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ELI LILLY AND COMPANY

Disputing Investor,

-and-

THE GOVERNMENT OF CANADA

Disputing Party

NOTICE OF INTENT TO SUBMIT A CLAIM TO ARBITRATION UNDER NAFTA
CHAPTER ELEVEN

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Pursuant to Articles 1116, 1117 and 1119 of the *North American Free Trade Agreement*¹ and with a view to resolving this dispute amicably through the consultations and negotiations contemplated by *NAFTA* Article 1118, the disputing investor Eli Lilly and Company respectfully serves the Government of Canada with this Notice of Intent to Submit a Claim to Arbitration under Chapter Eleven of the *NAFTA*.

I. NAMES AND ADDRESS OF DISPUTING INVESTOR AND ITS ENTERPRISE

1. Eli Lilly and Company is a corporation organized under the laws of the State of Indiana, United States of America, and thus is an enterprise of a Party (the United States) pursuant to *NAFTA* Article 1139. The registered address for Eli Lilly and Company is:

Lilly Corporate Center
Indianapolis, Indiana 46285 USA

2. Eli Lilly and Company submits this Notice of Intent to Submit a Claim to Arbitration both under *NAFTA* Article 1116 as an investor on its own behalf, and under *NAFTA* Article 1117 on behalf of an enterprise that it owns or controls directly or indirectly: Eli Lilly Canada Inc.
3. Eli Lilly Canada Inc., a corporation organized under the laws of Canada (the *Business Corporations Act*) is a wholly owned subsidiary of Eli Lilly and Company. The principal place of business for Eli Lilly Canada Inc. is:

Eli Lilly Canada Inc.
3650 Danforth Avenue
Toronto, Ontario, Canada
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4. The primary legal counsel for Eli Lilly and Company are Richard G. Dearden and Wendy J. Wagner of Gowling Lafleur Henderson LLP, 160 Elgin Street, Suite 2600, Ottawa. Correspondence should be directed to the attention of:

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¹ *North American Free Trade Agreement*, 32 I.L.M. 289 and 605 (1993) [*NAFTA*].

II. FACTUAL BACKGROUND

(a) Canada Is Obligated To Grant Patents For Inventions That Are New, Non-obvious and Useful

5. Developed systems of patent law grant patents for inventions that are: (1) new, (2) involve an inventive step (non-obvious), and (3) are capable of industrial application (useful). These conditions precedent to patentability are embodied in international agreements that Canada has signed and ratified.
6. Pursuant to Article 27 of the *Agreement On Trade-Related Aspects of Intellectual Property*², Canada is obligated to grant a patent if the following conditions are met:

“...patents **shall be available** for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are **capable of industrial application**. (5) (emphasis added)

[Fn (5)]. For the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “**useful**” respectively.”
7. Likewise, Article 1709(1) of the *NAFTA* obligates Canada to grant a patent for inventions that are new, non-obvious and useful:

“...each Party **shall make patents available** for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are **capable of industrial application**. For purposes of this Article, a Party may deem the terms “inventive step” and “capable of industrial application” to be synonymous with the terms “non-obvious” and “**useful**”, respectively.”
8. The mandatory obligation to make a patent available for an invention that meets the conditions precedent to patentability confers the exclusive right on the patent holder to make, use or sell the patented product or process. The Agreements obligate Canada to

² *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994, 1869 UNTS 299; 33 ILM 1197 (1994) [*TRIPS Agreement*].

enforce these rights during the lifetime of the patent, such that Canada must protect the patent rights associated with patents that meet the conditions precedent to patentability.

9. The *TRIPS Agreement* and *NAFTA* do not define the terms “capable of industrial application” or “useful”. The *Concise Oxford English Dictionary* broadly defines “useful” as “able to be used for a practical purpose or in several ways”.
10. Any ambiguity in the meaning of the terms “capable of industrial application” or “useful” is properly resolved by reference to their use as terms of art in the patent law of the United States and Europe, which formed the basis for the language used in *TRIPS* Article 27(1) and *NAFTA* Article 1709(1).³
11. The terms “capable of industrial application” and “useful” appeared in the first drafts of the *TRIPS Agreement* submitted nearly simultaneously by the European Communities and the United States of America. All subsequent composite drafts retained the terms and used wording that is virtually identical to the present text. The general concepts of “capable of industrial application” and “useful” were not the subject of debate during the negotiation of the *TRIPS Agreement*.
12. Patent statutes in Canada, the United States and Europe incorporate the condition precedent of “capable of industrial application or “useful” in a similar manner. Canada’s *Patent Act* defines an “invention” as “any new and **useful** art, process, mechanism, manufacture or composition of matter” or improvement thereof⁴. In the United States, §101 of the *Patent Act* defines what is patentable in similar terms: “Whoever invents or discovers any new and **useful** process, machine, or composition of matter, or any new and **useful** improvement therefore.”
13. The *European Patent Convention* establishes that inventions which are new, involve an inventive step, and are **susceptible of industrial application** are patentable. A broad

³ *NAFTA* Chapter 17, including Article 1709(1), was based on the Dunkel Draft of the *TRIPS Agreement* - see *Canada-Patent Protection of Pharmaceutical Products – Complaint by the European Communities and their Member States – Report of the Panel*, March 17, 2000, WT/DS114/R.

⁴ Section 2 *Patent Act*.

definition is given to “industry” – an invention is “susceptible of industrial application “if it can be made or used in any kind of industry, including agriculture”.

14. As a term of art, in the United States, a “useful” invention is one that has “specific and substantial” utility. Specific utility requires that there be a defined use for the subject matter of the claimed invention. Substantial utility requires the invention to have a practical or “real world” application. The law presumes that if there is an asserted utility that is “credible”, rejection for want of utility is inappropriate.
15. Under U.S. law, for therapeutic and pharmacologic utilities, the credibility of the disclosed use, if questioned as being incredible, may be established by a reasonable correlation between the activity of the compound and the asserted use. The asserted utility need not be supported by data and the mere initiation of clinical trials would fulfill the requirement of utility. The United States Federal Court of Appeals for the Federal Circuit in *Re Brana* explained:

“Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. **The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.**”⁵

Questioning the credibility of an asserted use, however, is rare. More typically, the condition precedent of an invention having utility is met by the assertion of a specific and substantial use, and to deny a patent on an invention requires proof of inoperability or inutility.

16. In Europe, the threshold to meet the requirement of “susceptible of industrial application” is similarly very low. If the utility of the invention is not self-evident, a proposed use can be indicated in general terms. There is a minimal requirement that a use be specified and

⁵ *In re Brana*, 51 F.3D 1560 (Fed Cir. 1995) at 1568 (emphasis added).

“plausible”, a standard that is met unless the proposed use is “merely speculation” and therefore implausible. As in the United States of America, the standard when applied to therapeutic and pharmacologic utilities acknowledges that requiring actual evidence of therapeutic utility would unduly impede research and development:

If that were so, it is suggested that this “would cause UK bioscience companies great difficulty in attracting investment at an early stage in the research and development process”.

This consequence is said to arise from the reasoning of the Court of Appeal (and hence of Kitchin J), on the basis that there will normally be a need to conduct tests to provide experimental data to establish to the standard they require that a protein (or its antagonists) have therapeutic use. This in turn is said to lead to two problems. **First, such tests will or may involve clinical work, which as I understand it, would be hard to keep confidential, especially in the age of the internet. Secondly, such tests would often be expensive to run, and, as already mentioned, funding would be hard to obtain for a project of this sort which had no protection in the form of a patent application.**⁶

17. Both the *TRIPS Agreement* and *NAFTA* specifically require signatories to make patent rights available “without discrimination as to field of technology,” with the effect that a more burdensome utility requirement cannot be imposed on inventions having therapeutic or pharmacologic applications as compared to other types of inventions.

(b) Disclosure Obligations

18. A patent application must disclose the claimed invention in a manner that is sufficiently clear and complete for the invention to be put into practice. Sufficient disclosure is a separate requirement from the conditions precedent to patentability (eg. “useful”). Disclosure is a precondition to obtaining a patent, and insufficient disclosure can be a ground to invalidate a patent.
19. The *Patent Cooperation Treaty*⁷ harmonizes national requirements for disclosure in a patent application so that an applicant for a patent can prepare a single international patent application that can be filed in all Member countries. The *PCT* prohibits Member

⁶ *MGS v Eli Lilly*, [2011] UKSC 51, paras 100-101. (emphasis added)

⁷ The *Patent Cooperation Treaty*, signed June 19, 1970; entered into force Jan. 24, 1978, 8 UST 7645; TIAS 8733 1160 UNTS 231 [*PCT*].

countries from imposing more onerous disclosure obligations than those required by the *PCT*, as this would defeat the single application objective. Specifically, Article 27(1) of the *PCT* states:

“No national law shall require compliance with requirements relating to the form or contents of the international application **different from or additional** to those which are provided for in this Treaty and the Regulations.”

20. Article 27(4) of the *PCT* permits an applicant to insist before national courts of Member countries that the requirements provided for by the *PCT* and the Regulations be applied to the applicant’s international application.
21. Article 27(5) of the *PCT* accords to Member countries the freedom to prescribe substantive conditions of patentability, however, this freedom does not extend to “requirements as to the form and contents of applications”. The “substantive conditions of patentability” do not include disclosure requirements, which are a matter of form and content.
22. The *European Patent Convention*⁸ illustrates the distinction between “substantive conditions of patentability” and matters of form and content. Part II of the *European Patent Convention*, “Substantive Patent Law”, deals with the substantive conditions precedent of novelty, inventiveness and utility (“susceptible of industrial application”) and whether the subject matter of the invention is patentable. Patent disclosure requirements are not included under Part II of the *Convention* but rather are dealt with under Part III, “The European Patent Application”. Specifically, Article 83, “Disclosure of the Invention”, requires that: “The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.”
23. Article 5 of the *PCT* sets out an identical basic disclosure obligation to the *EPC*: “The description 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.”

⁸ Convention on the Grant of European Patents (European Patent Convention). 1973. 1065 U.N.T.S. 199, 5 October 1973, entry into force 7 October 1977. [hereinafter the *EPC*].

24. Rule 5 of the Regulations under the *PCT* sets out the formal requirements for the contents of an international patent application, including those relating to disclosure of utility/industrial applicability⁹. Rule 5.1(a)(iv) provides that the description shall:

“...indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry and the way in which it can be made and used, or, if it can only be used, the way in which it can be used...”.

25. The *PCT* form and content requirements relating to utility/industrial applicability do not require disclosure in the patent application of evidence or proof to support the asserted utility of the invention, though national authorities may require patentees to furnish this type of information separately from the patent application. *PCT* Article 27(2)(ii) states:

“The provisions of paragraph (1) do not preclude any national law from requiring, once the processing of the international application has started in the designated office, the furnishing: ... of documents **not part of the international application** but which constitute proof of allegations or statements made in that application...”.

26. The notes relating to Article 27(2)(ii) accompanying the text of the *PCT* in the Records of the Washington Conference, 1970, state: “Allegations or statements to be provided may relate...to the fact that the invention is usable or operational from certain purposes...The documents supporting such allegations may be affidavits...laboratory notes, etc.”.

27. The *TRIPS Agreement* imposes disclosure obligations consistent with the *PCT*; Article 29(1) states:

Members shall require that an applicant for a patent 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 or, where priority is claimed, at the priority date of the application.

⁹ The Guidelines for the Processing by International Searching and Preliminary Examining Authorities of International Applications Under the Patent Cooperation Treaty at Chapter 14§14.01 note that “industrially applicable” and “utility” may be deemed synonymous by patent offices.

28. Consistent with the *PCT* and *TRIPS Agreement*, in both the United States and Europe, the utility of the invention must be disclosed if it would not be apparent to a skilled person. However, evidence of utility need not be disclosed in the patent itself.
29. In the United States, there is a clear distinction between the condition precedent of utility in §101 of the *Patent Act* and the separate disclosure requirement (i.e., that the patented invention must be described and enabled by the specification). The enablement requirement in §112 does not require a patent applicant to provide evidence supporting utility in the patent specification. Evidence of utility need not be provided at all unless the patent examiners have reason to doubt the credibility of the asserted utility. In *Re Brana*, the Federal Circuit Court of Appeals stated that:

...the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.¹⁰

Clearly the "rebuttal evidence" need not be provided in the specification. Furthermore, a patent cannot be invalidated post-grant due to a lack of evidence of utility set out in the patent specification.

30. Under the *European Patent Convention*, the condition precedent of susceptible of industrial application in Article 52(1) likewise is distinct from the disclosure requirements in Article 83. Article 83 does not require proof of utility to be included in the patent specification. Evidence of utility is only required if the asserted use is inherently implausible. The patent applicant may then be required to submit evidence of utility beyond that set out in the specification.¹¹ Post grant, national courts have held that there is no requirement in the *EPC* that the specification must demonstrate by experiment that the invention will work or explain why it will work.¹²

¹⁰ *In Re Brana*, *supra* at 1566.

¹¹ T 0939/92 *Triazole/AgrEvo* 2.6.1.

¹² *Conor v. Angiotech*, [2008] UKHL 49, para. 19.

(c) International Framework for the Protection of Patents

31. Canada is a party to international treaties that require Member countries to offer a uniform level of substantive patent protection on a non-discriminatory basis.
32. The *TRIPS Agreement* and *NAFTA* Chapter 17 obligate the Parties to accord national treatment to holders of intellectual property rights. In addition, both Agreements establish minimum levels of protection for intellectual property rights, including patent protection.
33. The *Patent Cooperation Treaty*, created to provide patent applicants with a cost-effective and efficient system for the filing of international patent applications, harmonizes the requirements for international applications so that such applications will have the same effect as a national application in each member country in which protection is sought.¹³
34. The 1883 *Paris Convention for the Protection of Industry Property* administered by the World Intellectual Property Organization, to which Canada is a contracting party, obligates contracting parties to grant the same patent protection to nationals of other contracting states as it grants to its own nationals.¹⁴

(d) Canadian Legal Developments – Utility and Disclosure

35. Recent developments in Canadian jurisprudence have resulted in the invalidation of numerous pharmaceutical and biopharmaceutical patents on the ground of inutility. The invalidated patents relate to medicines that were approved as safe and effective by Health Canada and are in fact highly effective for the prevention and treatment of disease. In short, these inventions are undeniably useful in fact. As a result of this jurisprudence, Canada is contravening its international obligations to enforce patent rights and to make patent rights available without discrimination as to the field of technology.

¹³

¹⁴ *Paris Convention for the Protection of Industrial Property*, as last revised at Stockholm, (WIPO, as amended September 28, 1979), 21 UST 1583, 828 UNTS 305, Article 2.

36. Canadian patent law is codified within the federal *Patent Act*. The conditions precedent to patentability are set out in the definition of “invention” in section 2 of the *Patent Act*, which mirrors the relevant *TRIPS* and *NAFTA* provisions:

“invention” means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter;...”

1. The “Promise Doctrine”

37. In a series of decisions issued since 2005, the Federal Court of Canada and the Federal Court of Appeal have created a new judicial doctrine whereby utility is assessed not by reference to the requirement in the *Patent Act* that an invention be “useful”, but rather against the “promise” that the courts derive from the patent specification. This non-statutory “promise doctrine” is not applied in any other jurisdiction in the world.
38. If the Federal Courts do not construe a promise from the patent, the statutory requirement for utility that historically required only a “scintilla of utility” applies. However, if the Federal Courts derive a “promise” from the patent specification (for example, to treat a human disease with fewer side effects) then utility is measured against that promise, and the patentee is required to prove that it had demonstrated or soundly predicted the promised result as of the date the patent was filed.
39. The adoption of the “promise doctrine” by the Federal Courts marks a departure from the law established by the Supreme Court of Canada in *Apotex Inc. v. Wellcome Foundation Ltd.*¹⁵ In that case, the Supreme Court of Canada held that a patent cannot have been granted for “mere speculation,” rather, the inventor must be able to establish that the utility of the patent was demonstrated or based on a sound prediction at the date of filing of the patent application.
40. Importantly, the Supreme Court of Canada held that in the case of pharmaceutical patents, utility could be established on the basis of a sound prediction before the effectiveness of the medicine for the claimed use had been verified by tests. Based on this

¹⁵ [2002] 4 S.C.R. 153, 2002 SCC 77 [AZT].

principle, the Supreme Court of Canada held that a new use (treatment and prevention of the disease HIV) of an old compound (AZT) was soundly predicted, even though the compound had not yet been tested in animals or humans.

41. In the years since *AZT* was decided by the Supreme Court of Canada, the Federal Courts departed from the approach in *AZT* in two respects: (a) by measuring utility not against the invention as claimed, but as against the “promises of the patent” that the courts find are either explicitly stated or implied in the patent disclosure; and (b) elevating the quantum of data needed to demonstrate or soundly predict usefulness, to such a degree that even human clinical data in patients may not be adequate. Notably, the “promise doctrine” can lead to the absurd result of a clearly useful invention (approved as safe and effective by Health Canada) being held invalid for not being “useful”.
42. The “promise doctrine” contravenes *TRIPS* Article 27(1) and *NAFTA* Article 1709(1) by imposing onerous and additional utility requirements that have had the effect of denying patent rights for inventions which meet the conditions precedent to patentability. The application of the “promise doctrine” has resulted in the invalidation of numerous commercially successful patents, including Lilly’s patent for the drug Strattera which is the subject of this Notice.
43. The “promise doctrine” not only contravenes Canada’s treaty obligations, it is also discriminatory, arbitrary, unpredictable and remarkably subjective. A patentee cannot know how the promise will be construed by the Federal Courts. Some Justices have looked only to the claims to derive the promise, other Justices have derived a promise from statements made within the patent disclosure, while others have “implied” a promise from the nature of the disease treated by the invention.
44. The Federal Courts’ decisions regarding Pfizer’s Latanoprost illustrates the uncertainty and unpredictability that the “promise doctrine” creates for patentees in Canada.

Latanoprost is a drug for the treatment of glaucoma or ocular hypertension. The patent claims a novel compound, which was claimed to reduce intraocular pressure associated with glaucoma or ocular hypertension, without causing substantial ocular irritation.

Before the patent application was filed, the inventors synthesized the compound and tested it in cats, rabbits, monkeys and humans.

45. In a challenge to the Latanoprost patent by generic drug company Pharmascience, the trial judge rejected the proposition that the patent promised an “absence of side effects”, and upheld the utility of the patent on the basis that the medicine was proven useful to reduce intraocular pressure without causing substantial ocular irritation. The decision was upheld by the Federal Court of Appeal.

Generic drug company Apotex subsequently challenged the same patent and asserted that the patent promised the “chronic” treatment of glaucoma. The trial judge rejected this proposition consistent with the ruling in the Pharmascience challenge. However, the Federal Court of Appeal overturned the trial judge and held that because glaucoma is a chronic disease, the “implied” promise of the patent was “chronic use of the compound for a chronic medical condition”. According to the Federal Court of Appeal, the results obtained from single dose human studies completed at the date of filing of the patent could not be soundly predicted to apply to chronic use.

46. The arbitrariness and absurdity of the Judge-made “promise doctrine” is further illustrated by the fact that the ability to demonstrate or soundly predict the utility of a pharmaceutical or biopharmaceutical patent may be lower if there is human clinical trial data than when other forms of evidence such as *in vitro* data is available.
47. While it would be reasonable to expect that the likelihood that the courts will find the patent useful would increase as the data approaches human clinical trial data, an analysis of the case law suggests otherwise. The type of data relied on by the patentee in support of utility now appears to have little or no correlation to a positive decision on utility in Canada. This stands in stark contrast to the United States, where the availability of human clinical trial data establishes *prima facie* a presumption of utility.
48. Lilly has experienced this absurd paradox in relation to its patent for Strattera (atomoxetine) that is the subject of this Notice, and also in relation to its patent for Zyprexa (olanzapine). In a decision rendered on September 10, 2012, the Federal Court of

Appeal dismissed an appeal from a decision of the Federal Court that invalidated the Zyprexa patent on ground of inutility. If Lilly's application for leave to appeal to the Supreme Court is denied, it will have exhausted all domestic remedies regarding Zyprexa.

49. The '113 Patent for Zyprexa claims the use of the compound olanzapine for the treatment of schizophrenia. At the time the '113 Patent for Zyprexa was filed in Canada, Lilly had conducted extensive, comprehensive pre-clinical work, one completed clinical trial in human patients, and four completed clinical trials in healthy volunteer studies, all of which were disclosed within the patent and showed positive results regarding the drug's antipsychotic effects.
50. In the patent infringement action, the Federal Court held that the '113 Patent was novel, unobvious and met the disclosure sufficiency requirements. The court further found that olanzapine is a useful drug for the treatment of schizophrenia, its utility as a compound with potential antipsychotic properties and low side effects in humans was demonstrated at the date of filing, and its use in the treatment of schizophrenia was soundly predicted.

The Court nonetheless invalidated the patent, not because it failed to meet the statutory requirement to be "useful", but because it failed to meet an elevated standard of utility of "marked superiority" over other known antipsychotic agents - a standard that was derived by reference to "promises" made within the patent disclosure. According to the Court, "marked superiority" was determined to include an implied promise of superiority over the longer term because schizophrenia is a chronic condition. The Court implied this promise notwithstanding that Health Canada had approved the drug for acute use. The Court then concluded that Lilly had not done enough work to obtain the patent because it failed to fulfill Canada's unique "promise doctrine" by which utility was assessed. This decision was absurd in light of the fact that Lilly had conducted extensive pre-clinical and clinical tests prior to filing its patent application and notwithstanding that olanzapine is in fact useful (it was approved by Health Canada as safe and effective and used by patients in Canada and other jurisdictions).

51. The divergence between Canadian law and international norms is demonstrated by the fact that the foreign counterparts to the '113 Patent for Zyprexa have been challenged in 16 other countries, but no foreign court has found the '113 patent invalid for inutility. Only one jurisdiction in the world has invalidated the olanzapine compound patent on the basis of inutility - Canada.
52. By construing the "promise of the patent" as the standard against which utility is assessed, the Canadian Federal Courts are in effect requiring proof of the effectiveness of the compound in treating a disease or disorder at the date of filing of the patent application, which imposes a significantly higher onus on the patentee than the standard of credible or plausible utility that is mandated by the *TRIPS Agreement* and *NAFTA*. Ironically, Health Canada approved Strattera and Zyprexa as safe and effective and these drugs were used by hundreds of thousands of patients at the time the Federal Courts found they were not useful.
53. The application of the "promise doctrine" imposes an unacceptable hurdle to patentability, not least due to the Catch-22 situations it creates. To establish non-obviousness, a patent application may need to describe the expected advantages over previous inventions or "prior art". The advantages stated, relevant only to the requirement that the invention be non-obvious, are then construed as the "promise of the patent," against which utility is measured. This imposes a new condition precedent to patentability that the invention be "more useful than" a previous invention, which is unsanctioned by the international treaty obligations binding on Canada.
54. Furthermore, a patent applicant who seeks to comply with the enhanced obligations for proof of utility by conducting longer term clinical studies prior to the filing of the patent application risks facing an allegation of invalidity on the basis of lack of novelty or obviousness, in that the public availability of such studies would be alleged by generic competitors to give rise to anticipation.
55. The "promise of the patent" doctrine also *de facto* discriminates against pharmaceutical and biopharmaceutical patents, contrary to the *TRIPS* and *NAFTA* requirement that patents be made available in all fields of technology. In theory, the same standard of

utility applies to all patents and requires “a mere scintilla” of utility. However, the Federal Courts’ decisions clarify that the “mere scintilla” standard will not apply where a “promise” is construed from the specifications of the patent:

“Where the specification does not promise a specific result, no particular level of utility is required; a “mere scintilla” of utility will suffice. However, where the specification sets out an explicit “promise”, utility will be measured against that promise”... ¹⁶

56. The creation of the “promise doctrine” has led to a dramatic increase in the number of patents invalidated for lack of utility. From 1980 to 2005, there were 33 utility attacks. Out of these 33 attacks, only 2 patents were invalidated for lack of utility and both were invalidated based on inutility in fact (i.e. the claimed invention was devoid of utility). Since 2005, there have been 53 utility attacks (with 39 cases pending). Out of these 53 attacks, 17 patents have been invalidated for lack of utility – all are pharmaceutical or biopharmaceutical.
57. The Canadian Judge-made law on utility and the “promise doctrine” has been codified within the Canadian Intellectual Property Office’s *Manual of Patent Office Practice*, and therefore now exists as a both a hurdle to initial patentability and an obstacle to enforcement of patent rights. The *Manual of Patent Office Practice* describes the “promise of the patent” as follows:

Where the utility of an invention is self-evident to the person skilled in the art, and no particular promise has been made in regard to any advantages of the invention (e.g. if the invention was to simplify a known invention), the self-evident utility is sufficient to meet the required standard.

Where, however, the inventors promise that their invention will provide particular advantages (e.g. will do something better or more efficiently or will be useful for a previously unrecognized purpose) it is this utility that the invention must in fact have.

¹⁶ *Astrazeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023, para. 86, citing *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197 (CanLII), 2010 FCA 197 at para 76.

58. The *Manual of Patent Office Practice* further states that: “[u]nless the inventor is in a position to establish utility as of the time the patent is applied for, on the basis of either demonstration or sound prediction, the Commissioner “by law” is required to refuse the patent” and that “[t]he utility to which the court is referring, of course, is that promised by the inventors”.

2. Disclosure

59. In recent decisions, Canadian Courts have imposed a new, non-statutory disclosure obligation that applies where the utility of the patent is found to be based on a sound prediction. The requirement is directly contrary to Canada’s obligations under the *Patent Cooperation Treaty* and manifestly unfair, in that it could never have been anticipated by patentees at the time they filed their patent applications.
60. The *Patent Cooperation Treaty* is incorporated by reference into Canada’s patent legislation.¹⁷ Section 27(3) of the *Canadian Patent Act*, which mirrors the disclosure requirements in the *Patent Cooperation Treaty* and the *TRIPS Agreement*, directs that:

The specification of a patent must

- (a) Correctly and fully describe the invention and its operation or use as contemplated by the inventor;
- (b) Set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;
- (c) In the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and
- (d) In the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.

¹⁷ *Patent Rules*, SOR/96-423, s.51 and Regulatory Impact Analysis Statement excerpts, C Gaz II, pp. 2754, 2800, as amended, SOR/99-291, C Gaz II, pp.1846, 1850.

61. Prior to the decision of the Supreme Court of Canada in the 2002 *AZT* case, there was no requirement to disclose the factual basis of the prediction in the patent, where the utility of a patent was based on a sound prediction.¹⁸
62. In *AZT*, the Court did not directly address the issue of disclosure and simply stated that a sound prediction requires: (1) a factual basis; (2) an articulable and “sound” line of reasoning from which the desired result can be inferred from the factual basis; and (3) proper disclosure. The Supreme Court of Canada did not state in *AZT* that the contents of the patent had to contain all of this information.
63. Subsequent to the Supreme Court of Canada’s decision in *AZT*, the Federal Courts have invalidated numerous pharmaceutical patents (such as *Strattera*) on the ground that the patent specification did not adequately disclose the factual basis or the sound line of reasoning for a sound prediction of utility.¹⁹ As a result, pharmaceutical patents are being invalidated for a failure to meet a disclosure requirement that did not exist at the time the patent applications were filed, has no basis in Canada’s patent legislation, and is directly contrary to *PCT*, *TRIPS Agreement* and *NAFTA* obligations.
64. The onerous and non-statutory disclosure obligations imposed by Canada’s Federal Courts have now been incorporated into the practice of the Canadian Intellectual Property Office through its *Manual of Patent Office Practice*.
65. Relevant excerpts from Section 9.0.4.01 of *Manual of Patent Office Practice* include:

The factual basis needed to render the line of reasoning sound must be disclosed. If some or all of the facts being relied on are found in another publicly available document, this document must be properly identified. Any necessary facts that are not otherwise publicly available must be included in the description.

...

¹⁸ *Monsanto Company v. Commissioner of Patents*, [1979] 2 S.C.R. 1108; *Ciba Geigy*, (1982), 65 CPR (2d) 73 (FCA).

¹⁹ See *Eli Lilly v. Apotex Inc.* 2009 FCA 97 [raloxifene]; *Novopharm Ltd. v. Eli Lilly & Co* 2010 FC 915; aff’d *Eli Lilly & Co. v. Teve Canada Ltd* 2011 FCA 220 [atomoxetine – *Strattera*]; *Apotex Inc. v. Sanofi-Aventis*, 2011 FC 1486 [clopidogrel].

The person skilled in the art must also appreciate the sound line of reasoning that connects the factual basis to the conclusion that the invention has the promised utility. Here again, the description must provide whatever explanation is necessary to supplement the common general knowledge of the person skilled in the art so as to permit them, in view of the factual basis provided, to soundly predict that the invention will have the utility proposed.

66. Imposing national form and content requirements beyond those required by the *PCT* discriminates against foreign-origin patent applications that are prepared in accordance with the harmonized international standards, and then filed in Canada.
67. While the conditions precedent to patentability and disclosure requirements are separate obligations, the more onerous non-statutory requirements imposed by the courts in relation to both requirements interact in a manner that is fatal to valid pharmaceutical and biopharmaceutical patents. Specifically, the “promise doctrine” makes it virtually impossible for patentees to show that utility was “demonstrated” at the date of filing, such that patentees must rely on sound prediction. Once in the realm of sound prediction, the patentees are required to meet disclosure obligations that could not have been anticipated at the date of filing.
68. The result of the imposition of the non-statutory disclosure obligations is that patents are invalidated on the basis of insufficient disclosure, even though the patentee has shown that utility was soundly predicted (and notwithstanding Health Canada approved the drugs as safe and effective), and even though the patent specification met *PCT* requirements by clearly teaching how to make and use the invention.
69. Lilly’s patents for Strattera and Zyprexa are not the only Lilly patents that have fallen victim to the retroactively applied, burdensome, disclosure obligations. In 2009, Lilly’s patent for the drug Evista (the ‘356 Patent) was invalidated on grounds of insufficient disclosure in proceedings under Canada’s *Patented Medicines (Notice of Compliance) Regulations*. The ‘356 patent claims that the compound raloxifene is useful in treating or preventing osteoporosis. The application Judge held that an abstract from a Hong Kong study that concluded that raloxifene showed promise as a skeletal antiresorptive would have provided a sufficient basis upon which a sound prediction of utility could be made,

but because there was no disclosure of the study in the patent, it was invalid. The decision was upheld on appeal.

(e) Invalidation of the Strattera Patent

70. The '735 Patent relating to the drug Strattera²⁰ was filed in Canada on January 4, 1996 and expires on January 4, 2016. The patent claims the use of the compound atomoxetine for treating attention-deficit hyperactivity disorder (“ADHD”) in adults, adolescents and children.
71. Atomoxetine is a non-stimulant medication that functions to enhance the availability of norepinephrine, a neurotransmitter that plays a significant role in attention and focus. Atomoxetine provides an alternative to the stimulant therapies often used for ADHD, which are not effective for some patients.
72. The Strattera Patent disclosed the way in which atomoxetine could be used in the treatment of ADHD, included a specific description of how to use atomoxetine to treat ADHD, criteria for identifying the relevant patient population, and preferred routes of administration and preferred daily doses.
73. Strattera was approved for use in Canada on December 24, 2004. The drug is commercially successful. Global sales in 2011 amounted to \$620.1 million.
74. The generic drug company Novopharm²¹ sought to invalidate the Strattera patent in an action brought before the Federal Court, alleging a number of grounds including inutility. In a decision issued on September 14, 2010, the Federal Court trial Judge invalidated the Strattera Patent on the sole ground of inutility.
75. In support of the utility of the Strattera patent, Lilly relied on the conduct of a Massachusetts General Hospital Study, a seven-week placebo controlled, double blind, cross-over pilot study involving 22 adult patients with ADHD. The results of the study, obtained prior to the filing of the Canadian patent application, showed a positive and

²⁰ The “Strattera Patent”.

²¹ The name of the company is now “Teva Canada Ltd.”.

statistically significant response for atomoxetine over placebo that met the predetermined standard set by evaluators.²² These results were published in a prestigious peer-reviewed journal and accepted by health regulators in the dossier leading to the approval of atomoxetine,

76. The Trial Judge rejected Lilly's assertion that it need only show that atomoxetine had a "mere scintilla of utility", in reliance on the unique Canadian doctrine of the "promise of the patent". Specifically, the Judge held:

"utility is measured against the inventive promise of the patent. ... An invention is only useful if it does what the inventor claims it will do. In this case the requirement of utility would be met if, at the Canadian filing date of the '735 Patent, there was sufficient evidence that atomoxetine was clinically useful in treating some patients with ADHD or, alternatively, that such efficacy could be soundly predicted.

77. The Trial Judge then read into the patent an "implied" promise (i.e. not stated anywhere within the patent specification) that was derived from the nature of ADHD as a chronic condition. In the view of the Federal Court Judge, to meet the utility requirement, Lilly would have had to have demonstrated or soundly predicted the clinical effectiveness of atomoxetine for long-term treatment of ADHD at the date of the filing of the patent application.
78. The decision held that the utility of atomoxetine for the "long-term treatment of ADHD" had not been "demonstrated" by the MGH Study, since it was a "clinical trial that was too small and too short in duration to provide anything more than interesting but inconclusive data".
79. The Trial Judge stated that in some cases, a study such as the MGH Study might provide a basis for a sound prediction of utility, but held that Lilly was unable to rely on the doctrine of sound prediction because Lilly did not disclose the MGH Study in the patent, and that "in a case involving a claimed sound prediction of utility, it is ...beyond debate that an additional disclosure obligation arises".

²² *Novopharm Ltd. v. Eli Lilly and Company*, 2010 FC 915 at para. 20.

80. The Trial Judge dismissed Lilly's objection that the validity of the Strattera Patent was being assessed against a more rigorous disclosure obligation than existed when the patent was filed in 1996, on the basis that these more burdensome disclosure obligations had been determined by earlier decisions of the higher courts that were binding upon him.
81. In a judgment rendered on July 5, 2011, the Federal Court of Appeal dismissed Lilly's appeal from the Federal Court trial decision that invalidated the Strattera Patent. The Federal Court of Appeal rejected Lilly's argument that the Trial Judge erred in measuring the utility of the patent against an "implicit" promise that atomoxetine would work in the long term, and also rejected Lilly's argument that too high a standard of utility was applied, since: "the patent specifically promised that atomoxetine is a clinically effective treatment of ADHD".
82. Lilly had argued regarding the issue of disclosure that the Strattera Patent was based on an international application, and that, pursuant to Article 27(4) of the *PCT*, Lilly was entitled to insist that the form and content rules established by the *PCT* and Regulations be applied to its Strattera application.

The Court of Appeal rejected the argument in reliance on another Federal Court of Appeal decision that held that disclosure of utility was a matter of "substance" not governed by the *PCT*. The Court conceded that the earlier ruling did not refer to Article 27(4) of the *PCT*, but found this to be "immaterial".

83. Lilly applied for leave to appeal to the Supreme Court of Canada. The application for leave to appeal was dismissed on December 8, 2011, therefore exhausting all domestic appeals regarding the Strattera Patent.
84. In the United States, the U.S. Court of Appeals for the Federal Circuit upheld the same Strattera patent, which was filed one year earlier. The decision demonstrates the sharp divergence of Canadian law from internationally accepted standards.
85. Like in Canada, a generic drug manufacturer alleged that the U.S. patent was invalid for failure to disclose experimental data demonstrating the effectiveness of clinical treatment. The U.S. patent contained identical disclosure to the Canadian patent; however, at the

date of filing of the U.S. patent, the MGH Study had been initiated but not completed. Nevertheless, the U.S. Courts upheld the Strattera patent on the basis that the patent disclosed as a matter of fact a practical utility for the invention, namely the treatment of ADHD. The asserted utility was not so incredible so as to require provision of additional information to the U.S. Patent and Trademark Office. The Court held:

The utility of this product to treat ADHD is not so incredible as to warrant the special procedures that are authorized for use when the examiner doubts the described utility, as in *In re Swartz*, 232 F. 3d 862 (Fed. Cir. 2000) (cold fusion); *Newman v Quigg*, 877 F. 2d 1575, modified 886 F. 2d 329 (Fed. Cir. 1987) (perpetual motion); and for subject matter in once notoriously intractable areas such as cures for baldness or cancer.²³

86. The U.S. Court of Appeals further held that even if the asserted utility had not been demonstrated by a completed clinical trial, the mere initiation of a clinical trial justifies presumptive utility:

... The *Manual of Patent Examining Procedures* instructs examiners to give presumptive weight to the utility for which human trials have been initiated:

... as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility. ...²⁴

The Court of Appeals found that the disclosure was adequate stating: “The ‘590 Patent describes and enables the utility of atomoxetine to treat ADHD”.

III. CANADA’S VIOLATIONS OF NAFTA CHAPTER ELEVEN

87. Canada, through its own actions and through the actions of the Canadian courts, is responsible for measures inconsistent with its commitments under *NAFTA* Chapter Eleven, including without limitation: (1) judicial decisions invalidating the Strattera Patent on grounds of inutility; (2) the failure of the Government of Canada to rectify the Judge-made law on utility in a manner that is consistent with Canada’s treaty obligations;

²³ *Eli Lilly & Co. v. Activis Elizabeth LLC*, Appeal No. 2010-1500 (Fed. Cir. July 29, 2011), at p. 14.

²⁴ *Ibid*, p. 14.

and (3) Canada's incorporation of the Judge-made law on utility into Canadian law. These measures breach Canada's investment obligations under Article 1110 (Expropriation and Compensation), as well as Articles 1105 (Minimum Standard of Treatment) and 1102 (National Treatment).

88. The Strattera Patent constitutes intangible property acquired in the expectation or used for the purposes of economic benefit or other business purposes. By reason of Canada's breach of its investment obligations, Eli Lilly and Company, an investor of a Party, has incurred damages in relation to its investments such as the Strattera Patent. Lilly must be compensated for Canada's failure to comply with its NAFTA Chapter Eleven obligations. These *NAFTA* breaches include without limitation, the following:

(a) Canada's Breach of Obligations Under Article 1110 - Expropriation

89. *NAFTA* Article 1110 prohibits Canada from directly or indirectly nationalizing or expropriating the investments of a U.S. company in its territory, except (a) for a public purpose; (b) on a non-discriminatory basis; (c) in accordance with due process of law and the minimum standard of treatment under international law; and (d) on payment of compensation.

90. Through the measures in issue, Canada has directly expropriated the Strattera Patent. Lilly's patent rights in Strattera extended through January 4, 2016. Canada took these rights away prematurely on September 14, 2010. As of that date, Lilly no longer had the exclusive right to make, use and sell its patented product.

91. In the alternative, Canada has indirectly expropriated the Strattera Patent through the measures in issue. The foremost consideration when an indirect expropriation is alleged is the effect of the measures complained of and whether they have deprived the investor of substantially all of the value of its investment. The measures in issue have had the effect of destroying the value associated with the Strattera Patent, namely, the exclusive right to make, use and sell the patented product.

92. A judicial decision that is contrary to the host State's treaty obligations is an illegal decision.²⁵ The judicial decisions invalidating the Strattera patent are illegal from the perspective of international law and therefore constitute an expropriation.
93. The judicial decisions invalidating the Strattera Patent are contrary to Canada's international treaty obligations, including without limitation, the following:
- (i) The *TRIPS Agreement* and *NAFTA* obligations to make patents available when the conditions precedent to patentability established by those agreements are met and the obligation to enforce valid patents: the effect of the judicial "promise doctrine" is to impose an additional condition precedent and a more onerous standard of utility than that mandated by the treaties ("capable of industrial application"/"useful").
 - (ii) The *TRIPS Agreement* and *NAFTA* obligations to make patents available and to enforce patent rights without discrimination as to field of technology: the judicial decisions *de facto* discriminate against pharmaceutical and biopharmaceutical patents. In the past ten years, numerous Canadian patents relating to highly effective, commercially successful medicines have been invalidated on grounds of inutility, while only one single patent relating to a different field of technology had a claim invalidated on this ground. (*Eurocopter*)
 - (iii) The *PCT* prohibition against imposing form and content requirements relating to international patent applications that are different from or additional to those provided in the *PCT* and Regulations: the more burdensome disclosure obligations that apply where utility is based on a sound prediction are different from and additional to those provided in the *PCT* and Regulations.
 - (iv) The *PCT* obligation that allows a patentee to insist before the national courts that the requirements provided for by the *PCT* and Regulations be applied to the applicant's international application: the Federal Court of Appeal arbitrarily disregarded Lilly's request that the Court acknowledge and apply this obligation.
 - (v) The *Paris Convention*, *TRIPS Agreement* and *NAFTA* national treatment obligations: the judicial decisions treat national patent applications prepared and drafted in accordance with Canada's more burdensome disclosure obligations more favourably than foreign patent applications prepared in accordance with the *PCT*.

²⁵ *Saipem S.P.A. v. The People's Republic of Bangladesh*, ICSID Case No. ARB/05/07, Award, 30 June 2009.

94. The Government of Canada is responsible under international law for the acts of the judiciary as an organ of the State. The Canadian Government and governmental bodies also caused the expropriation of the Strattera Patent by omitting to rectify the Judge-made law on utility and disclosure and by incorporating this law into the practices of the Canadian Intellectual Property Office through the *Manual of Patent Office Practices*.
95. These acts and omissions cannot be considered as *bona fide*. Patent law is statutory. The Government of Canada has a positive obligation to ensure Canadian law complies with Canada's international treaty obligations, as well as the reasonable investment-backed expectations of the investor.²⁶
96. Lilly could not reasonably have expected that Canada's patent regime, on which its investment in the Strattera Patent was predicated, would develop in a manner that departs so markedly from Canada's international obligations, nor could it expect that such developments would completely deprive Lilly of the fruits of its investment. In short, the new and additional requirements that Canada's Federal Courts have created would be unfathomable to investors in pharmaceuticals on the dates *TRIPS* and *NAFTA* came into force.
97. Lilly has not been compensated for the expropriation of the Strattera Patent. The expropriation is contrary to patent law's public purpose of early disclosure, is discriminatory, and does not accord with due process of law or the minimum standard of treatment under international law.

(b) Canada's Breach of Obligations Under Article 1105 – Minimum Standard of Treatment

98. *NAFTA* Article 1105(1) obligates Canada to "accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security."

²⁶ *Fireman's Fund v. Mexico*, ICSID Case No. ARB(AF)/02/01 (17 July 2006); *Glamis Gold, Ltd. v. The United States of America*, UNCITRAL, Award, 8 June 2009.

99. The judicial decisions invalidating the Strattera Patent, the failure of the Government of Canada to rectify the Judge-made law on utility and disclosure, and the incorporation of these new and additional requirements into the practices of the Canadian Intellectual Property Office are measures that violate the principle of fair and equitable treatment.
100. The combined effect of the measures constitutes a sudden, arbitrary and discriminatory alteration of the framework governing Lilly's investment that contravenes Lilly's most basic and legitimate expectations of a stable business and legal environment.
101. Lilly could not have anticipated that the requirement for utility at the time of its investment (a "mere scintilla") would be so drastically altered by the adoption into Canadian law and practice of the doctrine of the "promise of the patent," which has been applied discriminatorily to invalidate pharmaceutical and biopharmaceutical patents.
102. At the time of its investment, Lilly reasonably relied on disclosure obligations that were enshrined in domestic law through the incorporation by reference of *PCT* requirements, and could not have anticipated that non-statutory, new and additional disclosure obligations adopted years later would be retroactively applied to invalidate the Strattera Patent.
103. The measures furthermore violate the "full protection and security" requirement of Article 1105(1), which likewise includes basic requirements of legal security.
104. The Federal Courts have acted contrary to Canada's international obligations. Every wrongful act of a state entails the international responsibility of the state – this covers the conduct of any state organ, including the judiciary.

(c) **Canada's Breach of Obligations Under Article 1102 – National Treatment**

105. Pursuant to Article 1102, "[e]ach Party shall accord to investments of investors of another Party treatment no less favourable than it accords, in like circumstances, to investments of its own investors with respect to the establishment, acquisition, expansion, management, conduct, operation and sale or disposition of investments". It is well-

established that *NAFTA* Article 1102 covers “*de facto* treatment”, or that which is neutral on its face but results in a differential and less favourable treatment.

106. The measures in issue *de facto* discriminate against Lilly, a U.S. investor, when compared to domestic investors, by requiring the Strattera patent (which was filed on the basis of an international application) to meet elevated and additional standards for utility and disclosure that are not required by the laws of the United States of America, the European Union, or the harmonized *PCT* rules. The measures in issue disadvantage foreign nationals and render their patents especially vulnerable to attack by insisting on proof of utility and disclosure of evidence that is not required by the foreign applicants’ own national jurisdictions or international rules.
107. The measures in issue also *de facto* result in less favourable treatment to Lilly as compared to domestic generic competitors, who by virtue of the application of the measures are able to reap the economic benefits associated with Lilly’s investments, thus destroying Lilly’s market share and associated profits.

IV. RELIEF SOUGHT AND APPROXIMATE AMOUNT OF DAMAGES CLAIMED

108. Eli Lilly and Company seeks, through consultations, to have the Government of Canada rectify the situation of non-compliance resulting from the Judge-made law on utility and disclosure and remedy the violations of the investment obligations owed to Eli Lilly and Company regarding its patent for Strattera. If the consultations are unsuccessful, Eli Lilly and Company will submit, in its own right, and on behalf of its enterprise Eli Lilly Canada Inc., a claim for arbitration seeking compensation for the damages caused by or arising out of Canada’s measures that are inconsistent with its obligations contained in Part A of Chapter 11 of *NAFTA*, along with interest and costs. Eli Lilly and Company estimates damages in an amount of not less than CDN \$100 million.

Date: November 7, 2012



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