

Trade Agreements and Pharmaceutical Patent Protection:
Implications for the Governance over Pharmaceutical Products in
Canada

Danalyn Byng

Introduction

This paper will explore the theme of Globalization and Trade Deals; more specifically, the laws and regulations of international trade deals that govern the intellectual property protection of pharmaceutical products. As Canada participates in a number of international trade agreements, the focus of this paper is to look at the impact that intellectual property protection (commonly referred to as patent protection) has had on the affordability and accessibility of pharmaceutical products to Canadians. This paper will also go on to examine whether current trade deals that emphasize the importance of lengthy patents are effective in achieving their stated goals.

In the last few decades, the reach of globalization has grown to create rapid changes in our global and national economy. It has allowed for international capital flows and exchange of goods and services, essentially creating what we now know to be a global marketplace. Alongside this, we have seen the intensification of what has now become a crucial element of globalization – trade liberalization. Over time, this has translated into the creation of trade agreements between countries, essentially allowing certain industries to become “multinational” in scope. In the middle of this has been the pharmaceutical industry; now a prime example of how globalization and free trade acts to provide further growth and profit for large industries.

Embedded in trade agreements are laws and regulations in place to protect these industries, and in the case of the pharmaceutical industry there is the existence of what is referred to as intellectual property protection. Commonly known as “patent protection,” there has been an almost inseparable link between the pharmaceutical industry, patent protection, and trade agreements (Lexchin, 2001, p. 1). Within the last decade, drug prices have nearly doubled - (Lexchin, 2001, p. 5) and many studies have contributed this exponential growth of price to extensive patent laws.

History of Pharmaceutical Policy in Canada

Starting in 1987, Canada saw its first extensive changes to the country’s Patent Act that would effectively lengthen the period of patent protection for pharmaceutical products. The first major change came in the form of Bill C-22, which secured protection from compulsory licensing for new drugs for a minimum of seven years. Within a period of five years, this patent protection more than doubled to a length of twenty years and was followed by a series of other amendments to the Patent Act. During this time, the Canadian government was immersed in negotiating international trade agreements that called upon the synchronization of Canada’s policy on intellectual property with that of other industrialized countries (Lexchin, 1992, p. 5). It was found that portions of Canada’s Patent Act that focused on compulsory licensing for pharmaceutical products was incompatible with certain agreements that were being drafted by the World Trade Organization (WTO) (Smith, 2000). The specific WTO agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) contained “minimum” provisions and standards for the protection of intellectual property that Canada had not met. Since all WTO agreements apply to all WTO members (which includes Canada), it was necessary for the federal government to further modify the Patent Act by introducing Bill C-91, the Patent Act Amendment Act, 1992, in the House of Commons. This served to implement the necessary TRIPS provisions on intellectual property, and to also meet the requirements of the provisions mandatory for involvement in the North American Free Trade Agreement (NAFTA.) Included in Bill C-91 was the abolishing of compulsory licensing, and patent life being changed from 17 years from date patent granted to 20 years from date patent filed (Lexchin, 2001, p.2). Needless

to say, Canada's historical involvements in international trade agreements have had a clear impact on policy formation and implementation surrounding the creation, pricing, and use of pharmaceutical products.

In the present, Canada and the European Union have been negotiating a new trade agreement called the Canada-European Union Comprehensive Economic & Trade Agreement (CETA). The intention of this agreement is to see to reducing tariffs and trade restrictions; however it does include a series of further revisions to Canada's laws that govern intellectual and patent protection for brand-name drugs. The argument of the European and "big-pharma" proponents of these changes falls under the idea that Canada's legal regime for intellectual property is not on par to European standards – despite the fact that Canada upholds intellectual property standards at the levels of those required by the WTO and NAFTA. The EU has put forth three proposed changes in their negotiations, and they are as follows:

(1) Extending the term of patent protection by up to five years if drugs are stuck in the regulatory approval process; (2) lengthening the period of data exclusivity, which prevents generic companies from using data from clinical trials to create similar drugs, from eight years to 10 years or more; and (3) strengthening notice of compliance regulations, which ensure that generic companies are respecting patents, by adding an appeals process (Picard, 2011).

Considerable policy decisions would have to be made in order to accommodate these proposed changes. In response, proponents and opponents to Canada's ever-lengthening patent protections laws have argued heatedly about what benefits and downfalls they can see that these changes will have on Canada's economy, consumer behaviour, and public and private sector health care costs.

Strengths and Weaknesses of Policy Decisions

For those pushing the amendments to intellectual property laws in Canada, their argument stands behind the reasoning that there are still currently factors that obstruct the full potential of patent laws. While Canada does uphold international standards that provide a 20-year life for patents, lengthy clinical trial and regulatory approval processes take away from this time – resulting in a much shorter period of market exclusivity for these products. Brand-name pharmaceutical companies strongly argue that this results in an insufficient amount of time to make up the heavy costs of research and development that were necessary for creating the new drugs. This has further implications for the foreign investment and funding of Canadian-based research and development. Canada's Research-Based Pharmaceutical Companies (the industry organization for brand-name drug companies) argue that without intellectual property regimes being at the same level of those in European and American markets, there is little incentive for pharmaceutical companies to invest in Canadian-based research and development (Trichur, 2011).

The first two of the three proposed amendments were put forth in order to combat these "time-frame" obstacles. The final proposed EU amendment acts upon another type of patent legislation known as the Patented Medicines (Notice of Compliance) Regulations. It calls on Canada to grant pharmaceutical companies a vigorous appeals process against generic manufacturers, "to ensure that generic companies are respecting patents" (Picard, 2011). Once a generic drug has been deemed safe and effective by Health Canada and the Minister of Health, they are granted a "Notice of Compliance" to begin selling the generic drug in the market. There

is currently no appeals process available for brand-name drug companies to fight against this decision making.

Critics and those opposed to strengthening patent laws have argued that even existing patent protection is too excessive and costly, and that further changes could add upwards of \$2.8 billion per year in extra costs to Canadians (Grootendorst & Hollis, 2011, p. 3). According to the Canadian Institute for Health Information, spending on drugs made up about 16% of the health care dollar last year – at \$31.1 billion. This number continues to grow each year (CIHI, 2010). There is no denying that the use of pharmaceuticals has become integral to improving the health of many: they protect from illness, cure diseases, and help to manage chronic health conditions. If we consider the prescribing practices of most doctors, it is unlikely that one would leave a doctor's appointment without a prescription – no matter what the health condition. Knowing this, it is important to recognize that a significant proportion of spending on pharmaceuticals comes from out-of-pocket spending, totalling \$4.6 billion last year (CIHI, 2010). This has been cause for concern for many as most coverage for pharmaceuticals in Canada is not under any provincial public insurance plans (CIHI, 2010). Users of pharmaceutical drugs must depend on private insurance plans, and coverage may not always be comprehensive. Furthermore, some Canadians may completely lack prescription drug coverage. Here it is important to note another consequence of globalization: that of the growing reliance on contract and casual workers. Most of these temporary and part-time workers are not eligible for employee benefits that would include drug coverage. With the costs of pharmaceuticals on the rise, the impact on Canadians could potentially be very harmful for the future generations of workers and users of the Canadian health care system.

An increasing number of opponents to these trade agreements have also highlighted a number of other issues with the reasoning of brand-name drug industries to extend and strengthen patent laws. There has been concern over the practice of using tactics to extend patent protection beyond the 20 years allotted by current legislation. The first tactic, termed “evergreening,” occurs when manufacturers develop re-makes of existing drugs in order to extend the patent life of their products (Hore, 2004, p. 5). These re-makes are not much more different from older drugs, and not more effective. Studies in the United States of drugs that were approved between 1998 and 2002 found that only 14 percent were truly innovative, 9 percent were updated versions of older drugs, and 77 percent were re-makes of existing drugs, commonly known as “me-too” drugs (Terry, 2007, p.145). This reality calls into question the validity of the brand-name drug companies’ argument that patent protection is needed to make up the extensive research and development costs. It would make sense if the majority of drugs created were “truly innovative,” but they are not. Another tactic has been used in response to “Notice of Compliance” regulations: many brand-name pharmaceutical companies have been known to purposely start court cases, asserting that their patents are infringed by generic products, because they know this will automatically keep the generic competitor out of the market for 24 months (whether or not their assertion has validity) (Hore, 2004, p. 3). The addition of an appeals process will therefore work solely to further delay the approval of generic drugs and extend their monopoly of the market.

These methods are tried and true – they allow brand-name pharmaceutical companies to continue to extort profit from the market, at the cost of having affordable pharmaceuticals available to the public. Abbott (2006) highlights that large amounts of revenue can be guaranteed through patent protection – as new products will essentially have secured protected markets, without the competition of any generic drugs. These revenues can be used to cover research and

development costs; however, “they may also be used to cover the costs of stronger global sales forces, more extensive advertising and promotion, and political lobbying” (p. 28) – all of which are strategies that encourage the growth of profit. These examples are proof that the pharmaceutical industry is primarily profit driven, and that extending and strengthening patent legislation in Canada will only work to unnecessarily add more money to the pocket of this industry.

How to Approach the Problem

The 2002 Romanow Commission on the Future of Health Care identified these areas of concern in pharmaceutical patenting, and responded with the following recommendation: “the federal government should review this issue, determine what constitutes a legitimate extension of patent protection, and also consider ways of streamlining the approval of generic drugs” (Romanow, 2002, p. 209). Since this recommendation was made, the federal government has since gone on to attempt further trade deals with other countries that carry with them compulsory advances of patent legislation. There have been no government-lead reviews of this issue – the fate of affordable pharmaceuticals for Canadians appears to remain in the powerful hands of “big-pharma” – especially if these trade agreements are successful. Grieshaber-Otto & Sinclair (2004) point out that “oversight by an international trade body committed to expanding commercial opportunities for foreign providers [is] both highly problematic and fundamentally undemocratic” (p. 31). The evidence now points to the understanding that perhaps the government truly considers the security of international trade agreements as enough to constitute the legitimate extension of patent protection.

Referencing back to the lecture on Globalization and International Trade Deals given by P. Holyoke (2011), it can easily be seen in the case of the pharmaceutical industry that it is almost impossible to separate the impact of free trade from the consequences of pricing and cost in this market. Trade agreements have increasingly allowed a very important part of health care “to be managed by a profit-making group” (Armstrong & Armstrong, 1991, p.3). It is multi-national companies that dominate the brand-name sector of the pharmaceutical industry (Pazderka, 1999, p. 29). And so it is these multi-national companies that have the most to win from a multi-national trade agreement that allows them to have strong patent protection for their brand-name drugs in their biggest markets world-wide. The accompanying impact of choices made about patent systems will be wide spread, “influencing the size of future investment in medical research, the availability of resulting therapies, how the financial burdens are distributed...and finally the health of consumers” (Lanjouw, 2005, p. 3).

It is important to note here that before strong patent protection legislation came to Canada in the late eighties, the existence of compulsory licensing created substantial savings for consumers and governments. It allowed cheaper generic substitutes for brand-name prescription drugs to be created and marketed to the public in much easier ways than what exists in the present-day. Consequently, it largely impacted the profit capabilities of patent holding multinational brand-name companies, to which they responded with “publicizing their reluctance to invest and conduct research and development in Canada” (Pazderka, 1999, p. 30). Now, the abolishing of compulsory licensing and creation of strong patent protection has become a main component to many trade agreements. It is clear that the demands made by multi-national pharmaceutical companies are now tied up and masked as the demands of international trade agreements.

Conclusion

Over the last two decades, the government of Canada has faced pressures from all sides regarding patent legislation. As the pull of globalization has increased, so too have these pressures. There is pressure to follow through with international trade agreements, to meet the demands of large industries, and the pressure to foster affordable health care for Canadian citizens. Permanand & Altenstetter (2004) note that policy makers face overlapping and at times competing regulatory tasks:

(There) is a responsibility to the consumer in terms of guaranteeing that only safe, good-quality and efficacious medicines make it to the market. Next is the balancing of health care budgets with regard to controlling health expenditures and drug costs. And third...given the economic contribution of the sector, is to promote a regulatory environment conducive to business (p. 39).

As can be seen with the most recent CETA negotiations, even “small” proposed changes can have major negative impacts on the affordability of pharmaceuticals. The implications of denying the implementation of the requirements of these trade agreements can be major. It is very difficult to find a “middle ground” in a time where the forces of globalization and trade liberalization are so strongly felt. Unfortunately, most of the time it is “big pharma” that benefits from these trade agreements, and even more unfortunate is the reality that the success and security of these trade agreements ride on the government’s acceptance of these changes to patent legislation. Needless to say, policies that have been developed in this area have been a failure to Canada’s Health Care system and to all those that use it. Little to no benefit has come to those who rely so heavily on pharmaceutical therapies as they have become increasingly more expensive and inaccessible.

References

Abbot, F. (2006). The Cycle of Action and Redaction: Developments and Trends in Intellectual Property and Health. In P. Roffe, G. Tansey & D. Vivas-Eugui (Eds.), *Negotiating Health: Intellectual Property and Access to Medicines* (27-40). London: Earthscan.

Armstrong, P. & Armstrong, H. (1991). *Health Care as a Business: The legacy of free trade*. Ottawa: Canadian Centre for Policy Alternatives.

Canadian Institute for Health Information. (2010). *Drug Expenditure in Canada, 1985-2010* [Data file]. Retrieved from http://secure.cihi.ca/cihiweb/products/drug_expenditure_2010_en.pdf

Grieshaber-Otto, J. & Sinclair, S. (2004). Key trade treaty rules and health safeguards. In *Bad Medicine* (chapter 2). Retrieved from http://www.policyalternatives.ca/sites/default/files/uploads/publications/National_Office_Pubs/bad_medicine.pdf

Grootendorst, P. (2009). *Patents, public-private partnerships or prizes: How should we support pharmaceutical innovation?* Hamilton, ON: Program for Research on Social and Economic Dimensions of an Aging Population, McMaster University.

Grootendorst, P. & Hollis, A. (2011, February 7). The Canadian-European Union Comprehensive Economic & Trade Agreement: An economic impact assessment of proposed pharmaceutical intellectual property provisions. Retrieved from http://www.canadiangenerics.ca/en/news/docs/02.07.11CETA_EconomicImpactAssessment-FinalEnglish.pdf

Hore, E. (2004). *Patently absurd: Evergreening of pharmaceutical patent protection under the patented medicines (Notice of Compliance) regulations of Canada's Patent Act*. Toronto, ON: Canadian Generic Pharmaceutical Association.

Lanjouw, J. (2005). *Patents, Price Controls and Access to New Drugs: How policy affects global market entry* (National Bureau of Economic Research Working Paper 11321). Retrieved from <http://www.nber.org.ezproxy.library.yorku.ca/papers/w11321.pdf>

Lexchin, J. (1992). *Pharmaceuticals, patents and politics: Canada and Bill C-22*. Ottawa, ON: The Canadian Centre for Policy Alternatives.

Lexchin, J. (2001). Globalization, trade deals and drugs: Heads the industry wins, tails Canada loses. *Canadian Centre for Policy Alternatives Briefing Paper Series: Trade and Investment*, 2(8). Retrieved from http://www.policyalternatives.ca/sites/default/files/uploads/publications/National_Office_Pubs/brief2_8.pdf

Lexchin, J. (2005). Intellectual property rights and the Canadian pharmaceutical marketplace: where do we go from here? *International Journal of Health Services*, 35(5), 237-56.

Permanand, G. & Altenstetter, C. (2004). The politics of pharmaceuticals in the European Union. In E. Mossialos, M. Mrazek & T. Walley (Eds.), *Regulating pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality* (38-54). Maidenhead: Open University Press.

Pazderka, B. (1999). Patent Protection and Pharmaceutical R&D Spending in Canada. *Canadian Public Policy*, 25(1), 29-46.

Picard, A. (2011, February 7). EU trade deal could cost Canadian drug plan billions. *The Globe and Mail*. Retrieved from <http://www.theglobeandmail.com/life/health/eu-trade-deal-could-cost-canadian-drug-plans-billions/article1896747/>

Romanow, R. J. (2002) *Building on Values: The Future of Health Care in Canada*. Saskatoon: Commission on the Future of Health Care in Canada.

Smith, M. (2000). Patent protection for pharmaceutical products in Canada: Chronology of significant events. Retrieved from Library of Parliament, Parliamentary Research Branch: <http://dsp-psd.communication.gc.ca/Collection-R/LoPBdP/BP/prb9946-e.htm>

Silbermann, J. M. (1996). The North American Free Trade Agreement's effect on pharmaceutical patents: a bitter pill to swallow or a therapeutic solution? *Journal of Contemporary Health Law and Policy*, 12(2), 607-36.

Terry, K. (2007). *Rx for Health Care Reform*. Nashville: Vanderbilt University Press.

Trichur, R. (2011, October 3). EU trade deal is riding on changes to Canada's drug-patent laws. *The Globe and Mail*. Retrieved from <http://www.theglobeandmail.com/news/national/time-to-lead/eu-trade-deal-is-riding-on-changes-to-canadas-drug-patent-laws/article2189928/>