NAFTA – THE POLITICS BEHIND DRUG PRODUCTION

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Abstract

In the year 1993, the Canadian federal government ratified the North American Free Trade Agreement (NAFTA), with the ostensible purpose of improving trade relations and economic prosperity for the country. For ratification to proceed, and in response to pressure from the pharmaceutical industry, between 1987 and 1993 significant changes were made to Canada's Patent Act. Changes included the elimination of a system of compulsory licensing and the strengthening of intellectual property rights (IPRs). Compulsory licensing allows competitors to produce drugs still under patent without the consent of the patent holder, if public interest, such as a public health emergency, warrants it, thus challenges drug monopolies and leads to lower prices, whereas intellectual property rights have the opposite effect – they lengthen patent protections, thus shielding patent holders from competition and leading to higher prices.

The pharmaceutical industry strongly opposed compulsory licensing, and lobbied for strong IPRs, arguing that research and development (R&D) required for pharmaceutical innovation involved high risks and costs and that weak IPRs (weak by their standards) undermined job creation by the industry. Since then, R&D risks, in Canada and elsewhere, have all but decreased, the promised jobs are nowhere to be seen, and increasing drug prices have led to medication non-compliance on the part of a growing number of Canadians, with significant impact on the public's health.

This paper argues that to ratify NAFTA, laws were changed by the federal government to align with US IPR laws and serve the interests of transnational drug corporations, by creating an environment in which they could easily monopolize the national drug market, thus undermining the interests of the vast majority of Canadians. In so doing, the federal government has done an injustice to taxpayers, who were de facto made to subsidize unreasonable prices for Big Pharma, while the promises of increased Canadian R&D investments or job creation were never fulfilled.

I aim to answer three questions: 1) Why is drug development treated as a market good rather than a public good or service? 2) How do provisions within NAFTA, a treaty signed by representatives of the Canadian state, deal with the tension between private corporate interests and public needs? 3) What discursive mechanisms within NAFTA legitimize private intervention and drug development and production? I perform a critical discourse analysis (CDA) on relevant key provisions from Chapter 17 of NAFTA as a means of answering these questions.

Keywords: pharmaceutical policy, intellectual property rights, NAFTA

Table of Contents

Introduction

Government expenditure on pharmaceutical drugs has been rising in Canada (Collier, 2009; Kondro, 2007; Lexchin, 1993; 1997; 2005). This is true in other industrialized nations, yet significantly less so, as all of them except for the United States include a national Pharma care program which apparently reduces costs (Morgan & Boothe, 2016). As of 2015, drug expenditures are the fastest growing health care expense in Canada (Canadian Institute for Health Information, 2017a). As NAFTA was negotiated, pharmaceutical corporations involved in drug development repeatedly raised the issue of intellectual property rights (IPR). These corporations considered Canadian IPR laws weak in comparison to the legislation in the U.S due to the compulsory licensing scheme permitted under the Patent Act, a system that allowed a generic drug manufacturer to produce a brand name drug while it was still on patent. Therefore, as the Canadian state agreed to ratify NAFTA, it amended the Patent Act in Canada in 1993 to meet IPR standards proposed by the pharmaceutical industry. The most significant change made by the government was the removal of the provisions which allowed for compulsory licensing.

Compulsory licensing had been a part of the Patent Act in Canada since 1923 (Lexchin, 1993). However, its impact on drug production was not significant, as the generic drug manufacturer had to produce the drug in Canada and the Canadian drug market at the time was too small to support domestic drug manufacturing (Lexchin, 1993). Only 49 applications were submitted and 22 were granted from 1923 to 1969 (Lexchin, 1993) and it was not until 1969 when another change was made to the Patent Act which lifted the condition that these generic drugs must be made domestically. The 1969 amendment allowed for the active ingredient of a drug to be imported into Canada (rather than domestically produced). After this change, generic drug manufacturers took greater advantage of the compulsory licensing structure. From 1970 to

1978, 142 compulsory licenses were issued for 47 drugs, in other words over 6.5 times more compulsory licenses were issued in those 8 years when compared to the number compulsory licenses issued from 1923 to 1969.

During the NAFTA negotiations, compulsory licensing was deemed to be incompatible with Chapter 17, Article 1709, paragraph 10 of NAFTA. The pharmaceutical industry opposed compulsory licensing as it considered it a potential threat to the market exclusivity of their drugs (and therefore the bottom line), even if the financial loss encountered by this industry appears minimal. According to the Eastman Report (1985), the industry lost 3.1 percent of the Canadian market to generic manufacturers. In addition, net profits after taxes in the pharmaceutical industry consistently remain higher than all other Fortune 500 companies (Angell, 2004; Light & Lexchin, 2012). In addition, the pharmaceutical industry did not reduce their spending on R&D since 1969 when the compulsory licensing provisions were expanded to allow for easier approval (Guennif, 2017). These high profits notwithstanding, compulsory licensing was removed from the Patent Act in 1993 with the passing of Bill C-91. And yet, compulsory licensing was itself a mere response to what has been all along and deeper, systemic problem: this is that drug research, development and production is in for-profit hands, specifically, the hands of transnational corporations (TNCs). It is an established, legal fact that the first fiduciary responsibility of TNCs is to prioritize the interests of shareholders, i.e., to maximize the return on their investments. In contrast, crown corporations, which are government owned, can be, and are, held accountable to the public.

The federal government has also continued to provide tax credits to pharmaceutical companies to conduct research and development (R&D) in Canada. Granting tax credits as a strategy to encourage drug R&D in the Canadian market has seen mixed success. From 1993 to

2000 the industry was investing at least 10 percent of sales revenue in R&D (Lindberg, 2016). However, since 2001 there has been a steady decline in their R&D investments. Since 2013, the R&D to sales ratio has been under 5 percent, well below the 10 percent agreed upon figure by the pharmaceutical industry and federal government in return for increased IPR protection (Lexchin, 1997). Indeed, commercial production is not the only way to manufacture drugs. There exists sound research showing the plausibility and desirability of publicly-financed drug development, but only if we assume that the goal of drug development is to meet public needs. Indeed, as Dean Baker has shown, there are economic inefficiencies with the current model of drug development (Baker, 2001; 2008). Inefficiencies include capital spent on marketing new drugs, wasted research towards developing very similar drugs that are currently available. Most new drugs are variations of existing drugs (Angell, 2004). Minor variations to existing drugs that are patented as new or improved drugs are known as me-too drugs. Marcia Angell, former editor of the New England Journal of Medicine, states that there would be little financial incentive for pharmaceutical companies to invest in R&D toward the discovery of new drugs when me-too drugs receive patent protection (2004). In addition, there is little or no development of drugs to treat so-called neglected illnesses, diseases are rare enough such that the cost of R&D could not be recovered by the number of users for the drug (i.e. orphan diseases), and further, there is lack of transparency when it comes to sharing research findings with the public, or even with other researchers (Baker, 2008).

For this MRP, I will use a framework which centers on the theory of an active state. Critical political economy posits that the role of this discipline is to study the relationship between states, markets and classes. Two representatives of the school, Leo Panitch and Sam Gindin (2012), uphold this view and challenge mainstream ideas about a presumed, weak,

noninterventionist neoliberal state. As a significant body of research conducted by these two authors, as well as by Vicente Navarro, shows, in modern, capitalist states, the principles of laissez-faire and non-intervention, are rarely, if ever held in practice (Navarro, 2007; Panitch & Gindin, 2012). While state retrenchment or inaction can be observed in the funding of public services, such as social housing (Bryant, 2010; Hackworth, 2008) state intervention or action is demonstrated when creating laws to organize markets to favor business interests. As critical comparative political economy argues, there are no markets without states, and a key goal of this discipline is precisely to account for the relationship between states, markets and classes. Panitch also notes that when social relations of class within states are ignored, the pattern of determining state action or inaction is missed (Panitch, 1999). In other words, formulating a pattern is difficult if class power his left out of the analysis of the relationship between states and markets.

The state-market relationship is a field where the class struggle appears clearly regarding IPR: the legal framework for the issuance, validity and enforcement of patent laws cannot possibly happen without the involvement of the federal government. IPR provisions in NAFTA reinforce and allow the state to reproduce conditions that favor the reproduction of drugs with little additional benefit (me too drugs for instance), to the expense of medically useful pharmaceuticals. Therefore, I draw from theoretical lenses that posit that the state is actively responsible for creating the conditions that incentivize the creation of me-too drugs, and the lengthening of patent protection that harm public interests, as they lead to increasing drug prices (Lexchin, 2007; Light & Lexchin, 2012). The state uses multiple mechanisms to aid with the continuation of this status quo: in the case relevant to this MRP, IPR protection of the products of industry, R&D tax credits, and the privatization of drug development are merely three ways in which the Canadian state reproduces this status quo.

Statement of Problem

The purpose of this paper is to examine the consequences of the Canadian state ratification of NAFTA and the modifications concerning compulsory licensing that the Canadian state agreed to implement. Consequences include: 1) high drug prices; 2) broken R&D promises; and, most importantly, 3) the exclusion of legitimate alternatives, i.e., public funding of drug development. The tightening of IPR laws was lobbied for by the industry. Granted, it was drug companies that insisted on the modifications, by demanding the inclusion of increased patent protections are a trade-off to invest in drug R&D in Canada. Nevertheless, it was the Canadian state, and specific governments officials, that agreed to them, as without their approval the modifications would have never been granted (Lexchin, 1997). Canadians should question the involvement of these companies in drug development, yet importantly, they should also question the behavior of the Canadian state. After all, corporations do not have a duty to act in the best interest of the public, yet governments in a democracy do, and legitimate alternatives to for-profit drug development are possible and do exist (Baker, 2008). This conundrum, i.e., that the development of pharmaceuticals, a basic health care need, is in private, for-profit hands, poses at least three key questions;

1. Why is drug development treated as a market good rather than as a public good or service?
2. How do provisions within NAFTA, a treaty signed by representatives of the Canadian state, deal with the tension between private corporate interests and public needs?
3. What are discursive mechanisms within NAFTA that legitimize private intervention and drug development and production?

Methods

In this paper, I perform a critical discourse analysis (CDA) of five key provisions in Chapter 17 of the NAFTA text. Chapter 17 outlines the intellectual property rights (IPR) thus is most relevant to the pharmaceutical sector. Articles 1705 though 1708 and 1710 through 1721 are excluded from this analysis. These articles are less relevant to the pharmaceutical industry. The articles excluded from analysis are available in Appendix A in their entirety. The CDA will be informed by the work of two scholars, Norman Fairclough (1989; 1992; 2003) and Teun van Dijk (1993; 1995). Briefly, these scholars propose that language plays a critical role in the production, maintenance and reproduction of ideologies of domination (Fairclough, 1989). For instance, Fairclough (1989) proposes that class relations are not explicitly stated or reproduced in discourse, but rather are institutionalized through discourse, and that the task of CDA is to reveal this normalization of class relations through a close examination of how discourse legitimizes, or challenges, actual practices. In turn, Van Dijk proposes that ideologies are acquired by members of a group or culture (Van Dijk, 1995). Ideologies are the representation of social characteristics of a group such as identity, norms and values. As it applies to my investigation, when analyzing trade agreements, it is important to consider the benefits of these agreements as trade will continue to occur. In Canada, where high prices are a key reason why patients do not comply with medical recommendations (Law, Cheng, Dhalla, Heard, & Morgan, 2012), we should question whether stronger IPR legislation benefits the public or rather serves the purpose of maintaining market exclusivity, i.e., protects the most powerful pharmaceutical corporations from competitors. My theoretical framework and methods are useful to understand these issues because key provisions in so-called “free trade agreements”

may have little to do with trade or freedom and much to do with benefiting only some members of society. In this MRP I argue that IPR are merely one such provision.

Data

The CDA relies on an analysis of 5 key provisions in Chapter 17 of NAFTA. This section is labelled as intellectual property and is the most relevant section on the pharmaceutical industry. The provisions which are analyzed are Articles 1701, 1702, 1703, 1704 and 1709. These articles are most relevant to the pharmaceutical sector. The full text of the NAFTA agreement is transcribed, along with a textual analysis guided by the approach of two scholars in CDA studies, Norman Fairclough and Teun van Dijk. The full text of the NAFTA agreement is available on the Government of Canada website through Global Affairs Canada. The NAFTA text itself is the primary source of data for this analysis. Historical data from the Patented Medicines Prices Review Board (PMRPB), the Canadian Institute for Health Information (CIHI) and other academics have also been used in this paper to investigate the impact on the pharmaceutical industry in Canada since the ratification of NAFTA.

Theoretical Considerations

The CDA is informed by the theoretical lens of an active state. The theory posits that the government is not a neoliberal, non-interventionist entity, but rather the state is actively involved in facilitating the ratification of NAFTA. Panitch and Gindin (2012), two holders of this view, note a clear example of where legal firms had acted as a liaison with both Wall Street and the government. Furthermore, these corporations had even collaborated with the government to draft policies to build governance and capital structures (Panitch & Gindin, 2012). With IPR, the Canadian Intellectual Property Office (CIPO) is responsible for the issuance of patents. Along with the Patent Act, both the agency and legal system for patent issuance are handled by the federal government. Moreover, foreign policy and trade are also handled through the federal

government. The federal government is responsible for negotiating on trade agreements, such as NAFTA, but also is responsible for implementing changes to federal laws to ratify such agreements. While the pharmaceutical industry benefits greatly from patent protection as a form of market exclusivity, I propose that the federal government is the "active state". For NAFTA to be ratified, it was the federal government, not the pharmaceutical industry, which has the legal power and jurisdiction to amend the Patent Act and introduce Bills C-22 and C-91 to ratify NAFTA. Therefore, I argue that the increase in IPR protection is has not been caused solely by the demands of the industry, but also from the intervention of the Canadian state.

History of Compulsory Licensing

Drugs are the fastest growing health care expense in Canada. Drug expenditure growth has exceeded that of hospitals and physicians in 2015 (Canadian Institute for Health Information, 2017a). Compared to other industrialized nations with universal health coverage, drug expenditure costs in Canada have risen at a faster rate. The main difference is that Canada currently does not have a national pharmacare program. A universal pharmacare program has advantages such as lowering government expenditure on drugs, improved access to essential medicines and lower hospitalization rates (Law, Cheng, Dhalla, Heard, & Morgan, 2012; Morgan, Law, Daw, Abraham, & Martin, 2015; Morgan, Li, Yau, & Persaud, 2017). For instance, a comparison conducted by Morgan et al. (2007) on Canadian (British Columbia as reference) and New Zealand drug prices suggests there would be significant savings with a national formulary (one method of managing a national pharmacare program). New Zealand utilizes a national formulary which is a list of drugs that the government covers for citizens under their pharmaceutical plan. The savings on drug expenditure of the four largest drug classes would range from 21 percent to 79 percent (Morgan, Hanley, Mcmahon, & Barer, 2007). New

Zealand can also negotiate rebates from the manufacture and purchase drugs in bulk as a single payer to negotiate lower prices (Morgan, Hanley, Mcmahon, & Barer, 2007).

In addition, several studies have concluded that price control mechanisms, such as compulsory licensing, have allowed for drug expenditures to be lower than without these policies (Lexchin, 1997; 2005; 2007; Kuek, Phillips, & Kohler, 2011). While Canada does not have a national pharmacare plan, compulsory licensing allowed for drug expenditures to be lowered. Lexchin (1997) reports that compulsory licensing did save at least 211 million dollars in drug expenditure costs. Generic drug competition typically reduces the cost of a drug by about 25 percent when the generic enters the market. When there are four or five companies which are producing the same drug, the savings are approximately 50 to 60 percent of the patented drug's price (Lexchin, 1997). While not an ideal solution compulsory licensing did, to an extent, bring drug prices lower than if these policies had not been enacted.

While some scholars have indicated that IPR laws can be beneficial, the reason why patent protection exists should also be examined. According to the Canadian Intellectual Property Office (CIPO),

> "…patents protect investments and allow inventors to profit financially from their creativity. This gives an attractive incentive for research and development, which ultimately benefits all Canadians. Without the possibility of patent protection, many people might not take the risk of investing the time or money needed to create or perfect new products. Without such activity, our economy would suffer…"

IPR legislations, such as patents, were designed to encourage the development and disclosure of new inventions. Patents for necessary medical goods can provide alternative

incentives for multinational corporations as compared to independent inventors. There are high barriers to entry to the drug production market, the competition is restricted by IPR laws, and there is information asymmetry within the industry. Thus, this market is exceedingly difficult to enter for a new start up firm. High barriers to entry in a market can lead to what is known as a market failure in economics. Market failures are situations which arise when the allocation of goods is not efficient. In other words, there is an opportunity for changes to be made for the betterment of society. Economists Richard Caves and Michael Porter have indicated that significant barriers to entry is a market failure, which results from allocative inefficiency and socially excessive costs (Caves & Porter, 1977). According to Caves & Porter, high barriers to entry in an industry create a situation where incumbent companies earn higher profits than they ought to when compared to the benefits they provide to society. Such factors allow for ruling elites to perpetuate ideologies and class structures that allow them to maintain their social position, such as agreements like NAFTA, passed off as “economically beneficial” for “society”.

In Canada, an amendment to the Patent Act in 1923 allowed for compulsory licensing to begin (Douglas & Jutras, 2008). Generic drug manufacturers could produce drugs which were still on patent without approval from the patent holder. The generic drug manufacturer would apply for this license through the Commissioner of Patents. If granted, the patent holder would still obtain a royalty, although no legal action could be taken against the generic firm that had been granted the compulsory license.

In 1983, the Minister of Consumer and Corporate Affairs had decided that there should be a change to the 1969 amendments on the compulsory licensing scheme. In comparison to the U.S., Canada is a small market and the pharmaceutical companies were not going to increase investments in R&D in a smaller market which restrictions were placed on their market

exclusivity (i.e. compulsory licensing). As a means of increasing the attractiveness of the Canadian market to the multinationals, compulsory licensing needed to be removed. Also, in 1983, the federal government did allow for tax credits towards funds spent on R&D. However, it wasn't until 1985 when the government clarified upon the interpretation as to what R&D activities were eligible. On all R&D salaries and expenditures, the federal government allowed a 20 percent reduction in costs, furthermore provinces also had provisions set into place which also allowed for these multinationals to qualify for provincial tax credits. Essentially a drug company could invest R&D into Canada while obtaining approximately 40 percent back in the form of tax credits (taxation relief). This push from both the federal and provincial governments was a way to incentivize R&D investment in Canada.

Given the concerns from the industry, coupled with the desire to generate growth within the pharmaceutical industry in Canada, Bill C-22 was introduced in 1987. The market had a positive reaction to the passing of Bill C-22, stock market gains (increases in asset value) of 8.5 percent were observed (Shapiro & Switzer, 1993). Considering that the Canadian pharmaceutical market was no more than 2 percent of global pharmaceutical sales, this increase is significant and signaled a positive reaction from shareholders. This bill introduced significant changes to the compulsory licensing structure. A major change was the addition of a period of exclusivity for patent holders against compulsory licenses. Prior to 1987, patented drugs did not have a period of exclusivity from compulsory licenses. While this change did not eliminate compulsory licensing, it effectively nullified the clause where a patent holder could object to a compulsory license. By allowing for a period of exclusivity, it was the first step toward tighter IPR legislation. The patent holder did not have to worry about a generic drug manufacturer producing

their patented drug for a period of 7 to 10 years (Grootendorst, Bouchard, & Hollis, 2012). These changes had reduced the effectiveness of compulsory licensing system.

In 1991, Arthur Dunkel, the Director General of the General Agreement on Tariffs and Trade (GATT) had compiled a draft for the Uruguay round of GATT negotiations (also known as the Dunkel text). Within this text, Article 31 was deemed to be incompatible with Canada's (non-functional) compulsory licensing scheme. Article 1709 paragraph 10 is a nearly identical copy of Article 31 in the Dunkel text. As means of ratifying NAFTA, Canada completely abolished the compulsory licensing scheme in 1993 when Bill C-91 came into law. Due to Bills C-22 and C-91, there was an increased investment from the pharmaceutical industry (Lexchin, 1997). R&D investments increased from 6.1 percent of sales in 1988 to 11.8 percent of sales in 1995. However, this growth in R&D investment was not sustained. According to the 2015 Patented Medicine Prices Review Board (PMPRB) annual report, from 2001 to 2014, R&D to sales ratio industry wide has been under 10 percent. R&D to sales ratio from these pharmaceutical companies has never returned to the levels seen between 1993 to 1998. In 1993, Bill C-91 became law and removed the compulsory licensing scheme entirely from the statute. While pharmaceutical policy is set at both federal and provincial levels, the federal government is relatively unaffected by its own policies (Anis, 2000). The federal government sets IPR legislation, initial approval and labeling of prescription drugs, however the federal government does not purchase drugs. The provincial governments do not handle pricing of drugs or have influence over the market competitiveness and, yet they are responsible for funding all health care services, including drugs (Anis, 2000).

The Political Economy of Power

Power relations are always that of struggle (Fairclough, 1989). Social systems that require the maximization of profit and power to be achieved by furthering the exploitation of another will always contain this power struggle (Fairclough, 1989). Pharmaceutical multinationals have increased their corporate power in Canada in multiple ways. The first is through the expansion of multinational drug companies. According to Industry Canada, 10 pharmaceutical companies accounted for half of all Canadian drug sales in 2016. From these 10 companies, Apotex, is the only Canadian based drug company listed. Furthermore, brand name drugs accounted for 62 percent of total Canadian drug market sales in 2015 (Lindberg, 2016). From 1991 to 2015, the sales of patent drugs have increased year over year (except in 1994 and 2010) (Lindberg, 2016).

The second is through the market exclusivity from IPR. Despite NAFTA being presented as a trade agreement, IPR in NAFTA requires the signatory countries to ratify the agreement through their domestic laws. This process involves government intervention despite political rhetoric which passes NAFTA off as a means of increasing trade with the U.S. and Mexico. In fact, trade barriers often do not lead to high prices of commodities. Trade barriers rarely increase prices by more than 15 or 20 percent, while patents on drugs can increase drug prices by 300 to 400 percent (Baker, 2008). State intervention to the benefit of corporate interests is not new. One such example is with the U.S. agricultural industry. The U.S. federal government had participated in the transfer of public land and natural resources to private hands (Panitch & Gindin, 2012). This allowed for the commercial exploitation of these resources, allowing for-profit corporations to grow in this sector of the economy (Panitch & Gindin, 2012). In Canada, Bill C-22 in 1987 had strengthened IPR laws by giving drug companies between 7 to 10 years of

protection against compulsory licensing depending of if the active ingredients were domestically produced or imported (Lexchin, 1993). In 1993, Bill C-91 become law, eliminating compulsory licensing entirely (Douglas & Jutras, 2008). Bill C-91 also increased the patent length in Canada from 17 years from the date the patent was granted to 20 years of protection from the date the patent was filed.

A third way as to how pharmaceutical companies maintain their corporate power involves the patent system itself. Unique to the pharmaceutical industry is that patent is the final product i.e. the drug (Lehman, 2003). In the case of other products, such as a computer (PC), patents are granted on several components. For instance, the processor can be patented because of the design of the semiconductors, the manufacturing process of other components themselves can also be patented etc. The PC itself is not what is patented, various manufactures can produce PCs, however the inventions and innovations to internal components, manufacturing processes and semiconductor designs are what these patents protect. The pharmaceutical industry is unique as the patent equals the final product. This prevents both generic drug companies and other pharmaceutical companies from producing a drug still under a patent. Compared to other industries (such as consumer electronics), the patent for drugs provides market exclusivity to the patent holder.

Findings

Article 1701 of the NAFTA text defines the nature and scope of obligations for Canada, Mexico and the United States for IPR. This section defines the foundation of IPR for the signatory nations. Below I transcribe the original text:

Article 1701

Article 1701: Nature and Scope of Obligations

1. Each Party shall provide in its territory to the nationals of another Party adequate and effective protection and enforcement of intellectual property rights, while ensuring that measures to enforce intellectual property rights do not themselves become barriers to legitimate trade.

2. To provide adequate and effective protection and enforcement of intellectual property rights, each Party shall, at a minimum, give effect to this Chapter and to the substantive provisions of:

(a) the *Geneva Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of their Phonograms,* 1971 (Geneva Convention);

(b) the *Berne Convention for the Protection of Literary and Artistic Works,* 1971 (Berne Convention);

(c) the *Paris Convention for the Protection of Industrial Property,* 1967 (Paris Convention); and

(d) the *International Convention for the Protection of New Varieties of Plants,* 1978 (UPOV Convention), or the *International Convention for the Protection of New Varieties of Plants,* 1991 (UPOV Convention).

If a Party has not acceded to the specified text of any such Conventions on or before the date of entry into force of this Agreement, it shall make every effort to accede.

3. Annex 1701.3 applies to the Parties specified in that Annex.

As can be seen, the text stresses the protection and enforcement of IPR laws, while at the same time ensuring that domestic legislation does not become a barrier to legitimate trade. While

global trade is not unique to neoliberalism, the precedent set by this article is profound. It is not explicitly stated, although this approach in theory allows either the U.S. or Mexico to engage in a lawsuit against Canada if they deem government legislation regarding IPR as a "barrier to trade". Furthermore, there is no concrete definition as to what constitutes legitimate trade. Canada has repeatedly been the subject of lawsuits from the pharmaceutical industry under NAFTA regarding IPR (Eli Lilly and Company v. Government of Canada, 2013).

Article 1702 is a single sentence. It reads:

Article 1702

Article 1702: More Extensive Protection

A Party may implement in its domestic law more extensive protection of intellectual property rights than is required under this Agreement, provided that such protection is not inconsistent with this Agreement.

Clearly, removing this article in the agreement would not have changed the meaning of NAFTA in any way. In fact, this article only serves to further justify the tightening of IPR laws. Policy change towards tightening IPR legislation can be marketed by the federal government to the public as a means of aligning Canadian interests with NAFTA.

Article 1703 is where equal treatment of parties is mentioned. Per NAFTA, the signatory nations cannot give preference or more favourable treatment to their domestic parties (or firms) than they do to parties from the other signatory nations. It reads:

Article 1703

Article 1703: National Treatment

1. Each Party shall accord to nationals of another Party treatment no less favorable than that it accords to its own nationals with regard to the protection and enforcement of all intellectual property rights. In respect of sound recordings, each Party shall provide such treatment to producers and performers of another Party, except that a Party may limit rights of performers of another Party in respect of secondary uses of sound recordings to those rights its nationals are accorded in the territory of such other Party.

2. No Party may, as a condition of according national treatment under this Article, require right holders to comply with any formalities or conditions in order to acquire rights in respect of copyright and related rights.

3. A Party may derogate from paragraph 1 in relation to its judicial and administrative procedures for the protection or enforcement of intellectual property rights, including any procedure requiring a national of another Party to designate for service of process an address in the Party's territory or to appoint an agent in the Party's territory, if the derogation is consistent with the relevant Convention listed in Article 1701(2), provided that such derogation:

(a) is necessary to secure compliance with measures that are not inconsistent with this Chapter; and

(b) is not applied in a manner that would constitute a disguised restriction on trade.

4. No Party shall have any obligation under this Article with respect to procedures provided in multilateral agreements concluded under the auspices of the World Intellectual Property Organization relating to the acquisition or maintenance of intellectual property rights.

The primary objective of this article is to state that domestic companies or firms should not be allowed additional protections against firms from the other signatory countries. The article attempts to rationalize this stance by linking this provision to free trade. Traditional barriers to trade, such as tariffs and quotas, have been decreased considerably even before NAFTA came into effect (Trew, 2017). The Canada-United States Free Trade Agreement which was came into force in January 1989 was responsible for removing many tariffs prior to the ratification of NAFTA. Furthermore, the term "disguised restrictions" is quite broad. The NAFTA text does not adequately describe what can and cannot be constituted as "disguised restrictions on trade". Theoretically, nearly any type of government intervention which could provide nationals of Canada an advantage against U.S. or Mexican based firms, such as subsidies or tax breaks, can be considered as disguised barriers to trade. According to the Office of the United States Trade Representative (USTR), some of these disguised barriers to trade can include the following;

- Local content requirements, i.e., requirements to purchase domestically-manufactured goods or domestically-supplied services
- Subsidies or other preferences that are only received if producers use local goods, locally-owned service providers, or domestically-owned or developed IP, or IP that is first registered in that country;
- Requirements to provide services using local facilities or infrastructure;
- Measures to force the transfer of technology or IP;
- Requirements to comply with country- or region-specific or design-based standards that create unnecessary obstacles to trade
- Unjustified requirements to conduct or carry out duplicative conformity assessment procedures in-country.

Barriers to trade can be perceived as any type of restriction a company may have entering a foreign market. Article 1703 in NAFTA is intentionally vague as to which specific barriers to trade that are prohibited under the agreement. As per the USTR, a Canadian based drug company given a subsidy to conduct basic research can be perceived to be a barrier to trade as that same treatment is not applied to foreign companies.

The language in Article 1703 (as with other articles in NAFTA) is deliberately ambiguous. It has been left intentionally obscure because there is no way around the fact that Article 1703 challenges the sovereignty of a nation. Article 1703 on national treatment can be invoked in a lawsuit against the Canadian government because of any type of policy change they may decide to implement. Nations should be allowed to give preferential treatment to their own organizations. Current IPR laws have limited the number of drugs which can be produced by alterative means such as through generic drug manufacturers. Therefore, this monopoly on the drug market is what allows for patented medicines to be far more expensive than they should be, especially for drugs with little to no therapeutic benefit. Research has shown that the more firms that are producing the same drug, the cost of that drug will decrease substantially (Lexchin, 1993). Multinational corporate interests are not going to act in the best interest of the public, there is no fiduciary duty to do so. The Canadian government is aware of this reality. Public drug expenditures have been rising year over year. Drug spending had increased by 4.2 percent per capita. (Canadian Institute for Health Information, 2017b). Drugs have outpaced physician and hospital spending since 2015 (Canadian Institute for Health Information, 2017a). The ratification of trade agreements as well as the Patent Act fall under the responsibility of the federal governemnt. The decisions made by representatives of the federal government on the ratification of NAFTA, introduction of Bill C-22 and C-91 affect the provincial governments more as they

are responsible for drug procurement. In fact, federal government intervention has been a part of economic policy in the Canada and the U.S. for decades. It's no secret that the federal government (both in the U.S. and Canada) has an active role in shaping the market. Regarding IPR, the U.S. government has threatened against trade sanctions for nations which do not comply (Panitch & Gindin, 2012). This political move allowed for IPR laws to be strengthened within Canada. Increasing IPR for increasing commerce between Canada and the U.S. is counterintuitive as IPR laws do not allow for free trade. Rather, it provides market exclusivity for a health care need, medicines.

Article 1704 prevents parties from allowing any legislative action that can challenge patents that are issued. It reads:

Article 1704

> **Article 1704: Control of Abusive or Anticompetitive Practices or Conditions**
>
> Nothing in this Chapter shall prevent a Party from specifying in its domestic law licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. A Party may adopt or maintain, consistent with the other provisions of this Agreement, appropriate measures to prevent or control such practices or conditions

In fact, the compulsory licensing system in Canada was one such system, and was deemed to be incompatible with NAFTA by all parties in the Uruguay round of the General Agreement on Tariffs and Trade (GATT) (Douglas & Jutras, 2008). Compulsory licensing allowed for a generic drug company to obtain a license to manufacture a drug that was still on patent if approved by the Commissioner of Patents. If granted, the patent holder was not able to object to the issuance of the compulsory license and they would receive a four percent royalty

fee. The use of the term anticompetitive is contingent on who makes the argument. A multinational pharmaceutical manufacturer which generates tens of billions of dollars per year would not require the same amount of protection as a small biotechnology firm.

Article 1709 is the section of NAFTA that explicitly deals with patents. Previous sections do incorporate elements of IPR protection, although 1709 is explicitly labelled for as the provision for patents. It reads:

Article 1709

Article 1709: Patents

1. Subject to paragraphs 2 and 3, each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For purposes of this Article, a Party may deem the terms "inventive step" and "capable of industrial application" to be synonymous with the terms "non-obvious" and "useful", respectively.

Unlike previous articles, 1709 uses language which is clear. For instance, the beginning of 1709 paragraph 1 makes a direct statement that all member parties must make patents available for any inventions. The provision even goes as far as to say that processes (not only just the products) should also be patentable. The statement is very clear in the language used, it is difficult to misconstrue the meaning. The specific nature of the language used is also deliberate. From the other articles in Chapter 17 which were analyzed, Article 1709 is the most direct and comprehensible.

No mention is made of any considerations to who the patents will be granted to (in terms of corporate power and size), although Article 1704 does indicate that the market place should be

free of anticompetitive practices, indicating that the provisions should apply to all nationals of the member states. The provision goes on to state that such inventions should be new and capable of industrial application. The terms new and useful by themselves do not have any metric as what can be constituted as new and useful. Drug companies often push out new medications which offer no therapeutic advantages over existing drugs and are granted patents for these "new drugs". Furthermore, the research from drug companies which shows these new drugs having therapeutic and efficacy improvements are cherry picked for marketing to physicians. There is a strong publication bias present within this industry as reported by several researchers (Davidson, 1986; Dickersin, 1990; Yaphe, Edman, Knishkowy, & Herman, 2001).

Under 1709 paragraph 1, these drug companies benefit considerably (with the granting of new patents) as they present (flawed) findings which indicate a benefit over existing drugs. Most new drugs, approximately 85 percent to 90 percent, do not have any improvement over existing ones (Light, Lexchin, & Darrow, 2013). The introduction and continued production of these drugs ("me-too") has also been observed for at least the past 35 years (Light, Lexchin, & Darrow, 2013). The patent is granted to these large multinational drug companies and the price of pharmaceutical drugs remains high as there is no competitor which can produce the same drug with a far lower markup than the patent holder. Me-too drugs allow for the company to produce drug similar drugs under a patent which would delay a generic drug from entering the market. Such drugs would only be beneficial to society only if the costs are lowered. The median price discount observed in a recent study was only 4 percent (Régnier, 2013). While it seems that this issue should not exist under Article 1709 as the new inventions should be "new and useful", the terms are left intentionally vague and without any quantification as to what efficacy new drugs should have over existing ones.

> 2. A Party may exclude from patentability inventions if preventing in its territory the commercial exploitation of the inventions is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that the exclusion is not based solely on the ground that the Party prohibits commercial exploitation in its territory of the subject matter of the patent.

Paragraph 2 indicates the provisions in which a party may exclude inventions from patentability. Ironically, this section advises that inventions necessary to protect human life and health can be excluded from patentability. Advancements in medicine, including breakthrough drugs, such as Sofosbuvir (Bhatia, Singh, Grewal, & Natt, 2014), the development of vaccines, and other therapeutic advances have enabled humans to be cured from some illnesses as well as life-saving treatment for others have undoubtedly aided in the protection of human life and the improvement of health. The more companies that are producing the same medicine, the lower the average selling of these drugs becomes which in turn means that government expenditure will be decreased on these drugs (Lexchin, 2007). The last sentence of paragraph 2 limits what a party can exclude from patentability. A member party cannot exclude, for instance drugs, from patentability if it is deemed that the restriction is only to prevent commercial exploitation. In other words, if the restriction is placed on granting a patent for the sole purpose of prohibiting commercial exploitation, this would not be allowed under the agreement. The contradiction occurs because no metric is provided for proving that such restrictions are not only to limit corporate interests. Big pharma has been backed by public funds to conduct research and development while seeking to patent their “inventions” because of a need to maintain their “protection” from the competition.

3. A Party may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than microorganisms; and

(c) essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production.

Notwithstanding subparagraph (b), each Party shall provide for the protection of plant varieties through patents, an effective scheme of *sui generis* protection, or both.

Paragraph 3 outlines three additional categories in which a party can exclude from patentability. Section (a) does allow for a party member to exclude diagnostic and therapeutic methods of treatment although referring to paragraph 2, the party cannot simply exclude from patentability what they deem is corporate exploitation. This renders section (a) essentially null and void. At face value, paragraph 3 seemingly allows for a great degree of flexibility when determining what can be excluded from patentability. All the conditions mentioned in paragraph 2 and 3 must be also be aligned with the conditions from paragraph 1 of Article 1709.

4. If a Party has not made available product patent protection for pharmaceutical or agricultural chemicals commensurate with paragraph 1:

(a) as of January 1, 1992, for subject matter that relates to naturally occurring substances prepared or produced by, or significantly derived from, microbiological processes and intended for food or medicine, and

(b) as of July 1, 1991, for any other subject matter,

that Party shall provide to the inventor of any such product or its assignee the means to obtain product patent protection for such product for the unexpired term of the patent for such product granted in another Party, as long as the product has not been marketed in the

Party providing protection under this paragraph and the person seeking such protection makes a timely request.

Paragraph 4 advises the signatory parties of a timeline as to when to conform to these terms on patents for pharmaceutical and agricultural chemicals. Within Article 1709, this is the first explicit mention of the word pharmaceuticals. It is evident that, despite previous mentions of items that could be interpreted as medicines (therapeutic methods of treatment, inventions necessary to protect human life, etc.), that drugs are in a different category and therefore not subject to the same exclusions on patentability. Keeping pharmaceutical drugs as a separate entity allows for these products to be patented and kept off the list of patent exemptions. This distinction is very convenient for drug companies as they can continue to pursue patents for their new drugs, even though these drugs may not be new or useful.

5. Each Party shall provide that:

(a) where the subject matter of a patent is a product, the patent shall confer on the patent owner the right to prevent other persons from making, using or selling the subject matter of the patent, without the patent owner's consent; and

(b) where the subject matter of a patent is a process, the patent shall confer on the patent owner the right to prevent other persons from using that process and from using, selling, or importing at least the product obtained directly by that process, without the patent owner's consent.

6. A Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of other persons.

Paragraph 5 section (a) is part of the reason why compulsory licensing in Canada no longer exists. Furthermore, paragraph 6 allows for exceptions to the exclusivity of patents. However, all pharmaceutical companies which have shareholders need to generate profit to retain these investors. It is in the drug companies interest to keep their patented medicines on patent to keep the flow of cash they enjoy while they have major selling drugs under patent. Any threat to this scheme, such as compulsory licensing, can be considered as a threat to their business interests.

7. Subject to paragraphs 2 and 3, patents shall be available and patent rights enjoyable without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced.

8. A Party may revoke a patent only when:

(a) grounds exist that would have justified a refusal to grant the patent; or

(b) the grant of a compulsory license has not remedied the lack of exploitation of the patent.

9. Each Party shall permit patent owners to assign and transfer by succession their patents, and to conclude licensing contracts.

10. Where the law of a Party allows for use of the subject matter of a patent, other than that use allowed under paragraph 6, without the authorization of the right holder, including use by the government or other persons authorized by the government, the Party shall respect the following provisions:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and

conditions and such efforts have not been successful within a reasonable period of time. The requirement to make such efforts may be waived by a Party in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill that enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the Party's domestic market;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances that led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, on motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization shall be subject to judicial or other independent review by a distinct higher authority;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial or other independent review by a distinct higher authority;

(k) the Party shall not be obliged to apply the conditions set out in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anticompetitive. The need to correct anticompetitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions that led to such authorization are likely to recur;

(l) the Party shall not authorize the use of the subject matter of a patent to permit the exploitation of another patent except as a remedy for an adjudicated violation of domestic laws regarding anticompetitive practices.

11. Where the subject matter of a patent is a process for obtaining a product, each Party shall, in any infringement proceeding, place on the defendant the burden of establishing that the allegedly infringing product was made by a process other than the patented process in one of the following situations:

(a) the product obtained by the patented process is new; or

(b) a substantial likelihood exists that the allegedly infringing product was made by the process and the patent owner has been unable through reasonable efforts to determine the process actually used.

In the gathering and evaluation of evidence, the legitimate interests of the defendant in protecting its trade secrets shall be taken into account.

12. Each Party shall provide a term of protection for patents of at least 20 years from the date of filing or 17 years from the date of grant. A Party may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes.

Paragraph 10 and its following subsections outline the uses of patented materials outside of cases as defined in paragraph 6. The use of patented materials is severely limited, and this clause exists only to provide exemptions in cases of urgent crises. Paragraph 12 closes off with formulating the basis of the patent length for member nations.

Analysis

Globalization of Trade

Trade agreements allow for nations to come to a consensus as how to increase diplomatic relations and commerce with one another. Even without NAFTA, free trade with the U.S. would still occur, it is the benefits of NAFTA which need to be examined. The ratification of trade agreements involves the changing of a nation's political structure and policies. In the case of NAFTA, Canada had passed Bill C-91 into law which removed the compulsory licensing as a means of giving in to the demands of the multinational pharmaceutical industry. Similarly, in Mexico changes were made to their patent laws to conform with NAFTA (Baca, 1994). In the United States, there are no formal provisions for compulsory licensing within the Patent Act (Baca, 1994). Both Canada and Mexico were put in a position whereby they were required to change their domestic laws to align with the U.S. Stronger patent laws were advocated for by the multinationals. Such changes to domestic policies are not in the best interest of the nationals of that member state. For example, under the compulsory licensing scheme, Canada had developed

a more robust generic drug industry (Lexchin, 1997). The increased amount of new generic drugs under the scheme allowed for the growth of the provincial drug plans. These plans enabled subsidized drug purchases for welfare recipients and elderly patients. Compulsory licensing was a reactionary policy and did not address other concerns of the industry. Issues such as tax breaks for pharmaceutical companies, public financing of drug development and the exclusivity of patents were not addressed. However, it provided at least some mechanism for keeping government expenditure on drugs lower (Lexchin, 1993). Under the promise of increased investments in R&D for the Canadian drug market, the federal government had decided to allow the strengthening of IPR. Unfortunately, the PMPRB Annual report shows that R&D expenditures in Canada for the industry have been below the 10 percent figure agreed upon by the federal government and the industry since 2001 (Lindberg, 2016).

Are “free markets” really free?

NAFTA, like other trade agreements such as the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (formerly known as the TPP) and Comprehensive Economic Trade Agreement (CETA) bring promise of the opening of markets and allowing free trade to occur more readily between member states. NAFTA outlines the framework of how the “free trade” system should work amongst it’s member nations. The problem is that there are restrictions placed on nations in terms of what they can do domestically. NAFTA is quite contradictory to itself regarding IPR laws. Chapter 17 of NAFTA advocates for strengthening IPR laws. As previous mentioned Canada and Mexico did have significant changes made to their Patent Act to allow for the ratification of NAFTA. The free market system is really a misnomer as with the drug industry a patent is issued for the sole purpose of keeping other corporations away from cannibalizing the sales of the patent holder. This policy change comes at the federal

level and by being a signatory to NAFTA, domestic laws are changed to benefit the shareholders and owners of these corporations at the expense of the public. NAFTA has an impact on Canadians; drug prices have increased and IPR laws have been strengthened (Lexchin, 2007). Creating favourable markets for specific industries is nothing new. Panitch & Gindin (2012) make note of another industry which required substantial government intervention. In the farming and agricultural industry, the government played a large role through policy change. Domestic policies such as the transferring of land from the state to private hands enabled domestic farmers to flourish. Furthermore, the businesses which happened to declare bankruptcy were given leniency and workers who sought to strike against their employers were punished. Such examples demonstrate the continued involvement of the state to allow for domestic companies to grow and be awarded advantages against foreign competition.

NAFTA provisions allow for Canada to withdraw from the agreement. Given the relative size of the U.S. economy compared to Canada, along with the fact the U.S. is Canada's top export partner makes a Canadian withdrawal from NAFTA unlikely. Furthermore, according to an EKOS Poll conducted in June 2017, 81 percent of Canadians were in favour of keeping NAFTA. A Canadian withdrawal would not only see heavy criticism from the U.S. and Mexico, the Canadian public also is in favour of keeping the agreement, making a withdrawal even less likely.

Is it fair?

The language used within NAFTA itself is neutral. In political discourse, this strategy of is used to disguise the ideology of the discourse (Van Dijk T. A., 2002). All the provisions mentioned list the U.S., Canada and Mexico as the Parties. Despite the differences in gross

domestic product (GDP), the three signatory nations are described as equals. This hides the fact that NAFTA is primarily a U.S. document. The interests of American corporate powers are underline NAFTA. This case is also most evident when looking at U.S. laws regarding IPR. U.S. laws were not required to be changed to implement NAFTA. It was a shift for Canada and Mexico to align their laws with the U.S. While the official text treats all parties as equals, the difference in relative size in these markets is not mentioned. A trade agreement cannot be fair to all parties if there are considerable differences in the size of the markets in which the provisions pertain.

The U.S. gains more benefit from NAFTA in respect to increased IPR legislation as most of the large pharmaceutical companies are based out of the U.S. According to Pharma Exec, an industry magazine, a 2017 analysis was done of the top 50 drug companies by revenue from 2016 figures. Amongst this list, 16 out of the top 50 pharmaceutical companies were headquartered in the U.S., including Pfizer, the largest drug company by measure of revenue. Only one is based in Canada, it ranked 28th in terms of revenue. None of the top 50 pharmaceutical companies by revenue from 2016 are headquartered in Mexico. I conducted a basic analysis from these figures to determine how much U.S. based firms take in as revenue as a percentage of the 50 firms listed. The 16 U.S. firms comprise 45 percent of the total revenue from these top 50 firms. It is clear to see who is benefiting given that 16 U.S. drug companies are in the top 50 drug companies and only one is headquartered in Canada while none are from Mexico. The wording of the NAFTA is such that it appears to provide all parties equal benefit although when examining revenue, it is much easier to see who is currently benefiting with the changes in domestic IPR laws. When 45 percent of all revenue from the top 50 largest drug companies comes from the U.S. alone, it is clear they dominate the pharmaceutical industry

globally. Canada does not stand to gain any market advantages from increased IPR protection as the drug companies headquartered in Canada are far smaller in size and consequently in revenue as well.

A Non-interventionist State?

One of the central tenets of neoliberalism is the retrenchment of the state from economic and social activities (Navarro, 2007). The proposed logic is that the economic and social needs of the population can be addressed through the private sector. State intervention would be an unnecessary added cost and solutions for societal problems can be addressed through market-based solutions. Furthermore, neoliberalism also proposes that increased investments and commerce require stimulation by means of allowing the mobility of labour, capital, goods and services (Navarro, 2007). To accomplish this, barriers to trade, such as national borders, would need to be eliminated (in a political sense). However, when looking at NAFTA through a neoliberal political economy lens, we see that state intervention does not decrease. Rather specific policies are implemented from the federal levels of the party states to create a favourable business climate for the beneficiaries of such policies, chief among them the pharmaceutical multinationals. With drugs, the patent is essentially granted to the final product (Lehman, 2003). In other industries, for instance personal computers (PCs), the final product is not what is patented, rather highly specific components and processes are patented. This means that a PC manufacturer can hold multiple patents for a single product they produce, however the patent itself does not mean they are granted exclusivity to create PCs. In this aspect, it is easier to understand how the pharmaceutical industry benefits more with IPR than in other industries.

Furthermore, Chapter 17 in NAFTA is quite loaded with provisions which involve direct government involvement and enforcement of policy. Article 1701 paragraph 1 starts off

immediately advising that member parties are required to provide adequate protection and enforcement of IPR. In a twist of irony, the same provision proceeds to then advise that the measures taken to enforce IPR do not themselves become barriers to trade. For generic drug manufacturers, the very existence of IPR (and enforcement thereof) is what gives the drug multinationals the clearest advantage over their generic counterparts. Despite NAFTA also outlining in Article 1709 paragraph 1 that patents should be granted when inventions are new and useful. Language used which does not incorporate any quantifiable standard which these new inventions can be measured.

Competition in the market is a reoccurring theme within Chapter 17. With Article 1704, NAFTA directly affects domestic laws of the signatories. Control of anticompetitive practices or the abuse of IPR laws can only be handed at the domestic level. There is no supranational organization which allows for patents to be valid internationally (between nations without trade agreements or other economic and political unions). The enforcement of patent protection happens domestically. To ensure that this enforcement is in position domestic laws were required to change to accommodate NAFTA. As a result, provisions such as Article 1704 provide the avenue for changing domestic laws to ensure that there is a standardization of IPR law amongst the parties. In addition, government intervention to create a more desirable market for these multinationals by imposing restrictions creates barriers for other drug companies as well. The companies who are competing with one another are not doing so on a “level playing field”. Rather they can use their patent portfolios as a means of restricting others in the industry. Neoliberal practice is not to reduce government intervention but to change the nature of this intervention (Navarro, 2007). These interventions are what benefit the elite classes in society, furthering social inequalities. Big pharma can continuously apply for new patents for drugs with

little to no therapeutic advantages and keeps these prices higher through exclusivity conferred by patents. This is a practice known as "evergreening" which allows for the same drug to be patented for longer than the 20 years stipulated in NAFTA. Slight modifications made to these older drugs to extend the patent life is a process which further delays new generic drugs from entering the market and allows for the patent holder to maintain their exclusivity on a drug. Drug manufacturers can apply for multiple patents on a single drug, a process known as stockpiling (Dwivedi, Hallihosur, & Rangan, 2010). The patent expiry dates are not all the same as additional patent applications would have been filed after the initial patent was issued. These patents delay the entrance of generic drugs into the market. In the past, this has caused an 8-year delay from generics entering the market. (Lexchin, 2011). During this time, the patent holder still maintains exclusivity and profits from the higher prices associated with brand name drugs. This can keep a drug under patent for several years after the initial 20-year patent expires. Another strategy is presenting consumers with a successor drug. When a patent is about to expire on a drug, the drug company would release a successor drug and apply for a patent extension (Dwivedi, Hallihosur, & Rangan, 2010). Typically, these evergreened drugs do not provide any significant advantage over the existing drug (Collier, 2013). These patents delay the entrance of generic drugs into the market. This process only aims to prolong existing patents for as long as possible.

Myths from the Industry

The drug industry has long cited claims that drug development is costly and high risk. Because of their investment, they would need some type of assurance that their intellectual property is safeguarded. The truth of the matter is that drug research and development (R&D)

costs are held in secret by these companies. There is little transparency in the numbers that are presented for how much it costs to produce a new drug. The most common figure that is used is 802 million dollars. This figure is derived from a study originally conducted by DiMasi et al. (2003). In 2016, a revised study was conducted by the same authors. The updated estimate for bringing a new drug to market is approximately 2.6 billion USD (DiMasi, Grabowski, & Hansen, 2016). Canadian figures were derived from a simple currency conversion of the initial study. The study was based on a survey of 10 drug companies. The R&D costs which were provided to the authors was kept confidential and was unverifiable. It is worth mentioning that 24 firms were invited, however only 10 companies participated. Essentially just under 60 percent of those invited were not included within the study. Research shows that a significant portion of new drugs that produced have little to no therapeutic advancements (Light & Lexchin, 2012; Morgan, et al., 2005). An important question emerges if this study is to be questioned. If no standard exists or baseline was determined, what expenses can be deemed to be legitimate R&D costs? If mergers, acquisitions or other administrative changes have occurred during the collection period selected by the authors, would these figures (while not being directly involved in drug development) be accounted for in the participating company's breakdowns of R&D figures? Also, the data given to the authors was not presented within the study. Therefore, it is unknown if the firms provided a clear breakdown of their R&D costs. Alternatively, the authors may have been provided information that could not be parsed further and took it at face value. Without seeing the actual data, it becomes impossible to determine how transparent these companies were with the authors. Although what can be determined is that the lower the reported figures, the more criticism the pharmaceutical industry would face. Consequently, there is a financial motive for keeping these R&D figures as high as possible.

Granting patents for these drugs would seem contradictory to Article 1709 paragraph 1. In NAFTA, there is no measurement or threshold which these inventions should meet to qualify as new and useful. Although as the drug industry still requires marketing these drugs to physicians and bulk drug buyers such as provinces, they need some data to support that the new drugs are an "improvement" over existing ones. Clinical trials which are sponsored by the industry are more likely to demonstrate improvements over previous drugs (Davidson, 1986; Dickersin, 1990; Yaphe, Edman, Knishkowy, & Herman, 2001). Given the ambiguity of Article 1709, drug companies can apply for patents for these "new" inventions. If a patent is not granted for whatever reason, they still have the loose definition of "new" and their own clinical trials to support their claims under Article 1701.

Drugs Inc. – State Sponsored Drug Protection

Big Pharma, while not entirely ethical, still operates their business within the confines of the law. Simply put, drug companies will proceed with actions which are financially beneficial to them while still respecting the law. It is through the federal government which provides different ways for drug companies to take advantage of their privileged positions. While a lot of the discussion is about patent laws, the state still does reinforce the ideologies through other means. NAFTA is an agreement which Canada could have attempted to either renegotiate or not sign altogether. In addition, CETA is another agreement which was signed in October 2016 which also includes an entire chapter on intellectual property like NAFTA. The federal government's actions thus far seem to agree with the pharmaceutical sector, especially considering this industry benefits more from extended IPR laws than others. While this paper will not go in depth about

CETA, I will mention that the IPR provisions in CETA are quite like those in NAFTA. They are both vague, far reaching and encourage the signatories to continuously push for the domestic enforcement of these policies. As seen with NAFTA, this implication would mean the amendment of domestic laws to comply with CETA. The federal government is still very much involved in shaping the marketplace. Under the guise of free markets and reducing barriers to trade, the government has been shaping the drug market to favour these multinationals. The federal government has continued to create favourable IPR legislation for Big Pharma through agreements such as CETA.

Furthermore, another means of how the government has essentially sponsored these Big Pharma is through heavy subsidization of drug R&D. As previously mentioned, drug companies often do cite that drug R&D is very expensive and it is also a high-risk endeavour. The government, both at federal and provincial levels, provides significant subsidies to the industry for conducing R&D. (Lexchin, 2016). Federal R&D tax incentives had included immediate write offs for current costs (of R&D), machinery and equipment costs in addition to a 20 percent taxable credit (Lexchin, 2016). KMPG also conducted a report in 2014 which had demonstrated that Canada had R&D tax programs which produced negative income taxes (Lexchin, 2016). This means that the refundable tax credit value is higher than the corporate income tax rate charged to the pharmaceutical companies. Drug R&D in Canada did increase after changes were made to the Patent Act as well as after NAFTA came into effect. However, these increases in investments from the industry should not be considered the only factor as to why these increases occurred. Federal and provincial tax credits for R&D conducted within Canada had grown (Grootendorst & Di Matteo, 2007). While tax incentives for R&D were in place since 1983, the definition of eligible R&D activities was changed in 1985 (Pazderka, 1999). The eligibility

requirements for R&D activities was broadened. (Madore, 1998). The general tax credit is set at 20 percent of R&D activities. Moreover, unused R&D tax credits can be carried forward for 10 years (Madore, 1998). While at the federal level there was no significant changes since Bill C-22 was enacted in 1987 (for stronger IPR protection, increased patent length), the tax credit for positions for R&D in Quebec, for instance, was doubled from 10 percent to 20 percent. It can be argued that increased IPR protection with Bill C-22 did help spur investments, although R&D tax credits are also very important in determining where pharmaceutical companies conduct their R&D. In a strictly business sense, it would be logical for a pharmaceutical company to invest in R&D in the provinces where they will receive the most tax benefits.

The main problem that is not being addressed here is twofold. The first problem is that R&D from private companies is being subsidized when they put very little focus on basic research themselves (Light & Warburton, 2011; Light & Lexchin, 2012). This type of research is almost exclusivity conducted at universities or other government research facilities (Angell, 2004). The second problem is the eligibility criteria to receive these benefits as outlined in the Income Tax Act is not specific enough.

> **Under Subsection 37 of the Income Tax Act 1985**,
>
> Scientific research and experimental development
>
> 37 (1) Where a taxpayer carried on a business in Canada in a taxation year, there may be deducted in computing the taxpayer's income from the business for the year such amount as the taxpayer claims not exceeding the amount, if any, by which the total of
>
> (a) the total of all amounts each of which is an expenditure of a current nature made by the taxpayer in the year or in a preceding taxation year ending after 1973

(i) on scientific research and experimental development related to a business of the taxpayer, carried on in Canada and directly undertaken by the taxpayer,

(i.01) on scientific research and experimental development related to a business of the taxpayer, carried on in Canada and directly undertaken on behalf of the taxpayer,

(i.1) by payments to a corporation resident in Canada to be used for scientific research and experimental development carried on in Canada that is related to a business of the taxpayer, but only where the taxpayer is entitled to exploit the results of that scientific research and experimental development,

(ii) by payments to

(A) an approved association that undertakes scientific research and experimental development,

(B) an approved university, college, research institute or other similar institution,

(C) a corporation resident in Canada and exempt from tax under paragraph 149(1)(j), or

(D) [Repealed, 1996, c. 21, s. 9(4)]

(E) an approved organization that makes payments to an association, institution or corporation described in any of clauses A to (C)

to be used for scientific research and experimental development carried on in Canada that is related to a business of the taxpayer, but only where the taxpayer is entitled to exploit the results of that scientific research and experimental development, or

> (iii) where the taxpayer is a corporation, by payments to a corporation resident in Canada and exempt from tax because of paragraph 149(1)(j), for scientific research and experimental development that is basic research or applied research carried on in Canada

Subsection 37 (1) (a) (iii) of the Income Tax Act states that the taxpayer can be a corporation which can be exempted from tax for scientific research and experimental development conducted in Canada. Furthermore, this provision states that this research can be basic or applied research. Also, the statute also uses the word "incremental". The meaning of this word for the pharmaceutical industry can basically be interpreted as any research period. Any type of research conducted which has the intention of advancing medicine, no matter how small, would legally be eligible. Essentially the government has given pharmaceutical companies the "free pass" on paying less taxes because of them conducting research regardless of whether it is beneficial to society.

The provisions in the Income Tax Act allow for both applied research and basic research to be eligible, however this "research" that is being conducted may be of little benefit to the public. Most of R&D costs, about 67 percent, are encountered during phase three clinical trials (Collier, 2009). When this phase is reached, the chances of success (i.e. approval) are about 60 percent. This would mean that by the time a new drug reaches phase three trials, the company has a much greater chance of success than before this point. The uncertainty of their investments is no longer a cause for concern. In addition, the trials conducted prior to entering phase three trials are much lower in cost as well. With drugs that are considered me-too drugs, these clinical trials will be quite large. Small differences between an existing drug and a new drug being developed will not be found in smaller sample sizes. The smaller the therapeutic advancement,

the larger the study group for a clinical trial will need to be for these statistically significant differences to be found. Under the Income Tax Act, “evergreening” or any attempt thereof to do so is encouraged by the policy. The policy does not favour those companies which are conducting basic research. The tax credits are valid for both. This inherent flaw in the Income Tax Act allows for pharmaceutical companies to take advantage and develop more drugs which are in that “me-too” category rather than invest in basic research. Development of therapeutically similar drugs is of a lower cost than conducting basic research and far less risky.

Most of the basic research conducted is financed publicly in institutions such as universities. As Light & Lexchin (2012) report, pharmaceutical companies spend very little on basic research to discover new molecules. In their 2012 study, they found that over 80 percent of all funds for basic research to discover new drugs comes from public sources. Marcia Angell gives a perfect example of how pharmaceutical companies use government financed research to obtain patents for research they did not conduct themselves. AZT was the first drug to be brought to market for the treatment of HIV/AIDS (Angell, 2004). In 1964 the AZT molecule was synthesized at the Michigan Cancer Foundation as a possible treatment for cancer. It turned out that AZT was not effective at treating cancer although in 1974 German researchers found it to be effective against viral infections in mice. Burroughs Wellcome (later acquired by GlaxoSmithKline) obtained the molecule as a possible treatment for the herpes virus. In 1985, it was determined that AZT was effective against the HIV virus. Burroughs Wellcome had conducted the clinical trials required for FDA approval. Within 6 months the FDA granted the approval for the drug. In Angell’s example of AZT, most of the research already occurred within publicly funded institutions. In the end, the patent was still granted to a private company. Drug companies still ask for protections as means of maximizing their profits. The drug companies do

not require these protections. Despite publicly funded organizations performing basic research, their innovations are patented to private drug companies. These companies are then marketing these drugs at high markups and granted patent protection through these same governments. In Canada, there is little societal benefit as drug coverage is not a part of health care. In addition, government sponsored drug programs such as the Trillium Drug Program increases government drug expenditures as not all drugs have generic counterparts because of the patent validity period.

The government has continued to provide incentives to the drug industry despite the lack of R&D commitment in Canada. Through legislation in the Patent Act allowing for extensive IPR protections to tax benefits in the Income Tax Act, the government is actively sponsoring Drugs Inc. The solution is simple. The government needs to change their policies. As a means of increasing R&D investment in Canada, the pharmaceutical industry should still maintain their taxable benefits to a certain extent. Although the government should amend the statute to specify what activities qualify. Firstly, there needs to be a distinction made for basic research and applied research. Currently the government is already funding institutions which conduct this research. Unfortunately, as described with the example of AZT these publicly funded institutions are not recognized for their efforts toward advancing medicine. Patents should not be granted for 20 years for new molecules discovered through breakthrough research conducted in publicly funded institutions.

Political Discourse – Confusion through obscurity

Politicians tend to avoid making obvious statements in favour of being indirect (Obeng, 1997). NAFTA, as a trade agreement is inherently political in nature. Both the written discourse, the actual agreement itself, and political speeches on the subject are conducted in a dishonest

manner. Politicians tend to communicate to the public indirectly though means of evasion and convolution, both in written and spoken discourse. As shown in the findings section of this paper, the NAFTA document contains instances where there is both are present. NAFTA is a document which is on public record. The signatory nations all host the document on their respective government's websites for access to any members of the public who wish to examine the document. Any document which is accessible to the voting public should be written in a manner where the language is clear, concise and comprehensible. In addition, the public who are responsible for voting (and extending the terms of) politicians should be able to comprehend the policies being brought forth to them by these very same politicians.

While Obeng (1997) describes indirectness in political discourse from the perspective of mostly verbal discourse, I propose this means of analyzing spoken discourse can apply to written discourse as well. Furthermore, I also propose that obscurity is another element used in such written political discourse (trade agreements) to gain public support for decisions which would otherwise be controversial. The obscure full text of NAFTA is available to the public, although politicians have decided to focus on publicly speaking about the benefits of the agreement. This evasion or diversion of public attention away from the actual agreement is what allows for indifference or tolerance for an agreement. Given information which is comprehensible, the public would not be supportive of NAFTA and other similar agreements. The obscurity of the text discourse also allows politicians to twist the narrative into a positive one through verbal discourse for political gain.

Public opinion on NAFTA over time has changed over time in Canada and the U.S. The Angus Reid Institute is a Canadian non-profit research foundation which conducts statistical public opinion polling research and policy analysis. According to the institute, in 1993 58

percent of Canadians surveyed were moderately to strongly opposed to NAFTA (Angus Reid Institute, 2016). In 2014 the same poll was conducted again, and the results were more evenly divided. 34 percent of Canadians surveyed responded that NAFTA was beneficial to Canada. 31 percent of respondents said the agreement was detrimental while the remaining 35 percent said the agreement did not positively or negatively affect Canada (Angus Reid Institute, 2016). The Pew Research Center, a well-known institute has also conducted a similar poll in the U.S. Overall in 2017, 51 percent of Americans believe NAFTA was a benefit to the U.S. while 39 percent believed it was not beneficial (Stokes, 2017).

When digging deeper into the numbers, the partisan gap is far more noticeable. 30 percent of Republicans believe NAFTA was a good thing, leaving 70 percent believing it was detrimental. While for the democrats, nearly the opposite case was found true. 68 percent of the democrats believed it was positive while 32 percent believe NAFTA harmful to the U.S. After running a campaign in which U.S. President Trump publicly announced his dissatisfaction for the agreement it is no surprise that there is a clear majority on the Republication side which do not support the agreement. However, the fact remains throughout 1994 to the present day, the agreement of the text has not changed much while public opinion on NAFTA has shifted. The politics in the U.S. have been much stronger regarding NAFTA than in Canada. During the 2015 federal election, the main trade related campaign promise was regarding the TPP. A renegotiation of NAFTA was not part of any of the federal party's platform for the 2015 election in Canada as it was for Trump's campaign throughout 2016.

Policy Recommendations

NAFTA – To stay or not to stay

The federal governments efforts have been conservative in the past to Big Pharma. Compulsory licensing was a method of government cost control which did curb costs (Lexchin, 1997). Although since then there have been Bills C-22 and C-91 as well as the signing of NAFTA. IPR provisions under Chapter 17 of NAFTA are both broad in scope and vague in language. The agreement itself can be interpreted differently by the government and Big Pharma.

Health care in Canada should include comprehensive pharmaceutical coverage. This is currently a field in which Canada lags the rest of the developed world. Generic drugs are capped at a fixed ratio of the brand name drug, a method of controlling the final price of a generic drug. In Ontario, this happens to be at 25 percent of the selling price of the brand name drug. Furthermore, having more generic drugs in the market allows for more real competition and as a result prices tend to be lower (Lexchin, 2007). The federal government would need to seriously reconsider the benefits obtained from being a signatory of NAFTA. Under the Trump administration, there has been several mentions of a possible NAFTA renegotiation. Although with the ongoing rhetoric it is difficult to accurately predict if NAFTA be renegotiated let alone discarded. One possibility for Canada would be a withdrawal from NAFTA. The provisions would allow for any member party to withdraw from the agreement if a written notice is provided to the other parties.

While proposing to leave NAFTA seems like a radical measure, it is worth realizing that there is another agreement in place with the U.S. The Canada-U.S. Free Agreement (CUSFTA) came into effect in 1989 and was never withdrawn. If Canada (or the U.S. for that matter)

withdraws from NAFTA, CUSFTA would remain in effect. Free trade between Canada and the U.S. would continue as CUSFTA was responsible for eliminating tariffs. CUSFTA also does not allow for foreign companies to challenge laws in Canada. Granted this would depend on if the U.S. administration would be willing to forgo NAFTA and keep CUSFA. From the perspective of pharmaceutical drugs, it would most certainly be helpful, although the process of Canadian withdrawal from NAFTA may not be seen in a favourable light politically by either the U.S. or Mexico.

Under NAFTA, the federal government could face litigation if they were found to be in violation of any of the provisions. Given the nature of these provisions and variations in the interpretation of the text, several legal motions can be upheld in a court of law. This is a concern as the ambiguous nature of the provisions allow for a wider range of possible interpretations. Furthermore, any government intervention into the market for any reason, including the improvement of health policies, to control pharmaceutical companies can be considered as a barrier to trade.

R&D Tax Subsidies – Closing the legal loophole

The federal government must reconsider the amount of subsidization they offer to these multinational drug companies. Pharmaceutical companies do not conduct much basic research themselves (Light & Lexchin, 2012). Over 80 percent of the funds for public research of new drugs and vaccinations are from public sources. The financial burden of basic research has been placed in the hands of the government to finance institutions such as universities and research facilities. It should be mentioned that drug companies are for profit organizations. Shareholders put their money into the company seeking a return on their investments. Risky ventures such as

investing basic research is not financially justifiable to shareholders. For profit corporations have opposing core values than publicly funded research institutes or research universities. By providing tax incentives to these companies, the government is not acting in the best interest of the public. When these drug companies also patent their drugs, no benefit is given to the government for these subsidizations. Patents in the pharmaceutical sector are somewhat unique, the patent is granted for the final product rather than a specific component or processes. This means that when a drug is patented the patent is effective for the drug in its entirety, effectively eliminating out any competition for the patent holder. Ironically IPR protections which allow for the granting of these patents have an entire section dedicated to them while Article 1704 in said section denounces any intervention or anticompetitive behaviour into the market.

Furthermore, R&D investment to sales ratio has seen a decline since 2000 (Lindberg, 2016). According to the 2015 annual report by the PMPRB, the R&D to sales ratio has never again reached the agreed upon figure of 10 percent last reached in 2000. Also, this ratio has been in steady decline without any recent upward trend. No longer is the pharmaceutical industry keeping up with commitments to R&D and promises for job growth have not been kept either (Lexchin, 1997).

Finally, the government needs to be clear as to what eligible R&D activities are. Currently the 1985 revision to the Income Tax Act is how these organizations can have their R&D significantly subsidized. The language used is very broad and both applied and basic research is covered. The government should keep R&D tax credits available for pharmaceutical companies although this provision should have restrictions. Firstly, the pharmaceutical company should be conducting basic research. The industry is doing less basic research than what the government is financing through their institutions. Keeping this R&D tax incentive for those

organizations willing to conduct basic research may spur investment from the drug industry in Canada.

The second restriction should have provisions as to the specific activities which can be tax deductible. Organizational changes such as mergers or acquisitions should not be reported as to being part of R&D expenditures when they are not directly related to the research itself. The third restriction should be that the reporting of R&D should be done in a consistent manner for the government to determine the total eligible credit which can be applied to the organization. A standard method for reporting R&D costs to the government needs to be developed. The government should specify more clearly what would qualify for this tax deduction and any drug companies who choose to take advantage of the credit should be prepared to be audited to validate the accuracy of their R&D tax claim.

Revising the Patent Act

Improving IPR protection has been a key tenet in NAFTA as well as newer agreements such as the TPP and CETA. Drug companies readily invest in markets with tight IPR laws as it gives them a monopoly of the markets in which they enter. However, the federal government should not exclude revising the Patent Act.

Currently the Patent Act has three major flaws. The first is that not all parties responsible for conducting research towards and invention or innovation are recognized. The case of AZT is quite relevant to illustrate this example. Drug research, especially basic research for discovery and advancement of knowledge is conducted through publicly funded institutions. When a drug company undergoes the phase three trials (which are the costliest element of R&D) for these previously researched and discovered compounds, they can be awarded the patent for providing proof of efficacy and safety.

The Patent Act currently does not have any considerations which stakeholders were involved throughout the drug discovery process. In addition, no consideration is also made for who completed research before the compound underwent clinical testing. The federal government can decide to set these provisions into the Patent Act when deciding to issue a patent. If there was a significant public investment in a development of a drug, the public should be given benefit for the investment.

I propose to change the Patent Act in two different ways. The first would be to allow for multi-party patents. In this system, the publicly funded institution or private laboratory and drug company which brought the drug to market would receive a patent granting exclusivity. With this method, the government could allow for generic drug production to occur much faster as they would be the co-patent holder. The government could license the patent to a generic drug firm or produce the drug if the capacity exists contingent on the facility. The drug company therefore knows there is going to be a potential competitor in the Canadian market. This pressure has been shown to reduce the price of brand name drugs by 40 to 65 percent (Cohen, 2006).

The second method would be to allow a royalty to contributions made from the public sector to the discovery or research into the development of a drug. If Big Pharma ends up bringing the drug to market, a royalty of a fixed percentage of Canadian sales would be given to the organization responsible for conducting the research. While the drug company still retains the patent, the organizations responsible for investments in R&D can file for a royalty claim if they are able to provide the research which led to the breakthrough allowing for the drug company bring the drug to market. Like the first amendment, these provisions do not need to necessarily be used to be effective. Putting forth these changes into the Patent Act allow for the government to police the industry as they are a key stakeholder in R&D.

The second flaw of the Patent Act is there is no measure of what metric should be used to deem an invention or innovation as new and useful. This holds particularly true in the pharmaceutical space where upwards of 90 percent of new drugs are not an improvement over existing one (Light, Lexchin, & Darrow, 2013; Light & Lexchin, 2012). It is not the lack of innovation that causes many new drugs to be little to no more therapeutically effective than existing ones as Big Pharma claims. Rather it should be considered that the Patent Act encourages a certain business model from the industry. Patents are granted for "new" and "useful" inventions. These terms are arbitrary and truly in the eye of the beholder. Currently the bar is set very low for drugs to obtain a patent. Efficacy and safety must be demonstrated through clinical trials. The baseline level of efficacy a new drug would need to need to surpass is that of a placebo. In other words, a drug company can claim that they have a new drug which is "new" because it is a different compound compared to their other drugs. Secondly, they can claim it is "useful" because it surpassed the efficacy of a placebo in a clinical trial. The recommendation I make here is that the federal government should adjust the Patent Act. The terms new and useful should be more specific in nature. Drug companies need to provide evidence that a new drug is more considerably effective than their existing drugs.

The current gold standard for trials are randomized control trials (RCTs). While the logic behind RCTs is rational, it is irrational to expect drug companies, which have profit maximization a priority, to report accurate trial results. The federal government should consider implementing a system which allows the independent testing of new drugs through public funds. These systems can eliminate a conflict of interest, the party seeking patent approval is also the same party which is conducting the clinical trials to gain patent approval (Baker, The benefits

and savings from publicly funded clinical trials of prescription drugs, 2008). The federal government should strongly consider these changes

Limitations

Provincial Differences on R&D

This paper, as any research paper, has limitations which should be addressed. The first limitation is the generalizability of these findings and policy recommendations to all provinces and territories in Canada. Regarding the first research question, the viewpoint of this paper was done at a federal level. The federal policy approach was taken as trade policies involve federal governments and policies however there are also subnational effects on policy. For example, the pharmaceutical sector in Canada is not evenly distributed geographically. According to the 2015 PMPRB annual report, Ontario encompasses 52.3 percent of R&D expenditures from the industry. This means that federal policies concerning the pharmaceutical industry such as the R&D tax credits are more relevant to Ontario and Quebec. 81 percent of the R&D expenditures from the industry is spent in two provinces alone. Based on the policy recommendation suggested previously, the tightening of the R&D tax credits may disproportionally affect the industry in Western Canada and the Maritimes. Therefore, sweeping policy changes at the federal level may hinder the pharmaceutical sector in Western Canada and the Maritimes.

Furthermore, these smaller provinces may not have the budgets to build major research centres in their province. In Ontario and Quebec, these provinces have far larger budgets in which more funds can be allocated for government financed R&D. While Ontario and Quebec should still be considering why they have put private for-profit drug companies at the forefront of R&D, the smaller provinces do not have the same leverage and infrastructure. As the pharmaceutical industry may be one of few sources of R&D and drug innovation in the smaller

provinces, there can be a clear incentive to keep federal and provincial R&D tax credits. Moreover, Ontario and Quebec can still pressure the pharmaceutical industry to contribute more to basic research by making the recommended R&D tax credit policy changes at the provincial level.

Conclusion

Trade agreements are here to stay. Economies are more intertwined, and nations enter diplomatic relations with other nations for the to benefit from one another. That being said, how these agreements are negotiated is not ruled by any natural (i.e., physical) law, and exactly who benefits should remain at the center of any trade agreement the federal government chooses to draft, sign or ratify. Trade agreements like NAFTA have wide reaching provisions that have caused a shift in domestic policies in Canada. The U.S. has been a promotor of trade liberalization and American firms have pushed for a means of liberalizing trade outside of their borders (Panitch & Gindin, 2012). Canadian leaders have also been quick to sign on to more trade agreements with other nations. Canada signed off on the TPP and CETA, two trade agreements which also have similar IPR provisions as NAFTA.

Big Pharma has benefited, at the expense of the public, from changes to IPR laws since NAFTA was ratified. Bill C-22 and C-91 paved the way for NAFTA ratification by strengthening patent laws, allowing a period of exclusivity for drugs from compulsory licensing and eventually completely removing compulsory licensing. During the negotiations, industry promises of keeping R&D investments in Canada were not followed through upon and drug expenditure had increased significantly. Drug price increases have influenced the Canadian public. 10 percent of Canadians have reported that they do not take their medications due to cost (Law, Cheng, Dhalla, Heard, & Morgan, 2012). Furthermore, over 26 percent of Canadians

without drug insurance have reported drug noncompliance because of high costs. Without government intervention for cost containment measures, these figures are only expected to rise.

Chapter 17 of NAFTA allows for parties to gain protection for the inventive and industry applicable innovations or inventions. In other words, new and useful inventions are granted patent protections. These patent laws existed as a means of protecting independent inventors. The pharmaceutical industry has surpassed 1 trillion US dollars. This is not an industry which requires protection for their inventions. Moreover, the advancements to medicine with contributions from Big Pharma have been exaggerated. Research indicates that 85 to 90 percent of newer drugs show little to no therapeutic benefit over existing drugs (Light & Lexchin, 2012). The drug sector has operated within the confines of law. Incentives such as R&D tax credits and strong IPR protection have fueled a business model of incremental revision to existing drugs.

The Canadian government has placed private drug corporations at the center of drug development to further trade and economic policy over the health of Canadians. The Canadian government has provided generous R&D tax credits, essentially subsidizing the R&D conducted by Big Pharma. The industry does not conduct much basic research. Both in the U.S. and Canada, basic research is financed in majority by the government. The industry has benefited two-fold from this situation. Strong IPR protection keep the market artificially controlled and allow for the monopolization of markets by these multinational corporations. Secondly, R&D activities such as phase three trials are considered as eligible R&D activities under Canada's Income Tax Act. Phase three trials are the costliest portion of drug development and approval. For as long as these incentives exist, Big Pharma will continue to tweak their existing drugs and conduct large scale clinical trials to obtain small (but statistically significant) findings to justify why they need to be granted a patent.

Industry claims for protection are also unfounded. A 2003 study, with updated figures from 2016 has become the most widely used statistic for quoting the cost of drug production. The Tufts Center which produced theses two studies is funded heavily through the pharmaceutical sector. IPR laws were meant to spur innovation and provide an incentive for independent inventors to continue developing new products. The problem lies within the structure of present day patent protection. The pharmaceutical companies are very large multinational organizations. The R&D development costs compared to marketing costs are staggering. These corporations do not need to have any additional protection granted for them. The only purpose of this protection is for capital gain through market exclusivity. NAFTA evades these facts and allows for major multinationals to use these provisions to their advantage. There is no element of NAFTA which seeks to limit corporate power, in fact NAFTA is an agreement with the purpose of increasing corporate power. The federal government had made promises when it introduced the R&D tax credits as a means of increasing R&D investment in the industry in Canada. The job creation promises, and R&D investments have not come to fruition since 2001. Furthermore, NAFTA as a trade agreement does not recognize that these multinationals are for profit entities. An agreement which creates favourable conditions towards for profit companies is the opposite of should be done to benefit the public. In addition, the intervention from the state once it goes against the corporate powers can be challenged as anti-competitive behaviour.

Finally, the state continues to justify these policy decisions on the basis that it will improve the economy. Trade agreements continue to be signed as a means of creating increasing global commerce and trade. Politicians run campaigns which require funding (more so in the U.S. than in Canada) and the contributing parties will not finance a candidate which not serve

their interests. Drug production can be placed under the control of a public system. There is no need to continue to allow for profit private entities to produce drugs at such high markup costs. By providing the federal government nothing but a higher bill to pay on pharmaceuticals, perhaps it is time for politicians to reconsider their stance on who pushes the pills.

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Appendix A: NAFTA Provisions in Chapter 17 Excluded from Analysis

Article 1705: Copyright

1. Each Party shall protect the works covered by Article 2 of the Berne Convention, including any other works that embody original expression within the meaning of that Convention. In particular:

- (a) all types of computer programs are literary works within the meaning of the Berne Convention and each Party shall protect them as such; and
- (b) compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations, shall be protected as such.

The protection a Party provides under subparagraph (b) shall not extend to the data or material itself, or prejudice any copyright subsisting in that data or material.

2. Each Party shall provide to authors and their successors in interest those rights enumerated in the Berne Convention in respect of works covered by paragraph 1, including the right to authorize or prohibit:

- (a) the importation into the Party's territory of copies of the work made without the right holder's authorization;
- (b) the first public distribution of the original and each copy of the work by sale, rental or otherwise;
- (c) the communication of a work to the public; and
- (d) the commercial rental of the original or a copy of a computer program.

Subparagraph (d) shall not apply where the copy of the computer program is not itself an essential object of the rental. Each Party shall provide that putting the original or a copy of a computer program on the market with the right holder's consent shall not exhaust the rental right.

3. Each Party shall provide that for copyright and related rights:

- (a) any person acquiring or holding economic rights may freely and separately transfer such rights by contract for purposes of their exploitation and enjoyment by the transferee; and
- (b) any person acquiring or holding such economic rights by virtue of a contract, including contracts of employment underlying the creation of works and sound recordings, shall be able to exercise those rights in its own name and enjoy fully the benefits derived from those rights.

4. Each Party shall provide that, where the term of protection of a work, other than a photographic work or a work of applied art, is to be calculated on a basis other than the life of a natural person, the term shall be not less than 50 years from the end of the calendar year of the

first authorized publication of the work or, failing such authorized publication within 50 years from the making of the work, 50 years from the end of the calendar year of making.

5. Each Party shall confine limitations or exceptions to the rights provided for in this Article to certain special cases that do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.

6. No Party may grant translation and reproduction licenses permitted under the Appendix to the Berne Convention where legitimate needs in that Party's territory for copies or translations of the work could be met by the right holder's voluntary actions but for obstacles created by the Party's measures.

7. Annex 1705.7 applies to the Parties specified in that Annex.

Article 1706: Sound Recordings

1. Each Party shall provide to the producer of a sound recording the right to authorize or prohibit:

- (a) the direct or indirect reproduction of the sound recording;
- (b) the importation into the Party's territory of copies of the sound recording made without the producer's authorization;
- (c) the first public distribution of the original and each copy of the sound recording by sale, rental or otherwise; and
- (d) the commercial rental of the original or a copy of the sound recording, except where expressly otherwise provided in a contract between the producer of the sound recording and the authors of the works fixed therein.

Each Party shall provide that putting the original or a copy of a sound recording on the market with the right holder's consent shall not exhaust the rental right.

2. Each Party shall provide a term of protection for sound recordings of at least 50 years from the end of the calendar year in which the fixation was made.

3. Each Party shall confine limitations or exceptions to the rights provided for in this Article to certain special cases that do not conflict with a normal exploitation of the sound recording and do not unreasonably prejudice the legitimate interests of the right holder.

Article 1707: Protection of Encrypted ProgramCarrying Satellite Signals

Within one year from the date of entry into force of this Agreement, each Party shall make it:

- (a) a criminal offense to manufacture, import, sell, lease or otherwise make available a device or system that is primarily of assistance in decoding an encrypted program carrying satellite signal without the authorization of the lawful distributor of such signal; and

- (b) a civil offense to receive, in connection with commercial activities, or further distribute, an encrypted program carrying satellite signal that has been decoded without the authorization of the lawful distributor of the signal or to engage in any activity prohibited under subparagraph (a).

Each Party shall provide that any civil offense established under subparagraph (b) shall be actionable by any person that holds an interest in the content of such signal.

Article 1708: Trademarks

1. For purposes of this Agreement, a trademark consists of any sign, or any combination of signs, capable of distinguishing the goods or services of one person from those of another, including personal names, designs, letters, numerals, colors, figurative elements, or the shape of goods or of their packaging. Trademarks shall include service marks and collective marks, and may include certification marks. A Party may require, as a condition for registration, that a sign be visually perceptible.

2. Each Party shall provide to the owner of a registered trademark the right to prevent all persons not having the owner's consent from using in commerce identical or similar signs for goods or services that are identical or similar to those goods or services in respect of which the owner's trademark is registered, where such use would result in a likelihood of confusion. In the case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed. The rights described above shall not prejudice any prior rights, nor shall they affect the possibility of a Party making rights available on the basis of use.

3. A Party may make registrability depend on use. However, actual use of a trademark shall not be a condition for filing an application for registration. No Party may refuse an application solely on the ground that intended use has not taken place before the expiry of a period of three years from the date of application for registration.

4. Each Party shall provide a system for the registration of trademarks, which shall include:

- (a) examination of applications;
- (b) notice to be given to an applicant of the reasons for the refusal to register a trademark;
- (c) a reasonable opportunity for the applicant to respond to the notice;
- (d) publication of each trademark either before or promptly after it is registered; and
- (e) a reasonable opportunity for interested persons to petition to cancel the registration of a trademark.

A Party may provide for a reasonable opportunity for interested persons to oppose the registration of a trademark.

5. The nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to the registration of the trademark.

6. Article 6bis of the Paris Convention shall apply, with such modifications as may be necessary, to services. In determining whether a trademark is wellknown, account shall be taken of the knowledge of the trademark in the relevant sector of the public, including knowledge in the Party's territory obtained as a result of the promotion of the trademark. No Party may require that the reputation of the trademark extend beyond the sector of the public that normally deals with the relevant goods or services.

7. Each Party shall provide that the initial registration of a trademark be for a term of at least 10 years and that the registration be indefinitely renewable for terms of not less than 10 years when conditions for renewal have been met.

8. Each Party shall require the use of a trademark to maintain a registration. The registration may be canceled for the reason of non-use only after an uninterrupted period of at least two years of non-use, unless valid reasons based on the existence of obstacles to such use are shown by the trademark owner. Each Party shall recognize, as valid reasons for non- use, circumstances arising independently of the will of the trademark owner that constitute an obstacle to the use of the trademark, such as import restrictions on, or other government requirements for, goods or services identified by the trademark.

9. Each Party shall recognize use of a trademark by a person other than the trademark owner, where such use is subject to the owner's control, as use of the trademark for purposes of maintaining the registration.

10. No Party may encumber the use of a trademark in commerce by special requirements, such as a use that reduces the trademark's function as an indication of source or a use with another trademark.

11. A Party may determine conditions on the licensing and assignment of trademarks, it being understood that the compulsory licensing of trademarks shall not be permitted and that the owner of a registered trademark shall have the right to assign its trademark with or without the transfer of the business to which the trademark belongs.

12. A Party may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take into account the legitimate interests of the trademark owner and of other persons.

13. Each Party shall prohibit the registration as a trademark of words, at least in English, French or Spanish, that generically designate goods or services or types of goods or services to which the trademark applies.

14. Each Party shall refuse to register trademarks that consist of or comprise immoral, deceptive or scandalous matter, or matter that may disparage or falsely suggest a connection with persons, living or dead, institutions, beliefs or any Party's national symbols, or bring them into contempt or disrepute.

Article 1710: Layout Designs of Semiconductor Integrated Circuits

1. Each Party shall protect layout designs (topographies) of integrated circuits ("layout designs") in accordance with Articles 2 through 7, 12 and 16(3), other than Article 6(3), of the *Treaty on Intellectual Property in Respect of Integrated Circuits* as opened for signature on May 26, 1989.

2. Subject to paragraph 3, each Party shall make it unlawful for any person without the right holder's authorization to import, sell or otherwise distribute for commercial purposes any of the following:

- (a) a protected layout design;
- (b) an integrated circuit in which a protected layout design is incorporated; or
- (c) an article incorporating such an integrated circuit, only insofar as it continues to contain an unlawfully reproduced layout design.

3. No Party may make unlawful any of the acts referred to in paragraph 2 performed in respect of an integrated circuit that incorporates an unlawfully reproduced layout design, or any article that incorporates such an integrated circuit, where the person performing those acts or ordering those acts to be done did not know and had no reasonable ground to know, when it acquired the integrated circuit or article incorporating such an integrated circuit, that it incorporated an unlawfully reproduced layout design.

4. Each Party shall provide that, after the person referred to in paragraph 3 has received sufficient notice that the layout design was unlawfully reproduced, such person may perform any of the acts with respect to the stock on hand or ordered before such notice, but shall be liable to pay the right holder for doing so an amount equivalent to a reasonable royalty such as would be payable under a freely negotiated license in respect of such a layout design.

5. No Party may permit the compulsory licensing of layout designs of integrated circuits.

6. Any Party that requires registration as a condition for protection of a layout design shall provide that the term of protection shall not end before the expiration of a period of 10 years counted from the date of:

- (a) filing of the application for registration; or
- (b) the first commercial exploitation of the layout design, wherever in the world it occurs.

7. Where a Party does not require registration as a condition for protection of a layout design, the Party shall provide a term of protection of not less than 10 years from the date of the first commercial exploitation of the layout design, wherever in the world it occurs.

8. Notwithstanding paragraphs 6 and 7, a Party may provide that the protection shall lapse 15 years after the creation of the layout design.

9. Annex 1710.9 applies to the Parties specified in that Annex.

Article 1711: Trade Secrets

1. Each Party shall provide the legal means for any person to prevent trade secrets from being disclosed to, acquired by, or used by others without the consent of the person lawfully in control of the information in a manner contrary to honest commercial practices, in so far as:

- (a) the information is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons that normally deal with the kind of information in question;
- (b) the information has actual or potential commercial value because it is secret; and
- (c) the person lawfully in control of the information has taken reasonable steps under the circumstances to keep it secret.

2. A Party may require that to qualify for protection a trade secret must be evidenced in documents, electronic or magnetic means, optical discs, microfilms, films or other similar instruments.

3. No Party may limit the duration of protection for trade secrets, so long as the conditions in paragraph 1 exist.

4. No Party may discourage or impede the voluntary licensing of trade secrets by imposing excessive or discriminatory conditions on such licenses or conditions that dilute the value of the trade secrets.

5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

7. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.

Article 1712: Geographical Indications

1. Each Party shall provide, in respect of geographical indications, the legal means for interested persons to prevent:

- (a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a territory, region or locality other than the true place of origin, in a manner that misleads the public as to the geographical origin of the good;
- (b) any use that constitutes an act of unfair competition within the meaning of Article 10bis of the Paris Convention.

2. Each Party shall, on its own initiative if its domestic law so permits or at the request of an interested person, refuse to register, or invalidate the registration of, a trademark containing or consisting of a geographical indication with respect to goods that do not originate in the indicated territory, region or locality, if use of the indication in the trademark for such goods is of such a nature as to mislead the public as to the geographical origin of the good.

3. Each Party shall also apply paragraphs 1 and 2 to a geographical indication that, although correctly indicating the territory, region or locality in which the goods originate, falsely represents to the public that the goods originate in another territory, region or locality.

4. Nothing in this Article shall be construed to require a Party to prevent continued and similar use of a particular geographical indication of another Party in connection with goods or services by any of its nationals or domiciliaries who have used that geographical indication in a continuous manner with regard to the same or related goods or services in that Party's territory, either:

- (a) for at least 10 years, or
- (b) in good faith,

before the date of signature of this Agreement.

5. Where a trademark has been applied for or registered in good faith, or where rights to a trademark have been acquired through use in good faith, either:

- (a) before the date of application of these provisions in that Party, or
- (b) before the geographical indication is protected in its Party of origin,

no Party may adopt any measure to implement this Article that prejudices eligibility for, or the validity of, the registration of a trademark, or the right to use a trademark, on the basis that such a trademark is identical with, or similar to, a geographical indication.

6. No Party shall be required to apply this Article to a geographical indication if it is identical to the customary term in common language in that Party's territory for the goods or services to which the indication applies.

7. A Party may provide that any request made under this Article in connection with the use or registration of a trademark must be presented within five years after the adverse use of the protected indication has become generally known in that Party or after the date of registration of the trademark in that Party, provided that the trademark has been published by that date, if such date is earlier than the date on which the adverse use became generally known in that Party, provided that the geographical indication is not used or registered in bad faith.

8. No Party shall adopt any measure implementing this Article that would prejudice any person's right to use, in the course of trade, its name or the name of its predecessor in business, except where such name forms all or part of a valid trademark in existence before the geographical indication became protected and with which there is a likelihood of confusion, or such name is used in such a manner as to mislead the public.

9. Nothing in this Chapter shall be construed to require a Party to protect a geographical indication that is not protected, or has fallen into disuse, in the Party of origin.

Article 1713: Industrial Designs

1. Each Party shall provide for the protection of independently created industrial designs that are new or original. A Party may provide that:

- (a) designs are not new or original if they do not significantly differ from known designs or combinations of known design features; and
- (b) such protection shall not extend to designs dictated essentially by technical or functional considerations.

2. Each Party shall ensure that the requirements for securing protection for textile designs, in particular in regard to any cost, examination or publication, do not unreasonably impair a person's opportunity to seek and obtain such protection. A Party may comply with this obligation through industrial design law or copyright law.

3. Each Party shall provide the owner of a protected industrial design the right to prevent other persons not having the owner's consent from making or selling articles bearing or embodying a design that is a copy, or substantially a copy, of the protected design, when such acts are undertaken for commercial purposes.

4. A Party may provide limited exceptions to the protection of industrial designs, provided that such exceptions do not unreasonably conflict with the normal exploitation of protected industrial designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking into account the legitimate interests of other persons.

5. Each Party shall provide a term of protection for industrial designs of at least 10 years.

Article 1714: Enforcement of Intellectual Property Rights: General Provisions

1. Each Party shall ensure that enforcement procedures, as specified in this Article and Articles 1715 through 1718, are available under its domestic law so as to permit effective action to be taken against any act of infringement of intellectual property rights covered by this Chapter, including expeditious remedies to prevent infringements and remedies to deter further infringements. Such enforcement procedures shall be applied so as to avoid the creation of barriers to legitimate trade and to provide for safeguards against abuse of the procedures.

2. Each Party shall ensure that its procedures for the enforcement of intellectual property rights are fair and equitable, are not unnecessarily complicated or costly, and do not entail unreasonable timelimits or unwarranted delays.

3. Each Party shall provide that decisions on the merits of a case in judicial and administrative enforcement proceedings shall:

- (a) preferably be in writing and preferably state the reasons on which the decisions are based;
- (b) be made available at least to the parties in a proceeding without undue delay; and
- (c) be based only on evidence in respect of which such parties were offered the opportunity to be heard.

4. Each Party shall ensure that parties in a proceeding have an opportunity to have final administrative decisions reviewed by a judicial authority of that Party and, subject to jurisdictional provisions in its domestic laws concerning the importance of a case, to have reviewed at least the legal aspects of initial judicial decisions on the merits of a case. Notwithstanding the above, no Party shall be required to provide for judicial review of acquittals in criminal cases.

5. Nothing in this Article or Articles 1715 through 1718 shall be construed to require a Party to establish a judicial system for the enforcement of intellectual property rights distinct from that Party's system for the enforcement of laws in general.

6. For the purposes of Articles 1715 through 1718, the term "right holder" includes federations and associations having legal standing to assert such rights.

Article 1715: Specific Procedural and Remedial Aspects of Civil and Administrative Procedures

1. Each Party shall make available to right holders civil judicial procedures for the enforcement of any intellectual property right provided in this Chapter. Each Party shall provide that:

- (a) defendants have the right to written notice that is timely and contains sufficient detail, including the basis of the claims;
- (b) parties in a proceeding are allowed to be represented by independent legal counsel;

- (c) the procedures do not include imposition of overly burdensome requirements concerning mandatory personal appearances;
- (d) all parties in a proceeding are duly entitled to substantiate their claims and to present relevant evidence; and
- (e) the procedures include a means to identify and protect confidential information.

2. Each Party shall provide that its judicial authorities shall have the authority:

- (a) where a party in a proceeding has presented reasonably available evidence sufficient to support its claims and has specified evidence relevant to the substantiation of its claims that is within the control of the opposing party, to order the opposing party to produce such evidence, subject in appropriate cases to conditions that ensure the protection of confidential information;
- (b) where a party in a proceeding voluntarily and without good reason refuses access to, or otherwise does not provide relevant evidence under that party's control within a reasonable period, or significantly impedes a proceeding relating to an enforcement action, to make preliminary and final determinations, affirmative or negative, on the basis of the evidence presented, including the complaint or the allegation presented by the party adversely affected by the denial of access to evidence, subject to providing the parties an opportunity to be heard on the allegations or evidence;
- (c) to order a party in a proceeding to desist from an infringement, including to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, which order shall be enforceable at least immediately after customs clearance of such goods;
- (d) to order the infringer of an intellectual property right to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of the infringement where the infringer knew or had reasonable grounds to know that it was engaged in an infringing activity;
- (e) to order an infringer of an intellectual property right to pay the right holder's expenses, which may include appropriate attorney's fees; and
- (f) to order a party in a proceeding at whose request measures were taken and who has abused enforcement procedures to provide adequate compensation to any party wrongfully enjoined or restrained in the proceeding for the injury suffered because of such abuse and to pay that party's expenses, which may include appropriate attorney's fees.

3. With respect to the authority referred to in subparagraph 2(c), no Party shall be obliged to provide such authority in respect of protected subject matter that is acquired or ordered by a person before that person knew or had reasonable grounds to know that dealing in that subject matter would entail the infringement of an intellectual property right.

4. With respect to the authority referred to in subparagraph 2(d), a Party may, at least with respect to copyrighted works and sound recordings, authorize the judicial authorities to order recovery of profits or payment of pre-established damages, or both, even where the infringer did not know or had no reasonable grounds to know that it was engaged in an infringing activity.

5. Each Party shall provide that, in order to create an effective deterrent to infringement, its judicial authorities shall have the authority to order that:

- (a) goods that they have found to be infringing be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to avoid any injury caused to the right holder or, unless this would be contrary to existing constitutional requirements, destroyed; and
- (b) materials and implements the predominant use of which has been in the creation of the infringing goods be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements.

In considering whether to issue such an order, judicial authorities shall take into account the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of other persons. In regard to counterfeit goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.

6. In respect of the administration of any law pertaining to the protection or enforcement of intellectual property rights, each Party shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith in the course of the administration of such laws.

7. Notwithstanding the other provisions of Articles 1714 through 1718, where a Party is sued with respect to an infringement of an intellectual property right as a result of its use of that right or use on its behalf, that Party may limit the remedies available against it to the payment to the right holder of adequate remuneration in the circumstances of each case, taking into account the economic value of the use.

8. Each Party shall provide that, where a civil remedy can be ordered as a result of administrative procedures on the merits of a case, such procedures shall conform to principles equivalent in substance to those set out in this Article.

Article 1716: Provisional Measures

1. Each Party shall provide that its judicial authorities shall have the authority to order prompt and effective provisional measures:

- (a) to prevent an infringement of any intellectual property right, and in particular to prevent the entry into the channels of commerce in their jurisdiction of allegedly infringing goods, including measures to prevent the entry of imported goods at least immediately after customs clearance; and
- (b) to preserve relevant evidence in regard to the alleged infringement.

2. Each Party shall provide that its judicial authorities shall have the authority to require any applicant for provisional measures to provide to the judicial authorities any evidence reasonably

available to that applicant that the judicial authorities consider necessary to enable them to determine with a sufficient degree of certainty whether:

- (a) the applicant is the right holder;
- (b) the applicant's right is being infringed or such infringement is imminent; and
- (c) any delay in the issuance of such measures is likely to cause irreparable harm to the right holder, or there is a demonstrable risk of evidence being destroyed.

Each Party shall provide that its judicial authorities shall have the authority to require the applicant to provide a security or equivalent assurance sufficient to protect the interests of the defendant and to prevent abuse.

3. Each Party shall provide that its judicial authorities shall have the authority to require an applicant for provisional measures to provide other information necessary for the identification of the relevant goods by the authority that will execute the provisional measures.

4. Each Party shall provide that its judicial authorities shall have the authority to order provisional measures on an *ex parte basis* , in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.

5. Each Party shall provide that where provisional measures are adopted by that Party's judicial authorities on an *ex parte basis* :

- (a) a person affected shall be given notice of those measures without delay but in any event no later than immediately after the execution of the measures;
- (b) a defendant shall, on request, have those measures reviewed by that Party's judicial authorities for the purpose of deciding, within a reasonable period after notice of those measures is given, whether the measures shall be modified, revoked or confirmed, and shall be given an opportunity to be heard in the review proceedings.

6. Without prejudice to paragraph 5, each Party shall provide that, on the request of the defendant, the Party's judicial authorities shall revoke or otherwise cease to apply the provisional measures taken on the basis of paragraphs 1 and 4 if proceedings leading to a decision on the merits are not initiated:

- (a) within a reasonable period as determined by the judicial authority ordering the measures where the Party's domestic law so permits; or
- (b) in the absence of such a determination, within a period of no more than 20 working days or 31 calendar days, whichever is longer.

7. Each Party shall provide that, where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where the judicial authorities subsequently find that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, on request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.

8. Each Party shall provide that, where a provisional measure can be ordered as a result of administrative procedures, such procedures shall conform to principles equivalent in substance to those set out in this Article.

Article 1717: Criminal Procedures and Penalties

1. Each Party shall provide criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. Each Party shall provide that penalties available include imprisonment or monetary fines, or both, sufficient to provide a deterrent, consistent with the level of penalties applied for crimes of a corresponding gravity.

2. Each Party shall provide that, in appropriate cases, its judicial authorities may order the seizure, forfeiture and destruction of infringing goods and of any materials and implements the predominant use of which has been in the commission of the offense.

3. A Party may provide criminal procedures and penalties to be applied in cases of infringement of intellectual property rights, other than those in paragraph 1, where they are committed wilfully and on a commercial scale.

Article 1718: Enforcement of Intellectual Property Rights at the Border

1. Each Party shall, in conformity with this Article, adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark goods or pirated copyright goods may take place, to lodge an application in writing with its competent authorities, whether administrative or judicial, for the suspension by the customs administration of the release of such goods into free circulation. No Party shall be obligated to apply such procedures to goods in transit. A Party may permit such an application to be made in respect of goods that involve other infringements of intellectual property rights, provided that the requirements of this Article are met. A Party may also provide for corresponding procedures concerning the suspension by the customs administration of the release of infringing goods destined for exportation from its territory.

2. Each Party shall require any applicant who initiates procedures under paragraph 1 to provide adequate evidence:

- (a) to satisfy that Party's competent authorities that, under the domestic laws of the country of importation, there is *prima facie* an infringement of its intellectual property right; and
- (b) to supply a sufficiently detailed description of the goods to make them readily recognizable by the customs administration.

The competent authorities shall inform the applicant within a reasonable period whether they have accepted the application and, if so, the period for which the customs administration will take action.

3. Each Party shall provide that its competent authorities shall have the authority to require an applicant under paragraph 1 to provide a security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to these procedures.

4. Each Party shall provide that, where pursuant to an application under procedures adopted pursuant to this Article, its customs administration suspends the release of goods involving industrial designs, patents, integrated circuits or trade secrets into free circulation on the basis of a decision other than by a judicial or other independent authority, and the period provided for in paragraphs 6 through 8 has expired without the granting of provisional relief by the duly empowered authority, and provided that all other conditions for importation have been complied with, the owner, importer or consignee of such goods shall be entitled to their release on the posting of a security in an amount sufficient to protect the right holder against any infringement. Payment of such security shall not prejudice any other remedy available to the right holder, it being understood that the security shall be released if the right holder fails to pursue its right of action within a reasonable period of time.

5. Each Party shall provide that its customs administration shall promptly notify the importer and the applicant when the customs administration suspends the release of goods pursuant to paragraph 1.

6. Each Party shall provide that its customs administration shall release goods from suspension if within a period not exceeding 10 working days after the applicant under paragraph 1 has been served notice of the suspension the customs administration has not been informed that:

- (a) a party other than the defendant has initiated proceedings leading to a decision on the merits of the case, or
- (b) a competent authority has taken provisional measures prolonging the suspension,

provided that all other conditions for importation or exportation have been met. Each Party shall provide that, in appropriate cases, the customs administration may extend the suspension by another 10 working days.

7. Each Party shall provide that if proceedings leading to a decision on the merits of the case have been initiated, a review, including a right to be heard, shall take place on request of the defendant with a view to deciding, within a reasonable period, whether these measures shall be modified, revoked or confirmed.

8. Notwithstanding paragraphs 6 and 7, where the suspension of the release of goods is carried out or continued in accordance with a provisional judicial measure, Article 1716(6) shall apply.

9. Each Party shall provide that its competent authorities shall have the authority to order the applicant under paragraph 1 to pay the importer, the consignee and the owner of the goods appropriate compensation for any injury caused to them through the wrongful detention of goods or through the detention of goods released pursuant to paragraph 6.

10. Without prejudice to the protection of confidential information, each Party shall provide that its competent authorities shall have the authority to give the right holder sufficient opportunity to have any goods detained by the customs administration inspected in order to substantiate the right holder's claims. Each Party shall also provide that its competent authorities have the authority to give the importer an equivalent opportunity to have any such goods inspected. Where the competent authorities have made a positive determination on the merits of a case, a Party may provide the competent authorities the authority to inform the right holder of the names and addresses of the consignor, the importer and the consignee, and of the quantity of the goods in question.

11. Where a Party requires its competent authorities to act on their own initiative and to suspend the release of goods in respect of which they have acquired prima facie evidence that an intellectual property right is being infringed:

- (a) the competent authorities may at any time seek from the right holder any information that may assist them to exercise these powers;
- (b) the importer and the right holder shall be promptly notified of the suspension by the Party's competent authorities, and where the importer lodges an appeal against the suspension with competent authorities, the suspension shall be subject to the conditions, with such modifications as may be necessary, set out in paragraphs 6 through 8; and
- (c) the Party shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith.

12. Without prejudice to other rights of action open to the right holder and subject to the defendant's right to seek judicial review, each Party shall provide that its competent authorities shall have the authority to order the destruction or disposal of infringing goods in accordance with the principles set out in Article 1715(5). In regard to counterfeit goods, the authorities shall not allow the re exportation of the infringing goods in an unaltered state or subject them to a different customs procedure, other than in exceptional circumstances.

13. A Party may exclude from the application of paragraphs 1 through 12 small quantities of goods of a non-commercial nature contained in travellers' personal luggage or sent in small consignments that are not repetitive.

14. Annex 1718.14 applies to the Parties specified in that Annex.

Article 1719: Cooperation and Technical Assistance

1. The Parties shall provide each other on mutually agreed terms with technical assistance and shall promote cooperation between their competent authorities. Such cooperation shall include the training of personnel.

2. The Parties shall cooperate with a view to eliminating trade in goods that infringe intellectual property rights. For this purpose, each Party shall establish and notify the other Parties by January 1, 1994 of contact points in its federal government and shall exchange information concerning trade in infringing goods.

Article 1720: Protection of Existing Subject Matter

1. Except as required under Article 1705(7), this Agreement does not give rise to obligations in respect of acts that occurred before the date of application of the relevant provisions of this Agreement for the Party in question.

2. Except as otherwise provided for in this Agreement, each Party shall apply this Agreement to all subject matter existing on the date of application of the relevant provisions of this Agreement for the Party in question and that is protected in a Party on such date, or that meets or subsequently meets the criteria for protection under the terms of this Chapter. In respect of this paragraph and paragraphs 3 and 4, a Party's obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention and with respect to the rights of producers of sound recordings in existing sound recordings shall be determined solely under Article 18 of that Convention, as made applicable under this Agreement.

3. Except as required under Article 1705(7), and notwithstanding the first sentence of paragraph 2, no Party may be required to restore protection to subject matter that, on the date of application of the relevant provisions of this Agreement for the Party in question, has fallen into the public domain in its territory.

4. In respect of any acts relating to specific objects embodying protected subject matter that become infringing under the terms of laws in conformity with this Agreement, and that were begun or in respect of which a significant investment was made, before the date of entry into force of this Agreement for that Party, any Party may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Party. In such cases, the Party shall, however, at least provide for payment of equitable remuneration.

5. No Party shall be obliged to apply Article 1705(2)(d) or 1706(1)(d) with respect to originals or copies purchased prior to the date of application of the relevant provisions of this Agreement for that Party.

6. No Party shall be required to apply Article 1709(10), or the requirement in Article 1709(7) that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the text of the Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations became known.

7. In the case of intellectual property rights for which protection is conditional on registration, applications for protection that are pending on the date of application of the relevant provisions of this Agreement for the Party in question shall be permitted to be amended to claim any enhanced protection provided under this Agreement. Such amendments shall not include new matter.

Article 1721: Definitions

1. For purposes of this Chapter:

confidential information includes trade secrets, privileged information and other materials exempted from disclosure under the Party's domestic law.

2. For purposes of this Agreement:

encrypted program-carrying satellite signal means a program-carrying satellite signal that is transmitted in a form whereby the aural or visual characteristics, or both, are modified or altered for the purpose of preventing the unauthorized reception, by persons without the authorized equipment that is designed to eliminate the effects of such modification or alteration, of a program carried in that signal;

geographical indication means any indication that identifies a good as originating in the territory of a Party, or a region or locality in that territory, where a particular quality, reputation or other characteristic of the good is essentially attributable to its geographical origin;

in a manner contrary to honest commercial practices means at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by other persons who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition;

intellectual property rights refers to copyright and related rights, trademark rights, patent rights, rights in layout designs of semiconductor integrated circuits, trade secret rights, plant breeders' rights, rights in geographical indications and industrial design rights;

nationals of another Party means, in respect of the relevant intellectual property right, persons who would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Geneva Convention (1971), the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (1961), the UPOV Convention (1978), the UPOV Convention (1991) or the *Treaty on Intellectual Property in Respect of Integrated Circuits* , as if each Party were a party to those Conventions, and with respect to intellectual property rights that are not the subject of these Conventions, "nationals of another Party" shall be understood to be at least individuals who are citizens or permanent residents of that Party and also includes any other natural person referred to in Annex 201.1 (CountrySpecific Definitions);

public includes, with respect to rights of communication and performance of works provided for under Articles 11, 11bis(1) and 14(1)(ii) of the Berne Convention, with respect to dramatic, dramatico-musical, musical and cinematographic works, at least, any aggregation of individuals intended to be the object of, and capable of perceiving, communications or performances of works, regardless of whether they can do so at the same or different times or in the same or different places, provided that such an aggregation is larger than a family and its immediate circle of acquaintances or is not a group comprising a limited number of individuals having

similarly close ties that has not been formed for the principal purpose of receiving such performances and communications of works; and

secondary uses of sound recordings means the use directly for broadcasting or for any other public communication of a sound recording.

Annex 1701.3

Intellectual Property Conventions

1. Mexico shall:

- (a) make every effort to comply with the substantive provisions of the 1978 or 1991 UPOV Convention as soon as possible and shall do so no later than two years after the date of signature of this Agreement; and
- (b) accept from the date of entry into force of this Agreement applications from plant breeders for varieties in all plant genera and species and grant protection, in accordance with such substantive provisions, promptly after complying with subparagraph (a).

2. Notwithstanding Article 1701(2)(b), this Agreement confers no rights and imposes no obligations on the United States with respect to Article 6bis of the Berne Convention, or the rights derived from that Article.

Annex 1705.7

Copyright

The United States shall provide protection to motion pictures produced in another Party's territory that have been declared to be in the public domain pursuant to 17 U.S.C. section 405. This obligation shall apply to the extent that it is consistent with the Constitution of the United States, and is subject to budgetary considerations.

Annex 1710.9

Layout Designs

Mexico shall make every effort to implement the requirements of Article 1710 as soon as possible, and shall do so no later than four years after the date of entry into force of this Agreement.

Annex 1718.14

Enforcement of Intellectual Property Rights

Mexico shall make every effort to comply with the requirements of Article 1718 as soon as possible and shall do so no later than three years after the date of signature of this Agreement.