

Intellectual Property
Rights Protection and the
Biopharmaceutical Industry:

HOW CANADA MEASURES UP

Kristina M. Lybecker

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Executive summary

An extensive body of evidence demonstrates that patents and other intellectual property protections are critical to the future of innovation and the development of new treatments and cures. A strong legal regime is essential for a robust innovation-based biopharmaceutical industry. This study examines the legal architecture required for more effective intellectual property protection for the innovative biopharmaceutical industry. It also reviews the existing Canadian legal framework as well as global best practices, which leads to several recommendations for Canadian IP legislation.

For Canada, the legal architecture surrounding intellectual property rights protection and the national regulatory regime are powerful forces shaping the biopharmaceutical industry, its profitability, productivity, and innovative future. These dimensions also have consequences for Canadian patients, the Canadian economy, and access to future medical innovations. In the course of ongoing trade negotiations, several aspects of the Canadian IPR system have come under scrutiny and changes to these elements have become a central discussion point. This paper describes existing IP policy in Canada, compares it to global norms and regimes, evaluates the strengths and weaknesses of the Canadian system, and recommends improvements and reform.

There are five areas of concern regarding Canadian IP protection for the biopharmaceutical industry: (1) the period of patent term restoration (also called “sui generis protection”), (2) weak enforcement of patents (e.g., no patent linkage right of appeal for innovators), (3) a patent utility standard that is higher than and inconsistent with international norms, (4) the duration and scope of regulatory data protection, and (5) the lack of an orphan drugs regime. The paper examines each of these in turn, analyzing the specific weaknesses of Canadian legislation and how these elements measure up against other nations.

The intellectual property environment in Canada clearly has consequences for this country’s global competitiveness. Overall, there are numerous deficiencies that weaken intellectual property protections within Canada relative to what is provided in other industrialized nations. The result is an IP regime characterized by significant uncertainty and instabil-

ity for biopharmaceutical firms. Weaknesses such as onerous patentability requirements, insufficient enforcement mechanisms, and inadequate anti-counterfeiting measures place Canada in the company of Mexico, Malaysia, China, and Russia in the IP Index rankings. These rankings make a difference to prospective investors and signal Canada's lack of support for knowledge-based industries, especially the biopharmaceutical industry. Fundamentally, Canada is a global outlier, providing inadequate intellectual property protection for the biopharmaceutical industry.

This paper also considers the consequences of changing the Canadian IP architecture and what Canada stands to gain. Benefits will include reduced legal ambiguity and litigation through increased predictability, greater research and development expenditures, increased foreign direct investment, additional job creation in the biopharmaceutical and related industries, productivity gains, greater biopharmaceutical self-sufficiency, faster launch times for new medicines, and additional innovation on cutting-edge treatments and therapies.

A comparison of Canada's legal framework with global best practices leads to several recommendations for Canadian IP legislation. Specifically, Canada should provide innovative biopharmaceutical firms with patent term extensions in order to recover time lost due to mandatory governmental regulatory and marketing approvals. In addition, Canada should remedy issues of weak enforcement by providing patent owners with an effective patent linkage right of appeal. Changes must be made to Canada's IP laws in order to restore certainty to Canada's distorted patent system and clarify the expectations of the patent utility doctrine. Canada should also extend data protection regulations and increase the scope of products that may be classified as "innovative drugs." Finally, Canadian policymakers should enact legislation to define a rare disease and encourage Canadian firms to intensify their research and development of new therapies. The adoption of these changes would help to bring the Canadian regime in line with international standards.

Introduction

International trade agreements have long driven countries to change the legislation defining their intellectual property rights regimes. At present, Canada is negotiating two international trade agreements: the Comprehensive Economic and Trade Agreement (CETA) with the European Union, and the Trans-Pacific Partnership Agreement (TPP) with Australia, Brunei Darussalam, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam. These negotiations have refocused attention on Canada’s intellectual property regime, and rekindled the debate over intellectual property rights protections in the biopharmaceutical industry.¹ While Canada has slowly made efforts to bring its IP regime into accord with global norms and expectations, the constant tension between the innovative industry and generic producers means that Canada is never at the forefront of global standards (Dawson, 2015: 2). On the one side, criticism comes from some in the European Union and the innovative biopharmaceutical industry who argue that Canada’s protection of intellectual property falls short of international standards. On the other, public health advocates argue that additional protections will put critical

¹ The terms “pharmaceutical” and “biopharmaceutical” are used interchangeably in this document. It is important to distinguish between traditional small-molecule drugs and biologics. The chemical structures of traditional “small molecule” pharmaceuticals are generally well defined. Accordingly, laboratory analysis can determine all of the components so replication (generic production) is fairly straightforward. In contrast, due to their complexity, biologics are very difficult and sometimes impossible to characterize scientifically. In many cases, some of the components of a finished biologic may be unknown. According to Amgen (2012), “a biologic medicine is a large molecule typically derived from living cells and used in the treatment, diagnosis or prevention of disease. Biologic medicines include therapeutic proteins, DNA vaccines, monoclonal antibodies, and fusion proteins.” Many biologics are produced using recombinant DNA (rDNA) technology and are made by genetically engineering living cells to produce the required proteins rather than through chemical synthesis. In addition, biologics are considerably larger than “small molecule” drugs—often 200 to 1,000 times their size—and are significantly more complex structurally. Given both the size of biologics and their sensitivity, these medicines are almost always administered through an injection into a patient’s body (Lybecker, 2013).

medicines out of reach, especially reducing access for the most vulnerable populations.

The debate over intellectual property rights in the biopharmaceutical industry and access to medicines elicits passionate arguments from both defenders and opponents. Few public policy issues are defined by such strong emotions and rally advocates to so vehemently defend their positions. Law, economic policy, and public health all play a part in public policies focused on access to medicines. For both the biopharmaceutical industry and patients the stakes are immense, spanning industry profits and human life. Given the magnitude of the issue and the global attention it has garnered, it is not surprising that intellectual property rights (IPRs) for the biopharmaceutical industry are a sticking point and perhaps the most contentious element in the ongoing trade treaty negotiations.

For Canada, the national regulatory regime and the legal architecture surrounding intellectual property rights protection are powerful forces shaping the biopharmaceutical industry, its profitability, productivity, and innovative future. These dimensions also have consequences for Canadian patients, the Canadian economy, and access to future medical innovations. In the course of ongoing trade negotiations, several aspects of the Canadian IPR system have come under scrutiny and changes to these elements have become central to the discussions. This paper describes existing IP policy in Canada, compares it to global norms and regimes, evaluates the strengths and weaknesses of the Canadian system, and recommends improvements and reforms.

The Unique Nature of the Biopharmaceutical Industry

The unique structure of the innovative biopharmaceutical industry necessitates a variety of intellectual property protection mechanisms. In particular, the industry is characterized by a research and development (R&D) process that is lengthy, expensive, uncertain, and risky. According to DiMasi and colleagues, the estimated cost of developing a new medicine is US\$2.6 billion (DiMasi, Grabowski, and Hansen, 2016).² In addition, the time required to develop a new drug is also significant, averaging 10 to 15 years without any guarantee of success (PhRMA, n.d.). While these figures are highly controversial, biopharmaceutical innovation is unquestionably an expensive and lengthy undertaking.³ For the biopharmaceutical industry, innovation and its protection are essential and the source of both profits and growth. As such, patent protection is disproportionately more important for ensuring that the innovator appropriates the returns to R&D for the biopharmaceutical industry than virtually any other. Extending the findings of the 1987 “Yale Survey” (Levin, Klevorick, Nelson, and Winter, 1987), the “Carnegie Mellon Survey” established that while patents are again considered “unambiguously the least effective appropriability mechanisms,” the drug industry and other scholars regard them as strictly more

² It is important to note how DiMasi’s estimates were calculated. Capitalizing out-of-pocket costs to the point of marketing approval at a real discount rate of 10.5% yields a total pre-approval cost estimate of \$2,558 million (2013 dollars). Adding an estimate of post-approval R&D costs increases the cost estimate to \$2,870 million (2013 dollars) (DiMasi et al., 2016: 20).

³ The calculation is controversial because of the “time costs” that are included in the measure: “The figure includes two basic components. One is the average amount of money that is actually spent, which Tufts calls ‘out-of-pocket’ costs and amounts to \$1.395 billion. Then there are ‘time costs,’ which is another way of saying opportunity costs, of \$1.16 billion. This is the return that investors could be expected to forgo if the money had been invested elsewhere while a drug is being developed” (Silverman, 2014). Critics argue that the \$2.6 billion figure overestimates the true cost of drug development.

effective than alternative mechanisms (Cohen, Nelson, and Walsh, 1996). The industry's disproportionate reliance on patents and other forms of intellectual property protection is confirmed in numerous other studies.⁴

In essence, IPR protections provide innovative biopharmaceutical firms with an assurance of some return on their investment, thus creating incentives for the development of new technologies that could otherwise be easily replicated and sold by competitors. Due to the tremendous fixed costs required to develop new treatments and cures, a significant potential exists for free riding by follower firms, a market failure that would prevent investment in innovation were it not for the patents and other forms of intellectual property protections that provide a limited period of market exclusivity or other such incentives. Fundamentally, patents amount to an efficiency tradeoff. Society provides innovators with a limited period of market exclusivity to encourage innovation in exchange for public access to this knowledge. In exchange for the temporary static loss from market exclusivity, society gains complete knowledge of the innovation through disclosure, a permanent dynamic gain. Through this tradeoff, the existing patent system corrects the market failure that would stymie innovation. In its *Apotex Inc. v. Wellcome Foundation Ltd.* finding, Justice Binnie wrote for the Supreme Court of Canada, "A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*" (para. 37).

The biopharmaceutical industry is characterized by a number of legal and economic issues that distinguish it from other research-intensive industries. Danzon (1999) describes three features that are particularly noteworthy. First, given that the biopharmaceutical industry is characterized by an unusually high rate of R&D, intellectual property protection provides for the potential for significant market power and monopoly pricing that raises numerous public health policy questions surrounding prices and profits. Second, virtually every aspect of the industry is heavily regulated, from safety and efficacy to promotion and advertising, to pricing and reimbursement. Danzon describes the impact of these regulations as "profound and multidimensional even within a single country, affecting consumption patterns, productivity, R&D and hence the supply

⁴ These include: Levin, Klevorick, Nelson, and Winter (1987), Taylor and Silberston (1973), Scherer (1997), Mansfield (1986), Mansfield, Schwartz, and Wagner (1981), and Tocker (1988). These studies are echoed by arguments from within the pharmaceutical industry: Mossinghoff (1998), Peretz (1983), Mossinghoff (1987), Paine and Santoro (1995), Smith (1990a, 1990b), and Mossinghoff and Bombelles (1996).

Table 1: Drug Development Process and Comparisons

Drug Development Phases	Innovative Companies	Generic Companies
Research and Development	2-6.5 years (early stage development)	6 months – 1 year (secure active ingredient and formulation)
Tests and Trials	7 years for 60% of total costs	3-6 months for \$1 million
Time from Laboratory to Market	11-13 years	2.25-6.5 years
Estimated Total Costs	\$897 million	\$4 million
Time to Recoup Investments	7-9 years	No time limit

Source: Merck website, reproduced in CIPC, 2011: 12.

of future technologies” (Danzon, 1999: 1056). Lastly, while research and development costs are borne solely by the innovator, the resulting product is a global public good. “Each country faces an incentive to adopt the regulatory policies that best control its pharmaceutical budget in the short run, free-riding on others to pay for the joint costs of R&D and ignoring cross-national spillovers of national regulatory policies through parallel trade and international price comparisons” (Danzon, 1999: 1056). The combination of these characteristics defines a set of unique economic and legal challenges for the innovation of new drugs and the public health policies that surround their production, marketing, and distribution.

Innovative companies make far greater investments in time, resources, and financial support than do generic firms. Notably, innovation-based companies spend more than 200 times that which generic companies spend on the development of a particular drug (CIPC, 2011: 10). In addition, the investment of time, from laboratory to market, is also close to double for innovative companies relative to generic producers. Table 1 highlights the differences in the drug development processes of innovative and generic companies. For innovative biopharmaceutical companies, the development process is expensive, risky, and time consuming, all of which points to the need for strong IP protection to encourage investment and ensure companies are able to recover their investments.

The risk involved in biopharmaceutical development is starkly illustrated in a recent report by Biotechnology Innovation Organization (BIO),

which reports that less than one of every 10 drugs that enter clinical trials is ultimately approved by the Food and Drug Administration in the United States. The report finds a success rate of merely 9.6%, a calculation that is significantly smaller than the widely-cited 11.8% figure from a 2014 study by the Tufts University's Center for the Study of Drug Development.⁵ The International Federation of Pharmaceutical Manufacturers and Associations (2012) estimates that more than 3,200 compounds were at different stages of development globally in 2011, but only 35 new medicines were launched (Dawson, 2015).

Fundamentally, research-based biopharmaceutical companies incur greater expenses and risk in the development of their products than do generic manufacturers. These investments of time and financial resources should be recognized and the effective patent life should be sufficient to recoup these investments. Continued investment and innovation are contingent upon strong, effective intellectual property protection and the ability of innovative firms to recoup their investments. Patents and other forms of intellectual property protection are disproportionately important to the research-based biopharmaceutical industry. Consequently, the legal architecture necessary to foster a robust innovation-based industry is multifaceted and is a powerful force shaping the biopharmaceutical industry, its profitability, productivity, and innovative future.

⁵ Notably, the BIO study has been described as the “largest-ever study on biopharmaceutical clinical development success rates” (BIO, 2016: 3). The study analyzed more than 7,400 drug programs by 1,103 companies. In contrast, the Tufts study only considered 1,442 drugs from the top 50 drug companies with clinical trials between 1995 and 2007 (Seiffert, 2016).

Canada's Current IP Protection for Pharmaceuticals

In Canada, there are three components mapping out the legal framework surrounding intellectual property rights protection in the biopharmaceutical industry. The primary intellectual property law enacted by the legislature is the *Patent Act* (R.S.C., 1985, c.P-4). Beyond this, there are two additional pieces of legislation expanding on the implementation of the regulations: the *Patented Medicines (Notice of Compliance) Regulations* (SOR/93-133) and “Data Protection” found in Canada’s *Food and Drug Regulations* (C.R.C., c.870). In addition, Canada is a signatory to several multilateral treaties, one of which is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which governs intellectual property protection for the biopharmaceutical industry. Canada is also a signatory to the North American Free Trade Agreement (NAFTA), a regional economic integration treaty which also addresses intellectual property protection for the biopharmaceutical industry.⁶

After almost twenty years of compulsory licensing^{7, 8} of prescription drugs, Canada restored full patent protection to biopharmaceutical

⁶ Smith (2000) gives an excellent description of relevant pieces of legislation and the chronology of significant events.

⁷ “Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO’s agreement on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement” (World Trade Organization, 2006).

⁸ In 1923, Canada’s “Patent Act was amended to provide for compulsory licensing for manufacturing purposes for food and drug patents. In relation to patented medicines, the amendment allowed a compulsory license to be granted if a medicine’s active ingredients were manufactured in Canada. (A compulsory license is a statutory license that gives the licensee the right to manufacture, use, or sell a patented invention before the patent expires. Licenses could be granted without the consent of the patent holder and the licensee was required to pay a royalty.) ... [Then

drugs when it repealed the 1969 amendments to the *Patent Act*, with the legislative changes, made in 1987 and 1992. On the road to NAFTA, the negotiations over the Free Trade Agreement (FTA) between Canada and the United States resulted in the amendments to the *Patent Act* contained in Bill C-22, which entered into effect on 7 December 1987. Bill C-22 provided a patent term of 20 years from the date of application, as of 1989. It also guaranteed patent owners a period of protection from compulsory licensing for 10 years in the case of license to import and seven years (if the chemical was sourced in Canada) in the case of license to manufacture, from the date of the first Notice of Compliance after 27 June 1986.

Beyond this, the *Patent Act* was again modified in 1992, under Bill C-91. In this case, the changes were made to implement the provisions on intellectual property contained in the World Trade Organization's (WTO) TRIPS provisions. With exceptions for compulsory licenses in existence before the Act came into force, Bill C-91 eliminated compulsory licenses for biopharmaceutical products. Notably, Bill C-91 provides for product patents for biopharmaceutical innovations beyond the process patents that were already available. The bill does include a "stockpiling" exemption, and an "early working" exception, under which a "generic drug manufacturer could develop a generic version of a medicine and take whatever steps were necessary to meet the regulatory requirements pertaining to its sale before the expiry of the relevant patents" (section 55.2(1)) (Smith, 2000).

The intellectual property protection afforded to the biopharmaceutical industry through these three key legal regimes plays out across several important areas: patents, patent linkage, and data exclusivity. The status of each is described briefly below.

Patents

The primary intellectual property law enacted by the federal government is the *Patent Act*, which sets the patent regime in Canada. To be patentable, an invention must be of patentable subject matter, novel, useful, and non-obvious. In accordance with the WTO treaty, Canadian patents for biopharmaceutical products and processes provide for 20 years of exclusivity for an invention disclosed in the patent application. Given the complexity of biopharmaceutical innovation it is common for a single drug to embody many technologies and be protected by many patents with distinct expiry dates. These patents may cover a variety of product dimensions, such as chemical structure, formulation, or method of administration.

in 1969,] the Patent Act was amended to permit compulsory licenses to import medicines into Canada" (Canada, 2008).

Patent linkage

The *Patented Medicines (Notice of Compliance) Regulations* (NOC Regulations)⁹ provide for patent linkage, balancing the interests of innovator companies with those of generic manufacturers. The patent linkage regulations connect the regulatory approval of generic drugs to patents for innovative drugs. Prior to marketing a generic drug, before Health Canada will issue marketing authorization, the generic producer must address the patents asserted to be relevant by the innovator company. The generic firm may await expiry or claim the relevant patent is invalid or not infringed. The result is that generic firms may first face a summary proceeding to determine patent validity and later risk litigation if infringement is claimed. In like manner, the innovating firm may face litigation under the *NOC Regulations* and also in defending a patent's validity. Through the patent linkage, the *NOC Regulations* seek to balance the incentives for innovation and the timely arrival of generic competition to the market.

Data exclusivity

Finally, Canada's *Food and Drug Regulations* protect the data exclusivity of innovators. Innovative drugs are protected from generic competition by Canadian law for a period of eight years through the protection of innovator data. Accordingly, the "Minister of Health cannot grant a market authorization to a product that would directly or indirectly rely on the clinical trials sponsored by the firm that obtained the regulatory approval" (Grootendorst and Hollis, 2011: 8). This exclusivity specifically applies to the first chemical entity launch in Canada. That is, it does not apply to new indications for existing drugs.

Issues of concern

Given the structure of Canadian IP protection for the biopharmaceutical industry, it is essential to explore the areas in which the regime falls short. There are five areas of concern to consider:

⁹ A Notice of Compliance (NOC) is the marketing authorization provided by Health Canada which legally permits a manufacturer to bring a new drug to market in Canada. The authorization is granted only after a safety and efficacy review of the regulatory submission has been completed, usually through the submission of clinical trial data. Health Canada is the federal entity responsible for national public health.

- » The period of patent term restoration (also called “*sui generis* protection”)
- » Weak enforcement of patents (e.g., no patent linkage right of appeal for innovators)
- » A patent utility standard that is higher than, and inconsistent with, international norms
- » Duration and scope of regulatory data protection
- » No orphan drugs regime

Each of these areas is examined below and includes an analysis of the specific weaknesses of Canadian legislation and how these elements measure up against other nations.

Patent term restoration

Patent term restoration (PTR) legislation provides a grant of additional patent life in compensation for effective patent life lost due to regulatory requirements and administrative delay. In most other nations, innovators are able to recover a portion of the patent term spent in clinical trials and in the regulatory approval process. In the United States, Japan, and the European Union, up to five years of lost time may be recovered. Currently, Canada’s intellectual property regime does not include any form of patent term restoration for time lost due to mandatory government regulatory delays.¹⁰

While Canadian law provides for 20-year patent terms, as required by the WTO’s TRIPS Agreement, Canadian law provides proportionally less patent life to biopharmaceutical innovations as a result of the absence of a PTR provision. Under Canadian law, drugs usually have an effective period of market exclusivity ranging from seven to nine years (CIPC, 2011: 7). In the United States and European Union the effective patent life is lengthened through the restoration of time lost due to regulatory delays, up to five years beyond the 20 years from the filing date, for a maximum market exclusivity period of 15 years (CIPC, 2011: 11). Biopharmaceutical innovators are penalized with shorter effective patent lives due to the lapse between the filing of a patent and the grant of market authorization. Given the complexity of biologic medicines, the length of time required for clinical testing and regulatory approval is longer than that necessary for

¹⁰ Notably, through the CETA negotiations, Canada has agreed to implement a “*sui generis* protection” period of between two and five years.

traditional small-molecule medicines. Accordingly, the remaining effective patent life of biologics is shorter.

In comparison, within the United States, the 1984 *Patent Term Restoration and Competition Act* provides innovators one patent extension per product. Moreover, the legislation provides that the innovator company has the discretion to determine on which patent the extension is sought. The maximum extension allowed is five years, but the total remaining patent term from the date of marketing approval cannot exceed 14 years. Specifically, the extension is calculated as 50% of the period of clinical trials in addition to the full regulatory review period. As in the United States, the European Union also provides a patent term extension, known as a Supplemental Protection Certificate (SPC). This certificate is provided for a single patent per product, on a country-by-country basis. While the maximum allowable extension is five years, the total remaining patent term cannot exceed 15 years.

An extensive body of empirical work establishes that patent protection is disproportionately more important in the biopharmaceutical and chemical industries than in most other sectors to ensure that the researcher appropriates the returns to R&D.¹¹ Notably, Canada is the only country among the G8.¹² nations that does not currently offer any form of patent term restoration (IPIC, 2012: 18). The restoration of up to five years of patent life, as is the practice in other jurisdictions, would lengthen the effective patent term of innovative therapies, enhancing the incentives to invest in the research and development costs necessitated by these treatments.

Weak enforcement of patents

Canada's *Patented Medicines (Notice of Compliance) Regulations* (PM (NOC)) include several elements that undermine Canada's effective enforcement of patents, notably the nature of patent dispute proceedings, and the lack of an effective right of appeal for patent owners. Though

¹¹ Overall, while patents are again seen as "unambiguously the least effective of the appropriability mechanisms," the drug industry regards them as strictly more effective than alternative mechanisms (Cohen, Nelson, and Walsh, 1996: 14). This is confirmed by the industry's high propensity to patent both product innovations (overall highest propensity at 99%) and process innovations (fourth highest propensity at 43%) (Cohen, Nelson, and Walsh, 1996: 21-22). For a list of other studies supporting this claim, please see footnote 4.

¹² The G8 or "Group of Eight" consists of the world's eight largest economic powers: Canada, France, Germany, Italy, Japan, Russia, the United Kingdom, and the United States.

required under both the TRIPS Agreement and NAFTA, there is plentiful evidence that the PM (NOC) Regulations do not reliably provide “expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements” (PhRMA, 2015b: 65).

As the industry trade group PhRMA described in the *National Trade Estimate Report on Foreign Trade Barriers* (2015), there are several major reasons to believe that proceedings under the PM (NOC) Regulations are problematic. Specifically,

With respect to patents that are listed on the Patent Register, when a generic producer files an Abbreviated New Drug Submission seeking marketing approval on the basis of a comparison to an already approved brand-name product, it must address any such listed patents that are relevant. In doing so, the generic producer may make an allegation that patents are not valid or will not be infringed. It must notify the patent owner of any such allegation. The patent owner then has a right to initiate judicial procedures to challenge any such allegation. If procedures are triggered, approval of the generic drug is stayed for a maximum period of up to 24 months pending judicial review.

In the United States, such a challenge to an allegation of non-infringement or patent invalidity proceeds as a full action for infringement on the merits. However, under the Canadian PM (NOC) Regulations, a challenge proceeds by way of summary judicial review aimed only at determining if the allegation is “justified.” As a result of the summary nature of the proceeding, there is no discovery and there may be constraints on obtaining and introducing evidence and cross-examination. This, in combination with various other limitations and shortcomings... can make it difficult for the patent owner to prove its case. (PhRMA, 2015: 3)

Beyond the problematic proceedings under the PM (NOC) Regulations, Canada does not provide patent owners with an effective right of appeal. As described by the Intellectual Property Institute of Canada, the Canadian process proceeds as follows:

In principle, either the generic or the patentee may [challenge] an adverse holding in PM (NOC) [*Patented Medicines (Notice of Compliance) Regulations*] proceedings to the Federal Court of Appeal. However, if the generic is successful, the Minister of Health will normally issue the NOC almost immediately. Once the NOC has been issued, the Federal Court of Appeal will refuse to hear the appeal on the basis that it is moot. The patentee’s recourse is to

bring an infringement action against the generic, from which there is a right of appeal. (IPIC, 2012: 21)

The right of appeal would allow innovative biopharmaceutical companies to more effectively appeal court decisions in which a patent is ruled invalid. This is a process that, in Canada, has been available to challengers but not to patent-owners. That is, PM (NOC) Regulations provide that a generic version may be approved for marketing following a court decision, in the first instance, in favour of the generic manufacturer. However, once the NOC has been issued, any appeal filed by the patent owner becomes moot and the innovative firm must start new proceedings outside of the PM (NOC) framework under the *Patent Act*. That is, decisions under PM (NOC) proceedings are summary in nature, and do not decide upon validity, but still are made final by this inability to appeal. In essence, the patent owner is forced to begin again, reinitiating a case that may have been in litigation under the Regulations for up to two years. In contrast, generic producers have the right of appeal if the patent owner prevails in the first instance under the patent linkage system, and they may also attempt to impeach a patent under the *Patent Act* if unsuccessful under the PM (NOC) Regulations.

Given that the treatment of innovator and generic companies differ, the system is inherently inequitable and discriminatory. Fundamentally, innovative biopharmaceutical companies are denied an effective right to appeal the NOC decision prior to market access for the generic product, while the generic company would have the right to appeal if the court rules in favour of the innovator company. Sanofi-Aventis Canada summed up the problems faced by the research-based industry in a 2010 press release noting, “Canadian innovative pharmaceutical companies have no effective right of appeal when facing intellectual property challenges. This lack of government policy leadership is leading to genericization of branded medicines even while they are still under patent protection. This threatens the company’s ability to maintain its R&D investments, capital expenditures and job creation opportunities” (IPIC, 2012: 14).

This inequitable treatment also creates a climate of uncertainty and litigiousness, where innovators cannot know if or when their patents will be dismissed, without the opportunity for direct appeal, by courts. Accordingly, a grant of the innovator right of appeal would ensure that patent owners as well as generic producers would be treated in a balanced and equitable way with respect to the validity of a patent.

Patent utility doctrine

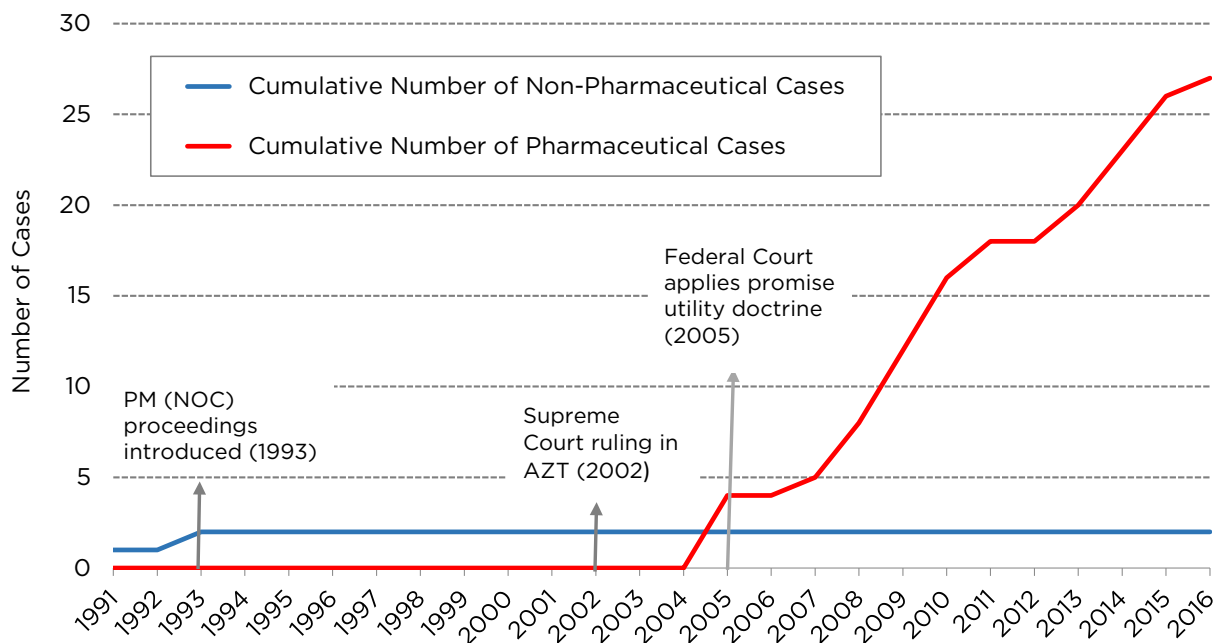
One of the requirements of patentability is the “utility” requirement. To fulfill this, an invention must be capable of a specific industrial application. That is, the invention can be made and/or used in some type of industry. It is important to recognize that the utility requirement is not unique to Canada. Rather, this requirement is an essential component of patent systems the world over, and is applied to all patented inventions. However, Canadian courts have interpreted the utility requirements in a manner that differs from all other developed countries and has a differential impact on the biopharmaceutical industry.

The Canadian judiciary’s application of Canada’s heightened patent utility standard, also known as the “promise doctrine,” is a serious concern because it creates significant uncertainty for innovators and undermines the incentives for investment, especially in the biopharmaceutical sector. The established international standard for a patent is that an invention must be novel, non-obvious, and “useful or capable of industrial application.” Through the promise doctrine, the Canadian system holds innovators to a different standard. As McDermid (2014) noted, the promise doctrine makes Canada the “only developed country in the world with a patent utility standard that is inconsistent with both NAFTA and TRIPS.”

The promise doctrine is composed of three components: “a process where the judge subjectively interprets the ‘promise of the patent’ from the patent application; a requirement that the promised utility either be demonstrated or be based on a ‘sound prediction’ of utility on the date of the patent application; and a requirement that evidence establishing a ‘factual basis’ and ‘sound line of reasoning’ for the predicted utility be disclosed in the original patent application” (McDermid, 2014: 1). Ultimately, the Canadian judiciary has created a heightened standard for patentable utility that has so far had a disproportionate impact on biopharmaceutical patent cases.¹³

The promise doctrine creates significant uncertainty for innovative industries because it both requires innovators to see into the future to “soundly predict” the usefulness of the innovation and also provide sufficient information in the patent application to demonstrate that the innovation will fulfill this promise. In the context of the biopharmaceutical industry, this necessitates an elevated and impractical evidentiary burden. McDermid (2014) explains, “To ‘soundly predict’ how a new medicine would be used, innovators must complete extensive human clinical trials

¹³ While the promise doctrine has impacted the biopharmaceutical industry most significantly, in 2013 the Federal Court of Appeals upheld a ruling that a patent covering helicopter landing gear was invalid (Kappos, 2014).

Figure 1: Canadian Patent Utility Cases, 1991-2016

Source: PhRMA, 2016b.

before filing a patent application. However, for a patent to be granted, inventions must be new and useful. If an invention has undergone Phase II human clinical trials, which are consistently published in medical journals, the innovator risks the validity of the patent because the invention will no longer be new. Fulfilling the terms of Canada's patent promise doctrine could therefore lead innovators to invalidate the novelty of their invention" (McDermid, 2014: 1).

Since 2005, Canadian courts have revoked 28 patents for innovative medicines either completely or partially due to patent utility issues, despite Health Canada's regulatory approval of these drugs as safe and effective. Figure 1 depicts the increase in Canadian patent utility cases over time; it separates cases from the biopharmaceutical industry and those from other industries.

It is particularly worth noting that this is not an issue of the quality of patent applications. "The ironic result is that courts in effect have been saying that Canadian patent examiners were wrong in concluding that a new pharmaceutical was 'capable of industrial application,' or useful, even though all the facts subsequent to the grant support that conclusion. Every pharmaceutical patent revoked on this basis was obviously *capable of*

Table 2: Canadian Federal Court Decisions Revoking Biopharmaceutical Patents Based on Inutility as of May 2, 2016

	Product	Relevant Citation(s)
1	FOSAMAX / alendronate	<i>Merck & Co. Inc. v. Apotex Inc.</i> , 2005 FC 755.
2	BIAXIN / clarithromycin	<i>Abbott Laboratories v. Canada (Minister of Health)</i> , 2005 FC 1095.
3	BIAXIN / clarithromycin	<i>Abbott Laboratories v. Canada (Health)</i> , 2005 FC 1332, aff'd 2007 FCA 153.
4	ALTACE / ramipril	<i>Aventis Pharma Inc. v. Apotex Inc.</i> , 2005 FC 1283, aff'd 2006 FCA 64.
5	REVATIO / sildenafil	<i>Pfizer Canada Inc. v. Apotex Inc.</i> , 2007 FC 26, aff'd 2007 FCA 195.
6	EVISTA / raloxifene	<i>Eli Lilly Canada Inc. v. Apotex Inc.</i> , 2008 FC 142, aff'd 2009 FCA 97.
7	PROVIGIL / modafinil	<i>Shire Biochem Inc. v. Canada (Health)</i> , 2008 FC 538.
8	VALTREX / valacyclovir	<i>Glaxosmithkline Inc. v. Pharmascience Inc.</i> , 2008 FC 593.
9	EVISTA / raloxifene	<i>Eli Lilly Canada Inc. v. Novopharm Limited</i> , 2009 FC 235.
10	ALTACE / ramipril	<i>Sanofi-Aventis Canada Inc. v. Apotex Inc.</i> , 2009 FC 676, aff'd 2011 FCA 300.
11	NORVASC / amlodipine besylate	<i>Ratiopharm Inc. v. Pfizer Limited</i> , 2009 FC 711, aff'd 2010 FCA 204.
12	EBIXA / memantine	<i>Lundbeck Canada Inc. v. Ratiopharm Inc.</i> , 2009 FC 1102.
13	AVAPRO / irbesartan	<i>Sanofi-Aventis Canada Inc. v. Ratiopharm Inc.</i> , 2010 FC 230.
14	REVATIO / sildenafil	<i>Pfizer Canada Inc. v. Ratiopharm Inc.</i> , 2010 FC 612.
15	NEXIUM / esomeprazole magnesium	<i>AstraZeneca Canada Inc. v. Apotex Inc.</i> , 2010 FC 714.
16	STRATTERA / atomoxetine	<i>Eli Lilly and Company v. Teva Canada Limited</i> , 2010 FC 915, aff'd 2011 FCA 220.
17	XALATAN / latanoprost	<i>Apotex Inc. v. Pfizer Canada Inc.</i> , 2011 FCA 236, rev'g 2010 FC 447.
18	ZYPREXA / olanzapine	<i>Eli Lilly Canada Inc. v. Novopharm Limited</i> , 2011 FC 1288, aff'd 2012 FCA 232.
19	LYRICA / pregabalin	<i>Pfizer Canada Inc. v. Pharmascience Inc.</i> , 2013 FC 120.
20	ZOMETA / ACLASTA / zoledronic acid	<i>Novartis Pharmaceuticals Canada Inc. v. Teva Canada Limited</i> , 2013 FC 283.
21	PATADAY / PATANOL / olopatadine	<i>Alcon Canada Inc. v. Cobalt Pharmaceuticals Co.</i> , 2014 FC 149.
22	NEXIUM / esomeprazole magnesium	<i>Pharmascience Inc. v. AstraZeneca Canada Inc.</i> , 2014 FCA 133, rev'g 2012 FC 1189.
23	NEXIUM / esomeprazole magnesium	<i>AstraZeneca Canada Inc. v. Apotex Inc.</i> , 2014 FC 638, aff'd 2015 FCA 158.
24	CIALIS / tadalafil	<i>Eli Lilly Canada Inc. v. Mylan Pharmaceuticals</i> , 2015 FC 125.
25	DIAMICRON / gliclazide	<i>Servier Canada Inc. v. Apotex Inc.</i> , 2015 FC 108.
26	Fluoro nucleosides (of Idenix)	<i>Gilead Sciences v. Idenix Pharmaceuticals</i> , 2015 FC 1156
27	ALIMTA / pemetrexed	<i>Eli Lilly Canada Inc. v. Hospira</i> , 2016 FC 47

Source: Canadian Patent Utility Coalition, 2016.

industrial application since *in fact* it was subsequently industrially applied, approved by Health Canada as safe and effective, and used by hundreds of thousands—even millions—of patients” (CPUC, 2016: 1). Table 2 provides a complete list of the products for which patents were revoked on the basis of inutility as of May 2, 2016.

Each of these cases involves a retrospective challenge to patented drugs with well-established markets. Overall, innovative biopharmaceutical companies have endured more than \$1.1 billion in lost Canadian sales through the premature termination of their patents (Ezell and Cory, 2016). Moreover, virtually all of these cases were initiated by Canadian generic drug companies. In essence, the generic firms sought to “get a patent revoked in order to allow them to copy intellectual property and sell their own versions of the drugs in Canada. For if a drug isn’t ‘useful,’ why would a company want to contest its patent? The patent doctrine has allowed Canadian companies to unfairly take intellectual property without contributing to genuine innovation” (Ezell and Cory, 2016: 1). It is the case that Canada’s promise doctrine is both idiosyncratic and illogical. In essence, the policy penalizes biopharmaceutical innovators for producing drugs that are better than their original promise (Wein, 2015).¹⁴ That is, if a drug is discovered to treat a different disease than the one identified in the patent, the Canadian courts may invalidate the patent since it did not “soundly predict” the “promise” of the patent. This “Promise Doctrine” requires that a drug must not just be useful for *some* purpose (as is the standard in the United States and the European Union), but that it must also deliver *exactly the purpose promised* in the patent filing (Wein, 2015).

Regulatory data protection

Although complementary, patents and data exclusivity protection operate in distinct ways to provide incentives for innovation. Patents provide protection for innovations that meet the standards of patentability and are novel, nonobvious, and useful. For biopharmaceutical innovation, patents protect both breakthrough discoveries and incremental improvements. Given the length of time needed for research and development, as well as the patent-approval processes, effective patent terms rarely correspond to regulatory approval by Health Canada. As a result, the patents on innovative therapies may expire shortly after the products make it to market. In contrast, regulatory data exclusivity protects the tremendous investments

¹⁴ This is exemplified in two current cases: *Eli Lilly and Company v. Government of Canada* NAFTA dispute (decision pending), and the upcoming Supreme Court of Canada case, *AstraZeneca v Apotex*.

of time, talent, and financial resources required to establish a new therapy as safe and effective. Accordingly, this protection follows from the requirement that competing firms seeking regulatory approval of the same or a similar product must independently generate the comprehensive preclinical and clinical trial data needed to establish safety and efficacy, rather than rely on or use the innovator's data, that is, the proprietary data generated through pre-clinical and clinical trials. Clinical trials ensure that drugs are safe and effective, but they command a great cost, resulting from years of effort and millions of dollars in expenses. According to a study by Torsensson and Pugash (2008), clinical trials now account for approximately 60% of the total cost of drug research and development. Accordingly, regulatory data protection may prevent generic entry given that generic companies generally prefer to wait to use innovator data rather than bear the substantial cost of generating their own data. Prior to the ratification of NAFTA and TRIPS, pre-clinical and clinical trial data were treated as trade secrets in the United States and the European Union, but not in Canada. While the implementation of these trade agreements resulted in more uniform international rules, the length and extent of data protection in Canada lags behind that in the United States and the European Union. Generic manufacturers may choose to wait a set period of time after which they are able to use the innovator's prior approval in an abbreviated regulatory approval, or they may independently generate the data. Regulatory data protection is not an extension of patent rights and it does not prevent the introduction of a generic version, provided that the innovator's data is not used to secure marketing approval. At a fundamental level, data exclusivity protection encourages biopharmaceutical firms to invest the necessary time and financial resources in establishing the safety and efficacy of their product and prevents competitors from free-riding on these efforts for a limited period of time.

In Canada, data protection may be granted for a period of eight to eight-and-a-half years. However, the drugs must meet certain criteria to be eligible in that data exclusivity does not apply to new applications for existing drugs. The maximum term of data protection is 8.5 years: no abbreviated submission (the submission for approval of a generic version of the drug) is permitted for six years, no regulatory approval of abbreviated submissions will be given for an additional two years, and an additional six months are provided for submissions that include pediatric studies. As in the case of traditional small molecule drugs, Canada currently provides a base period of eight years of data protection for biologic drugs, though data protection is arguably more important for biologic drugs relative to traditional small molecule drugs.

In contrast, the United States provides five years of exclusivity in addition to FDA approval time for chemical entities. In the case of biologics, the United States provides 12 years of data exclusivity. Within the European Union, under Directive 2004/27/EC, there is a provision for data exclusivity and extensions of 8+2+1 years, with no distinction between biologics and small molecule drugs (Grootendorst and Hollis, 2011). Specifically, this time is broken down this way: no abbreviated submission is permitted for eight years, no regulatory approval for that abbreviated submission will be granted for an additional two years, and an additional year of data exclusivity can be added for significant changes (new indications). Moreover, European sponsors (those applying for approval) are required to conduct pediatric studies where applicable.

Canada lags behind other nations in the provision of data exclusivity protections and there is reason to believe that this discrepancy harms Canadian innovation. The justification for enhanced data exclusivity laws may be found in the incentives provided to research-based firms to produce the data required for regulatory approval. “The pharmaceutical and agrochemical industries have often successfully argued that if regulators allow an equivalent product (a ‘generic’) to go to market on the strength of the test data provided by the originator company, there would be no incentive for anyone to produce the test data necessary to obtain market approval” (Krattinger et al., 2007).¹⁵ Admittedly, data exclusivity regimes do differ across countries in nature, scope, and extent of protection. However, stronger regimes clearly enhance the incentive to innovate. Unfortunately, it has become clear that both Health Canada and Canadian courts have interpreted data protection for innovative drugs in such a narrow manner so as to reduce or in some cases nullify the intent of data protection as an incentive for innovation.

Orphan drugs

“Orphan drugs” are those that treat rare diseases, specifically defined as a condition affecting fewer than 5 in 10,000 people. As described by Dawson (2015), the vast majority of these diseases are tied to genetic factors such that development of treatments and cures is tremendously expensive and the market for such medicines is very small. In an effort to create incen-

¹⁵ Given that generic firms rarely undertake clinical trials or search for new indications, spillover benefits of reduced data exclusivity/earlier access to data are likely very limited in this area.

Table 3: Comparison of Canadian and Non-Canadian biopharmaceutical IP Regimes

	Japan	Canada	European Union	United States
Right of Appeal	Canada and US are the only major countries with "linkage" regimes	PM(NOC) regulations that link market approval to patent validity CETA: Government commitment to ensure equivalent and effective rights of appeal	No "linkage" regimes like in Canada or US However, provisional measures (e.g. interlocutory relief) also available in EU to prevent patent infringement	Linkage regime similar to Canada's (the "Hatch Waxman" system) Absence of problematic inequities: e.g. innovators have a right of appeal Provisional measures available
Data Exclusivity	8 years re-examination period + generic approval time (1+ years) 4 years re-examination period + generic approval time (1+ years) for new indications	8 years exclusivity No extensions for new indications Restrictions on Scope of Products	10 years exclusivity 1 year extensions for new indications	Chemical Entities 5 years exclusivity + FDA approval time (1+ years) 3 year extension for new indications
Patent Term Restoration	Maximum 5 years additional market exclusivity to one or more patents	CETA: Maximum 2 years additional market exclusivity	Maximum 5 years additional market exclusivity Maximum combined patent/Supplemental Protection Certificates (SPC) post approval market exclusivity of 15 years	Maximum 5 years additional market exclusivity Maximum combined post-approval market exclusivity 14 years
Orphan Drug IP Incentives	Extension of re-examination period up to 10 years	None	10 years market exclusivity	7 years market exclusivity

Source: Innovative Medicines Canada, 2016.

tives for the development of drugs for these conditions, many jurisdictions offer longer periods of market exclusivity to increase the probability that innovators will be able to recover their research and development costs. In the United States, seven years of market exclusivity is provided. In the European Union, 10 years of market exclusivity is offered and a similar period is offered in Japan.¹⁶ In contrast to other industrialized nations, Canada provides no incentives (IP or otherwise) to encourage the development of orphan drugs. According to the Canadian Organization for Rare Disorders, only 60% of rare disease treatments are available to Canadian patients. Moreover, they usually launch in Canada with a delay of several years relative to other nations (Dawson, 2015: 21). Admittedly, this may be a function of more than just the Canadian IP regime.

In summary, there are many dimensions of the Canadian IP regime that are inadequate for effective protection of biopharmaceutical innovation. Table 3 provides a comparison of IP regimes across jurisdictions.

Consequences of Canada's current IP protections

The Canadian intellectual property environment clearly creates consequences for Canada's global competitiveness. Table 4, from the World Economic Forum, demonstrates that Canada's rank and score in "Innovation Factors" is strikingly low and certainly undermines Canada's overall index ranking.¹⁷ In the World Economic Forum's 2015-2016 report, Canada ranks 13th with a comprehensive score of 5.31, a small improvement over 2014-2015 where Canada ranked 15th with a comprehensive score of 5.24. Notably, this overall improvement resulted from a lower budget deficit, while Canada's rank in "Innovation Factors" did not improve and the nation continues to place 24th in that category. At the same time, com-

¹⁶ Notably, this provides a longer period of exclusivity than the patent term restoration legislation which provides a maximum of five years of additional market exclusivity.

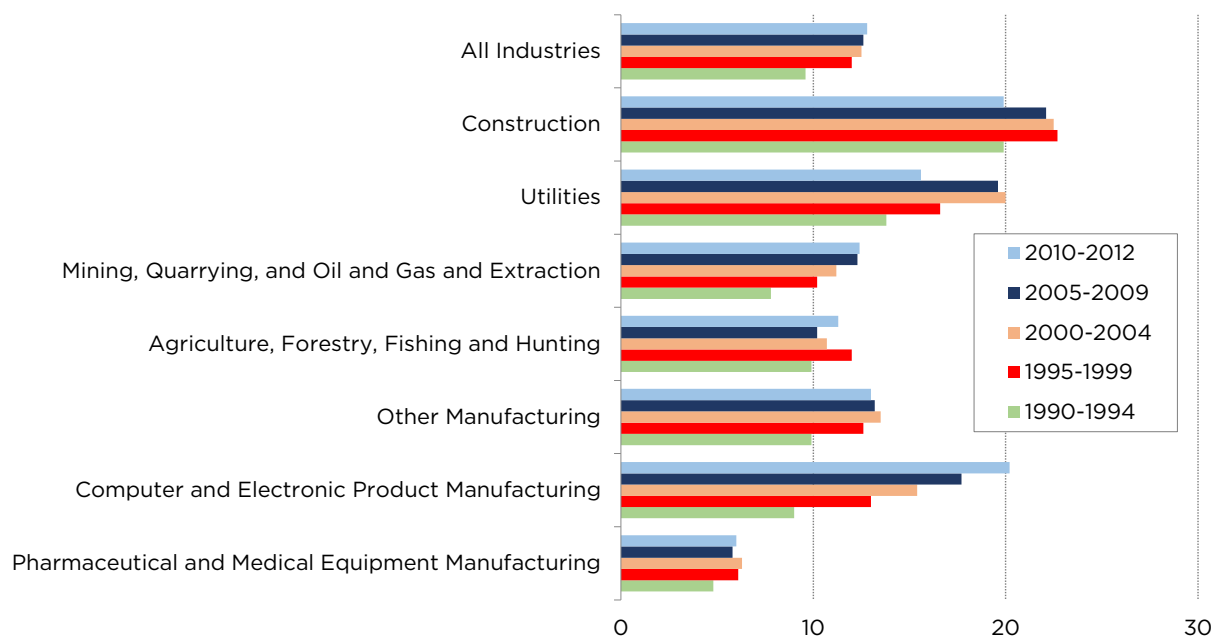
¹⁷ According to its mission statement, "The World Economic Forum is an international institution committed to improving the state of the world through public-private cooperation. It builds, serves and sustains communities through an integrated concept of high-level meetings, research networks, task forces and digital collaboration... The Forum was established in 1971 as a not-for-profit foundation and is headquartered in Geneva, Switzerland. It is independent, impartial and not tied to any special interests, working in close cooperation with all major international organizations. The Forum strives in all its efforts to demonstrate entrepreneurship in the global public interest while upholding the highest standards of governance. Moral and intellectual integrity is at the heart of everything it does" (World Economic Forum, 2016).

Table 4: The Global Competitive Index 2015-2016

Country/Economy	Overall Index		Basic Requirements		Efficiency Enhancers		Innovation and Sophistication Factors	
	Rank	Score	Rank	Score	Rank	Score	Rank	Score
Switzerland	1	5.76	2	6.26	4	5.55	1	5.78
Singapore	2	5.66	1	6.36	2	5.7	11	5.19
United States	3	5.61	30	5.27	1	5.76	4	5.59
Germany	4	5.53	8	5.95	10	5.31	3	5.61
Netherlands	5	5.5	7	6.05	9	5.31	6	5.46
Japan	6	5.47	24	5.52	8	5.33	2	5.66
Hong Kong SAR	7	5.46	3	6.2	3	5.57	23	4.8
Finland	8	5.45	11	5.95	13	5.22	5	5.5
Sweden	9	5.43	13	5.9	12	5.24	7	5.45
United Kingdom	10	5.43	25	5.52	5	5.49	9	5.28
Norway	11	5.41	6	6.06	11	5.29	13	5.16
Denmark	12	5.33	12	5.91	16	5.15	10	5.25
Canada	13	5.31	16	5.77	6	5.45	24	4.77
Qatar	14	5.3	5	6.13	21	5.05	12	5.18
Taiwan, China	15	5.28	14	5.84	15	5.19	16	5.06
New Zealand	16	5.25	9	5.95	7	5.33	25	4.66
United Arab Emirates	17	5.24	4	6.17	17	5.11	21	4.83
Malaysia	18	5.23	22	5.59	22	5.01	17	5.05
Belgium	19	5.2	23	5.56	18	5.09	15	5.14
Luxembourg	20	5.2	10	5.95	23	5	18	5.04
Australia	21	5.15	15	5.79	14	5.21	26	4.61
France	22	5.13	26	5.48	19	5.08	20	4.97
Austria	23	5.12	20	5.61	24	4.89	14	5.16
Ireland	24	5.11	27	5.46	20	5.06	19	4.98
Saudi Arabia	25	5.07	17	5.7	30	4.69	29	4.18

Source: Schwab, *Global Innovation Index 2015-2016*: 8, table 2.

Figure 2: Share of Patent Applications with at Least One Canadian Inventor, Selected Industries



Source: Brydon, et al., 2014: 7.

pany spending on R&D ranks 26th and the nation's capacity to innovate is ranked 23rd out of a total of 140 countries (Schwab, 2015: 25). Importantly, the World Economic Forum reports that the most problematic factor for doing business in Canada is "Insufficient Capacity to Innovate" (Schwab, 2015: 132).

These results echo trends seen in other statistics. According to the World Intellectual Property Organization (WIPO), both intellectual property filings and foreign intellectual property filings in Canada are falling (WIPO statistical country profile, as reported by the Canadian Chamber of Commerce, 2014: 6).¹⁸ Further, it is clear that these trends are specific to the biopharmaceutical and medical devices industries. According to a recent study by Brydon, Chesterley, Dachis, and Jacobs, "Canadian patent data shed new light on domestic 'value added' by sector, and show that Canadian innovative output—as measured by domestic patent applica-

¹⁸ IP filings are those done by Canadians, while foreign IP filings are those done by citizens of other nations. The numbers reflect the innovativeness of Canadians, as well as the value that foreign innovators place on Canadian IP protection.

tions—is high in utilities, construction, and computers and electronics, relative to other sectors. However, the pharmaceuticals and medical equipment sector has a low share of Canadian inventors applying for patents for the Canadian market” (Brydon et al., 2014: 1). This claim is illustrated in figure 2, which depicts the share of patent applications with at least one inventor in Canada.¹⁹

Overall, there are numerous deficiencies that weaken intellectual property protections within Canada relative to what is provided in other industrialized nations. The result is an IP regime characterized by significant uncertainty and instability for biopharmaceutical firms. The 2016 IP Index, compiled by the US Chamber of Commerce, places Canada in the middle of the pack (GIPC 2016a: 28). Weaknesses such as onerous patentability requirements, insufficient enforcement mechanisms, and inadequate anti-counterfeiting measures place Canada in the company of Mexico, Malaysia, China, and Russia in the IP Index rankings. These rankings make a difference to prospective investors and signal Canada’s lack of support for knowledge-based industries, especially the biopharmaceutical industry. Fundamentally, Canada is a global outlier, providing inadequate intellectual property protections for the biopharmaceutical industry.

¹⁹ Other global indicators of Canada’s problematic IP regime signal that the promise doctrine is of particular concern: In April 2016, the Special 301 Report of the Office of the United States Trade Representative expressed “... serious concerns about the lack of clarity and the impact of the heightened utility requirements for patents that have been imposed by Canadian courts.” Further, the World Trade Organization, in its 2015 *Trade Policy Review* (TPR) report on Canada, made note that Canadian courts had continued to develop the promise doctrine during the review period. A number of countries also raised issues with Canada’s utility standards in their submissions to the TPR.

The Global Context

Any cross-country comparison of patent regimes is best done by examining nations enjoying success with innovation. In the context of the biopharmaceutical industry, it is useful to examine the countries that are the most innovative as well as the emerging markets that hold the greatest promise. Assuming that a nation's ability to attract greater research and development spending fosters increased innovation and proxies for an innovation-inducing IP regime, the nations with the largest R&D expenditures possess intellectual property regimes worth examining. Table 5 presents the figures for research and development spending by geographic region for PhRMA (Pharmaceutical Research and Manufacturers of America) member companies in 2013.

Over the past five decades, a multitude of scholars have demonstrated that patents foster *ex-ante* innovation, motivating the investment of time and talent because of the prospect of financial gain from those endeavors. This claim is supported by the “work of economists such as Arrow (1962), Griliches (1963), Schmookler (1966), Kitch (1977), Reinganum (1981), Klemperer (1990), Romer (1990), Gilbert and Shapiro (1990), Grossman and Helpman (1991), Scotchmer (1999), and Gallini (2002)” (Phelps 2015). These findings are echoed in an OECD report by Park and Lippoldt (2008): “Focusing on technology transfer to developing countries, the study finds that stronger levels of patent protection are positively and significantly associated with the inflows of high-tech products, like pharmaceutical goods, chemicals, aerospace, computer services, information, and office and telecom equipment.”

The question then becomes whether R&D spending by PhRMA member countries is a reasonable proxy. Table 6, below, presents the data on the top 25 global biopharmaceutical corporations, by global sales, in 2014. Given that all but four of the top 25 companies are PhRMA members, it is reasonable to believe that their regional spending is indicative of innovation-friendly IP regimes.

While the highest levels of research and development spending done by PhRMA member companies, as described in table 6, is a good first pass and indicative of an IP regime that facilitates innovation, it is worth considering other measures as well. Figure 3, prepared by the Global Intellec-

Table 5: 2013 R&D by Geographic Area, PhRMA Member Companies

Geographic Area		Dollars (\$ millions)	Share (%)
Africa	Egypt	14.7	0.0
	South Africa	39.2	0.1
	Other Africa	17.1	0.0
Americas	United States	40,396.0	78.3
	Canada	545.1	1.1
	Mexico	97.6	0.2
	Brazil	138.1	0.3
	Argentina	97.5	0.2
	Venezuela	11.2	0.0
	Colombia	41.1	0.1
	Chile	18.1	0.0
	Peru	12.2	0.0
	Other Latin America (Other South American, Central American, and all Caribbean nations)	299.6	0.6
	Asia-Pacific	Japan	913.7
China		372.3	0.7
India		26.9	0.1
Taiwan		44.8	0.1
South Korea		39.3	0.1
Other Asia-Pacific		150.4	0.3
Australia	Australia and New Zealand	237.4	0.0
	Europe		
	France	335.1	0.6
	Germany	660.5	1.3
	Italy	207.1	0.4
	Spain	213.3	0.4
	United Kingdom	1,401.2	2.7
	Other Western European	4,652.9	9.0
	Czech Republic	39.7	0.1
	Hungary	29.5	0.1
	Poland	76.9	0.1
	Turkey	27.2	0.1
	Russia	76.9	0.1
	Central and Eastern Europe (Cyprus, Estonia, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, Malta, and other Eastern European countries and the Newly Independent States)	131.4	0.3
Middle East	Saudi Arabia	4.3	0.0
	Middle East (Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan, and Qatar)	73.7	0.1
Uncategorized		171.3	0.3
Total R&D		51,613.6	100.0

Source: PhRMA Annual Member Survey, 2015a: 7.

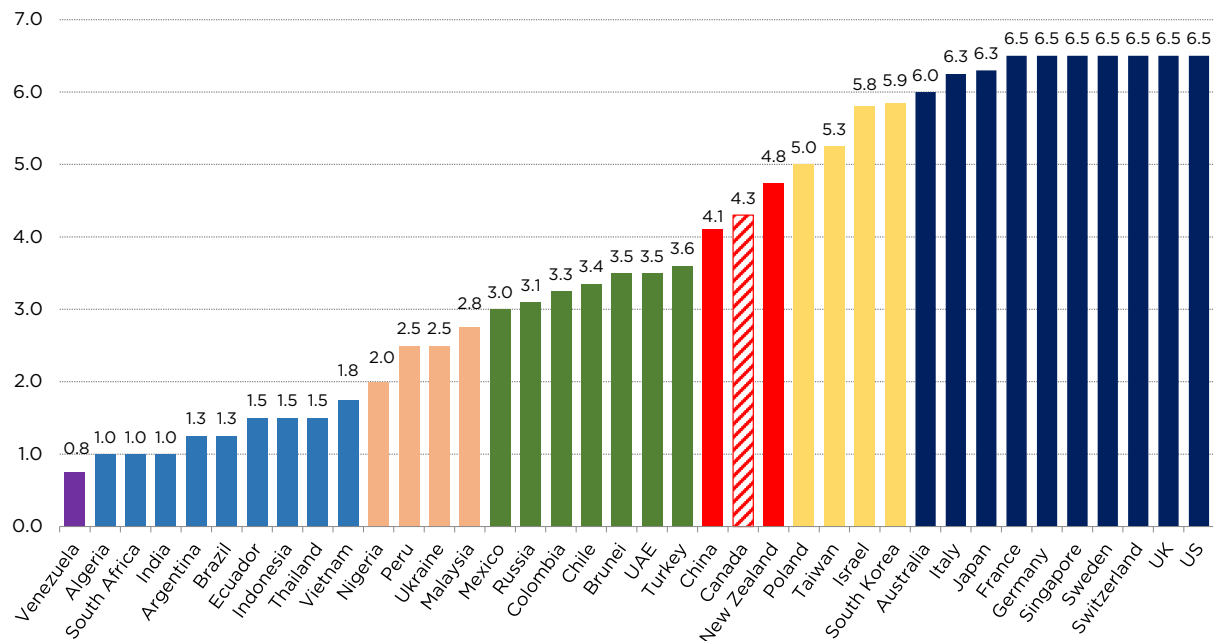
Table 6: Top 25 Biopharmaceutical Companies by Global Sales

	Company	2014 (\$m)	2013 (\$m)	Growth (\$m)	Growth (%)
1	Novartis	\$47,101	\$47,468	-\$367	-1
2	Pfizer	\$45,708	\$47,878	-\$2,170	-5
3	Roche*	\$39,120	\$39,163	-\$43	0
4	Sanofi	\$36,437	\$37,124	-\$687	-2
5	Merck & Co.	\$36,042	\$37,437	-\$1,395	-4
6	Johnson & Johnson	\$32,313	\$28,125	\$4,188	15
7	GlaxoSmithKline	\$29,580	\$33,330	-\$3,750	-11
8	AstraZeneca	\$26,095	\$25,711	\$384	1
9	Gilead Sciences*	\$24,474	\$10,804	\$13,670	127
10	Takeda	\$20,446	\$19,158	\$1,288	7
11	AbbVie	\$20,207	\$18,790	\$1,417	8
12	Amgen	\$19,327	\$18,192	\$1,135	6
13	Teva	\$18,374	\$18,308	\$66	0
14	Lilly	\$17,266	\$20,962	-\$3,696	-18
15	Bristol-Myers Squibb	\$15,879	\$16,385	-\$506	-3
16	Bayer	\$15,486	\$14,854	\$632	4
17	Novo Nordisk	\$15,329	\$14,877	\$452	3
18	Astellas	\$14,099	\$13,508	\$591	4
19	Boehringer Ingelheim	\$13,830	\$15,789	-\$1,959	-12
20	Actavis*	\$13,062	\$8,678	\$4,384	51
21	Otsuka	\$11,308	\$11,226	\$82	1
22	Daiichi Sankyo	\$10,430	\$12,067	-\$1,637	-14
23	Biogen Idec	\$9,398	\$6,668	\$2,730	41
24	Baxter*	\$8,831	\$8,347	\$484	6
25	Merck KGaA	\$7,678	\$8,399	-\$721	-9

Source: PMLive, 2016.

* = *not* PhRMA member companies.

tual Property Center (GIPC), presents national scores for the category that measure the strength of an economy's environment for patents, related rights, and limitations. "As in past editions of the Index, Canada's score in this category is the lowest of all developed high-income OECD economies and is closer to that of China, Turkey, the UAE, and Brunei than that of Singapore, the United Kingdom, United States, Japan, and other high performers" (GIPC, 2016a: 27). According to the GIPC ranking, Canada continues to be the OECD economy with the weakest national IP environ-

Figure 3: Strength of Patents, Related Rights, and Limitations

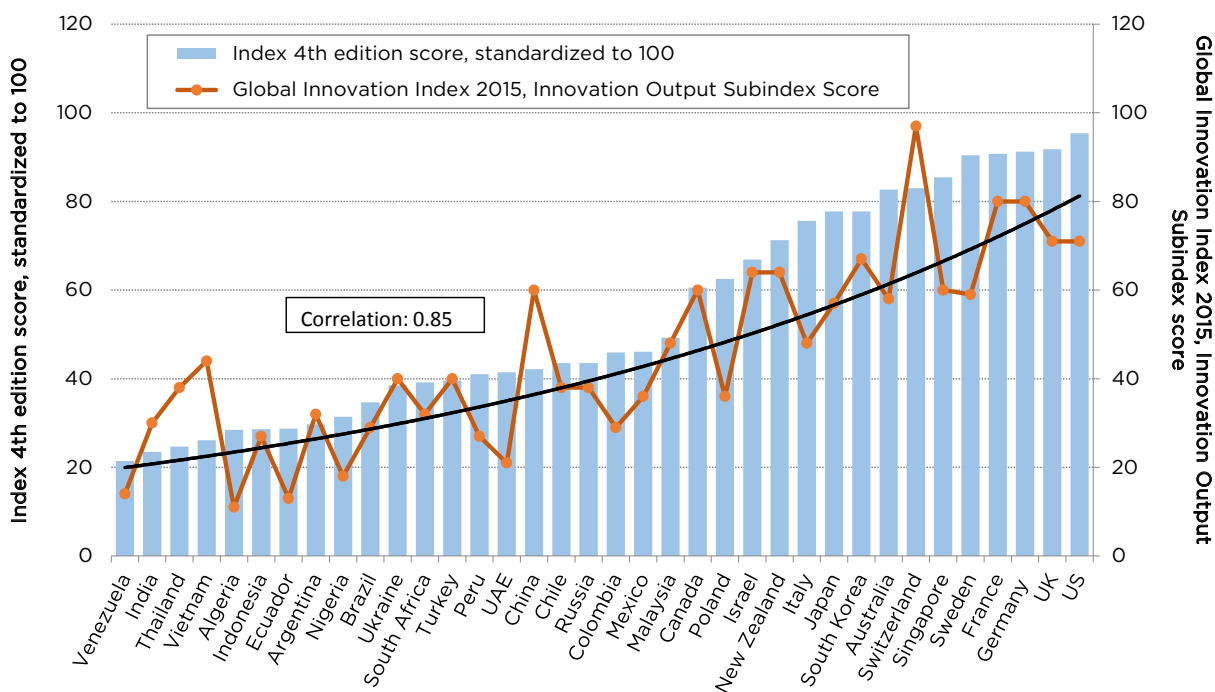
Source: GIPC, 2016a: 27.

Note that this score is calculated across seven indicators with a maximum score of seven.

ment and the lowest overall score. This is the position Canada has occupied in each of the four published editions. This is particularly disheartening in light of the fact that the Index has more than tripled the number of economies sampled over the four published editions^{20, 21} (GIPC, 2016a: 25).

²⁰ The first edition of the GIPC IP Index was published in 2013 and included 11 nations: Australia, Brazil, Canada, Chile, China, India, Malaysia, Mexico, Russia, United States, and United Kingdom. The fourth edition, published in 2016, includes 38 economies, including: Algeria, Argentina, Australia, Brazil, Brunei, Canada, Chile, China, Colombia, Ecuador, France, Germany, India, Indonesia, Israel, Italy, Japan, Malaysia, Mexico, New Zealand, Nigeria, Peru, Poland, Russia, Singapore, South Africa, South Korea, Sweden, Switzerland, Taiwan, Thailand, Turkey, Ukraine, United Arab Emirates, United Kingdom, United States, Venezuela, and Vietnam.

²¹ Canada “has improved its overall score in each edition of the Index—remains an outlier among high-income OECD economies. Despite increasing in each edition of the Index, Canada’s score is still the lowest of all OECD economies and its national IP environment has consistently remained closer to middle-income economies such as Malaysia and Mexico than to top Index performers such as the United States and the United Kingdom” (GIPC, 2016a: 22).

Figure 4: IP Protection is Strongly Linked to Innovation

Source: GIPC, 2016b: 9.

The Global Intellectual Property Center analysis also considers the economic benefits delivered by strong intellectual property rights regimes. These include innovation, job creation, and investment. Figure 4 provides data on innovation, presenting the correlation between the GIPC's Index Score and the Global Innovation Index's Scores. The figure reveals that Canada falls between Mexico and Malaysia (ranked just below Canada), and Poland and Israel (ranking just above Canada). As described by the GIPC report, "Economies maintaining robust IP environments produce nearly 70% more knowledge-based, technological and creative outputs than do economies whose overall IP environment requires improvement" (GIPC, 2016b: 9). This claim is supported for the biopharmaceutical industry by calculating the correlation between biopharmaceutical R&D spending and national IP Index scores. The correlation between the two series is 0.297. While other national characteristics are important, the calculation does indicate that a nation's level of IP protection is strongly correlated with greater biopharmaceutical R&D expenditures.²²

²² The calculation was made for the 22 nations that appeared in both series.

Consequences of Change and What Canada Stands to Gain

The suggested changes will clearly have consequences for Canada, benefiting both the Canadian economy and Canadian patients. Benefits will include reduced legal ambiguity and litigation through increased predictability, greater research and development expenditures, increased foreign direct investment, additional job creation in the biopharmaceutical and related industries, productivity gains, greater biopharmaceutical self-sufficiency, faster launch times for new medicines, and additional innovation on cutting-edge treatments and therapies. This section considers the many dimensions of these policy changes individually.

Economic growth

Knowledge-based industries are the engines of economic growth and vital to national well-being and global competitiveness. “Economies with state-of-the-art IP environments produce nearly 70% more innovative output,” according to the GIPC (2016a: 3). Moreover, close to triple the workforce is concentrated in knowledge-intensive sectors in countries that are characterized by IP-friendly regimes (GIPC, 2016a: 3). Specifically, within economies with advanced IP rights in place, the firms are approximately 50% more likely to invest in R&D activities (GIPC, 2016a: 3). “In 2013, the Canadian innovative biopharmaceutical sector invested over \$1 billion in research and development, having a \$3 billion impact on the Canadian economy and supporting approximately 46,000 direct and indirect jobs across the country” (PhRMA, 2014: 1). A growing body of empirical evidence demonstrates that stronger intellectual property protections, in combination with other policies, increase economic development, foreign direct investment (FDI) and innovation.²³ Multiple studies establish that

²³ An excellent review of this literature is provided by Pugatch, Torstensson, and Chu (2012). Their study documents the findings of more than 40 studies which demonstrate the positive correlation between intellectual property rights, foreign direct investment, trade and economic development. These studies examine both industrialized and developing nations from all regions of the globe.

the rate of return to society from corporate research and development and other innovative activities is at least twice what the innovator receives.²⁴

As Pham (2010) describes, IP-intensive industries sustain greater long-term economic growth, generate trade surpluses, and pay both highly-skilled and low-skilled employees more than non-IP-intensive industries. Overall, these findings confirm the importance of innovation and intellectual property in job creation, higher wages, exports, and sustained economic growth, further emphasizing the need for a hospitable environment for innovation (Pham, 2010: 4–6).

In addition, economic studies demonstrate that every dollar invested in medical innovation generates an average of three dollars in future health benefits (Moore, Snyder, and Hughes, 2011). Moreover, these benefits extend beyond the health sphere, and produce significant spillovers into the broader economy. Murphy and Topel (2006) demonstrate that between 1970 and 2000, medical innovation was the source of more than half of all economic growth.

Of course, it must be recognized that the gains from stronger IP protection for pharmaceuticals in Canada—a small nation that is largely a net importer of patented medicines—may be substantially lower than in the US or Europe. This is not to say that the benefits are insubstantial, however.²⁵

Job creation

The biopharmaceutical industry is a significant creator of jobs in the Canadian economy. The industry contributes \$3.8 billion to the Canadian economy each year and the life science sector supports 31,000 jobs (Innovative Medicines Canada, 2016). Following the amendments to the *Patent Act* in 1987, Canada's research-based biopharmaceutical companies reported an increase in full-time employment by member companies from 14,521 in 1987 to 45,999 in 2011²⁶ (Lexchin, 2001: 9; and KPMG, 2012: iv).

²⁴ For example, see Mansfield (1991), Jones and Williams (1998), and Brynjolfsson, Hitt and Yang (2000).

²⁵ Although IP is not the only factor driving inbound investment, Canadian biopharmaceutical affiliates of multinational corporations indicate that their international headquarters perceive the national IP regime as sometimes uncompetitive and also unpredictable, which does not help them to drive investment to Canada (Charles River Associates, 2015).

²⁶ While this increase following the change is suggestive, the growth presented here may admittedly stem from sources other than a strengthened IP regime.

Table 7: Annual Contribution of the Innovative Biopharmaceutical Industry to the Canadian Economy

Types	Direct & Indirect Contribution
Value Added (excluding indirect corporate taxes)	\$3 billion
Employment (FTE)	45,999
New Infrastructure (January 2011 – September 2012)	\$450 million
R&D	\$1.08 billion

Source: KPMG, 2012: iv.

Table 7 depicts the annual contribution of the innovative biopharmaceutical industry to the Canadian economy.

Treatments and cures

According to the Canadian Intellectual Property Council, the research-based biopharmaceutical industry funds 27% of all health science research and development in Canada (CIPC, 2011: 5). Moreover, the biopharmaceutical industry is a leading source of research and development in Canada. Twenty biopharmaceutical companies were among Canada's top 100 R&D spenders in 2013 (Research Infosource, 2014). Further, spending on R&D by Canada's research-based biopharmaceutical companies grew from \$106 million in 1987 to \$1.18 billion in 2011²⁷ (CIPC, 2011: 11). This last statistic is indicative of a positive trend that needs to be nurtured and continued with additional IP protections in the biopharmaceutical sector that will bring Canada's IP regime to a level similar to that found in other nations.

While the biopharmaceutical industry is a leading source of R&D spending and the absolute amount of spending has increased over time, the *rate* of spending in Canada is falling (percentage change from the previous year). Figure 5 makes this point graphically. A recent study by Charles River Associates, *The Wider Impact of the Promise of the Patent Doctrine in Canada*, reports that between 2005 and 2015, while improvements had been made to close to half of the medicines that prematurely lost patent protection in Canada under the utility promise doctrine, none of these improvements are available to Canadian patients (Charles River

²⁷ Inflation adjusted.

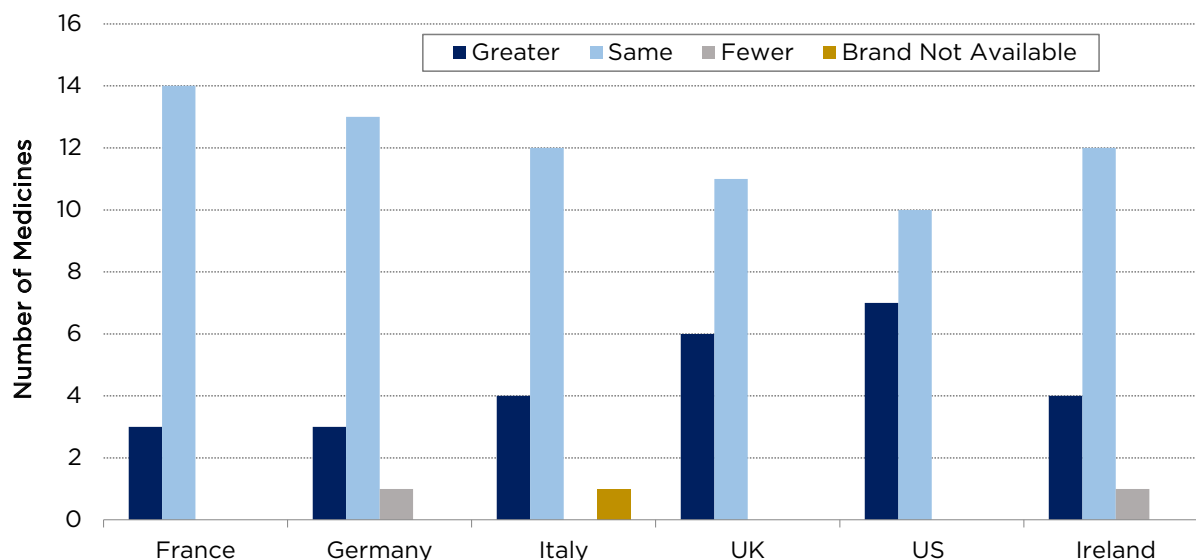
Figure 5: Canada's Falling R&D Expenditures

Source: PhRMA 2016a.

Associates, 2015). It is undeniable that Canadian patients are paying the price. As figure 6 shows, fewer medicines are available in Canada relative to the United States, the UK, France, Germany, Italy, and Ireland. Since the “promise doctrine” was introduced, the number of clinical trials conducted in Canada has decreased by 21% (PhRMA, 2016a). “Patent applications are up around the world, but dropped 8.7 percent in Canada between 2006 and 2012. Research and development spending declined by more than 30 percent over roughly the same period and, according to World Bank data, Canada is in the bottom 25 percent of G20 countries for biopharmaceutical patents filed by its own citizens” (PhRMA, 2016a). Stronger intellectual property protections would certainly help rectify this discrepancy.

In addition, there is some evidence to suggest that enhanced intellectual property protection may speed the launch of new therapies and access to new innovations (Wang, Ji, and Lin, 2003: 277). Lanjouw (2005) first showed that stronger IP protections, for both products and processes, correspond to faster launch times.

Figure 6: Fewer Medicines Available in Canada—Comparison of Available Formulations in Comparator Countries vs. Canada



Source: PhRMA 2016a.

The benefits of a vibrant innovative biopharmaceutical industry translate into treatments that enhance and extend life as well.²⁸ While much of the innovation discussed here was funded by sales in markets other than Canada (often larger markets with higher patented medicine prices), and while Canada may be able to “free ride” on other countries’ funding of innovation (in particular the United States), it is nevertheless true that stronger IP protection in Canada would add to pharmaceutical R&D at the margin. While it cannot be said which drugs in recent years were not approved or sold in Canada because of the absence of stronger IP protection, it is clear that stronger protection in Canada will increase the potential for R&D investment in the pharmaceutical industry. Over the past several decades, new medicines have increased longevity, accounting for 40% of the two-year increase in life expectancy achieved in 52 countries between 1986 and 2000 (Lichtenberg, 2003). Other examples include the treatment of HIV/AIDS and cancer. Since the mid-1990s and

²⁸ While government entities do fund medical research, most notably in HIV/AIDS, infectious disease, and oncology, much of this is basic research which is then developed and commercialized by private firms. Further, industry is the principal funder of research in most other areas, and is responsible for approximately 65% of US biomedical research (Dorsey et al., 2009; Moses and Martin, 2011).

the development of a new wave of medicines to treat HIV/AIDS, the death rate in the US from AIDS dropped about 70% (CASCADE Collaboration, 2003). In addition, in the years since 1971, our arsenal of cancer medicines has tripled. These new treatments account for 50–60% of the increase in six-year cancer survival rates since 1975 (Lichtenberg, 2004). In particular, data shows that in 2003 the total number of people who died of cancer went down for the first time in more than 70 years (Hoyert et al., 2006).

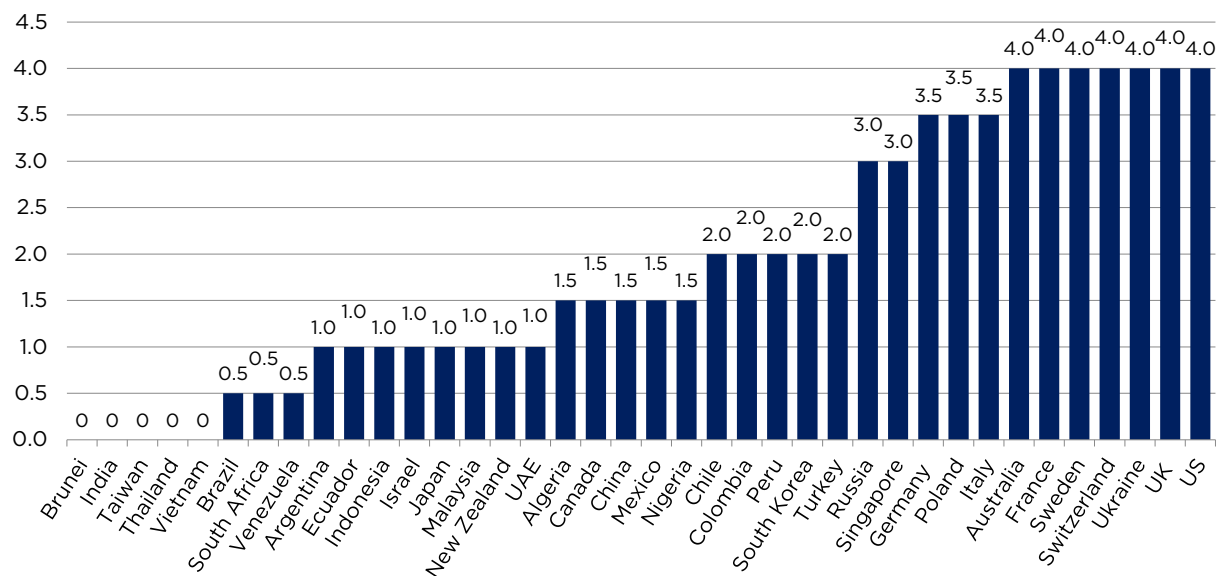
While there is good evidence that strong, effective IP protections foster innovation and more rapid access to a larger range of treatments and cures, this does come at a cost. One must examine the expense of this increase in social welfare and improved public health.²⁹

Trade benefits

Canada's domestic biopharmaceutical industry is important to the Canadian economy for another reason as well: international trade agreements. These trade agreements result in job creation and economic growth. According to former Prime Minister Stephen Harper, the Canadian-EU free trade agreement will add 80,000 new jobs, while estimates are that the deal will increase Canada-EU trade by \$37 billion annually (Roberts, 2014, September 26). The agreement will certainly boost the Canadian economy by providing Canadian companies with access to the EU's 500 million consumers (Whittington, 2014). Figure 7 depicts Canada's relative global performance in this context. "Participation in key international treaties is a reflection of a broader commitment to the international IP community and the highest IP standards. Remarkably, less than half of the 38 economies score at least 50% for this category. Five economies actually score a 0. The lack of participation and membership in international treaties is not limited to emerging or middle-income economies. Quite a few high-income and OECD economies score poorly in this category, including Brunei, Japan, Israel, New Zealand, and the UAE" (GIPC, 2016a: 32).

Moreover, increased domestic production resulting from stronger IP protection for medicines may serve to reduce the import penetration of the Canadian market, lessening Canada's dependence on foreign im-

²⁹ According to Lexchin and Gagnon (2013), the cost to Canadians of adopting a two-year patent term restoration could approach between \$850 million and \$1.6 billion annually. Like all estimates, these numbers are controversial and subject to important assumptions that may or may not prove accurate. However, it is worth acknowledging that the costs could be significant and the benefits of stronger IP protection should be weighed in that context.

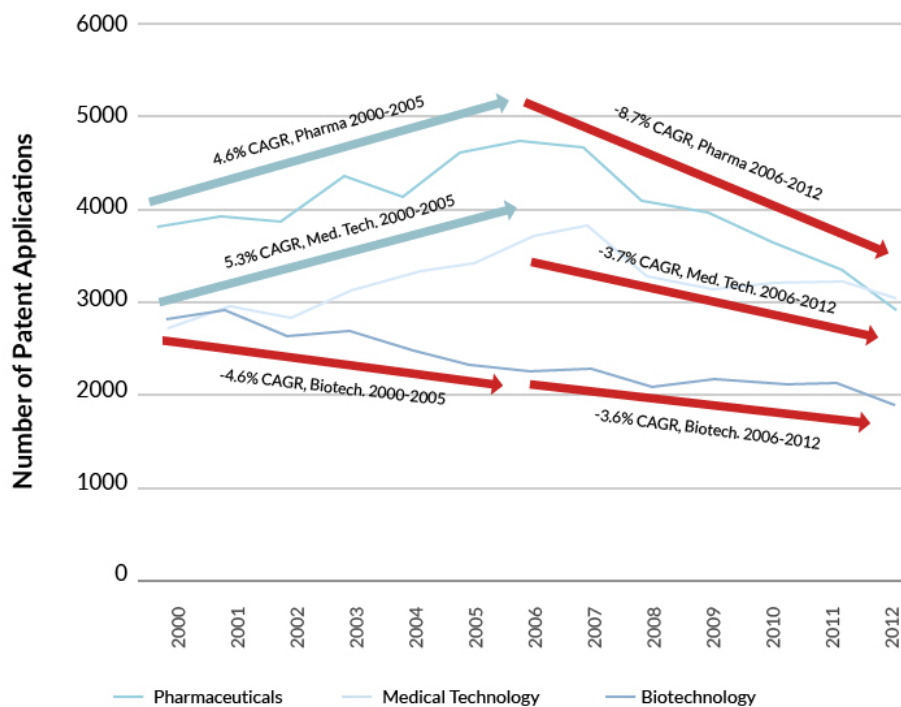
Figure 7: Membership in and Ratification of International Treaties

Note: “This category measures whether an economy (1) is a signatory of and (2) has ratified/acceded to international treaties on the protection of IP. The category consists of 4 indicators, with a maximum possible score of 4.”

Source: GIPC, 2016a: 32.

ports to supply domestic biopharmaceutical needs. This independence is surprisingly important, especially in the context of increasingly prevalent biopharmaceutical shortages in Canada and elsewhere. In 2010, the Canadian Pharmacists Association recognized that the “globalization of the drug market may be a contributing factor” (Canadian Pharmacists Association, 2010: 10). That is, international competition, a shortage of raw materials, more stringent production regulations, and quality assurance at specific manufacturing plants are all contributing factors. Given this, increased domestic production—and independence—may lessen the risk of a shortage. Although imports represented just 18% of the domestic market in 1983, by 2000, the percentage was 75.5% (Lexchin, 2001: 8). Greater domestic production may also lessen supply chain risk, including appropriate regulatory oversight of manufacturing facilities, and shorter transport links that reduce the risks of adulteration, counterfeit entry, and cargo theft. A stronger domestic industry would also generate increased self-sufficiency and increased investment in local production.

Figure 8: Canadians File Fewer Patent Applications since 2006



Source: PhRMA, 2016a.

Reduced risk and uncertainty

One of the great benefits of establishing an innovators' right of appeal would be the creation of greater stability and predictability for research-based biopharmaceutical companies. Uncertainty leads to disputes and to litigation. In the context of the Canadian biopharmaceutical industry, "it appears that the costs of litigating biopharmaceutical patents in Canada are well over \$100 million dollars annually" (Grootendorst, Bouchard, and Hollis, 2012: 546–547). In addition, the existing uncertainty has certainly taken a toll on Canadian innovation. Figure 8 depicts the drop in patent applications since 2006.³⁰

Greater certainty and predictability would reduce the risk surrounding investment in biopharmaceutical research and development, which would almost certainly make investments in this sector more attractive.

³⁰ While the trends obviously change in 2006, it is unclear why or what factors may have contributed to that change.

Ironically, Scofield points out that even generic manufacturers see the potential for benefits to the process of legal appeals: “the generic drug industry is willing to entertain a change in the avenues for legal appeals, if it means making a more coherent system for an industry known for its litigious nature” (Scofield, 2012: 2).

Given the litigious nature of this industry, the potential benefits from the adoption of an effective innovators’ right of appeal are tremendous. The “pharmaceutical space is where all the big patent litigation is happening in Canada right now. \$22.3 billion is spent annually by Canadians on prescription drugs, of which 58% are patented. The developing case law in this area is therefore very lucrative and high-stakes. This year, about 64% of all Canadian patent litigation will be dedicated to pharmaceuticals alone” (Siu, 2012: 1). Not surprisingly, the biopharmaceutical space is the most litigious in Canada. Accordingly, additional clarity and coherence could greatly reduce these numbers and the corresponding costs. Moreover, statements by generic manufacturers indicate that reduced uncertainty surrounding patentability standards and greater predictability in the legal arena would benefit all parties.

In the context of the debate over increased intellectual property rights protections for the biopharmaceutical industry, it is essential to recognize that IP policy cannot be considered medical innovation policy. Intellectual property rights (patents, data exclusivity, and other forms of IP protection) are but one means of promoting innovation. While there are many alternatives, patents are valuable, effective, and widely used because they link innovation to market based incentives. Not surprisingly, the success of the global patent system has led to its use as the primary means of protecting biopharmaceutical innovation. The future promise of stronger IP protections and an enhanced regime necessitate the adoption of the proposed changes to Canadian IP law. These changes will ensure that future treatments and cures are available to Canadian patients and that the economy reaps the benefits of a robust domestic innovative biopharmaceutical industry.

Recommendations for Improvement and Reform

This study has examined the legal architecture that is required for more effective intellectual property protection for the innovative biopharmaceutical industry. An extensive body of evidence demonstrates that patents and other intellectual property protections are critical to the future of innovation and the development of new treatments and cures. A strong legal regime is essential for a robust innovation-based biopharmaceutical industry. A review of the existing Canadian legal framework and global best practices leads to several recommendations for Canadian IP legislation.

Patent term extension

In contrast to all other G7 nations, Canada alone fails to provide a patent restoration term, an extra period of patent protection as compensation for time lost due to regulatory approval delays. Although a Canadian patent provides the same 20-year term as other nations, standard under the WTO TRIPS Agreement, the effective patent life for biopharmaceuticals is significantly shorter in Canada since there is no provision for the reduction in effective patent life due to the lapse between the filing of a patent and the grant of market authorization. This is an area where Canada differs significantly from the United States and the European Union. In the United States, the 1984 *Patent Term Restoration and Competition Act* provides for a maximum extension of 5 years, but the total remaining patent term from the date of marketing approval (patent term + extension) cannot exceed 14 years. The provision gives innovator companies one patent term extension per product. Moreover, the firm has the discretion to determine on which patent the extension is sought. In the European Union, the patent term extension is called a Supplemental Protection Certificate (SPC). The provision is available for a single patent per product, and a maximum extension of 5 years is available. As in the United States, the total patent term (patent term + SPC) is limited and cannot exceed 15

years. Duration is the time between the date of first regulatory approval in an EU Member State and date of filing of the patent application, less five years, with a maximum duration of five years. Within the EU, the extension must be applied for on a country-by-country basis.

It is worth noting that Canada is currently in the process of negotiating the Canada-EU Comprehensive Trade and Economic Agreement (CETA), and that patent term restoration is a component of these negotiations. In the course of the negotiations, the Canadian government has proposed two years of patent term restoration. While this is a valuable starting point, the two-year period still fails to match the extensions provided by other industrialized nations. This study recommends that Canada implement legislation granting a potential patent term extension to innovator firms to help them recover a fraction of the time they have spent attaining regulatory and marketing approval. A restoration period of up to five years, as is the practice in other jurisdictions, would provide valuable, additional effective patent life for innovative therapies. Such legislation would necessarily increase the incentives for the pharmaceutical sector to invest in the research and development costs that such treatments and cures require.

Right of appeal

The institution of a right of appeal would allow innovative biopharmaceutical companies to more effectively appeal court decisions in which a patent is ruled invalid. That is, an equivalent right of appeal should be available to patent owners just as it is available to challengers. “An unsuccessful generic always has a right of appeal because any loss it suffers means that its Notice of Compliance does not issue. There are many cases where a generic has successfully exercised its right to appellate review; the VIAGRA decision from the Supreme Court of Canada is... [a] recent example. However, where an innovator loses a PM (NOC) case, its legal options are limited to bringing an action for patent infringement, and perhaps a motion for an interlocutory injunction (which have often been dismissed in the past)” (Tanner, 2012). Currently, without the right of appeal, innovators invariably see their only recourse as one of lengthy and expensive patent infringement proceedings, which can only compensate for monetary damages rather than remove the infringing generic from the market.

This existing, inequitable treatment creates a climate of uncertainty and litigiousness for innovators, such that they cannot know if or when the courts will dismiss their patents, without giving them the opportunity for direct appeal. Accordingly, granting an effective innovator right of appeal would ensure that patent owners as well as generic producers would

be treated in a balanced and equitable way with respect to the validity of a patent. This would restore fairness and balance to the patent linkage system.

As in the CIPC (2011) report, the recommendation of this study is not for an “additional” right of appeal for innovators; merely that innovators have the same opportunity to appeal an adverse decision as do the generic drug manufacturers. Considering the average PM (NOC) trial period, an innovator appeal could potentially even be heard within the existing timeframe of the 24-month stay, or with only a few additional months added to the stay period (CIPC, 2011).

Patent utility doctrine or “promise doctrine”

Over the past twelve years, Canadian courts have invalidated at least 28 biopharmaceutical patents based wholly or partially upon the uniquely stringent interpretation of the patent utility doctrine. Most of these drugs were important, beneficial, widely-used medicines. That these drugs are widely prescribed and used would seemingly establish their “utility”; indeed, in most countries, this would go a long way toward establishing usefulness. However, under the Canadian interpretation of the promise doctrine, at the time of application, patent owners must be able to “soundly predict” precisely how the invention will be used when commercialized. That is, in Canada, “the courts have turned utility into a test of an inventor’s ability to predict the future” (Stevens and Schultz, 2016: 1).

Canada holds biopharmaceutical innovators to an impossible standard. “While data obtained pre-filing may be relevant to showing a demonstrated utility, any argument for a sound prediction of utility may be limited to what is actually disclosed in the patent. The law thus raises questions as to what a patent must disclose, distinct from the support/enablement requirements in the *Patent Act*” (Garland and Lainson, 2012: 33). Within the biopharmaceutical industry specifically, patents are applied for at an early stage on the road to commercial development. Innovators rely on patents to demonstrate the potential value of the invention, and to secure the investments needed to bring the innovation to fruition and finance clinical testing.³¹

Canada needs to adopt a provision within the *Patent Act* specifying precisely what is required for utility, which would help to clarify the law. Changes must be made to Canada’s IP laws in order to restore certainty to Canada’s distorted patent system and ensure that innovators from Canada and around the world will continue to provide new medicines and other

³¹ Please see Phelps (2015) for a list of scholars whose work supports this claim.

innovative products to Canadian consumers (Stevens and Schultz, 2016). Alternatively, since the promise doctrine arose out of jurisprudence, it is up to the Supreme Court to provide clarity.

Regulatory data protection

Innovative drugs are protected from generic competition in Canada through the protection of innovator data for eight years. Unfortunately, Canada does not provide data protection for any subsequent new use of a previously approved drug. While data exclusivity regimes differ across countries in nature, scope, and extent of protection, protection in Canada lags behind. As the IPIC (2012) describes, in the European Union, Directive 2004/27/EC provides for data exclusivity extensions of 8+2+1 years. In contrast, the United States provides 5 years of data exclusivity with eligibility for an additional three years for exclusivity limited to new and essential clinical trials. In the case of biologics, the United States provides 12 years of data exclusivity.

This study recommends that Canada adopt language that provides for more expansive data exclusivity protection, such that new uses, rather than solely “innovative drugs” (following a strict interpretation of the Canadian regulations by Health Canada and the Federal Court), are eligible for protection. Beyond such protection for traditional small-molecule drugs, additional protection should be provided for the data generated through the clinical trials of biologics, since the length, complexity, and expense of these trials are significantly greater than those incurred for traditional small-molecule drugs. The justification for strengthening data exclusivity laws rests in the incentives provided to innovative firms to produce the data required for regulatory approval: “The pharmaceutical and agrochemical industries have often successfully argued that if regulators allow an equivalent product (a “generic”) to go to market on the strength of the test data provided by the originator company, there would be no incentive for anyone to produce the test data necessary to obtain market approval” (Krattinger et al., 2007).

Technology inevitably evolves faster than the legal architecture that surrounds it. Data exclusivity protections provide a straightforward legal step to catch up to the science that brings us biologic medicines. The period of data exclusivity provides innovative biopharmaceutical firms with an incentive to invest in the testing data necessary to prove a drug’s safety and efficacy by granting them a measure of certainty that they will enjoy a fixed amount of time during which they maintain proprietary control of the test data that resulted in the approval of their drug before they make that data available to generic imitators, as required. Improving the scope

of data protection would also have benefits for generic manufacturers, since innovative products that are never introduced into the Canadian market will never be genericized in Canada either.

Orphan drug regime

As described earlier, Canada is one of the few industrialized nations without a framework for the approval of orphan drugs or a policy for providing incentives for research on rare diseases.³² Given that approximately one in 12 Canadians,³³ two-thirds of them children, are affected by a rare disorder, this policy void is of great concern (Canadian Organization for Rare Disorders, 2016). Unfortunately, the lack of a policy translates to a lack of drugs. According to an analysis by the Canadian Organization for Rare Disorders, only 50% of orphan drugs approved in the US or EU were approved by Health Canada, and of these, most were recommended as “do not list” by the Canadian Agency for Drugs and Technologies in Health (CADTH), the body that recommends drugs to the public plans” (Wong-Rieger, 2013: 2). Pieces of legislation designated to encourage the development of treatments for rare diseases was passed in the United States in 1983, introduced in Japan in 1993, in Australia in 1997, and in the European Union in 1999. Given that Canada is such an outlier in this area, this study recommends legislation that defines what a rare disease is, and provides incentives for Canadian firms to intensify their research and development of new therapies. This process should include both a specifically designed approach for the review and approval of treatments for rare disorders, and additional exclusivity to encourage research in this area. Notably, Canadian firms already do research on rare conditions and new legislation would encourage growth of this vital sector. More than 35 Canadian companies have received US Food and Drug Administration Orphan Product designation for their innovations (BIOTECanada, n.d.(a)). In the 25 years since the passage of the *US Orphan Drug Act*, an estimated 280 new therapies have been developed for the US market, benefiting more than 14 million patients (BIOTECanada, n.d.(b)). This contrasts with the 10 orphan drug therapies developed prior to the passage of the Act (BIOTECanada, n.d.(b)). As described by BIOTECanada, “there are strong correlations between the presence of orphan drug regulations and drug innovation by biopharmaceutical and biotech companies and this is mainly attributed to the incentives contained within those regulations to

³² Appendix 1 provides the definitions of rare disorders from a variety of countries.

³³ This equates to approximately 2.8 million Canadians (Canadian Organization for Rare Disorders, 2016).

encourage sponsors of Orphan medicinal products to continue to engage in research and development that finds cures for rare diseases” (BIOTE-Canada, n.d.(b)).

This study examines the legal architecture necessary for more effective intellectual property protection for the innovative biopharmaceutical industry. Admittedly, the appropriate legal framework will depend on the type of industry a nation hopes to facilitate. In the Canadian case, the historic tension between the innovative biopharmaceutical industry and generic manufacturers has resulted in a mixed bag of policies, some of which appear to undermine IP rights. In the case of the promise doctrine, Canadian law looks like industrial policy for Canadian generic industry rather than intellectual property protections. Obviously the legislation that fosters the growth of a prospering generic industry differs from that which nurtures a robust innovation-based biopharmaceutical industry. For example, the compulsory licensing provisions contained in the 1969 amendments to the *Patent Act* contributed in a significant way to the growth of the Canadian generic industry (Pazderka, 1999: 29). In like manner, Grootendorst and Hollis (2011) predict differential impacts of changes in exclusivity periods across the branded and generic biopharmaceutical industries.

Conclusions

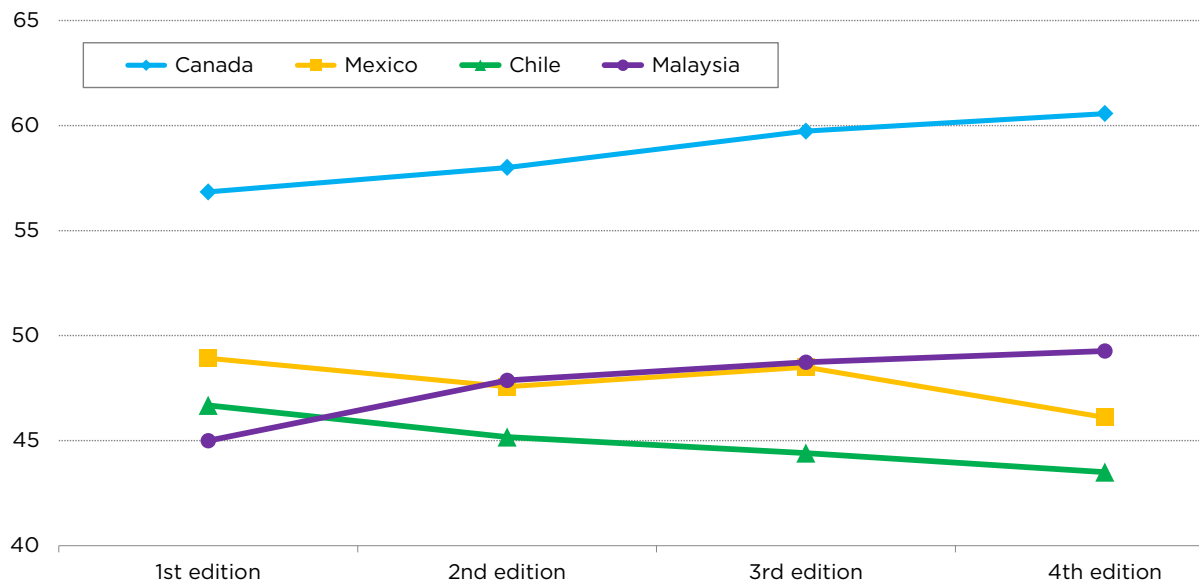
Intellectual property rights drive the future of medicine. At the 2010 World Economic Forum, Bill Gates stated that, “the key reason that we’re making progress against these diseases is that there’s been an incentive for drug companies to invent, and they’ve invented great drugs” (Gates, 2010).

Canada’s incremental approach is questionably adequate to maintain the nation’s compliance with international agreements, but certainly insufficient to attract investment and encourage the domestic biopharmaceutical industry to grow. Canada’s IP regime has improved over time, providing stronger protection to innovators. “Canada—which has improved its overall score in each edition of the Index—remains an outlier among high-income OECD economies. Despite increasing in each edition of the Index, Canada’s score is still the lowest of all OECD economies and its national IP environment has consistently remained closer to middle-income economies such as Malaysia and Mexico than to top Index performers such as the United States and the United Kingdom” (GIPC, 2016a: 23). While this trend is visible in figure 9, it is clear that there are opportunities to do more.

The biopharmaceutical industry’s research and development process is lengthy, expensive, uncertain, and risky. Accordingly, in comparison to other industries, biopharmaceutical firms are disproportionately reliant on patents and other forms of intellectual property protection to ensure that innovators are able to appropriate the returns to R&D. Biopharmaceutical patents protect both process and product innovations. Moreover, they give incentives for the investment needed for the development of treatments and cures that have enhanced and extended lives worldwide. This innovation requires protection and this protection necessitates a tradeoff. Strong, effective intellectual property rights provide that time-limited market exclusivity in exchange for continued investment in innovation.

Historically, international trade agreements have acted as catalysts for Canada to re-envision the intellectual property protection it makes available to the innovative biopharmaceutical sector. Strong precedents were set with Canada’s accession to the North American Free Trade

Figure 9: Overall Total Score as a Percent of the Available Score Index for the Middle Four Economies of the Original Eleven



Source: GIPC, 2016a: 21.

Agreement (NAFTA) in 1992, and again with the Marrakesh Agreement, which established the World Trade Organization (WTO) in 1995. The ratification of these agreements led to important changes to Canadian patent law and signaled strong support for a vital, domestic, innovation-based biopharmaceutical industry. This is particularly relevant as Canada continues negotiations for the Comprehensive Economic and Trade Agreement (CETA) with the European Union, and the Trans-Pacific Partnership Agreement (TPP) with Australia, Brunei Darussalam, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam. Not surprisingly, current negotiations are sharply focused on how to reframe intellectual property protection in the biopharmaceutical sector.

Current negotiations, and this study, both focus on changing five aspects of the Canadian IP regime to more strongly protect intellectual property rights for the innovative biopharmaceutical industry. Specifically, Canada should adopt legislation providing a period of patent term restoration. That is, innovative biopharmaceutical firms should be eligible for patent term extensions in order to recover time lost due to mandatory governmental regulatory and marketing approvals. In addition, Canada should remedy issues of weak enforcement by providing patent owners with an effective patent linkage right of appeal. The adoption of the innov-

ator's right of appeal would level the playing field, allowing both innovator and generic firms the right of appeal if the court rules against them. Changes must be made to Canada's IP laws in order to restore certainty to Canada's distorted patent system and clarify the expectations of the patent utility doctrine. Also, Canada should extend data protection regulations and increase the scope of products that may be classified as "innovative drugs."³⁴ Finally, Canadian policymakers should enact legislation to define what a rare disease is and give Canadian firms incentives to intensify their research and development of new therapies. The adoption of these changes would help to bring the Canadian regime in line with international standards.

The changes proposed in this study would serve to strengthen the intellectual property provisions in Canada for the research-based biopharmaceutical industry, thereby encouraging innovation and the stream of benefits that flow from this sector. A large body of empirical research demonstrates that knowledge-based industries are the engines of economic growth. Competition for these industries is fierce and increasingly global in scope. According to the Canadian Intellectual Property Council, "[i]f Canada wants to keep attracting investment and high paying jobs, some work still needs to be done to achieve the same kind of IPR protection that other jurisdictions, such as the United States and the European Union, offer" (CIPC, 2011: 10).

³⁴ Given that Canada has a "one track" data protection system, similar to the EU, it may be difficult to legislate changes to differentiate levels of product protection as is done in the United States.

Appendix 1: Rare Disease Definitions

Organization	Rare Disease Definition
US Food and Drug Administration	“The number of people affected by the disease or condition for which the drug is to be developed is fewer than 200,000 persons; or there is no reasonable expectation that the sales of the drug will be sufficient to offset the costs of developing the drug for the US market and the costs of making the drug available in the United States.”
European Medicines Agency	“The medicine must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; the prevalence of the condition in the EU must not be more than 5 in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorised, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.”
Japan’s Ministry of Health, Labour and Welfare	“The number of patients who may use the drug should be less than 50,000 in Japan. The drugs should be indicated for the treatment of serious diseases, including difficult-to-treat diseases. In addition, they must be drugs for which there are high medical needs satisfying one of the following criteria: 1. There is no appropriate alternative drug or treatment. 2. High efficacy or safety is expected compared with existing products.”
Australia’s Therapeutic Goods Administration	“The medicine must be intended to treat, prevent or diagnose a rare disease; or must not be commercially viable to supply to treat, prevent or diagnose another disease or condition. For a vaccine or in vivo diagnostic agent, the application must also state that the vaccine or agent will be administered in Australia to not more than 2,000 people in each year after it is registered for use for the disease or condition.”
Health Canada (proposed definition)	“A drug intended for the diagnosis, treatment, mitigation or prevention of a life-threatening, seriously debilitating, or serious and chronic disease or condition affecting not more than five in ten thousand persons in Canada, and the drug is not currently authorized by the Minister or if currently authorized, it will provide a potentially substantial benefit for the patient distinguishable from the existing therapy.”

Source: Canadian Agency for Drugs and Technologies in Health, 2016.

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About the author



Kristina M. Lybecker

Kristina M. Lybecker is an Associate Professor of Economics in the Department of Economics and Business at Colorado College in Colorado Springs, CO. She received her Ph.D. in Economics in 2000 from the University of California, Berkeley. Prof. Lybecker's research analyzes the difficulties of strengthening intellectual property rights protection in developing countries, specifically in the context of the pharmaceutical and environmental technology industries. Her recent publications have also addressed alternatives to the existing patent system, the balance between pharmaceutical patent protection and access to essential medicines, and the markets for jointly produced goods such as blood and blood products, and the role of international trade agreements in providing incentives for innovation. Prof. Lybecker has testified in more than a dozen states on the economics of pharmaceutical counterfeiting. In 2016 she was awarded the Thomas Edison Innovation Fellowship by the Center for the Protection of Intellectual Property (CPIP) at George Mason University School of Law. She has also worked with the US Food and Drug Administration, Reconnaissance International, PhRMA, the National Peace Foundation, the OECD, the Fraser Institute, and the World Bank, on issues of innovation, international trade, and corruption.

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Prof. F.G. Pennance*

Prof. George Stigler* †

Sir Alan Walters*

Prof. Edwin G. West*

* deceased; † Nobel Laureate