

**Strong Medicine:
Can Free Trade
Agreements
Cure Canada's
Pharmaceutical Ills?**

Pills Patents & Profits III

**By Stefania
Bartucci
and Laura Dawson**

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EXECUTIVE SUMMARY

International trade negotiations have long shaped Canada's intellectual property (IP) regime for pharmaceutical products. In its current round of negotiations with the European Union and Asia Pacific states, Canada faces complex and difficult choices regarding pharmaceutical IP reform. The challenge is how to achieve a successful conclusion to the negotiations while balancing important domestic public health and economic objectives.

A robust IP regime stimulates R&D by allowing innovators to recover their costs, which encourages the introduction and use of new drugs. It also encourages the creation of a market for knowledge and technology. However, the benefits of strong IP protection have to be balanced against potential increases in drug costs and the economic impact of rent seeking.

In light of pressure to reform IP rules through various international agreements, Canada needs to take into account how the proposed provisions will affect our domestic institutions and industry, specifically:

- an innovative pharmaceutical sector, directly employing 15,000 people, and contributing \$1 billion in R&D investment in Canada;
- an emerging biopharmaceutical sector which has promising growth implications for Canada's knowledge economy but may fail to thrive because of high-upfront costs and global competition;
- a generic pharmaceutical sector, employing over 11,000 people and providing affordable drugs to Canadian consumers and for export; and
- public and private sector drug buyers seeking the latest innovations, secure access, affordable prices, and product safety.

To conclude the CETA negotiations, Canada may have to agree to significant domestic policy changes in the areas of patent term extension, data exclusivity, and right of appeal for innovators. The results of these negotiations will set the parameters of Canada's bargaining position on intellectual property commitments in the TPP negotiations. Unless the CETA results in significant domestic reforms, Canada may be faced with demands for more extensive IP commitments in the TPP.

As these important trade negotiations move forward, our recommendations are as follows:

- 1. Objective analysis of the potential effects of IP reform in Canada** – If there is indeed a threshold beyond which the costs of stronger IP outweigh the benefits, it is essential to explore what that threshold might be. The Government of Canada should produce, and make public, a study of how potential reforms in IP policy will affect the domestic pharmaceutical industry and the health care sector.
- 2. Review the system that supports pharmaceutical sector innovation** – An evaluation of the other programs and tools to stimulate innovation in the pharmaceutical sector will assist in determining the relative impact of IP on innovative activity.. This evaluation can inform our negotiating positions in future trade agreements, and any other proposed changes to Canada's domestic IP regime.
- 3. Obtain commitments from the innovative pharmaceutical industry for R&D expenditures in Canada** – Stronger IP will provide these companies with more certainty of market exclusivity, and thus enhance the extent to which they can recover R&D investment. However, the effects of stronger IP on drug expenditure and availability are uncertain, and there is a possibility that IP reform will increase the costs of drugs for provincial governments and other consumers. Given the ambiguity associated with these potential impacts, if Canada agrees to stronger IP for pharmaceuticals, it should do so in exchange for a commitment from industry to spend a certain percentage of sales on R&D in Canada, similar to the agreement made between industry and the government in the late 1980s.

SOMMAIRE EXÉCUTIF

Depuis longtemps, les négociations commerciales internationales façonnent le régime canadien de propriété intellectuelle (PI) en matière de produits pharmaceutiques. La présente ronde de négociations avec l'Union européenne (UE) et les États de l'Asie-Pacifique confronte le Canada à des choix difficiles et complexes à l'égard d'une réforme de la propriété intellectuelle. Le défi est de découvrir la manière de parvenir à une heureuse conclusion des négociations tout en équilibrant les importants objectifs économiques et de santé publique nationale.

Un régime de PI solide favorise la R&D en permettant aux innovateurs de recouvrer leurs coûts, ce qui encourage l'introduction et la diffusion de nouveaux médicaments. Il soutient également la création d'un marché du savoir et de la technologie. Cependant, on doit viser un équilibre entre, d'une part, les avantages d'une PI forte et, d'autre part, le potentiel de hausse des coûts des médicaments et les conséquences économiques de la recherche de rentes.

Compte tenu de la réforme de la réglementation de la propriété intellectuelle qui s'impose en raison de divers accords internationaux, le Canada doit tenir compte de l'incidence des dispositions proposées sur ses institutions et son industrie, en particulier sur :

- un secteur pharmaceutique innovateur qui emploie directement 15 000 personnes et génère au Canada 1 milliard de dollars en investissements dans la R&D;
- un secteur biopharmaceutique naissant qui a un potentiel prometteur pour la croissance de l'économie du savoir au Canada, mais qui risque de ne pas se développer en raison des coûts initiaux élevés et de la concurrence mondiale;
- un secteur pharmaceutique générique qui emploie plus de 11 000 personnes et fournit des médicaments à des coûts abordables pour les consommateurs canadiens et les exportateurs;
- des acheteurs publics et privés de médicaments à l'affût des plus récentes innovations, d'un approvisionnement garanti, de prix abordables et de produits sûrs.

Pour réussir les négociations de l'Accord économique et commercial global (l'AÉCG), le Canada pourrait devoir accepter des changements significatifs de politique intérieure en matière de prolongation des brevets, d'exclusivité des données et de droit d'appel pour les innovateurs. Le résultat de ces négociations délimitera notre position dans nos négociations avec le Partenariat transpacifique (PT) en matière d'engagements à l'égard de la propriété intellectuelle. À moins que les résultats de l'AÉCG ne se soldent par des réformes intérieures importantes, le Canada pourrait devoir faire face à une demande d'engagements de la part du PT à l'égard d'un élargissement de la propriété intellectuelle.

Comme ces importantes négociations commerciales progressent, nos recommandations sont les suivantes :

- 1. L'analyse objective des effets potentiels de la réforme de la PI au Canada** – s'il y a bien un seuil au-delà duquel les coûts d'une PI plus forte l'emportent sur les avantages, il est essentiel de tenter de le cerner. Le gouvernement canadien devrait produire et rendre publique une étude des incidences sur l'industrie pharmaceutique nationale et le secteur des soins de santé des réformes de la politique de propriété intellectuelle qui pourraient être réalisées.
- 2. La revue du système qui soutient l'innovation dans le secteur pharmaceutique** – une évaluation des autres programmes et outils axés sur l'innovation dans le secteur pharmaceutique aidera à déterminer l'impact relatif de la propriété intellectuelle sur l'activité d'innovation. Cette évaluation pourrait servir de guide pour nos négociations d'accords commerciaux à venir et pour toutes les propositions de changements du régime de propriété intellectuelle au Canada.
- 3. L'obtention d'engagements de la part de l'industrie pharmaceutique innovatrice à effectuer des dépenses de R&D au Canada** – le renforcement de la PI assurera à ces entreprises, avec plus de certitude, un marché exclusif et accentuera ainsi la mesure dans laquelle elles peuvent rentabiliser leurs investissements en R&D. Toutefois, les effets d'un renforcement de la PI sur les dépenses en médicaments et leur disponibilité sont incertains. La réforme de la PI pourrait augmenter les coûts des médicaments assumés par les gouvernements provinciaux et le reste des consommateurs. Compte tenu de l'ambiguïté associée à ces répercussions potentielles, le Canada ne devrait s'engager à renforcer la PI dans le domaine pharmaceutique qu'à la condition d'obtenir de l'industrie son engagement à allouer un certain pourcentage de son chiffre d'affaires à la R&D au Canada, tout comme elle l'avait fait à la fin des années 1980.

INTRODUCTION¹

International trade agreements have been a driving force behind changes to Canada's domestic intellectual property (IP) regime for pharmaceutical products. Since the mid-1980s, Canada has made significant changes to its IP regime in order to comply with international commitments in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the North American Free Trade Agreement (NAFTA). Canada is once again faced with external pressure to reform its IP regime through our trade negotiations with the European Union (EU) in the Comprehensive Economic and Trade Agreement (CETA) and in the Trans-Pacific Partnership (TPP).

The primary component of intellectual property protection for pharmaceuticals is the patent. Patents provide a temporary exclusivity period so that innovators can recover costly investments made in the research and development (R&D) of a pharmaceutical product. Patents are mandated by TRIPS and NAFTA, and most nations have a patent system, although the national implementation of those systems varies widely.

Canada must strike a balance between affordable medicine and innovation in pharmaceuticals.

Canada's overarching objective when negotiating pharmaceutical IP in trade agreements is to strike a balance between public health needs, namely access to affordable medicines, and economic aims, such as promoting innovation and competition in the pharmaceutical sector. It is with this objective in mind that Canada negotiates intellectual property commitments in international trade agreements. This compromise reflects Canada's institutional makeup and the composition of the domestic pharmaceutical industry.

Canada's pharmaceutical industry is a mix of research-based (or 'innovative') pharmaceutical companies that are multinational enterprises (MNEs); generic pharmaceutical companies, both Canadian and multinational, and a small but growing domestic innovative biopharmaceutical sector. Canada also has a lucrative market for pharmaceutical products. We spend over \$900 per capita on prescription and over-the-counter medicines, second only to the United States (US).² About 45 percent of total drug expenditure in Canada is financed by the public sector, mostly provincial/territorial governments, and the remainder is funded by private health insurers and individuals.³

This paper will examine some of the underlying considerations that shape Canada's position on pharmaceutical IP reform at international negotiating tables. The next section will outline the nature and composition of the pharmaceutical industry in Canada and then we will examine the economic literature on costs and benefits of IP protection. We then turn to a discussion of Canada's trade and negotiating interests and whether these are consistent with Canada's long-term interest in affordable medicines on the one hand and a competitive domestic industry on the other.

CANADA'S PHARMACEUTICAL INDUSTRY

Distinct Supply and Demand Interests

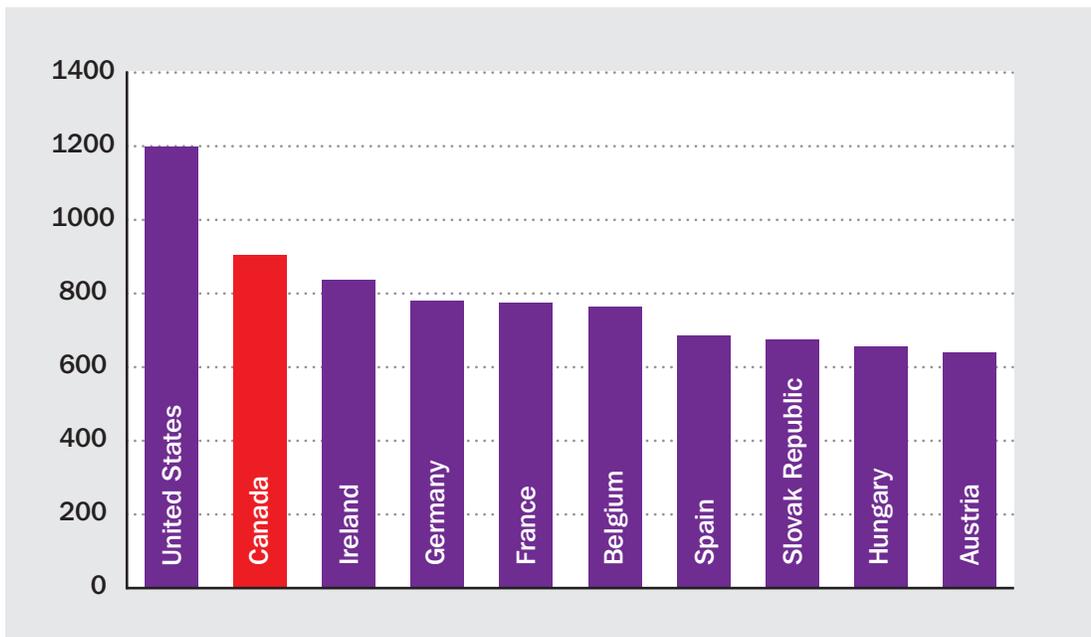
On the supply side, Canada's pharmaceutical industry includes a diverse mix of research-based (or 'innovative') manufacturers – most of which are multinationals headquartered in the US, United Kingdom, Denmark, France, Switzerland, and Japan; manufacturers of generic pharmaceuticals, including both Canadian and multinational firms headquartered in Germany, Israel, Switzerland, and the US, and a biopharmaceutical sector, comprised of about 180 small-and medium-sized enterprises (SMEs), many of which are privately owned.⁴

Canada's pharmaceutical sector directly employs about 27,000 people. The generic pharmaceutical industry accounts for about 45 percent of this employment, and the remaining 55 percent are employed by research-based or biopharmaceutical companies.⁵

On the demand side, Canada is one of the largest per capita drug consumers in the OECD (see figure 1).⁶

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FIGURE 1 Per capita expenditures on pharmaceutical goods, top 10 OECD countries, 2010



Source: Drug Expenditure in Canada, 1985 to 2012. Canadian Institute for Health Information, April 2013.

Total drug expenditures in 2012 were \$33 billion, representing 16 percent of total health expenditures in Canada. Brand-name drugs account for 76 percent of sales and 40 percent of prescriptions, while generic drugs account for 24 percent of sales and 60 percent of prescriptions.⁷

Pharmaceutical Research and Development in Canada

R&D investment relative to sales has declined since 2000.

Research-based, generic, and biopharmaceutical companies all invest in research and development (R&D) in Canada, albeit in different types and stages. Most basic research (often referred to as drug discovery) in Canada is carried out by academic health research institutions, government research labs, hospitals, and small and medium-sized biopharmaceutical companies, which partner with (or are acquired by) multinational pharmaceutical companies for later stages of development and commercialization.

According to the Patented Medicine Prices Review Board, in 2011 research-based pharmaceutical companies invested approximately \$1 billion in Canada, which accounts for 6.7 percent of total sales revenue.⁸ The ratio of R&D to sales in Canada peaked in 2000, and has declined steadily ever since (see figure 2).

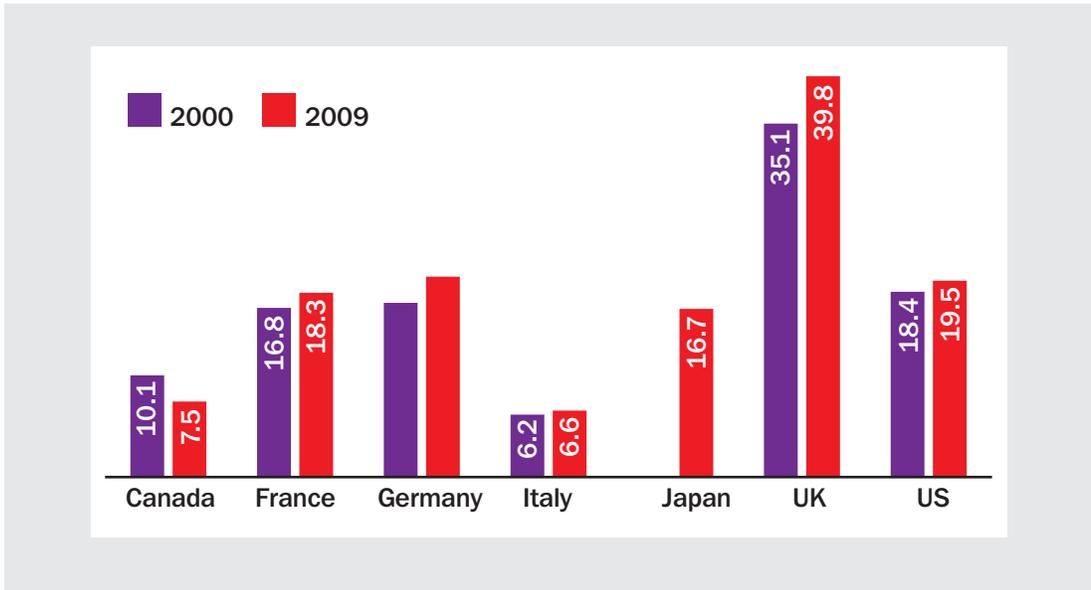
FIGURE 2 R&D to sales ratio as a percent in Canada, 1988-2011



Source: Patented Medicine Prices Review Board, *Annual Report 2011*.

Canada now has one of the lowest R&D to sales ratios as compared to G7 countries (see figure 3) and to Australia, where this ratio has been greater than 10 percent since 2008-09.⁹

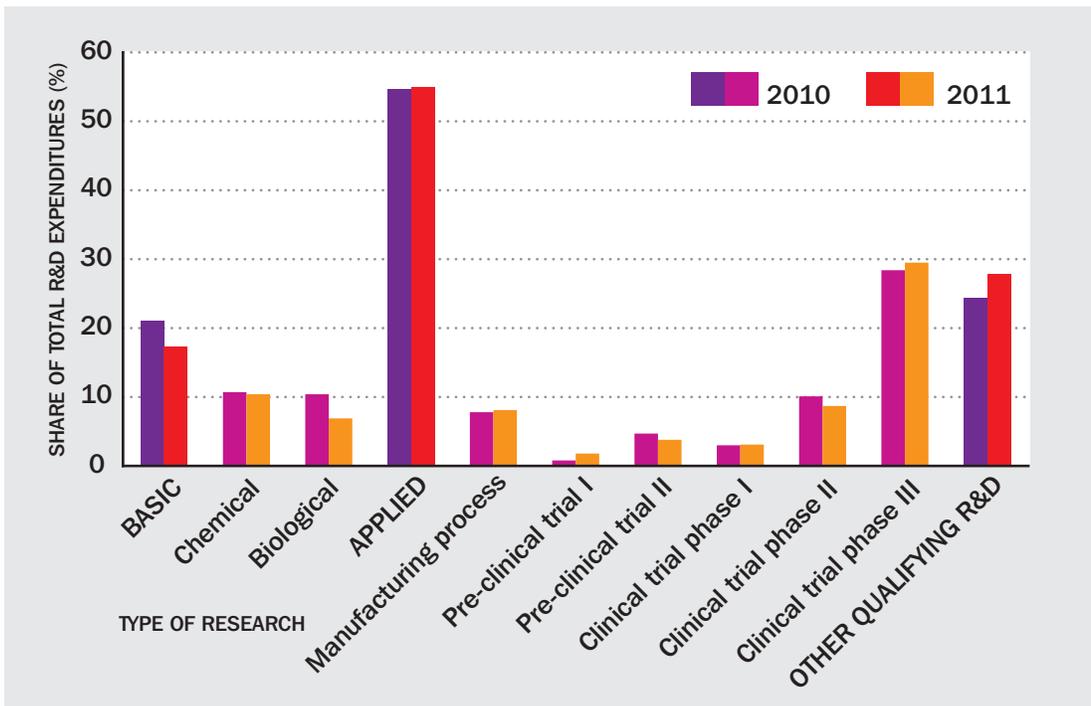
FIGURE 3 R&D to sales ratios in G7 countries, 2000 and 2009



Sources: Patented Medicine Prices Review Board, *Annual Report 2011*; Japan Pharmaceutical Manufacturers Association.

Research-based pharmaceutical companies in Canada invest in both basic research and applied research (which includes clinical trials and manufacturing processes), although most investment is concentrated in the latter (see figure 4).

FIGURE 4 Share of total R&D expenditures by type of research, 2010 and 2011

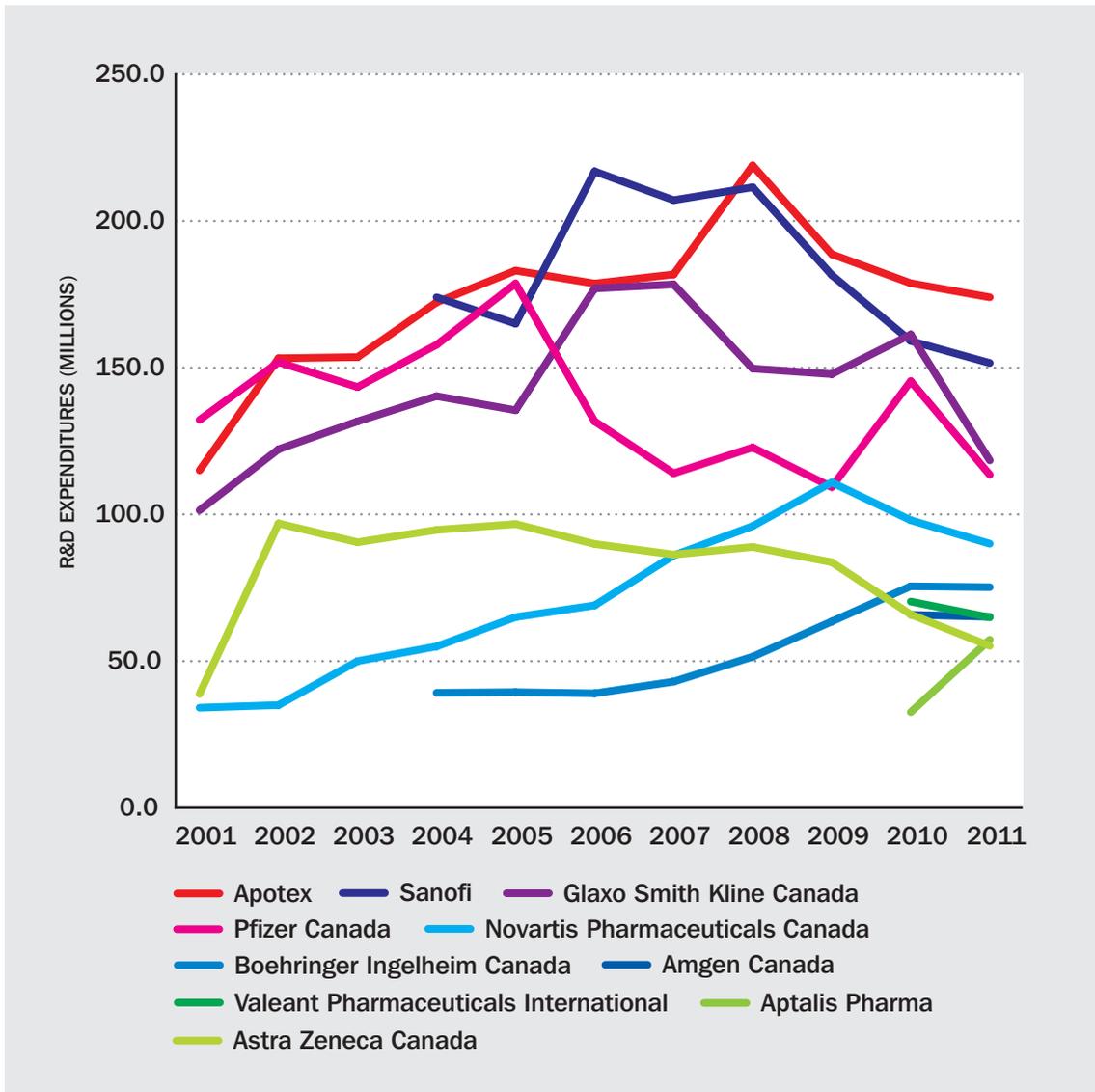


Source: Patented Medicine Prices Review Board, *Annual Report 2011*.

“Basic research” is defined as work that advances scientific knowledge without a specific application in mind. “Applied research” is directed toward a specific practical application, comprising research intended to improve manufacturing processes, pre-clinical trials, and clinical trials. “Other qualifying research” includes drug regulation submissions, bioavailability studies, and Phase IV clinical trials.

Generic companies invest R&D funds in the enhancement and development of formulas, in clinical trials, and in finding solutions to increase patient compliance with medicines. In 2011, of the top 10 pharmaceutical companies that invested in R&D in Canada, one firm (Apotex) was a generic, while the rest were multinational research-based companies (see figure 5).¹⁰

FIGURE 5 Top 10 pharmaceutical R&D spenders in Canada, 2001-2011



Source: Research Infosource. 2012. *Top 100 Corporate R&D Spenders List*.

The Costs of Drug Development

The costs of drug development are much higher for research-based and biopharmaceutical companies than for generic companies, since generic companies do not have to make large investments in applied research to generate their own data (see table 1). The development of innovative drugs is also characterized by a high rate of failure. The failure of a molecule to proceed to the next stage of development can occur at any time. Although failure is most common in early stages of research, it can occur during any phase of clinical trials, after a company has made a substantial investment in time and capital towards a particular drug candidate.

Similarly, the costs of developing biopharmaceuticals are quite high due to the nature of the process. Many biologics are manufactured in a living system such as a microorganism or plant or animal cell, using DNA cloning and sequencing methods. This process is time-consuming, and requires highly skilled labour and strict process controls to ensure consistent outcomes. As a result, a single biopharmaceutical product can cost up to \$1.5 billion to manufacture.

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TABLE 1 Time and cost of drug development, by type of company

Development from lab to market	Research-based	Generic	Biopharmaceutical
Time	11-13 years	3-6 years	10-15 years
Cost	\$1.3 billion	\$4 million	\$1.5 billion

Sources: Canadian Intellectual Property Council. 2011. *Innovation for a Better Tomorrow*. <http://www.ipcouncil.ca/uploads/Innovation%20for%20a%20Better%20Tomorrow.pdf>; BIOTECCanada. "Financing." <http://www.biotech.ca/en/policy-matters/financing.aspx>.

Industry Tensions

The positions of generic and innovative companies on intellectual property protections for pharmaceutical products are informed by the costs of drug development, investment levels in R&D, and the availability and affordability of medicines.

Innovative companies, arguing in favour of stronger IP, do so based on the rationale that high costs and high risk in drug development necessitate longer periods of market exclusivity in order to recuperate substantive investments in R&D.

Generic companies, on the other hand, point out that R&D investment in Canada by innovative companies has been declining since 2000.¹¹ They argue that further extending market exclusivity for innovative drugs results in delayed access to affordable medicines, and significantly higher costs for drugs, the burden of which would be borne in large part by provincial governments.

To some extent, each argument holds some truth. The next section will examine the relationship between patents, innovation, and competition, evaluating the academic and economic literature behind these claims.

THE COSTS AND BENEFITS OF IP PROTECTION

Development of new products and processes is an important source of economic growth, particularly in developed economies at the technological frontier. New knowledge and technical information is expensive to produce but it is highly valued when experimentation yields results. However, when information becomes available to the public for free (a 'public good'), it represents a market failure in economic terms because, if innovators cannot profit from their development investment, there is no incentive for future innovation.

It can take up to \$1.5 billion to discover, develop, and gain regulatory approval for a new medicine but, once the formula is known and tested, it is far less expensive to manufacture a generic copy. Many drugs can be imitated through reverse engineering. Without protections for the intellectual property associated with the original drug, innovators would be unable to recover the costs associated with their investment and would not invest in the costly process of developing and bringing to market new drugs.¹²

Market failures can be corrected by providing intellectual property rights to innovators for a set period of time. These rights allow innovators to make a profit from their investment and prevent free riding from competitors who would otherwise use their IP to manufacture the product themselves.

IP encourages knowledge spillovers and creates a market for new processes and technology.

There is a considerable body of research that supports the positive relationship between stronger IP and R&D investment in the pharmaceutical sector. A 2011 study by Yee Kyoung Kim et al. found that stronger patent protection provides incentives to create and commercialize innovations with larger inventive steps.¹³ A 2007 Canadian study by Grootendorst and Di Matteo found strong evidence that domestic pharmaceutical R&D in Canada increased by \$4.4 billion between 1988 and 2002, following the 1987 changes to the *Patent Act*.¹⁴

In exchange for providing an innovator with a finite period of market exclusivity through a patent, society gains complete knowledge of the innovation through the disclosure of technical information. The patent system allows knowledge that formerly had to be kept within a firm as a trade secret to move into the public sphere.¹⁵ In this sense, IP encourages knowledge spillovers and creates a market for new processes and technology. In fact, recent decades have seen significant restructuring of the pharmaceutical industry as firms increasingly rely on partnerships and joint ventures with public and private sector entities in both the discovery and development phases of research.¹⁶

Although intellectual property rights are effective at stimulating innovation in the pharmaceutical sector, there are some unresolved issues. First, there is some question over the relative importance of IP in attracting investment versus other factors such as the availability of highly skilled labour, access to quality research institutes and universities, and public support for R&D through grants, tax credits, and so on. Secondly, there is a dearth of research to help identify the appropriate level of IP that will stimulate innovative activity without unduly stifling competition.

The large multinational enterprises in the innovative pharmaceutical industry make global R&D investment decisions based on a host of factors. The potential to realize economies of scale, the presence of knowledge spillovers, access to highly skilled labour, and favourable tax treatment are all determinants of the location of investment in R&D.¹⁷ In fact, models of ‘open innovation’, whereby MNEs partner with academia and government to take a product from discovery to market, are becoming more common in the industry, suggesting that proximity to academic and research institutions is a significant determinant of R&D investment.¹⁸ It is difficult to determine the extent to which IP stimulates pharmaceutical sector innovation relative to other factors.

Indeed, there may be a threshold level of IP protection beyond which it no longer promotes innovation, and can actually have the reverse effect. A 2007 study by Allred and Park concludes that “in developed countries patent reforms have positive effects on innovation and on diffusion up to some point, beyond which market power effects have net negative effects.”¹⁹ The indication of an optimal level of IP suggests that at some point, the costs associated with IP outweigh the benefits. Determining this threshold will be different for every country, depending on the structure of its market, institutions, and the composition of the industry. Nevertheless, accepting the premise that some level of IP protection contributes to the development and availability of important, life-saving medications, we now examine some of the costs of strong IP protection.

Market exclusivity affords patent holders a time-limited monopoly position, during which they are the only seller of a particular drug, and as such are able to set its price on the market. Consistent with Canada’s TRIPS obligations, Canada’s *Patent Act* provides 20 years of patent protection from the filing of the patent. This allows innovators to recover their investments in R&D, but it also results in higher drug prices for buyers for the duration of the patent, since buyers are price-takers in a non-competitive market.²⁰ This has implications for health care costs, and the accessibility and affordability of drugs for governments, private insurers, and individuals.²¹

Some studies have indicated that extending patent terms could result in higher drug costs for buyers in Canada²² but it is difficult to measure the effects of patent terms on price since other factors including governmental price regulation, drug listings and formularies,²³ and trends in the prescribing behavior of physicians all affect the prices of pharmaceutical products in Canada.²⁴

Rent seeking activities, which are finding ways to profit from an existing regulatory regime or regulatory gap, also affect drug costs.²⁵ Such activities include litigation associated with patent and regulatory challenges in the court system, and the opportunity cost of allocating resources towards rent-seeking as opposed to innovative activity.²⁶ For example, changes to Canada’s *Patent Act* in 1993 resulted in a much higher volume of litigation in the pharmaceutical sector.²⁷ Some studies have shown that the rates of litigation in pharmaceutical/health sectors are double that of other sectors.²⁸ The IP system has also led to defensive patenting behavior – when patents are taken in order to prevent others from doing so – and the costs of navigating these overlapping patent rights can be considerable, especially for small firms with limited resources.²⁹

It is difficult to determine the relative importance of IP in stimulating innovation.

Summary

A robust IP regime stimulates R&D by allowing innovators to recover their costs and thus encourages the introduction and use of new drugs to manage health issues. It also encourages the creation of a market for knowledge and technology.

On the other hand, there may be a certain point beyond which strengthened IP protections have the opposite effect, and can potentially stifle innovation by creating high costs and restricting access to technical information.

Furthermore, the benefits of strong IP protection have to be balanced against potential increases in drug costs for governments and other buyers, and the economic impact of rent seeking. A telling example is that the changes to Canada's *Patent Act* in the 1980s and 1990s produced upswings in both innovation and litigation to protect or challenge patent rights.

The benefits of strong IP protection have to be balanced against potential increases in drug costs.

In light of pressure to reform the IP regime through various international agreements, Canada needs to take into account how the proposed provisions will affect its domestic institutions and industry. Specifically, Canada has:

- an innovative pharmaceutical sector, directly employing 15,000 people, and contributing around \$1 billion in R&D investment in Canada;
- an emerging biopharmaceutical sector which has promising growth implications for Canada's knowledge economy but may fail to thrive because of high-upfront costs and global competition;
- a generic pharmaceutical sector, employing over 11,000 people and providing affordable drugs to Canadian consumers and for export; and
- public and private sector drug buyers seeking the latest innovations, secure supply, affordable prices, and product safety.

Trade negotiations with the EU and TPP have brought pharmaceutical IP issues into the policy spotlight in Canada. Debate has been polarized, with different parts of the pharmaceutical industry making opposing claims on the potential effects of IP reform. There is very little in the way of objective analysis that examines the potential costs and benefits of IP reform in Canada as a whole. We are bound by the commitments we make in trade agreements, since Canada would face consequences (in the form of sanctions or monetary penalties) if it reneged on its obligations. As such, comprehensive and impartial cost-benefit analysis is crucial to help Canada's negotiators shape their bargaining positions at international negotiating tables.

The next section will discuss major policy changes in IP for pharmaceutical products since the 1980s and how these have evolved in response to commitments made in international agreements.

INTELLECTUAL PROPERTY REGULATION (IPR)

Canada's overarching objective when negotiating pharmaceutical IP in trade agreements is to strike a balance between public health needs, namely access to affordable medicines, and economic aims, such as promoting innovation and competition in the pharmaceutical sector. It is through this lens that Canada filters its bargaining position in international trade negotiations.

Since the mid-1980's, Canada has made significant changes to its IP regime in order to comply with international commitments in the Agreement on Trade-Related Aspects of Intellectual Property Rights and the North American Free Trade Agreement. Canada is once again faced with external pressure to reform its IP regime through our trade negotiations with the EU in CETA and with trading partners in the Americas and Asia Pacific through the TPP.

Between 1985 and 1994, Canada participated in a series of key international trade negotiations: the Canada-US Free Trade Agreement (CUSFTA); the Uruguay Round TRIPS negotiations; and NAFTA. Although CUSFTA did not directly deal with intellectual property, the final agreement did include a provision that "the Parties shall cooperate in the Uruguay Round of multilateral trade negotiations and in other international forums to improve protection of intellectual property."³⁰

It was within this context that the Government of Canada introduced substantial changes to the *Patent Act* in 1987. Bill C-22 amended the Act for pharmaceutical products in a few notable ways:

- It guaranteed patent holders market exclusivity for a period of between 7 and 20 years before a generic version of a product could enter the market (deferred compulsory licenses); and
- it increased the patent term from 17 years after issuance to 20 years after filing.

Bill C-22 also established the Patented Medicine Prices Review Board (PMPRB), a quasi-judicial agency charged with monitoring and regulating the prices of patented drugs to ensure they are not excessive. As well, the PMPRB monitors and reports on research and development expenditures made by innovative drug companies.³¹

Compulsory licensing had been a controversial part of Canada's IP regime for pharmaceuticals since 1923. These licenses gave generic manufacturers the right to manufacture, use, or sell a patented invention before the expiry of the patent, and without the patent holder's consent. As the TRIPS and NAFTA negotiations neared conclusion, it became clear that Canada's compulsory licensing regime would be inconsistent with the emerging agreements.³²

Consequently, Bill C-91, enacted in February 1993, contained provisions to replace compulsory licensing with a patent linkage system. Patent linkage prevents the government health regulator

Canada must balance public health needs and economic goals when negotiating pharmaceutical IP.

from approving a generic drug until the relevant patent expires unless a patent holder consents, if the patents are proven to be invalid, or if there is no infringement of any patent rights. Patent holders have the right to delay the market introduction of a generic drug for up to 24 months while the patent invalidity issues are being adjudicated. Although neither NAFTA nor TRIPS required patent linkage, the US had adopted a similar system in 1984.

The innovative pharmaceutical industry in Canada was a strong proponent of these changes, and made several commitments to the government contingent on the passing of Bill C-91. Of these, the most important was a commitment to achieve an R&D to sales ratio of 10 percent by 1996, and to maintain that ratio in subsequent years provided that the regulatory environment remained stable.³³

Data protection (also referred to as data exclusivity) is another area of pharmaceutical IP protection that has been influenced by international negotiations. Data protection regulations prevent a competitor from filing a submission for a generic drug that directly or indirectly relies on the innovator's clinical trial data for approval for a certain period of time following market approval of the innovative drug. Both TRIPS and NAFTA contain provisions on data protection: TRIPS does not specify a time period, while NAFTA requires a minimum of five years.

In order to comply with these commitments, Canada introduced five years of data protection in 1995. These changes appeared to fulfill the commitments made in TRIPS and NAFTA, but were heavily contested by the pharmaceutical industry, and the Federal Court of Appeal ruled that they were ineffective in practice.³⁴ As a result, Canada amended the Regulations in 2006 to provide innovative drugs with eight years of exclusivity (plus an additional six months if the drug is studied for use with children).

The US and EU seek to increase IP regulation.

Since the conclusion of the TRIPS negotiations, the US and EU have increasingly sought to strengthen IPR beyond the standards of TRIPS through bilateral trade negotiations. Agreements such as the Australia-US FTA (AUSFTA), the US-Korea FTA (KORUS), the EU-Korea FTA, and more recently, the EU-India FTA (currently under negotiation), include provisions to extend IP commitments beyond TRIPS. Examples of TRIPS-plus provisions include patent term extension, expansion of the scope of patentable subject matter, longer periods of data protection, and patent linkage.

The inclusion of TRIPS-plus provisions in bilateral trade agreements allows the EU and US to assert their relatively stronger bargaining positions in order to oblige their negotiating partners to commit to higher standards of IP. Some have argued that the imposition of these commitments on other countries restricts their flexibility to regulate in their national interest.³⁵ Maskus claims that “the distinctiveness in patent rules reflects differences in preferences, business environments, technological capacities, and approaches to regulation.”³⁶ If so, then stricter international harmonization of IP standards could mean reduced domestic policy discretion and the foregoing of national preferences.

The next section discusses major dynamics at play in the CETA and TPP intellectual property negotiations as they affect Canada's regime for pharmaceutical products. The appendix provides a more detailed comparison of the IP regime for pharmaceutical products in Canada, the US, and the EU.³⁷

Canada-EU Comprehensive Economic and Trade Agreement

Since 2009, Canada and the EU have been engaged in negotiations towards a Comprehensive Economic and Trade Agreement (CETA). The negotiations appear to be in the final stretch, but conclusion has been delayed by a set of contentious issues. One of these issues is disagreement over proposed changes to Canada's IP regime for pharmaceuticals. The EU cites 'deficiencies' with Canada's system as the impetus for proposing their reforms.³⁸ Since the agreement has not been finalized, leaked text³⁹ of the chapter provides some indication of the EU negotiation position:

- **Patent Term Restoration** – This proposal lengthens the patent term by up to five years to compensate for the time expended in clinical trials and due to regulatory delays.⁴⁰
- **Data Exclusivity** – Information submitted by an innovator to seek approval for a pharmaceutical product cannot be used by a generic company seeking Health Canada approval for a generic version of that product for eight years, and no approval of a generic product can be granted for 10 years if its approval relies on the use of the innovator's data. This protection can be extended for up to one more year if the drug is authorized for new indications.⁴¹
- **Right of Appeal** – This provision, relating to Canada's patent linkage system, would allow innovators to appeal a court decision that allows the approval of a generic product.⁴²

If accepted, these reforms would more closely align Canada's IP regime for pharmaceutical products with the European Union. The debate in Canada over how to respond to the proposals is highly polarized. The research-based pharmaceutical industry association Rx&D suggests that these changes will foster innovation, investment, and employment in the innovative pharmaceutical industry.⁴³ The biotechnology industry association BIOTECCanada also supports the proposals, noting that IP reform is essential in order to attract investment in the industry.⁴⁴ Conversely, the Canadian Generic Pharmaceutical Association believes that the changes will "restrict competition in Canada from cost-saving generic drugs through the further extension of market protection mechanisms."⁴⁵ There is no discernible middle ground in the public debate.

Another element unique to CETA is the participation of the provinces at the negotiating table. While intellectual property is a federal responsibility, the provinces and territories have been involved in the negotiations from the beginning, and their agreement will be essential to concluding the negotiations. As substantial buyers of pharmaceutical products in Canada, some provinces have expressed concern that these provisions will result in higher drug costs and have requested compensation if the federal government agrees with EU demands.⁴⁶

To conclude the CETA negotiations, Canada may have to agree to significant domestic policy changes. Moreover, the agreement with the EU may set the parameters of the commitments we make in the TPP negotiations.

The Trans-Pacific Partnership

The TPP is promoted as an “ambitious, next-generation, Asia-Pacific trade agreement.”⁴⁷ Its negotiating parties include Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the US, and Vietnam. These countries account for nearly 40 percent of global GDP and about one-third of all world trade.⁴⁸

The TPP is an important agreement for Canada. It will be our first foothold into prosperous Asian markets and, since it involves our two NAFTA trading partners, it will be a chance to address outstanding issues with them. The TPP provides a new trade forum for countries in the Asia-Pacific region looking to expand international trade relations, especially preferential access to the US. In the absence of progress in the WTO, TPP membership may broaden to include the Philippines, South Korea, and others.

CETA will set the parameters of Canada's commitments in the TPP negotiations.

Intellectual property provisions for pharmaceuticals have been a contentious issue in the TPP. The US, the dominant force in the negotiations, is seeking TRIPS-plus IP protection that is similar to the provisions contained in KORUS or the Australia-US FTA. Other negotiating parties, meanwhile, prefer to adhere more closely to the commitments

made in TRIPS. The US tabled an IP proposal in the September 2011 round of TPP negotiations. Some of the provisions include:

- **Patent Term Restoration** – The US seeks patent term restoration, but the proposal as outlined in the leaked text does not state a specific length of time.
- **Data Exclusivity** – This proposal differs from that in CETA, owing to differences in US IP law. The TPP proposal seeks data exclusivity for five years, plus an additional three years with proof of new use or form of an approved chemical entity.⁴⁹
- **Patent/registration Linkage** – As mentioned, Canada already has in place a patent linkage system, as does the US. The US proposal seeks to institute this system in all member countries.
- **Scope of Patentability** – These reforms are not part of Canada's agreement with the EU. This provision looks to expand patentability to require countries to permit patent applications on modifications of variations of new forms of existing medicines, formulations, dosages, and combinations, independent of whether or not they provide enhanced therapeutic benefits.
- **Exclusions from Patentability** – Also not found in CETA (and contrary to the TRIPS agreement), the US proposes that TPP patents be made available for diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.⁵⁰

Several members, including Peru, New Zealand, Australia, and Chile have expressed opposition to these reforms, and the proposal has not been debated since March 2012 but new discussions are expected in the summer of 2013.⁵¹

The dynamics of the TPP are complex, since the negotiations comprise countries at different stages of development. In order to accommodate these differences, there has been debate over whether to provide special treatment such as longer phase-in times and voluntary, not mandatory, obligations for developing countries like Peru, Vietnam, and Brunei. However, other countries such as Chile and Singapore are likely to oppose this structure if it means that they would have to adhere to the standards of developed countries. However, the US may choose to re-table a very similar proposal later this year, and could look to garner support from Japan, and perhaps Canada as well.

The outcome of these negotiations is uncertain. The membership of the TPP is diverse, and many members already have bilateral trade agreements with the US, suggesting that the US may have less leverage to steer the negotiations in favour of its proposals. However, there is significant pressure on the US administration from the research-based pharmaceutical industry to include strong IP protections in the final agreement. PhRMA, the US industry association, has undertaken an advocacy campaign to ensure the interests of its members are represented in the TPP text.⁵² As well, the US views this agreement as an opportunity to set the future standards for the region. In fact, some observers have suggested that the IP provisions can be seen as a challenge to laws in India and China, and an effort to ensure that the US standards will ultimately be globalized to include those countries.⁵³

TPP will be Canada's first foothold in prosperous Asian markets.

Unless CETA results in significant domestic reforms, Canada will face pressure from the US to adhere to more extensive IP standards in the TPP. The US has consistently taken issue with aspects of Canada's IP regime, which has resulted in Canada's being placed on their IP Watch List.⁵⁴ Furthermore, the research-based pharmaceutical and biotechnology industries in the US have pointed to Canada as an "outlier" because of our lack of patent term restoration, a higher patent utility standard for pharmaceuticals, and no right of appeal for brand-name drug makers in patent linkage proceedings.⁵⁵

CONCLUSIONS

Canada faces complex and difficult choices regarding pharmaceutical IP reform as part of its trade negotiations with the EU and the TPP. The challenge is in achieving a successful conclusion to the negotiations while balancing important domestic public health and economic objectives.

In light of international pressure for reforms, Canada must take into account how the proposed provisions will uniquely affect the diversity of our industry and institutions: a pharmaceutical sector that includes strong generic, research-based, and biopharmaceutical companies, and a public health care system whereby governments are significant buyers of prescription medicines. A comprehensive cost-benefit profile of the effects of strengthening IP in Canada is essential to determining informing our negotiating positions at the international level.

Nearly all of the reforms proposed by the EU and US favour innovative pharmaceutical companies.

Nearly all of the reforms proposed by the EU and US directly or indirectly favour the interests of research-based pharmaceutical industry (see the appendix). In order to determine whether such reforms are in Canada's interests, we need to ascertain whether the potential benefits in investment and competitiveness in the innovative sector are worth potential costs to domestic consumers and generic manufacturers. Any change in IP policy for pharmaceuticals should aim to facilitate growth for the entire industry, while taking into account the potential impact on health expenditures.

As we have argued, it is difficult to discern the influence of IP on R&D investment. Canada has a strong biopharmaceutical sector, made of mostly small and medium enterprises that concentrates mainly on discovery and preclinical stages of research, but also takes some inventions through the clinical trial phase. This part of the industry has thrived under the current IP regime, suggesting that the current IP regime is effective or perhaps that other factors such as tax incentives, knowledge spillovers from publicly-funded research institutes, venture capital have been more influential in stimulating growth.

Research-based companies invest mostly in applied research, but R&D as a percentage of sales has been declining for over a decade. This may be due to an unfavourable IP climate, but it is difficult to know to what extent this is the case. The innovative pharmaceutical sector is dominated by multinational companies, which make spending decisions based on a global scope. Factors influencing MNE investment decisions include IP protection but also market size, regulatory policy, and a concentration of highly skilled labour.

The outcome of the CETA negotiations may require some changes to our domestic IP regime. Since we are the weaker partner at the table in terms of market size, some compromise on the tough issues will be required in order to reap the benefits of an overall agreement. Although the outcome of the TPP negotiations is difficult to predict, Canada will likely face a situation similar to CETA. Ultimately, Canada's position in the TPP will be largely dependent on any changes that arise from implementation of CETA.

RECOMMENDATIONS

Our recommendations are as follows:

- 1. Objective analysis of the potential effects of IP reform in Canada** – If there is indeed a threshold beyond which the costs of stronger IP outweigh the benefits, it is essential to explore what that threshold might be for Canada. The Government of Canada should produce, and make public, a study of how potential reforms in IP policy will affect the domestic pharmaceutical industry and the health care sector. Academic research has been helpful in laying out some of the theoretical considerations, but there is a need for an exhaustive and independent assessment of the potential costs and benefits for Canada.⁵⁶
- 2. Review the system that supports pharmaceutical sector innovation** – An evaluation of the use, effectiveness, and availability of other programs and tools to stimulate innovation in the pharmaceutical sector will assist in determining the relative impact of IP on innovative activity. Part of this evaluation should involve a comprehensive survey of the pharmaceutical sector in Canada to identify which policies and programs are most important to decision-making. This evaluation can inform our negotiating positions in future trade agreements, and any other proposed changes to Canada's domestic IP regime.
- 3. Obtain commitments from the innovative pharmaceutical industry for R&D expenditures in Canada** – Stronger IP will provide these companies with more certainty of market exclusivity, and thus enhance the extent to which they can recuperate R&D investment. However, the effects of stronger IP on drug expenditure and availability are uncertain, and there is a possibility that IP reform will increase the costs of drugs for provincial governments and other consumers. Given the ambiguity associated with these potential impacts, if the Government of Canada agrees to stronger IP for pharmaceuticals, it should do so in exchange for a commitment from industry to spend a certain percentage of sales on R&D in Canada, similar to the agreement made between industry and the government in the late 1980s.

AUTHOR BIOGRAPHIES



Stefania Bartucci, Research Director at Dawson Strategic, has strong knowledge of international economics and the international trading system. She has produced practical, business-focused analysis of trade, market access and regulatory issues for public and private sector audiences and is a subject matter specialist in borders, infrastructure and transportation, energy and government procurement. Ms. Bartucci has held previous positions with research institutions, government relations companies and political organizations. Ms. Bartucci holds an MA in International Affairs from the Norman Paterson School of International Affairs (specialization in

trade policy) and an Honours BA in Economics and Political Science from the University of Toronto.



Laura Dawson is the President of Dawson Strategic and provides advice to business on cross-border trade, market access and regulatory issues. Previously, she served as senior advisor on U.S.-Canada economic affairs at the United States Embassy in Ottawa. As a specialist in U.S.-Canada economic relations, Dawson contributed to the launch of the U.S.-Canada Regulatory Cooperation Council, the Border Vision Strategy, and the bilateral Government Procurement Agreement. From September to December 2011, she was a Public Policy Scholar at the Woodrow Wilson International Center for Scholars in Washington, DC researching policy options to rebuild North American competitiveness.

She has conducted research for clients and scholarly publications in investor-state dispute settlement, cross-border labor mobility, government procurement, technical barriers, energy, telecommunications, financial services, softwood lumber, foreign investment review and corporate-social responsibility in the extractive sector.

From 1998 to 2008, she was a senior associate at the Centre for Trade Policy and Law advising governments in developing and transition economies on trade and investment issues. Dawson taught international trade, Canada-U.S. relations and policy analysis at the Norman Paterson School of International Affairs and holds a PhD in political science.

Appendix 1

MAJOR PHARMACEUTICAL POSITIONS IN CETA AND TPP

	Canada	US (dominant in TPP negotiations)	EU
Patent Term	20 years	20 years	20 years
Entitlement to Patent First to file versus first to invent	First to file	First to file (as of March 2013)	First to file
Patent Term Extension Intended to extend the patent term to compensate for a lengthy regulatory approval process	Not available	Maximum extension of 5 years but total patent term from date of marketing approval cannot exceed 14 years	Maximum extension of 5 years but total patent term (including extension) cannot exceed 15 years
Permanent Injunction Prevents a competitor from using a patented invention without the permission of the patent holder	Discretionary (i.e., at the discretion of the courts), but the courts have consistently granted a permanent injunction to a successful patent holder	Discretionary, not granted routinely	Availability determined based on national case law in patent matters of the respective member states
Interlocutory Injunction Prevents a competitor from carrying out what the patent holder claims is an infringement of its patent, pending the outcome of a trial.	Discretionary, and difficult for a patent holder to obtain	Discretionary, granted sparingly	Governed by national law, and the ease of obtaining interlocutory injunction varies by jurisdiction.

	Canada	US (dominant in TPP negotiations)	EU
<p>Data Protection/ Exclusivity A period of time following market authorization of a medicine during which a generic manufacturer cannot rely in whole or in part on the clinical data generated and submitted to authorities by the innovator</p>	<p>The maximum term for innovative drugs is $6+2+0.5 = 8.5$ years:</p> <ul style="list-style-type: none"> - No submission from generic manufacturer for 6 years - No regulatory approval of a generic equivalent for additional 2 years - An additional 6 months is granted for submissions that include pediatric studies 	<p>The maximum term is $5 + 3 + 0.5 = 8.5$ years:</p> <ul style="list-style-type: none"> - No submission from generic manufacturer for 5 years, unless patents are challenged (patents cannot be challenged within first 4 years of drug approval) - An additional 3 years data exclusivity for significant changes (new indication) - An additional 6 months for submissions that include pediatric studies. <p>For biological drugs, the maximum term is 12 years, with an additional 6 months for pediatric studies.⁵⁷</p>	<p>The maximum term is $8+2+1= 11$ years:</p> <ul style="list-style-type: none"> - No submission from generic manufacturer for 8 years - No regulatory approval for an additional 2 years - An additional 1 year data exclusivity for significant changes (new indication)
<p>Patent Linkage Prevents a generic drug until the relevant patent expires</p>	<p>Patent linkage is available via the Patented Medicines (NOC) Regulations. Maximum duration is 24 months. In practice, this system is similar to interlocutory injunction.</p>	<p>Patent linkage is available. Maximum duration is 30 months. The courts examine these disputes as patent infringement cases.</p>	<p>No patent linkage, but the use of interlocutory injunction prevents a generic from launching until the litigation is complete or the parties have settled</p>

	Canada	US (dominant in TPP negotiations)	EU
<p>Appeals (related to patent linkage system. Allows for an effective right of appeal by a patent holder from an adverse decision in an NOC proceeding in the Federal Court)</p>	<p>In principle, either the generic or the patent holder may appeal an adverse NOC decision. If the generic is successful, however, the government will normally issue drug approval almost immediately. Once the approval has been issued, the Federal Court of Appeal will refuse to hear the appeal on the basis that it is moot.</p> <p>The patent holder's recourse is to bring an infringement action against the generic, from which there is a right of appeal.</p>	<p>Yes, any unsuccessful party may appeal</p>	<p>Yes, any unsuccessful party may appeal</p>
<p>Remedies</p>	<p>Damages are the standard remedy for patent infringement. While the general principles of damages are the same in all jurisdictions, there is considerable variation in the detailed rules used by the courts to calculate damages.</p>		

ENDNOTES

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- 7 Industry Canada, *op.cit.* Brand-name drugs account for a much greater percentage of total expenditures because these drugs are more expensive than their generic versions. Generic versions of innovative drugs are less expensive because generic firms can use the safety and effectiveness data (such as data from clinical trials) provided by innovative companies to regulatory authorities in order to prove bioequivalency. Industry Canada, *Pharmaceutical Industry Profile*, http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html. Accessed April 2013.
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- 53 Flynn et al. 2012. "The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement." *American University International Law Review* 28(1): 156.
- 54 United States Trade Representative. 2013. 2013 *Special 301 Report*. Available at <http://www.ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf>.
- 55 2013. "U.S. Industry Representatives Blast Canadian Patent, Copyright Regimes." *Inside U.S. Trade*.
- 56 The Council of Canadian Academies, an independent, not-for-profit corporation that produces science-based, expert assessments that inform public policy development, is well-equipped to perform this work.
- 57 The US offers a shorter term of data protection for small molecule drugs than for biologic drugs based on the rationale that development of a biologic drug is far more complex and costly than for small molecule drugs such that a longer minimum term of market exclusivity is required for biologic drugs to provide an adequate incentive to innovate in this field.



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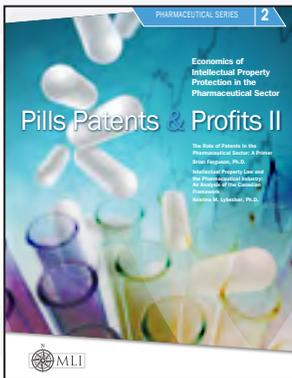
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The Canadian Century
By Brian Lee Crowley,
Jason Clemens, and Niels Veldhuis

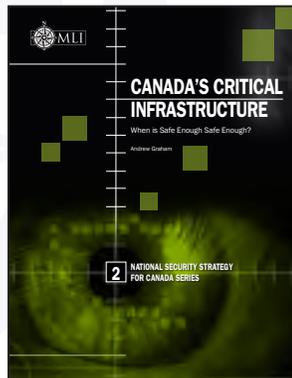
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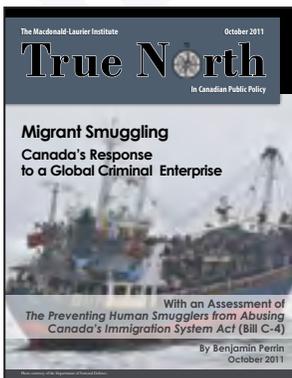
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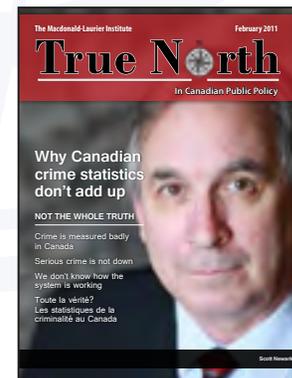
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MACDONALD-LAURIER INSTITUTE

True North in Canadian Public Policy

CONTACT US: Macdonald-Laurier Institute
8 York Street, Suite 200
Ottawa, Ontario, Canada K1N 5S6

TELEPHONE: (613) 482-8327

WEBSITE: www.MacdonaldLaurier.ca

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What people are saying about the Macdonald- Laurier Institute

I commend Brian Crowley and the team at MLI for your laudable work as one of the leading policy think tanks in our nation's capital. The Institute has distinguished itself as a thoughtful, empirically-based and non-partisan contributor to our national public discourse.

PRIME MINISTER STEPHEN HARPER

As the author Brian Lee Crowley has set out, there is a strong argument that the 21st Century could well be the Canadian Century.

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PETER NICHOLSON, FORMER SENIOR POLICY
ADVISOR TO PRIME MINISTER PAUL MARTIN

The reports and studies coming out of MLI are making a difference and the Institute is quickly emerging as a premier Canadian think tank.

JOCK FINLAYSON, EXECUTIVE VICE PRESIDENT
OF POLICY, BUSINESS COUNCIL OF
BRITISH COLUMBIA

Very much enjoyed your presentation this morning. It was first-rate and an excellent way of presenting the options which Canada faces during this period of "choice"... Best regards and keep up the good work.

PRESTON MANNING, PRESIDENT AND CEO,
MANNING CENTRE FOR BUILDING DEMOCRACY