IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN OF THE NORTH AMERICAN FREE TRADE AGREEMENT AND THE UNCITRAL ARBITRATION RULES (1976)

BETWEEN:

ELI LILLY AND COMPANY

Claimant/Investor

AND:

GOVERNMENT OF CANADA

Respondent/Party

(Case No. UNCT/14/2)

NON-DISPUTING PARTY *AMICUS CURIAE* SUBMISSION OF INTELLECTUAL PROPERTY LAW PROFESSORS
12 FEBRUARY 2016

Simon J. Elliott, Ph.D. J.D
Foley & Lardner LLP
3000 K Street, N.W., Suite 600
Washington, DC 20007-5109
Phone: +1 202.295.4726
Email: SJElliott@foley.com

CONTENTS

NON-DISPUTING PARTY *AMICUS CURIAE* SUBMISSION OF INTELLECTUAL PROPERTY LAW PROFESSORS[1]

SUMMARY OF THE ARGUMENT

The *quid pro quo* common to all patent systems is the grant of a property right in return for disclosing how to make and use a new invention that is capable of industrial application. The general requirement for disclosure is stated liberally in international agreements. As TRIPS[2] Article 29(1) provides, the standard is merely that the application "shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date." The distinct requirement for industrial application, also called "usefulness" or "utility," finds voice in Article 27 of TRIPS and Chapter 17 of NAFTA.[3] NAFTA Article 1709(1) states that "each Party shall make patents available for any inventions … ***capable of industrial application***."

Thus, there is international consensus that an application must disclose not only how to make an invention, but must explain *how* it may be usefully applied. As a general rule, a greater disclosure of possible useful applications is regarded as a benefit to the public and international practice is for a patent application to set forth the many useful applications of an invention.[4]

Recent court decisions in Canada have turned these long standing international understandings and practices into a cudgel against patent owners. Canada's "promise utility doctrine" construes disclosure of the potential practical benefits of an invention as a promise that the patent must fulfill as of its filing date. The standard essentially demands that inventors delay their patent application until they have developed the invention sufficiently to soundly predict its

---

[1] As set forth in our Application for Leave to File a Non-Disputing Party Submission, the *amicus curiae* is a group of law professors who teach and research patent law and international intellectual property law who are concerned with the efficient and effective function of the global innovation economy. Further details are supplied in the Application.

[2] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the General Agreement on Tariffs and Trade. Signed at Marrakesh on April 24, 1994.

[3] North American Free Trade Agreement, effective January 1, 1994.

[4] *See, e.g.*, World Intellectual Property Organization (WIPO) "The practical requirements of industrial applicability/ utility requirements under national and regional laws," http://www.wipo.int/export/sites/www/scp/en/meetings/ session_5/pdf/scp5_inf.pdf, see also WIPO standing committee on the law of patents, "'Industrial applicability' and 'utility' requirements: commonalities and differences." http://www.wipo.int/edocs/mdocs/scp/en/scp_9/scp_9_5.pdf

efficacy as a marketable product. This is much later than the global norm, requires far more evidence than the global norm.

Since the parties and other *amici* address NAFTA Chapter 11 arguments as well as the evolution and application the industrial application requirement in Canada, *amici* here focus on two further insights. First, the promise utility doctrine, as practiced in Canada, is unique: it runs counter to the global trend and is not found in the contemporary patent law of major patent-granting jurisdictions. Thus, disclosures that are considered desirable and beneficial under international norms are used in Canada as a basis to invalidate a patent. Second, the doctrine's unusual nature is further highlighted by its inconsistency with the function and goals of the patent system. For reasons explained below, this result is particularly harsh for innovation in new drugs and treatments for disease.

We believe, therefore, that the promise utility doctrine contravenes NAFTA Article 1709, a point that ultimately supports Eli Lilly & Company's claim against the Government of Canada under NAFTA Chapter 11.

ARGUMENT

I. Canada's Promise Doctrine Departs Greatly from International Understanding of the Industrial Application Requirement

Canada cannot avoid its obligation under NAFTA Article 1709(1) to grant a patent to any invention "capable of industrial application" by simply adopting a singular interpretation of that requirement. NAFTA and other international patent agreements largely state their obligations broadly, leaving signatories latitude to establish and administer their patent laws. However, the discretion retained by signatories under these agreements does not render their obligations meaningless, lest the agreement itself also be rendered meaningless. Canada has departed so far from the international understanding of "industrial application" that it can no longer claim to be in agreement on this obligation with its partners in NAFTA or other international patent treaties.

Outside of Canada, the standard for industrial application or utility as interpreted and applied is liberal, focusing on concepts such as "plausibility" or "credibility." Stringent standards for utility, particularly accurate predictions and proof of a product's specific value in the marketplace, are definitely not the norm. The long-standing and clear trend outside Canada is

toward more liberal requirements, making Canada's recent increasing stringency a notable departure in the opposite direction. This trend is particularly notable among the top patent-granting countries, the "IP5,"[5] which are working towards increased harmonization of their substantive laws. We summarize below the major standards in Europe, Japan and the USA, as well as the United Kingdom.

A. Europe Applies a Liberal "Plausibility" Standard to Utility

In Europe, "utility," or industrial application,[6] is judged according to a liberal standard. Article 57 of the European Patent Convention ("EPC") states "[a]n invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture." Before the European Patent Office and the Board of Appeal of the European Patent Office, utility is not normally an issue for pharmaceutical inventions.

In the relatively less common cases where industrial application has been raised with respect to biotechnology, medical and pharmaceutical inventions, the Board of Appeal of the European Patent Office has applied the "plausibility test." Under this standard, the application as filed must provide a *prima facie plausible* technical teaching, and industrial applicability is denied only if there are "serious doubts substantiated by verifiable facts."[7]

In adopting this liberal plausibility standard for industrial applicability for bio-pharmaceuticals, the Board of Appeal recognized and was motivated by the economic and practical realities that govern pharmaceutical innovation. As the Board observed in case T 0609/02 "AP-1 complex/SALK INSTITUTE" 2004:[8]

> It is a well-known fact that proving the suitability of a given compound as an active ingredient in a pharmaceutical composition might require years

[5] The top 5 jurisdictions for patent filings are China, the USA, Japan, the Republic of Korea, and the Europe Patent Office. World Intellectual Property Organization, World Intellectual Property Indicators-2015 Edition. http://www.wipo.int/export/sites/www/ipstats/en/wipi/2015/pdf/wipi_2015_patents.pdf

[6] Article 52 of the European Patent Convention sets forth "industrial" application as one of the requirements for patentability: "European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application."

[7] Decision of the Board of Appeal of the European Patent Office T 0018/09 (Neutrokine/Human Genome Sciences) 2009.

[8] Decision of the Board of Appeal of the European Patent Office T 0609/02 (AP-1 complex/SALK INSTITUTE) 2004.

> and very high developmental costs which will only be borne by the industry if it has some form of protective rights. Nonetheless, variously formulated claims to pharmaceutical products have been granted under the EPC, all through the years. The patent system takes account of the intrinsic difficulties for a compound to be officially certified as a drug by not requiring an absolute proof that the compound is approved as a drug before it may be claimed as such.

In fact, the evidence required "for a sufficient disclosure of a therapeutic application"[9] is much more early stage:

> it is not always necessary that results of applying the claimed composition in clinical trials, or at least to animals are reported. . . It is required that the patent provides some information in the form of, for example, experimental tests, to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se.

Such a sufficient disclosure is judged by whether data, such as in vitro data, reflects a therapeutic application to the skilled person.[10] T 0609/02 stands in part for the proposition that an in vitro effect may be sufficient to establish industrial applicability and could be supported by post-published evidence of efficacy. [11]

Another Board decision concerning a patent that disclosed the gene sequence for a new protein "neutrokine," T 18/09 "Neutrokine/Human Genome Sciences" 2009,[12] further illustrates Europe's liberal standards with respect to evidence of industrial applicability. In that case, the patent disclosed the gene sequence for neutrokine and predicted its properties based on a computer analysis and alignment to known compounds. The opposition alleged that "no therapeutic and/or diagnostic use for neutrokine-α was disclosed" because the patent included no

[9] *Id*. at point 9.

[10] *Id.*

[11] *Id.* However, in that case, the party failed to present its in vitro evidence at the time of the application, and in fact there was "***no evidence*** at all of its potential effectiveness." *Id.* at point 10 (emphasis added). The appellant's later filed evidence thus "could not justify the recognition of sufficiency of disclosure." *Id.*

[12] Decision of the Board of Appeal of the European Patent Office T 18/09 (Neutrokine/Human Genome Sciences) 2009.

evidence of demonstrated properties or the production of antibodies.[13] The Board disagreed, finding that "the '*immediate concrete benefit*' is manifest" to the person of ordinary skill based on the disclosure of the protein sequence and analysis.[14]

The Board also declined to hold the patent application's broad promises of utility against the patentee. The specification included "a wide range of activities and conditions for which neutrokine-α could be useful."[15] In the first instance, the broad statements of industrial applicability were plausible and supported by post-published evidence that neutrokine behaved in a way consistent with the predictions of the patent.[16] Just as important, the Board was apparently sanguine about the potential over-breadth of this list, having confidence that it should not be understood as a false promise because "a skilled person would distinguish the positive technical information . . . from other allegedly contradictory and broad statements found in the patent-in-suit . . . ." [17] As the Board observed:

> the skilled person regards the long listing of possible actions of Neutrokine-α and of medical conditions in which it might take part as the enumeration or generalisation of the properties of the members of the TNF ligand superfamily. This is seen as the frame in which the newly found molecule has to be placed as one could *prima facie* have a reasonable expectation that most of them could in fact be present. [18]

The Board further noted that listing a large range of possible uses was a common and accepted practice in patent drafting.[19]

As these cases illustrate, Canada's jurisprudence on industrial applicability diverges greatly from the standards used before the EPO. In Europe, industrial applicability is a matter of plausibility, specifically a *prima facie* plausible technical teaching. That *prima facie* case can be based on relatively early stage evidence, such as, in the cases above, experimental tests, evidence

[13] *Id*. at page 19.

[14] *Id*. at point 22, emphasis added.

[15] *Id*. at point 26.

[16] *Id*. at point 24.

[17] *Id*. at point 26.

[18] *Id*.

[19] *Id*. at point 27.

of in vitro effect, or computer analysis, provided that the person of ordinary skill can understand the concrete benefit. Moreover, early, broad promises of utility are not held against the patentee so long as a plausible case was made. And, if a plausible case is made, post application evidence may bolster it.

B. The United Kingdom Has Followed Europe's Lead With Respect to Industrial Applicability

The United Kingdom (UK) once imposed a utility standard that was more stringent than major economies, but was still far more liberal than Canada's promise doctrine. Unlike Canada, the UK has recognized that its approach to industrial applicability was out of step with its international obligations and the realities of research and commercialization of biopharmaceutical innovation. Persuaded by the Board's decision concerning Neutrokine in case T 18/09, the UK embraced Europe's more liberal standard.

Initially, a lower court invalidated the patent that the UK had granted on Neutrokine-α because it found that the evidence of industrial applicability was insufficient.[20] The court criticized the patent application as "confusingly long, diffuse, and widely expressed,"[21] said that it "contains extravagant and sometimes contradictory claims,"[22] and observed that the "functions" of Neutrokine-α "were, at best, a matter of expectation and then at far too high a level of generality to constitute a sound or concrete basis for anything except a research project."[23]

The UK Supreme Court reversed, motivated in part by ensuring that the UK's understanding of industrial applicability was consistent with the standard applied under the European Patent Convention and with other jurisdictions. The decision cited heavily to the reasoning of T 18/09 and adopted the plausibility standard elucidated by the European Board of Appeal.[24] The Court recognized that this standard instituted a different "principle about the

[20] *Human Genome Sciences Inc. v Eli Lilly and Company* [2008] EWHC 1903 (Pat), [2008] RPC 29.

[21] *Human Genome Sciences Inc.* (Appellant) *v Eli Lilly and Company* (Respondent) Michaelmas Term [2011] UKSC 51, at point 6, citing to [2008] RPC 29, paras 100-133.

[22] [2008] RPC 29, para 134.

[23] [2008] RPC 29, para 234.

[24] *Human Genome Sciences Inc. v Eli Lilly and Company* [2011] UKSC 51.

amount of information that was needed to show that the invention was susceptible of industrial application." [25] The Court also rejected the lower court's criticism of the practice of wide assertions of utility.

The UK Supreme Court was also motivated by the realities of biopharmaceutical research and made extensive note that overly high standards for utility and disclosure stifled innovation. This impact fell particularly hard on medical and biotechnology inventions because inventors in those areas needed patent protection to justify further investment in research.[26] If a large amount of research were required to demonstrate utility, not only would it undermine research but place inventors in a quandary as to the timing of filing an application:

> If the application is filed early, … [t]he company will be left with no patent protection, but would have disclosed its invention in the published patent application to competitors. If the application is filed late, there is a risk in such a competitive environment where several companies may be working on the same type of research projects, that a third party will already have filed a patent application covering the same or a similar invention, in which case the company may not be able to gain any patent protection for its work and by continuing their programme they may risk infringing that third party's patents.[27]

C. Japan Also Applies a Liberal Standard for Industrial Applicability

Japan applies a standard similar to Europe and the USA, with a focus on removing from consideration implausible or impossible claimed inventions. The Japanese approach to the relationship between the disclosure and utility is also similar to European practice, rejecting inventions that are not plausibly supported by the disclosure (i.e., that are impossible or at least implausible).[28] Japanese patent law thus reaches results similar to Europe and the USA. It does so by different means, however, as the law requires industrial applicability but does not provide a

[25] *Id* at point 165.

[26] *Id.* at points 98, 143.

[27] *Id.* at point 97.

[28] *See, e.g.,* World Intellectual Property Organization (WIPO) "The practical requirements of industrial applicability/utility requirements under national and regional laws," http://www.wipo.int/export/sites/www/scp/en/meetings/session_5/pdf/scp5_inf.pdf

statutory definition. Instead, the Examination Guidelines[29] issued by the Japan Patent Office (JPO) provide a list of excluded inventions.

D. The USA's "Specific, Substantial and Credible" Requirement Is a Further Example of the Global Norm of Liberal Utility Standards

For almost 200 years, US patent law has not required anything more than a showing of some use of an invention in order for it to meet the utility requirement. As Supreme Court Justice Joseph Story explained in 1817, the law "does not look to the degree of utility; it simply requires, that it shall be capable of use."[30] Since the mid-twentieth century decision in *Brenner v. Manson*,[31] US courts "have required a claimed invention to have a *specific* and *substantial* utility" in order for a patent to satisfy the utility requirement that is now codified in § 101 of the 1952 Patent Act.[32] In response to hundreds of patent applications claiming isolated DNA fragments in the 1990s, the US Patent Office ultimately required in 2001 that patentees could not rely on generalized and vague utility claims about the role of DNA as such in disease identification and treatment: patentees must identify just one real-word use (substantial utility) that is specific to the claimed subject matter (specific utility) that is understandable to a person skilled in the art(credible).[33]

In affirming the validity of the USPTO's 2001 Utility Guidelines, the US Court of Appeals for the Federal Circuit stated in 2005 in *In re Fisher* that "a patent applicant need disclose only a single specific and substantial utility pursuant to *Brenner*" in order to be issued a valid patent under the utility requirement.[34] Although some have argued that this is an allegedly heightened utility requirement, the *Fisher* court agreed with the US government's argument in the case "that the utility threshold is not high,"[35] explaining further that a patent must specify

---

[29] http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/files_guidelines_e/03_0100_e.pdf

[30] *Bedford v. Hunt*, 3 F. Cas. 37, 37 (C.C.D. Mass. 1817). See also *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (Story, Circuit Justice) (explaining that "whether [the invention] be more or less useful is a circumstance very material to the interests of the patentee, but of no importance to the public").

[31] *Brenner v. Manson*, 383 U.S. 519 (1966).

[32] *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (citing *Brenner*, 383 U.S. at 534-35) (emphases added).

[33] *See Utility Examination Guidelines*, 66 Fed. Reg. 1092 (Jan. 5, 2001).

[34] *Fisher*, 421 F.3d at 1370.

[35] *Id.* The US government supported the USPTO's 2001 Utility Guidelines, and it opposed Fisher's patent application as failing the utility requirement in this case. *Id.* at 1370-71. Thus, this admission by the US government

only a "'real-world' value to the claimed subject matter" and that it only "must disclose a use which is not so vague as to be meaningless."[36] US patent applications need not disclose every possible use nor therapeutic effectiveness under healthcare regulatory standards, but merely *a use* in order to be valid under the US utility requirement in patent law. The US thus applies a standard that echoes the plausibility standard under European law – meaningful, useful in some way as of the time disclosed, and believable.[37]

In the realm of therapeutic and pharmaceutical inventions, US courts have recognized the realities of biopharmaceutical research with respect to determining sufficient evidence of utility. Thus, the Court of Customs and Patent Appeals ruled that an applicant for a patent on a drug need only show a "sufficient probability of safety in human therapy"—which need not necessarily involve clinical evidence,[38] and that a drug may be "useful" even though it has not been shown to be safe for use under Food and Drug Administration standards.[39] The evidentiary standard was whether persons skilled in the art would correlate the observable results in a model system to probable results in human therapy.[40]

Importantly, US courts have steadfastly maintained that the patent office plays a distinctly different role from health and safety regulators, warning that the USPTO should not confuse "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption."[41] In a key 1995 case, *In re Brana*,[42] the patent application had disclosed compounds and demonstrated their

---

that "the utility threshold is not high" and the *Fisher* court's agreement with the US government's arguments in this case are important. *Id*.

[36] *Id.* at 1371.

[37] In the US, credibility is an evidentiary matter. See US Patent Office's Manual of Patent Examining Procedure (http://www.uspto.gov/web/offices/pac/mpep/s2107.html, accessed February 12, 2016) (stating that "Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.").

[38] *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962).

[39] *In re Anthony*, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969).

[40] *Hartop* 311 F.2d at 257.

[41] *In re Brana*, 51 F.3d at 1567.

[42] *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995).

effectiveness in mouse models of cancer. The USPTO had rejected the claims because "the specification failed to describe any specific disease against which the claimed compounds were active" and "the tests disclosed in the specification were not sufficient to establish a reasonable expectation that the claimed compounds had a practical utility (i.e. antitumor activity in humans)."[43] The Federal Circuit Court of Appeals reversed, finding that the favorable comparison with other specific anti-leukemia compounds was an implicit assertion of utility, and that the asserted utility was supported. The *Brana* court held that the PTO's requirement for *demonstrated* utility was incompatible with its function of determining patentability, as opposed to the US Food and Drug Administration's (FDA) function of determining safety and efficacy.[44] In the terms of *Brenner* and *Fisher*, the applicant had identified a "real-world use" of the "claimed invention" sufficient to meet the utility requirement in US patent law,[45] despite the fact that the claimed invention ultimately may be deemed insufficient for FDA regulatory approval as a therapeutic treatment in the healthcare market.

In sum, US law also further reflects and contributes to the global norm of permissible standards for utility or industrial applicability.

E. Canada's Utility Doctrine Departs Drastically from the Global Trend Toward Increasing Harmonization of Utility Standards in a Liberal Direction

Canada's departure from global norms with respect to patent utility runs counter to the long historical trend toward increasing harmonization of industrial application/utility standards in a liberal direction. While very recent history has seen harmonization slow in multi-lateral bodies such as the World Intellectual Property Organization, and the exact wording of statutory provisions likely will never be identical,[46] the drive toward harmonization remains unabated. For

[43] *Id.* at 1563-34.

[44] *Id*. at 1567.

[45] *Fisher*, 421 F.3d at 1371.

[46] Even in the absence of a single, substantive standard, international agreements to industrial application/utility standards are not meaningless. The latitude to administer such standards does not allow a party to avoid an obligation by adopting an interpretation that dramatically departs from how the other parties understand and administer the same standard.

example, in the 2004 free trade agreement between the USA and Australia,[47] Article 17.9(13) states "Each Party shall provide that a claimed invention is useful if it has a specific, substantial, and credible utility." The "specific, substantial, and credible utility" standard is also found in Article 18.8(10) of the Korea-US trade deal.[48]

Importantly, the world's major patent granting jurisdictions have converged on a relatively liberal standard for utility/industrial applicability. Since at least 2001, a "trilateral project" between the European, Japanese and US patent offices has focused on harmonization of utility/industrial applicability standards.[49] Although the terms used may differ, a 2008 study of utility standards found that "all three Patent Offices agree as to the standard of utility/industrial applicability."[50] A central goal of harmonization was to "ensure delivery of more efficient services to users and promote the benefits of the patent system."[51]

The major jurisdictions for innovation and patent law thus now have a very low threshold for "utility" or "industrial applicability," excluding only highly generalized and abstract, incredible or implausible industrial applications. The amount of information to demonstrate utility, such as the "specific, substantial and credible" standard in the USA, and the "plausible" standard in Europe, requires only a credible basis to support a claimed utility, and does not punish patent applicants for broader assertions of possible industrial applications. The clear trend outside Canada is to converge toward liberal standards of utility.[52]

---

[47] Australia – United States Free Trade Agreement, signed May 18, 2004; effective January 1, 2005.

[48] Free trade agreement between the United States of America and the Republic of Korea (KORUS-FTA), signed June 30, 2007, effective March 2012.

[49] Trilateral Project B3b, 'Report on Comparative Study on Biotechnology Patent Practices' (2001) http://www.trilateral.net/projects/biotechnology/B3b.pdf. The report examines a series of hypothetical claims and shows unanimity with respect to how all three offices would address the issue of utility/industrial applicability in each instance.

[50] S. Thambisetty, "Legal Transplants in Patent Law: Why Utility is the New Industrial Applicability" LSE Law, Society and Economy Working Papers 6/2008 London School of Economics and Political Science Law Department.

[51] 2003 WIPO press release: "WIPO and Trilateral Offices agree to Reinforce Ties" (2003) PR/2003/361. http://www.wipo.int/pressroom/en/prdocs/2003/wipo_pr_2003_361.html

[52] To the extent that other jurisdictions ever required high standards of demonstrated utility, they have moved away from them, with some explicitly recognizing that stringent standards for demonstrating utility are particularly inappropriate for biotechnology, pharmaceuticals and medical treatment patents. *See, e.g., Human Genome Sciences Inc.* (Appellant) *v Eli Lilly and Company* (Respondent) Michaelmas Term [2011] UKSC 51, at point 97 (discussed in detail *supra*).

Canada's "promise utility doctrine" is thus an extreme outlier that is not found in the contemporary patent law of any of Canada's major trading partners or other significant patent-granting jurisdictions. Where other nations are neutral, or even reward applicants for disclosing possible utility, recent Canadian decisions under the doctrine construe such disclosures as a promise that must be fulfilled. Where other nations expect the patent application to disclose a "credible" or "plausible" utility, and may use post filing evidence to support the disclosure, the Canadian courts require that applicants be able to demonstrate or accurately predict a very high degree of utility at the time of filing. While the UK has adopted the European plausibility standard, and dropped its own standards, which it found were discriminatory against biotechnology and other medical technologies and out of step with European practice,[53] the promise doctrine of Canada has created a standard far more demanding than that previously applied in the UK in the modern era.

The unusual nature of Canada's doctrine is illustrated by the "switch" in disclosure that the promise doctrine forces on a patent applicant. In the USA and Europe, a failure to disclose any industrial application may lead to invalidation, but stating an unproven utility is not a basis for invalidation. The clear incentives are for disclosing any "plausible" (EPO) or "credible" (USA) industrial application. The incentives are reversed under Canada's promise doctrine: the lowest utility standards are applied only where no utility is disclosed, while the disclosure of any plausible utility triggers the promise doctrine and leads to invalidation if the promised utility is not demonstrated or soundly predicted at the time of filing. A patent applicant wishing to file in Canada would have to prepare a patent application completely different from that normally prepared for the rest of the world.

Such a greatly divergent standard in a major global economy not only upends harmonization, but is so great that we cannot see how Canada's "promise doctrine" complies with any reasonable understanding of "capable of industrial application" set forth in NAFTA Article 1709(1). The Canadian doctrine also has a specific effect on trade in the NAFTA region, as it is particularly detrimental to brand-name pharmaceuticals (which are mostly US based, like Eli Lilly & Co) and favorable to their generic competitors (which have a strong presence in

[53] *Id.*

Canada, such as Novopharm, which challenged Eli Lilly's patents and was founded in Canada in 1965; and Apotex, founded in Canada in 1974).

Our concerns are shared by *amici*, and by the US government (a party to NAFTA), which appears to regard the promise doctrine as inconsistent with treaty obligations, and particularly targeting US companies.[54]

II. Canada's Promise Utility Doctrine Is Incompatible with the Functions and Institutions of the Patent System

The path from the lab to the marketplace is often long and challenging. The patent system should occupy an early place on that path, securing property rights in deserving inventions. Those property rights then secure the investments necessary to develop an invention into a product and commercialize it. If the product must be regulated, as in the case of pharmaceuticals, such oversight happens at a later stage. The promise doctrine in Canada confuses the property-granting function of a patent office with the oversight function of a regulatory agency. In doing so, it also undermines the opportunity to secure financing for product development and disrupts the appropriate flow of information about the innovation.

A. Excessively Stringent Utility Requirements Place Inventors in a Catch-22 Where They Cannot Secure the Investment Needed to Satisfy the Standard

The utility requirement is typically calibrated to ensure that an invention is advanced sufficiently to begin commercial development. With a credible or plausible utility, an inventor can secure a property right. That property right helps secure further funding on the path from lab to market. An overly strict utility standard, such as found in Canada's promise doctrine, requires extensive further research and potentially even clinical trials to show that the new product does what it claims before a patent may be obtained. This demand impractically pushes the time of patenting further down the path of commercialization—the very path that a patent is supposed to open. The delay in getting a property right makes it less likely an inventor can secure the necessary funding to satisfy the more stringent standard.

[54] US Trade Representative, 2014 Special 301 Report to Congress, available at https://ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf.

The burden of the promise doctrine falls particularly heavy on individual inventors, small companies, and universities. Under the current international model of pharmaceutical drug development, universities and small companies typically perform the early stage identification of a class of molecules and specific lead compound. The difficulty is the next step—the one the promise doctrine seems to ask inventors to make before seeking a patent. Further testing is vastly expensive. It takes an estimated $US 1.4 billion in out of pocket costs to develop a new drug that obtains marketing approval, a process that typically takes several years and includes the conduct of pre-clinical testing and then three phases of clinical trials on human volunteers.[55] To take that next step, a patent right is absolutely necessary for small companies and universities to secure funding for ongoing research costs and/or to negotiate a sale or license of the patent to a large pharmaceutical company that has the resources and institutional expertise to bring a drug to market.

Under the promise doctrine, extensive and expensive late-stage research may often be required to obtain the data necessary for complying with the doctrine's heightened utility requirements. The only entities with access to large sources of funding without a patent, and able to able to keep the research secret for many years prior to even filing for a patent, are large vertically integrated corporations. Even these companies will find drug development much riskier and more expensive (and thus, less attractive and less likely to be undertaken) if they must spend more money prior to gaining the security of a patent.

B. The Promise Doctrine Is Incompatible with the Patent System's Incentives Toward Early Disclosure of Inventions

The promise doctrine contradicts the patent system's incentives to disclose an invention promptly. An inventor trying to satisfy the standard safely will likely be compelled to do much more than early-stage research. Particularly in the case of pharmaceuticals an inventor must do significant further research or even clinical trials to show that the new products do what the patent may be understood to claim. Such research is not only expensive, but it moves the moment of patentability to just prior to commercial launch. During almost all of this time the invention would have to remain secret, as pre-patenting public disclosure would be grounds for

[55] Tufts Center for the Study of Drug Development, Cost Study (2014) http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study.

denial of the patent.

Such delayed disclosure cuts against the patent system's many direct incentives for early disclosure. The first to file a patent application to an invention is presumed by law to have been the first inventor, while disclosure, public use, or commercialization of the invention before filing may be grounds to invalidate a patent. These provisions send a clear message to the inventor: "Disclose soon or risk losing your chance for a patent." Utility requirements that follow the global norm add a small caveat to this message: "In your rush to disclose, don't waste the time of the patent office or impede the work of others attempting to determine a use for an undeveloped discovery." By contrast, the promise doctrine counsels significant delay, which is grossly misaligned with the rest of the patent system.

This misalignment becomes even clearer when one considers the patent system's most fundamental requirements for patentability – novelty and inventive step. These requirements represent significant challenges for any patentee and are typically more stringent than utility. To the extent an inventor and his potential investors and business partners value patents – and they typically do – they will want to dispose of the uncertainty surrounding these major issues by promptly filing for and obtaining a patent. Ironically, the promise doctrine urges them to wait while they first develop more evidence regarding the usefulness of the product – the one issue that inventors, businesses, doctors, patients, and the consuming public are all better positioned to determine for themselves.

The patent system's incentives toward early disclosure are neither incidental nor unimportant. Early public disclosure and patenting identify what areas of research have been "claimed," thus preventing the social cost of wasted duplicative efforts.[56] Moreover, the earlier a patent is available, the sooner this property right can serve as the basis for commercial collaboration and investment, which are cornerstones of the innovation economy, and increasingly lauded and recognized as beneficial forms of "open innovation."

The problems created by the promise doctrine's incentives toward delayed disclosure are

---

[56] Edmund W. Kitch, *The Nature and Function of the Patent System,* 20 J.L. & ECON. 265 (1977); Yoram Barzel, *Optimal Timing of Innovations,* 50 REV. ECON. & STAT. 348 (1968).

further compounded by its uniqueness to Canadian patent law. In the rest of the world, applications are filed as soon as there is sufficient data for a "plausible" or "credible" utility, because of all the strong incentives described above. Under international treaties, patent applications are published 18 months after filing and thus would be prior art to any later filed application. Yet, in Canada, compliance with the promise doctrine's heightened utility requirements may require a long period of secrecy and extensive research and development before a patent application can even be *filed*. By the time the patent is ready for filing in Canada under its stringent promise doctrine, the Canadian patent application would already be anticipated and obvious in view of the earlier international patent application to the same invention. The net effect is a significant barrier to patent protection for pharmaceuticals in Canada.

C. The Promise Doctrine is Incompatible with the Institutional Role and Competencies of the Patent System

The promise doctrine conflates two distinct, very different roles of government agencies. Patent offices determine whether an inventor qualifies for a property right. Regulators regulate the use and enjoyment of such property rights, among many other things.[57] By calling on the patent system to do a searching examination of the efficacy of a claimed invention, the promise doctrine asks it to do something it is neither competent nor well-positioned to do.

The liberal standard of industrial applicability applied by patent offices outside of Canada is one that courts and patent offices are suited to address. A patent examiner within a particular subject area should be able to understand the technology behind an application to judge if it has credible utility; if it is new or a trivial embellishment of an existing product; and if it defies the laws of physics or chemistry. Patent offices are set up to undertake this analysis.

For regulating the public sale and use of drugs, a higher standard and a very different review process applies. Regulatory authorities such as Canada's Health Canada or the USA's Food and Drug Administration have both the mandate and skills to determine if medicines are safe and effective. Pharmaceutical companies must provide regulators with a host of

[57] A distinction made by courts in the USA (*e.g., Brana*, 51 F.3d 1560, *id.*) and Europe (*e.g.,* T 609/02, T 18/09, *id.*).

documentation including trial protocols and amendments, clinical study reports, certificates of analysis, case report forms, and electronic datasets of individual clinical trial participant data. The regulatory agency has sufficient resources and trained staff to review and understand this documentation. Regulators can demand further studies to prove a point of efficacy, or mitigate a risk that was not apparent until later in development. They can limit approval to only specific indications or formulations, or require that the drug be labeled with various warnings. Agencies can impose sanctions on companies that fabricate data or otherwise mislead.

The mandatory and iterative process of regulatory review for drug approval is extremely different from that applied to patents. Patent examiners conduct a limited review driven by a single filing date, with limitations on what amendments and further data can be added. Patent offices have a much more limited authority, expertise, and capacity to review data. Reflecting this role, most countries have a single patent office devoted to all technologies. By contrast, the complexity of regulatory review requires most governments to have separate agencies and regulatory schemes addressing human drugs, animal drugs, vaccines, biological products, food, agricultural chemicals, industrial chemicals, and more.

The promise doctrine conflates the role of the patent office with that of the regulator, because it would require a patent office and a patent examiner to address issues such as specific efficacy and to review extensive, complex evidence, such as clinical trials. An examiner would need access to and fully understand the reams of clinical trials data generated during the process of drug development, to understand if the drug is effective and fulfills the "promise" made in the application stage.[58] As US Courts once had to remind the US Patent and Trademark Office, the patent system should not "confuse[] the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption."[59]

[58] We must resort to hypothetical descriptions here because, after years of court decisions, Canada has yet to undertake the extensive reform of its patent office and procedures that the promise doctrine would seem to demand. Rather, it is content to let the Canadian Intellectual Property Office continue to operate a process that its courts say results in invalid patents. This failure is telling—the promise doctrine places impracticable demands on the patent system.

[59] *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995).

CONCLUSION

All evidence suggests that the international standards for utility or industrial application were broadly similar when NAFTA was concluded in 1994, and have since continued towards increased harmonization such that the major economies and centers for innovation now follow essentially and substantively the same standard. This standard plays an important role in the patent system, ensuring that useful inventions are disclosed early and receive prompt consideration for their novelty and obviousness by a patent office. By allowing early stage inventions to receive a patent, inventors can use the property right to secure investment in further development and commercialization. This security is essential for pharmaceutical research and development, which is risky and costly.

In the last decade, Canada's courts have asserted a theory of utility, the "promise doctrine," that is not just different from international practice, but completely contrary to it. The doctrine is especially harsh on innovator pharmaceutical patents, leading to invalidation of previously granted patents that have been upheld in other jurisdictions. The recent divergence in utility standards is so great that we cannot see how the promise doctrine complies with Canada's obligations under NAFTA Art. 17, thus ultimately supporting Lilly's case against the Government of Canada pursuant to NAFTA Chapter 11.

Respectfully submitted,

/Simon Elliott/

Simon J. Elliott, Ph.D. J.D
Foley & Lardner LLP
3000 K Street, N.W., Suite 600
Washington, DC 20007-5109
Phone: +1 202.295.4726
Email: SJElliott@foley.com

Counsel for Non-Disputing Party Amicus Curiae
Intellectual Property Law Professors