perspective, with its focus on capital, will be used to capture the interplay between domestic and transnational capital interests. The pluralist perspective will be used to capture the importance of public opinion, activists, and NGOs. The statist perspective argues that the state has an independent interest, and will be used to analyze the role of the Canadian government in the legislation. Each of these theories will also be used to assess the impact the relevant actors had on the legislation.

This thesis will examine the factors that influenced government, the goals and objectives of each actor, and how the government responded to these pressures. It will argue that even though all the actors are important, not all are equally influential. Two in particular are decisive. First the issue must satisfy the interests of transnational capital. Secondly, it must be politically feasible for the government. Provided these two criteria are met, other factors such as public opinion, and international recognition may or may not become important.

Bill C-9 met these criteria. Once the government confirmed that domestic capital forces were interested in amending the Patent Act, and Food and Drugs Act, to allow for the export of generic medicines it made moves to do so. The support of the NGO and activist community ensured it was politically feasible for the government to do so. Ultimately transnational capital played the most important role in determining how the legislation was drafted. They successfully influenced C-9 in a way that ensured it would be ineffective in exporting generic drugs. Other actors, mainly the NGOs, played a secondary, but significant role. The alliance between NGOs and domestic capital was especially important, and gave each group a level of influence it would not have had on its own.

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**Legislative History of Bill C-9: An Act To Amend the  
Patent Act and The Food and Drugs Act**

- 25 September 2003 Industry Minister Allan Rock announces that the Canadian Government will change its patent laws to allow for the export of generic medicines.
- 27 September 2003 Prime Minister Chrétien signals his support for the legislation.
- 30 September 2003 Liberal Cabinet Ministers meet to discuss the legislation. The intent is to have it through Parliament by Christmas of that year.
- 6 November 2003 Prime Minister Chrétien personally introduces Bill C-56, "An Act to Amend the Patent Act and the Food and Drugs Act" to Parliament.
- 7 November 2003 Liberal government decides to send the issue to a Parliamentary Committee for review.
- 12 November 2003 37<sup>th</sup> Parliament 2<sup>nd</sup> Session (September 30 2002 – November 12 2003) is prorogued. Bill C-9 dies on the table.
- 2 February 2004 37<sup>th</sup> Parliament 3<sup>rd</sup> Session begins. Former Finance Minister Paul Martin is now Prime Minister.
- 12 February 2004 Bill C-9 is introduced. The chair confirms it is the same as Bill C-56. C-9 is given its first and second reading and sent to the Standing Committee on Industry, Science and Technology for review.
- February-April 2004 The Standing Committee reviews C-9. Actors submit reports and make oral presentations to the committee.
- 28 April 2004 The Standing Committee makes its report on Bill C-9, now entitled "The Jean Chrétien Pledge to Africa Act" to the House of Commons.
- 4 May 2004 The House of Commons reads C-9 for the third and final time. It passes with a vote of 229-0 in favour. The Senate reads C-9 for the first time.
- 11 May 2004 The Senate reads C-9 for the second time
- 13 May 2004 The Standing Committee makes its report to the Senate. The Senate reads C-9 for the third time.

14 May 2004

Bill C-9, "An Act to Amend the Patent Act and the Food and Drugs Act," entitled "The Jean Chrétien Pledge to Africa Act" receives Royal Assent.

### Terms and Abbreviations

3 x 5	The WHO initiative to have three million people receiving HIV/AIDS treatment by the end of 2005
ACP	African, Caribbean and Pacific Group of States
HIV/AIDS	Acquired Immune Deficiency Syndrome
African Group	A group of African states, and sixteen supporters, that put access to medicines issues on the agenda at the WTO Fourth Ministerial Conference in Doha
ARV Drugs	Anti-retroviral Drugs
Bill C-56	The Canadian government's first attempt at allowing the export of generic medicines.
Bill C-9	Canada's legislation allowing the production and export of patent protected drugs. Known as the Jean Chrétien Pledge to Africa Act
C&CA	Consumer and Corporate Affairs (A federal Department)
CCIC	Canadian Council for International Cooperation
CDMA	Canadian Drug Manufacturers Association (An association of generic drug producers that was a predecessor of the CGPA)
CFP	Canadian Foreign Policy
CGPA	Canadian Generic Pharmaceutical Association
CIPRO	Treatment for Anthrax patented by Pharmaceutical corporation Bayer
Compulsory License	A licence that can force the patent holder to release the information on the patented product to the licensee. The TRIPS agreement included a caveat that allowed states to override patents in cases of national emergency
DATA	Debt HIV/AIDS Trade Africa. An activist group founded by U2 rock star Bono
DFAIT	Department of Foreign Affairs and International Trade

Doha Declaration	A result of the WTO Fourth Ministerial Conference in Doha, Qatar. Recognized that the TRIPS agreement should not prevent states from addressing their health care needs. Was expanded in after Doha with several implementation agreements.
DRIE	Department of Regional and Industrial Expansion
Eastman Commission	A commission studying the effect compulsory licensing had on drug prices and innovation
EATG	European HIV/AIDS Treatment Group
Eligible Countries	Those countries legally allowed to import generic drugs under the WTO's Doha Declaration
EC	European Community
EU	European Union
FTA	Free Trade Agreement (Between Canada and the United States)
FTAA	Free Trade Area of the Americas
G8	Group of Eight
GATT	General Agreement on Tariffs and Trade
Global Fund	Stephen Lewis' primary organization to fight HIV/AIDS
HIV	Human Immunodeficiency Virus
IFPMA	International Federation of Pharmaceutical Manufacturers Associations (Brand-name manufacturers)
MSF	Médecines Sans Frontières (Doctors Without Borders)
NBAC	National Biotechnology Advisory Committee
OAU	Organization of African Unity
ODA	Official Development Assistance
Off Patent	Drugs previously patented that are now open to all manufacturers
Pharma	Name for the brand-name Pharmaceutical lobby

PMAC	Pharmaceutical Manufacturers Association of Canada (An earlier version of Rx&D)
Right of First Refusal	A clause which would allow brand-name companies to adopt contracts negotiated by generic manufacturers
Rx&D	Canada's research based Pharmaceutical lobby
SAARC	South Asian Association for Regional Cooperation
Schedule One	A list of drugs eligible to be exported
Schedule Two	Permits countries identified as "least-developed" by the United Nations to import generic medicines
Schedule Three	Originally restricted eligibility of importing generic medicines to states identified by the United Nations as "developing" to WTO members. Subsequently, five more countries were added to the list.
TRIPS	Trade-related aspects of intellectual property rights
TRIPS-plus	Patent protections that are greater than what is required by the original TRIPS Agreement
UNICEF	United Nation's Children's Fund
WTO	World Trade Organization

**Chapter 1:  
Introduction**

## 1.1 Introduction

Although it has been diagnosed since 1981,<sup>1</sup> it is in the last decade that HIV/AIDS has become a global pandemic. Recognized as such by the World Health Organization, calls to address the HIV/AIDS crisis have become increasingly urgent. It is estimated that 34.6-42.3 million.<sup>2</sup> Seventy-five percent of these cases, totalling over thirty million people, are in Africa.<sup>3</sup> When Latin America is included ninety-five percent of HIV/AIDS cases occur in developing regions.<sup>4</sup>

Although HIV/AIDS has no cure drugs are available to treat this disease. Three drugs, collectively known as anti-retroviral (ARV) drugs, increase the quality and length of life. Access to ARV drugs is made difficult by the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which keeps purchasing costs high. The TRIPS agreement (1994) grants patent protections to the corporation that creates the drug, giving the patent holder total control over supply of the drug and preventing competition. In August 2003 the WTO changed its regulations to allow generic versions of patent-protected drugs to be exported in certain circumstances.

On 1 October 2003, the Canadian government announced it would amend its Patent Act and Food and Drugs Act to allow generic drug producers to export their products to states that lacked the ability to produce them.<sup>5</sup> This announcement was supported by a broad coalition of NGOs, activists, and generic producers. On 6

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<sup>1</sup> AVERT <http://www.avert.org/statsum.htm>

<sup>2</sup> United Nations, *2004 Report on the Global HIV/AIDS Pandemic* (July, 2004). Available: [http://www.unHIV/AIDS.org/bangkok2004/GAR2004\\_html/GAR2004\\_00\\_en.htm](http://www.unHIV/AIDS.org/bangkok2004/GAR2004_html/GAR2004_00_en.htm)

<sup>3</sup> James Orbinski, "The G8 Fails Global Health," *Canadian Medical Association Journal* 167 (September 2002): 481.

<sup>4</sup> Caroline Thomas, "Trade Policy and the Politics of Access to Drugs," *Third World Quarterly* 23 (2002): 252.

<sup>5</sup> *Médecins Sans Frontières Press Release*, "Amending Canada's Patent Act to Allow Exports of Generic Medicines," 1 October 2003.

November 2003 Bill C-56 “An Act to Amend the Patent Act and the Food and Drugs Act” was introduced in the House of Commons. Expecting Parliament to be prorogued the next day, Bill C-56 was to be rushed through. The Liberal House Leader achieved all-party support for Bill C-56, and it was pushed through the first two readings. However, C-56 never reached the required third reading. Upon closer examination of C-56, civil society organizations withdrew their support pending amendments on key aspects of the bill. They were supported by the New Democratic Party, and instead of going to a third reading, C-56 was sent to the House of Commons Standing Committee on Industry, Science and Technology for further examination. When Prime Minister Chrétien prorogued Parliament on 12 November 2003, C-56 died on the table.<sup>6</sup>

The death of C-56 was not the end of Canada’s commitment to allow generic producers to export their products. On 14 November 2003, a group of civil society organizations such as HIV/AIDS Law Canada, Médecines Sans Frontières, along with UN Ambassador on HIV/AIDS Stephen Lewis, began canvassing outside the Toronto Convention Centre, where the Liberal Party was holding its national convention to inaugurate Paul Martin. The intent was to hold the Liberal party accountable to its commitment. Bill C-9, which was a modified version of C-56, underwent its first and second reading on 12 February 2004. After some examination it received a third reading on 13 May 2004, and was given royal assent on 14 May 2004.<sup>7</sup>

## 1.2 Analytical Approach

This paper is a case study in the formulation of Canadian policy. It examines the interests and motivations which lay behind the passage of Bill C-9, which amended the

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<sup>6</sup> Stephen Chase, “Committee to Work HIV/AIDS Bill Into Shape,” *Globe and Mail*, 8 November 2003.

<sup>7</sup> Bill C-9, *Library of Parliament*, available

<[http://www.parl.gc.ca/common/Bills\\_ls.asp?lang=E&Parl=37&Ses=3&ls=C9&source=Bills\\_Individual](http://www.parl.gc.ca/common/Bills_ls.asp?lang=E&Parl=37&Ses=3&ls=C9&source=Bills_Individual)>

Patent Act and the Food and Drugs Act to allow generic manufacturers to produce and export patent protected drugs.

Understanding the Canadian government's decision requires a detailed analysis of policy formulation. It is necessary to examine what actors determine policy, and how they exercise their influence. It will be necessary to examine the degree of influence civil society, capital interests, and other actors have on the policy-making process. Finally, explaining this decision requires an understanding of the distinction between the practice and rhetoric of foreign policy.

One question this thesis will examine is the degree to which the policy decisions made by government are based on economic or business interests, even as ethical issues are given a high profile in Canadian foreign policy rhetoric. The business interest is the drive for profit. Lobbyists for this group hold that the profit motive is in the public interest, and beneficial to all. The case study I have chosen is one in which, *prima facie*, ethical concerns have been paramount. Given this, what weight did the moral arguments of the NGO community carry against the economic power of transnational Pharmaceutical companies. To what extent was Bill C-9 motivated by the interests of Canada's generic drug manufacturers? Is it plausible that legislation such as C-9 can meet both ethical and business interests?

Prominent figures, such as Stephen Lewis and U2 lead singer Bono, along with organizations such as Médecines Sans Frontières (MSF), the Canadian HIV/AIDS Legal Network, and World Vision, which have been recognized elements of Canadian society for decades, and whose charity work and high profile give them credibility and status, have all campaigned vigorously on this issue. While these groups and individuals took

different approaches, they all advocated restricting patent protection in order to allow the export of generic medicines. Collectively, they were well organized and vocal. The 'celebrity' status of some groups and individuals in this lobby helped ensure that they were heard when they spoke, whether it was on television, the print media or other forums.

As independent organizations they were able to criticize or praise government according to their beliefs. They were able to force issues on the agenda which the government might have preferred to ignore. Ultimately they played a role in how government was perceived by the general public. If they approved of government policies, as Bono did in campaigning for Paul Martin, they could create positive perceptions. If they did not approve, as Stephen Lewis did not in numerous public statements criticizing the lack of response to the HIV/AIDS crisis, they can create negative perceptions.

Another interesting aspect of the study of Bill C-9 is the role competing economic interests play in determining foreign policy. The brand-name companies, represented by Canada's Research Based Pharmaceutical Companies (Rx&D), were opposed to any legislation that would restrict patent protections. A competing business interest, the producers of generic medicines, represented by the Canadian Generic Pharmaceutical Association (CGPA), supported legislation that would limit the patent protections given to Rx&D members. On the matter of Bill C-9, these interests were contradictory. While neither can be ignored, neither can be fully satisfied. The arguments of both groups must be taken into consideration when drafting legislation that impacts patent law in Canada.

### 1.3 Generic producers vs. Brand-name companies

Generic producers and brand-name companies have a history of conflict prior to Bill C-9. In 1923 the Canada Patent Act was amended to include food and drugs. This amendment protected both the finished product, and the active chemical ingredients used in that product, but only allowed compulsory licenses to be issued for the process by which the product was created.<sup>8</sup> Having access to the process was useless to the licensee, as they could not use it without the active chemical ingredient. In the 1950s and 1960s federal commissions identified patent protection as a key factor in inhibiting competition - resulting in Canada having some of the highest drug prices in the world. They identified the restrictive nature of compulsory licensing as one reason for this.<sup>9</sup> In March 1969 the government passed Bill C-102, which allowed for compulsory licenses to be issued for active ingredients or finished products. Concerns over price equity and welfare, overrode concerns about disincentives for innovation.<sup>10</sup> A side effect of this legislation was the growth of a domestic generic drug industry.<sup>11</sup>

Brand-name Pharmaceutical companies attacked Bill C-102, while the generic producers defended it. Arguing that C-102 adversely affected their ability to recoup their investment, brand-name companies challenged the bill numerous times in court. They continually lost these challenges. In the 1970s and 1980s the political climate shifted again. Government concerns shifted from price and equity to innovation and investment.<sup>12</sup> The federal government's National Biotechnology Advisory Committee

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<sup>8</sup> Robert Marshall, "Autonomy and Sovereignty in the Era of Global Restructuring," *Studies in Political Economy* 59 (1999): 125.

<sup>9</sup> Ibid, 126.

<sup>10</sup> Ibid.

<sup>11</sup> Ibid.

<sup>12</sup> Ibid, 127.

(NBAC) identified intellectual property incentives as a way of increasing investment in the Pharmaceutical sector. In 1983 the Liberal government created another commission, the Eastman Commission, to examine compulsory licensing. The Eastman Commission did not make its report until 1985, under the Mulroney government. This commission concluded that, since its inception in 1969, compulsory licensing had stimulated competition and saved Canadians approximately \$211 million dollars.<sup>13</sup> The Eastman Commission also concluded that Canadian patent holders had historically low commitments to R&D in Canada, and that compulsory licenses had not changed this.

The Conservative government had decided to push ahead with changes to the Patent Act before the Eastman commission made its report. Reflecting the Conservative government's preoccupation with trade and deregulation, Bill C-22 would nullify C-102 and bring Canadian law more in line with American and international standards by extending patent protections from four to ten years. Bill C-22 became the centre of many conflicts. It encompassed regional issues, issues between the Senate and House of Commons, and the conflict between generic producers and brand-name companies.<sup>14</sup>

The Pharmaceutical Manufacturers Association of Canada (PMAC), representing sixty-seven, largely foreign, patent-holding Pharmaceutical companies, gained the bureaucratic support of the Department of Regional Industrial Expansion (DRIE). The DRIE believed that C-22 would generate investment in the new field of biotechnology.<sup>15</sup> Opposing this group was the Canadian Drug Manufacturers Association (CDMA) and its bureaucratic supporter, the Department of Consumer and Corporate Affairs (C&CA). The

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<sup>13</sup> Ibid, 128.

<sup>14</sup> Leslie Pal and Campbell Robert, "The Long and Winding Road: Bill C-22 and the Politics of Drug Patents," *The Real Worlds of Canadian Politics*, 58.

<sup>15</sup> Ibid, 94.

C&CA, was responsible for applying the compulsory licensing policy, and had a vested interest in perpetuating this system.<sup>16</sup> Representing seventeen Canadian-owned companies, the CDMA was much smaller and not as well organized.<sup>17</sup>

Both the CDMA and PMAC hired lobbyists to make their case. Under the Liberal government, the CDMA lobby had been successful in neutralizing the tilt towards investment. It was this lobby that led to the Eastman Commission.<sup>18</sup> The CDMA was not nearly as successful in gaining the ear of the Mulroney government. PMAC, on the other hand, had great success with Mulroney's administration. It hired 'Government Consultants Inc.,' the most powerful lobby group in Canada.<sup>19</sup> Mulroney had declared Canada a 'scavenger' when it came to intellectual property.<sup>20</sup> The Conservative worldview strongly supported PMAC's agenda. The government ignored the Eastman Commission's report, and went ahead with the changes. This was a zero sum game for both industries. The generic producers had been created by, and continued to benefit from C-102.<sup>21</sup> These benefits came at the cost of patent holders' market share. If one side gained, the other lost –there was no possibility of a consensus.

C-22 was just a first step in extending patent protections. On 23 June 1992, the Mulroney government introduced Bill C-91. C-91 would extend patent protection to twenty years and eliminate compulsory licenses all together.<sup>22</sup> The fights that had occurred over C-22 repeated themselves with the introduction of C-91. Again the CDMA

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<sup>16</sup> Ibid.

<sup>17</sup> Ibid, 62.

<sup>18</sup> Ibid, 68.

<sup>19</sup> Ibid, 69.

<sup>20</sup> Ibid, 71.

<sup>21</sup> Marshall, 126.

<sup>22</sup> Ibid., 133.

and PMAC hired lobbyists to make their cases. Again the PMAC out muscled the CDMA.

During these debates there were international pressures on Canada to change its patent laws. The debates over C-22 occurred during the same time Prime Minister Mulroney and President Reagan were discussing the Free Trade Agreement (FTA). Under the Reagan administration, patent protections were moved to the top of the US trade agenda.<sup>23</sup> In 1985 Reagan and Mulroney met at the 'Shamrock Summit,' where patent policy was one of the key items discussed. Later that year the US Trade representative listed Canada's patent legislation as one of the 'irritants.'<sup>24</sup> Although the government denied any link between patent policy and free trade, the evidence suggested a strong connection. On 5 October 1987 a draft of the FTA was tabled in Washington. This draft which was different than the one tabled in the House of Commons stated that, "Canada has agreed to pass the pending amendments contained in Bill C-22."<sup>25</sup> Another indication of things to come was an article in the *Washington Post*, which cited a US summary of the agreement claiming that Canada had agreed to adequately protect pharmaceutical patents.<sup>26</sup>

Concurrent with the debates over C-91, the international community was adopting new intellectual property standards. In 1994 the Uruguay Round replaced the General Agreement on Tariffs and Trade (GATT) with the World Trade Organization. One result of these talks was the TRIPS agreement. The TRIPS agreement internationalized largely American intellectual property protections. It set patent protections at twenty years, and

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<sup>23</sup> Ibid, 131.

<sup>24</sup> Ibid.

<sup>25</sup> Ibid, 132.

<sup>26</sup> Ibid.

changed the purposes of compulsory licensing. It was only to be used for emergency situations. Patent holders had won several key victories at the international level. These victories gave them an increasing amount of power at the domestic level. Generic producers could no longer import or export patented medicines. Despite these defeats the battles between generic producers and patent holders continued. Generic producers continued to promote their 'cost effective' option, while patent holders promoted 'investment and innovation.' The stage was set for C-9.

#### **1.4 Actors and Factors**

##### **1.4(A) Canada's Research-Based Pharmaceutical Companies (Rx&D)**

Rx&D is the national association representing the 22 000 employees of over fifty brand-name Pharmaceutical companies operating in Canada. Though none of its members are based in Canada they must have offices and/or branch plants to become members of the association. Rx&D's roots go back to 23 April 1914 when representatives of ten Pharmaceutical and toilet products companies formed the, "Canadian Association of Manufacturers of Medicinal and Toilet Products." Since then it has had a variety of inceptions. In 1965 it became the Pharmaceutical Manufacturers Association of Canada (PMAC). On 1 May 1999, it changed its name to Canada's Research-Based Pharmaceutical Companies (Rx&D) in order to reflect the evolution of the Pharmaceutical industry in Canada.<sup>27</sup>

Rx&D sales dominate the Pharmaceutical market in Canada. In the year 2004, Rx&D companies reported revenues of \$13.2 billion, accounting for 83.1% of Canada's

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<sup>27</sup> Rx&D, About Rx&D, < [http://www.canadaPharma.org/home\\_e.htm](http://www.canadaPharma.org/home_e.htm)>

\$15.9 billion dollar drug market.<sup>28</sup> This is largely due to the enormous sums of money Rx&D spends on advertising. Rx&D has fought heavily to protect and extend patent rights in Canada. It has engaged in political battles over legislation that amends patent law in Canada. It fought to protect and/or extend patent protections with Bill C-102 (1969), C-22 (1987), C-91 (1993), and C-9 (2004).

As the representative of international corporations, Rx&D focuses its lobbying efforts on the Department of Foreign Affairs and International Trade (DFAIT). Rx&D wants Canada to be a place where transnational capital invests. In order for this to happen Canada must be perceived as a state that is open to investment. In general, transnational capital holds that this requires lower taxes, less government spending, and the reduction of debts and deficits. Specific to the Pharmaceutical sector is the protection of patent rights. Rx&D argues that patent protections are necessary to encourage Pharmaceutical investments in Canada. Domestically it was successful in doing this with the introduction of C-22 and C-91. As the representative of transnational capital, and an organization dedicated to preserving and extending patent protections, Rx&D was a significant actor in the debates over C-9.

#### **1.4(B) Canadian Generic Pharmaceutical Association (CGPA)**

The Canadian Generic Pharmaceutical Association (CGPA) is the national association of generic drug producers. It represents twenty generic drug companies, that employ roughly 10 000 people.<sup>29</sup> The first generic drug association in Canada was the Canadian Drug Manufacturers Association (CDMA), which was founded in 1967 and

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<sup>28</sup> Patented Medicine Prices Review Board. <<http://www.pmprb-cepmb.gc.ca/english/view.asp?x=436&mid=385>> (2004)

<sup>29</sup> Canadian Generic Pharmaceutical Association, About CGPA <<http://www.cdma-acfpp.org/en/about/index.shtml>>

represented seventeen Canadian-owned companies. In 2002 the CDMA became the CGPA. About half the CGPA members are Canadian-owned.<sup>30</sup> In 2004 CGPA members made roughly \$2 billion dollars, totalling 12.5% of the drug market.<sup>31</sup> Like Rx&D, generic producers have engaged in battles over legislation that would change Canadian patent law. It engaged in industrial warfare against Rx&D over Bill C-102 (1969), C-22 (1987), C-91 (1993), and C-9 (2004). As the representative of domestic capital, and an organization promoting the reduction and/or elimination of patent protections the CGPA played an important role in the debates over C-9.

#### **1.4(C) International Agreements**

International agreements are a constraining factor on the policy options of signatory states. Internationally, the body governing patent laws is the WTO. It does this through the TRIPS agreement. As a member of the WTO, and a signatory of the TRIPS agreement, Canada is obligated to follow the standards set by this agreement. The TRIPS agreement internationalized largely US domestic patent laws. The United States set the standard by ensuring the TRIPS agreement included twenty-year patent protections, and allowed for the issuing of compulsory licenses only in cases of national emergency. Signatories to the agreement are committed to adjusting their domestic patent laws to meet these standards. The TRIPS agreement governs the export of generic medicines. Signatories must remain TRIPS-compliant, even when dealing with non-signatories.

#### **1.4(D) Non-governmental Organizations (NGOs)**

Non-governmental organizations claim to be interested in maximizing access to medicines. Many NGOs attempted to influence the legislation. Two NGOs, Médecines

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<sup>30</sup> Canadian Generic Pharmaceutical Association, Members <http://www.cdma-acfpp.org/en/members.shtml>

<sup>31</sup> Patented Medicine Prices Review Board. <<http://www.pmprb-cepmb.gc.ca/english/view.asp?x=436&mid=378>> (2004)

Sans Frontières and the Canadian HIV/AIDS Legal Network, were especially active. The NGOs believed that the best way of increasing access was minimizing patent protections, thus removing disincentives for generic producers. NGOs claimed to be interested in the humanitarian issues surrounding access to medicines. NGOs are not blind to the profit motive, but felt that issues of access should not be dependent solely on business interests. NGOs were empowered by the number of them that took part in the process, the credibility they had with the Canadian public, and their alliance with the CGPA. They were constrained by a lack of financial resources, which prevented them from doing things such as hiring lobbyists, and a multi-issue focus, that divided their attention. NGOs played an important role in influencing Bill C-9.

While many NGOs were involved in this issue there were a few that took the lead. Prior to the government's announcement to amend its patent laws, a large group of NGOs had been writing to the government. Religious organization such as Kairos, developmental organizations such as the North-South Institute, and charitable organizations such as World Vision wrote to the government. After the government announced its intent to amend the patent laws, these organizations continued to do so. Two NGOs in particular took the lead in addressing the House Committee, looking at the legalities of the legislation, and working with the CGPA. The first was MSF, which has always had a strong focus on access to medicines issues. The second was the Canadian HIV/AIDS Legal Network, which covers a large range of issues, domestic and international, dealing with HIV/AIDS.

MSF and the Canadian HIV/AIDS Legal network took the lead because of the role they play in Canadian politics. Most of the press releases were joint statements made

by the following groups: The Canadian Coalition to End Global Poverty, the Canadian Council on International Cooperation (CCIC), Canadian HIV/AIDS Legal Network, World Vision, Canadian Labour Congress, The United Church of Canada, MSF, Oxfam, and Interagency Coalition and AIDS and Development. Many of these groups also made submissions to the Standing Committee on Industry Science and Technology, which was responsible for studying the issue. However, none of the NGOs had nearly as many submissions, or went into as much detail as the Canadian HIV/AIDS Legal Network, and to a lesser extent MSF. It is my belief that there was a loose coalition here. MSF's 'Campaign for Access to Essential Medicines,' had established it as the dominant force advocating increased access to medicines. The Canadian HIV/AIDS Legal Network was the main legal advocacy groups for people infected with HIV/AIDS. The other NGOs were more multi-focused, choosing to advocate other issues such as debt relief, famine relief, and/or trading practices.

I believe they agreed to support MSF and the Canadian HIV/AIDS Legal Network, as part of a loose coalition. They attached their name to the letters, and made some submissions to the House Committee, but did not focus a lot of their resources on this one issue. They were not totally absent from this issue, nor were they completely engaged. They chose to follow the two NGOs who were the established leaders in this field. They made sure the government knew that MSF and the Canadian HIV/AIDS Legal Network were supported, but did not let this issue distract them from their many other advocacy roles.<sup>32</sup>

#### **1.4(E) Activists and Movement Leaders**

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<sup>32</sup> Former MSF Director David Morley stated that MSF and the Canadian HIV/AIDS Legal Network could afford to be more 'bullish' in their approach as they were single issue organizations, whereas the other NGOs needed to be prepared to make 'trades'

Activists and movement leaders also influenced the government's decision to allow the export of generic medicines. There were two movement leaders who were especially active and influential. Stephen Lewis has been involved in Canadian politics since the 1960s and 1970s when he was an MPP in the Ontario legislature. He has also been very active at the United Nations. From 1984 to 1988 he was the Canadian Ambassador to the United Nations. From 1995 to 1999 he served as the Deputy Director of the United Nations Children's Fund (UNICEF). In June 2001 UN Secretary-General Kofi Annan appointed him as his special envoy for HIV/AIDS in Africa.<sup>33</sup> Being a high profile Canadian, and an expert on the HIV/AIDS epidemic, made Lewis an especially relevant actor. Like the NGOs and CGPA, Lewis argued that the best way to increase access was decreasing patent protections.

The second movement leader of importance was rock band U2's lead singer, Paul David Hewson, better known as Bono. Bono, an Irish citizen, is famous because of the success of his band U2. Bono has used his status and influence to advocate on behalf of Africa. He has actively engaged the Liberal Party of Canada on this and other related issues. On several occasions he met Prime Minister Chrétien, and Finance Minister Martin to push for debt relief and increased aid spending. He once again engaged in discussions with the Liberal Party when the decision to amend the Patent Act and Food and Drugs Act was announced. Bono's high celebrity status and his continued discussions with the Liberal Party make him an important actor in the debates over Canada's decision to amend the Patent Act and Food and Drugs Act. Bono also argued that patent protections should be decreased.

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<sup>33</sup> Biographical details of Stephen Lewis can be found at:  
<<http://www.un.org/ga/HIV/AIDS/StephenLewisBio.html>>

#### **1.4(F) Public Opinion**

Public opinion is a contextual factor that determines policy. At the very least it sets broad limits for policy options. However, public opinion has the potential to be a very important factor. In the case of Bill C-9 it was not.<sup>34</sup> This does not mean that the government did not take public opinion into account. The potential power of public opinion ensures that the government wants the public to view it in a positive light. Generally the public will support any move that purports to save lives and help those in need. The public is even more likely to support these ideas if it does not cost them anything. On the issue of amending the Patent Act and The Food and Drugs Act, the importance of public opinion lay in the ability of movement leaders and NGOs to mobilize the public behind their cause.

#### **1.4(G) Government Interests**

The Canadian government had a vested interest in this legislation. All the other actors and factors attempted to influence C-9 legislation, but it was the Canadian government that had the final say in how C-9 was drafted. The Canadian government had to balance numerous interests in doing so. In addition to balancing the interests of other groups, the Canadian government had its own interests. It wanted to maintain a positive image internationally, increase its prestige domestically, and advance business interests.

As a signatory to the TRIPS agreement it was not able to violate these principles, and as such did not propose the legislation until changes to the TRIPS agreement made it legal to do so. The Canadian government also had an interest in presenting a positive image at the domestic level. Doing so increased its chances of preserving its power. In order to achieve this objective the Canadian government had to pay close attention to all

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<sup>34</sup> I could not find any public opinion polls on this issue

of the actors and factors. It could not ignore any of the actors, nor could it meet all of their demands.

### **1.5 Theories of Relation**

This thesis examines several different theories. I will argue that independently these theories are inadequate to explain the Canadian government's decision to ratify C-9. However taken together they are able to do so. As each theory focuses on one actor's motivation, and the influence of that actor, the theories are not contradictory. Rather they interact with each other to provide a comprehensive explanation of Bill C-9, and Canadian policy in general. The neo-Marxist perspective provides the framework within which I use the other two theories. I believe that the neo-Marxist perspective, with its emphasis on the importance of transnational capital is the most relevant. However, it cannot properly capture the details of this legislation. In order to understand why the government made the choices it did, I use two other theories. The pluralist theory captures the importance of competing interest groups –in this case NGOs, Rx&D, movement leaders, and the CGPA. The statist theory emphasizes the importance of an independent state interest, which is often, but not always congruent with the interests of capital. As such it is possible use them concurrently in order to create a framework for analyzing Canadian policy in general, and C-9 in particular. Together they examine a range of issues that cover the relevant actors – businesses, NGOs, movement leaders, and government.

#### **1.5(A) Neo-Marxist**

The neo-Marxist perspective believes that the state is the terrain in which class struggles are played out. In many circumstances capital interests use the state as a

mechanism of promoting the advancement of a bourgeois class, and their material interests.<sup>35</sup> This perspective is critical of the state apparatus, and the motivations behind the state's actions. This perspective holds that the structure of capital has created a set of norms that pervade society and the decision-making processes of government.<sup>36</sup> It is necessary to distinguish between the structural power of capital, and the power of individual firms or fractions of capital. The states support for business reflects the structural power of capital. While there can be instances of policy formulation where there is not much to be gained in making this distinction there are occasions where different factions of capital have opposing objectives. In relation to Canadian policy it is important to note that the same forces giving capital interests domestic influence are also acting at the international level.

The current supremacist bloc,<sup>37</sup> which formed in conjunction with the emergence of a neoliberal order, exists both inside and outside the state. It is part of local political structures as well as serving to create a global civil and political society.<sup>38</sup> This bloc is given power through organizations such as WTO, which form the legal mechanisms through which it can be exclusive. This creates what Gill refers to as a 'new constitutionalism' which confers privileged rights on corporate capital while constraining mechanisms that represent other interests.<sup>39</sup>

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<sup>35</sup> Gill, "Globalisation, Market Civilisation and Disciplinary Neoliberalism," *Millennium: Journal of International Studies*, 24(3) (1995): 400.

<sup>36</sup> Stephen Gill and David Law, "Global Hegemony and the Structural Power of Capital," *International Studies Quarterly* 33 (1989): 480.

<sup>37</sup> Defined by Gill as, "Rule by a non-hegemonic bloc of forces that exercises dominance for a period over apparently fragmented populations, until a coherent form of opposition emerges."

<sup>38</sup> Stephen Gill, "Globalisation, Market Civilisation and Disciplinary Neoliberalism," *Millennium: Journal of International Studies* 24(3) (1995): 400.

<sup>39</sup> *Ibid*, 413.

NGOs are often viewed as powerful forces opposing capital. NGOs are perceived to have a larger focus than the narrow self-interest attributed to capital. While this perception gives NGOs an ideological advantage, overcoming capital interests remains a difficult task. Historically NGOs have focused on Canadian foreign policy through lenses of justice and human rights, challenging capitalist norms in the process.<sup>40</sup> Pratt has shown that historically those promoting a more ethical foreign policy have had victories that are few and insecure.<sup>41</sup> Dependence on the state and private donors limits the material influence of NGOs. This is not to say that NGOs have become powerless, but rather that they face a serious disadvantage when confronting capital interests. In the case of C-9 the objectives of NGOs and activists were similar to the objectives pursued by national capital. This was not due to an agreement in ideology or motivation, but a genuine convergence of interests. This convergence of interests gave both groups influence they would not have had independently.

According to neo-Marxists, claims that the government is listening to groups other than capital are questionable. Non-capital actors have had some success, but as Nuefeld states, it is the form, not the substance of democracy that has been adopted.<sup>42</sup> National forums tend to be closed-door affairs in which only the elite are invited to participate.<sup>43</sup> Other processes that do not require invitations such as the 'Foreign Policy Dialogue' carry little weight in influencing policy-making. Instead they give the Canadian government a way of creating a perception of inclusiveness, while continuing

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<sup>40</sup> Brian Tomlinson, "Defending Humane Internationalism: The Role of Canadian NGOs in a Security-Conscious Era," International Journal (Spring, 2002), 273.

<sup>41</sup> Cranford Pratt, "Ethical Values and Canadian Foreign Policy: Two Case Studies," International Journal 56(1) (Winter 2000-2001), 52.

<sup>42</sup> Mark Neufeld, "Democratization in/of Canadian Foreign Policy: Critical Reflections," Studies in Political Economy 52 (Spring, 1999): 106.

<sup>43</sup> Ibid.

its normal practices. Moreover, in the current era of globalization and neo-liberalism, capitalist norms and practices have pervaded everyday life to such a degree that democratic governments are accountable to a second polity, that of market forces.<sup>44</sup>

Both Nuefeld and Sjolander are critical of this process. Neufeld emphasizes that ethical concerns such as human rights are continuously downplayed by the government when determining trade relations.<sup>45</sup> Democratization of foreign policy would be a popular move with the counter-consensus, which is partly why it has not occurred.<sup>46</sup> Instead the state continues to listen to, and reflect, capital interests. Sjolander also emphasizes the role of trade in determining foreign policy. As she states, “trade policy is the tail that has begun to wag the foreign policy dog.”<sup>47</sup> Bill C-9 is a trade issue. Its ratification allowed Canadian firms to sell their products to previously inaccessible markets. There is much potential for gain or loss to particular sections of capital in allowing generic producers to sell patented medicines to Third world states. Understanding these interactions is necessary to properly understand the ratification of C-9.

In this case transnational capital is represented by the brand-name pharmaceutical companies, whereas the producers of generic Pharmaceuticals are largely Canadian. In the US the political activities of the Pharmaceutical multinationals are organized by the lobby group PHARMA, which is the single largest lobby.<sup>48</sup> Although not as strong in Canada as its counterpart in the US, Rx&D is an influential organization. In Canada the power of Rx&D is somewhat offset by the power of the CGPA. At the domestic level,

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<sup>44</sup> Ibid, 412.

<sup>45</sup> Ibid, 103.

<sup>46</sup> Ibid, 110.

<sup>47</sup> Claire Sjolander, “International Trade as Foreign Policy: ‘Anything for a Buck’”, in Gene Swimmer, ed., How Ottawa Spends 1997-98. Seeing Red: A Liberal Report Card (Ottawa: Carleton University Press, 1997), 112.

<sup>48</sup> The Observer, “Big Pharma Puts Block on Cheap Drug Imports,” 3 August 2003.

capital's structural power is bestowed upon it by a widespread acceptance that economic growth and prosperity are dependent on private enterprise for investment and innovation.<sup>49</sup> This view of private investment is of particular importance when it is coupled with the consistently higher priority that is given to economic growth, over other issues such as environmental protection, public health, or social policy.<sup>50</sup>

The widespread adoption of neoliberal principles has increased the importance of national capital, relative to other groups attempting to influence policy. These same principles have also decreased the influence of national capital relative to transnational capital. Transnational capital is able to move between states in an effort to find favourable conditions. This ability to move between states allows transnational capital to play states off against each other in their search for investment. It also shields transnational capital from localized recessions.<sup>51</sup> While the ability of capital to do this tends to be exaggerated, the brand-name drug companies have made it clear that Canada is not an investment priority, and that they could withdraw their investment. Given the focus on the accumulation of wealth, it is only natural that states become linchpins of particular regimes of accumulation, simultaneously trying to generate new capital from within, while attracting foreign capital.<sup>52</sup> In relation to Bill C-9, the neo-Marxist perspective would hypothesize that the Canadian government would not do anything that seriously undermines intellectual property rights. Thus C-9 may be tabled and passed, but it will not threaten Rx&D's position in Canada.

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<sup>49</sup> Stephen Gill and David Law, *The Global Political Economy: Perspectives, Problems, and Policies*, (The Johns Hopkins University Press: Baltimore, 1988): 86.

<sup>50</sup> Stephen Gill and David Law, "Global Hegemony and the Structural Power of Capital" *International Studies Quarterly* 33 (1989): 480.

<sup>51</sup> *Ibid*, 486.

<sup>52</sup> *Ibid*, 479.

### 1.5(B) Pluralist

The pluralist model is based on the observation that interest groups influence government decisions. Society is made up of individuals with specific interests. These groups realize they are more likely to achieve their goals if they band together with other groups who have similar objectives. Unlike the neo-Marxist perspective which sees class as the foremost cleavage, the pluralist perspective, while conceding the importance of economic factors, views other lines of division as being equally important.<sup>53</sup>

The pluralist model recognizes that policy-making is often a competition between elites. Some groups possess greater resources than others, and some demands tend to receive a more sympathetic ear from government. The result is that some parts of society, especially the poor and uneducated, are less likely to mobilize, and thus be excluded from elite competition.<sup>54</sup> In his explanation of neopluralism Nossal states that while all have an equal opportunity to express their policy preferences to the state, some actors are more equal in their ability to translate their preferences into action.<sup>55</sup>

Coleman and Skogstad observed that some groups seemed to have privileged access to the policy making process. This access persisted over time, and groups enjoying these advantages were able to exclude others from entering the policy-making process in their area. Thus, policy was divided into separate areas dominated by long-term participant groups with policy areas and interests. These groups formed what Coleman

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<sup>53</sup> Stephen Brooks and Lydia Miljan, "Public Policy in Canada: An Introduction," (Oxford University Press, Don Mills Ontario, 2003): 34.

<sup>54</sup> Ibid, 35.

<sup>55</sup> Kim Richard Nossal, "Analyzing the Domestic Sources of Canadian Foreign Policy," International Journal 39(1) (Winter 1983-4): 4.

and Skogstad refer to as 'policy communities.' The links that developed between these groups and policy makers were termed 'policy networks.'<sup>56</sup>

The pluralist perspective views public opinion as an influential factor in determining policy. Joseph Schumpeter likens the political process to a market place in which the parties are the competing sellers, the voters the purchasers, and the policies the products. As such political leaders structure their policies on the basis of demands, or on anticipated reactions.<sup>57</sup> The pluralist perspective holds that the outcome of legislation depends on the pressure applied by different groups, and how the public responds to these groups. It also emphasizes the importance of government's electoral concerns.

### **1.5(C) Statist**

No matter how powerful and influential these groups are, they remain outside the state apparatus. A proper analysis requires an examination of the apparatus itself. The idea that there is an independent government interest must be considered when discussing policy formulation. The statist perspective holds that the state and its officials have interests that can diverge from, or coincide with, interests of external actors.<sup>58</sup> The state is sure to use its significant resources to ensure that its preferences will prevail over those of other actors.<sup>59</sup> The state subscribes to liberal views about the desirability of capitalism. The statist perspective argues that the state holds the promotion of capitalism in general, and Canadian capitalism specifically, to be in the national interest.<sup>60</sup>

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<sup>56</sup> William D. Coleman and Grace Skogstad, "Policy Communities and Public Policy in Canada: A Structural Approach," (Copp Clark Pitman Ltd., Mississauga Ontario, 1990): 25.

<sup>57</sup> Kim Richard Nossal, "Analyzing the Domestic Sources of Canadian Foreign Policy," International Journal 39(1) (Winter 1983-4): 4.

<sup>58</sup> Kim Richard Nossal, "Mixed Motives Revisited: Canada's Interest in Development Assistance," Canadian Journal of Political Science 21(1) (March 1989): 38.

<sup>59</sup> *Ibid*, 45.

<sup>60</sup> *Ibid*, 42.

As an entity pursuing its own interest, the state is careful to limit the influence of external actors. Nossal outlines four assumptions of statist theory. The first is that officials of the state have their own interests and preferences, and do not slavishly pursue the interests of others. The second is that the preferences of the state may, but are not necessarily, divergent from the interests or preferences of civil society. The third is that if the preferences of the state and civil society diverge, the state will act on its desires. Finally the statist theory assumes that the government has the power to prevail in any conflict of interest between state and society.<sup>61</sup> Nossal argues that the state has an interest in organizational maintenance, prestige, and limiting net expenditures.

Undoubtedly there is a role for altruism in formulating policy. It is disturbing that so many people are unable to access life saving medicines. State officials are not immune to these facts. However even the most well-meaning official is limited by the state apparatus. There are mandated limits to altruism that tend to be exclusive and discretionary.<sup>62</sup>

The statist perspective explicitly refers to term state structures, and the non-elected officials who occupy these positions. It is not very clear on the role of elected government officials. The distinction is even more difficult in Canada, where the federal Liberal Party has dominated electoral politics in the 20<sup>th</sup> century, and the very early 21<sup>st</sup> century. The Liberal party has come to be known as Canada's 'natural governing party.' This thesis will largely focus on the role of elected officials, and their interests. References to statist theory will use the term 'state' perspective. References to the interests and objectives of elected government officials will be termed 'government'

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<sup>61</sup> Kim Richard Nossal, "Analyzing the Domestic Sources of Canadian Foreign Policy," International Journal 39(1) (Winter 1983-4): 4.

<sup>62</sup> Ibid, 120.

perspective. The statist perspective would hold that the state would not want to radically change current intellectual property practices, as doing so would not be in its interests. The governmental perspective would emphasize that elected officials have their own interests in this legislation that goes beyond the stated intent of the bill. Elected officials will favour legislation that maximizes their prospects of re-election, and will therefore favour legislation that is popular with the public.

### **1.6 The role of Capital and NGOs in the Passage of Bill C-9: A Preliminary Sketch**

As Canada began moving towards amending the Patent Act and the Food and Drugs Act, transnational capital voiced its opposition, while national capital voiced its support. Two profit-driven interests with the same general goals had opposing viewpoints on a piece of legislation. Both of these groups attempted to influence the Canadian government in an attempt to promote its agenda. Transnational capital achieved an early 'victory' with the creation of Bill C-56, which contained many stipulations that favoured patent holders. At the last minute a coalition of groups opposed to C-56 prevented it from being ratified by parliament. Among these groups was the CGPA, which claimed that the bill "was not effective as currently worded."<sup>63</sup> Of particular concern was the 'right of first refusal' clause, which allowed contract negotiated between generic distributors and recipients to be adopted by brand-name companies. When Parliament re-convened under the leadership of Prime Minister Paul Martin, Bill C-56 was reintroduced and passed as Bill C-9. Many of the concessions made to the brand-name companies in Bill C-56, including the right of first refusal, were removed. However, the bill as a whole favoured the interests of transnational capital. These clauses that were removed, were there in the

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<sup>63</sup> The Canadian Generic Pharmaceutical Association, "Generic Drug Industry Offers Improvements to Access to Medicine Bill," [http://www.cdma-acfpp.org/en/news\\_releases/index.shtml](http://www.cdma-acfpp.org/en/news_releases/index.shtml) (26 May, 2004).

first place in order to satisfy transnational capital interests. Their removal was the result of a compromise, and the inclusion of a 'commercial elements' clause that decreases the effectiveness of the C-9. One of the issues this thesis will examine is the degree to which Canadian national capital, activists and NGOs, prevailed over transnational capital. To say that the ratification of C-9 was a victory for any of the actors would be an oversimplification.

### **1.7 Methodology**

The initial intent of this thesis was to examine Canada's decision to amend the Patent Act and the Food and Drugs Act. The intent was to highlight how Western nations failed to follow the rules they enforced on Third World nations, through organizations such as the WTO. I had a basic knowledge of several cases of "Western hypocrisy." I was aware of the US government coercing African nations to abandon agricultural subsidies, while continuing to subsidize its own agriculture. I was aware of the EU choosing to set milk quotas at extremely high levels so that purchasers would not turn to non-EU states to meet their demand. Most importantly I was aware of Canada's decision to override Bayer's patent on CIPRO in the weeks following September 11<sup>th</sup>. Canada made this decision, despite supporting US attempts to extend and enforce patent protections at the WTO. This more than any of the other issues caught my interest for two reasons. First because it was a Canadian issue, in which Canada was a perpetrator, and not a 'victim,' as it often claims to be. Second because it is an issue of life and death for many people around the world. Length and quality of life of people infected with deadly diseases, are directly correlated to the ability of those people to access medicines.

A brief glance into this issue revealed to me Canada's stated intention of exporting generic medicines to eligible countries. This caught my interest, as it was a way to explore Canada's decision to override Bayer's patent in the larger context of access to drugs. At this time I was also interested in how Canadian foreign policy was formulated. I was able to incorporate these interests by using Canada's decision to allow for the export of generic medicines as a case study of how foreign policy is determined. As I read, I realized that foreign policy cannot be understood apart from broader policy analysis, and that C-9 was influenced as much by domestic factors as it was by international concerns. This was the final transition, as it became a thesis to examine how Canadian policy is formulated, using Bill C-9 as a case study. I chose to interpret this legislation through the lens of three theories – neo-Marxist, statist, and pluralist.

Many of the events that surrounded this issue were happening as I was writing this thesis. This ensured that my research, and subsequently my thesis, was constantly evolving to incorporate what was happening politically. It began with Bill C-56, entitled "An Act to Amend the Patent Act and The Food and Drugs Act," which amended the Patent Act and the Food and Drugs Act, to allow for the export of generic medicines. When Prime Minister Chrétien resigned C-56 had not passed, and it died on the table. I chose to examine why the government decided to make these amendments, why it wanted to rush them through Parliament, and why it failed to do so.

When Parliament resumed the *Act to Amend the Patent Act and The Food and Drugs Act* was re-tabled as Bill C-9. It was immediately sent to committee for further study. Here I study what happened at the committee meetings. I examine what actors

were invited, who had influence, and go into the details of the legislation. I ask which actors were listened to, which factors considered, and why this was the case.

After two months in committee C-9 was re-introduced to the House of Commons. Now entitled "The Jean Chrétien Pledge to Africa Act," C-9 was in its final form. I examine how the actors reacted to the final legislation, and hypothesize as to how effective it will be in getting generic medicines to eligible countries. I base my analysis on the reactions of the relevant actors.

I use a mix of primary and secondary sources. My secondary sources are derived from the policy literature. They are used to introduce the theories I am using. They are also used to provide information on some of the key issues that set the context for my case study. They provide background on the WTO, the history of the Pharmaceutical industry in Canada, and the Canadian government's interest in Africa.

The primary sources I use are newspaper articles, parliamentary debates, committee debates, interviews, submissions made to the committee by the actors invited to participate, and press releases. Although not used often the parliamentary and committee debates provide insight as to how the government was responding to the various interests. Often they are used to confirm statements made by interviewees, and the secondary sources, and are not cited.

In my readings I have become convinced that on this issue there is no such thing as an unbiased source. The closest thing was the *Globe and Mail*, which was my predominant media source. Generally the *Globe and Mail* favoured the principles behind the legislation, and portrayed the NGOs and CGPA arguments as the best way to achieve

those principles. Occasionally I sought out other media sources such as the *National Post* to capture an alternate perspective.

The submissions and press releases were very useful. They captured the positions of the relevant actors. Even if the statements made in these documents were false, the statements themselves show where an actor stood on the issue, and how they intended to promote their interest. Of all the primary sources used these were the most valuable. They are exactly the same as what the actors presented to government, and have not been filtered through the media or other mediums. As well they are being made for the government to view. This captures how the actors relate to government, and decreases some of the showboating that occurs in the media.

The interviews were also helpful. They helped expand on some of the ideas made in the media and submissions. As well, talking to a representative of each actor helped me understand how the actors perceived and related to each other. Much of what was said in the interviews served as a confirmation of what I already knew, however much of it was also new ideas that would not have occurred to me otherwise.

Finally I am aware that in most pieces of legislation, there are debates that occur behind closed doors. Bill C-9 is no exception. Arrangements, agreements, and decisions are made out of the public eye. The interviews helped me to get just a small piece of this. However I am sure there was much more. This thesis examines and interprets what happened in the public debates. Although important, what happened behind closed doors is beyond its scope.

## **1.8 Chapter Outline**

Chapter 2 focuses on how international agreements impact access to medicines. It begins by briefly highlighting the severity of the HIV/AIDS epidemic. It then examines the history of patent negotiations at the WTO, and international debates surrounding patent protections. This chapter largely focuses on the TRIPS agreement, and how that agreement is interpreted. This is an important agreement to examine, as it shaped the option available to the Canadian government. The chapter then examines the debates over the circumstances under which patent protections can be overridden. It concludes with an examination of the decision to allow TRIPS agreement signatories, one of which is Canada, to export generic medicines. The discussions that took place at the international level were largely duplicated in the Canadian context.

Chapter 3 begins with Canada's unprecedented announcement that it would amend its patent laws to allow for the export of generic medicines. This chapter focuses on possible reasons for this decision. It also re-introduces the actors, factors, and theories introduced in chapter 1. It captures these actors' interests by examining the reactions they had to the legislation. Finally it examines the methods each actor used to influence the legislation, and hypothesizes as to the effectiveness of those methods. It is designed to show how the actors articulate their interests, and how the government responds to them.

Chapter 4 begins by highlighting how the NGO community got the issue back into Parliament. After this brief introduction, the main focus is the details of The Jean Chrétien Pledge to Africa Act. It examines how the government originally formulated the legislation, and why it took the form it did. It then analyzes how the actors' reacted to various parts of the legislation. It concludes with an analysis of why Schedule One was

left in, while the right of first refusal was taken out. The intent is to show how the actors attempt to maximize their influence, and under what criteria they are heard.

Chapter 5 concludes the thesis. It begins with an analysis of actors' reactions to the final legislation. It will summarize the actors and factors introduced in chapter 1, and expanded upon in chapter 3 and chapter 4. It will also re-introduce the theories first used in chapter 1. Using the theories, it will interpret the actions of the actors, based on what we know of them through the first four chapters. The conclusion will show that the government did its best to compromise between various positions. Ultimately capital interests were the most, but not only, significant influence. It will also conclude by stating that thus far, C-9 has failed to achieve its stated intent of exporting generics to eligible countries, however there is hope that at some point this legislation will be effective in doing so.

## **1.9 Conclusion**

This chapter introduced several important elements in order to understand the Canadian government's decision to amend the Patent Act and the Food and Drug Act, to allow for the export of generic medicines. It introduced the relevant actors, provided a brief history of how those actors have engaged the Canadian government and/or its citizens, and the source of those actors influence. It also introduced three theories, neo-Marxist, pluralist, and statist, through which C-9 will be interpreted. It highlighted the strengths and weaknesses of each theory, and how the theories can be used in conjunction with each other to explain the Canadian governments decision.

**Chapter 2**  
**HIV/AIDS As An Issue: Historical Responses**

## **2.1 Introduction**

The Canadian government's decision to amend the Patent Act and The Food And Drugs Act would not have been legal had it not been for intense negotiations at the WTO. This chapter will examine the issues and politics surrounding these negotiations. It will show that many of the key issues, actors and factors relevant at the WTO negotiations were also present in the Canadian debates. This chapter will discuss where Canada stands on the issue of patent protection, and set the context for Bill C-9.

This chapter reveals how strong patent protections make it difficult for certain states and their citizens to access medicines. It also highlights the ability of public opinion to force an issue on an agenda, and the importance of smaller groups forming coalitions to increase their influence. Finally it reveals the power of transnational capital interests, and the ability of this capital to use the state as a mechanism of promoting its interest.

This chapter demonstrates the power of transnational capital by highlighting how actions of the US and other like-minded states reflect the interests of the pharmaceutical companies. It also shows that powerful as transnational capital is, there are other actors and factors that can also be influential, at least when certain criteria are met. When these criteria are met, the power of transnational capital can sometimes be countered by other groups and coalitions. The neo-Marxist perspective is not proven wrong in these circumstances, but it is unable to effectively capture the nuances of the situation.

## **2.2 HIV/AIDS as an Issue**

The numbers are staggering. Worldwide over 40 million people have been infected with HIV/AIDS.<sup>64</sup> In North America and Western Europe, HIV/AIDS is an incurable disease. In Africa the HIV/AIDS epidemic is a catastrophe, with death and infection rates not known since the Bubonic Plague ravaged Europe in the 15<sup>th</sup> and 16<sup>th</sup> centuries. HIV/AIDS is a global phenomenon. However it is so strongly concentrated in Africa that any discussions and proposed solutions to the endemic must be focused on that region. Currently seventy-five percent of people living with HIV reside in Africa.<sup>65</sup> This translates into roughly thirty million people in Africa currently infected with HIV,<sup>66</sup> with another twenty million having died over the previous twenty years.<sup>67</sup> HIV/AIDS hits people in their prime, with the highest rates of infection among those aged twenty-five to forty. The concentration of HIV/AIDS in this age range has major impacts, not the least of which is the elimination of entire sectors of agriculture and industry. It also changes family structures by targeting those in their prime. Most diseases target the young and old, but HIV/AIDS targets those in their prime. Orphaned children are being cared for by their grandparents. The consequences of HIV/AIDS extend beyond death tolls, and into the very sustainability of African economies.

### **2.3 The TRIPS Agreement and Accessibility**

Three drugs, collectively known as anti-retroviral (ARV) drugs can be used to treat HIV/AIDS. ARV drugs extend life expectancy by twenty years, significantly improve the quality of life, and decrease the communicability of the HIV/AIDS virus.

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<sup>64</sup> Mark A. Wainberg, "Patently Wrong: Developed Nations Must Ensure that Intellectual Property Rights Are Respected," The National Post, 19 November 2003.

<sup>65</sup> James Orbinski, 481.

<sup>66</sup> Kristine Novak, "The WTOs Balancing Act," The Journal of Clinical Investigation 112 (November 2003): 1269.

<sup>67</sup> Wainberg.

The existence of treatments, coupled with the inability of large segments of people to access those treatments, helped force the issue onto the WTO agenda. For the past five years the TRIPS agreement, which governs who produces and distributes ARV drugs, has been challenged by those wanting to ensure that citizens of lesser-developed countries (LDCs) can secure a steady and affordable supply of medicines.

The TRIPS agreement prevents the cheap sale of pharmaceutical products by granting a twenty-year patent to the pharmaceutical company that creates a product. This means that the company receiving the patent has a twenty year monopoly on that product.<sup>68</sup> The cost of producing the drugs is the same regardless of whether they are produced by a patent holder, or a generic drug manufacturer. Generic drugs are therefore cheaper to purchase, as generic producers do not have to recoup the costs of Research and Development (R&D).

By protecting patent rights, the TRIPS agreement leaves the production and distribution of drugs to the patent holder. With no equivalent product on the market, major Pharmaceutical corporations are able to charge what they believe will maximize profits. This practice, known as monopoly pricing, results in extremely high drug prices relative to a competitive market, as most people and/or governments in First World countries can afford to pay. Conversely, most African nations cannot afford to purchase these drugs. The US has consistently held that high prices are not a barrier to drug access, and that problems are the fault of third world governments.<sup>69</sup> The US holds that poor infrastructure; along with an inability to deliver health care items is the main barrier to

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<sup>68</sup> Alan Cassalls, "In Wake of 9/11, Drug-Patent Rules Change," Canadian Medical Association Journal 166 (February 2003): 366.

<sup>69</sup> Frederic M. Abott, "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting A Dark Corner at The WTO," Journal of International Economic Law 5 (2) (2002): 483.

access. While these issues cannot be ignored, prohibitive pricing does create barriers to access.

Competition, which is only possible without complete patent protection, is considered the single largest factor in reducing drug prices. If a drug patent expires in the US, the average price of that drug drops to 60% of the original price when a generic version is marketed. When there are ten competitors the price of the drug falls to 29% of the price prior to the patent's expiration.<sup>70</sup> In Brazil, which has strong generic competition, the price of ARV drug 3TC is 36% cheaper than the same product in South Africa. The price of another ARV drug AZT is 94% cheaper than the same product in South Africa!<sup>71</sup> Although the amounts differ, generic competition consistently leads to cheaper drug prices.

Brand-name pharmaceutical companies make very little money in Third World countries, yet they consistently oppose changing international patent laws to allow generic medicines to be produced in, or exported to, these states. The predominant reason for this is a fear that loosening patent regulations will result in drugs being smuggled back into first world markets, which would undercut prices there.<sup>72</sup> US trade representative Robert Zoellick stated that it was necessary to strike

...the right balance between addressing the needs of the poorest countries while *ensuring intellectual property protections* that foster the future development of lifesaving drugs.<sup>73</sup> [Emphasis added]

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<sup>70</sup> Abott, 472.

<sup>71</sup> Médecines Sans Frontières, *Brazilian Generic Drugs in South Africa –The Background*, <<http://www.accessmed-msf.org/prod/publications.asp?scentid=29120021037154&contenttype=PARA&>> (29 January, 2002)

<sup>72</sup> Fiona Fleck, "No Deal in Sight on Cheap Drugs For Poor Countries," *British Medical Journal*, 326 (March 2003): 465.

<sup>73</sup> Ibid.

Unfortunately for LDCs the US has consistently pushed for a 'balance' that favoured patent protections over access.

The TRIPS agreement included a provision that allowed LDCs to purchase generic drugs. Article 31 of the TRIPS agreement governs how states can access generic drugs. First, a country must attempt to obtain a voluntary license from the patent holder. Failing this they can issue a compulsory license, which puts patented drugs off patent.<sup>74</sup> In times of national emergency countries can simply declare drugs off patent and purchase them from generic drug manufacturers.<sup>75</sup>

The original provision made it impossible to export generic drugs under a compulsory license, as the license could only be issued for domestic markets. Article 31(f) of the TRIPS agreement states:

Any such use [of compulsory licenses] shall be authorized *predominantly for the supply of the domestic* market of the Member authorizing such use."<sup>76</sup> [Emphasis added]

As China, Brazil, India and South Africa are the only LDCs capable of manufacturing drugs on a large enough scale, this stipulation effectively prevented most LDCs from taking advantage of compulsory licenses.

#### **2.4 Doha Declaration**

On 14 November 2001 the Doha Declaration was signed. It was a result of the Fourth Ministerial Conference of WTO members, which was held in Doha Qatar. Prior to this conference there had been several important preliminary meetings that were used to

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<sup>74</sup> Peter J. Hammer, "Differential Pricing of Essential HIV/AIDS Drugs: Markets, Politics and Public Health," *Journal of International Economic Law* (2002): 900.

<sup>75</sup> WTO TRIPS Agreement Article 31. The Entire Agreement is Available at <  
[http://www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/trips_e.htm)>

<sup>76</sup> Article 31(f) the TRIPS Agreement

set the agenda. A growing awareness of how the TRIPS agreement hindered access to medicines, forced the issue on the agenda, and the WTO could not ignore the access to medicines issue.<sup>77</sup> Coming into this conference states, aware that this issue would be predominant, made coalitions and prepared positions in advance. In the months prior to the Fourth Ministerial Conference, various actors submitted papers highlighting the issues they wished to see on the agenda.

On 20 June 2001, the TRIPS Council convened to discuss the concerns of the actors, in an attempt to set the agenda for the Fourth Ministerial Conference in November of that year. Two cohesive groups had emerged. The first was a US-EU block, which consisted of the US and like-minded states (US, Canada, Switzerland, Australia, and Japan), and the EU. The second group was the LDC states which consisted of the G-77, Organization of African Unity (OAU), South Asian Association for Regional Cooperation (SAARC), and the African Caribbean and Pacific Group of States (ACP), and sixteen other supporting states,<sup>78</sup> collectively known as the Africa Group.

Frustrated by the market's inability to deliver medicines, and by their inability to use compulsory licenses, the Africa Group arrived at Doha with an agenda. Prior to Doha, members of this group met in Zanzibar, Tanzania in order to issue their own declaration.<sup>79</sup> Led by Brazil and India, LDCs exerted enormous pressure on their Western counterparts.<sup>80</sup> This declaration was very comprehensive, and included statements on unfair trading practices, and a lack of resources to assist in preparing for international

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<sup>77</sup> Ellen, T'Hoen. "TRIPS, Pharmaceutical Patents and Access to Essential Medicines: A Long Way From Seattle to Doha," *Chicago Journal of International Law* 24 (June 2002): 49.

<sup>78</sup> Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela

<sup>79</sup> Surya P Subedi, "The Road From Doha: The Issues For The Development Round of the WTO and the Future of International Trade," *International Comparative Law Quarterly* 52 (April 2003): 430.

<sup>80</sup> Helen Frankish, "Patent Laws High on the Agenda at WTO," *Lancet* 358 (November 2001): 1706.

conferences. The Africa Group adopted a common stance on access to drugs, and proposed that there be a separate declaration on access to medicines. The Africa Group stated that the TRIPS agreement made it difficult for them to use compulsory licenses, made it impossible for states with insufficient manufacturing capacity to access cheap medicines, and asked for an evaluation of the effects the TRIPS agreement had on public health, with an emphasis on access to medicines.<sup>81</sup>

The US led bloc, of which Canada was a part, and European Communities also submitted papers for consideration. The European Communities' paper expressed sympathy for the concerns of the African Group, but took a hard line industrial perspective on the issue of compulsory licensing. The US also took a hard line, arguing that price was only one factor in the public health equation, that patents were not an obstacle to access, and that compulsory licenses should be used sparingly.<sup>82</sup> Each group made their presentation to the TRIPS council, and the result was the scheduling of an informal session, on 25 July 2001, to consider the issue. The result of the 25 July 2001 meeting was the scheduling of a formal session of the TRIPS Council for 19 and 21 of September to examine the issue in more detail.

In the period between the June 2001 and September 2001 meetings, both sides were active. Each side began preparing its formal positions, and drafting papers. The heart of the African Group's draft paper was that, "nothing in the TRIPS Agreement should prevent members from taking measures to protect public health."<sup>83</sup> The US draft paper once again echoed the arguments of the brand-name Pharmaceutical industry, and supported strong patent protections, and pushed for TRIPS-plus provisions. The EU

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<sup>81</sup> T'Hoën, 50.

<sup>82</sup> Abott, 482.

<sup>83</sup> Ibid, 483.

paper was slightly different, but generally supportive of the positions laid forth by the US. The September meetings did not create any common ground between the two groups, and the task of developing a compromise was left in the hands of the WTO Secretariat.

On 10 October 2001 a preliminary text was presented. On 27 October 2001, the Secretariat provided two alternatives, labelled 'Option 1,' and 'Option 2.' Option 2 used vague language to propose how the TRIPS agreement could be used to address health epidemics. Realizing that there would be no negotiations on other issues such as investment and competition without a meaningful result on medicines the US group had to go with Option 1, which was preferred by the African Group. Option 1 acknowledged the TRIPS agreement should not prevent members from taking measures to protect public health, and that all the provisions in the TRIPS agreement should provide flexibility for this purpose. In a closed negotiating session, Brazil, one of the most powerful LDC countries, and a nation with an extremely well developed generic industry, and a government that had decided to issue compulsory licenses by declaring HIV/AIDS a national emergency, and the US worked out a compromise on Option 1, in which the US accepted a strong result in support of the African Group's position, that was very close to the original demands.<sup>84</sup> At the Fourth Ministerial Conference access to medicine was the core issue, and this was the core paper in addressing it.

The rather short document, referred to as "The Declaration on the TRIPS Agreement and Public Health" contained seven points. The second point emphasized the need for the TRIPS agreement to be part of any solutions addressing the HIV/AIDS crisis

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<sup>84</sup> Ibid.

in Africa.<sup>85</sup> Article four of the agreement, which was the biggest concession given to LDCs, stated

We agree that *the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health...The agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and...to promote access to medicines for all.*<sup>86</sup> [Emphasis added]

While this article did not specify how LDC's could use the TRIPS agreement to protect public health, it became a rallying point for them in post-Doha negotiations.

Finally, article six recognized the problems caused by the domestic market condition of TRIPS Article 31(f), and mandated that a solution should be found by the end of 2002. Article 6 states:

We recognize that WTO Members with insufficient or no manufacturing capacities in the Pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to *find an expeditious solution to this problem and to report to the General Council before the end of 2002.*<sup>87</sup> [Emphasis added]

There are several reasons why the Declaration on the TRIPS Agreement and Public Health was accepted by WTO members. First of all was the bad publicity drug companies had received since their attempt to sue South Africa. In South Africa over twenty percent of people are infected with HIV.<sup>88</sup> In February 1998 President Nelson Mandela issued a compulsory license for essential HIV/AIDS drugs. The South African

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<sup>85</sup> World Trade Organization, Paragraph 2, "Declaration on the TRIPS Agreement and Public Health." < [http://www.wto.org/english/tratop\\_e/trips\\_e/pharmpatent\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm) > (14 November 2001).

<sup>86</sup> World Trade Organization, Paragraph 4, "Declaration on the TRIPS Agreement and Public Health." < [http://www.wto.org/english/tratop\\_e/trips\\_e/pharmpatent\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm) > (14 November 2001).

<sup>87</sup> World Trade Organization, Paragraph 6, "Declaration on the TRIPS Agreement and Public Health." < [http://www.wto.org/english/tratop\\_e/trips\\_e/pharmpatent\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm) > (14 November 2001).

<sup>88</sup> Hammer, 900.

government was taken to court by a conglomerate of Pharmaceutical companies.<sup>89</sup> The US supported the drug companies by putting South Africa on a special watch list, and denied it preferential treatment.<sup>90</sup> The drug companies only backed down when the international community successfully portrayed them as self-interested protectors of intellectual property at the cost of the public interest.<sup>91</sup> This was a public relations disaster for drug companies. This ideological defeat had long lasting repercussions that hindered them in future negotiations.

A second reason for the declaration was the strength of the LDC coalition prior to the meetings. The union of G77, OAU, SAARC, and ACP countries gave developing countries greater salience. Abott goes so far as to say that the emergence of a cohesive group of LDCs was the most notable development of Doha.<sup>92</sup> In his words:

These members demonstrated that by establishing a coalition, and maintaining it throughout a negotiating process, they could prevent themselves from being outmanoeuvred by the EU-US block.<sup>93</sup>

By banding together LDCs achieved some of their objectives at Doha, the most important being recognition of problems caused by the 'domestic use' section of the TRIPS agreement.

Even with all the LDCs working together, the US block still wielded significant power. Even though they were cohesive and had a strong mandate, LDCs lacked the resources of the US coalition.<sup>94</sup> Article 6 passed because it was an agreement in principle, but did not concretely address LDC concerns. It simply set a deadline for dealing with

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<sup>89</sup> T'Hoën, 43.

<sup>90</sup> Thomas, 256.

<sup>91</sup> Hammer, 901.

<sup>92</sup> Frederic M. Abott, "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting A Dark Corner at The WTO," *Journal of International Economic Law* 5 (2) (2002): 479.

<sup>93</sup> *Ibid*, 469.

<sup>94</sup> T'Hoën, 53.

these issues. In many ways Doha was a positive development for LDCs, as it acknowledged the legitimacy of their concerns. It was an important acknowledgement, but in the immediate aftermath of the negotiations it remained just that - an acknowledgement. The importance of Doha's failure to set goals would become clear immediately after the conference.

## 2.5 Doha to Cancun

The optimism LDCs felt at Doha quickly eroded. The Declaration on the TRIPS Agreement and Public Health specified that the access problems caused by the 'domestic use only' section of TRIPS Article 31(f) were to be resolved by the end of 2002.<sup>95</sup> However, the US never fully accepted the Doha Declaration, and immediately began bilateral and multilateral efforts to pressure countries to enforce patent protections. One example is the US position in the Free Trade Area of the Americas (FTAA) negotiations. These negotiations involved thirty-four countries of the western hemisphere, only two of which belong to the first world (US and Canada). In these negotiations the US pushed for the reinforcement and extension of patent protections above and beyond the rules set forward in the TRIPS agreement. These TRIPS-plus demands included extending patent terms beyond twenty years, and further limiting the circumstances for issuing compulsory licenses.<sup>96</sup>

The US made similar demands in free-trade negotiations with five Central American countries (Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua), the South African Customs Union (Botswana, Lesotho, Namibia, South Africa, and

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<sup>95</sup> World Trade Organization, Paragraph 6, "Declaration on the TRIPS Agreement and Public Health." <[http://www.wto.org/english/tratop\\_e/trips\\_e/pharmpatent\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm)> (14 November 2001).

<sup>96</sup> Médicines Sans Frontières, "Doha Derailed: A Progress Report on TRIPS and Access to Medicines," <[www.accessmed-msf.org](http://www.accessmed-msf.org)> (2003): 4.

Swaziland), and with Morocco, Bahrain, and Australia. Contrary to the intent of the Doha Declaration, the US pressured all these countries to adopt TRIPS-plus agreements. Despite these pressures the LDC bloc remained cohesive, and continued to press for a resolution that would address its concerns. The African group proposed deleting all aspects of Article 31 related to the 'domestic markets' stipulation.<sup>97</sup> The US proposed a solution that would only allow compulsory licences for three diseases: HIV/AIDS, TB, and Malaria.<sup>98</sup>

With the 31 December 2002 deadline fast approaching, negotiations were accelerated. A compromise agreement, the 'Motta Text,' was reached. This text listed a large number of diseases, including HIV/AIDS, TB and Malaria, for which compulsory licenses could be issued. The majority of the diseases on the list either had no cure, or could be cured by drugs that were already off patent, and therefore not regulated by the TRIPS agreement.<sup>99</sup> How the treatment of other diseases should be regulated by the TRIPS agreement was not resolved. The implication was that compulsory licenses would only be issued for diseases on the list. However, this was not legally entrenched. The African bloc was willing to accept this text, as it guaranteed them the ability to issue compulsory licenses for some diseases, but did not explicitly deny them the ability to issue compulsory licenses for diseases not on the list.

Concerning diseases not on the list, the Motta Text was no more specific than the Declaration on the TRIPS Agreement and Public Health it was meant to clarify. For this reason the US, once again representing Pharmaceutical interests, vetoed the proposal on

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<sup>97</sup> Ibid.

<sup>98</sup> Mary Moran, "Reneging on Doha: An MSF Analysis of Recent Attempts to Restrict Developing Countries use of Compulsory Licensing to a Set List of Diseases," *Médecins Sans Frontières*, (May, 2003).

<sup>99</sup> Fiona Fleck, "US Blocks Deal on Cheap Drugs," *British Medical Journal* 326 (January, 2003): 9.

16 December 2002. The European Commission (EC) proposed a compromise text that would involve the World Health Organization (WHO) in any compulsory licensing decisions.<sup>100</sup> The EC compromise was rejected by all parties, the US refused to withdraw its veto, and the Motta Text was not ratified.

Despite pressure from Europe, Africa, and NGOs, the US did not change its position. The 2002 deadline specified by Paragraph 6 of the Doha Declaration had not been met, and no compulsory licenses had been issued since the Doha Declaration.<sup>101</sup>

## 2.6 Cancun

LDCs continued to pressure for changes to the TRIPS agreement after the 2002 deadline passed. On 30 August 2003, just ten days prior to the WTO Fifth Ministerial Conference in Cancun, Mexico, an agreement was reached in Geneva. The WTO adopted the ‘Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.’<sup>102</sup> Article 2(A)(ii) clarifies paragraph 6 of the Doha Declaration, as it relates to TRIPS Article 31(f). This article allows countries without manufacturing capacity to import generic drugs. Article 2(A)(ii):

Confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has *insufficient or no manufacturing capacities* in the Pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this decision.<sup>103</sup> [Emphasis Added]

Essentially this allowed LDC’s to import patented medicines. There are a series of conditions attached, such as requiring LDC’s to report how many drugs they are ordering

<sup>100</sup> T’Hoen, 61.

<sup>101</sup> Moran.

<sup>102</sup> World Trade Organization, “Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,” < [http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm) > 30 August 2003.

<sup>103</sup> World Trade Organization, Article 2(A)(ii), “Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,” <[http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm) > (30 August 2003).

(Article 2b). Article 5 also prevents importation from being stopped by other WTO member states.

## **2.7 Conclusion**

This chapter provided a survey and analysis of the international debates surrounding the TRIPS agreement. There were two reasons for doing this. The first was to introduce the actors and factors that influenced C-9. Some of the names and mechanisms used were different, however the positions and arguments of these groups are the same as they were in the debates over C-9. The second was to put Canada's decision to amend the Patent Act and the Food and Drugs Act in an international context.

The TRIPS agreement made US patent laws the international norm. By creating monopolies on products, the TRIPS agreement clearly made it difficult for largely African states and citizens to access ARV drugs. Getting this fact acknowledged was extremely difficult for African states. The transnational Pharmaceutical companies, who benefited the most from strong patent protections, used the states such as Canada and the US to promote their interests. They attempted to create a perception that R&D was directly connected to incentives provided by patent protections. They also argued that, due to the poor infrastructure of many African states, high drug prices were not a barrier to access.

Despite the power of the transnational Pharmaceutical companies, they were not able to fully protect their interests. Strong public opinion caused by the magnitude of the crisis, combined with a well-organized opposition, forced the issue on the agenda. The Pharmaceutical companies used their resources throughout the process but were not always successful in achieving their objectives. They were forced to withdraw a lawsuit

against South Africa, due to the bad publicity it was generating. They were not able to keep the issue of patent law and access off the agenda, however they successfully ensured that the resolutions to this problem were in principle. When it was decided that patent laws could be overridden for the purposes of exporting and importing generic medicines, transnational capital challenged the first country to amend its law accordingly – Canada. The issues and debates that had occurred at the international level repeated themselves at the domestic level in Canada.

**Chapter 3:**  
**Bill C-56, "An Act to Amend the Patent Act and the Food and Drugs Act."**

### **3.1 Introduction**

This chapter begins with the Canadian government's announcement that it would table Bill C-56, "An Act to Amend the Patent Act and the Food and Drugs Act," to allow for the export of generic medicines. It begins with an examination of how the bill was introduced, the response it received, and the stages it went through - culminating in a commitment by Prime Ministerial candidate Paul Martin to table it again should he become the Prime Minister.

Beyond analyzing what happened, this chapter attempts to explain the more difficult question of why it happened. After describing and analyzing the response of government officials, this chapter re-introduces the actors and factors from chapter one. In order to explain why this decision was made, there is an examination of the influence the relevant actors and factors exerted on the Canadian government prior to the announcement. The chapter then proceeds to describe and examine the actors reactions to the announcement, followed by an analysis of how they responded to the tabled amendments to the Patent Act and the Food and Drugs Act.

The chapter concludes by examining the actors' objectives, and the process that occurred. It will examine what the objectives were, and gauge how successful the actors were in achieving them. This comparison will be used to discern which actors and factors were the most influential and why. Drawing from these conclusions, the theories will be briefly re-introduced in an attempt to answer the broader question of how Canadian policy is formulated.

### **3.2 The Surprise Announcement**

On 25 September 2003, the Canadian federal government announced its intention to amend the Patent Act and the Food and Drugs Act, to allow for the export of generic medicines.<sup>104</sup> The government's announcement to change Canadian patent law to allow for the export of generic drugs was unexpected and unprecedented. If this legislation passed, Canada would be the first country to take advantage of the flexibility provided by the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health reached at the WTO Fifth Ministerial Conference.

Following the decision reached at Cancun to allow states without sufficient capacity to import generic medicines, activists and NGOs had been pressing the Canadian government to adjust its patent laws to make it legal for generic producers to export their products. The generic drug industry had also signalled its support for legislation of this type. Industry Minister Allan Rock's decision to respond to these groups surprised all the relevant actors, including Cabinet Ministers, and the Prime Minister himself. Rock made the initial announcement without consultation or warning. These groups were invited to participate at the drafting stage of the legislation, but they were not direct participants in original decision to amend the Patent Act and the Food and Drugs Act.

Normally government initiatives follow a process of drafting policy documents, then sending these drafts to committee for examination.<sup>105</sup> Instead a single individual at a high, but not the highest, level of government, introduced this initiative publicly.

As Industry Minister, Allan Rock was an influential member of the Chrétien government. In September 2001, it was Rock who stated that Canada would override

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<sup>104</sup> Eric Reguly, "Vigilance Still Needed on Drug Patent Laws," The Globe and Mail, 27 September 2003.

<sup>105</sup> Drew Fagan, Heather Scofield, and Steven Chase, "Ottawa Scrambles To meet HIV/AIDS-drug Pledge," Globe And Mail, 4 October 2003.

Bayer's CIPRO patent in the interests of public health.<sup>106</sup> This decision was used by those who disagreed with the arguments of brand-name companies to pressure the Canadian government to change its patent laws. On 23 September 2003, Stephen Lewis challenged Rock, referencing the CIPRO affair in which Rock had been prepared to waive patent law. Lewis asked if this could be done for Canadians, then why not for Africans.<sup>107</sup> Lewis, speaking from Nairobi while attending a Pan-African conference on HIV/AIDS called on Canada to take a lead among G7 nations to ease patent laws.<sup>108</sup>

Rock responded on 25 September 2003, by announcing that the government would follow Lewis' recommendation to amend the Patent Act and Food and Drugs Act to allow for the export of generic medicine.<sup>109</sup> The support of the Prime Minister and other Cabinet Ministers would have lent Rock's announcement credibility, but Rock proceeded without consulting them. Immediately after Rock's announcement other Ministers started voicing their support. Foreign Affairs Minister Bill Graham phoned from New York to signal his approval.<sup>110</sup> Most importantly, Member of Parliament, and Prime Ministerial candidate Paul Martin voiced his support for the initiative.

On 27 September 2003, Prime Minister Chrétien gave his conditional support. He made it clear that Pierre Pettigrew was to lead the effort.<sup>111</sup> Prior to becoming a politician, Rock had performed legal work for the generic producers.<sup>112</sup> Throughout the

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<sup>106</sup> Amy Harmon and Robert Pear, "Canada Overrides Patent for Cipro to Treat Anthrax," New York Times 19 October, 2001.

<sup>107</sup> Drew Fagan, Heather Scoffield, and Steven Chase, "Ottawa Scrambles To meet HIV/AIDS-drug Pledge," Globe And Mail, 4 October 2003.

<sup>108</sup> Heather Scoffield and Steven Chase, "Ottawa Heeds Call on HIV/AIDS," Globe and Mail, 26 September 2003.

<sup>109</sup> Ibid.

<sup>110</sup> Drew Fagan, Heather Scoffield, and Steven Chase, "Ottawa Scrambles To meet HIV/AIDS-drug Pledge," Globe And Mail, 4 October 2003.

<sup>111</sup> Ibid.

<sup>112</sup> Reguly.

1990s, Rock was a Health Minister who had been in the generic producers' camp, and was not trusted by the brand-name companies. His announcement to override Bayer's patent on CIPRO only worsened this reputation. Pettigrew on the other hand had a solid reputation with brand-name companies, many of which are based in Montreal with him.

The debates over C-102 and C-91 had a regional element to them. The brand-name companies were largely located in Montreal, while the generics were generally in Toronto. Those taking the sides of the generic companies were portrayed as anti-Quebec. It does not appear that the same level of regional conflict occurred in the C-9 debates. Pettigrew was chosen by Chrétien because of the positive reputation he had with the brand-name companies. Part of the reason he developed this relationship was due to his presence in Montreal. Apart from this however, there does not seem to be a regional element to C-9. The bill passed unanimously, as it was supported by members of the Bloc Québécois members present at the time.

Presiding over Canada's participation in the WTO talks which led to the decision to allow generic producers to be exported, Pettigrew had supported the brand-name companies by ensuring that the WTO decision was on principle only, while the details remained unresolved. Because of his efforts to work with the US at the TRIPS Council meetings and the Fourth Ministerial Conference, Pettigrew had the confidence of the brand-name companies. The Prime Minister's office believed that giving Mr. Pettigrew the file would be the best way to proceed.<sup>113</sup> Chrétien wanted somebody who was on good terms with the brand-name industries to handle the issue. As the legislation

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<sup>113</sup> Ibid.

advanced, Rock would stay the most bullish in pushing it through, while Pettigrew remained extremely cautious.<sup>114</sup>

On 30 September Rock met with House Leader Don Boudria to elicit his support in pushing the issue through Parliament. As House Leader, it was Boudria's job to ensure that legislation passed smoothly. On 30 September 2003, the Cabinet Ministers met for the first time since Rock's announcement. Pettigrew chaired the meeting, but Rock spoke first. Boudria informed the Ministers that he had obtained the support from the opposition parties necessary to push the amendments to the Patent Act through Parliament.<sup>115</sup>

Strong support in government for the idea was due to more than just the stated commitment to Africa made by Chrétien. In 2003, Health Minister Anne McLellan's office produced a 'concept paper' on how to address the HIV/AIDS crisis. This unpublished paper identified drug costs as an impediment to access. It highlighted the WHO target of having three million Africans in treatment program's by the end of 2005. Ottawa's fiscal situation made this an impossible goal for CIDA to achieve alone. Changing patent laws to allow generic producers to sell their products was a way to help Ottawa meet its commitment without having to spend money. It would be a policy that had a big impact with little cost.<sup>116</sup>

One of the primary goals of the meeting was speed.<sup>117</sup> The Cabinet Ministers agreed to pack the bill into the fall agenda in hopes of pushing it through before Parliament prorogued prior to the election. Government lawyers and aides had already

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<sup>114</sup> Drew Fagan, "Ottawa's HIV/AIDS Drug Plan Caught Up in Debate," Globe and Mail, 24 October 2003.

<sup>115</sup> Drew Fagan, Heather Scoffield, and Steven Chase, "Ottawa Scrambles To meet HIV/AIDS-drug Pledge," Globe And Mail, 4 October 2003.

<sup>116</sup> Ibid.

<sup>117</sup> Statement by Mr. Serge Marcil (Parliamentary Secretary to the Minister of Industry, Lib.), [http://www.parl.gc.ca/37/2/parlbus/chambus/house/debates/153\\_2003-11-07/han153\\_1215-e.htm](http://www.parl.gc.ca/37/2/parlbus/chambus/house/debates/153_2003-11-07/han153_1215-e.htm)

begun working on the details of the amendments. The stated objective was to conduct a 'surgical strike' that would balance generic producer and brand-name interests, while ensuring a flow of cheap medicines to the Third World. Interestingly the Liberal government came under attack for not moving fast enough on the bill. Lewis wanted the bill to pass as quickly as possible, and advocated for its introduction into Parliament as a show of commitment by the Canadian government. He suspected that delays were caused more by brand-name pressures, than by issues of complexity.<sup>118</sup> Opposition MPs questioned why it had taken so long for the bill to enter Parliament after Rock's announcement.<sup>119</sup> Given the promise made by the Liberal Party to move quickly on this legislation, they were right to question the reason for the delays. The delay reflected the lack of research and preparation by the Liberal Party. The government was not prepared for the complexity of its initiative, and the desire to push it through as quickly as possible became a desire to get it right the first time.<sup>120</sup>

Not all Ministers expressed approval of Rock's decision. At first, Susan Whelan, the Minister for International Co-operation expressed displeasure at not being consulted. Her office had historically felt unfairly criticized by Lewis. In one instance Whelan had met with Lewis and asked for proposals to help alleviate HIV/AIDS. Whelan's office claims that Lewis' staff never responded to follow up calls. Whelan pointed to CIDA's contribution to the Global Fund, in an effort to show that Lewis had unfairly singled out Canada.<sup>121</sup>

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<sup>118</sup> Ibid.

<sup>119</sup> Parliamentary Debates, Hansard Index – Patent Act, 37<sup>th</sup> Parliament 2<sup>nd</sup> Session

<sup>120</sup> Drew Fagan, "Ottawa's HIV/AIDS Drug Plan Caught up in Debate," Globe And Mail, 24 October 2003.

<sup>121</sup> Steven Chase and Drew Fagan, "Drug Companies Balk at Ottawa's HIV/AIDS Plan," Globe and Mail 27 September 2003.

In the initial stages, following the announcement, but prior to the drafting of the legislation to amend the patent laws, the relevant actors took their traditional positions. Stephen Lewis praised Canada for the initiative, saying it had answered the call. The generic manufacturers voiced their support and desire to begin exporting drugs as soon as possible. The international association of brand-name companies initially took a critical stance. Harvey Bale, representing the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) stated that the initiative was mere window dressing. He also stated that it would be a, “negative black eye that could very well affect the investment climate [in Canada].”<sup>122</sup> He also questioned whether the initiative would really help, emphasizing the importance of investing in Africa’s infrastructure. Finally, he finished by stating that Stephen Lewis was leading, “us all down the primrose path to a dead end.”<sup>123</sup>

Rx&D quickly distanced itself from these comments. They had never recovered from the public relations nightmare in South Africa and knew that contentious comments, such as those made by Bale, would generate bad publicity, that would do little to advance their interests.<sup>124</sup> Rx&D chose to fight the public relations battle another way. It attempted to influence the legislation privately, while publicly showing support. It claimed to recognize that Canada had an opportunity to show international leadership by changing patent laws to improve access to drugs.<sup>125</sup> As patent holders, it is in the interests of these groups to promote Canada as a place of international leadership and innovation. Given these actors’ historical objectives and policy pursuits, none of these positions are

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<sup>122</sup> Ibid.

<sup>123</sup> Ibid.

<sup>124</sup> David Morley. Humanitarian Affairs Director: Médecins Sans Frontières, Interview, 27 June 2005.

<sup>125</sup> Heather Scofield and Paul Knox, “Big Canadian Drug Companies Embrace HIV/AIDS Plan,” Globe And Mail, 2 October 2003.

surprising. Each actor took the position that was natural to it, given their stance on the issue of patent laws. Once the legislation was drafted the actors were able to direct their praise and criticisms at the specifics of the proposed amendments.

On 6 November 2003, Chrétien personally introduced and sponsored Bill C-56 to Amend the Patent Act and the Food And Drugs Act, to allow for the export of generic medicines.<sup>126</sup> The delays prior to its introduction made it impossible to pass the Bill quickly in Parliament. First there were delays in introducing it into Parliament due to the complexity of the issue. After its formulation and introduction, there was opposition by NGOs, the CGPA, and Lewis.

Responding to these concerns, opposition parties began to question the validity of rushing the bill through Parliament. The opposition made its support for the bill conditional on a Liberal commitment to send C-56 to a parliamentary committee for review.<sup>127</sup> Government officials also acknowledged that the tabled version of the bill was not ready, and needed rewriting.<sup>128</sup> Finally, some Liberal Cabinet Ministers had warned Boudria not to pass the bill as they had promised industry and development group stakeholders that after the legislation was tabled, it would be left up for public discussion.<sup>129</sup>

Given the increasing level of criticism and strong desire from all groups to have input in the legislation, the Liberal Party chose to send C-56 to the House Committee on Industry, Science and Technology for further review.<sup>130</sup> NDP leader Alexa McDonough

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<sup>126</sup> Kim Lunman, "Chrétien Sets Sights on Drug Legislation for Legacy," Globe and Mail, 5 November 2003.

<sup>127</sup> Steven Chase, "Poor-Nation Drug Bill: Liberals Table It, But Admit It's Not Ready," Globe and Mail, 7 November 2003.

<sup>128</sup> Ibid.

<sup>129</sup> Ibid.

<sup>130</sup> Steven Chase, "Committee to Work HIV/AIDS Bill into Shape," Globe and Mail, 8 November 2003.

suggested the issue also be referred to a Parliamentary committee that deals with international development issues, so that C-56 remained driven by humanitarian concerns, however this motion was not adopted.<sup>131</sup> Her intent was to ensure that C-56 would not be used for the purposes of advancing business interests. On 12 November 2003 Parliament prorogued, and C-56 died on the table.

### **3.3 Causes of C-56: Reasons, Influences and Reactions**

This section will analyze the different factors and actors that influenced C-56. It captures the interests of the actors, and provides a cursory examination of how they promote their interests. It will analyze the methods and impact of these actors and factors, and use the theories to explain under what circumstances various groups are influential, and which groups predominate. By doing so it will begin to draw conclusions as to what groups matter and why.

#### **3.3(A) September 11<sup>th</sup>**

It was in the chaotic environment following September 11<sup>th</sup> that the first moves towards amending patent laws were made. In the weeks following September an unknown American perpetrator was using the US Postal Service to mail anthrax powder. The United States perceived the potential spread of anthrax as a grave threat to national security. In total, four United States citizens were infected with the disease. In Canada not one person was infected, yet the threat of an anthrax outbreak occurring was such that the government felt it necessary to take extreme measures.<sup>132</sup>

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<sup>131</sup> House of Commons Debates. 37<sup>th</sup> Parliament 2<sup>nd</sup> Session  
[http://www.parl.gc.ca/37/2/parlbus/chambus/house/debates/153\\_2003-11-07/han153\\_1350-e.htm](http://www.parl.gc.ca/37/2/parlbus/chambus/house/debates/153_2003-11-07/han153_1350-e.htm)

<sup>132</sup> Amy Harmon and Robert Pear, "Canada Overrides Patent for Cipro to Treat Anthrax," New York Times 19 October, 2001.

At this time CIPRO, the drug used to treat Anthrax, was still under patent protection. The company holding the patent, Bayer, promised to meet the Canadian government's request for enough tablets to treat one hundred thousand people.<sup>133</sup> Deciding that Bayer would not be able to meet the quota quickly enough, and that Bayer's prices were prohibitive, Rock threatened to issue a compulsory license, and ordered one million tablets from generic manufacturer Apotex. Eventually Bayer and Health Canada were able to reach an agreement that would allow Bayer to meet Canada's demand for CIPRO, at a cost significantly lower than originally offered. The decision by the Canadian government to issue a compulsory license became a rallying point for those attempting to increase the supply of generic medicines.

### **3.3(B) Activists and Civil Society**

Prior to the government's announcement to change the patent laws, activists, NGOs and generic producers had been promoting changes to the Patent Act and The Food and Drugs Act. They emphasized the recent WTO decision, and the legality of any changes the government should choose to make.<sup>134</sup> NGOs sent numerous letters to the government in an attempt to amend the Patent Act and the Food and Drugs Act.<sup>135</sup> Stephen Lewis was especially vocal. He challenged Prime Minister Chrétien to take action by reminding him of his frequently stated claims of concern for Africa.<sup>136</sup>

The NGOs' ideological commitment was supported by the generic manufacturers' stated intent to sell generic drugs at low costs. While these two groups were not working

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<sup>133</sup> Ibid.

<sup>134</sup> Richard Elliot, "Canada Can Carry Much More," The Hill Times, 23 September 2003. For other similar examples see the HIV/AIDS Legal Network's September 2003 Subheading at: <http://www.HIV/AIDSlaw.ca/Maincontent/issues/cts/patent-amend.htm>

<sup>135</sup> Ibid.

<sup>136</sup> Richard Elliot, "Canada Can Carry Much More," The Hill Times, 23 September 2003.

together, they were pursuing a similar objective that brought their interests in line with each other. The NGOs' campaign to amend the Patent Act and the Food and Drugs Act depended on the generic producers' desire to export ARV drugs.<sup>137</sup> NGOs strongly believed that amending the Patent Act and the Food and Drugs Act would result in a flood of low cost drugs to eligible states, immediately benefiting HIV/AIDS sufferers in recipient states. This made the issue much clearer for the government, as there seemed no doubt as to what would happen if the patent laws were changed. The perception of immediate benefits resulted in a government favourable to making changes.

Activists and NGOs had been the most vocal proponents of allowing generic versions of patented medicines to be exported, in order to increase accessibility. They hold that widespread access to ARV drugs is the best method of treating those with HIV/AIDS. Costing up to seven thousand dollars per person per year, current drug prices are prohibitive to all but the wealthiest individuals.<sup>138</sup> There is an inverse correlation between prices and access; access will only go up if prices come down, and prices will only come down if competition is created.

NGOs argue that the single greatest factor in lowering the prices of ARV drugs is competition. It is estimated that a supply of generic medicines would bring HIV/AIDS treatments down to fewer than one hundred US dollars per person per year.<sup>139</sup> NGOs also argue that the number of diseases eligible for generic production should be unlimited. By encouraging a supply of generic medicines, NGOs are arguing along the same lines as the CGPA. However this alignment is based on a coincidence of interests between the two

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<sup>137</sup> Steven Chase, "Generic Drug Makers Seek Export Rights," Globe and Mail, 11 September 2003.

<sup>138</sup> Steven Chase, "African Groups Applaud Canadian HIV/AIDS Plan," The Globe and Mail 6 October, 2003.

<sup>139</sup> Ibid.

groups, and not on a political relationship. NGOs believe in increasing the supply of generic medicines for humanitarian reasons, while generic producers support it for economic reasons. Referring to the pharmaceutical industry, director of MSF David Morley stated, "...the profit motive was far more important than the health and well-being of poor people in poor countries."<sup>140</sup>

Finally, NGOs have opposed the arguments advanced by transnational capital. They acknowledge the importance of R&D, but do not believe that potential gains in the future should hinder access in the present, as funding for R&D does not have to come at the cost of accessibility. They focus on the profits made by Pharmaceutical companies in the first world. The majority of Pharmaceutical companies profits are made in the first world, and therefore supplying generic drugs to Third World countries should not hinder R&D.<sup>141</sup> NGOs hold that if brand-name companies were interested in helping Third World countries they would provide their medicines at cost.<sup>142</sup>

### **3.3(C) Generic Manufacturers**

Generic manufacturers in Canada have a long history of animosity with Rx&D, as discussed in chapter one. The objectives of generic producers conflict with those of Rx&D. In a highly lucrative market, competition to supply is extreme, and the rewards are great. It is estimated that over thirty billion dollars of patented drugs have been opened up to generic producers over the past four years.<sup>143</sup> As brand-name companies

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<sup>140</sup> David Morley, "Drug Companies Focus on Profits, Not People," Victoria Times Colonist 20 April 2004.

<sup>141</sup> Editorial, "Drug Makers Should Join Fight Against HIV/AIDS," The Globe and Mail 26 September 2003.

<sup>142</sup> Ibid.

<sup>143</sup> Jed Seltzer and Ben Hirschler, "Generic Drug Makers Jump Legal Guns," The Globe and Mail 10 September 2003.

attempt to protect their exclusivity, generic producers are attempting to access these markets. The result is a history of litigation and lobbying by both groups.

In Canada the generic drug industry is extremely well developed and is strong enough to influence government.<sup>144</sup> Unlike other Western nations such as the U.S., Britain and France, brand-name companies do not have nearly as much influence in Canada.<sup>145</sup> Brand-name Pharmaceutical investment in Canada has been historically low, which limits the influence of this actor. Due to Canada's socialized health care system, and historically weak patent protection, the gap between generic producers and brand-name companies is smaller than in many other states. However, patent holders, as representatives of transnational capital, still have an advantage.

Generic producers began to lobby for the right to export their products within two weeks of the Cancun decision. Arguing in the interests of citizens of developing states, generic producers claim that allowing them to sell their products would significantly increase the number of Third World citizens receiving treatment. They claimed that since export to Third World countries was legal, opening up the market for competition is the morally correct choice to make.<sup>146</sup> The CGPA casually lobbied in Ottawa, arguing that the only decision now required allowing the export of generic medicines was a domestic one. They continually emphasized that if the Canadian government were to change the Patent Act and the Food and Drugs Act, they would be able to sell ARV drugs to African nations at lower prices than brand-name companies.<sup>147</sup>

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<sup>144</sup> Richard Elliot, "Canada Can Carry Much More," The Globe and Mail 23 September 2003.

<sup>145</sup> Stephanie Nolan, "Spearhead HIV/AIDS Fight, UN Envoy Tells Canada," The Globe and Mail 25 September 2003.

<sup>146</sup> Steven Chase, "Generic Drug Makers Seek Export Rights," The Globe and Mail 11 September 2003.

<sup>147</sup> Ibid.

Generic producers attempted to keep the focus on the humanitarian value of changing the patent laws, and away from the profits they would make should their recommendations be adopted. Ironically it is NGOs which were emphasizing the importance of the profit motive. NGOs were disappointed by the lack of enthusiasm the generic producers showed. This was because there was not a lot of money to be made by this bill.<sup>148</sup> As much as the generic producers said it was for humanitarian purposes, the lack of enthusiasm reflects their desire for capital gain. They became very encouraged once the NGOs joined the fight, as this increased the probability of the Patent Act and the Food and Drugs Act being changed.<sup>149</sup>

The CGPA was not as enthusiastic as the NGOs had hoped. It pursued the issue by writing letters to Senate Committees and government officials such as Pierre Pettigrew. Representatives of the CGPA appeared on various media outlets such as CBC's *The National*. The generic companies did not invest any money in this issue. They did not hire lobbyists, or take out advertisements. Their efforts were limited to letter writing, presentations, and media relations. While this lobby effort was not as strong as it could have been it influenced the government. The government needed to believe that the generics would export their products to pass legislation of this nature. When Stephen Lewis added his voice to the issue, the government was ready to respond.

### **3.3(D) Brand-name Companies**

Brand-name companies strenuously argued against limiting patent protections. From their perspective patent protections guarantee a return on R&D costs, and without this guarantee, there will be little investment in new products. Strong emphasis is put on

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<sup>148</sup> David Morley, *Interview*, 27 June 2005.

<sup>149</sup> Jeff Connell, CGPA Representative, *Interview* 23 June 2005.

the high level of spending that Rx&D companies do on research. They hold that the Pharmaceutical industry is more research-intensive than electronics, communications, and aerospace industries.<sup>150</sup> One estimate states that over seventeen percent of revenues are spent on R&D.<sup>151</sup>

Rx&D argued that current practices have increased access to medicines. It argued that distribution of medical supplies has increased exponentially since 1990, in large part due to the efforts of brand-name companies.<sup>152</sup> It emphasized that without its partnerships with governments and NGOs, people in developing countries would not have the access to drugs they currently do.<sup>153</sup>

Brand-name drug companies are concerned about what will happen to their profits in First World states should there be a massive supply of generic medicines sold to the Third World. They are concerned that medicines sold to Third World countries will be re-exported back to the First World via the black market.<sup>154</sup> Should this happen, brand-name companies would lose millions of dollars of revenue. NGOs hold that it is for this reason they oppose changing patent laws.

### **3.3(E) Government Position**

Although HIV/AIDS is not limited to Africa, this region has the highest levels of infection. With an estimated forty million cases of infection, HIV/AIDS has devastated Africa like no other region. Over the past ten years, Africa has become the focus of

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<sup>150</sup> Doug Branter, "Plenty of Research Behind New Pills," Victoria Times Colonist 12 April 2004.

<sup>151</sup> *Ibid.*

<sup>152</sup> Jacques Lefebvre, "Drug Firms Expand Access in Third World," Victoria Times Colonist 12 April 2004.

<sup>153</sup> *Ibid.*

\* In a rebuttal to these claims Executive Director of MSF, David Morley, wrote to the Times Colonist claiming that Rx&D's claims of partnerships were misleading and that brand-name companies have consistently opposed the objectives of NGOs. See: David Morley, "Drug Companies Focus on Profits, Not People," Victoria Times Colonist 20 April, 2004.

<sup>154</sup> Wainberg.

Canadian development policy. The Canadian International Development Agency (CIDA) states that the decision to make Africa its primary aid recipient is warranted by the extent of poverty in this region.<sup>155</sup> The government has traditionally claimed that development assistance was one of its primary goals. Former Prime Minister Jean Chrétien made numerous trips to Africa with the stated intent of encouraging trade and assisting development. While concrete contributions have not matched its rhetoric, there is some evidence that the Canadian government is making an effort to address the HIV/AIDS epidemic. In Kananaskis Prime Minister Chrétien committed fifty million dollars to help fund HIV/AIDS vaccine research.<sup>156</sup> In May 2004 Paul Martin announced one hundred and seventy million dollars to be given to HIV/AIDS programs.<sup>157</sup> In addition, Ottawa has announced two hundred and seventy million be donated to social development priorities, especially those concerning HIV/AIDS.<sup>158</sup> Canada is a major contributor to the Global Fund to Fight HIV/AIDS. The reasons for this focus on Africa is questionable.

The focus on Africa can be partly attributed to former Department of Foreign Affairs and International Trade (DFAIT) minister Lloyd Axworthy, and his human security agenda. In 1995 Axworthy was appointed the Minister of Foreign Affairs. He immediately took the lead, and seemed to shift Canada's foreign policy from trade issues to social responsibility. The 'Human Security Agenda' claimed to put Africa at the centre

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<sup>155</sup> Canadian International Development Agency, Statement on Africa and the Middle East, [http://www.acdi-cida.gc.ca/cidaweb/webcountry.nsf/africa\\_e.html](http://www.acdi-cida.gc.ca/cidaweb/webcountry.nsf/africa_e.html)

<sup>156</sup> Drew Fagan, Heather Scofield and Steven Chase, "Ottawa Scramble to Meet HIV/AIDS Drug Pledge," *The Globe and Mail*, 4 October 2003.

<sup>157</sup> Jeff Sallot, "HIV/AIDS plan Signals Foreign Policy Shift," *The Globe and Mail*, 13 May 2004.

<sup>158</sup> Drew Fagan, Heather Scofield and Steven Chase, "Ottawa Scramble to Meet HIV/AIDS Drug Pledge," *The Globe and Mail*, 4 October 2003.

of Canadian development policy.<sup>159</sup> Africa is manifestly a continent where human security is at risk, and therefore a continent that attracts a government focused on these issues.<sup>160</sup> Once Axworthy began promoting human security in Africa, Chrétien followed his lead.<sup>161</sup> Chrétien did not create the focus, but he was a willing partner in it. After Axworthy left office, Chrétien continued to push the African Agenda. As the host of the 2002 G8 Summit in Kananaskis, Chrétien was responsible for choosing the focus of the conference. As an extension of Canada's domestic concerns with this region, Chrétien chose to make it an international focus at the summit. Axworthy was responsible for introducing the 'African Agenda,' however it was Chrétien who ensured this remained a policy pursuit of Canada. Changing the Patent Act and the Food and Drugs Act became another way of providing assistance to this region – and this time it could be done without costing the government money.

The Canadian government's position on patent protections has been inconsistent. In September 2001 Canada announced it would override Bayer's patent on CIPRO without consulting Bayer, or going through the standard mechanisms for issuing compulsory licenses.<sup>162</sup> It did so despite the fact that during the WTO negotiations, Canada had argued alongside the United States and Switzerland against the weakening of patent laws.

The government had much to gain by changing the patent laws. One of the government's interest is prestige. When it announced its intention to change the Patent

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<sup>159</sup>Chris Brown, "Africa in Canadian Foreign Policy 2000: The Human Security Agenda," in Fen Hampson, Norman Hillmer and Maureen Molot, eds., *Canada Among Nations 2001: The Axworthy Legacy*, (Toronto, Oxford University Press, 2001): 196.

<sup>160</sup> Ibid, 197.

<sup>161</sup> Ibid.

<sup>162</sup> Amy Harmon and Robert Pear, "Canada Overrides Patent for Cipro to Treat Anthrax," New York Times 19 October, 2001.

Act and the Food and Drugs Act, the Canadian government appeared very impressive. Advocating for a G7 nation to implement the Cancun decision, Stephen Lewis targeted Canada. He specifically singled out Industry Minister Allan Rock, and Trade Minister Pierre Pettigrew, reminding them of their willingness to override Bayer's CIPRO patent. After the government first announced its decision to change its patent laws accolades poured in. Bono stood beside Paul Martin at the Liberal convention and stated that the world needed more Canadas.<sup>163</sup> European HIV/AIDS groups sent letters of appreciation to Martin for taking this initiative. Kofi Annan claimed that the legislation could save millions of lives.<sup>164</sup> NGOs such as UNICEF and MSF publicly thanked the government for taking such measures. Press agencies across the world were covering the issue.<sup>165</sup> As time passed and the legislation was drafted, much of the praise was withdrawn or turned to criticism, however the government received positive press, both internationally and domestically, with the initial announcement.<sup>166</sup>

This was also an important opportunity for Martin. During his time as Finance Minister he had presided over large budget cuts and a retraction of the welfare state. He had also been engaged in a very public leadership battle with Prime Minister Chrétien. Supporting this legislation provided him a way of showing his support for Chrétien.<sup>167</sup> Opposition MP Brian Masse believes it was also a way for him to soften his image to the

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<sup>163</sup> Steven Chase, "Provisions for Brand-Name Drug Firms Must Be Removed, Bono's Group Urges," The Globe and Mail 12 March 2004.

<sup>164</sup> Bill Graham, "Canada Leading the Way," The Toronto Star 10 November 2003.

<sup>165</sup> For examples see:

The London Free Press "Africa: Can Canada Help Save it From HIV/AIDS," 3 November, 2003 (available at <http://www.cptech.org/ip/health/c/canada/londonfreepress11032002.html>), Agence France Presse, "Canada First to Pass Law to Send Cheap HIV/AIDS Drugs to Poor Countries," 13 May 2004

<sup>166</sup> See "Canada Leading the Way," The Toronto Star (Opinion), 10 November 2003. A21.

<sup>167</sup> Brian Masse. Member of Parliament: Windsor West. Interview, 29 June 2005.

Canadian public, and address the social deficit he had created.<sup>168</sup> By leading Canada's humanitarian initiative, Martin himself would be perceived as a humanitarian.

Unfortunately for Martin the issue never caught on the way he wanted it too. Lexchin believed it resonated with the public, but did not sway any votes.<sup>169</sup> The legislation was not very controversial, as nobody could really vote against its principles, as doing so would be politically costly. This made it difficult for opposition parties to vote against it. Partisan debate was limited. The NDP generally sided with the NGOs, the Conservative Party with Rx&D, while the Liberals tried to strike a balance.<sup>170</sup> The committee meetings were not particularly raucous, and it passed without anyone voting against it.<sup>171</sup> While it did make the national agenda, it did not catch the eye of the Canadian public as a crucial election issue.<sup>172</sup>

### **3.3(F) Media Portrayal**

This author read well over fifty newspaper articles and press releases on this issue. It is my observation that although the media included comments from all the relevant actors, it was generally supportive of NGO arguments. When it included arguments from brand-name companies, these comments were generally not expanded upon. When they were, brand-name arguments were quickly countered by NGO statements. The media was not consistent in this approach. Often NGO arguments were given, without an opposing viewpoint stated. Brand-name arguments were made to seem

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<sup>168</sup> Ibid.

<sup>169</sup> Joel Lexchin. Associate Chair School of Health Policy and Management York University. Interview, 23 June 2005.

<sup>170</sup> Brian Masse, Interview.

<sup>171</sup> Ibid.

<sup>172</sup> David Morley, Interview.

narrow and self-serving, while NGOs were portrayed as altruistic actors pursuing the good of the disadvantaged in Africa who cannot help themselves.

Both the CGPA and NGOs spoke favourably about the media. The CGPA felt that the coverage, especially in the *Globe and Mail*, was fair and unbiased. Its representative believed that the *National Post* took the side of Rx&D, and hypothesized that it might be because of the high levels of advertising drug companies have in that particular newspaper.<sup>173</sup> Most likely it was due to the *National Posts'* pro-business ideology. David Morley of MSF, had been keeping a close eye on the issue in the news. He had even written a couple of articles in the *Victoria Times Colonist*. Upon seeing the coverage he remarked that the media was 'nice' to us.<sup>174</sup> He went on to say that it was because the media recognized the legitimacy of NGO arguments. Whether this is the reason is unclear, but with the exception of the *National Post* the media favourably portrayed the NGO's and CGPA.

### 3.4 Why the Announcement

Without a 'smoking gun' it is difficult to determine why Rock made this announcement. It began with the Canadian government's policy shift following September 11<sup>th</sup>. There is no reason to doubt the government's statement that it was intending to override the CIPRO patent because it believed doing so was in the best interest of the Canadian public. Once Bayer proved it could provide enough drugs to meet the Canadian government's need, and at an acceptable cost, the government abandoned this initiative.

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<sup>173</sup> Jeff Connell, Interview.

<sup>174</sup> David Morley, Interview.

It is not a coincidence that Rock made his announcement immediately after Stephen Lewis made his plea, singling out Canada. Rock had historically supported generic producers. It appears that caught up in the heat of the moment Rock saw this as a way to advance the interests of the generic industry. This author believes he made this decision independently of the other Ministers because of the desire to advance interests that they might not share, along with the sense of urgency he felt.

Had Rock changed his mind, or others in the government disagreed with the decision, they were unable to turn back. Once the announcement was made, it could not be undone. The NGO and activist response was too loud and public for the government to ignore the issue. Although other officials expressed their support, an expression that was necessary for legislation to pass, they had little choice. With an upcoming election, the public was more aware of the government's activities. Dissension and/or failure to keep promises would have repercussions at the polls. Regardless of how they felt, Rock had attracted enough media attention that those in office had to follow through. The announcement was made independently, however the decision to follow through can be credited to NGOs and activists who made sure that any other decision would have been politically harmful to those in office.

### **3.5 Conclusion**

Bill C-56 is an excellent example of a convergence of interests. Amending the Patent Act and the Food and Drugs Act was desired by numerous actors. This complicates the issue of determining which interests are prevalent in influencing government policy. It is however possible to rank the interests, by revealing under what circumstances each group had influence.

This author believes that the neo-Marxist perspective, which holds that the states support for business reflects the structural power of capital. The government is not a bystander in this process, and has some autonomy. In the case of C-56 two opposing capital interests presented themselves. This gave the government even more autonomy, as it would be promoting capital interests either way. The government listened to one capital interest by making the announcement, but listened to another by delaying legislation. The role and importance of competing capital interests will be examined in more detail in later chapters.

After the interests of capital had been met, the other actors able to exert influence. These actors are not insignificant; however they are secondary. Lewis pleaded with the Canadian government to change the patent laws to allow for the export of generic medicines. This author believes his plea was only successful because Canada's generic Pharmaceutical industry had already expressed an interest in selling their products. Had CGPA members not expressed interest in selling their medicines to Third World countries, Lewis' plea would not have received a response. This criterion applies to the other non-capital actors as well. Thus actors other than those representing transnational capital, only had influence after capital interests have been met.

The third group is the public. On this issue the public exerted little influence. I have argued that the power of the public lay in its potential to influence, more than any direct power. The non-capital actors, attempted to use the public to influence the legislation. After transnational capital interests and been met, it was in the government's interest to listen to public opinion. The activists and NGOs knew there was an upcoming election, and recognized that they could use public opinion to enhance their influence.

The government had moved so fast that the key actors had been almost completely left out of the process. They were able to voice their support or opposition, but were not invited to participate. They all felt excluded from the process, and had demanded a say in how the legislation was drafted. For this reason, the government was unable to pass it during Chrétien's final term as Prime Minister. It would have to die on the table, and could only be introduced by the next Prime Minister.

**Chapter 4:**  
**C-56 to C-9**

#### **4.1 Introduction**

This chapter begins by revealing how the activist community successfully ensured that Martin kept his commitment to amend the Patent Act and the Food and Drugs Act. It then goes into the details of the legislation. It picks out several key clauses, and examines the actors' reactions, methods, and motivations in relation to these clauses. It then analyzes what the result of these efforts was, for the purposes of clarifying the theoretical framework. It examines what actors are influential, and under what circumstances they are able to exercise their influence.

By picking out several clauses from the bill it will show that it is possible for an actor to lose under one set of circumstances, while succeeding in another. Each clause will be analyzed using a theoretical framework to explain the results. This chapter will conclude by questioning what the final result of C-9 will be in order to prepare the reader for the fifth and final chapter.

#### **4.2 The Issue Still Alive**

When C-56 died on the table, those wishing to see amendments to the Patent Act and the Food and Drugs Act were concerned. Martin had pledged his support for the bill, but there was a fear this would be a broken promise. On 14 November the Liberal Party was holding its national convention to inaugurate Paul Martin as Liberal Party Leader and Prime Minister of Canada. Activists and NGOs used this convention to remind Martin of his commitment to amending the patent laws. They dressed in hockey jerseys labelled 'Team Canada,' and advertised an opportunity to, "Shoot for the goal: Get the

bill right and get medicines to the people.”<sup>175</sup> They played a ‘hockey’ game consisting of a large pill-shaped hockey puck labelled ‘medicine.’ They continually tried to score a goal with the ‘puck’ however their efforts were blocked by a goalie entitled ‘Big Pharma.’ Signifying Pharma’s defeat, the activists eventually scored the winning goal.<sup>176</sup>

The convention was a unique opportunity for activists. It had the presence of the Liberal Party members and a large media contingent. The commitment to amend the patent laws had been recently made, and this canvassing was an attempt to hold the government accountable to that commitment. At one point they got inside the Liberal convention centre and distributed leaflets to delegates, explaining the importance of having moving quickly on the proposed amendments.<sup>177</sup> This event was more than just an opportunity to take pictures and use props to make a point. Activists also provided an ‘intellectual’ critique of C-56. They used the attention to make it clear that implementing C-56 as it stood would be akin to the government sabotaging its own initiative.<sup>178</sup>

These actions reveal an ‘alliance’ between the activists, and other groups pursuing the same agenda. All of the actors attempted to influence the government through parliamentary submissions, press releases and policy statements. The activists used creative, and stunt based forms of pressure to get media attention and make their arguments known. This form of advocacy is not utilized by the CGPA and NGOs, who needed to work within the system. They are dependant on portraying an image of respectability and credibility, which they would lose if they engaged the government in

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<sup>175</sup> This advertisement was sponsored by MSF, World Vision, Canadian HIV/AIDS Legal Network, and CAP HIV/AIDS. Available <http://www.HIV/AIDSlaw.ca/Maincontent/issues/cts/patent-amend/MediaAdvisory-StreetHockey-131103.pdf> 13 November 2003.

<sup>176</sup> Street Hockey For Global Health: Canadian Activists Dramatize Call on new Prime Minister to Pass Legislation Allowing cheaper Medicines for Developing Countries, Available <http://www.cptech.org/ip/health/c/canada/ngos11142003.html> 14 November 2003.

<sup>177</sup> Ibid.

<sup>178</sup> Ibid.

the same way as the activists. Using different methods of pursuing similar objectives played an important role in ensuring the government kept its commitment to amend the Patent Act and the Food and Drugs Act.

The Liberal leadership convention was also used by another person to promote changes to the Patent Act and the Food and Drugs Act. Unlike the activists, this man was invited, and was a key part of the convention's proceedings. Bono, world famous U2 front man, and founder of the activist group Debt HIV/AIDS Trade AFRICA (DATA), accepted an invitation to speak and perform at the convention.

It is difficult to measure the effect Bono's presence had on Martin. However it is unlikely that he would offer such a blatant show of support unless he felt the government was moving in what he, along with other activists and NGOs, felt was the correct direction. Bono's involvement in this issue did not end with the Liberal convention. He continued to lobby the Canadian government, and joined with other NGOs and activists in their critiques of C-56.

Bono's presence probably had a minimal affect on how the Canadian public felt about Paul Martin. It is my belief that Bono had an implicit understanding with Martin. In return for Martin making a commitment to Africa, including increased aid spending and amending patent laws, Bono would support the Liberal Party. His presence most likely generated awareness of the issue, however it was his follow-up that influenced the Liberal government. Like many other actors, Bono initially supported the initiative to amend the Patent Act and the Food and Drugs Act. It was his withdrawal of support more than his presence at the convention that influenced government.

#### **4.3 Going to Committee**

With these groups publicly challenging Martin, and given Martin's previously stated commitment to enacting C-56, it would have been politically harmful for him to let the issue drop. Upon taking the office of Prime Minister, Martin almost immediately reinstated the bill. On February 12<sup>th</sup> the chair read it, and confirmed that it was in the same form as its predecessor.<sup>179</sup> The chair sent the bill, now entitled C-9, to the Standing Committee on Industry, Science and Technology, for further review.

Each of the relevant actors made one or more submissions to the committee. Although they had already made their positions known, it was in this committee that the actors were able to address government directly. It was also their first chance to address the specifics of C-56, as the original legislation had been conceived and introduced too quickly for many of them to mobilize. At this time the proposed amendments to the Patent Act and the Food and Drugs Act had been made public for roughly four months. Each actor had been able to scrutinize the amendment and prepare a response. These responses were made known during the committee hearings.

#### **4.4 C-56 Legislation**

Almost immediately after the legislation was drafted and introduced it came under criticism. Most of this criticism came from the groups that had initially praised the government for the initiative. These groups did not change their interests, but upon examination of C-56 concluded that the way it was drafted was not in line with those interests. Three clauses in particular were distressing to those who had initially given their praise: Right of First Refusal, the limited list of drugs that could be exported, and prohibiting NGOs from contracting directly with generic drug producers.

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<sup>179</sup> House Debates 37<sup>th</sup> Parliament 3rd Session, 2<sup>nd</sup> Reading: Patent Act, Available [http://www.parl.gc.ca/37/3/parlbus/chambus/house/debates/009\\_2004-02-12/han009\\_1000-e.htm](http://www.parl.gc.ca/37/3/parlbus/chambus/house/debates/009_2004-02-12/han009_1000-e.htm)

The legislation signified an attempt by the government to please numerous actors. It was the government's hope that the existence of the legislation would meet the demands of the NGOs, while the details would appease the brand-name companies. Three of these clauses signify the government's attempt to remain true to international consensus. Since it was the WTO that allowed the overriding of patents, the government felt that only WTO states should be permitted to take advantage of these provisions. The limited list of diseases was based on a WHO list of essential medicines. Again the Canadian government used an international standard to determine the contents of the bill. The international community is also statist, and therefore states should have sovereignty over the products that enter their borders.

#### **4.5 Controversial Elements**

##### **4.5(A) Right of First Refusal**

The right of first refusal gave brand-name companies the right to take over contracts negotiated by generic manufacturers. It was strongly supported by the brand-name companies, but opposed by all other groups. Of all Bill C-56's elements, none was as adamantly opposed as the right of first refusal. The government most likely did not realize the amount, or intensity of the criticism they would receive for the right of first refusal clause.<sup>180</sup> This clause was inserted in an attempt to appease the brand-name manufacturers.

Aware of the stir it had caused by making the announcement, the Canadian government was moving forward very cautiously in an attempt not to get too far ahead of international consensus. As protecting patents are the international norm, overriding them is a much more radical move than preserving them. Already having decided to allow for

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<sup>180</sup> Joel Lexchin, Interview, David Morley, Interview

the export of patented drugs, the Canadian government wanted to make sure that any challenges to patent protections were as 'acceptable' as possible. First Canada sought permission from NAFTA to proceed.<sup>181</sup> Once the United States stated that it would not pursue the issue in NAFTA, the Canadian government tabled the legislation. Ottawa made it very clear that the right of first refusal was to be included in C-56. As one senior official stated:

Before a generic gets to copy a drug here and export it, we will want to know the Canadian Pharmaceutical [firm] holding that patent has had the opportunity to fill that contract.<sup>182</sup>

The Canadian government had already been radical enough by becoming the first government to advance such legislation – it did not want to challenge the global consensus any more than necessary.

Other groups challenged this fear of getting ahead of international consensus. They claimed that Ottawa would be setting the framework upon which other states implemented similar legislation. International groups, such as the European HIV/AIDS Treatment Group, sent letters to the Canadian government saying that including the right of first refusal would set a very poor precedent.<sup>183</sup> Other international actors, such as Bono, made the same claim. This criticism undermined one of the essential reasons for the right of first refusal, and contributed to its removal from the legislation.

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<sup>181</sup> Heather Scoffield and Steven Chase, "Canada to Seek Assent on HIV/AIDS Drug Plan: NAFTA Could Snag Exports to Poor Nations," The Globe and Mail, 7 October 2003. A11.

<sup>182</sup> Steven Chase and Drew Fagan, "Table Set for HIV/AIDS Drug Plan," The Globe and Mail, 1 November 2003. A7.

<sup>183</sup> Mauro Guarininieri, "E-Drug: New Canadian Bill on Generic producers," E-Drug 10 March 2004. Available: <http://www.essentialdrugs.org/edrug>

The CGPA was adamant that including the right of first refusal clause would prevent generic drugs from being provided to eligible countries.<sup>184</sup> Jim Keon, president of the CGPA stated that the very existence of a right of first refusal clause would dissuade generic producers from pursuing agreements or bidding on contracts under the initiative.<sup>185</sup> As one representative put it, “we are not negotiators for patent holding companies.”<sup>186</sup> The CGPA blames brand-name companies for the inclusion of this clause. They argued that the right of first refusal was a TRIPS-plus provision, and not required by any international agreements.<sup>187</sup>

They also argue that patent holders already had a de facto right of first refusal. If the brand-name company wishes, it may sell products at reduced prices. The problem was that brand-name companies were not doing this. If they were willing to provide products to Third World countries at affordable prices there would have been no need for paragraph six of the Doha Declaration, or the Cancun agreement.<sup>188</sup> The brand-name companies were not exercising this de facto right of first refusal. However they would exercise this clause if it were included in the legislation.

As brand-name companies do not need a right of first refusal clause to sell their products at reduced prices, they should not be allowed to wait and see what the generic manufacturers do. Ultimately, generic drug producers claimed that according patent holders the right of first refusal would prevent them from supplying their products to

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<sup>184</sup> Steven Chase, “Flawed Bill Will Impede Drug Access, Industry Says,” The Globe and Mail 20 February 2004.

<sup>185</sup> Canadian Generic Pharmaceutical Association Press Release, “Access To Medicines Bill Needs Major Changes to be Effective: Generic Drug Industry. Brand-name Drug Makers Hijack Canada’s Landmark Initiative.” 12 February 2004. [http://www.canadiangenericonducers.ca/en/news/feb\\_12\\_04.shtml](http://www.canadiangenericonducers.ca/en/news/feb_12_04.shtml).

<sup>186</sup> Jeff Connell, Interview 23 June 2005.

<sup>187</sup> Canadian Generic Pharmaceutical Association, “Bill C-9: An Act to Amend the Patent Act and the Food and Drugs Act: Comments From Canada’s Generic Pharmaceutical Industry,” February 2004. Available <http://www.canadiangenericonducers.ca/en/news>

<sup>188</sup> *Ibid.*

eligible countries.<sup>189</sup> Generic producers acknowledge that if brand-name companies exercise the right of first refusal, developing nations will receive the product at a lower price. The problem lies in the fact that generic producers will not negotiate the contracts in the first place if they know the patent holder could scoop contracts.

The CGPA outlined additional problems with the right of first refusal clause. It argued that patent holders would then have three rights of first refusal. First, as the generic producers argued, patent holders already were free to provide their products at cheaper rates. Second, is TRIPS Article 31(b), requiring that states attempt to negotiate a lower price with the patent holder before issuing a compulsory license.<sup>190</sup> The third would be the aforementioned clause in C-9 that would allow patent holders to take over contracts negotiated by generic producers. Referring to the right of first refusal, Lewis stated that it is a serious flaw, which would compromise the integrity of the legislation.<sup>191</sup>

In its submission to the committee Rx&D confirmed its interest in assisting the developing world. Rx&D began its presentation by changing the terminology used by NGOs and the CGPA. Patent holders were referred to as innovators. Finally, the right of first refusal was termed, 'equal opportunity to supply countries in need' (equal opportunity to supply).<sup>192</sup> For the purposes of properly capturing the Rx&D position, this thesis will use this terminology when referring to Rx&D's submission.

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<sup>189</sup> Ibid.

<sup>190</sup> The TRIPS Agreement is available at < [http://www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/trips_e.htm)>

<sup>191</sup> Steven Chase, "Flawed Bill Will Impede Drug Access, Industry Says," *The Globe and Mail* 20 February 2004.

<sup>192</sup> Canadian HIV/AIDS Legal Network Submission to the *Standing Committee on Industry, Science and Technology*, "Global Access to Medicines: Will Canada Meet the Challenge?" Available <http://www.HIV/AIDSlaw.ca/Maincontent/issues/cts/patent-amend.htm> 26 February 2004. Also See: Jean-Louis Roy. President Rights and Democracy, Speaking notes to the *Standing Committee on Industry, Science and Technology* Available [http://www.HIV/AIDSlaw.ca/Maincontent/issues/cts/patent-amend/Rights\\_Democracy\\_speaking%20notes.PDF](http://www.HIV/AIDSlaw.ca/Maincontent/issues/cts/patent-amend/Rights_Democracy_speaking%20notes.PDF), Joel Lexchin. Associate Chair School of Health Policy and Management York University: Brief to the *Standing Committee on Industry, Science and Technology*

Rx&D began its submission by stating its support for the humanitarian principles of Bill C-9, and the framework it set out. It stated their interests in the same principles as the CGPA, and more importantly the NGOs. The two principles they expressed an interest in protecting that were not contained in other actors' submissions were ensuring an alignment with Canada's international trade obligations, and producing no impact on Canada's domestic intellectual property regime.<sup>193</sup> Rx&D claimed the contents of its submission were a way to incorporate these two principles into the humanitarian effort of C-9.

The main concern of Rx&D was that it would not be informed when its patents were in question, and that they will not have an opportunity to negotiate to supply an importing country. Rx&D was aware that the right of first refusal was under heavy criticism. Its submission introduced an equal opportunity to supply clause. Under this clause, generic producers would be required to notify innovators if they were approached by a developing country. They would then have to set aside a thirty-day time period in order to allow both the generic and innovator to negotiate with the importing country to supply, or negotiate a voluntary licence with the generic.<sup>194</sup> If no agreement were reached between the innovator and the importing country and/or generic, the generic company would be legally permitted to apply for a licence to provide.

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[http://www.HIV/AIDSlaw.ca/Maincontent/issues/cts/patent-amend/submissions0304/Bill%20C-9\\_Lexchin%20Brief\\_Feb%202004.PDF](http://www.HIV/AIDSlaw.ca/Maincontent/issues/cts/patent-amend/submissions0304/Bill%20C-9_Lexchin%20Brief_Feb%202004.PDF) 23 February, 2004, Michael O'Connor. Executive Director Interagency Coalition on HIV/AIDS and Development: Notes for presentation to the *Standing Committee on Industry, Science and Technology* <http://www.icad-cisd.com/content/home.cfm?lang=e> 26 February 2004.

<sup>193</sup> Canada's Research Based Pharmaceutical Companies Submission to the House of Commons Standing Committee on Industry, Science and Technology Regarding Bill C-9. Available [http://www.canadaPharma.org/Meds/Submission\\_to\\_Industry\\_Committee\\_E.pdf](http://www.canadaPharma.org/Meds/Submission_to_Industry_Committee_E.pdf) 16 February 2004.

<sup>194</sup> Ibid.

They hold that this clause would do a better job of promoting the humanitarian objectives of C-9. Conducting negotiations simultaneously would result in the lowest possible prices. Rx&D also argued that this would not impact the supply of drugs. If a brand-name company received the contract, it could easily supply the drugs, as it was already producing them. If a generic producer received the contract it would have to produce the drugs anyway. Finally, the negotiations would have to be conducted over a thirty-day period. This will ensure that the supply of drugs to eligible countries is not delayed. Rx&D argued that this clause only gave them an opportunity to supply, as opposed to a right to supply. They would be given no special advantages, and would have to compete against generic producers.

This proposal was criticized by the NGOs. They agreed that this 'alternative' was the right of first refusal under a different name. The brand-name company holding the patent would be permitted to bid throughout the process, which would allow them to undercut contracts negotiated by generic producers.<sup>195</sup> The only difference between equal opportunity to supply and right of first refusal is that under the latter, contracts could be scooped after the generic producers had concluded negotiations, while under the former, they would be scooped at the beginning of the process.<sup>196</sup>

The NGOs made a counter proposal that they believed was less contentious to the CGPA. They proposed that the patent holder be notified if a generic company is requesting a licence to produce a patented product. Upon receiving notification the patent holder may grant a voluntary licence to the generic manufacturer within thirty days, and

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<sup>195</sup> Jean-Louis Roy. President Rights and Democracy, Speaking notes to the *Standing Committee on Industry, Science and Technology*

<sup>196</sup> Gauri Sreenivasan. Policy Team Member Canadian Council for International Co-operation: Speaking notes for presentation to the *Standing Committee on Industry, Science and Technology* available <http://www.google.ca/search?hl=en&q=CCIC&btnG=Google+Search&meta=9> March 2004.

receive a royalty of two percent. If they refuse to grant a voluntary licence, the Commissioner of Patents may grant a compulsory licence, and determine the royalty rate based on criteria that included in the bill. The bill would create a presumption of a two percent royalty rate, but would give the patent holder the opportunity to argue for a higher royalty rate, capped at four percent. In cases of dispute it would be determined after the licence has been issued, so that the supply of drugs would not be delayed.<sup>197</sup>

Rx&D argued against a fixed royalty rate of two percent, as this rate was not TRIPS compliant.<sup>198</sup> They held that generic producers should propose a royalty with its licence application to the Commissioner of Patents. Rx&D would then be permitted to suggest a different rate. In order to help the commissioner decide the royalty rate, Rx&D 'agreed' to a limited set of criteria including the status of the country, the fact it is a humanitarian and not a commercial initiative, and the value of the contract in Canadian dollars.<sup>199</sup> On 20 April 2004, the right of first refusal was removed from C-9.<sup>200</sup> A royalty rate of no more than four percent was kept in.

Both the NGOs and CGPA saw the removal of this clause as a great victory.<sup>201</sup> The CGPA said it would not have happened without Stephen Lewis. It believed that it would not have been influential enough to remove the clause on its own.<sup>202</sup> The NGOs knew this was a compromise. They argued for the removal of many clauses in the bill, knowing that the government would take some out and leave others in. Of particular

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<sup>197</sup> Richard Elliot. Director of Legal Research and Policy, Canadian HIV/AIDS Legal Network: Speaking notes for presentation to the *Standing Committee on Industry, Science and Technology* available <http://www.HIV/AIDSlaw.ca/Maincontent/issues/cts/patent-amend.htm> 26 February, 2004.

<sup>198</sup> Canada's Research Based Pharmaceutical Companies Submission to the House of Commons Standing Committee on Industry, Science and Technology Regarding Bill C-9

<sup>199</sup> Ibid.

<sup>200</sup> Allison Dunfield, "Ottawa Scraps Clause in Generic Drug Bill," *The Globe and Mail*, 20 April 2004.

<sup>201</sup> Jeff Connell, *Interview*, David Morley, *Interview*.

<sup>202</sup> Jeff Connell, *Interview*.

concern were the right of first refusal and the limited list of diseases.<sup>203</sup> If one got removed the other would not. In the words of one MP, it put the government in a position where it could make the ultimate compromise.<sup>204</sup>

The Canadian government's response to these debates provides insight to how policy is formulated. The neo-Marxist perspective, emphasizing the power of transnational capital, would hold that a clause such as the right of first refusal would remain part of the legislation. The fact that the government decided to remove it does not prove the neo-Marxist perspective wrong, but reveals that in certain circumstances there are obstacles in place that not even transnational capital can overcome. The government acts in its own interest. Generally this means listening to, and promoting the desires, of transnational capital. However, in this case, the NGO-CGPA alliance, along with comments from movement leaders Bono and Lewis, and international AIDS organization convinced the Canadian government that listening to transnational capital was not in its interest.

Bono had praised Martin for his commitment to amend the Patent Act and the Food and Drugs Act. "The world needs more Canadas," he had said. At the Liberal convention, Bono told Martin that he would follow up to ensure that the promise was kept, and warned that if Martin did not keep the promise he (Bono) would "become the biggest pain in [Martin's] ass."<sup>205</sup> Upon seeing how the legislation was drafted, Bono did

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<sup>203</sup> David Morley, Interview.

<sup>204</sup> Brian Masse, Interview.

<sup>205</sup> Steven Chase, "HIV/AIDS Drug Bill Fatally Flawed, Activists Warn," The Globe and Mail, 12 March 2004.

just that. He publicly warned Martin that the legislation was inherently flawed. Bono stated that the right of first refusal gave brand-name companies too much power.<sup>206</sup>

The involvement of so many actors opposing the right of first refusal made it clear to the government that keeping this clause in would be extremely politically costly. The government understood this, and removed the clause. This is indeed a major defeat for transnational capital. It is however only one defeat amongst a long list of successes. Transnational capital, represented by Rx&D, would have preferred its interests be protected on this issue. The fact they were not, did not prevent Rx&D from succeeding in promoting its interests on other elements of the bill, and quite possibly the bill as a whole.

#### **4.5(B) Limited List of Drugs**

A second controversial element of C-9 was the limited list of diseases eligible to be treated by generic drugs. This list, known as a Schedule One, determined what drugs that could be exported under C-9. Drugs to treat three of the most common diseases, HIV/AIDS, TB, and Malaria, are on the list, but many other drugs were excluded. The CGPA opposed this clause due to the difficulty of adding drugs to the list. Changes to Schedule One would require an Order-in-Council, approval, which would limit Canada's ability to react quickly to changing demands and needs.<sup>207</sup>

The CGPA stated that a list of drugs is a TRIPS-plus provision. Under the Implementation of Paragraph 6 of the Doha Declaration, Pharmaceutical products are defined as any products necessary to address public health needs recognized by the Doha

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<sup>206</sup> Agence France-Presse, "Bono's Pressure Group Says Canada Must Live up to HIV/AIDS Commitments," 11 March 2004.

<sup>207</sup> Canadian Generic Pharmaceutical Association, "Bill C-9: An Act to Amend the Patent Act and the Food and Drugs Act: Comments From Canada's Generic Pharmaceutical Industry," February 2004. Available <http://www.canadiangenericproducers.ca/en/news>

Declaration.<sup>208</sup> It argued that the decision of which drugs to import should be left up to the importing country, not the Canadian government. Interestingly the CGPA once again used international regulations to support their claims. Historically, international regulations have served to protect patent holders. That the CGPA was appealing to these regulations in order to make its argument reflects a reversal of the roles traditionally taken by brand-name companies and generic producers. Prior to the Implementation of Paragraph 6 of the Doha Declaration, the TRIPS agreement was used by brand-name companies to protect patent protections. Now, actors wishing limit patent protections are appealing to the TRIPS agreement as a reason for doing so.

The NGOs also opposed Schedule One. While the CGPA opposition was based on legal and profit-oriented concerns, NGO opposition focused on the morality of Schedule One. The products listed on Schedule One would be based on products appearing on the WHO Model List of Essential Medicines.<sup>209</sup> The WHO list was only a model, and not suited to addressing the health needs of particular countries in specific contexts. The list was not comprehensive enough to include all health needs. In essence the WHO list would become a 'gatekeeper' in determining which generic products could be exported.<sup>210</sup> The purpose of the WHO list is to maximize accessibility; Schedule One would use this list to decrease access.

In its submission to the House Committee Rx&D did not address the issue of Schedule One. However, it is a reasonable assumption they would want as few drugs as possible on the list. Its views can be extrapolated based on its actions after the bill's

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<sup>208</sup> Ibid.

<sup>209</sup> Canadian HIV/AIDS Legal Network Submission to the *Standing Committee on Industry, Science and Technology*, "Global Access to Medicines: Will Canada Meet the Challenge?" Available <http://www.HIV/AIDSlaw.ca/Maincontent/issues/cts/patent-amend.htm> 26 February 2004.

<sup>210</sup> Ibid.

passage. Prior to the passage of C-9, Bayer successfully lobbied to keep its pneumonia drug, moxifloxacin off Schedule One.<sup>211</sup> NDP MP Brian Masse, attempting to get pneumonia drug moxifloxacin on the list, was contacted by Bayer's director of national policy to argue against moxifloxacin's inclusion.<sup>212</sup> Two days prior to C-9's return to the House of Commons, moxifloxacin was on the list. On 4 May 2004, the day of C-9's introduction, moxifloxacin had been removed.<sup>213</sup> MP Masse claimed that this representative of the problems caused by including Schedule One. Schedule One made C-9 susceptible to lobbying efforts over what drugs to include. Leaving these decisions in the hands of importing governments circumvents this problem. Although far less controversial than the right of first refusal, or perhaps because it did not generate as much controversy, Schedule One was not removed from the bill. Instead Ottawa added five drugs to the list.<sup>214</sup>

This issue highlights the importance of a strong and unified opposition. The CGPA-NGO alliance opposed both this clause and the right of first refusal clause. They were joined in the fight against the right of first refusal by numerous other actors. The result was a total victory, with the government deciding to remove the right of first refusal clause. In this case the CGPA-NGO alliance remained strong and unified, however the actors that joined them in fighting the right of first refusal, especially Bono, Lewis, and the international HIV/AIDS groups, were either not there, or not very vocal. The result was the CGPA-NGO alliance still had some influence, but not nearly as much. The strength and unity of their alliance resulted in a small compromise, but nowhere near

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<sup>211</sup> Glen McGregor, "Drug Bill Lets 'Big Pharma' Call the Shots," Ottawa Citizen 4 May 2004.

<sup>212</sup> Ibid.

<sup>213</sup> Ibid.

<sup>214</sup> Allison Dunfield, "Ottawa Scraps Clause in Generic Drug Bill," The Globe and Mail, 20 April 2004.

the total victory they had achieved before. Transnational capital interests were predominant here. The inclusion of Schedule One, despite the fact it was not part of the TRIPS agreement, the Doha Declaration, or the accords interpreting the Doha Declaration, show the degree of transnational capital's influence.

This issue also highlights the fear the NGOs and CGPA had of transnational capital's power. Rx&D successfully managed to preserve its interests by including Schedule One. It also ensured that it could actively protect its interests by forcing any actor wanting to add a drug to the list to receive an Order-In-Council. Should an actor attempt to do this, Rx&D will be able to use its resources to thwart these efforts. This is what the CGPA-NGO alliance, and MP Masse were afraid of. The fact that non-transnational capital actors are concerned about Rx&D's ability to influence the drugs on the schedule reveals how influential this body is.

#### **4.5(C) NGO Ability to Contract With Generic Producers**

The original draft of C-9 stipulated that contracts to purchase generic drugs could only be arranged between generic producers and recipient governments. While this was the original intent of the legislation, both generic producers and NGOs wished to extend the purchasing power beyond sovereign governments, and into the hands of NGOs. NGOs argued that they played an important role in delivering health care services in developing countries.<sup>215</sup> They argued that Bill C-9 should take this reality into account by allowing them to purchase and distribute medicines. NGOs stated that they would have to be approved as a government agent by the host country in order to distribute generic

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<sup>215</sup> Canadian HIV/AIDS Legal Network Submission to the *Standing Committee on Industry, Science and Technology*, "Global Access to Medicines: Will Canada Meet the Challenge?" Available <http://www.HIV/AIDSlaw.ca/Maincontent/issues/cts/patent-amend.htm> 26 February 2004.

medicines from Canada.<sup>216</sup> The CGPA also argued that NGOs were delivering essential healthcare services to countries in crisis, and should be allowed to access its products.<sup>217</sup> Any other arrangements would create unnecessary barriers to health access, resulting in fewer people receiving generic treatments.<sup>218</sup> Again the CGPA challenged the legislation on legal grounds, while the NGOs challenged it on moral ones.

It is difficult to extrapolate conclusions on the importance of the various actors, as Rx&D said nothing on this issue. It does reveal that in the absence of transnational capital interests, other actors step in to fill the void. In circumstances such as this, alternate actors predominate. The source of their influence can only be partially accredited to them. More likely, they are made influential by the lack of a countering perspective. NGOs argue that they have an important role to play in distributing drugs. The government believed these arguments, when there was no opposition from Rx&D. This author believes that had Rx&D felt this was a crucial issue, and used the resources to protect its interests, the resolution would have been different.

#### **4.6 Analysis of Controversial Factors**

While the three issues discussed were the most important to the NGOs, Rx&D and the CGPA had concerns about other elements of the bill. For the most part the CGPA and NGO positions were quite similar, but the CGPA submission did include one suggestion that the NGOs did not. The CGPA recommended that the Canadian

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<sup>216</sup> Ibid.

<sup>217</sup> Canadian Generic Pharmaceutical Association, "Bill C-9: An Act to Amend the Patent Act and the Food and Drugs Act: Comments From Canada's Generic Pharmaceutical Industry," February 2004. Available <http://www.canadiangenericproducers.ca/en/news>

<sup>218</sup> Ibid.

government purchase and distribute generic drugs itself.<sup>219</sup> It recommended that Canada use part of its foreign aid spending in order to do so. In response to this claim the government reiterated that it was up to the private sector to distribute the drugs. Industry Minister spokesman Ian Jack stated:

We have created a framework that allows these drugs to be exported to countries in need. It's now up to the companies and [non-government organizations] to use this process. At the end of the day the government *doesn't manufacture or sell these products*. [Emphasis added]<sup>220</sup>

The CGPA responded by saying it was not enough for the government to just pass the legislation, and pat itself on the back. If the government really wanted to make a difference, it would play a direct role in ensuring the supply of generic medicines.<sup>221</sup> It is clear why the NGOs did not adopt this proposal. This proposal makes the CGPA appear greedy and self-interested. While the CGPA wanted a redistribution of spending, the NGOs wanted increased aid spending. There was no alliance on this issue, and convergence of interests on this issue, and as such the government did not adopt the CGPA proposal.

Rx&D also had another element of their submission that was significantly different from the interests articulated by the other actors. NGOs have long argued that the reason Rx&D opposes generic medicines being sold to LDCs, an area where they make very little money, is a fear of the drugs being re-imported into lucrative first world markets. Rx&D's submission reflect intense concern over this issue. Rx&D's submission to the house committee contained forty-six recommendations. Of these forty-six points

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<sup>219</sup> Canadian Generic Pharmaceutical Association, "Bill C-9: An Act to Amend the Patent Act and the Food and Drugs Act: Comments From Canada's Generic Pharmaceutical Industry," February 2004. Available <http://www.canadiangenericproducers.ca/en/news>

<sup>220</sup> Steven Chase, "Liberal's Discount Medicine Plan Panned," The Globe and Mail, 19 November 2004.

<sup>221</sup> Jeff Connell, Interview.

eighteen were devoted to ensuring there is a clear and transparent process. These 'administrative' amendments are attempts to protect its interests by making it more difficult for generic producers to obtain licenses. They include increasing the number of forms to be filed, greater opportunities to challenge patent concessions, and limiting the length of contracts.

Of even greater importance to Rx&D was ensuring that drugs were not re-imported into first world markets. Fully twenty-two of the forty-six points were devoted to this issue. Rx&D made suggestions as to how re-importation could be prevented. These suggestions generally consisted of limiting how and when generic medicines were provided. In an attempt to limit the export of generic medicines, Rx&D argued that without clear process, and strong limitations on the export of generic drugs, re-importation would be inevitable. That Rx&D spent so much time on these two issues highlights its continued opposition to any form of arrangement with generic producers.

#### **4.7 Commercial Elements Clause**

After all the arguments and submissions were made, Rx&D pursued one objective that could have far reaching consequences. It successfully argued that contracts could not be too commercial in nature, as this was a humanitarian objective. The government agreed with this argument, and section 21.17 of C-9 included a commercial elements clause. This clause prohibited generic producers from charging over twenty-five percent of the patent holder's price in Canada. If Rx&D believed that this was being done, they could sue the generic company. It was this clause that caused the CGPA and NGOs to fear continued litigation, which would prevent the export of generic medicines. Although not nearly as controversial as the right of first refusal, the commercial elements clause

was extremely worrisome to the NGOs and the CGPA. The NGO-CGPA alliance claimed that limiting price to twenty-five percent of the domestic price would make it difficult for them to secure profitable contracts.

Once again the NGOs and CGPA had the same position. However, their reasons were different. The NGOs wanted no conditions attached to the legislation. Their focus was on making the legislation as feasible for CGPA members as possible. While they were not directly concerned about CGPA member profits, they knew that it was the profit motive that would cause CGPA members to distribute their products. Thus, the NGOs supported the humanitarian objectives of Bill C-9, while opposing this clause. They believed that this attempt to keep C-9 for humanitarian purposes only, would decrease its effectiveness, and therefore result in legislation that was less humanitarian. Conversely, the CGPA opposed this clause as it decreased their ability to make a profit. They were already at a disadvantage in competing with China and India, and this clause put them at an even greater disadvantage.

The NGOs, CGPA, and their allies also questioned the reason for this clause.<sup>222</sup> The purpose of the legislation was to ensure that drugs being supplied to Africa were being sold at the lowest possible price. It should have been irrelevant whether or not the lowest price exceeds twenty-five percent of the Canadian domestic market. This bill is about removing disincentives for the generic producers – not creating incentives.<sup>223</sup> The generic producers were not making these products, and it would take time and effort to begin doing so. If they did not feel they could recoup their investment, they would not begin production, and there would not be an increased supply of drugs.

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<sup>222</sup> The various NGO reactions can be found at the Canadian HIV/AIDS Legal Network website <<http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend.htm>>

<sup>223</sup> Jeff Connell, Interview.

Part of the reason this clause did not generate as much reaction was the way it was introduced into the legislation. It was included in one of the final drafts. It was not addressed or introduced in any of the submissions by the NGOs, CGPA, Rx&D, or any other actor. The NGOs and CGPA had time to react to it, but did not have time to mobilize around it in the same way they did around the right of first refusal. Their alliance remained strong and unified, however they were not able to generate the public awareness they had when opposing the right of first refusal. The result was that this clause was introduced and protected by transnational capital. In this instance transnational capital was extremely influential. Not only was this clause introduced, it was done so behind closed doors. Nothing in the debates or submissions prepared the NGO-CGPA alliance. When questioned about why this stipulation was there all the CGPA representative could say was, "The brands told them [government] to. We didn't ask for it, and neither did the NGOs."<sup>224</sup> This more than any other element shows the power of transnational capital. They lost a battle over the right of first refusal, achieved a compromise on Schedule One, but ultimately introduced an amendment that could make the legislation completely ineffective.

The CGPA argued that they already had to compete with India and China on price, and that limiting their profit potential to 25% would make it difficult for them to compete. Currently the international generic drug market is dominated by India and China, and to a lesser extent Brazil. These countries are able to manufacture and sell their products on such a large scale, that it would be difficult for the relatively small firms based in Canada to compete. Instead, the Canadian firms claim that they are able to

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<sup>224</sup> Ibid.

compete by offering higher quality products.<sup>225</sup> Given this information it is likely that CGPA members are already at a competitive disadvantage. Parts of the bill that put them at an even bigger disadvantage significantly decrease their opportunity to sell their products.

For the NGOs the test of how humanitarian the legislation is, is how many generic drugs are exported under it –not the price CGPA members sell their products at. From the NGO perspective it is better to have Third World states overpaying for Canadian products, than not being able to afford any medicines at all. If no drugs are imported under this legislation, transnational capital has proven to be the most influential actor.

#### **4.8 Conclusion**

This chapter introduced three controversial elements of C-9. This author believes that these elements were put on the agenda because of the strength, unity and commitment of the CGPA-NGO alliance. The first was the right of first refusal, which would allowed brand-name companies to scoop contracts negotiated by generic producers. This clause was removed from the final draft. The second was Schedule One, which stipulated what drugs were allowed to be exported under C-9. This clause was kept in, however five drugs were added to it. It is possible to add more drugs through an Order-In-Council. The third controversial element was the ability of NGOs to contract with generic producers. The original legislation did not allow NGOs to contract directly with generic producers, but it was amended to give them this power.

These clauses of C-9 provide a good example of what actors are the most influential, and under what circumstances. Each of the actors got something they wanted,

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<sup>225</sup> Jeff Connell Interview

while being denied something else. This can be explained by looking at the circumstances that impacted their level of influence. Coming into the House Debates transnational capital had exercised the most influence. Rx&D had successfully extended patent protections under the Mulroney government. Internationally the Pharmaceutical lobby protected their patents through the TRIPS agreement. Historically the Canadian government had supported transnational capital at the international level. When the debates over C-9 were beginning, Rx&D had a greater level of influence. It successfully put in a right of first refusal clause, Schedule One, and other favourable clauses. That the government chose to include these clauses, before formally consulting the stakeholders, shows how influential Rx&D was. The government could have introduced a bill that was favourable to the NGOs or CGPA, but it did not. Transnational capital interests were so pervasive, that the government included favourable conditions automatically.

However, as powerful as it is, transnational capital interests are not always supreme. While transnational capital had the greatest say in the legislation, it would have preferred to avoid the debates entirely. Other interests were able to force these issues on the agenda. Doing so was very difficult, and required a strong alliance from a large group of actors. First of all the Canadian government, which traditionally sides with transnational capital, had to be convinced that changing the patent laws was in its own interests. Convincing the government of this required a coalition of NGOs, national capital, and movement leaders. Only when these groups worked toward a common objective did the government respond. This pattern repeated itself in the debates over the details of the legislation. When there was a strong convergence of interests between several actors, transnational capital either lost completely or was forced to compromise.

When this convergence was absent, transnational capital was successful. When there was a convergence, but it did not generate popular support, transnational capital won.

Together these actors decided how C-9 was drafted. Whether C-9 will result in any generic medicines being exported from Canada remains to be seen. Understanding this fact is essential to interpreting the theoretical arguments presented in chapter one. Thus far, no drugs have been exported under this legislation. Although the future is unknown, reasoned assumptions can be made based on the actors reactions to C-9. Knowing these reactions, and making reasonable assumptions about the probability of generic drugs being exported under this legislation, is crucial to understanding the core influences in the policy-making process.

## **Chapter 5: Conclusion**

## 5.1 Introduction

This final chapter will use the theoretical arguments first introduced in Chapter One to create a theoretical framework for understanding how Canadian policy is formulated. The pluralist perspective will be introduced to capture the role of competing interest groups. The statist perspective will be introduced to show that there is an independent government interest. The neo-Marxist perspective will be used to highlight the importance of capital relative to other actors. It will examine how the actors have responded to the Jean Chrétien Pledge to Africa Act. It will combine these responses, with the statements and positions of the first three chapters, to capture a 'big picture' perspective. It will then use the theories to interpret the meaning of the events. It will offer a framework for understanding how policy is formulated, and conclude with a discussion about why the neo-Marxist perspective is the best one for understanding C-9 in particular, and Canadian policy in general.

## 5.2 The Final Report

On 4 May 2004 the House of Commons, by a vote of two hundred and twenty-nine to zero, passed Bill C-9. On 13 May 2004 the Senate read it for the third and final time.<sup>226</sup> On 14 May 2004, C-9 received Royal Assent, and the amendments to the Patent Act and the Food and Drugs Act became law. The stated intent of the bill was to, "facilitate access to pharmaceutical products in the developing world, in order to address

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<sup>226</sup> HIV/AIDS Vancouver Island, "Canada Powers Ahead on Cheap HIV/AIDS Drugs for Poor Countries," 4 May 2004.

public health problems, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”<sup>227</sup>

It is estimated that it would take roughly two years for C-9’s impact, if any, to be known.<sup>228</sup> Key actors’ comments on the legislation however, provide a good basis for speculation on its effects. Some comments were positive, and others were negative. Taken together they highlight how each actor expresses its interests and attempted to influence policy.

### 5.3 Reactions

#### 5.3(A) Government Reaction

Not surprisingly, the government applauded its own piece of legislation. Prior to its introduction, during its tenure in the House of Commons, and after its passage Martin praised the government’s effort. In a statement before the House of Commons Martin applauded Canada for being the first country to adopt this type of legislation stating that, “I [Martin] am pleased and proud that Canada was able to lead the world in this effort.”<sup>229</sup> Martin claimed that the legislation could be hailed as a model to the world.<sup>230</sup> Other Liberal officials also commented on the legislation. When the decision to amend the patent laws was first announced then Foreign Affairs Minister Bill Graham signalled his support, claiming that Canada was leading the world.<sup>231</sup> Just after the legislation had been tabled, Liberal MP Brent St. Denis, who was the chair of the committee reviewing C-9 stated, “the government has found the right balance between making sure the generic

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<sup>227</sup> The entire bill is available at the House of Commons Website:

[http://www.parl.gc.ca/37/3/parlbus/chambus/house/bills/government/C-9/C-9\\_1/90247bE.html](http://www.parl.gc.ca/37/3/parlbus/chambus/house/bills/government/C-9/C-9_1/90247bE.html)

<sup>228</sup> Heather Scofield and Simon Tuck, “HIV/AIDS Plan Could Take 2 Years, Firms Say,” The Globe and Mail 3 October 2003.

<sup>229</sup> Ibid.

<sup>230</sup> Allison Dunfield, “Ottawa Scraps Clause in Generic Drug Bill,” The Globe and Mail, 20 April 2004.

<sup>231</sup> Bill Graham, “Canada Leading the Way,” The Toronto Star 10 November 2003.

producers have the right to do this, and keeping a downward pressure on price.”<sup>232</sup>

Attending the 15<sup>th</sup> International HIV/AIDS Conference in Bangkok, Liberal MP Aileen Carroll claimed that many members of the international community had spoken to her about Canada’s initiative.<sup>233</sup>

The praise from generic producers, NGOs and activists that had been offered when the government announced its intent to change the patent laws was withdrawn upon seeing how the legislation initially was drafted. Conversely the initial criticism from the brand-name companies had become ‘supportive.’ The revised Bill C-9 received support from activists, NGOs, and the brand-name companies. This support was more cautious and reserved than the initial accolades, but from the government’s perspective, it was preferable to the criticism received when C-56 was first introduced.

The praise of the NGOs and CGPA was focused on the removal of the right of first refusal. This decision received the support of many of the most vocal critics. Bono publicly praised Martin for removing the clause.<sup>234</sup> When Martin announced that the Canadian government was going to increase its contributions to fight HIV/AIDS, Bono was at his side as a show of support.<sup>235</sup> Lewis also praised the decision stating that, “the government has by and large honoured the position it took last September, when it announced the legislation.”<sup>236</sup> He went on to say that, “this kind of thing keeps Canada in

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<sup>232</sup> Saul Chernos, “Activists Claim Partial Victory on Export of Generic Drugs,” Inter Press Service, 5 May 2004.

<sup>233</sup> Aileen Carroll, “Our Leading Role in the Fight Against HIV/AIDS,” The National Post, 16 July 2004.

<sup>234</sup> Steven Chase, “Bill on Cheap Drugs for Poor Countries May Still Impede Generic Firms, Critics Say,” The Globe and Mail 21 April 2004.

<sup>235</sup> Jeff Sallot, “HIV/AIDS Plan Signal Foreign Policy Shift,” The Globe and Mail, 13 May 2004.

<sup>236</sup> Saul Chernos, “Activists Claim Partial Victory on Export of Generic Drugs,” Inter Press Service, 5 May 2004.

the lead...this is a real breakthrough and shows real political guts from Paul Martin.”<sup>237</sup>

In a joint statement, MSF, Oxfam, the Canadian HIV/AIDS Legal Network, and the Canadian Council for International Cooperation (CCIC) praised Canada for dropping the right of first refusal.<sup>238</sup> These groups did criticize certain elements of the bill. However, with one exception, their overall tone was generally supportive.

The government attempted to distance itself from the possibility that drugs might not be exported under C-9, by emphasizing that it was not responsible for getting the drugs to recipient countries. This was an initiative to allow generic drugs to be exported to countries in need, and therefore it remained up to the generic drug companies to do the exporting, as they were the ones who were meant to profit.<sup>239</sup> Liberal spokesman Ian Jack stated, “We have created a framework that allows these drugs to be exported to countries in need...At the end of the day the government doesn’t manufacture or sell these products.”<sup>240</sup> With this decision, the Canadian government had secured its interests. It had found a way to receive international and domestic prestige, and potentially aiding domestic capital, without having to spend any money.

For the government the stakes were high. It wanted a way to appear prestigious, while protecting the interests of transnational capital. If it could do this, it would have successfully protected its interests. At first the government’s perceived its interest to be closely tied to transnational capital interests. This remained true for the most part, however it was forced to grant some concessions on key issues. The strength of the opposition to the right of first refusal clause forced the government to meet the demands

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<sup>237</sup> Sue Bailey, “Changes to HIV/AIDS Drug Bill Draws Fire From Experts,” Times-Colonist, 21 April 2004.

<sup>238</sup> “Groups Call for More Amendments to HIV/AIDS Bill,” Canadian Press, 20 April 2004.

<sup>239</sup> Steven Chase, “Liberal’s Discount Medicine Plan Panned,” The Globe and Mail, 19 November 2004.

<sup>240</sup> Ibid.

of the NGO-CGPA community. The government was afraid that if it kept this clause in it would be criticized instead of praised. In order to avoid this it removed the clause, and received praise for doing so. From a government perspective, the ideal situation would be all actors praising the legislation. Given the nature of the issue, this would be impossible, but the government did well. It successfully managed to promote the praise it received, while muting the criticism.

### **5.2(B) Brand-name Reaction**

The brand-name companies signalled their general support for the bill. They had learned the lesson from South Africa, and did not want bad publicity. The media was already portraying them unfavourably, and their credibility with the public was weak at best.<sup>241</sup> Rx&D based its response on the humanitarian objectives of the bill. Once again, it claimed to agree with the overall principles of the legislation, despite the fact it had concerns about the amendments.<sup>242</sup> Rx&D criticized the NGOs, but praised the government. In reference to the removal of the right of first refusal, and the decision not to include an equal opportunity supply clause, Rx&D expressed disappointment that their full participation in the provision of medicines was not wanted.<sup>243</sup> It argued that being notified of, and permitted to bid for the impending contracts would give recipient nations more options, and would result in lower prices.<sup>244</sup> In its line of argument, the inclusion of a right of first refusal or equal opportunity to supply would have made the bill more humanitarian, not less so, as was argued by the NGOs and generic producers.

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<sup>241</sup> David Morley, Interview.

<sup>242</sup> Rx&D Press Release, "Moving Forward on Bill C-9," 20 April 2004. Available [www.canadaPharma.org](http://www.canadaPharma.org)

<sup>243</sup> Ibid.

<sup>244</sup> Steven Chase, "Heed new HIV/AIDS Plan, Lewis Urges Ottawa," The Globe and Mail, 7 April 2004.

They did not extend this criticism very far however. Instead Rx&D complimented the government, and once again the Canadian government received praise for the legislation. Russell Williams, the president of Rx&D stated, “the passage of this unprecedented humanitarian legislation speaks volumes of Canada and Canadians and reflects the compassion and reality of action that will soon benefit those in need of our help.”<sup>245</sup> This reaction shows Rx&D had an understanding of the forces behind the bill, and that continued opposition would only result in bad publicity.

Rx&D also made it clear that if generic drugs were not supplied to countries in need, the fault would lie with the CGPA and not them. They emphasized that they would not enter into litigation with generic producers over supply contracts with developing nations.<sup>246</sup> They stated that it was important to ensure that generic supply contracts were in line with international law, but that as long as this remained true they would not interfere. Once again Rx&D sought support from the international system to bolster their case.

Rx&D did not criticize the bill, but it pursued one objective that would have far reaching consequences for its formulation and its effectiveness. Rx&D argued that contracts could not be too commercial in nature. The result was that generic companies could not sell their products at more than 25% of the price they were charging in Canada. This clause helped Rx&D by reducing incentives for generic firms to export drugs. The

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<sup>245</sup> Rx&D Press Release, “Moving Forward on Bill C-9,” 20 April 2004. Available [www.canadaPharma.org](http://www.canadaPharma.org)

<sup>246</sup> Steven Chase, “Bill on Cheap Drugs for Poor Countries May Still Impede Generic Firms, Critics Say,” The Globe and Mail, 21 April 2004.

NGOs and the CGPA were very critical of this aspect of the bill, but were not able to create as much controversy over this issue, due to the way it was implemented.<sup>247</sup>

Transnational capital did well with this legislation. It suffered a major loss when the right of first refusal was taken out. However the bill has a whole favours their interests. They also demonstrated their knowledge of the importance of public relations. Realizing the discontent caused by the right of first refusal, Rx&D proposed an 'alternative,' and argued that their option would create even lower prices! As unbelievable as this notion was, it does reveal that Rx&D has realized the importance of public opinion, and wants to be seen positively.

It is difficult to determine what constitutes a 'win' and a 'loss' for transnational capital. The fact these debates are happening in the first place shows that other actors and factors can force an issue, even against the desires of transnational capital. However, it is not beyond transnational capital's ability to use this issue to its advantage. If it can publicly portray itself as a supporter of the C-9's humanitarian principles, while privately working to hinder the legislation, it will have achieved a victory. Rx&D has successfully managed to do this. If no drugs are exported under the legislation, it will be members of the CGPA, not members of Rx&D, who are blamed. Transnational capital lost the battle to keep this legislation off the government's agenda, however when it came to influence the contents no other single actor had the same level of influence.

### **5.3(C) NGO Reaction**

The NGO reaction was a mix of approval and criticism. Unlike the previous NGO efforts, the reaction to the final draft of C-9 lacked cohesion. Responses ranged from

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<sup>247</sup> Canadian HIV/AIDS Legal Network, "Reaction to Bill C-9, The Jean Chrétien Pledge to Africa Act," 16 May 2004. <[www.aidslaw.ca](http://www.aidslaw.ca)>

grudging approval to outright condemnation. The major points of agreement were the approval centred on the decision to remove the right of first refusal clause, and the criticism of the commercial elements clause.

The NGOs giving reserved approval commended the government for addressing the four 'controversial' issues they had brought up.<sup>248</sup> With the exception of the right of first refusal, none of the issues had been addressed in quite the manner the NGOs wanted. Having said this, the government did make some concessions, and walked a fine line between keeping the original legislation, and addressing the concerns of one of the vocal NGOs. For example, instead of removing Schedule one, the government added drugs to the list. Instead of prohibiting non-WTO less-developed countries from purchasing generic medicines, it required them to declare a national emergency. Finally, instead of allowing only governments to purchase generic drugs, the government changed the wording of the legislation to allow 'other' entities to make purchases.<sup>249</sup> Responding to NGO criticisms of the amendments, the government stated that it had sought to strike the right balance between Canada's humanitarian objectives and maintaining the integrity of its intellectual property regime.<sup>250</sup>

Unity between NGOs was extremely important. During the drafting stages of the legislation the NGOs remained unified. They spoke as one voice, pursuing the same objectives. It was not until after the final legislation had been passed that NGOs began

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<sup>248</sup> Prominent NGOs in this category include Canadian HIV/AIDS Legal Network, CCIC, KAIROS, and Oxfam.

<sup>249</sup> For a good summary of the NGO reaction see, Canadian HIV/AIDS Legal Network, Submission to the Standing Committee on Industry Science and Technology on Proposed Government Amendments to Bill C-9, an Act to Amend the Patent Act and the Food and Drugs Act, 19 April 2004. Available [www.HIV/AIDSlaw.ca](http://www.HIV/AIDSlaw.ca)

<sup>250</sup> Allison Dunfield, "Ottawa Scraps Clause in Generic Drug Bill," The Globe and Mail, 20 April 2004.

expressing themselves independently of each other. By this time unity was not nearly as important, as the legislation had already been finalized and passed.

The NGOs opposed to the legislation dismissed the concessions to the NGOs as, in their view, the final legislation would not necessarily result in any generic drugs being exported.<sup>251</sup> This group argues that this legislation failed the international community.<sup>252</sup> MSF was particularly bitter over the CGPA's failure to embrace an MSF plan to manufacture and distribute drugs.<sup>253</sup> MSF and like-minded NGOs believe that the final legislation will fail to send drugs to needy countries, and thus fails in its stated intent. Former MSF director David Morley hypothesizes that one of the reason for the different reactions might be that MSF is a single-issue organization, while the other NGOs have multiple interests. As such they are willing to accept the legislation as it stands in order to make gains on another issue. Conversely, MSF focused entirely on the issue of access to medicines, and no other areas where it could get something from the government.<sup>254</sup>

Both groups of NGOs had reservations about the process following the passing of the legislation. The Canadian HIV/AIDS Legal Network warned that even though lobbying to influence the legislation had ended, the work needed to be continued.<sup>255</sup> Richard Elliot, the research director of the Network was concerned that Rx&D would use its resources to prevent the sale of generic medicines. In one instance drug holder Bayer

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<sup>251</sup> MSF is the most prominent NGO in this category

<sup>252</sup> MSF, "Bill C-9: How Canada Failed the International Community," 29 April 2004. Available: [http://www.msf.ca/press/2004/042904\\_C9.htm](http://www.msf.ca/press/2004/042904_C9.htm)

<sup>253</sup> Steven Chase, "Liberal's Discount Medicine Plan Panned," The Globe and Mail, 19 November 2004.

<sup>254</sup> David Morley, Interview

<sup>255</sup> Saul Chernos, "Activists Claim Partial Victory on Export of Generic Drugs," Inter Press Service, 5 May 2004.

approached an MP to keep the pneumonia treatment moxifloxacin off the list of approved drugs.<sup>256</sup>

These concerns are reasonable, but are being overstated by the NGO community. I believe that given the nature of C-9, it would be difficult but possible for generic producers to sell to Third World states. There are many disincentives, but C-9 does allow for the export of generic medicines. Generic producers will not be jumping at the chance to supply medicines, as there is little potential for profit. However it is doubtful they would be doing so even if all of their conditions were met. Their criticisms were as much about keeping in line with their ideological position as they were about the elements of the bill itself.

The varied NGO reactions make it difficult to analyze their perspective of the final piece of legislation. What can be said is that at best, the NGOs gave reserved approval for the bill, and at worst outright condemnation. None of the NGOs gave total approval, while most of them did not condemn it outright either. Even Lewis, Bono and others, who had given their seemingly total approval, had reservations. Bono stated that the government must still put money into AID programs, while Lewis stated that the bill still had some flaws, such as the commercial elements clause and the Schedule One, that needed work. In the end however, the NGOs can only interpret and estimate what, if any, effects the bill will have. It is the actions of CGPA members that will determine whether generic drugs will be provided to needy countries. Unfortunately, given the CGPA reaction to C-9, the outlook is not good.

NGOs would argue that they do not have a self-interest in this legislation, and therefore could not be considered winners or losers. They argue that it is the people who

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<sup>256</sup> Glen McGregor, "Drug Bill Lets 'Big Pharma' Call the Shots," The Ottawa Citizen, 4 May 2004.

need these medicines that are the losers. To a certain extent this argument is correct. NGOs do not gain or lose resources or influence based on the contents of the legislation.

When levels of influence are examined, NGOs did well under certain circumstances. When a set of criteria was met, NGOs were able to exert quite a bit of influence. If the government thought it was in its interest to listen to them, if they were joined by other actors, and/or in the absence of an opposing viewpoint the NGO community was extremely influential. If these criteria were not met, NGO influence was severely diminished.

### **5.3(D) CGPA Reaction**

For the CGPA to find C-9 a feasible option, it must create a market for their products in needy countries. The CGPA stated that C-9 did not achieve this objective. Unlike the activists, Rx&D, and some of the NGOs, the CGPA was unreservedly critical of the legislation. Apart from a few brief statements of support, the CGPA did not praise the legislation. What limited support was given was based on progress that had been made compared to C-56. Like the NGOs, the CGPA highly approved of the government's decision to remove the right of first refusal clause. Apart from this however, they remained critical. The limited proclamations of support included such statements as, "progress has been made but..."<sup>257</sup>

The main complaint of the CGPA was that the bill did not establish a framework that would allow them to sell their products. It believed that the 'commercial' clause made it too easy to for patent holders to sue.<sup>258</sup> The CGPA argued that the clause made little sense from an ideological or practical standpoint. From an ideological perspective, it

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<sup>257</sup> Allison Dunfield, "Ottawa Scraps Clause in Generic Drug Bill," The Globe and Mail, 20 April 2004.

<sup>258</sup> Ibid.

argued that its members should have the right to sell for any price and to anyone, provided they were in congruence with international trade law and intellectual property law. It held that if one of its members had spent time and effort developing a product, the firm should be allowed to sell that product to any actor willing to purchase it.<sup>259</sup> From a practical standpoint, the CGPA argued that the legislation made it too easy for Rx&D to sue its members.<sup>260</sup> Jim Keon, President of the CGPA, stated that despite the progress that had been made, “other amendments open[ed] up a hornets nest of potential court battles that will ultimately undermine the purpose of the legislation.”<sup>261</sup> They also claimed that the regulation makes it difficult and costly for them to research, produce and export drugs, which they would have to sell below cost.<sup>262</sup> Both the government and Rx&D responded negatively to these statements.

Eric Dagenais, the Director of Patent Policy with Industry Canada defended the government’s legislation. He stated that the government recognized that generic producers should be making some type of return in order to encourage their participation, and that a twenty-five percent figure was the correct amount.<sup>263</sup> He also stated that the legislation was important regardless of whether it led to shipments, as it offered an alternative drugs supplier when poor countries negotiate with patented drug makers. Rx&D also dismissed the CGPA’s concerns. It accused the generic producers of spending

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<sup>259</sup> CGPA Press Release, “Government Amendments to Bill C-9 Fall Short,” 20 April 2004. Available: [http://www.canadiangenericproducers.ca/en/news/apr\\_20\\_04.shtml](http://www.canadiangenericproducers.ca/en/news/apr_20_04.shtml)

<sup>260</sup> Steven Chase, “Liberal’s Discount Medicine Plan Panned,” *The Globe and Mail*, 19 November 2004.

<sup>261</sup> Allison Dunfield, “Ottawa Scraps Clause in Generic Drug Bill,” *The Globe and Mail*, 20 April 2004.

<sup>262</sup> Steven Chase, “Liberal’s Discount Medicine Plan Panned,” *The Globe and Mail*, 19 November 2004.

<sup>263</sup> Saul Chernos, “Activists Claim Partial Victory on Export of Generic Drugs,” *Inter Press Service*, 5 May 2004.

its energy on excuses rather than on producing medicines for export, and claimed that if a generic producer followed the guidelines, it would not have to worry about lawsuits.<sup>264</sup>

It is estimated that it will take roughly two years for the legislation to take effect. It is difficult to tell whether the CGPA truly found the legislation unworkable or if they were simply criticizing, in an attempt to get more changes made.<sup>265</sup> This author believes it is most likely a combination of both. There will be a review of the legislation in two years. To criticize, in the hopes that changes would be made, is a reasonable thing to do. Having said that, it has been slightly over one year since the bill was passed. Since then no generic drugs have been exported under this legislation.<sup>266</sup> Whether this is due to flaws in the legislation, or the fact the amendments have not been there long enough for generic producers to take advantage of them remains to be seen. Nevertheless it is worrisome that no moves have been made to supply generic medicines to needy countries as a result of C-9.<sup>267</sup>

The generic producers are afraid of what will happen if drugs are not exported under this legislation. The government has stressed that it is up to the private sector to sell the drugs. Rx&D has said the generic producers are making excuses. If it takes too long for drugs to be exported, and/or no drugs are exported, the generic producers will be blamed.<sup>268</sup> In many ways the government drafted the legislation, then threw responsibility at the feet of the generic producers.<sup>269</sup>

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<sup>264</sup> Steven Chase, "Liberal's Discount Medicine Plan Panned," The Globe and Mail, 19 November 2004.

<sup>265</sup> Ibid.

<sup>266</sup> David Morley, Interview, Joel Lexchin, Interview, and Jeff Connell, Interview

<sup>267</sup> Brian Masse, Interview

<sup>268</sup> Ibid.

<sup>269</sup> Ibid.

If any of the groups ‘lost’ it was the CGPA. It had neither the capital resources of Rx&D, nor the moral credibility of the NGOs. Throughout the entire process the CGPA was dependent on its alliance with the NGOs. It argued many points, the vast majority of which were convergent with NGO arguments. This was not a coincidence – representatives from both groups met each other in order to create common policies.<sup>270</sup> Without this alliance the CGPA would have been totally ineffective in promoting its interests. The CGPA also has the most to lose. If no drugs are exported under this legislation, its members will be blamed. The CGPA, working closely with the NGOs, gained some minor victories. Given the recent resolutions of the conflicts between the CGPA and Rx&D, it is unlikely that the CGPA would have been very effective on its own. At the very least NGOs could use a public perception of their morality to try and influence government. The CGPA did not even have this option, as their moral arguments were not seen as being any more credible than those of Rx&D.

#### **5.4 Optimism**

Despite their strong criticisms, the NGOs and CGPA displayed a level of reserved optimism about the legislation. They agreed that it was flawed, but they also agreed that a flawed bill was far better than no bill at all. They were committed to working within the framework it set out, in the hopes that drugs would be sent under this legislation. Doing so would be difficult, but is better than two years ago when it would have been illegal.<sup>271</sup>

There was also a belief that this legislation would inspire other countries, especially the EU.<sup>272</sup> If C-9 did inspire the EU to adopt similar legislation, while avoiding the pitfalls, it will have indirectly achieved its objective. While this is not how the CGPA

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<sup>270</sup> David Morley, Interview.

<sup>271</sup> David Morley, Interview, Jeff Connell, Interview.

<sup>272</sup> Joel Lexchin, Interview.

or NGOs wanted it to be done, if the results are there then it would be indirectly effective. Having said this, all parties agree that the bill is not effective until the drugs are sent – something they are still waiting for.<sup>273</sup>

### **5.5 Reflection on Theories**

Understanding C-9, the broad context of Canadian policy formulation, requires a return to the theoretical perspectives introduced in the first chapter. The three theoretical perspectives used were: 1) The neo-Marxist perspective, with its focus on the increasing importance of transnational capital, 2) The statist perspective with its focus on an independent government interest 3) The pluralist perspective, which emphasizes the importance of competing interest groups. Throughout the thesis all of these theories were used. The neo-Marxist perspective is predominantly used. The pluralist perspective is rarely used, and the statist perspective falls somewhere in between.

The pluralist perspective would see this legislation as the result of competing elite interest groups pursuing their objectives. The influential groups, were long time participants in Canadian politics. The interest groups that attempted to influence this legislation were established experts in their fields. They also consisted of numerous members. Instead of individual pharmaceutical corporations attempting to influence government, the CGPA and Rx&D spoke on behalf of the brand-name and generic companies. There were numerous NGOs participating in the process, however two took the lead. MSF's, 'Access to Medicines' campaign is the established campaign for increasing access to medicines. It is not the only campaign of this kind, however it is the best established, and therefore most influential. The Canadian HIV/AIDS Legal Network is the main AIDS advocacy group in Canada. Again it is not the only advocacy group, but

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<sup>273</sup> David Morley, Interview, Jeff Connell, Interview.

is the most influential and knowledgeable in terms of how Canadian legislation affects those with HIV/AIDS.

Neo-pluralism believes that how political leaders believe the public will react plays a role in determining the policies they pursue. I wish to show that public opinion, or at least a fear of it played a role in the legislation. At certain points, actors, especially the government and transnational capital, fear negative public reaction. All of the actors attempted to use this to their advantage, believing that influencing public opinion would influence the government's decisions. Rx&D and the CGPA were careful to argue on the basis of the humanitarianism of the legislation. Realizing the backlash against the term right of first refusal, Rx&D 'withdrew' its support for this clause, and proposed an 'alternative' entitled equal opportunity to supply. If public opinion were irrelevant, Rx&D probably would not felt the need to bother doing this. The government based its decision to remove the right of first refusal on a fear of public opinion. The NGO-CGPA alliance opposed many of C-9's clauses, however it was the actions of Bono and Lewis, and the public interest they have, which resulted in the clause being withdrawn. This is a consistent pattern throughout the process. The decision to include a commercial elements clause, probably the biggest concession made to transnational capital, was purported as a way of keeping the legislation 'humanitarian.'

The media also played a role in this aspect of the legislation. For the most part the arguments and discussions occurring in the committee's and legislature, would be communicated to the public through the media. The actor's usage of humanitarian language was a way of conveying their good intentions to the public. For the most part the media, especially the *Globe and Mail*, portrayed the NGOs positively, but called into

question the motivations of Rx&D, and to a lesser degree the CGPA. It is rare that the public mobilizes around an issue. However the actors will continue to speak to it, out of an awareness and fear, of what could happen if the public does mobilize.

The statist perspective, as outlined by Nossal, looks at what the government interest is. This perspective holds that the government is both a sovereign and dominant political entity. The government will often promote the interests of transnational capital, and to a lesser extent national capital, but this is because of a perception that doing so is in its own interests, and not due to any influence of these actors. If the government feels it is in its interest is to oppose the business interests, it will do so. In the case of C-9 the government wanted a way to create prestige, which Nossal holds is one of its interests, while protecting transnational drug companies. This interest did not change. When the government saw how strong the opposition to the right of first refusal was it removed the clause. However, it did not abandon its interest in gaining prestige, while protecting the transnational drug companies. It introduced a different clause, under a different name, that had a similar impact as the right of first refusal, but did not create as much controversy. The government successfully promoted its interests in prestige, while advancing the interests of transnational capital, but ensuring that contracts were for humanitarian purposes only.

This author feels the neo-Marxist perspective is the most relevant in explaining policy formulation. While I do not believe it can fully explain the politics surrounding C-9, I believe it is much closer than any of the other theories. The elements I do not feel it properly addresses are due to the complexities of the Canadian political process, and although not insignificant, they are secondary to the degree and complexity of the factors

and motivations this theory is able to capture. Many of the elements of the neo-Marxist perspective are played out in the debates surrounding C-9. The neo-Marxist perspective holds that there is a second polity to which the government is accountable. It was not until changes were made to the TRIPS agreement that Canada was able to amend its domestic patent laws. The neo-Marxist perspective argues that transnational capital uses the government to promote its interest. At the TRIPS Council meetings in 2001, Canada joined the US, Switzerland, Australia, and the EU in promoting the interests of the transnational pharmaceutical companies.

The neo-Marxist perspective holds that capital interests as a whole have grown in importance relative to other actors, and that transnational capital has grown relative to national capital. I do not believe that C-9 would have been introduced, had the CGPA not stated their interest in selling products to the Third World market. Once it was introduced however, the legislation reflected the interests of transnational capital. The response of national capital to the bill was negative. National capital claimed that, despite the removal of the right of first refusal clause, the bill was too restrictive for them to sell their products internationally. They claimed that it was not one issue, but an accumulation of little restrictions that prevented them from taking advantage of the bill. The creation of the bill, along with the removal of right of first refusal was an ideological defeat for transnational capital. However, if no drugs are exported under it then the victory is only ideological. Transnational capital's material interests will remain secure.

## **5.6 Conclusion**

This thesis has examined a Canadian policy issue in an attempt to analyze how Canadian policy is formulated. Using Bill C-9 as a case study, it has examined a variety

of aspects of the bill from a variety of perspectives. C-9 makes an excellent case study, due to the range of issues it covers. It encompasses foreign policy issue, public policy issue, international law, developmental issues, and trade issues.

By using C-9, this essay was able to establish and examine the motivations and objectives of the government, and the actors trying to influence it. It also enabled the author to examine how these groups pursued their objectives. Examining the reasons for the bill, the lobbying to change it, and the government's response, makes it possible to determine the amount of influence these actors have over government.

One alliance consisted of NGOs, activists, and the CGPA. These actors are not always allied with each other. However in the case of C-9 they were pursuing similar objectives. Each of these actors wanted to ensure the legislation made it as easy as possible, within the confines of TRIPS, to export generic medicines. As the lobby group for the generic producers, the CGPA spoke with one voice. Although there were many different NGOs involved, and no umbrella organization representing them all,<sup>274</sup> they spoke and acted cohesively. Doing so helped them keep their influence. When divided, they are less influential.

This level of unification and agreement between ideological actors and capital actors, gave them influence. When the government announced its decision to remove the right of first refusal, they achieved one of their most important objectives, and in doing so, defeated transnational capital interests. This was the most controversial aspect of the legislation, and the only one that Rx&D tried to protect in its submission (albeit under a different name).

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<sup>274</sup> Although the Canadian HIV/AIDS Legal Network took the lead.

The second group, consisting of patent holders represented by the umbrella organization Rx&D, argued against making changes to the Patent Act. When it became clear that the government was going ahead, Rx&D attempted to protect its interests, by making transparency and mechanisms against re-importation the main focus of its submission. It continually agreed to the principles behind the legislation, using this argument to support its claim that it was a humanitarian, and not a commercial, effort. This argument led to the inclusion of a commercial elements clause, which limited how much generic producers companies could charge for their products. This clause sparked controversy. However, by the time the first group could react, the legislation had already been introduced in Parliament, and the government clearly was not willing to send it back to a committee again. The bill passed with this clause intact – a move Rx&D strongly supported.

To say that this bill is a victory for one group and a defeat for another would oversimplify a complex issue. The removal of the right of first refusal clause would seem to signify that the alliance of NGOs, activists, and generic producers won. While this statement is true, it is only one perspective. A second perspective is that there have been no generic drugs exported under C-9, and therefore the legislation can be seen as a victory for transnational capital. This perspective is also limited in its scope. Just as the first group would have preferred not to have the ‘commercial element’ clause included, Rx&D would have preferred the right of first refusal in. In this sense, both groups gained ground in some areas, while losing it in others.

Amidst all of this was the Canadian government. Each group attempted to influence the Canadian government. Throughout the process the Canadian government

attempted to protect its interests. It received praise for its announcement, followed by strong criticism when the legislation was first drafted. Accusations that the government was sabotaging its own initiative caused it to review the legislation. If the bill came under too much criticism, the government would lose the international praise it had first received. However it could not move too far toward the NGO position due to the power of transnational capital. Receiving international accolades and support was, if not a factor, a very important bi-product of the legislation.

In conclusion there are many different factors influencing government policy. Many of these factors are contradictory, and the government is forced to attempt to balance them. Sometimes it is successful, and at other times not. With C-9, the government managed to strike a balance between opposing actors. While it did not allay all criticism, it managed to mute much of it. As an organization accountable to the public, and indeed empowered by the public, congratulatory praise is worth more than just feeling good about oneself. It is a necessity for political parties to remain in power, for if they do not receive support in the media, and/or other public forums, they will not receive support at the polls. With this piece of legislation, the Canadian government successfully navigated the political maze, and advanced its own interest while doing so.

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