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“INNOVATION FOR A BETTER TOMORROW: A CRITIQUE”

Edward M. Iacobucci*
Osler Chair in Business Law
Faculty of Law, University of Toronto

* The author wishes to thank Gilbert's LLP for providing invaluable background on the pharmaceutical industry and its legal regulation.

EXECUTIVE SUMMARY

Canada and the European Union are negotiating a comprehensive economic and trade agreement that will affect many Canadian industries, including pharmaceuticals.

In January 2011, the Canadian Intellectual Property Council of the Canadian Chamber of Commerce released a report calling for extension of pharmaceutical intellectual property (“IP”) rights in Canada as part of these negotiations. The CIPC Report asserts that Canada’s IP regime “lags behind” international competitors, and increasing IP protection is necessary to promote jobs and innovation. The report contains three main recommendations: introduce a right of appeal for patentees after a loss in linkage proceedings, increase the data exclusivity period for new drug products from eight to ten years, and increase the length of pharmaceutical patent terms by up to five years.

In supporting expanded pharmaceutical IP in Canada, the CIPC Report compares a number of narrow aspects of the Canadian pharmaceutical IP regime to correspondingly specific provisions elsewhere. The Report fails to appreciate that, in its totality, pharmaceutical IP in Canada is already stronger than that in any other industrial sector in Canada, and is in many ways stronger than pharmaceutical IP in the European Union and United States. For example, in Canada, brand pharmaceutical companies benefit from:

- *an automatic injunction against generic entry up to 24 months long;*
- *two rounds of patent infringement litigation on the same set of patents;*
- *no statutory incentive for generic pharmaceutical companies to challenge patents;*
- *regulatory data protection that lasts several years longer than the international average; and*
- *the ability to obtain patents on multiple aspects of a drug without any mechanism for generic companies to oppose a patent except through litigation.*

Aside from its inadequate comparisons, the CIPC’s recommendations are based on fundamentally flawed premises that are unexplained and unsupported in the CIPC Report:

1. **Failure to Acknowledge Extra Costs to Canadian Consumers:** Pharmaceutical IP reflects a trade-off between innovation and access to medicine, yet the report ignores the substantial and predictable costs that will be visited on consumers and governments if Canadian pharmaceutical IP rights are further expanded.
2. **Unjustified Link Between IP, Employment and R&D:** Although enhancing innovation is laudable, there is no economic reason or empirical evidence that suggests that extending IP protection in Canada will meaningfully increase jobs or research and development (R&D) spending in Canada. To the contrary, pharmaceutical R&D appears to be moving toward countries having weaker IP, such as India and China.

In sum, the CIPC Report fails to provide a justification for expanding IP rights for pharmaceutical products.

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I. INTRODUCTION

The Canadian Intellectual Property Council of the Canadian Chamber of Commerce recently released a report calling for greater protection of intellectual property (IP) rights in pharmaceuticals in Canada.¹

The report, “Innovation for a Better Tomorrow: Closing Canada’s Intellectual Property Gap in the Pharmaceutical Sector” (“CIPC Report”), makes three specific recommendations, and generally admonishes the Canadian government for not doing more to protect IP in the pharmaceutical sector. Its basic critique is that the government is failing adequately to encourage research and development (R&D) in the Canadian pharmaceutical sector, with negative consequences for innovation and health outcomes in Canada, and for jobs, the latter consideration being particularly important in today’s difficult economic times.

In this response, commissioned by the Canadian Generic Pharmaceutical Association (CGPA), I review and critique the arguments and recommendations in the CIPC Report. While commissioned by the CGPA, the views expressed in this document are my own.

IP rights, especially patents, are an important driver of the profits of influential participants in the Canadian pharmaceutical industry. But the arguments that the CIPC Report advances in favour of expanded IP rights are unpersuasive. They treat several highly contestable questions as having clear answers, and this certitude weakens the force of the Report as a policy document.

My response will proceed as follows. In Section II, I consider the basic logic of the CIPC Report’s approach. There are two seemingly crucial premises in their approach. First, greater IP protection in Canada will spur greater innovation to the benefit of Canadians, and will create jobs in the Canadian pharmaceutical sector. Second, the inappropriate weakness of Canadian IP becomes clear when one compares Canadian law with foreign law, particularly in the US and EU. Both premises are highly contestable.

On the first point, the CIPC Report largely ignores the trade-offs that underlie optimal IP policy. Section II reviews the importance of competing considerations, particularly in the pharmaceutical sector. On the second point, the CIPC Report does not establish a connection

¹ The membership of the Canadian Chamber of Commerce includes several brand-name pharmaceutical companies, including Baxter Corporation, Boehringer Ingelheim (Canada) Ltd., Canada’s Research-Based Pharmaceutical Companies (Rx&D) and Hoffmann-La Roche Limited. Online: <http://www.chamber.ca/index.php/en/links/C56/>.

between expanding Canadian IP rights and innovation and jobs. Briefly put, the Report fails to appreciate the potentially weak relationship between *Canadian* IP law and the *global* drivers of innovation and jobs.

Section III of this critique turns to the specific recommendations of the CIPC Report.

1. **Right of Appeal:** The first CIPC recommendation is that Canada should grant IP rights holders an effective right to appeal a decision on a patent challenge in a linkage proceeding. The CIPC Report underappreciates the existing protection that pharmaceutical IP rights-holders have relative to other IP rights-holders, including the right to litigate patent infringement and validity both in linkage proceedings and separate infringement proceedings, and fails thus to appreciate a principled reason to oppose reform. The Report does not acknowledge that generic companies have weaker incentives to challenge an incumbent's patent than the incumbent has to defend that patent. The report offers no principled reason to confer another advantage upon pharmaceutical IP rights holders through additional appeal rights.
2. **Data Exclusivity:** The second specific recommendation the CIPC Report offers is that Canadian law should offer longer data exclusivity periods. However, not only do patents themselves protect incentives to innovate, but Canada instituted one of the most aggressive data exclusivity regimes in the world in October 2006, extending protection to eight years (or 8.5 years, where pediatric exclusivity is granted). There is no sound line of reasoning supporting an extra two to three years of protection, particularly given the limited experience with the present regime.
3. **Patent Term Restoration:** The third recommendation is that Canada should establish a system for extending pharmaceutical patent terms to compensate for time spent obtaining regulatory approval to market the drug; this is done by way of patent term restoration (PTR) in the US, and supplementary protection certificate (SPC) in the EU. Canada already confers several advantages on pharmaceutical patentees that, in many cases, more than offset the absence of a PTR regime. Moreover, there is no clear connection between expanding pharmaceutical patent terms and increasing research and development or jobs in Canada. Finally, extending patent terms is likely to substantially increase costs and litigation on major products and is prone to abuse. Again, the CIPC Report does not provide any principled basis for its recommendation.

In summary, the CIPC Report raises a number of important policy questions but, in answering them, fails to consider fundamental counter-arguments to its position. Perhaps this is unsurprising for an advocacy piece, but it is a severe shortcoming in a document that purports to be taken seriously as a guide to policy.

II. CANADIAN IP LAW AND INNOVATION

The basic thinking underlying the CIPC Report is captured by the following quotations:

Intellectual property is the economic engine of progressive countries. IP rights can drive job creation, economic growth and innovation. As Canada continues to climb out of the recession, focusing attention on IP as a key economic theme is vital to thrive...If we properly protect IP in Canada, we can grow jobs and investment in the knowledge-based economy. It's clear – proper IP protection equals jobs and investment in a nation. (CIPC Report, Executive Summary, p. 2)

Without the dedication of the research-based pharmaceutical companies investing billions in trying to find new medicines, our lives would be tremendously different, our life expectancy would be much shorter and bloodletting and enemas might still be the favoured techniques to treating almost everything. (CIPC Report, p. 5)

While undoubtedly pharmaceutical medicines have contributed significantly to the quality of life in Canada and elsewhere, the CIPC Report lacks any subtlety in drawing strong connections between more extensive IP rights with the well-being of Canadians. Before turning to the Report's specific recommendations, it is helpful to take a step back from the details and assess the general approach of the Report. This general approach informs each of the specific recommendations in the Report; thus, the weakness of the general approach is an important consideration underlying the conclusion that the Report fails to make a persuasive case for any of its recommendations.

The CIPC urges greater protection of IP in the pharmaceutical sector. There are two general considerations that oppose the strengthening of IP rights in the Canadian pharmaceutical sector that are missing from the CIPC's analysis. First, the CIPC Report stresses the benefits of IP without acknowledging its costs. While IP is socially valuable in promoting innovation, there are also social

welfare losses that result from the reduction or elimination of competition that IP rights imply. I will call these the “static” costs of IP. No analysis of IP in the pharmaceutical sector, or in any other sector, is credible without accounting for the basic trade-off between innovation and these static costs. Second, the Report does not acknowledge the tenuous connection between Canadian IP laws and domestic R&D or innovation, which is another crucial oversight. Canada is but a small player in the global market for pharmaceutical drugs, and Canadian IP laws are likely to have a second-order effect on global innovation, but a profound impact in reducing domestic competition and increasing prices. I elaborate on each point in turn.

The Benefits and Costs of IP

IP rights undoubtedly make valuable contributions to society. IP protects innovators from competition and thus provides a market-based reward for costly investment in innovation. Without IP protection, an innovator risks earning no financial returns for its innovation since others can reproduce and compete in selling the innovation, driving economic profits to zero. Anticipating such competition, the would-be innovator has very little incentive to incur the costs of research into new or better products. IP addresses these innovation incentive problems by limiting competition in selling the patented product. In the pharmaceutical setting, IP protection has protected innovation in a range of products that improve quality of life, and indeed save lives.

But to say that IP protection generates social benefits is not to say that such protection should be unlimited. In understanding the reasons for limits on IP rights, begin by considering a basic question: if patents were unambiguously positive for Canadians, as the CIPC Report tends to suggest, why would patents be time-limited? If encouraging innovation through a rich prize for invention were the only consideration, IP rights in the pharmaceutical sector, or any other sector, should be infinitely-lived; this would create an even larger prize for innovators and, on the CIPC’s logic, create jobs and improve quality of life.

The reason why IP rights have time limits, of course, is that there are significant costs associated with IP. In the pharmaceutical sector, patent rights associated with a useful drug dramatically limit competition in the production of that drug. The natural reaction of a seller of any good that faces significant demand for its product and limited competition is to raise prices, whereas a competitive seller is constrained to set prices at or close to marginal cost. Higher prices create social costs by, for example, deterring some consumers that would realize net benefits from access

to a product even after paying its cost of production from buying the product. The prices of patented drugs, in particular, are higher than they would be without IP protection, which increases costs to consumers and reduces usage of the drug in a socially undesirable way.

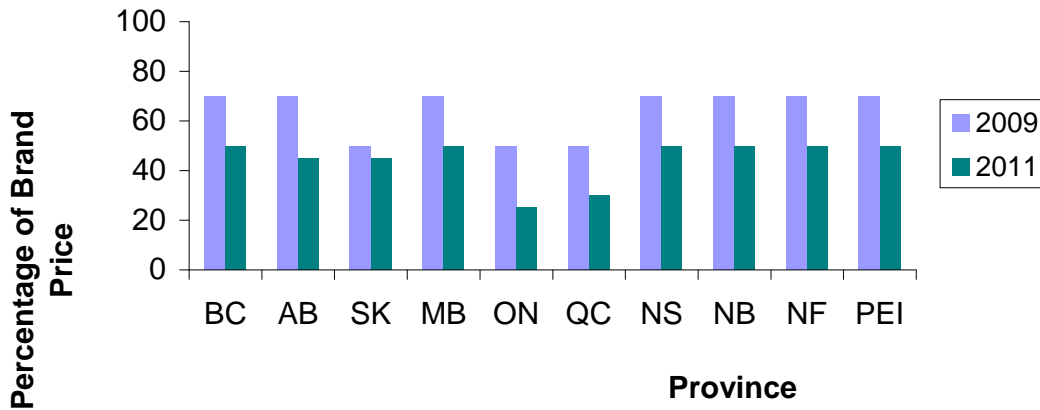
The pharmaceutical market, to be sure, does not work in the same way as many other markets given the presence of regulation, and public and private insurance plans. An extensive review of how the benefits of competition specifically manifest in the sector is beyond the scope of this critique. Suffice it to say that competition generates greater social benefits because of lower prices and/or higher usage of pharmaceuticals than monopoly. There are several reasons to suppose that this will be true.

1. When generics enter, public and private plans obtain competitive drug benefit prices for reimbursement of a particular drug; competition brings pricing benefits that monopoly does not. This is especially the case after recent provincial reform of generic pricing, causing generic prices around the country to fall from 50-75 percent of the brand price to 25-45 percent of the brand price, depending on provincial market characteristics and trade restrictions (see table below). Lower, competitive prices for drugs tend to reduce the cost of private insurance plans, and bring potential social benefits by allowing public plans to reallocate resources to other aspects of the provincial health care systems, including other pharmaceutical products which are not currently reimbursed by provincial or private health care plans.
2. Canadian consumers purchase \$4.6 billion of prescription pharmaceuticals out of pocket (i.e. not through insurance). This represents 15.4% of total Canadian drug expenditure.² These consumers will be especially price-sensitive, and some will be driven from the market by high monopoly prices.
3. While the Competition Bureau has observed that rebates channel some of the benefits of competition in pharmaceuticals only to pharmacies and not consumers, even this generates an indirect (albeit suboptimal) benefit to consumers in the form of more and better pharmacies. Moreover, regulators in several provinces have banned rebates and

² CIHI 2010 “Drug expenditure in Canada, 1985-2009.” Last accessed 15 April 2011 at http://secure.cihi.ca/cihiweb/products/dex_1985_to_2009_e.pdf.

continue to look for further ways to ensure that the benefits of competition in drugs are fully passed on to consumers in lower prices by pharmacies.³

Falling Generic Prices Across the Country



In summary, drug prices will tend to be lower and consumption higher in the presence of competition. While one must be cautious in drawing inferences from a case study, especially given the multitude of factors that may influence the price and quantity of drugs consumed outside of IP rights, such as marketing expenditures, a possible example of the influence of competition is found in the case of Lipitor. When this drug became genericized in mid-2010, annual revenues fell significantly by \$350 million even as quantity increased slightly relative to 2009.⁴ There is an essential trade-off in considering strengthening patent protection in the pharmaceutical sector. While greater IP protection tends to promote innovation in socially beneficial drugs, it also hinders the distribution of drugs once invented. Managing this trade-off has been the stated goal of Canadian pharmaceutical patent policy, which represents a “balance between effective patent enforcement over new and innovative drugs with the timely market entry of their lower-priced generic competitors.”⁵

³ The Competition Bureau has produced two very helpful reports on the significance of competition in the pharmaceutical sector. It observes that competition clearly exists on drugs that have been genericized, but modification of some regulatory and other institutional features would allow even greater benefits to be realized by consumers. See Competition Bureau Canada, “Canadian Generic Drug Sector Study” (2007) and Competition Bureau Canada, “Benefiting from Generic Drug Competition in Canada: The Way Forward” (2008).

⁴ Source: IMS.

⁵ Government of Canada: Regulations Amending the Patented Medicines (Notice of Compliance) Regulations. *Canada Gazette Part II* 2006, 140(21): 1503-1525. More specifically this statement is found in the Regulatory Impact Analysis Statement accompanying the 2006 amendments.

The CIPC Report, by focusing only on the innovation effect and essentially ignoring the static costs of IP protection, fails to offer a credible basis for altering the resolution of this trade-off reflected in the status quo in Canada.

Costs to buyers from high prices, and potentially weaker innovation incentives, result from reduced competition and are considerations cutting against increasing IP rights. Another concern, one that is the mirror opposite of the emphasis of the CIPC Report, is employment. The CIPC Report suggests that increasing IP protection is vital to protect jobs in the research-based pharmaceutical sector. I shortly consider the important influence of global markets on Canadian pharmaceutical markets, but even from a narrow domestic perspective, the Report does not consider the negative effects of increased IP protection on employment. In particular, the Report ignores the effect of employment of IP on generic drug manufacturing. Rx&D reports 15,000 jobs in the branded pharmaceutical industry in Canada,⁶ and CGPA reports 10,000 in the generic industry.⁷ Any analysis of the effect of IP rights on employment cannot ignore the generic side of the ledger. It is possible that strengthening IP protection in pharmaceuticals would reduce employment in the pharmaceutical sector to an extent that more than offsets any gains in employment from research. Consideration of international markets bolsters the connection between stronger IP and lower Canadian employment in pharmaceuticals, as I discuss below.

To summarize, IP protection generates social benefits in promoting innovation. But it does not follow that because some IP protection is good, more IP protection must be better. There are trade-offs because of the costs of IP resulting from weakened competition. The CIPC Report neglects these costs and thus lacks a credible basis for its analysis of IP in the pharmaceutical sector, or for its recommendations. The Report, by omitting these considerations, does not offer a persuasive argument for changing the status quo.

It is worth adding that there is one respect in which the CIPC Report's proposals to strengthen IP protection could create social costs without any offsetting benefits. The CIPC Report proposes expanding IP rights for pharmaceuticals. If applied to existing IP, this would result simply in a windfall for current IP-holders at the expense of consumers without spurring additional innovation for these already-marketed pharmaceuticals. Current IP-holders by definition have

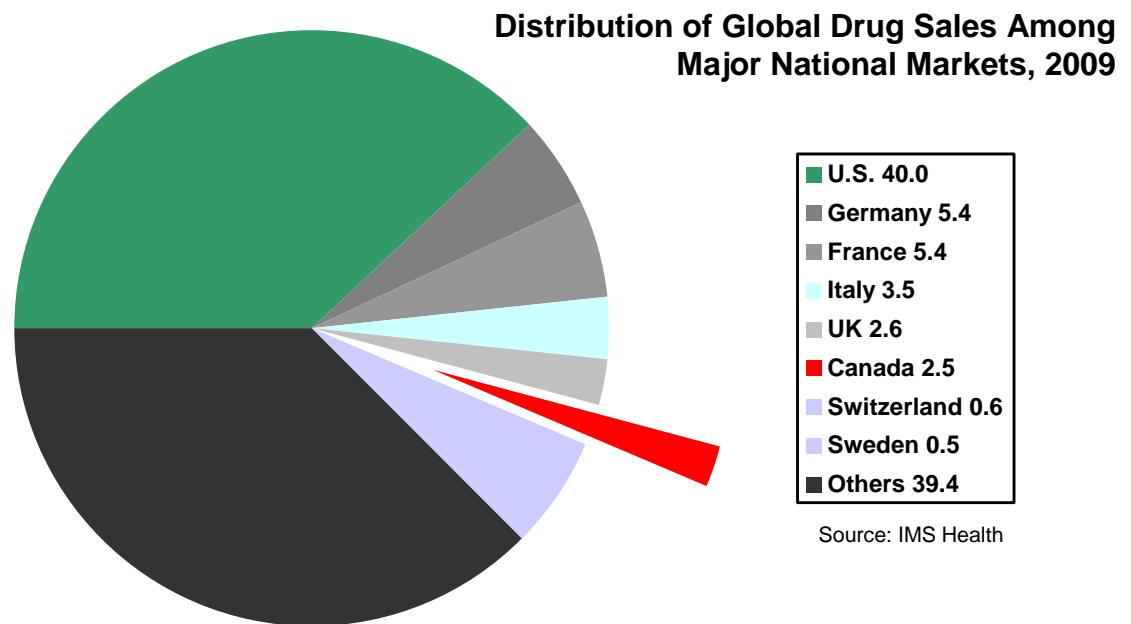
⁶ Rx&D, "Corporate Information" (2010). Accessed online: <https://www.canadapharma.org/en/about/CorporateInformation.aspx>.

⁷ CGPA, "Advocacy" (2011). Accessed online: http://www.canadiangenerics.ca/en/advocacy/economic_benefits_f.asp.

already innovated and obtained their IP rights without these enhanced protections for IP in place. The additional wealth to patentees from the proposed changes in IP, if applied retroactively, cannot spur innovation and would simply confer billions of dollars in profits on existing patentees at the direct expense of social welfare.

Failure to Appreciate the Global Nature of Pharmaceutical Investment

IP always presents trade-offs, even setting aside the influence of global markets on Canada, as the last section showed. But global markets are an important addition to the analysis. Canadians invent and buy only a fraction of the pharmaceuticals that are produced globally. As this section shows, the case for strengthening IP rights in Canada becomes much weaker in light of this reality. The benefits to Canadians of increasing IP protection are smaller, while the costs increase.



On the benefits side of the ledger, firms invest in innovation based on the anticipated profits to be earned from a particular invention from global sales. Firms will not innovate based only on profits from Canada (2.5 percent of the global market), but will anticipate sales around the world. This relegates Canadian influence on global innovation incentives to a minor role. If, for example, Canada were to eliminate IP protection altogether (which would of course violate its international trade obligations), the global incentives to create innovative drugs would only fall fractionally. To

realize the benefits of innovation, Canadian patent law presumably must be strong enough to provide incentives for companies to obtain regulatory approval for a drug in Canada, but the law is unlikely to have a significant effect on innovation itself. When the CIPC Report extols the innovation incentives provided by the Canadian IP regime, it does not account for the existence of international realities, which diminish the import of Canadian law dramatically.

Similar logic applies to the benefits of IP protection for job creation that the CIPC Report emphasizes. Pharmaceutical firms seeking to maximize profits will not only assess the potential global profits available from pursuing a new drug, but will also consider the global landscape when deciding where research is optimally conducted. There is little intrinsic economic connection between Canada's IP laws and its attractiveness as a destination for research and development – the firms can take advantage of Canadian IP laws whether or not they conduct research here, just as they can take advantage of foreign IP law when choosing to conduct research in Canada.

Factors such as human capital in Canada are much more economically important than Canadian IP law in influencing the site of research activities.⁸ For example, the Patented Medicine Prices Review Board (“PMPRB”) Annual Report from 2009 reports that while the Canadian patent-protected drug industry spends about 7.5% of pharmaceutical revenues on R&D, the Swiss drug industry spends over 100% of its revenues on R&D.⁹ The difference between Swiss and Canadian research levels may arise from a host of factors, including the location of the headquarters of brand name drug manufacturers, but cannot be explained by differences in IP law between the countries.

More evidence of the weak connection between local IP and investment is found in the decisions by branded drug companies to establish production facilities in several jurisdictions not renowned for their protection of IP, such as India and China. A management professor at the Wharton School notes “all the leading pharmaceutical companies have set up research operations in India.”¹⁰ Examples of such operations in India and China include Pfizer's “100-member captive

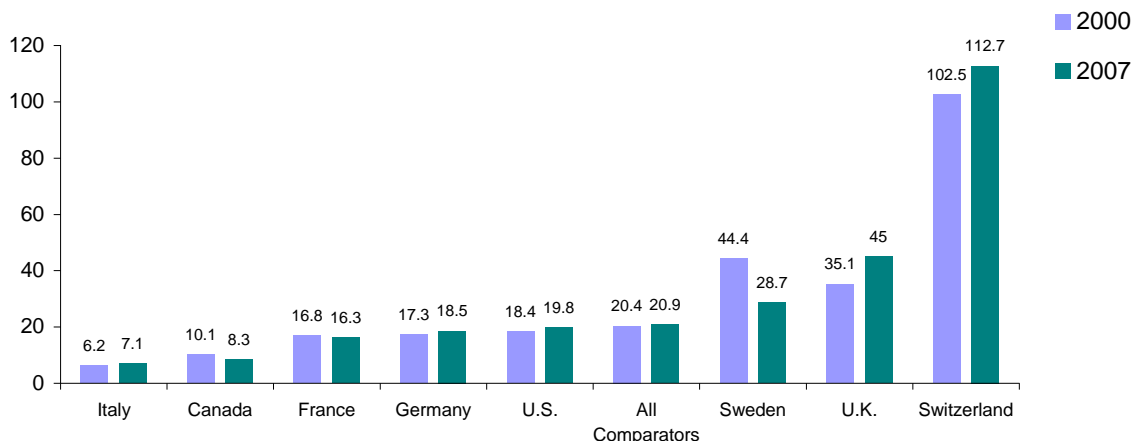
⁸ Kuemmerle, for example, conducted an empirical study of the factors that might drive foreign direct investment of pharmaceutical and electronics firms in R&D facilities. He found that human capital indicators, like tertiary education and the number of Nobel Prize winners in the hard sciences in a country, helped attract FDI of this kind: Walter Kuemmerle, “The Drivers of Foreign Direct Investment Into Research and Development: An Empirical Investigation” (1999) 30 *Journal of International Business Studies* 1. He did not even consider legal protection of IP as a potential driver of such investment.

⁹ Patented Medicine Prices Review Board, “Annual Report 2009” (2010) at page 40, Figure 22.

¹⁰ [Knowledge@Wharton](http://knowledge@wharton.upenn.edu/article.cfm?articleid=1278), “R&D in India: The Curtain Rises, The Play Has Begun...” (November 2005). Accessed online: <http://knowledge.wharton.upenn.edu/article.cfm?articleid=1278>, quoting Professor [Harbir Singh](#).

operation in Mumbai that manages and analyzes data gathered from clinical trials”¹¹ and movement of US and UK antibiotic research to a new facility in China¹²; Roche’s China R&D Center opened in 2004 in Shanghai;¹³ and Novartis’ 2009 announcement of its USD 1 billion investment to build the “largest pharmaceutical R&D institute in China.”¹⁴

R&D-to-Sales Ratio for Canada and Seven PMPRB Comparator Countries, 2000 and 2007



The CIPC Report asserts that, as a matter of fact, there was a flourishing of R&D activity in Canada following the decision to bolster Canadian IP protection in 1987. The PMPRB Annual Report in 2009 reports that while R&D as a percentage of drug sales for reporting companies was 6.1% in 1988, it was 7.5% in 2009.¹⁵ The ratio was higher in intervening years, but the ratio has for nine years been below the 10% ratio that was committed to at the time of the 1987 legal changes. In the intervening period, Canada has abolished compulsory licenses, introduced a linkage regime allowing patent-holders to automatically delay regulatory approval of generic drugs by up to two years, and introduced an eight-year data exclusivity and an additional six-month pediatric exclusivity regime. Nevertheless, the data do not reflect a long-term change in R&D patterns since 1987. In

¹¹ Knowledge@Wharton, “Human Capital: Can India Bridge the Knowledge Gaps Needed for Research?” (November 2005). Accessed online: <http://knowledge.wharton.upenn.edu/article.cfm?articleid=1274>.

¹² Jack Dini, “Pfizer Goes to China”, *Hawaii Reporter* (April 14, 2011). Accessed online: <http://www.hawaiireporter.com/pfizer-goes-to-china/123>.

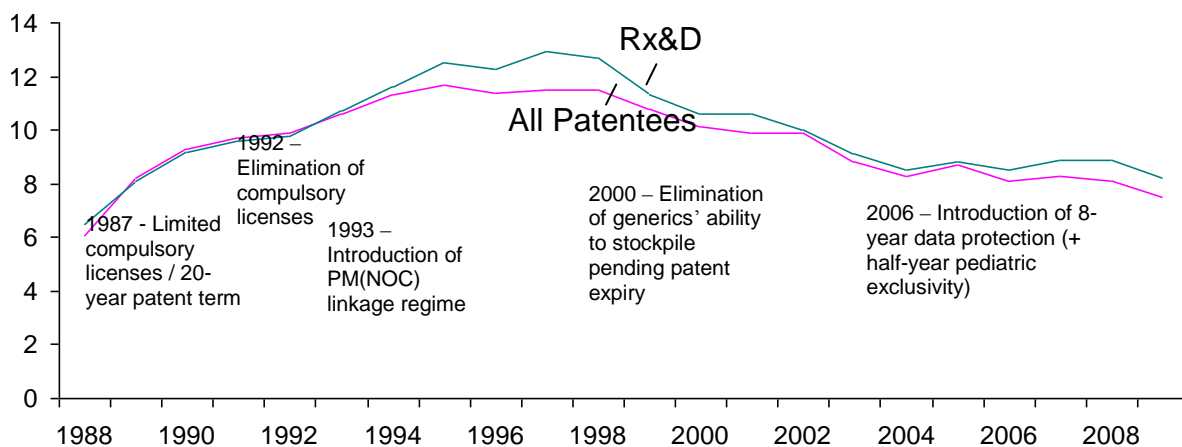
¹³ F. Hoffmann-La Roche Ltd., “Roche China Introduction”. Accessed online: <http://careers.roche.com/cn/en/Campus/Inside-Roche/Roche-China-Introduction.html>.

¹⁴ Novartis Media Releases, “Novartis announces USD 1 billion investment to build largest pharmaceutical R&D institute in China” (November 2009). Accessed online: <http://www.novartis.com/newsroom/media-releases/en/2009/1352116.shtml>.

¹⁵ Patented Medicine Prices Review Board, “Annual Report 2009” (2010) at page 36, Table 18.

any event, it is clear that the R&D-based pharmaceutical companies failed to sustain their public commitment to devote 10% of sales to domestic R&D.

R&D-to-Sales Ratios Amid Canadian Drug IP Reform



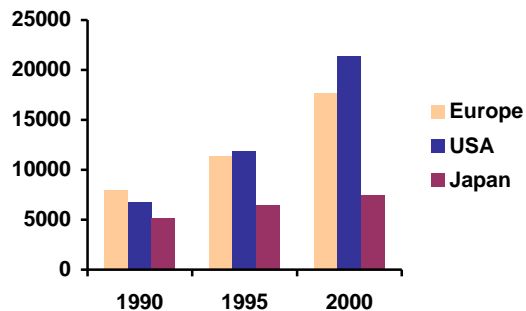
Even if the R&D pharmaceutical companies had met their commitments, and there were a notable short-term increase in R&D, the Report makes no attempt to describe a causal connection between stronger Canadian IP law and local investment in R&D. The increase, such as it was, could have been coincidental. For example, the CIPC Report does not ask whether any increase in R&D activity in Canada might have reflected greater investment in R&D activity worldwide that had little to do with Canadian IP law. Evidence from the US indicates that pharmaceutical R&D expenditure as a percentage of sales increased over the 1980s; any increase in Canada could simply have reflected general trends.¹⁶ Europe and Japan appear to have followed similar trends throughout the 1990s.¹⁷

¹⁶ See James Graham, “Trends in U.S. Regulatory Approvals of Biopharmaceutical Therapeutic Entities” M.Sc. Thesis, MIT 2005, Figure 4.

¹⁷ World Health Organization, “Priority Medicines for Europe and the World – Appendix: Dossier Statistics 2004 (2004). Accessed online: http://archives.who.int/prioritymeds/report/append/DossierStatistics2004_apx82.ppt.

Even if there were a short-term increase, and even if it were connected with legal reform, any boost in spending was likely simply to have reflected a political deal: the research-based companies promised greater local R&D if the government strengthened Canadian IP law. The potential political connection between IP protection and jobs does not reflect any inherent economic relationship between the two. Changing Canadian IP law alone will not create a boost to research spending in Canada, contrary to the assertions of the CIPC Report. Moreover, as seen from the results of the last political deal between the Federal government and the pharmaceutical industry, any government expectation of increased domestic R&D, whether through trade concessions or a political deal, is neither enforceable nor likely to be long-term. But the increased IP protection, and associated costs, will have long-term consequences.

Pharmaceutical R&D Expenditure in Europe, USA and Japan, 1990-2003
Millions of National Currency Units x 100



Source: EFPIA member associations, PhRMA, JPMA

Even accepting the highly contestable premise that the government should be engaged in manipulating specific labour markets, the CIPC Report neglects to consider whether transferring value to pharmaceutical companies through greater patent protection at the expense of those in need of medicine is an optimal approach to buying jobs in the sector. The PMPRB Report of 2009 reports that only 7.5% of Canadian branded drug revenues (or \$1 out of every \$13 earned) are spent on R&D in Canada, as noted above. Grootendorst and Hollis (2011) have calculated that \$8 in industry drug premiums would be required to purchase an additional \$1 in R&D spending in Canada.¹⁸ There are alternative means of increasing pharmaceutical employment other than changing IP law that may be more plausible. For example, carefully-crafted tax concessions tied to employment and/or increased R&D would likely be more effective.

The assertions that Canadian IP law has a significant impact on innovation and on jobs in Canada are contestable at best in a world in which Canada is a minor influence. Canadian IP laws do, however, have a profound impact on Canadian consumers regardless of the existence of a global

¹⁸ Grootendorst and Hollis (2011). “The Canada-European Union Comprehensive Economic & Trade Agreement: An Economic Impact Assessment of Proposed Pharmaceutical Intellectual Property Provisions.” Accessed online: http://www.canadiangenerics.ca/en/news/docs/02.07.11CETA_EconomicImpactAssessment-FinalEnglish11.pdf.

pharmaceutical sector. The high prices associated with increased IP rights arise in Canada even if Canadian IP law has only a slight effect on global innovation, or research in Canada. Moreover, in a globalized world, the profits that arise in Canada from the sale of patented pharmaceuticals will in large part accrue to foreign shareholders. Canada has experienced a growing trade deficit in pharmaceuticals, with imports exceeding exports by a record \$6.4 billion in 2009. Most of these imports are patent-protected medicines originating from the EU; conversely, most of these exports are generic medicines. Under these trade conditions, revenues from an increase in IP protection will tend to flow to foreign entities without any reciprocal benefit to Canadians.

Total Canadian Pharmaceutical Trade (2000–2009)¹⁹			
Year	in \$billions		
	Exports	Imports	Trade deficit
2000	1.6	5.3	3.7
2001	2.1	6.4	4.3
2002	2.3	7.3	5
2003	3	8.2	5.2
2004	3.6	8.6	5
2005	3.9	9.1	5.2
2006	5	10.4	5.4
2007	6.3	11.3	5
2008	6.2	11.6	5.4
2009	7	13.4	6.4

The policy implication of the tenuous nexus between Canadian IP law and global innovation and research is that Canada should not strengthen Canadian IP law. To strike a balance between many countries' self-interested incentives to weaken domestic IP law and the globally desirable effects on innovation that result from ensuring some degree of IP protection, most countries around the world have entered into the TRIPS agreement which sets out a minimum standard of IP rights that signatory countries commit to adopting. Although large economies with strong pharmaceutical lobbies, such as the US and EU, sought more onerous minimum standards in TRIPS, other countries resisted. TRIPS reflects a trade-off between these competing interests, establishing the concept of clinical data protection (though not necessarily exclusivity) and a patent term of twenty

¹⁹ Source: Statistics Canada. Accessed online: http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_bn00021.html.

years from the date of filing. It is worth noting that TRIPS contains many IP flexibilities especially geared toward promoting access to medicines when IP acts as an undue barrier.²⁰

In urging IP protection that goes beyond that in TRIPS, the CIPC Report fails to provide a reason or even raise the question of why deviating from TRIPS beyond Canada's existing IP regime would be favourable for Canada. In fact, Canada has already gone well beyond its TRIPS commitments by introducing an eight-year data exclusivity period and requiring generic companies to adhere to a patent linkage regime with an automatic 24-month injunction (as described elsewhere in this response). In introducing sweeping changes strengthening the pharmaceutical IP framework in 2006, including the eight-year data exclusivity period, Health Canada and Industry Canada announced that the changes would, amongst other things, "eliminate a significant trade irritant with both the United States and Europe..."²¹ The CIPC Report does not explain what has changed in the short period since 2006 that would justify further deviations from Canada's TRIPS commitments.

This last point leads to another serious flaw in the approach of the CIPC Report, a flaw that essentially follows from the shortcomings of the Report pointed out already. A central theme of the argument in the Report is that Canada's IP laws are weak relative to the rest of the world and that therefore Canada's IP laws should be strengthened in order to stay competitive. There are two basic problems with this argument. First, the Report fails to establish that Canadian law is weak. Second, the Report offers no reason for Canada to alter its laws in light of decisions taken abroad. I consider each point in turn.

The CIPC Report is flawed in its approach to international comparisons. IP regimes vary internationally along a wide variety of dimensions. In concluding that Canadian law is inappropriately weak, the CIPC Report focuses on very narrow comparisons of certain dimensions of Canadian law to correspondingly narrow dimensions elsewhere. This is not appropriate. It could be that relative stringency on one dimension is more than offset by laxity on another dimension in a country's laws. It is too simplistic to select and compare issues in isolation. This fallacy is revealed in the next section, when specific recommendations of the CIPC Report are discussed. Any

²⁰ Flexibilities in TRIPS include parallel importation (Article 6), compulsory licensing (Article 30), and limited exceptions that do not unreasonably conflict with normal exploitation of patents (Article 31).

²¹ Government of Canada, "Government of Canada Proposes Amendments to Intellectual Property Rules for Pharmaceuticals." Ottawa: December 12, 2004. Accessed online: <http://www.ic.gc.ca/eic/site/ic1.nsf/eng/02335.html>.

conclusions on the overall strength of the Canadian IP regime for pharmaceuticals would require something more comprehensive than what the CIPC Report provides.²²

In any event, the argument that Canada should strengthen its laws in order to be competitive with IP laws of foreign countries is based on non sequiturs. There is little intrinsic economic connection between a domestic IP regime (at least of a relatively small country like Canada) and global or local incentives to innovate, and investment and employment in R&D. There is thus no competitive dynamic between foreign and Canadian IP law that requires a Canadian response. Moreover, even setting aside international effects, IP law confronts a trade-off between short run costs from higher prices and longer run benefits from global innovation. IP law must reflect this trade-off, and it is therefore not the case that the best IP law is always the strongest, perhaps especially in an age of rising healthcare costs that are increasingly difficult to control.

Furthermore, when considering a comparison of Canadian law with foreign law, it is essential to be mindful of the kinds of political influences on legislation that may exist in different countries. If, for example, IP holders are politically influential in a particular jurisdiction such as the European Union or the United States, it would not be surprising for the IP regime in that jurisdiction to be especially strong. This could reflect cynical political lobbying by self-interested companies,²³ but it could also reflect self-interested global politicking by a particular jurisdiction. A country may calculate that a world with greater IP rights is a better world for it, perhaps because of profits flowing to local producers from foreign consumers, and hence it adopts a particularly strong IP regime in the hopes of using this example to influence other jurisdictions to adopt it. The potential effectiveness of this political strategy is illustrated by the CIPC Report, which clearly treats foreign law as somehow providing an essential benchmark for Canadian legislators. But simply because foreign interests may push for stronger IP around the world does not imply that Canada should capitulate. Political influences on IP law suggest that Canada should be very sceptical of the claim that foreign approaches indicate that more protection is better.

Finally, the variations among IP regimes (that the Report does not consider) render impractical greater simultaneous harmonization with the EU and the US that the CIPC endorses.

²² While not focused specifically on pharmaceutical IP, it is noteworthy that the 2011 Global Intellectual Property Index concludes that Canada is a “Tier 1 Jurisdiction”, having one of the strongest IP systems in the world, with only three EU Member States (Germany, the United Kingdom and the Netherlands) ranked higher than Canada. The U.S. and Canada were ranked nearly identically in terms of patents. Taylor Wessing, “Global Intellectual Property Index: The Third Report” (May 2011). Accessed online: <http://cde.cerosmedia.com/1W4dc7bc2658c32012.cde>.

²³ When the United States extended copyright protection following extensive lobbying by the Walt Disney Company and others, the Act earned the nickname, “The Mickey Mouse Protection Act.”

Given significant interjurisdictional differences across a wide range of dimensions, it would be impossible to harmonize with both existing US and EU regimes simultaneously.

In summary, it is clear that:

- (a) there are trade-offs such that stronger IP protection is not always better IP protection, particularly in a globalized world in which Canadian IP protection may result in higher prices and lower employment in Canada but little additional innovation; and
- (b) relying on foreign law as a model for Canadian law (even if such foreign law could be shown to be stronger, which the CIPC Report fails to do) is dubious in light of the potential influence of political forces on foreign laws that have self-interest, and not the greater good, as their primary motivation.

In the circumstances, Canada would be well-advised to adhere to its TRIPS obligations, but should be wary to go further. The CIPC Report fails to offer a convincing case for strengthening the Canadian IP regime in pharmaceuticals.

III. SPECIFIC RECOMMENDATIONS

The CIPC Report makes three specific recommendations about legislative reform in Canada. This Section reviews those recommendations and the reasoning behind them, noting that each case has not been made.

(i) Appeal Rights

The CIPC Report urges the government to provide pharmaceutical patent-holders with a robust right to appeal an unfavourable decision of the Federal Court on what it calls a “patent challenge.” The Report is imprecise on this point, in that it is not a patent challenge that entails a limited right of appeal, but rather the Minister of Health’s decision to issue a Notice of Compliance to a generic manufacturer. The relevant institutional background is as follows:

- A generic manufacturer seeking to produce and sell that drug in Canada must file an application for a “Notice of Compliance” (NOC) from the Minister.
- The generic firm cannot sell the drug until receiving the NOC. The NOC will issue only if the Minister is satisfied that the drug is safe and effective, and that it

does not infringe a valid outstanding patent; this is the “linkage” between IP law and the approval of a drug.

- If a pharmaceutical company has listed one or more patents on Health Canada’s Patent Register in association with a drug, in its application for an NOC, the generic firm may challenge any patent that purports to cover the drug by alleging that the patent is either invalid or not infringed by the generic product.
- The purported patent-holder may respond to the patent challenge by asking the Federal Court to prohibit the Minister from issuing an NOC until a listed patent expires. Once the patent-holder has commenced such a proceeding, the Minister is prohibited from issuing the NOC to the generic for 24 months, unless within those 24 months, the patent expires or the Federal Court determines that the generic’s allegations of patent invalidity or non-infringement are justified.
- If the patent-holder succeeds in Federal Court, the generic has a right to appeal the denial of the NOC to the Federal Court of Appeal. If, on the other hand, the generic’s allegations of non-infringement or invalidity are successful, the Minister will generally, subject to non-patent health and safety issues, be in a position to issue the NOC immediately.
- Once the NOC has been issued, the Federal Court of Appeal will generally not consider an appeal of a patent-holder because of mootness: neither the Federal Court nor Federal Court of Appeal have authority to order the rescission of an NOC once issued.²⁴ *The CIPC Report asserts that the law in this narrow respect is unfair to pharmaceutical patent-holders and should be changed.*

There are two basic reasons to reject the CIPC Report’s logic on this question. First, the Report overlooks the distinctive and considerable advantages held by pharmaceutical patent-holders relative to other patent-holders in asserting their patents. Second, generic companies generally have weaker incentives to challenge patents than brand companies have to defend their patents, and this asymmetry would grow if an additional appeal right were introduced.

²⁴ See, e.g., *Eli Lilly Canada Inc. v. Novopharm Ltd.* 2007 FCA 359.

Existing Advantages Given to Pharmaceutical Patent-Holders

Pharmaceutical patent-holders have several advantages over other patent-holders. In respect of any non-pharmaceutical patents, anyone can sell a potentially infringing product at any time and the holder's recourse is to challenge any perceived infringement directly in court through an infringement action under the *Patent Act*. Initially, it must persuade a court of the equities in granting it injunctive relief to prevent ongoing participation in the market by the alleged infringer during the period until the case is decided. This type of relief is rarely granted by Canadian courts because it requires patentees to show, among other things, that the patentee would be irreparably harmed (e.g., due to the inability of the defendant to pay damages) if the alleged infringement were to continue.

This general approach to injunctions and non-pharmaceutical patent infringement in Canada contrasts sharply with that in the pharmaceutical setting. In the pharmaceutical setting, the patentee automatically obtains interlocutory injunctive relief that blocks competition in the patented product simply by filing a response to the application for an NOC by a generic. This interlocutory injunction may last up to 24 months. This is but one clear and weighty advantage. Indeed, in finding for a generic company in a dispute related to linkage proceedings, the Supreme Court of Canada described the automatic injunction as a “draconian” approach to protecting the patent-holder's rights.²⁵

Another advantage of the patentee in the pharmaceutical context is that they have two or more opportunities to litigate the invalidity and/or non-infringement of the same patent(s). First, the patentee may seek to deny the issuance of an NOC to the generic producer on the basis of its patent. The patentee has an important advantage in this NOC litigation because the generic producer must provide its theory of its case in its Notice of Allegation (NOA), even before discovery, and is prevented from arguing on any other basis even if a stronger argument becomes apparent later in the process.²⁶ In contrast, once the generic company's arguments have been crystallized, patentees are not constrained in their counterarguments. Patentees can even cure defects in their patents (to the extent allowable under the *Patent Act*) before the hearing of an NOC

²⁵ *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193 at para. 33.

²⁶ See e.g. *Pfizer Canada Inc. v. Novopharm Ltd.*, [2005] F.C.J. No. 1318, 2005 FCA 270 at para. 4; *Apotex Inc. v. Eli Lilly Canada Inc. et al.*, 2008 FCA 44.

proceeding to nullify the arguments raised in the generic company's NOA and possibly force them to endure another injunction by addressing the varied patent.²⁷

It is true that, if the trial judge sides with the generic and the NOC issues, there is no opportunity to appeal that decision given the mootness of any appeal. But on the other hand: if the generic appeals and loses, it normally cannot seek an NOC on the drug in the future even if the patent is ultimately found to be invalid, unless the generic pursues a full-blown action to obtain a declaration that the patent is invalid or not infringed.²⁸ If the patentee loses in the NOC proceeding, it can still seek to uphold the patent in an ordinary infringement action.²⁹

Compared to sellers of other kinds of products, the NOC proceeding presents an additional hurdle to companies seeking to market a generic pharmaceutical product that could raise IP issues; other industries only have to litigate the validity and/or infringement of the relevant patent once, while generic manufacturers may have to litigate twice. The two litigation approach also prolongs the period of patent-related uncertainty compared to one patent action. This additional barrier to entry afforded pharmaceutical patent-holders is, to my knowledge, unique to Canada.

Although Canada's NOC regime is modeled after the U.S. *Hatch-Waxman* linkage system, Canada's system requires two rounds of litigation to resolve patent issues. In the US, after generic companies allege that patents are invalid or not infringed, brand companies can only file a normal patent infringement action, which finally resolves all patent issues. That action and any appeals finally resolve the patent issues in dispute between the parties. In contrast, Canadian NOC proceedings do not resolve any of the patent issues in dispute; all such issues may be re-litigated in a subsequent infringement action (as well as in a claim for damages by the generic manufacturer for having been delayed to market, a feature of the landscape that I discuss in more detail below).

Generic drug companies are therefore forced to contend with a uniquely burdensome system in Canada where marketing after a patent-contentious regulatory approval is always at risk. This risk is not trivial: brand damages from generic entry can far exceed generic revenues, due to the much higher profit margins earned by brands from monopoly pricing in the absence of generics. Even if a

²⁷ *Sanofi-Aventis Canada Inc. v. Hospira Healthcare Corporation et al.*, 2009 FC 1077.

²⁸ *Sanofi-Aventis Canada Inc. v. Canada (Minister of Health)* 2008 FC 1062.

²⁹ As the majority put it at para. 27 in *Eli Lilly, supra*, denying an NOC appeal because of mootness:

“The main point of controversy between the parties ... can be addressed just as adequately in an infringement proceeding and those proceedings can produce an *in rem* decision as to the validity of the patent which the present [NOC] proceeding cannot do.”

generic company has good reason to believe it will win in a subsequent infringement proceeding, the risk of potential damages in the event of a loss is unsettling³⁰ and can only be fully avoided if the generic company delays entry until after a second patent proceeding.

In this context, it is not clear why fairness considerations require reform in favour of brand companies. Pharmaceutical patentees are unable to appeal a decision once an NOC issues but (a) they obtain an automatic interlocutory injunction by merely asserting a listed patent; (b) they are less restricted than generic companies are in their arguments at the NOC stage; (c) they may win at the NOC stage, which bars the generic from entering; and (d) even if they lose at the NOC stage, they may still pursue an infringement action and obtain a permanent injunction and damages, causing all generic launches to be at-risk. The NOC proceeding poses an additional obstacle to competition in the drug market compared to other areas of technology. There is little reason to presume that making the obstacle even more formidable by adding another right of appeal is fair or equitable policy.

Generics Require an Incentive to Challenge Weak Patents

The CIPC Report also errs by ignoring the unbalanced incentives inherent in pharmaceutical patent disputes. Specifically, the Report fails to consider the stronger incentives of the patentee to invest in litigation showing a patent is valid, relative to the weaker incentives of a lead generic to invest in litigation challenging the validity of a patent. The asymmetric incentives to litigate would be exacerbated if a further right of appeal were available to patentees.

A pharmaceutical company with a valid patent earns monopoly profits in sales of the drug subject to the patent. Entry by a generic dramatically shrinks these profits. While the competitive process in pharmaceutical patents is different from most markets because of insurance and regulation, as discussed above, prices and profits remain predictably related to the number of participants in the market. As the CIPC Report observes, prices of a drug fall by up to 75% following the entry of a generic. As a consequence, the generic may have only weak incentives to

³⁰ For example, in the case of the anti-psychotic drug Zyprexa (olanzapine), Teva succeeded in a NOC proceeding in 2007 and then won at trial in 2009 after Eli Lilly sued Teva for patent infringement on the same patents. In 2010, the Federal Court of Appeal remanded the case back to the trial judge. If the trial judge reverses his trial ruling, Teva could be liable for several years' worth of brand lost profits, far exceeding Teva's own profits due to the greater competition and lower prices faced by Teva.

litigate to challenge the patent, while the incumbent will always have a stronger incentive to defend the challenge to protect its monopoly profits.³¹

The weakness in the generic's incentives to challenge is exacerbated because successful issuance of an NOC in light of a finding of patent invalidity invites other generics to enter, leading quickly to robust, profit-reducing competition (manifest in varying ways, such as lower prices, and /or higher rebates to pharmacies for shelf space). In light of this anticipated outcome, the generic has relatively weak incentives to litigate initially to challenge patents in the NOC process while the incumbent has relatively strong motivation to defend its monopoly position.

There is no mechanism under the NOC Regulations, or otherwise, to offset this asymmetry. The NOC Regulations contain a provision allowing generics to recover their losses during the period that they would have been on the market but for the injunction.³² However, there has not been a single decision to date, since its inception in 1993, of any award of monetary compensation to a generic on this basis. More importantly, losses to the generic from an unjustified injunction pale in comparison to brand monopoly profits obtained during the injunction. First, since the generic price is a fraction of the brand price, generic profits are lower than brand profits. Second, since multiple generics typically enter all at once, the profits to any one generic challenger are small. Third, even if multiple generics do not enter, the brand typically launches an "authorized generic", cutting into generic competitors' price and market share.³³ Taken together, these factors make the filing of an NOC application to trigger an injunction by the brand company predictably profitable, even if the brand anticipates losing the case.

If the quality of issued patents is uncertain, it is potentially socially beneficial for questionable patents covering a drug to be challenged in court. This premise has been accepted in the United States, where the *Hatch-Waxman Act* explicitly grants extra rights to the first generic to file an application challenging patents if early market entry is achieved. This first entrant can obtain 180 days of market exclusivity as against all other generic applicants if it achieves entry before expiry of all relevant patents, although this exclusivity can be forfeited if the first-filing generic sits on its rights.³⁴ Representative Waxman explained the benefits of the 180-day exclusivity period as follows:

³¹ Moreover, because competition dissipates industry profits, the incumbent will predictably lose more than the challenger will gain, and thus will have stronger incentives to invest in litigation upholding the patent.

³² *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133, section 8, as amended.

³³ See Competition Bureau Canada, "Canadian Generic Drug Sector Study" (2007) at 18-19.

³⁴ The CIPC Report's failure to consider the concessions of the *Hatch-Waxman Act* to generic producers that first challenge a drug patent illustrates the dangers described in Section II of viewing aspects of an IP regime in isolation:

“As you know, the Hatch-Waxman Amendments created this incentive for generic companies who challenge patents on the brand name drug—in exchange for undertaking the costs and risks of patent litigation, the successful challenger is given 6 months of marketing without any other generic competition . . . The consequences of leaving inappropriate patents in place are far-reaching: it threatens to significantly delay generic competition, forcing consumers, businesses, and governments to unnecessarily pay monopoly drug prices for much longer periods. This has got to be a concern.”³⁵

The patent-holder has stronger incentives than the generic to litigate, and this can deter litigation: even if it is socially desirable to litigate and resolve the boundaries of the uncertain patent, no individual generic has sufficient profit incentives to bring the action knowing that it is thus opening the market to fierce competition and low prices.³⁶ Under Canadian conditions, with no incentive to the first-filing generic as in the US, adding an extra appeal for brands would further undermine generic companies’ socially desirable incentives to challenge questionable patents.

Although the European Union does not provide a litigation incentive, the EU has a separate mechanism for challenging patents that does not exist in Canada: opposition before the European Patent Office (EPO). Within nine months of a patent’s issuance, any person can make full written and oral submissions to challenge a patent. The EPO will then provide full written reasons for its decision to sustain, amend or revoke the patent. According to the European Commission, pharmaceutical patents are revoked 59.6 percent of the time and reduced in scope 15.4 percent of the time when this procedure is invoked.³⁷ In Canada, generic companies are forced to challenge

the Report decries and seeks to nullify the purported advantages of generic entrants found in the Canadian appeals process and not elsewhere, but neglects to consider the advantages clearly enjoyed by generics abroad that do not exist here.

³⁵ Rep. Henry Waxman, Statement to the Generic Pharmaceutical Association's First Annual Policy Conference: Securing the Future of Affordable Medicine (20 September 2005), online: http://www.waxman.house.gov/news_files/news_statements_generic_pharmaceutical%20_association_9.20.05.htm.

³⁶ An alternative understanding of this point is to recognize that selling a product covered by a questionable patent is risky for the entrant: it realizes (at best) profits that are limited by competition from the incumbent if it wins; while it must pay the incumbent lost monopoly profits if it loses.

³⁷ European Commission, “Pharmaceutical Sector Inquiry: Preliminary Report” (November 28, 2008). About 8% of patents are challenged in this manner: see Hall et al., *infra* note 38 at 11.

these patents before the courts, which is likely to be a more costly procedure than the European administrative process.³⁸

In summary, the CIPC Report makes two mistakes when it urges amendment to the appeals process. First, it does not take into account the extra obstacles that stand in the way of generic challengers to drug patents in comparison to patent challengers in other industries. The additional right of appeal seems only a minor offsetting consideration to these additional hurdles. Second, the Report fails to analyze the relative incentives of brands and generics to litigate questionable patents, which would be skewed further in favour of brand companies if an extra appeal were available. The report fails to offer a convincing reason to expand the NOC regime to include an additional appeal.

(ii) Data Exclusivity

Canada provides an eight year period (for innovative drugs) in which generic manufacturers seeking approval of a drug cannot rely on the data from trials generated by the pharmaceutical company that initially won approval to market the drug. An extra half-year, totalling 8.5 years, may also be available where pediatric studies have been conducted. Generic manufacturers may not file a submission for regulatory approval of any such drug for at least six years after the brand name company has obtained its marketing approval for Canada. Therefore, *even in the complete absence of any patent*, brand name companies benefit from a minimum of eight years of market monopoly in which to recoup their investment and make profits in Canada.

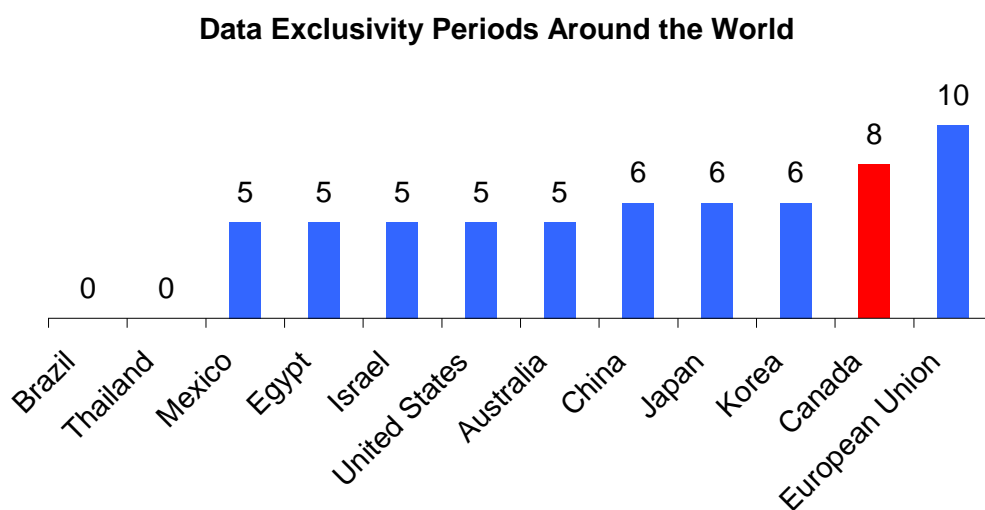
The CIPC Report argues that Canada is not competitive with the EU, which provides an additional two years' protection, and the US, that provides four more years of data protection for biological medicines.

The CIPC Report's submission on data exclusivity does not have a sound policy basis. The Report is imprecise in its international comparisons. While the US provides 12 years of protection for biological medicines, non-biological medicines (typical pharmaceuticals, which are smaller and typically easier to manufacture) containing new chemical entities get only 5 years of exclusivity (or 7 years if they are orphan drugs, which are drugs that affect very few patients), and other drugs get

³⁸ See Bronwyn H. Hall, Stuart J. H. Graham, Dietmar Harhoff, and David C. Mowery "Prospects for Improving U.S. Patent Quality via Post-grant Opposition" (2003) Competition Policy Center, University of California, Berkeley Working Paper CPC03-38 at pp. 10-11 (European EPO challenge procedure appears to cost less than U.S. litigation); Joseph Farrell and Robert Merges, "Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help" (2004) 19 Berkeley Technology Law Journal 943 (recommending administrative procedure as a cheaper and potentially more reliable option for challenging invalid patents than litigation).

only 3 years, if anything.³⁹ Moreover, 12 years of data exclusivity for biological medicines was a result of intensive political lobbying and remains extremely controversial, with the FTC issuing a report suggesting that no exclusivity period is necessary⁴⁰ and the Obama administration actively working to reduce the 12-year period to 7 years. In reality, the 5-year period contained in NAFTA represents the norm for data exclusivity in the U.S., both domestically and in its international trade negotiations.

Canada has more extensive data protection than the US; if harmonizing with the US were appropriate, it would result in a reduction of data protection associated with many patents. In fact, most countries have far less stringent data exclusivity regimes than Canada:⁴¹



The European Union, where many brand name pharmaceutical companies are headquartered, chose to adopt 10 years of data exclusivity. This is a policy decision that is at least partly offset by the fact that there is *no linkage* between patent status and regulatory approval in the EU. Once a generic manufacturer receives regulatory approval in the EU, that manufacturer is able to enter the market at any time and is not subject to any automatic injunction. To ignore this fact is to cherry-pick data when conducting a comparative review of international IP regimes.

³⁹ Although an additional 3 years of exclusivity are available beyond the typical 5-year period, this 3-year exclusivity extends only to changes to the product supported by new clinical studies and does not prevent generic entry.

⁴⁰ Federal Trade Commission, “Emerging Health Care Issues: Follow-on Biologic Drug Competition” (June 2009). Accessed online: <http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf> .

⁴¹ International Federation of Pharmaceutical Manufacturers & Associations, “Data Exclusivity: Encouraging Development of New Medicines” (July 2007). Accessed online: http://www.ifpma.org/documents/NR7758/IFPMA_Data%20Exclusivity_July07.pdf.

In any event, because of the points raised already about the dubious implications of global competition, even if it were the case that data exclusivity were greater elsewhere, this does not provide a reason for Canada to extend its exclusivity period.

The Report stresses the cost of producing the data in the first instance as an important consideration that would support lengthening the period of exclusivity, stating at p. 15:

“Data arising from clinical trials of a new drug are the product of years of effort and millions of dollars; it is the price to pay to demonstrate the safety of a drug and is essential to gaining government approval.”

Whether or not the costs of clinical trials justify the existence of a data exclusivity period when there exists a patent system intended to induce investment in innovation, they in no way imply that the legislature should extend the current period of data exclusivity. Just five years ago, after the EU had already implemented its current data exclusivity regime, Canada introduced its eight-year data exclusivity regime and made the following judgment in the Regulatory Impact Analysis Statement:

Due to the response from stakeholders regarding the term of data protection, the Government will now incorporate a no-filing period within the eight-year term of data protection. As a result, Canada will now provide for a six-year period (within the eight-year term) where a generic manufacturer will not be permitted to file a submission with the Minister. This will be followed by a no-marketing period of two years during which the Minister will not grant a notice of compliance to the generic manufacturer. ... *This change will provide an adequate incentive for innovators to invest in research, and to develop and market their products in Canada.*

No evidence has been put forth, in the CIPC Report or otherwise, that supports reopening the Canadian inquiry into the appropriate length of data exclusivity. Given that the current exclusivity period has only been in place since 2006, it is highly doubtful that there exists any meaningful evidentiary basis for departing from the status quo.

If the current incentive was described as “adequate” only five years ago, and there is no new evidence or theory on the impact of exclusivity periods, what is the policy justification for an extension? The CIPC Report asserts several times the necessity of maintaining data protection equivalent to the EU and US without ever considering why such a necessity exists (and without

being precise about the requirements found elsewhere). As noted in Section II, there is little reason to suppose that there is a cost to Canada from not “keeping up with the Joneses” in this context. Moreover, as is clear from a true international data exclusivity comparison, Canada is ahead of nearly all international comparators on this measure. The Report also mistakenly concludes that since some IP protection, in this case data exclusivity, is good, more must be better. In doing so, it ignores the costs of additional protection in suppressing competition.

iii) Patent Term Restoration

The CIPC Report calls for Canada to establish a “patent term restoration” period to account for the time devoted to regulatory approval associated with pharmaceutical patents. The Report emphasizes that the US and EU have such periods and urges Canada to mimic them. International comparisons do not provide a case for change, and the Report offers no independent reason in principle to lengthen the patent term in light of the time devoted to regulatory approval.

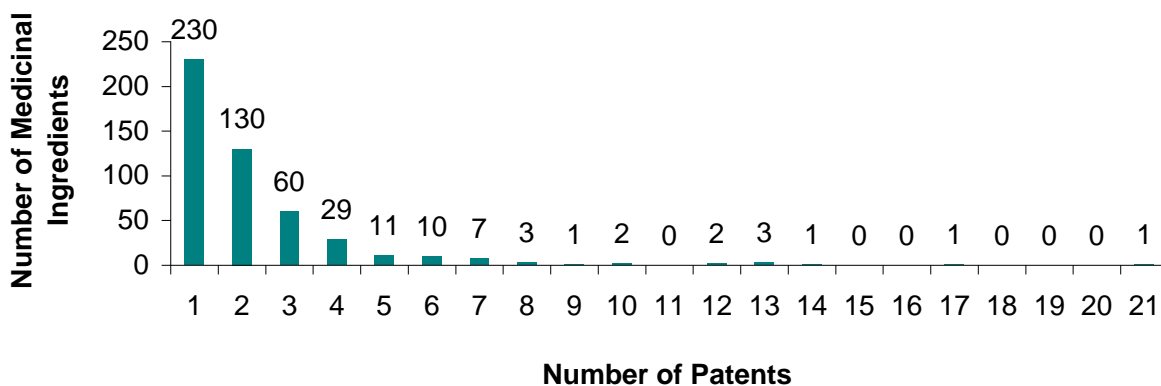
The CIPC Report’s basic premise in its analysis of PTR – that Canada’s IP protections are inadequate compared to other countries’ – is questionable at best. As with the other comparisons that the Report raises, the issue of patent term restoration cannot be viewed in isolation without factoring in the complete IP regime governing pharmaceutical patentees. Canada already provides an automatic injunction to brand companies as part of its linkage regime, with no exclusivity period for generic companies, as well as eight years of data exclusivity for brand companies that begins only when regulatory approval is obtained. Within Canada, pharmaceutical patent-holders have a number of advantages over other kinds of IP-holders. It is much too simplistic to point out that patentees in this sector may be disadvantaged because of regulatory delay and from this alone argue in favour of a PTR regime that other IP-holders do not have.

International comparisons of the PTR regime in isolation also do not help the CIPC’s case. The United States has patent term restoration, but only five years of data exclusivity in most cases. In addition, generic companies have a 180-day exclusivity as an incentive to challenge patents during which nationwide marketing is immediate and pricing is largely unregulated; this contrasts to Canada, which has no first-filer incentive and where marketing and pricing are subject to provincial approval. Europe has ten years of data exclusivity and patent term restoration, but no patent linkage or automatic injunction. Unlike the US and EU, Canada gives pharmaceutical patentees two opportunities to allege infringement – one at the linkage stage, then again once the generic enters the

market. In making its comparisons with the US and EU on PTR, the CIPC Report fails to look at Canada’s system as a whole.

In fact, even setting aside certain procedural advantages that brand companies in Canada have in litigation, the Canadian and US drug patent regimes in effect result in very similar patent protection periods, with the one of the two countries offering slightly longer or slightly shorter protection depending on the number, timing and strength of patents associated with the drug. To start, the CIPC Report seemingly starts with the premise that drugs are protected by one patent lasting twenty years. This is a false premise. According to Health Canada, the majority of medicinal ingredients are protected by at least two patents on the Patent Register, and 15 percent of drugs (which not surprisingly coincide with the top selling patented drugs in Canada) are protected by at least four distinct patents.⁴² Some products are protected by over 10 patents, even as many as 21, on the Patent Register alone. This does not even account for the vast array of patents on synthetic chemical processes and other aspects of drugs that cannot be listed on the Patent Register. Therefore, the notion of a ticking 20-year clock is inapt.

Patents Per Medicinal Ingredient



When one accounts for the number of patents underlying a drug, Canadian protection of pharmaceutical IP is often stronger than in the US. To illustrate by way of hypothetical example, consider three simplified situations depending on the number of patents, and hence (normally) inventiveness, of the drug:⁴³

⁴² Health Canada Office of Patented Medicines and Liaison, “Therapeutic Products Directorate Statistical Report 2009: *Patented Medicines (Notice of Compliance) Regulations* and Data Protection (C.08.004.1 of the *Food and Drug Regulations*)” (August 2010). Accessed online: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/docs/patmedbrev/patmrep_mbrevrap_2009-eng.php#a58.

⁴³ Regulatory and IP circumstances will of course differ by product. This example is meant to provide a simplified comparison of IP protection in Canada and the US for three typical but simplified scenarios.

1. **Very Inventive** – The drug is protected by two valid patents capable of preventing generic entry – one filed ten years before marketing approval after the compound was discovered, and one filed five years before marketing approval based on a separate innovation (e.g. related to the use of the drug or how it was formulated).
2. **Inventive** – The drug is protected by one valid patent capable of preventing generic entry – filed ten years before marketing approval after the compound was discovered.
3. **Not Inventive** – The drug is protected by one invalid patent capable of preventing generic entry – filed ten years before marketing approval in the US but not sufficiently inventive over known compounds to be enforced.

The CIPC Report is unclear regarding the point in the Molecule Development process that a patent is filed. Suppose conservatively that the patent is filed two years in, and regulatory review takes one year. These assumptions are consistent with the US branded pharmaceutical trade association, PhRMA's, breakdown of the development process, where discovery is said to last 3-6 years, after which development lasts 6-7 years.⁴⁴

Suppose that the brand company takes the following steps, which are typical in the industry:

1. The patentee files their patent application in the United States and then files a PCT international patent application one year afterward, eventually designating Canada as a country for which it desires a patent.
2. The patentee seeks a US patent term extension on the initial patent (the compound patent), since it is most likely to be upheld in court, and the patent extension would not be cut short by the US requirement that effective protection from patent term extension not exceed 14 years.⁴⁵ Suppose this patent term extension lasted 3.5 years, which is reflective of the average reported extension taking into account all factors.

In these very simplified circumstances, the patentee will end up with the following effective patent protection (after regulatory approval) in Canada and in the US:

⁴⁴ See http://www.phrma.org/sites/default/files/159/rd_brochure_022307.pdf.

⁴⁵ The patentee could alternatively seek a patent term extension on a subsequent patent, although if this patent is held invalid, then the patentee will lose patent protection once the compound patent expires.

	Not Inventive	Inventive	Very Inventive
United States	5 years	14 years	16 years
Canada	8 years	12 years	17 years

As can be seen, Canada provides more extensive protection than the US in two of the three circumstances, including providing a longer guaranteed protection regardless of patent protection. It should therefore not be surprising that, as reported by Grootendorst & Hollis, approximately half of generic drugs first approved in Canada in 2010 had actually been previously genericized in the US.⁴⁶ This suggests that Canada provides similar effective IP protection to pharmaceuticals to the US, contrary to the assertion otherwise in the CIPC Report.

In any event, even if it were true that the differences in PTR regimes internationally were meaningful, the CIPC Report nevertheless fails to show the relevance of these differences. The Report provides no compelling competitive reason for Canada to mimic IP protections, like a PTR regime, adopted elsewhere. If the US and/or the EU decides that it would prefer to confer greater profits on pharmaceutical companies by suppressing generic competition for longer periods, this does not imply that Canada should do the same. Canadian IP has a small effect on global innovation, and the location of such innovation, as discussed, but a large effect on high domestic prices for drugs. Given the strong protection of pharmaceutical IP that exists in Canada, it is clear that Canada in fact has not neglected pharmaceutical IP, but it would be entirely defensible as a policy matter for Canada to go to greater lengths than other jurisdictions to promote local competition through weaker IP and greater genericization.

Aside from dubious international comparisons, in advocating for a PTR regime, the CIPC Report appears to rely implicitly on the following argument: since governmental health regulations delay marketing of a drug, it is only right that the government compensate for and offset delay by extending patents. This argument also lacks a coherent basis. The purpose of a patent is to encourage investment in innovation, but the patent is time-limited in order to ensure the long term dissemination of that innovation. There is a trade-off and a judgment call about optimal patent length. There is little reason to conclude that simply because the approval process for

⁴⁶ Grootendorst and Hollis (2011), *supra* note 18 at pages 10-11.

pharmaceutical innovations may delay marketing of the drug that the effective patent term for pharmaceuticals should be longer than that for inventions in other fields of technology.

For one, inventions in other fields also take time and significant investments to get to market. For example, a patent application may be filed well before manufacturing facilities are in place or built. Moreover, a patent-holder may be required to advertise and promote the innovation before it can expect to realize significant profits that would help offset development costs. At a high level then, the approval process for drugs is at the least analogous to the delays that confront other kinds of innovation.

Indeed, obtaining Health Canada approval as imprimatur of safety and efficacy brings a benefit to the IP-holder itself. Some commentators have pointed out that the regulatory approval process is not simply about health and safety as a goal in itself, but it also plays an important role in bolstering *marketing* the health and safety of the drug to what might otherwise be a rationally sceptical public.⁴⁷ That is, even if the drug were safe and effective, without Health Canada approval consumers may not be confident in the drug. Thus, from an economic perspective, the approval process can be conceived as a kind of promotional exercise not different in kind from that which innovators in other sectors undertake. But such efforts in other sectors do not justify extension of the patent. The patent length is set to induce innovative efforts with the understanding that there will not necessarily be immediate marketing of an innovation at the same instant that the patent is granted.

The argument in response might be that while many innovations require pre-marketing efforts that delay the monetization of the invention, the delay in pharmaceuticals is systematically longer than the delay in other sectors. This would again prove too much: if one were to move away from a general approach to patent length in order to customize an idiosyncratic approach in the pharmaceutical sector, then one should take the same approach for every sector. Sectors other than pharmaceuticals may also raise circumstances that affect patentees' timing in getting to market, and thus might conceivably push optimal patent length up or down. Yet despite the wide variety of circumstances that influence each sector in which innovation occurs, Parliament presumably made a judgment that attempting to produce a rational code of patent length depending on particular circumstances would be unduly complicated, and perhaps also subject to cynical lobbying by innovators in particular sectors advocating ever-increasing patent terms to match their purportedly

⁴⁷ Ariel Katz, "Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry" (2007) 14 Michigan Telecommunications and Technology Law Review 1.

unique circumstances. (Such thinking may also underlie TRIPS, which calls for non-discrimination on the basis of technology.) The CIPC Report fails to offer a convincing reason why the pharmaceutical but not other sectors should have an idiosyncratic patent length.

There is another reason not to extend the patent period because of the time required for regulatory approval. The patentee itself is a potential cause of delay in obtaining approval. The patentee has full control over the following key dates:

- (a) **Patent application filing date:** A patentee can choose to file a patent before it has done extensive testing, in order to stake its claim. Alternatively, a patentee can keep its invention secret and file once it has more information, to extend the lifetime of the patent. Filing speculative patent applications at the earliest possible date would tend to increase the length of a patent term extension.⁴⁸
- (b) **Date of filing of New Drug Submission:** Drug sponsors often wait until a new drug application has been approved in the United States before filing in Canada. This tends to delay the time until final approval of the drug. Taking this delaying approach would lengthen the patent term extension.
- (c) **Diligence in pursuing New Drug Submission:** Drug sponsors can pursue drug applications diligently or slowly, depending on their motives. Lengthening the time of regulatory review will tend to lengthen any patent term extension.

If any delay is added to the overall term of the patent, the right-holder has weaker incentives to apply for and pursue approval in an efficient manner. Moreover, the patentee may have strategic reasons to delay approval; for example, the patentee may want to build the brand in a different jurisdiction where approval has been obtained before beginning to market in Canada. PTRs create perverse incentives for the patentee in the approval process.

Another strike against the PTR approach is that it creates costly litigation disputes. In the US and EU, the PTR regime has generated costly litigation over the particular contours of the extension in different cases.⁴⁹ The scope and timing of the PTR are inevitably uncertain for a

⁴⁸ If a patent term extension or restoration is tied to the date of issue of the patent, a patentee can choose to delay examination of the patent by the Canadian Intellectual Property Office (CIPO) for up to five years from the date of filing, and also can control the date of issue even after CIPO approves the patent.

⁴⁹ As stated by Trevor Cook in the abstract of his presentation at the Fordham Intellectual Property Law Institute's

number of reasons, including the reality that most pharmaceutical products are covered by multiple patents. The social deadweight losses from additional litigation that PTR rules generate provide another reason to reject them.

Even if the Report were more successful in establishing the case for patent length restoration for patented drugs, to be persuasive, it would need to set out the economic particulars of the pharmaceutical sector that would justify longer patents. The Report focuses on one and only one factor, regulatory delay, without considering a host of other considerations specific to the sector that might also affect optimal patent length. The purpose of a patent period is to protect the seller from competition such that it expects to earn profits sufficient to invest in research and to bring resulting products to market. If demand for pharmaceutical products were generally less price-sensitive (more “inelastic,” as an economist would say) than other kinds of inventions, then the seller would expect greater per-period revenues and profits than other kinds of patent-holders, all other things equal.⁵⁰ In this case, the optimal pharmaceutical patent length could be *shorter* than the norm, even accepting the existence of regulatory delay.

Another potentially relevant consideration is the cost of limited competition during the patent term. Given the health consequences of a lack of competition in the drug market, the social losses associated with drug patents during the term of the patent may be more acute than in other sectors.⁵¹ This too could call for shorter patent terms despite regulatory delay. TRIPS generally prevents shorter patent terms in the pharmaceutical sector as a matter of law, but the particular social costs of pharmaceutical patents may be reflected in the flexibilities that are geared to pharmaceuticals that the TRIPS framework accommodates.

18th Annual Conference, entitled “SPC Regime: Questions and Concerns 20 Years Later” (April 2010): “Although the SPC patent extension regime has been in existence for nearly 20 years, it is attracting an ever increasing amount of litigation, much of which puts into question whether it is achieving its original aims.” Accessed online: <http://fordhamconference.com/wp-content/uploads/2010/08/2010ConferenceProgram.pdf>.

⁵⁰ The role of doctors and insurance in the pharmaceutical market will tend to render demand less sensitive to price: see Competition Bureau, 2007, *supra* at p. 50.

⁵¹ In *Canada (Director of Investigation and Research) v. Hillsdown Holdings (Canada) Ltd.* (1992) CT-91/1, the Competition Tribunal discussed the potentially negative effects of a lessening of competition in the mergers context, questioning whether higher prices paid by consumers for goods acquired should be viewed, as the parties had suggested, as socially and legally neutral. The Tribunal at p. 96 chose an example from the pharmaceutical setting to cast doubt on the neutrality of high prices, stating, “The parties both rely on the judgment that the wealth transfer is a neutral one. A question posed during argument and which will be repeated here is, is this always so. If, for example, the merging parties in question were drug companies and the relevant product market related to a life-saving drug would economists say that the wealth transfer was neutral. The Tribunal does no more than raise this as a question.” The Tribunal’s doubts about neutrality in this example are consistent with the conclusion that concerns about an absence of competition in this sector are even more acute than in other industries.

In summary, the CIPC Report moves much too swiftly from pointing out the existence of regulatory delay to a recommendation of longer patent terms. Even if foreign regimes were relevant to Canadian IP policy, which they are not as a matter of economic logic, Canada already has one of the most stringent pharmaceutical IP regimes in the world. While a PTR regime does not presently exist, there are a number of other protections, such as extensive data exclusivity, that set Canada apart. Aside from international comparisons, the Report provides no reason in principle to establish a PTR regime. Regulatory delay is analogous to delays in other sectors that do not have longer patent length, and in any event there may be other considerations in the pharmaceutical sector that call for shorter patent lengths on net, not longer ones. If delays in regulatory approval are a problem for drug sponsors, then a more direct way of resolving the delays is to devote more public resources to achieving quick regulatory approval. Compensating companies for the delay with a longer market exclusivity doubly harms consumers by forcing them to endure both delay and monopoly prices for a longer period.

IV. CONCLUSION

The CIPC Report does not offer objectivity in its assessment of Canada's patent regime. It rather is a straightforward piece of advocacy on behalf of the branded pharmaceutical sector. The Report makes no effort to place Canada's patent law in an international context or address international relations, but instead simply asserts without justification that Canada would suffer if it fails to grant the same concessions to the pharmaceutical industry that the EU and US have made. The flaws in this basic approach undermine each of the CIPC Report's recommendations. Additionally, the specific arguments underlying each of the recommendations are unconvincing.