

CANADIAN CHAMBER OF COMMERCE

Eli Lilly and Company v. Government of Canada (ICSID Case No. UNCT/14/2)

Amici Curiae

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This brief posits that society benefits from a robust, predictable IPR regime that is consistent with international norms, that innovation is intrinsically tied to IPR, and that deviation from international norms on utility and sound prediction will have negative consequences on Canada's ability to attract investment and generate wealth in a global knowledge-based economy by introducing uncertainty into the business framework.

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Introduction:

This brief posits that society benefits from a robust, predictable Intellectual Property Rights (IPR) regime that is consistent with international norms; that innovation is intrinsically tied to IPR; and that deviation from international norms on utility and sound prediction will have negative consequences on Canada's ability to attract investment and generate wealth in a global knowledge based economy by introducing uncertainty into the business framework.

The broad interpretation of the promise of utility by Canadian courts, specifically where that promise is identified outside of patent filings, can be linked to declining investments. The inadmissibility of mathematical models as a reasonable approach to sound prediction is also troublesome.

While this uncertainty primarily impacts pharmaceutical investment, it has implications for other sectors such as biotech and aerospace, particularly in light of the Canadian business profile which is primarily comprised of small and medium-sized enterprises (SMEs), where access to capital is critical.

The Canadian Business Landscape:

SMEs in Canada are significant contributors to employment and job creation across the country. Innovative SMEs have the potential to drive improvements in productivity, competitiveness, and technological progress. Our focus is helping SMEs in Canada – those active in high tech sectors such as life science and advanced manufacturing – to better “appropriate”, or capture, the value of their inventions.

SMEs comprise 99% of all businesses operating in Canada. So-called ‘innovative SMEs’ have the potential over the long-term to contribute substantially to improvement in productivity, competitiveness, and technological progress in their sector and the economy as a whole.

Canada has fallen to 22nd on the World Economic Forum's (WEF) Competitiveness Index (CI) which is a key indicator in measuring innovation in global economies. High-growth enterprises in Canada which make a large part of the innovation metric are continuing to decline by 0.5% a year.

Evidence increasingly suggests that fostering SMEs' participation in innovation networks and collaborative ventures adds greater value to the innovation chain and

increases economic activity in Canada. Yet awareness of the IP regime in Canada by SMEs remains low.

Joint research and development (R&D) with industry and universities is prevalent in Europe where many countries ahead of Canada on the CI are located. Research from Oxford, Cambridge, Imperial College London and University College London has found that companies from Imperial Innovation's portfolio have raised 750 million pounds from investors. Imperial Innovation has a portfolio of 93 different companies, all of which would fall under the definition of an SME.

In Canada, this is a point of great concern. While 40% of R&D in Canada comes from higher education facilities, only half of Canadian companies have reported collaborating with a university or college. Canada has fallen behind countries such as Qatar, Korea and Malaysia on the WEF's CI.

Before bringing a product to market all firms must 'appropriate' or capture the value of their ideas. Many firms (or potential businesses resulting from innovation) are reluctant to engage in R&D in Canada knowing their efforts may be fruitless. In order for SMEs to feel comfortable collaborating with larger companies, other SMEs and research facilities with strong IP regime must be in place. Firms need to ensure freedom to operate (FTO) and to avoid patent infringement of third-party IPRs to minimize licensing fees and costly litigation. A strong IP regime will signal to financiers that their investments will be protected as well as profitable.

Formal IPRs benefit SMEs in a variety of ways – prevent others from practicing the invention; increase "knowledge trade" and partnership with others firms; and signal the value to potential investors (intangible assets such as IP make up 70% of firms asset value[up 20% from 1975]).

IP awareness in Canada is extremely low among SMEs in Canada, contributing to a deficit of IPR related functions in the economy. Lack of support mechanisms for SMEs in IPR has been costly and the complexity of Canada's IP regime has proven discouraging to businesses.

The Relationship Between Intellectual Property and Innovation:

IP is the economic engine of progressive countries. IPR can drive job creation, economic growth and innovation. A robust IPR regime also creates a framework of business certainty that drives investments in R&D, engineering, branding, marketing and manufacturing.

The International Chamber of Commerce (ICC) summarizes the benefits of a robust IPR regime:

Sectors that rely on IPR represent a significant part of developed and developing economies, in terms of GDP, employment, tax revenues and strategic importance. IPR also promotes foreign direct investment (FDI) and technology transfers in developed and developing countries. As the 'knowledge economy' advances, more and more of the value that firms and the overall economy achieve will come from high value-added intangibles - including IP in inventions, brands and works. In many companies even now, 80% or more of their market value is attributable to intangibles, including IP.

Effective IPR increases funding for research and development and other innovation, including by helping firms realize more value from innovations that are protected by IPR than those that are not. IPR underpins development of cultural expression and diversity, and promotes broader dissemination of innovations through publication and licensing.

Firms use IPR in diverse ways to help them develop, trade in, and secure income from their innovative products and services. Firms that use IPR generally succeed better and have a higher market value than those that do not.

Small and medium size enterprises (SMEs) use IPR more extensively in many cases than large companies. SMEs that use IPR report higher growth, income and employment than those that do not.¹

IPR helps provide consumers with innovative products and services in virtually every area of life, and helps protect consumers from counterfeit and pirated products. IPR

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ICC Commission on Intellectual Property and Business Action to Stop Counterfeiting and Piracy, *Intellectual Property: Powerhouse for Innovation and Economic Growth*, online: International Chamber of Commerce <<http://www.iccwbo.org/advocacy-codes-and-rules/areas-of-work/intellectual-property/ip-a-positive-force-for-society/>>.

encourages competition among diverse product, function and quality offerings, giving consumers a greater choice among the goods and services they want and need. IPR also provides important mechanisms to help address many of society's most important needs, from clean energy and reduced carbon emissions to health care and a truly “digital economy”.²

Innovation and IP as a Driver of Wealth Creation:

As an economic engine, an effective IPR regime is also an important mechanism in attracting foreign investment. According to the Office of the Secretary of the US Department of Commerce, “Although there is not a unanimous view on the subject, various studies have indicated that effective intellectual property rights protection can be an important factor in securing foreign direct investment and technology transfer, especially in high technology industries.”³

Examples cited are:

Edwin Mansfield, "Intellectual Property Protection, Foreign Direct Investment and Technology Transfer," International Finance Corporation Discussion Paper 19, The World Bank (1994): "Based on a combination of survey data, interview studies, and statistical analysis, we find that the strength or weakness of a country's system of intellectual property protection seems to have a substantial effect, particularly in high-technology industries, on the kinds of technology transferred by many U.S. firms to that country. Also, this factor seems to influence the composition and extent of U.S. direct investment there, although the size of the effects seems to differ greatly from industry to industry." p 1.

Edwin Mansfield, "Intellectual Property Protection, Direct Investment, and Technology Transfer: Germany, Japan and the United States," International Finance Corporation Discussion Paper 27, The World Bank (1995): "The findings indicate that, in relatively high-technology industries like chemicals, pharmaceuticals, machinery, and electrical equipment, a country's system of intellectual property protection often has a significant effect on the amount and kinds of technology transfer and direct investment to that country by Japanese

² ICC Commission on Intellectual Property and Business Action to Stop Counterfeiting and Piracy, *Intellectual Property: Powerhouse for Innovation and Economic Growth*, online: International Chamber of Commerce <<http://www.iccwbo.org/advocacy-codes-and-rules/areas-of-work/intellectual-property/ip-a-positive-force-for-society/>>.

³ U.S. Department of Commerce, *Overview of Intellectual Property Rights and TRIPS Agreement*, online: United States Department of Commerce <<http://www.osec.doc.gov/ogc/occic/ipr.html>>.

and German, as well as U.S. firms. Also, when a variety of relevant factors are held constant in an econometric model, the effects of such protection on U.S. foreign direct investment are substantial and statistically significant." p.1.

Ronald T. Rapp and Richard P. Rozek, "Benefits and Costs of Intellectual Property Protection in Developing Countries," *Journal of World Trade*, Volume 24, pp.75-102 (October 1990): "It has been shown that there are substantial benefits for developing countries from protection [sic] intellectual property. The benefits are in the form of investment and technology flowing to the country that protects intellectual property, access by local firms to this technology, and ultimately economic growth of the country as a whole." p. 101.

This corroborates anecdotal evidence of the link between robust IPR regimes and highly innovative economies. The Conference Board of Canada in its international ranking of patents by population, ranks Canada 14th out of 16 OECD countries. They argue that "counting patents is a means of gauging how well countries transform knowledge into usable inventions. Countries with more patents are in a better position to pioneer new-to-world technologies and therefore derive above-average economic gains from intellectual property."⁴ At the same time, The Conference Board, in its ranking of innovation scores of 16 countries, notes:

Despite a decade or so of innovation agendas and prosperity reports, Canada remains near the bottom of its peer group on innovation, ranking 13th among the 16 peer countries. This does not mean that Canadian inventions are themselves inferior. In fact, Canada produces some great inventions and inventors. Canada's low relative ranking means that, as a proportion of its overall economic activity, Canada does not rely on innovation as much as some of its peers.⁵

Canada's comparatively lower innovation scores are corroborated by the World Economic Forum⁶ and the OECD⁷ rankings.

⁴ How Canada Performs, *International Ranking: Canada benchmarked against 15 countries, Patents by Population*, online: The Conference Board of Canada <<http://www.conferenceboard.ca/hcp/details/innovation/patents-by-population.aspx>>.

⁵ How Canada Performs, *International Ranking: Innovation*, online: The Conference Board of Canada <<http://www.conferenceboard.ca/hcp/details/innovation.aspx>>.

⁶ Soumitra Dutta, Bruno Lanvin & Sacha Wunsch-Vincent, eds, *The Global Innovation Index 2015: Effective Innovation Policies for Development*, online: Cornell University, INSEAD & World Intellectual Property Organization at 32 <<https://www.globalinnovationindex.org/userfiles/file/reportpdf/GII-2015-v5.pdf>>.

⁷ OECD, *OECD Economic Surveys Canada*, online: Organisation for Economic Co-operation and Development <<http://www.oecd.org/eco/surveys/economic-survey-canada.htm>>.

Similarly, the Global Intellectual Property Center (GIPC) released an economic impact study in November 2015, linking the importance of intellectual property to innovation.⁸ In a separate report, released February 10, 2016, the GIPC gives Canada a relatively poor performing score of 4.3 of 7 on patentability, largely due to uncertainty resulting from invalidation of pharmaceutical patents.⁹

The trade off in patent law can be characterized as a commitment to innovation in exchange for exclusivity. This arrangement, on balance, benefits the public good. Patent law is assumed to create incentives to invest in, to engage in, and to take risks to do research and development that foster innovation and new goods and services that benefit the public more than the disadvantages associated with patents. This has been acknowledged by Canadian courts:

Teva Canada Ltd. v. Pfizer Canada Inc., [2012] 3 S.C.R. 625 The patent bargain encourages innovation and advances science and technology.

Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45 There is no doubt that two of the central objects of the Act are “to advance research and development and to encourage broader economic activity” (see *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66 (CanLII), [2000] 2 S.C.R. 1024, 2000 SCC 66, at para. 42).

Although some argue that the patent protection system inhibits innovation and advancement by binding ideas and processes, the opposite is actually true. As Sookman points out:

The reason that patents have not been proven to impede more than stimulate technological advance is simple: it does not happen. It does not happen for several reasons. First, experiments advancing technology rarely, if ever, generate commercial value. Thus patent owners have little, if any, incentive to license or inhibit research. Stated otherwise, even if a patent owner wanted to sue or license potential researchers, experiments do not produce income or a source of damages. See *id.* at 12. Second, in the modern age of technology, the character of technological advance has changed. The era when the Bell Labs or some other tech center could hire the most promising engineers and essentially invent everything for the world

⁸ Global Intellectual Property Center, *Employing Innovation Across America*, online: The U.S. Chamber of Commerce <<http://www.theglobalipcenter.com/ip-employs-innovation/>>.

⁹ Global Intellectual Property Center, *The U.S. Chamber International IP Index “Infinite Possibilities”*, online: The U.S. Chamber of Commerce at 77 <http://www.theglobalipcenter.com/wp-content/themes/gipc/map-index/assets/pdf/2016/GIPC_IP_Index_4th_Edition.pdf>.

has passed. With the vast specialization of all fields of research, advances in technology require great cooperation. A new product or a new direction in biotechnology or electronics will be produced by cooperation between a professor in Chengdu, China, a young programmer in Bangaluru, India, an engineer at a large corporation in Munich, Germany, a graduate student at Tokyo University, and a team at a small start-up company in Silicon Valley. The patent system can help inform each of them of the other and bring together their incremental advances to achieve the next generation of progress in some tiny corner of human progress.¹⁰

Other Sectors Impacted:

In the past decade, there have been 27 inutility decisions on 24 patents at issue. These decisions have impacted the pharmaceutical industry. However, as noted, the implications of this direction by the courts impact other industries as well. The broad interpretation of the promise of utility combined with a narrow acceptance of evidence of sound prediction has had implications for mechanical patents in the aerospace sector.

As Faggetter describes, the *Bell Helicopter Textron Canada Limiteé v Eurocopter* (“Eurocopter”), decision (and Canada’s Federal Court of Appeal upholding this invalidity ruling), extend uncertainty for doing business in Canada. While the patent in Eurocopter was upheld as valid, the fact that claims failed for lack of utility shows how the promise utility doctrine could have consequences in other sectors in the future.

Promised utility. Canada’s Patent Act, similar to the legislation in many other countries, provides that an invention must be useful to be patentable. If acclaimed invention is inoperable, then the claim is invalid.

Canadian courts, in interpreting the requirement for utility, have considered that if a patent promises a particular utility for an invention, the invention must achieve this promised utility to avoid invalidity of claims directed to the invention. Thus, while there is no requirement to promise a specific utility, if a promise is made, the question of whether the invention has utility has been assessed by reference to the explicit promise.

¹⁰ Barry Sookman, “Law and Innovation: Is Intellectual Property a Path to Progress”, (13 April 2014) online: Barry Sookman: Copyright, Intellectual Property, Computer, Internet, e-Commerce Law <<http://www.barrysookman.com/2014/04/13/law-and-innovation-is-intellectual-property-a-path-to-progress/>>.

In *Eurocopter*, the specification of the patent disclosed embodiments where the landing gear had a forward offset cross-piece and a further embodiment where this cross-piece had a backward offset. The specification stated that the landing gear reduced the problem of ground resonance (potentially dangerous vibrations that can occur on landing). This statement in the specification was considered by the Court to be a promised utility for all of the embodiments of the invention.

Sound prediction. Where there is an explicit promise, utility is established if the promised utility is demonstrated by the date of filing the patent application or if the promised utility is soundly predicted as of the filing date. A sound prediction is shown if (1) there is a factual basis for the prediction; (2) the inventor has a sound line of reasoning from which the desired result can be inferred from the factual basis; and (3) there is proper disclosure.

The patentee, Eurocopter, submitted that the doctrine of sound prediction was developed in the context of patents in the pharmaceutical field and argued that the inherent uncertainty of results in chemistry and biology had led to development of this doctrine. The patentee concluded from this that the doctrine of sound prediction should not apply to mechanical inventions, where there is no such inherent unpredictability.

Further, while the patentee admitted that it had never made the backward offset landing gear, it argued that it had nevertheless demonstrated utility of this landing gear as of the date of the patent application with mathematical models.

The Federal Court of Appeal disagreed with the patentee and held that the doctrine of sound prediction can apply to the field of mechanical inventions.

Regarding the mathematical models, the Court opined that “calculations and mathematical modeling are, by their very essence, a prediction of a given utility” and not a demonstration of utility. Thus, the patentee had to show the three requirements for a sound prediction.

Regarding the requirement for a factual basis, the Court stated:

Where the factual basis can be found in scientifically accepted laws or principles ... no disclosure of such factual basis may be required in the specification. On the other hand, where the factual basis is reliant on data which does not form part of the common general knowledge, then disclosure in the specification may indeed be required ...

Regarding the requirement for a sound line of reasoning, the Court noted that the soundness of the reasoning can be assessed by asking whether a skilled person would accept the logic presented in the specification.

The Court then stated that “where the sound prediction is based on ... common general knowledge and on a line of reasoning ... apparent to the skilled person (which is often the case with mechanical inventions), the requirements of disclosure” – that is, the third requirement for sound prediction – “may readily be met by simply describing the invention in sufficient detail such that it can be practiced.”

The Court noted that Eurocopter had no explanation in the patent relating to the promised effect of reduced ground resonance for the backward offset embodiment. The Court then stated “Eurocopter did not provide evidence that it had either demonstrated or soundly predicted the utility of the backward inclination embodiment prior to [the filing date]. Eurocopter did not do so in the patent specification and it failed to do so at trial.” The Court therefore upheld the invalidity of the claims covering this embodiment.

The Eurocopter decision is another step in the evolution of the sound prediction doctrine. The Eurocopter decision highlights the need for caution in Canada in making promises in a patent specification as to the utility of any invention.¹¹

Declining Investment Climate:

With respect to inutility decisions, in the same time period, there has been a corresponding decline in pharmaceutical investments in Canada. According to Industry Canada:¹²

- Pharmaceutical sales in Canada have a 2.5 percent share of the global market, making Canada the 9th largest world market. Since 2009, compound annual growth has slowed to 0.4 percent (*IMS Health Pharmafocus 2018*).

¹¹ Ron Faggetter, *Federal Court of Appeal affirms invalidity of all but a single claim for failure to meet promises in a mechanical patent* online: Smart & Biggar Fetherstonhaugh <http://www.smart-biggar.ca/en/articles_detail.cfm?news_id=793>; *Bell Helicopter Textron Canada Limitée v Eurocopter*, 2013 FCA 219.

¹² Industry Sector: Manufacturing & Life Sciences Branch, *Canada's Pharmaceutical Industry and Prospects*, online: Industry Canada <<https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/hn01768.html>>.

- In 2014, the manufacturing portion of the sector employed 26,300 people and over the last 5 years employment has fallen by 6.3 percent.
- Annual domestic pharmaceutical manufacturing production is valued at \$7.7 billion as of August 2014 with a declining compound annual growth rate of 2.5 percent since 2008 (Statistics Canada CANSIM table 304-0014).
- Total business expenditures on R&D by Canadian pharmaceutical companies has fallen below \$1 billion since 2011. From 2001 to 2013, industry R&D spending has fallen by 29 percent.

According to a recent life sciences industry survey by PWC, 67% of Canadian respondents indicated they were not confident about short term prospects for the industry and 59% indicated a lack of confidence in long term prospects.¹³ The primary reason cited for the lack of confidence was access to capital. Capital markets depend on business certainty.

A KPMG report commissioned by CanadaPharma (formerly Rx&D), points to declining investment in Canada, relative to global R&D spending:

- The Updated Survey reported total 2013 expenditures of \$1.276 billion (\$1.332 billion and \$1.301 billion for the 2012 and 2011 Survey respectively).
- The Updated Survey reported \$698.9 million (\$831.3 million and \$906.4 million for the 2012 and 2011 Survey respectively) of 2013 expenditures that are traditionally reported to Patented Medicine Price Review Board (PMPRB).

More broadly, a 2014 Science, technology and Innovation Council report indicates a worrisome decline in innovation spending in Canada:¹⁴

Despite efforts to improve Canada's lagging business innovation performance, it has continued to deteriorate. Canada has fallen further behind comparator countries on key business innovation performance indicators and the gap between Canada and the world's top five performers has widened. Of particular concern is the lack of research and development funding by businesses. Canada's ranking in business expenditures on R&D fell to 26th in 2013 from 18th in 2006. Total investment over the same time dropped by \$1 billion.

¹³ *The missing ingredient: Canadian Life Sciences Industry Forecast 2013*, online: PwC <<http://www.pwc.com/ca/en/industries/pharma-life-sciences/publications/canadian-life-sciences-industry-forecast.html>>.

¹⁴ STIC, *Canada's Innovation Challenges and Opportunities*, online: Science, Technology and Innovation Council <<http://www.stic-csti.ca/eic/site/stic-csti.nsf/eng/Home>>.

Notwithstanding a narrowing of the interpretation of the “promise doctrine” in the 2014 Plavix Decision, uncertainty remains. As Szweras and Rana note:

The Canadian court decisions post the PLAVIX Decision may suggest an increasing reluctance to find implicit promises and a consequently increased utility requirement. By focusing on claim language in order to find the promise, rather than any stray phrases in the disclosure, Canadian courts 23 2013 FC 1061 24 Ibid., at para 93. 25 Ibid., at para. 152 26 2014 FCA 250 27 Ibid. at para. 66 28 Ibid. at para. 77. may be moving away from a draconian application of the promise doctrine rule. However, Canadian courts may still look to inferred promises as a basis for invalidity in a post-PLAVIX world, as was the case in Alcon v. Cobalt Pharmaceuticals.²⁹ Until the Supreme Court of Canada or the tribunal in Lilly’s NAFTA challenge deals with issue, the promise doctrine may remain a live issue. As a result, the application of the promise doctrine may create some uncertainty for the Canadian patent landscape.¹⁵

Conclusion:

Innovation, invention, disruption and the creation of intellectual property and higher value products and services are the essential ingredients that will drive future economic prosperity across Canada’s business sectors. And yet, despite countless studies, reports and recommendations, Canadian business continues to be challenged on productivity, an essential measure of our ability to compete with both advanced and emerging markets.

Our public sector research is world leading but we fail to commercialize it. While our capacity to generate new ideas is competitive, our record of developing intellectual property into financial success stories trails our major trading partners. Fostering an “ideas economy” friendly environment where ideas are protected and nurtured is essential.

¹⁵ Melanie Szweras and Amar Rana, *Intellectual Property: Promise of the Patent post-Plavix* online: Bereskin & Parr LLP <http://www.bereskinparr.com/files/file/docs/June-July_2014%20-%20Promise%20of%20the%20Patent%20Post-Plavix.pdf>.

The ability of Canadian companies to compete globally is now being determined by their ability to innovate, adapt or disrupt old business models. Building on our leadership in traditional sectors, Canada must now generate economic growth through breakthrough ideas, processes and services. Streamlining and strengthening the intellectual property framework is the first step.

In Canada, many of our businesses and public institutions have failed to invest or partner in innovation at the rate required to drive success. Since 2010, federal R&D expenditures have fallen by 12% (after inflation, the drop is closer to 18%). If economic forecasts are borne out, federal R&D expenditures as a proportion of GDP will have fallen 26% in just 5 years.¹⁶ Both public and private sector R&D spending is vital for exports, jobs and wealth creation. There are 28 companies in Canada that spend more than \$100 million a year on R&D.

These failures to invest can be linked to failures in the intellectual property framework that deviates from international norms. Canada needs new strategies to foster Canadian patent generation and internationally competitive pools of Canadian intellectual property. But first, Canadian business needs the certainty that is derived from international patent law frameworks.

Respectfully submitted:

[signed]

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¹⁶ OCUFA, *Data Check: Federal commitment to R&D continues to decline* online: The Ontario Confederation of University Faculty Associations <<http://ocufa.on.ca/blog-posts/data-check/data-check-federal-commitment-to-rd-continues-to-decline/>>.