

DISCERNING MANIFESTATIONS OF CONTINENTAL GOVERNANCE IN THE NORTH
AMERICAN PHARMACEUTICAL INDUSTRY IN THE CONTEXT OF INTELLECTUAL PROPERTY
RIGHTS

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1.0 Introduction

Despite recent attempts, international agreements have failed to successfully harmonize intellectual property rights (IPRs) in North America. In particular, the Trade-Related Agreement on Intellectual Property Rights (TRIPS) and Chapter 17 of the North American Free Trade Agreement (NAFTA) have not resulted in convergence and integration of IPR policies in the United States, Canada, and Mexico. Furthermore, international IPR agreements have not resulted in the rise of continental governance in the North American pharmaceutical industry. In the context of the exploration at hand, “continental governance” is defined as the institutionalization and formalization of cross-border relationships between governments to the extent of creating a coherent policy framework and economic integration between participating actors. The lack of a formal North American market in the pharmaceutical industry and scant evidence of explicit intellectual policy coordination between the United States, Canada, and Mexico indicates that NAFTA’s Chapter 17 and TRIPS have failed as institutions promoting continental governance within the pharmaceutical industry. The North American pharmaceutical sector is most appropriately represented by a “hub-and-spoke” model, with the United States “hub” shaping the policy of the Canadian and Mexican “spokes” on a bilateral (Canada-U.S. and Mexico-U.S.) basis by interactions of actors in the government and the industry.

2.0 IP and the Pharmaceutical Industry

2.1 The Role of IPRs in Promoting Innovation

The pharmaceutical industry is influenced extensively by the structure of the IPR system. Estimates suggest that the average cost of developing a new brand name drug is CDN\$1 billion. Conversely, the development of a generic drug requires approximately CDN\$1 million.¹ To recover costs of research and development (R&D), brand name pharmaceutical companies seek IPR protection, which grants inventors of the medicine an effective monopoly on the production and sale of a drug for a given period of time, thus guaranteeing the patent holder exclusive privileges to profits.² Since weak IPRs hinder R&D, brand name pharmaceutical companies lobby for international standards that provide basic IPRs to ensure that the manufacturers can recoup the costs of R&D while distributing their drugs in foreign markets.³ While the high costs of R&D justify the use of the patent system as an incentive mechanism to promote innovation in the pharmaceutical industry, manufacturers of generic drugs argue that the twenty-year term of

¹ “Development” of a drug includes its introduction to the market and the pursuit of all legislative procedures required to introduce the drug to the market. Development does not include the costs of marketing the drug once the drug is on the market.

² The term of protection varies by country. Under the provisions of the TRIPS agreement, the period of protection is twenty years. The term of patent protection in less developed countries may be less than twenty years because TRIPS grants these countries an extended period of time to comply with the provisions of the Agreement.

³ In the case of patents, “basic” and “rudimentary” standards refer generally to those IPRs that have been accepted by all signatories of an international agreement. For example, the twenty-year term of patent protection was considered to be a “basic” standard. These standards are “basic” in that more stringent IPR protection could be demanded of all signatories had all of the signatories been willing to accept stricter IPR standards.

patent protection guaranteed by TRIPS provides excessive monopoly power to brand name drug manufacturers. This monopoly power, in turn, results in higher prices of patented drugs and decreases the accessibility of drugs to patients. Concerns about the necessary rewards for innovation and accessibility to drugs represent the archetypical struggle between manufacturers of brand name and generic drugs.

2.2 IPR Law in International Agreements

International IPR agreements, including TRIPS and NAFTA's Chapter 17, arose within the context of globalization and against a backdrop of the sparring concerns of the pharmaceutical industry. Multinational brand name pharmaceutical manufacturers supported strengthened global IPR standards. Strengthening and harmonizing IPR standards would provide incentives for drug manufacturers to innovate in a larger number of countries, decrease transaction costs of operating within foreign markets,⁴ and limit barriers to trade in pharmaceuticals.⁵ Both generic and brand name pharmaceutical manufacturers question the effectiveness of international IPR agreements: generic manufacturers assert that these agreements fail to encourage R&D efforts,⁶ while brand name manufacturers assert that the harmonization of IPR provisions under international agreements is not sufficient, thus failing to encourage R&D efforts.

Both NAFTA and TRIPS delineate specific (and similar) IPR guidelines to be adopted by the signatories.⁷ Chapter 17 of NAFTA entered into force on January 1, 1994 and established basic standards for IPR protection and enforcement in the United States, Canada, and Mexico. The agreement sets out provisions for national treatment, dealing with uncompetitive IPR practices, and definitions of what constitutes a patent.⁸ Chapter 17 also provides protection for a term of 20 years from the date of filing or 17 years from the date of grant, although a party may extend the protection term to compensate for delays caused by regulatory approval processes. Although there are no mechanisms for enforcement of the IPR provisions set out in NAFTA the agreement specifies that enforcement procedures shall be available under domestic law and can be used to prevent barriers to trade. The agreement does not take into account disparities among enforcement procedures implemented by various countries.

⁴ The understanding of "transaction costs" in this context is that of an economist. International standards lower transaction costs by reducing uncertainty of the manufacturers about the procedures that must be followed in foreign markets to achieve an objective – in this case, the patenting of drugs. The reduction in transaction costs is supposed to occur in theory; there may be other institutional barriers to the enforcement of these countries that does not result in lower transaction costs de facto.

⁵ A domestic exporter may choose not to engage in transactions with representatives in a foreign country if the exporter cannot enforce IPRs in the foreign country.

⁶ Some opponents of the international agreements argue that harmonized intellectual property rights standards encourage the transfer of technologies to countries where R&D facilities are inadequate rather than promoting the establishment of R&D facilities in these countries. An analysis of the validity of this claim is outside the scope of this paper.

⁷ Although there are several other international IPR agreements (such as the EU's IPR provisions), none of them are relevant to the discussion at hand because they do not concern the North American market, or they were instituted prior to the rise of the global pharmaceutical industry (such as the Paris Convention of 1883), or they aim at facilitating the administration of IPRs without setting out their specifications (including the Patent Cooperation Treaty of 1970, the United Nations' World Intellectual Property Office, and the Patent Law Treaty of 2000).

The TRIPS agreement was negotiated under the aegis of the General Agreement on Tariffs and Trade (GATT), drafted during the eight-year Uruguay Round negotiations, which concluded with the establishment of the World Trade Organization (WTO) on January 1, 1995. Since NAFTA served as a basis for TRIPS, a number of similarities and some identical clauses appear in both documents, although TRIPS requirements are more stringent than those of Chapter 17 of NAFTA.⁹ The TRIPS agreement then delineates provisions for national treatment, encouragement of technology transfer, promotion of public health and interest, and a methodology for dispute settlement under the WTO procedures.¹⁰ As a point of departure from NAFTA, TRIPS clearly sets out a patent term of 20 years from the date of grant. TRIPS requires members to comply with minimum IPR specifications; failure to comply with the specifications legitimizes the use of WTO enforcement mechanisms to ensure conformity. The adoption of the WTO's Dispute Resolution Body as the preferable method for resolving disputes signified the recognition of disparities that exist between national legal systems and variations in economic development.

3.0 Lack of Formal Continental Market in the Pharmaceutical Industry

Understanding the impact of international IPR agreements on the pharmaceutical industry requires an examination of the market for pharmaceuticals in North America. As such an exploration reveals, one cannot speak of a single North American market for pharmaceuticals. Instead, the pharmaceutical markets of the United States, Canada, and Mexico must be analyzed separately, revealing the discrepancies between the markets and illustrating the lack of continental coordination and governance within the industry. The limited coordination that does exist entails top-down directives from American headquarters to Canadian and Mexican subsidiaries.¹¹

The market clout of American pharmaceutical multinational corporations (MNCs) cannot be disputed: with American brand name pharmaceutical sales valued at USD\$181.8 billion per year, the brand name American pharmaceutical market is considered to be one of the most lucrative industries in the world, distantly followed by the European pharmaceutical market, with sales valued at USD\$88 billion.¹² Historically, American MNCs have played "immense hardball" in their lobby efforts to influence IPR policy and have largely determined the domestic and global policy agenda.¹³

⁸ *North American Free Trade Agreement Between the Government of the United States of America, the Government of Canada and the Government of the United Mexican States*, 1993.

⁹ Keith E. Maskus, *Intellectual Property Rights in the Global Economy* (Washington, D.C.: Institute for International Economics, 2000), 192.

¹⁰ *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1994.

¹¹ Industry Canada, "Highlights," *Sector Competitiveness Framework Series – Pharmaceutical Industry* (January 19, 2001). Available at <http://strategis.ic.gc.ca/SSG/ph01427e.html> (May 10, 2003).

¹² *IMS World Review*, "World Pharma Sales 2001: U.S. Still Driving Growth" (April 30, 2002). Available at http://www.ims-global.com/insight/news_story/0204/news_story>020430.htm (February 10, 2003).

¹³ Confidential interview with former Canadian government official (February 12, 2003).

Brand name pharmaceutical manufacturers tend to dominate the American pharmaceutical market while generic manufacturers traditionally tend to remain on the sidelines, both in their lobby efforts and the assertion of their market presence. The reticence of the generic corporations might be the result of the economic and political climate in the United States, which has exhorted market practices and largely shunned the welfare state, including assurance of accessibility to drugs for all members of society. As will be demonstrated subsequently, the industry group representing brand name manufacturers in the United States formed a unified front prior to the era of international institutions promoting trade liberalization and has since played a significant role in shaping the policies and practices within the pharmaceutical industry. With the rise of international institutions, the reach of the lobby efforts has extended into entrenchment of the dominant American beliefs into agreements affecting neighbouring countries, without much regard for variations in market structures, social institutions, and political frameworks within adjacent markets.

As the major trading partner of the United States with a much smaller economy the Canadian pharmaceutical industry has found itself particularly vulnerable to the influence of American pharmaceutical MNCs. The Canadian pharmaceutical market accounts for approximately 2 per cent of the global market and its brand name contingent is dominated primarily by subsidiaries of American MNCs.¹⁴ The brand name industry relies heavily on foreign direct investment (FDI) and technology transfer from American MNCs. The MNCs moved subsidiaries and branch plants into the Canadian market prior to trade liberalization to avoid regulatory barriers and engage in more effective local marketing strategies.¹⁵ The subsidiaries serve primarily the domestic Canadian market, exporting only 10 per cent of all output and importing raw materials, which results in a trade deficit in the pharmaceutical industry, with more than 60 per cent of the deficit accounted for by transactions with American parent companies of Canadian subsidiaries.¹⁶ Parent plants also benefit from patent royalties on products sold in Canada, which further contributes to the trade deficit within the industry. Headquarters of MNCs determine final decisions pertaining to R&D and long-term strategies. Despite patent reforms that favour brand name manufacturers, American MNCs view Canada as a restricted market constrained by stringent regulation of marketing of pharmaceuticals, inferior product features, lack of sales support, inconsistent quality of drugs, and high overhead costs.¹⁷ The primary reasons for subsidiaries to situate in Canada are favourable tax incentive for R&D and a faster lead time into the market facilitated by less extensive regulatory procedures.¹⁸

¹⁴ Industry Canada, "Highlights."

¹⁵ The regulatory environment for the marketing of drugs in Canada is drastically different from that in the United States; an exploration of the differences is outside the scope of this paper.

¹⁶ Industry Canada, "Highlights."

¹⁷ Industry Canada, "Changing Conditions and Industry Response," *Sector Competitiveness Framework Series – Pharmaceutical Industry* (January 19, 2001). Available at <http://strategis.ic.gc.ca/SSG/ph01429e.html> (May 10, 2003).

¹⁸ Industry Canada, "Changing Conditions and Industry Response."

In Canada, differences between brand name and generic drug manufacturers manifest themselves more clearly than in the United States. Domestic Canadian manufacturers dominate the generic industry, with two of the top ten companies ranked by sales being domestic generic manufacturers – Apotex (#3) and Novopharm (#8).¹⁹ In total, generic prescription sales were CND\$1.8 billion in 2002, representing 13.8 per cent of sales dollars and 40.3 per cent of all retail prescriptions filled in Canada.²⁰ The generic industry is also an avid exporter, selling more than 40 per cent of its output overseas.²¹ The robustness of the Canadian generic industry may be accounted for by the structure of the Canadian health care system, which gives rise to unique issues because of the division of powers between the federal and provincial governments. According to one industry source, the division of powers is a source of disagreement because the federal government determines the safety of pharmaceuticals and administers patents while the provincial government is responsible for determining the drug formularies that will be covered by provincial insurance programs, which cover approximately 40 to 45 per cent of drug costs. Therefore, the federal government deals primarily with brand name pharmaceutical companies, whereas provincial governments, which have an interest in affordable medicines, favour the generic industry.

The Mexican pharmaceutical industry is even more complex than that of Canada. In 1940, the Mexican pharmaceutical industry was comprised of sixty domestic manufacturers.²² During the protectionist era and the era of state development of the 1950's and 1960's, the Mexican Ministry for Trade and Industrial Development (Secretaria de Comercio y Fomento Industrial, SECOFI) instituted strict price controls and the Mexican Institute of Social Security (Instituto Mexicano del Seguro Social, IMSS) enforced stringent requirements for commercializing and marketing of pharmaceuticals.²³ These controls resulted in prices of drugs at one third of those in the developed world.²⁴ The government also limited exports by purchasing the majority of drugs manufactured in Mexico.²⁵ Unlike their counterparts in Canada and the United States, domestic Mexican pharmaceutical manufacturers were opposed to stringent patent controls. Since domestic manufacturers were involved with limited R&D activities, senior officials of the Association of Latin Pharmaceutical Companies (ALIFAR) and the Federation of Mexican Chemists and Pharmacists (FAQUIFARMEX) argued that providing more stringent patent protection would cause the industry to stagnate and bankrupt domestic companies; furthermore,

¹⁹ Teva, an Israeli generic manufacturer, recently purchased Novopharm.

²⁰ Canadian Drug Manufacturers Association web site (2003). Available at http://www.cdma-acfpp.org/en/resource_trends.html (April 5, 2003).

²¹ Industry Canada, "Highlights."

²² Bill F. Kryzda and Shaun F. Downey, "Overview of Recent Changes in Mexican Industrial Property Law and the Enforcement of Rights by the Relevant Government Authorities," *Canada-United States Law Journal* 21, no. 99 (1995), 100.

²³ Joan Brodovsky, *La industria mexicana en los años 90, in Apertura económica y desregulación en el Mercado de medicamentos: la industria farmacéutica y farmoquímica de Argentina, Brasil y México en los años 90*, ed. Jorge M. Katz (Buenos Aires: Alianza, 1997), 170-171.

²⁴ Brodovsky, 170-171.

²⁵ Brodovsky, 170-171.

the officials attested that an extension of the patent term would only be appropriate once the domestic companies were able to contribute significantly to R&D.²⁶

Drugs were considered to be public goods and only a few select manufacturers were granted licenses to produce particular drugs.²⁷ Most governmental research institutes purchased chemical materials developed abroad without providing patent protection to the imported chemicals.²⁸ MNCs and Mexican laboratories acquired drug technologies from abroad, frequently obtaining a license from the foreign manufacturer.²⁹ Despite the lax intellectual property standards, American MNCs comprised one-quarter Mexican pharmaceutical manufacturers by the mid-1980's.³⁰

Following the debt crisis of the early 1980's, Mexican political leaders decided that economic growth would be achieved most effectively through the liberalization of the Mexican economy. The new business environment resulted in reformed patent laws, first in 1987 under the Law on Inventions and Trademarks, which included patent protection for pharmaceuticals effective in 1997, and then in 1991, when patent laws protecting the pharmaceutical industry became effective immediately. These reforms stemmed largely from Mexico's participation in the Uruguay Round and TRIPS negotiations, as well as American pressure exerted on Mexican leaders.

The Mexican pharmaceutical industry is different from those of Canada and the United States because the Mexican pharmaceutical industry is divided into three, rather than two, distinct sectors: public, private, and generic. The private and generic sectors resemble those of the United States and Canada. The public sector is unique to Mexico and encompasses domestically produced generic drugs, brand name drugs researched in public laboratories, and "copycat" drugs, which are described subsequently.³¹ A number of companies in the public sector have been purchased by MNCs and currently the system is undergoing significant change under pressure from the United States, which calls for the Mexican Ministry of Health to ensure that the Mexican Social Security Institute (IMSS) and the Social Security Institute for Government Workers (ISSTE) purchase patented drugs only.³² Historically, both institutes purchased exclusively domestically produced generic drugs, but were forced to open bidding to American and Canadian firms eight years after the implementation of NAFTA. In 1992, 350 domestic

²⁶ Rosemary E. Gwynn, "Mexico," in *Intellectual Property Rights: Global Consensus, Global Conflict?*, ed. R. Michael Gadbar and Timothy J. Richards (London: Westview Press, 1988), 241-242.

²⁷ Brodovsky, 170-171.

²⁸ Brodovsky, 170-171.

²⁹ Brodovsky, 170-171.

³⁰ Brodovsky, 170-171.

³¹ Confidential telephone interview with Mexican representative of the brand name industry (February 20, 2003).

³² United States Trade Representative, "2003 National Trade Estimate Report on Foreign Trade Barriers: Mexico." Available at <http://www.ustr.gov/reports/nte/2003/mexico.pdf> (May 15, 2003).

Mexican manufacturers were operational; by 1997, 218 labs were operating, 40 of them subsidiaries of MNCs.³³

Strengthened IPRs in Mexico have resulted in an influx of foreign subsidiaries into the pharmaceutical market. The subsidiaries established patent strongholds and Mexico experienced a 385 per cent increase in prices in the past six years, although the price levels remained lower than those in the United States and Canada.³⁴ The abrupt price increase was accompanied by a 23 per cent growth in sales as restrictions on exports were removed and Mexican manufacturers began to export their drugs to South America.³⁵ Despite the more favourable IPR provisions, MNCs remained cautious about entering the Mexican market, expressing particular concerns about corruption, bureaucratic impediments, and lower pharmaceutical prices than those of other countries.³⁶ Empirical evidence suggests that Mexico's domestic pharmaceutical manufacturers have already felt the strain of increased international competition in the Mexican market: although domestic generic manufacturers have retained 80 per cent of the market share, 20 per cent of medicines are imported (as compared to complete self-sufficiency prior to trade liberalization).³⁷

The discernible presence of subsidiaries of American pharmaceutical MNC in Canada and Mexico result in significant American influence on the policies and practices of Canadian and Mexican brand name manufacturers. American headquarters evaluate the market and policy conditions in Canada and Mexico to decide the allocation of R&D according to what suits the American MNCs, largely depriving subsidiaries of the autonomy to make decisions with regard to R&D and technology transfer. Although subsidiaries have increased their ability to bid for specific drugs once Canada and Mexico demonstrated compliance with TRIPS, pharmaceutical production agendas remain in the hands of foreign manufacturers. Secondly, American subsidiaries in Canada and Mexico bypass non-tariff barriers by situating their operations within Canada and Mexico. Such penetration of the market by foreign subsidiaries allows actors with foreign interests to lobby from within national policy frameworks. As will be demonstrated subsequently, foreign interests are plainly evident in the lobby efforts of foreign subsidiaries and brand name pharmaceutical associations in Canada and Mexico.

There exists no coordination between generic industries within each of the countries, primarily because generic manufacturers in the United States have played a traditionally weak role in setting the policy agenda. Furthermore, Canada and Mexico tended to foster their own generic industries successfully, thus presenting limited incentives for foreign subsidiaries to

³³ Maryse Robert, *Negotiating NAFTA: Explaining the Outcome in Culture, Textiles, Autos, and Pharmaceuticals* (Toronto: University of Toronto Press Inc., 2000), 219.

³⁴ Brodovsky, 183-184.

³⁵ Canadian Embassy Mexico City Trade and Business Development Division, "Priority Sector Action Plan 2000-2001: Opportunities and Challenges," *Pharmaceuticals and Biotechnology*. Available at <http://www.dfait-maeci.gc.ca/mexico-city/trade/priorisectorpharmacet-en.asp> (February 16, 2003).

³⁶ Brodovsky, 189.

³⁷ Brodovsky, 189.

penetrate the domestic generic markets. With increasing globalization of the pharmaceutical industry, this trend may well be reversed.³⁸

Having examined the supply conditions of the North American pharmaceutical market, the demands and influence of the consumers must be taken into account when attempting to discern the existence of a formal continental market. The rise of patient groups has introduced civil society to the setting of a policy agenda. On the national level, the roles of patient groups include generating public awareness about diseases, funding and promoting medical research, participating in and designing clinical trials, maintaining local support networks for members, and providing social services, high profile campaigns, and coalitions within industry.³⁹ Patient groups also influence the R&D agenda, identifying demand for innovation in particular areas and encouraging collaboration between authors of studies, laboratories, and funding bodies.⁴⁰

Table 1 illustrates the breakdown of the American, Canadian, and Mexican consumer markets for pharmaceuticals. The particular characteristics of the consumer markets influence the conditions within the pharmaceutical industry, which is associated intimately with the health care industry. Examining the general trends depicted in Table 1, one notes the significant contingent of senior citizens that permeates the American and Canadian markets. Seniors' groups are interested in access to low-cost drugs and their influence on the pharmaceutical industry manifests itself in consumer lobby groups, which are analyzed subsequently. Of interest, as well, are the discrepancies in health care spending in the three countries, and the comparative contributions of private consumers to their health care costs, including out-of-pocket expenditures on health care. As noted in the table, Mexican out-of-pocket expenditures are relatively high, which presents difficulties for the Mexicans who may not be able to bear the brunt of health care costs, including the costs of pharmaceuticals. The Mexican government attempted to overcome this strife by engaging in pharmaceutical R&D and distribution, as will be demonstrated subsequently.

TABLE 1

CHARACTERISTICS OF PHARMACEUTICAL CONSUMER MARKETS IN NORTH AMERICA

Indicator	United States	Canada	Mexico
Total population (2001)	285,925,000	31,014,000	100,367,000
Dependency ratio (2001)	51%	46%	60%
Population over 60 years (2001)	16.2%	16.9%	7.1%
Fertility rate (2001)	2.0	1.6	2.6
Life expectancy at birth (2001)	77.0	79.3	74.2
Child mortality per 1000 (2001)	Males – 9 Females – 7	Males – 6 Females – 5	Males – 33 Females – 27
Adult (15 – 59 years of age) mortality per 1000 (2001)	Males – 144 Females – 83	Males – 98 Females – 59	Males – 179 Females – 101

³⁸ As exemplified by the purchase of Novopharm a Canadian manufacturer of generic drugs by Teva, an Israeli manufacturer of generic drugs.

³⁹ Dwijen Rangnekar, "Innovations in Ethical Drugs: A Framework for Analysis of the Role of Patient Groups" (School of Public Policy University College London Working Paper, July 2001), 197.

⁴⁰ Rangnekar, 198.

Life expectancy lost due to poor health (2001)	Males – 10.8% Females – 13.5%	Males – 11% Females – 12.6%	Males – 12.6% Females – 15.3%
Per capita GDP in international dollars (2000)	\$34,637	\$27,956	\$9,007
Total expenditure on health as percentage of GDP (2000)	13.0%	9.1%	5.4%
Per capita health expenditure in international dollars (2000)	\$4,499	\$2,534	\$483
Private expenditure on health as percentage of total expenditure on health (2000)	55.7%	28.0%	53.6%
Prepaid plans as percentage of private expenditure on health (2000)	62.5%	70.7%	3.8%
Out-of-pocket expenditure on health as % of total expenditure on health (2000)	15.3%	15.5%	49.5%

Source: World Health Organization

In the United States, the number of patient groups has grown dramatically in the last decade. 62 per cent of all new patient groups formed after 1980, with 37 new patient groups forming between 1990 and 1997.⁴¹ Twenty-three of the patient groups have a turnover of more than a million U.S. dollars.⁴² Patient groups bolster both sides of the IPR argument, siding with either generic manufacturers in lobbying for accessible medicines, or with brand name pharmaceutical manufacturers in lobbying for increased R&D.⁴³ Generic manufacturers are supported particularly by seniors' groups, since seniors face increasing drug costs and believe that access to lower-priced generic drugs will mitigate these costs.⁴⁴ The lobby efforts of these groups take the form of public awareness campaigns, indirect contact with the government, and direct communication with the generic industry associations.

Supporters of the brand name industry are usually patient groups associated with a specific disease, interested in the development of a particular drug. Several sources deem the HIV/AIDS group particularly successful in this area, primarily because the representatives of this group tend to be dynamic, well educated, resourceful, and eloquent.⁴⁵ Groups such as that representing HIV/AIDS patients work with brand name pharmaceutical corporations and industry associations, frequently receiving financial support for their efforts from the corporations and associations. The groups then raise public awareness about the issues and lobby the government to ensure that the needs of the interest groups are addressed. The groups usually call for further investment in R&D of new drugs and, indirectly, support the need for strong IPR protection deemed as necessary by the brand name corporations. Intensive lobbying efforts by the HIV/AIDS patient groups resulted in the enactment of the 1983 Orphan Drug Act, which granted these drugs fast track approval and 7-year market exclusivity.⁴⁶ The passing of this act

⁴¹ Rangnekar, 196.

⁴² Rangnekar, 196; expenditures by charities serving patient groups are not included in this figure.

⁴³ Rangnekar, 196.

⁴⁴ Rangnekar, 196.

⁴⁵ Confidential interview with Canadian academic (March 18, 2003); confidential telephone interview with American lawyer (April 9, 2003); confidential interview with American lawyer (April 10, 2003); confidential interview with representative of Canadian brand name industry (April 30, 2003); confidential interview with representative of Canadian brand name industry (February 20, 2003).

⁴⁶ Orphan drugs are those that treat diseases that affect less than one out of a thousand people. Rangnekar, 197.

was a landmark achievement that paved the way for strengthened lobby efforts by all patient groups.

Canadian consumer interest groups have a similar structure and lobbying interests as those in the United States. Patient groups affiliated with specific diseases lobby for continued and increasing protection of IPRs to ensure that brand name pharmaceutical companies continue to engage in R&D. On the other hand, seniors groups and social welfare advocates lobby for and support the generic industry, calling for the inclusion of generic drugs on provisional insurance formularies to decrease the costs of drug plans for employers and to ensure that pharmaceuticals are widely accessible to Canadian patients. There is no data available detailing the role of consumer groups in influencing policy change in Mexico.

To summarize, the tendency of American MNCs to impose top-down mandates for Canadian and Mexican brand name subsidiaries demonstrates the lack of a continental market in the pharmaceutical industry. As will be demonstrated subsequently, American consumers are discouraged from shopping across borders for pharmaceuticals. A continental market calls for the coordination of practices according to each country's comparative advantage and opening the market to the free flow of products across borders. There is no evidence that suggests that such flows exist between the three North American countries. The North American market remains fragmented along national lines, with little national autonomy permitted to Canadian and Mexican manufacturers in determining their output and R&D agendas.

4.0 Lack of Explicit IPR Policy Coordination in North America

4.1 Lobbying Practices and IPR Policy Change

The lack of a North American continental market for pharmaceuticals is an economic phenomenon resulting from a dearth of institutions that foster such an environment. From a political perspective, the lack of coordination among the three North American governments has prevented the rise of continental governance. In particular, lobbying tactics of corporations, industry associations, and consumers remain dedicated to influencing domestic policy rather than promoting policy coordination across borders. Although the Canadian and Mexican markets are penetrated by American subsidiaries, these subsidiaries lobby for their own interests specifically within the context of the Canadian or Mexican market, rather than within the context of the North American market. Thus, even though there are attempts to engage in governance from below by corporations and civil society, this governance is restricted within national boundaries and has not given rise to the coordination of governance from below across the continent.

Traditionally, American MNCs lobby at several different levels, using the vehicles of pharmaceutical associations, individual corporations, and consumer groups within the United States to influence American policy. The effectiveness of lobby efforts by brand name pharmaceutical manufacturers in the United States dates back to 1957, when Senator Estes

Kefauver and his Senate Subcommittee on Antitrust and Monopoly sought to address rising drug prices. The Subcommittee's recommendations – particularly the recommendations calling for compulsory licensing⁴⁷ – met with significant opposition from the brand name manufacturers, which reacted to the perceived assault on IPRs by forming the Pharmaceutical Manufacturers Association (PMA).⁴⁸ As a result of the PMA's lobby efforts, Congress eventually dismissed the Subcommittee's recommendations, with only an unorganized response from generic drug manufacturers.⁴⁹

In the 1980's, Presidents Carter and Reagan called for a commission, supported largely and enthusiastically by the PMA, to investigate and shorten the FDA drug approval times under the Drug Price Competition Act and Patent Term Restoration Act (the Waxman-Hatch Act).⁵⁰ The Act balanced the interests of the brand name pharmaceutical manufacturers with those of the generic manufacturers. Brand name manufacturers were satisfied by the Act's provision extending the term of patent protection to compensate manufacturers for the patent time lost during FDA review, as well as one-half of the time lost during clinical testing required by the FDA, with the total patent term capped at fourteen years (prior to the Act, effective patent terms lasted between seven and ten years).⁵¹ Generic manufacturers were satisfied by the Act's provision expediting the drug approval process of generic drugs by admitting drugs that were bioequivalent to brand name counterparts.⁵²

In 1986, two years after the passing of the Waxman-Hatch Act, Congress passed the Drug Export Amendment Act, acknowledging the increasingly global nature of the pharmaceutical industry. Prior to the passage of the Act, the FDA deemed illegal the exportation of drugs that had not been approved for sale in the United States; since this restricted the profits manufacturers could obtain abroad, the FDA provisions resulted in profit losses.⁵³ Under the new Act, a drug could be approved for export if American approval for sale in the United States was actively being sought; the drug was covered by an American investigational exemption; and the drug was going to be exported to one of twenty-one nations designated by the FDA.⁵⁴ The Act

⁴⁷ Compulsory licensing allows regulators to issue a license to a producer other than the patent holder to produce and sell a certain drug while the patent for the drug is still pending or in effect; the Subcommittee recommended that compulsory licenses be issued within three years of patent issue. Ronald W. Lang, *The Politics of Change: A Comparative Pressure-Group Study of the Canadian Pharmaceutical Manufacturers Association and the Association of the British Pharmaceutical Industry, 1930-1970* (Lexington, Mass.: Lexington Books, 1974), 13.

⁴⁸ Lang, 13.

⁴⁹ Lang, 13.

⁵⁰ The Independent Institute, *History of Federal Regulation: 1902-Present* (November 15, 2002). Available at <http://www.ficareview.org/history.shtml#sixteenth> (February 14, 2003).

⁵¹ Henry G. Grabowski and John M. Vernon, "Longer Patents for Increased Generic Competition in the U.S.: The Waxman-Hatch Act after One Decade," *PharmacoEconomics* 10, no. 2 (1996), 112.

⁵² Grabowski and Vernon, 112. The bioequivalency clause stipulated provision of an Abbreviated New Drug Application (ANDA), which allowed manufacturers of generic drugs to demonstrate that the effects and composition of their drugs were identical – bioequivalent – to those of brand name products.

⁵³ Barbara J. Culliton, "Omnibus Health Bill: Vaccines, Drug Exports, Physician Peer Review," *Science* 234 (December 12, 1986), 1313.

⁵⁴ Alan H. Kaplan, "Fifty Years of Drug Amendments Revisited: In Easy to Swallow Capsule Form," *Food and Drug Law Journal* 50 (1995), 179-196.

was endorsed by fifty-six groups, including the PMA, because the provisions of the Act would open the international market for the exported drugs.⁵⁵

Historically, the PMA has played a significant role in determining the American IPR agenda. Recently, the PMA changed its name to the Pharmaceutical Research and Manufacturers Association (PhRMA). PhRMA continues to lobby the American government through the publication of industry position papers, participation in government consultations, and political contributions. In the 2000 election cycle, PhRMA contributed US\$455,082 to support political campaigns, with 92 per cent of the contributions made to Republican candidates.⁵⁶ By the 2002 election cycle, PhRMA became the top contributor within the industry, spending US\$3,044,487, with 95 per cent of the contributions made to Republican candidates.⁵⁷

Yet another form of influence by MNCs arises from the intimate connections between representatives of the American government and experts in the pharmaceutical industry. For example, Donald Rumsfeld, the Secretary of Defence, previously worked for two American pharmaceutical companies, Gilead and G.D. Searle; Deborah Steelman, the White House Budget Director Advisor to the George W. Bush Campaign and the Chairman of the Quadrennial Advisory Council on Social Security and Medicare under President Bush Sr., was also employed by Eli Lilly and has represented Aetna, Bristol Myers Squibb, Johnson & Johnson, Pfizer, and PhRMA.⁵⁸ This revolving door between government and industry allows pharmaceutical experts to influence policy and practices within the industry, thus facilitating the entrenchment of interests of MNCs in policy.⁵⁹ The apparent lack of a similar hand-in-glove relationship between smaller domestic and generic pharmaceutical companies and the American government further supports the predominant influence of MNCs on policy.

In the United States, the Generic Pharmaceutical Association (GPhA) represents the interests of the generic pharmaceutical industry. The GPhA, consisting of 140 members, believes that brand name drugs are unnecessarily expensive and accessibility of drugs to consumers can be increased by weaker patent protection in the form of shorter patent terms, allowances for compulsory licensing, and provisions allowing for the stockpiling of generic drugs prior to patent expiration. The GPhA furthers its agenda by submitting position papers to legislative and regulatory officials, U.S. Congress, consumer organizations, academia, and trade press.⁶⁰ Expenditures on lobby efforts by the generic industry and trade groups amounted to US\$6,700,000 in 2001, significantly less than the US\$75,400,000 spent by brand name

⁵⁵ Kaplan, 179-196.

⁵⁶ Center for Responsive Politics, "Pharmaceutical/Health Products: Top Contributors 2000." Available at <http://www.opensecrets.org/industries/contrib.asp?Ind=H04&Cycle=2000> (February 10, 2003).

⁵⁷ Center for Responsive Politics, "Pharmaceutical/Health Products: Top Contributors 2002." Available at <http://www.opensecrets.org/industries/contrib.asp?Ind=H04&Cycle=2002> (February 10, 2003).

⁵⁸ The Consumer Project on Technology, "Revolving Door Between the U.S. Government and Industry: Version 2.0" (January 2002). Available at <http://www.cptech.org/ip/health/politics/revolvingdoor.html> (May 10, 2003).

⁵⁹ Worthy of note is that none of the representatives named in the study of the "revolving door" conducted by the Consumer Project on Technology "revolved" between the government and the generic manufacturers. This might be due to a selection bias on part of the Consumer Project on Technology, however.

companies and trade groups.⁶¹ The domestic nature of the industry and limited access to resources constrains the ability of the American generic industry to influence the policy agenda to an extent similar to that of brand name MNCs.

Lobby efforts of both generic and brand name pharmaceutical manufacturers are supported by patient associations, which contribute to political campaigns through Public Action Committees (PACs). Contributions by PACs with interests in the pharmaceutical industry totaled US\$6,470,267 in 2002.⁶² The propensity to support political campaigns by PACs should not be linked solely to interests in IPRs, however. The contributions are made in the interest of a large number of complex policy issues and are representative of the general stance of major industry players.

Unlike the American PhRMA, the Canadian association representing the interests of the brand name industry – Research Based Pharmaceutical Companies (Rx&D)⁶³ – is composed primarily of foreign MNCs. Rx&D's lobby efforts include consultations with various political stakeholder groups, direct contributions to political campaigns, and personal contact with government representatives. Canadian lobby efforts through campaign contributions have traditionally been less substantial than those in the U.S.⁶⁴ As one industry representative aptly commented, however, both generic and brand name pharmaceutical manufacturers have mastered “the art of political seduction.”⁶⁵

Brand name pharmaceutical companies in Canada, particularly branches of MNCs headquartered in the United States, have historically demonstrated significant lobbying power. A defeat of domestic interests to foreign interests within the industry manifested itself in the mid-1980's with the nearly simultaneous release of a report by Dr. H.C. Eastman, Chief Commissioner to the Commission of Inquiry on the Pharmaceutical Industry, and the tabling of an agenda presented by Prime Minister Brian Mulroney. Dr. Eastman's Commission called for continued compulsory licensing provisions,⁶⁶ as well as market exclusivity grants to the inventor, higher royalty rates, and payment of some R&D expenditures by generic companies.⁶⁷ Prime Minister Mulroney's agenda called for trade liberalization and equal treatment of international enterprises, transparency in IPRs, and the abolition of compulsory licenses, promoted largely by the PMAC.⁶⁸ Foreign interests prevailed and the Prime Minister's report resulted in the passing

⁶⁰ Generic Pharmaceutical Association Web Site. Available at <http://www.gphaonline.org/> (February 10, 2003).

⁶¹ Public Citizen, “Brand Name Drug Companies Versus Generics: Lobbying and Campaign Contributions.” Available at <http://www.citizen.org/documents/brandper cent20vpsper cent20generic.pdf> (February 12, 2003).

⁶² Public Citizen, “Brand Name Drug Companies Versus Generics.”

⁶³ Formerly known as the Pharmaceutical Manufacturers Association of Canada (PMAC).

⁶⁴ Confidential interview with former Canadian government official (January 15, 2003).

⁶⁵ Confidential interview with former Canadian government official (January 15, 2003).

⁶⁶ Originally offered by the Act to Amend the Patent Act, the Trade Marks Act, and the Food and Drug Act (Bill C-102), passed on September 23, 1968.

⁶⁷ Eric Wolfhard, *The Mote in GATT's Eye: Intellectual Property Rights and International Trade in the Uruguay Round* (Toronto: Ontario Centre for International Business, 1990), 83.

⁶⁸ Wolfhard, 83.

of Bill C-22 in 1987 and Bill C-91 in 1993, both of which reflected American IPR demands eventually embodied in TRIPS and Chapter 17 of NAFTA.⁶⁹

To appease the outcry of the generic manufacturers, Bill C-22 created the Patented Medicines Review Board (PMPRB), which monitors price increases of pharmaceuticals to ensure that they do not increase dramatically; acts as a quasi-judicial tribunal to remedy excessive pricing practices; and reports patterns in R&D and pharmaceutical pricing.⁷⁰ PMPRB's monitoring of Canadian pharmaceutical prices suggests that the prices of patented drugs have remained relatively stable between 5 per cent to 12 per cent below median international prices since 1994, increasing by only 0.1 per cent between 2000 and 2001, the latest period for which data is available.⁷¹ The contribution of the PMPRB to the stability of drug prices in Canada cannot be disengaged from other factors that may contribute to price stability, including the expiration of over 200 drug patents in the 1990's that encouraged the sale of less expensive generic drugs, thus driving down the average prices of drugs. While generic manufacturers viewed the role of controlling prices by the PMPRB as a success, the provisions of Bill C-91 mitigated the ebullience of the generics. Bill C-91 limited the use of compulsory licenses and was declared a victory by the MNCs, which were the primary benefactors of limits on compulsory licensing.

The Canadian generic pharmaceutical manufacturers are significantly more vocal and, indeed, more effective in affecting the policy agenda than their American counterparts. According to industry officials, lobby efforts of the Canadian Generic Pharmaceutical Association (CGPA) take the same forms as those of Rx&D, including consultations with stakeholders, direct contributions to political campaigns, and personal contact with government representatives.⁷² Several sources have noted the significance of the CGPA in influencing policy as an organized, coherent unity. GPhA, on the other hand, is unable to wield significant influence because of its small size in relation to PhRMA and its less unified structure of management than that of the CGPA.⁷³ The significant influence of the CGPA on the Canadian industry might also arise from the CGPA's lengthier existence, as well as from Canada's significantly different policy environment.⁷⁴

Mexico shares with Canada a historically strong lobby against strengthened patenting provisions. With a strong national presence and domestic interests, Mexican pharmaceutical trade associations have been the most active opponents of patent law amendments. The Pharmaceutical Industry Chamber (CANIFARMA, composed of 20 per cent foreign manufacturers), ALIFAR, and FAQUIFARMEX were particularly forceful in voicing their

⁶⁹ Wayne D. Critchley, "Drug Patents and Drug Prices: The Role of the PMPRB," Notes for an Address at the Patented Medicines Prices Review Board to Drug Patents Conference (Toronto, March 4, 2002), 3.

⁷⁰ Critchley, 3.

⁷¹ Patented Medicines Review Board, *Annual Report 2001* (June 20, 2002). Available at http://www.pmprb-cepmb.gc.ca/englis/report2001_1.asp (March 15, 2003).

⁷² Confidential interview with Canadian industry representative (January 31, 2003).

⁷³ Confidential interview with Canadian industry representative (January 31, 2003).

⁷⁴ Confidential interview with Canadian industry representative (January 31, 2003).

opposition.⁷⁵ Gradually, the lobby groups contesting the patent amendments realized that the Mexican administration was determined to alter the patent laws to secure an influx of foreign investment for R&D, and that the administration would not be swayed by the efforts of lobby groups.⁷⁶ Domestic forces gradually acquiesced their opposition to reform, entrenching foreign interests in policies under the guidance of a new generation of technocratic government officials who successfully pursued drastic reforms to patent laws. The reformed patent laws significantly affected the composition of the pharmaceutical industry in Mexico.

The lobby efforts of the pharmaceutical industries in the United States, Canada, and Mexico are distinct and not formally coordinated across international borders. While American interests filter through the U.S. borders to Canada and Mexico via subsidiaries, these subsidiaries must act within the domestic frameworks of the countries in which the subsidiaries operate. Thus, although the practices and interests of American MNCs can influence governments from within the nation, there exist constraints upon these actors arising from national circumstances and conditions within distinct domestic industries. Despite NAFTA and TRIPS, there exists no formal means for MNCs to influence national IPR policy. Thus, actors frequently resort to pressure tactics to promote change.

4.2 Negotiating NAFTA and TRIPS

The strength of American representatives and the vested interests of the pharmaceutical industry representatives in the IPR negotiations of NAFTA and TRIPS resulted in intense lobby efforts by American pharmaceutical MNCs and a disproportionate representation of American interests within the IPR provisions of both agreements.⁷⁷ Both TRIPS and NAFTA's Chapter 17 resulted in a de jure formalization of the gradual strengthening of IPR protection affecting the pharmaceutical industries of both Canada and Mexico to satisfy the demands of American companies.

In both Canada and the United States, associations of brand name pharmaceutical manufacturers influenced the agenda of the negotiations of Chapter 17 of NAFTA. This contribution by private actors to government negotiations was rooted in the 1987 American President's Commission in Industrial Competitiveness, which brought together representatives from the American business community to formally recognize the connection between trade and

⁷⁵ Gwynn, 170.

⁷⁶ Gwynn, 239.

⁷⁷ See Philippe Bennett, "TRIPS – A Victory for U.S. Industry," *Patent World* 62 (1994), 31; Peggy E. Chaudhry and Michael G. Walsh, "International Property Rights: Changing Levels of Protection Under GATT, NAFTA, and the EU," *Columbia Journal of World Business* 30, no. 2 (Summer 1995), 80-93; John Gero and Kathleen Lannan, "Trade and Innovation: Unilateralism v. Multilateralism," *Canada-United States Law Journal* 21, no. 81 (1995), 86; Wolfhard, Eric, *The Mote in GATT's Eye: Intellectual Property Rights and International Trade in the Uruguay Round* (Toronto: Ontario Centre for International Business, 1990), 8-9; Gadbow, R. Michael, and Rosemary E. Gwynn, "Intellectual Property Rights in the New GATT Round," in *Intellectual Property Rights: Global Consensus, Global Conflict?*, ed. R. Michael Gadbow and Timothy J. Richards (London: Westview Press, 1988), 39-67.

IPRs.⁷⁸ Prior to the Uruguay Round of GATT negotiations, twelve American MNCs active in the pharmaceutical industry formed the Intellectual Property Committee. Members of the Committee included representatives from Bristol-Myers, Dupont, Merck, and Pfizer.⁷⁹ Over one hundred firms in research-intensive industries, including the pharmaceutical industry, also formed the Intellectual Property Owners, Inc. to lobby for strengthened IPRs.⁸⁰

Even at the time of NAFTA negotiations, a close bond existed between the PMA and the United States Trade Representative, which allowed PMA to exert pressure on the USTR to ensure that strengthened intellectual property rights were at the forefront of negotiating agenda in NAFTA and TRIPS.⁸¹ The efforts of the brand name pharmaceutical manufacturers were bolstered by claims that piracy of intellectual property abroad contributed to an estimated loss of US\$4 billion in 1991.⁸² Once American business organizations established the support of the American government, the business organizations ascertained connections with foreign business associations to garner foreign support for international IPR standards. In fact, PMAC pledged between CND\$200 million and CND\$400 million in research and development spending in exchange for the Canadian government's compliance with Chapter 17.⁸³ Although the CDMA mounted a campaign against Chapter 17 and the elimination of compulsory licensing, the CDMA was unsuccessful in changing the policy agenda.⁸⁴ There was no documented resistance to Chapter 17 by the American generic manufacturers. The asymmetric nature of the negotiations, with significant influence by American brand name manufacturers, was far from ideal in establishing a trilateral agreement and exemplified the continued "hub-and-spoke" approach to policy formation in the pharmaceutical industry.

Under American pressure, including the aforementioned pressure exerted on Mexico by the USTR, Mexico made significant concessions to ensure its inclusion in NAFTA. Most significantly, the Mexican government wanted to protect the domestic pharmaceutical industry by not allowing Canadian and American companies to bid for pharmaceutical contracts with the Mexican government. The final agreement granted Mexico an eight-year period after the implementation of NAFTA when Canadian and American companies could not bid for contracts.⁸⁵ Furthermore, Mexico wanted a 15-year phasing-in period for Chapter 17 provisions, but was

⁷⁸ R. Michael Gadbow and Rosemary E. Gwynn, "Intellectual Property Rights in the New GATT Round," in *Intellectual Property Rights: Global Consensus, Global Conflict?*, ed. R. Michael Gadbow and Timothy J. Richards (London: Westview Press, 1988), 39.

⁷⁹ Helena Stalson, *Intellectual Property Rights and U.S. Competitiveness in Trade* (Washington, D.C.: The National Planning Association, 1987), 37.

⁸⁰ Stalson, 38.

⁸¹ Confidential interview with Canadian academic (March 13, 2003).

⁸² Peggy E. Chaudhry and Michael G. Walsh, "International Property Rights;" John Gero and Kathleen Lannan, "Trade and Innovation."

⁸³ Abraham Rotstein, "Intellectual Property and the Canada-U.S. Free Trade Agreement: The Case of Pharmaceuticals," in *Intellectual Property Rights*, ed. K.R.G. Nair and Ashok Kumar (New Delhi: Allied Publishers Ltd., 1994), 230.

⁸⁴ Rotstein, 230.

⁸⁵ M.A. Valencia, "Tratado de Libre Comercio Mexico, Estados Unidos y Canada – Posicion del Sector Farmaceutico" (CANIFARMA, 1993).

granted a ten-year schedule for compliance with the standards.⁸⁶ Having agreed to these standards, Mexico then consented to the provisions of TRIPS, which called for IPR standards similar to those of NAFTA.

The efforts of the Mexican government to liberalize trade and strengthen IPRs were supported by the Consejo Empresarial Mexicano para Asuntos Internacionales (CEMAI), an umbrella association of private Mexican businessmen and industrial chambers involved in international trade and the Mexican Pharmaceutical Industry Association (AMIF), representing forty-eight pharmaceutical MNCs.⁸⁷ Since MNCs were bearing the brunt of R&D costs without guaranteed IP protection, the MNCs sought an opportunity to secure compensation for their contribution to the industry, thus encouraging Mexico to participate in TRIPS and Chapter 17 of NAFTA.

American interests similarly dominated the negotiations of the TRIPS agreement. Stagnated TRIPS negotiations prompted Mr. Arthur Dunkel, the Director General of GATT, to offer a comprehensive overview of the TRIPS provisions in the Dunkel Draft, presented on December 20, 1991.⁸⁸ The framework was accepted by the United States, Europe, Japan, and Canada without contention because the provisions of the framework were compatible with the general trend of economic liberalization in these countries and since most domestic IPR systems in these countries already conformed to the specifications outlined in the Draft.⁸⁹ One industry expert calls the TRIPS negotiations “an asymmetric, non-transparent and autocratic process.”⁹⁰ Determining the extent of the expert’s claim is difficult because no record of TRIPS negotiations exists. Keeping records of negotiations was against the general practices within the GATT, thus obscuring the demands and concessions made during the GATT discussions.⁹¹ A number of industry experts, including those present at the TRIPS negotiations, attested that representatives of brand name pharmaceutical companies were “everywhere, even in negotiators’ hotels at night after the day of negotiations had concluded.”⁹² Trade lawyers recruited by large companies were also quite active in the negotiations. At the conclusion of the negotiations, TRIPS reflected clearly the demands of these lobbyists, calling for strengthened IPR protection among signatories.

4.3 The Failure of NAFTA and the Success of the WTO Dispute Settlement Body

Despite reflecting the interests of pharmaceutical MNCs, TRIPS and NAFTA do not offer MNCs a direct venue for articulating grievances about the practices of the governments and

⁸⁶ M.A. Valencia, “Tratado de Libre Comercio.”

⁸⁷ Gwynn, 243.

⁸⁸ K.R.G. Nair and Ashok Kumar, eds., *Intellectual Property Rights* (New Delhi: Allied Publishers Ltd., 1994), 10.

⁸⁹ Some less developed countries – India in particular – raised objections to the Dunkel Draft, but these concerns were mitigated by promises that less developed countries would be granted an extended period of time, recently extended from 2005 to 2016, to conform to the provisions of TRIPS.

⁹⁰ The South Centre, “Trade-Related Intellectual Property Rights: A New Regime,” *The TRIPS Agreement: A Guide for the South, The Uruguay Round Agreement on Trade-Related Intellectual Property Rights*. Available at <http://www.southcentre.org/publications/TRIPS/TRIPSmaintexttrans-01.htm> (March 10, 2003).

⁹¹ The South Centre, “Trade-Related Intellectual Property Rights.”

industries in other countries. Although NAFTA offers means of retaliation for non-compliance to IPR standards – namely through Chapter 11 (for investor-state disputes) and Chapter 20 (for disputes between states) – the USTR and PhRMA are reluctant to use NAFTA as a forum for addressing IPR disputes because there exists a “delicate balance of trade issues” that must be preserved; thus, governments prefer not to use NAFTA as a venue for addressing IPR concerns because TRIPS offers an enforceable venue for ensuing compliance to basic IPR standards.⁹³ Private actors in the pharmaceutical industry realize that they, in turn, are also in a delicately balanced relationship with their respective national governments and also refrain from using NAFTA as a venue for addressing IPR concerns for fear that their lobby efforts of the government may be compromised if trade issues of interest to the government are disturbed. Thus, NAFTA has been deemed a “dead venue” with regard to IPRs because NAFTA remains insufficiently institutionalized; does not offer a truly effective and reliable mechanism for the settlement of disputes and enforcement of its provisions, either by governments or private actors in the pharmaceutical industry; and is almost identical to TRIPS, which holds signatories accountable for their non-compliance with the agreement under the auspices of the WTO dispute settlement body.⁹⁴

Two cases that have been brought before the WTO have alleged that the Canadian government has failed to comply with the TRIPS agreement. In 1998, the European Union challenged Bolar provisions found in the Canadian Patent Act, stating that Bolar provisions were not fully compatible with Canada’s trade obligations under TRIPS. Bolar provisions allow generic manufacturers to engage in R&D and apply for regulatory approval prior to the expiration of the patent term. The WTO ruled, however, that Bolar provisions are fully compliant with Canada’s obligations to TRIPS.

In May 2000, the United States issued a complaint under the aegis of the WTO alleging that Canada’s Patent Act provided only 17 years of patent protection from the date of patent grant for patents issued before October 1, 1989.⁹⁵ This time, the WTO Panel ruled against Canada, finding Canadian practices inconsistent with Canada’s commitment to TRIPS, which provides 20 years of patent protection from the date of filing.⁹⁶ Canada appealed the ruling, but the WTO Appellate Body confirmed the findings of the Panel and Canada was given ten months to comply

⁹² Confidential interview with former Canadian government official (February 12, 2003).

⁹³ Confidential interview with Canadian representative of the brand name pharmaceutical industry (February 20, 2003); confidential interview with Canadian academic (March 18, 2003); confidential interview with Latin American academic (March 25, 2003); Confidential telephone interview with American lawyer (April 10, 2003); confidential telephone interview with American lobbyist for the generic pharmaceutical industry (April 10, 2003); confidential telephone interview with Canadian representative of the brand name manufacturers (April 30, 2003).

⁹⁴ Confidential interview with former Canadian government official (February 3, 2003); confidential interview with representative of the Canadian generic manufacturers industry (January 31, 2003); confidential telephone interview with American academic (April 15, 2003); confidential telephone interview with American academic (May 7, 2003); confidential telephone interview with American lawyer (May 7, 2003).

⁹⁵ Canadian Generic Pharmaceutical Association, “The Impact of the World Trade Organization (WTO) Rulings on Canada’s Prescription Drug Costs.” Available at http://www.cdma-acfpp.org/en/issues_international/wto.html (February 18, 2003).

⁹⁶ Canadian Generic Pharmaceutical Association, “The Impact of the World Trade Organization.”

with the Appellate Body decision. In response to the WTO ruling, the Government of Canada passed Bill S-17 (An Act to Amend the Patent Act) in June 2001 to ensure compliance with TRIPS.⁹⁷

The second complaint at the WTO was issued by the American government against Canada under pressure from Pfizer and Bristol-Myers Squibb, which were facing patent expiration on two medicines patented in Canada.⁹⁸ The amendment made to the Canadian patent protection term would extend the companies' monopoly on the marketing and sale of these drugs. Following Canada's appeal of the ruling, the Pfizer patent expired, but Bristol-Myers Squibb continued its intensive lobby efforts to convince the Canadian government to comply with the WTO ruling.⁹⁹ The interests of these corporations succeeded in effecting change in both Canadian policy and practice, exemplifying the (informal) influence of MNCs on policy agendas across borders, as well as a lack of government dialogue within the frameworks delineated by international agreements concerning IPRs. Instead, the WTO decision represented top-down influence by the U.S. on Canadian policy, made necessary by the lack of policy dialogue and policy coordination under the aegis of international agreements.

The lack of government cooperation between the United States, Canada, and Mexico with regard to IPRs stems from very different health care markets prevalent in each of the three countries; a "one-size-fits-all" solution would not satisfy everyone and no one is willing to compromise interests related to the health of citizens in favor of what may be perceived as commercial interests. The conflicting concerns of various stakeholders prevent direct cooperation vis-à-vis government negotiations. Furthermore, because explicit government cooperation on issues related to IPRs and the pharmaceutical industry may be perceived as questionable political strategy within the context of domestic health care and other social policies, NAFTA and TRIPS failed to promote government dialogue in the establishment of similar policies. This lack of coordination between the objectives and policies of the American, Canadian, and Mexican governments yields little support to the existence of continental governance in North America.

5.0 Modeling the North American Pharmaceutical Industry: The Hub-and-Spoke Approach

Since there exists little cross-border dialogue between the American, Canadian, and Mexican governments on the topic of IPR coordination, MNCs resort to pressure tactics to ensure their interests appear on the domestic and continental policy agenda. The market clout and reach of American MNCs provides the MNCs more opportunities to exert pressure on the Canadian and Mexican pharmaceutical industries through subsidiaries, via intrafirm investments in subsidiaries and lobbying the American government to pressure the Canadian and Mexican

⁹⁷ Canadian Generic Pharmaceutical Association, "The Impact of the World Trade Organization."

⁹⁸ Jacqueline D. Krokorian, "Planes, Magazines, & Automobiles, The Impact of WTO Decisions on Canadian Law & Policy, 1995-2002," Working Paper, University of Toronto (September 18, 2002).

⁹⁹ Krokorian.

governments for change. Such pressure tactics contribute to the construction of the hub-and-spoke relationship between MNCs in the United States and Canada, and the United States and Mexico. As implied by the hub-and-spoke model, any influence and dialogue within the industry on the North American continent is bilateral, largely devoid of a relationship between Canada and Mexico.

5.1 R&D Expenditures and Investment

One method used by American MNCs to entice Canadian and Mexican subsidiaries to endorse American interests is to the allocation of R&D expenditures. MNCs determine the location of parent and branch plants according to relative advantages of particular countries in specific activities. These advantages include resource abundance, liberal government policies, and a favourable institutional environment.¹⁰⁰ According to industry sources, decisions pertaining to the location of pharmaceutical subsidiaries are significant for a number of reasons, particularly economic and political, including the profit motive associated with strong IPR protection that allows companies to recoup the costs of R&D.¹⁰¹ Thus, both Canada and Mexico were encouraged to strengthen their IPRs under NAFTA and TRIPS to attract R&D expenditures.

An industry expert and former Canadian official present during NAFTA negotiations mentioned that the concessions that Canada made with regard to IPR protection, including the abolishment of compulsory licensing, were made in exchange for investment in R&D in Quebec.¹⁰² According to yet another industry source, however, Quebec's separatist government compromised Canada's bargaining power.¹⁰³ A review of the annual reports of major pharmaceutical manufacturers in Canada indeed indicates that R&D expenditures by Canadian subsidiaries have increased since 1994. Industry sources warn, however, that the increases may over represent the value of R&D expenditures for two reasons: (1) the inclusion of taxation benefits, transnational tax shelters, government subsidies, and cooperation of corporations with national research facilities and other corporations may inflate the value of reported R&D expenditures; and (2) the tendency of MNCs to decentralize their operations and their R&D may contribute to the increased level of R&D in foreign pharmaceutical manufacturer subsidiaries in Canada.¹⁰⁴

Mexican increases in R&D that have occurred since the implementation of NAFTA must be taken with a grain of salt and cannot be accepted without a consideration of the broader implications of shifting from dependence on domestic influence on the pharmaceutical market to

¹⁰⁰ J.H. Dunning, *Multinational Enterprise and the Global Corporation* (New York: Addison Wesley, 1993), 5.

¹⁰¹ Beyond favourable IPR protection, a propitious tax environment (including one that offers tax relief for R&D expenditures) determines the location of manufacturing facilities of MNCs. Canada has particularly favourable tax conditions for R&D activities, effectively decreasing the cost of R&D by 60 per cent, irrespective of exchange rates. Mexican tax breaks for R&D are approximately 30 per cent, while American tax breaks for R&D are only 20 per cent the value of R&D expenditures.

¹⁰² Confidential interview with former Canadian government official (February 12, 2003).

¹⁰³ Confidential interview with former Canadian government official (January 15, 2003).

¹⁰⁴ Bohumir Pazderka, "Patent Protection and Pharmaceutical R&D Spending in Canada," *Canadian Public Policy* 25, no. 1 (1999), 31.

foreign industry. Furthermore, industry experts assert that it is still too soon to evaluate the impact of the IPR regime introduced by NAFTA and TRIPS because the new IPR provisions were introduced relatively recently and have not yet had a chance to affect the pharmaceutical industry significantly. Increases in R&D expenditures in Mexico cannot be attributed to any specific phenomenon because of administrative obstacles and inaccessibility of data, including the tendency of MNCs in Mexico to aggregate activity reports from all countries in a single figure. Interviews with key experts indicate that the lack of significant R&D activity in the Mexican pharmaceutical industry is the result of policies that continue to favour government procurement of unpatented drugs and the lack of established institutions for the enforcement of IPRs.¹⁰⁵

Beyond R&D expenditures, the Canadian and Mexican pharmaceutical industries rely upon large amounts of foreign direct investment, especially from American firms. In research-intensive industries, import substitution and technology transfer encourages the use of technologies developed in foreign countries and acts as a disincentive to domestic R&D. Apart from delaying scientific and technological progress, foreign direct investment might be problematic because it increases the involvement of foreigners in the industry and provides foreign actors with the ability to make decisions pertaining to research agendas and management.

5.2 The Threat of the USTR

Apart from influence exerted directly by players within the industry, the American government also plays a significant role at the hub of the hub-and-spoke relationship of the North American pharmaceutical industry. Under the “Super” Section 301 of the Trade and Competitiveness Act of 1988, the USTR has the right to investigate countries that have “a history of violating existing laws and agreements dealing with intellectual property rights.”¹⁰⁶ In 2003, the USTR retains Canada on its Watch List under Super 301, alleging that Canada does not provide “effective data exclusivity protection, and systematic inadequacies in Canadian administrative and judicial procedures allow entry of infringing generic versions of patented medicines into the marketplace.”¹⁰⁷ Data exclusivity protects the original patentee of a drug from releasing information about the process used to produce the drug prior for a predetermined length of time after the drug’s release on the market. The United States offers data protection to pharmaceutical manufacturers, although no such protection is guaranteed by either NAFTA’s Chapter 17 or TRIPS. The USTR also alleges that since the year 2000 “Canada’s border measures have been the target of severe criticism by IP owners, who consider Canada’s border enforcement measures to be inconsistent with its TRIPS obligations.”¹⁰⁸ Industry sources

¹⁰⁵ Ruby Gonsen and Javier Jasso, “La Industria Farmaceutica y el Sistema de innovacion sectorial” (Febrero 2000). Available at http://www.nafin.com/portal/02info/indicadores/pdf/pdf/mv_2000/febrero/MV-FE00.pdf (January 20, 2003).

¹⁰⁶ J.M. Destler, “American Trade Politics” (Washington, D.C.: Institute for International Economics, 1995), 318.

¹⁰⁷ United States Trade Representative, *2003 Special 301 Report: Watch List*. Available at <http://www.ustr.gov/reports/2003/special301-wl.htm#canada> (May 15, 2003).

¹⁰⁸ United States Trade Representative, *2003 Special 301 Report: Watch List*.

indicate that although the presence of Canada on the Watch List will not provoke legal action against Canadian companies, designation by the Watch List does 'warn' potential investors of the 'dangers' of investing in Canadian industries that require data protection, such as the pharmaceutical industry.¹⁰⁹ Therefore, the USTR Watch List provides a covert method of influencing national policy agendas by threatening to endanger investment in the listed country.

Although initial attempts to liberalize the Mexican economy were the result of internal pressures, the pressures to implement stronger IPRs gradually mounted outside of Mexico as the United States sought to ensure that major trade partners conformed to the provisions of the newly negotiated TRIPS. The United States was the source of two-thirds of direct foreign investment in Mexico and Mexican authorities realized that liberalization of trade would further solidify the relationship and increase American investment in Mexico.¹¹⁰ Thus, in the late 1980's under pressure exerted by Mexico's placement on the USTR's "priority watch" list under Special 301, Mexico rapidly overhauled its IPR system.¹¹¹

Between 1999 and 2003, Mexico was removed from the USTR Watch List. In 2003, the United States decided to place Mexico on its Watch List once again, citing concerns about the lack of coordination between Mexican health officials and the Mexican Institute of Industrial Policy (IMPI).¹¹² The USTR responded to complaints by American MNCs that the Government of Mexico allowed Mexican companies to market copies of American drugs without regard to Mexican patents granted to MNCs.¹¹³ The USTR has mentioned that repercussions for Mexico's failure to comply to American demands may call for American retaliation using the mechanisms of TRIPS and NAFTA. Mexican officials allege that the claims of the USTR are the result of influence of MNCs on the American government; indeed, an official from the Federal Commission for the Protection against Health Risks (Comision Federal para la Proteccion Contra Riesgos Sanitarios) declares that the claims of the USTR are false and representative of American commercial interests.¹¹⁴

The threat of the USTR's Super 301 ominously looms over the Canadian and Mexican pharmaceutical companies, exemplifying the ability of American MNCs to influence the American government. This places the United States at the hub of the North American pharmaceutical industry, rendering the industry asymmetric and influenced to cater to the interests of the Americans, rather than to fostering a systematic formation of continental governance.

¹⁰⁹ Confidential telephone interview with American representative of the brand name industry (April 9, 2003).

¹¹⁰ United States Department of State Dispatch, "Fact Sheet: Mexico" 2, no. 38 (September 23, 1991), 713.

¹¹¹ Malcolm D. Rowat, "An Assessment of Intellectual Property Protection in LDCs from both a Legal and Economic Perspective – Case Studies of Mexico, Chile, and Argentina," *Denver Journal of International Law and Policy* 21, no. 2 (1993), 414-415.

¹¹² United States Trade Representative, *2003 Special 301 Report: Watch List*.

¹¹³ United States Trade Representative, *2003 Special 301 Report: Watch List*.

¹¹⁴ Juan Ramon Nava, Antonio Sanchez, and Daniel Millan, "Difiere diagnostico de medicina pirata," *Reforma* (May 15, 2003).

5.3 Recent Canadian and Mexican Responses to American Pressure

Both Mexican and Canadian governments have responded to American pressure, frequently conceding to the demands of the brand name pharmaceutical MNCs. Acquiescing to pressure by American MNCs and the American government further affirms the role of the Canadian and Mexican pharmaceutical industries as peripheries to the American core industry. Surprisingly, there is very limited resistance to American demands by domestic pharmaceutical industries in Canada and Mexico.

For years, American consumers seeking more affordable medicines have turned to Canada, where they could purchase pharmaceuticals at significantly lower prices than in the United States. The rise of the Internet provided a new venue for purchasing inexpensive drugs from Canada. American consumers can log on to a “pharmacy” web site in Canada and order drugs to be shipped to the United States at Canadian prices. Therefore, the American consumer benefits from the lower prices of Canadian drugs, as well as the price differential arising from the prevailing exchange rate.

American sources revealed great agitation with the Canadian government for its complacency about Internet pharmacies. GlaxoSmithKline Inc. (GSK) has been particularly ardent in attempting to curtail the export of drugs from Canada to the United States through Internet pharmacies. On March 21, 2003, the Competition Bureau permitted GSK to stop supplying Canadian Internet pharmacies with medicines.¹¹⁵ GSK stated concerns for sufficient drug supplies for Canadian customers and safety concerns about importing potentially untested drugs by American consumers as the rudimentary reasons for its appeal to the Competition Bureau.¹¹⁶ The Competition Bureau’s decision demonstrates that the interests of the MNCs result in the legitimization of these interests through government endorsement.

In Mexico, the United States has recently expressed discontent the proliferation of “copycat” drugs that are similar to specific brand name and generic medications, but have not been tested for bioequivalency. This is a problem prevalent in many less developed countries. Under the demands of the Americans – including pressure from both American MNCs and the USTR – the Mexican government is encouraging the generic industry to expand, hoping to replace “copycat” drugs in the public domain with bioequivalent, lower-cost alternatives to brand name drugs.¹¹⁷

The above examples illustrate the complacency of Canadian and Mexican governments and the lacuna in the interest of domestic pharmaceutical industries in changing the existing conditions. Therefore, the American MNCs and government cannot be blamed for their dominance within the industry, because the absence of domestic outcry – whether due to

¹¹⁵ GlaxoSmithKline Press Release, “GlaxoSmithKline Welcomes Competition Bureau Decision” (March 21, 2003). Available at http://corp.gsk.com/press_archive/press2003/press_03212003.htm (May 10, 2003).

¹¹⁶ “Cross Border Sales of Canadian Drugs in United States Brings Drug-Maker Ire,” *BioProcess International*, March 2003, 14.

¹¹⁷ Confidential telephone interview with former American government official (April 10, 2003).

restricted capacities or lack of interest – also contributes to the hub-and-spoke relationship within the North American pharmaceutical industry.

6.0 Implications of Findings for Continental Governance in North America

The findings presented above suggests that there is a significant amount of influence by American MNCs on the practices and IPR policies in the United States, Canada, and Mexico, although TRIPS and Chapter 17 of NAFTA have failed to effectively formalize this influence. Thus, it is difficult to conclude that there exists continental governance in the North American pharmaceutical industry. Reaching this conclusion yields the question of whether the North American pharmaceutical industry exhibits signs of continentalism. Working with the traditional understanding of continentalism – that from above or below – reveals the inadequacies of the existing model.

There are limited institutional venues that exist to affect the industry from above because decisions regarding IPR policies are made independently by the three governments, if within international frameworks. As discussed previously, NAFTA remains insufficiently institutionalized to provide governance from above, while TRIPS has not been used extensively to effect change in national policies (apart from the single U.S. – Canada case of extending the term of patent protection). Therefore, actors other than the national government can only exert influence and lobby for foreign policy change indirectly through lobbying national governments.

There exists limited evidence of inter-governmental continentalism from above, as there is no explicit coordination of government policy objectives. There exist no continental policy working groups seeking to coordinate the IPR systems and standardize practices in the pharmaceutical industry. Coercion and threats – rather than negotiation – appear to be the tools of choice to effect policy change. Under these conditions, the dialogue remains bilateral between the United States and Canada and the United States and Mexico, while the Canada and Mexico dialogue remains indiscernible. In fact, questioning experts regarding discussions between Mexico and Canada on the topic of IPRs elicits exasperated sighs and blank stares.

Searching for continentalism from below by examining activity by civil society organizations also leaves one wanting. The interests of civil society groups in each country are national, rather than continental or global, thus limiting efforts to coordinate activities.¹¹⁸ Even the Consumer Project on Technology, a unique online compendium of information about IPRs (and pharmaceuticals, among a number of different issues), does not focus its activities solely on the North American market, extending its lobby efforts to the global level while also lobbying intensively for policy change in the United States, where the organization is headquartered.

Having demonstrated that the traditional understanding of continentalism – that from above or below – is insufficient in defining the dynamics of the pharmaceutical industry and IPR

policies, a new theory may be advanced with regard to the continental forces affecting the pharmaceutical industry: market continentalism.¹¹⁹ Market continentalism is not analogous to a continental market, one in which borders cease to exist and free trade is promulgated – a vision propagated by the provisions of NAFTA and the objective of international free trade agreements. Despite the implementation of NAFTA, the continental market remains an amorphous entity; TRIPS also failed to truly unify the market to ensure that IPR provisions of Canada, the United States, and Mexico are truly interchangeable. Until the IPR, health care, and pharmaceutical approval systems are administratively uniform, and until specifications of the systems are no longer differentiated, there can be no true harmonization of IPRs and no true continental market for pharmaceuticals; determining whether or not such harmonization is desirable calls for an extensive moral, political, and economic discussion, which – unfortunately – is outside the scope of this paper.

Market continentalism is a concept that is more subtle and ephemeral in nature. It calls for an examination of market forces that are driving policy change and, more important, practices within a single industry. Since the effects of only a few policies and practices have isolated consequences, it is highly probable that the market forces driving change in one particular industry will reverberate in other (more or less) related industries, including industries connected by trade across borders. According to this particular assertion, the North American pharmaceutical industry does exhibit symptoms of market continentalism. In particular, market continentalism appears to be characterized by a dual approach by corporations: (1) use of lobby efforts of national governments to affect policy change and (2) coordination of corporate practices across borders to meet some predefined corporate objectives. Market continentalism is associated not with the removal of borders, but with attempts to influence policy and practices given the constraints of border to address the differences of the markets within separate countries. Allowing policies to be dictated by foreign actors, limiting the ability of nation states to act autonomously, is a danger that nations face when dealing with international institutions that do not lead to balanced contributions to governance in the North American pharmaceutical industry.

There is no explicit connection between market continentalism and continental governance in the pharmaceutical industry in North America. Although both concepts deal with issues of influence, market continentalism addresses influence through market clout and implies coordination among market players, while continental governance addresses influence through policy coordination among governments. Under these specifications, there is scant evidence for continental governance in the North American pharmaceutical market. NAFTA and TRIPS failed

¹¹⁸ Confidential interview with Canadian academic (March 19, 2003).

¹¹⁹ The concept of “market continentalism” as used in this paper was derived from Stephen Clarkson, “Researching a Non-Subject? North American Governance under NAFTA and after September 11th,” Woodrow Wilson International Center for Scholars “Work in Progress” (February 11, 2003).

as institutions to provide a framework for the coordination of policy objectives and approaches to IPR policy remain ad hoc, if ad hoc within the general spirit of NAFTA and TRIPS; lobby efforts and consumer interests can still sway national governments to pursue domestic policy agendas.

The lack of continental governance within the pharmaceutical industry can be viewed as a positive or a negative phenomenon – positive because a lack of continental governance suggests a certain national autonomy of governments in determining their policy agendas; negative because various undercurrents influencing national policy formation may lead to indirect influence on policy agendas by non-governmental actors. The issue of continental governance is particularly delicate in the context of IPRs, which impact not only the pharmaceutical industry, but other industries, as well, with implications for industrial organization of large sectors of the economy. Therefore, scholars and policy makers must be aware of the underlying currents within the industry that constrain the ability of governments to determine their industrial policy autonomously.

The pharmaceutical industry's global nature implies that no single issue affects only one country in isolation. In particular, under the auspices of TRIPS, the influence of the American government and lobby efforts of MNCs become global and the observable phenomenon is extended from market continentalism to market globalism. The proximity of the Canadian, American, and Mexican economies and their extensive trade relationships make the connections between the pharmaceutical industries of the three countries appear more explicit than the links within the global markets. Regardless of whether one examines the issues at the continental level or at the more extensive global level, however, the dominance of American MNCs and their attempts to influence both policies and practices of the national pharmaceutical industries remains a constant reality on both levels of analysis. Perhaps a more appropriate description – one that suits both the continental and global perspectives – for the phenomenon of attempts to standardize IPR policies and practices is “market Americanism,” by no means to be confused with “American governance.”

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