

Under the Arbitration Rules of the
United Nations Commission on International Trade Law and
the North American Free Trade Agreement
(Case No. UNCT/14/2)

ELI LILLY AND COMPANY

Claimant

v.

GOVERNMENT OF CANADA

Respondent

CLAIMANT'S MEMORIAL

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CLAIMANT'S MEMORIAL

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INTRODUCTION

1. Under the North American Free Trade Agreement (“NAFTA”), patents *must* be made available for innovations that satisfy three core criteria of patentability: novelty, non-obviousness, and utility. This case is about the third criterion, utility, and about Canada’s adoption of a new, radically different standard for determining whether inventions fulfill that requirement. Applying this new and unique utility standard, the promise utility doctrine, Canada’s Federal Courts have decided 23 times over the past nine years that a pharmaceutical patent lacks utility. This pattern stands in stark contrast with the record in Canada during the previous quarter century, when (i) not a single pharmaceutical patent was found to lack utility and (ii) only two patents outside of the pharmaceutical sector were found to lack utility, and only then because the patented inventions were shown subsequently not to work at all.

2. The cases decided under Canada’s promise utility doctrine are striking because everything that happened in the interval between the patent examiners’ decisions to grant the patents, and the invalidations of those patents, *confirmed* the patent examiners’ determinations that the inventions were indeed useful, *i.e.*, that they had utility. Canada’s health regulatory agency (“Health Canada”) found the drugs to be “safe” and “effective” – a higher standard than mere usefulness under patent law – and the drugs have been *used* by hundreds of thousands of Canadian patients.

3. The Claimant, Eli Lilly and Company (“Lilly”), is an innovative pharmaceutical company that relies on patent protection to justify the time-consuming and expensive task of developing new medicines. It takes on average US\$ 1 billion and 11-14 years for a pharmaceutical company to develop a new drug and bring it to patients in the marketplace. For every drug that succeeds, thousands of compounds have failed. Patents, and the time-limited rights that they provide, are vital economic incentives for this research-intensive industry.

4. This arbitration concerns two of Lilly’s patents that have been invalidated by the Canadian Federal Courts under its unique promise utility

doctrine. One is for Zyprexa, a revolutionary second-generation anti-psychotic used to treat schizophrenia and related psychotic disorders. The other is for Strattera, the first non-stimulant available to treat Attention Deficit Hyperactivity Disorder (“ADHD”). Both medicines have been approved by Health Canada as safe and effective and have been used by hundreds of thousands of patients in Canada. It is undisputed that the Zyprexa and Strattera patents are protected “investments” under NAFTA and that Lilly is a protected foreign investor under the Agreement.

5. In the 1990s, when Lilly sought patents for Zyprexa and Strattera, the patentability criterion of utility was a well-understood concept, both in Canada and around the world. Utility is a term of art in patent law that is synonymous with “useful” and “capable of industrial application.” To be patentable, an invention must have the capacity to be put to a specific, industrial use. It cannot be simply a fanciful invention or something that is inoperable on its face.

6. The utility requirement, while playing an important role in assuring that patents are granted only for useful arts, is a low threshold. As Canada’s Manual of Patent Office Practice from 1990 explained, the utility requirement is met so long as an invention is not “*totally useless*.” Utility is also a binary test, in that an invention either has utility or it does not. There are no degrees of utility. For the vast majority of patents, utility is summarily expressed or self-evident in the application. The utility of a pharmaceutical product is typically established simply by referencing the medical condition that the innovation is expected to treat. Unless the patent examiner has reason to believe that the invention cannot possibly work for a practical purpose, the utility test will be satisfied.

7. When NAFTA entered into force on 1 January 1994, all three Parties – Canada, the United States, and Mexico – shared this common understanding and practice with respect to utility. And since 1994, the United States and Mexico have maintained this well-understood definition of utility in their respective patent laws. Since utility is a low threshold, litigation involving

utility has been rare. According to one study that surveyed 300 U.S. patent validity cases (both pre- and post-NAFTA), only five cases involved a challenge to utility and only one that was successful. There are no known utility challenges in Mexico.

8. Canada maintains this traditional utility test. But where the Federal Courts subjectively construe a “promise of the patent,” a patent is subject to the unique promise utility doctrine even if it fulfills the traditional utility test. Without wading into the intricacies of the promise utility doctrine, two key facts stand out. The first is that the promise utility doctrine represents a dramatic departure from the traditional standard of utility embodied in NAFTA and applied to this day in the United States and Mexico. The second is that the promise utility doctrine is profoundly arbitrary and unpredictable. Even Canada’s generic industry, which has been the prime beneficiary of the pattern of patent invalidations under the promise utility doctrine, has recognized that the doctrine has resulted in a “free for all” and involves a “hopeless tangle of contradictory approaches.”

9. Canada’s promise utility doctrine has three core attributes, which together are responsible for Canada’s unique pattern of invalidating pharmaceutical patents.

- First, Canada’s Federal Courts subjectively scour the patent to identify one or more “promised” utilities. In conducting its search, the Court looks beyond the patent’s “claims” (*i.e.*, the carefully drafted terms that define the invention) and also analyzes the patent’s “disclosure” (*i.e.*, the more fulsome explanatory statement that allows others to make and use the invention at the end of the patent term).
- Second, the patentee is subject to a heightened evidentiary burden. The Court second-guesses the scientific evidence submitted in support of a patent’s utility to determine whether the patent’s “promise” has been “demonstrated” (*i.e.*, established) or “soundly predicted.” At the same time, Federal Courts refuse to consider any post-filing evidence – such as commercial use of the drug or the fact that Health Canada has found it to be safe and effective.

- Third, under an additional disclosure rule for “sound prediction” cases, any pre-filing evidence to support the prediction must be included in the patent application itself or it is excluded from consideration.

10. These three features of the promise utility doctrine operated together to deprive Lilly of its investments in the Zyprexa and Strattera patents in contravention of Canada’s obligations to protect investments under NAFTA Chapter 11. In the case of Zyprexa, the utility claimed was typical for a pharmaceutical patent. It identified the compound as useful for the treatment of schizophrenia. This assertion of utility was found to be acceptable by every patent examiner in the world who reviewed the patent application, including Canada’s examiners. Even the Canadian court deciding the case acknowledged the usefulness of the claim of treating schizophrenia. Nevertheless, the court looked for evidence to support an *implied* “promise” that Zyprexa would work “in the clinic in a markedly superior fashion with a better side-effects profile than other known antipsychotics.” Applying a heightened evidentiary burden, the court then held that Lilly had failed to “demonstrate” or “soundly predict” this promised utility as of the filing date.

11. In the case of Strattera, the utility claimed in the patent application was “for the treatment of ADHD.” As with Zyprexa, this assertion of utility satisfied every patent office in the world examining the application, including Canada’s. Even the Canadian court that invalidated the patent acknowledged that there was sufficient evidence to demonstrate the utility of this claim. But the court did not end its inquiry there; rather, it proceeded to construe a “promise” in the application – namely, that Strattera would be “clinically useful [to] effectively treat humans with ADHD . . . in the longer term.” Based on this *implied* “promise” – which appeared nowhere in the patent – the Court applied heightened scrutiny to the patent and held that Lilly had failed to “demonstrate” or “soundly predict” this “promised” utility.

12. The invalidation of the Zyprexa and Strattera patents under this unique promise utility doctrine engages Canada’s investment protection obligations under Chapter 11 of NAFTA. It is well-established that a State is

responsible for the acts of its judiciary no less than its executive or legislative branches. Here, Lilly has given the Canadian courts every opportunity to reverse course. The company appealed the invalidations of Zyprexa and Strattera all the way to the Supreme Court of Canada, which denied leave to hear both appeals and let stand the lower courts' invalidations of the two patents.

13. Canada's measures in respect of the Zyprexa and Strattera patents give rise to two cognizable claims under Chapter 11 that are within the competence of this Tribunal.

14. *First*, Canada's invalidation of the Zyprexa and Strattera patents constitutes an uncompensated expropriation, in violation of Article 1110 of NAFTA. It is indisputable that Canada's measures have deprived Lilly's investments of substantially all value – the classic hallmark of an expropriation. There is also no question that *if* Canada's measures are an expropriation, then that expropriation necessarily violates Article 1110. Canada has tendered no compensation to Lilly for its measures, and that by itself is sufficient to render Canada's expropriation wrongful under NAFTA.

15. The only real question for the Tribunal under Article 1110 is whether Canada can avoid responsibility for its measures by casting them as a non-compensable exercise of the state power to grant and revoke patents. But while international law recognizes that states may revoke property rights without necessarily committing an expropriation, that authority is not unlimited, and one of its boundaries is crossed when a state revokes a property right while violating a rule of international law, as Canada has done here.

16. NAFTA itself reflects this boundary in the specific context of intellectual property rights. Article 1110(7) of NAFTA recognizes that revocations of intellectual property rights that are inconsistent with Chapter 17 qualify as expropriations.

17. Canada's promise utility doctrine violates Chapter 17 of NAFTA. Chapter 17 requires Canada to provide patents to inventions, in all fields of

technology, that are “new, result from an inventive step, and are capable of industrial application [*i.e.*, have utility].” As the spike in inutility decisions for pharmaceutical patents reflects, Canada has clearly and substantially redefined utility as contemplated by NAFTA. If Canada can unilaterally reinterpret a core legal term in such a stark manner and with such severe consequences, legally operative words in NAFTA with internationally-accepted meanings could be susceptible to unilateral re-definition, such that NAFTA will no longer establish foundational requirements for patent protection. The promise utility doctrine’s exclusive and discriminatory impact on pharmaceutical patents also violates Canada’s obligation to extend intellectual property rights without regard to field of technology.

18. *Second*, Canada’s measures violate its obligations to afford “fair and equitable treatment” to Lilly’s investments under Article 1105 of NAFTA. While tribunals and commentators have debated the exact contours of the Article 1105 standard, there is no question that it embraces three protections that the promise utility doctrine violates: (i) protection against arbitrary treatment; (ii) protection of legitimate, investment-backed expectations; and (iii) protection against discriminatory treatment.

19. The promise utility doctrine is arbitrary at each step of the analysis because it is completely unpredictable and unreasonably difficult to satisfy. Inventors have no way of knowing what “promises” a Canadian court might subjectively find in the patent application. Patentees have no way of knowing how much evidence the court will require to satisfy those promises – *i.e.*, *in vitro* testing, animal testing, or comprehensive human clinical trials. And given the uncertain quantum of evidence needed to “demonstrate” utility, they have no way of knowing if they will need to establish utility based on a “sound prediction” – in which case the courts will refuse to consider evidence outside the patent application. As one might expect, the results of this promise utility doctrine have been chaotic. In the case of the drug latanoprost, for instance, two panels of the same court, reviewing the same patent, construed the “promise” of the patent in

dramatically different ways, one leading to a finding of utility and the other inutility.

20. When Lilly made its investments in the Zyprexa and Strattera patents, it could not reasonably have expected that Canada would promulgate such a unique and arbitrary doctrine – particularly one that violates Canada’s international obligations. Lilly relied on Canada’s patent law when it sought patent protection for Zyprexa and Strattera and launched those drugs in Canada. It also relied on the Zyprexa and Strattera patents themselves, which were issued after a careful review by Canada’s patent examiners in light of Canada’s utility requirement at the time. Those expectations have been completely and radically contravened by Canada’s application of the promise utility doctrine.

21. When Lilly lost its patent protection for Zyprexa and Strattera, Lilly’s competitors were able to enter the market and sell copies of Zyprexa and Strattera – the very medicines that, according to the Canadian Federal Courts, were useless. Lilly also lost the ability to enforce its patent rights against infringers and faced other consequences. Under governing principles of international law, Lilly is entitled to full reparations for these damages, which are directly attributable to Canada’s breaches of Chapter 11. In accordance with Article 9.1 of Procedural Order No. 1, Lilly reserves for the appropriate phase of this proceeding its statement of the *quantum* appropriate to satisfy this standard.

I. LILLY IS AN INNOVATIVE PHARMACEUTICAL COMPANY COMMITTED TO BRINGING GROUND-BREAKING MEDICINES SUCH AS ZYPREXA AND STRATTERA TO PATIENTS WORLDWIDE.

22. Eli Lilly and Company is one of the world's leading pharmaceutical companies.¹ Founded in 1876 as a small family-owned business with four employees, Lilly has been devoted to innovation from the start.² In 1886, Lilly became one of the first companies to create its own in-house research and development program by hiring a chemist full-time to study and improve existing pharmaceutical products.³ Over the years, Lilly's commitment to innovation has resulted in scores of transformational inventions, including the first class of oral and injectable antibiotics, among others.⁴

23. Today, Lilly markets pharmaceutical products in 125 countries and has approximately 39,000 employees worldwide.⁵ Lilly's state-of-the art research facilities and thousands of researchers around the globe are developing new medicines in areas as diverse as neuroscience, endocrinology, oncology, cardiology, and animal health, among others.⁶ The value of Lilly's drug

¹ Eli Lilly and Company is a corporation organized under the laws of Indiana, United States of America. Eli Lilly has its registered office at: Lilly Corporate Center, Indianapolis, Indiana 46285 USA. Office of the Secretary of State for the State of Indiana, Indiana Business Entity Report No. 183025-143 (Eli Lilly & Co.) (30 January 2013) (C-14); *See The World's Biggest Public Companies*, FORBES, 2014 (filtered for pharmaceutical industry) (C-191).

² James H. Madison, *Manufacturing Pharmaceuticals: Eli Lilly and Company, 1876-1948*, 18 BUS. AND ECON. HIST. 72 (1989) (C-15).

³ ELI LILLY & CO., *Heritage*, <http://www.lilly.com/about/heritage/Pages/heritage.aspx> (C-17).

⁴ Hannah Blake, *A History of Eli Lilly & Co.*, PHARMAPHORUM (29 July 2013), <http://www.pharmaphorum.com/articles/a-history-of-eli-lilly-co> (C-18); *see generally Eli Lilly Canada - Providing Answers That Matter: CPM talks to Gaetano Crupi, President and General Manager, Eli Lilly Canada*, CANADIAN PHARMACEUTICAL MARKETING (Fall 2001), <http://www.stacommunications.com/journals/cpm/images/cpmpdf/fall01/companylilly.pdf> (C-19).

⁵ ELI LILLY & CO., *Key Facts*, <http://www.lilly.com/about/key-facts/Pages/key-facts.aspx> (C-20).

⁶ ELI LILLY & CO., 2013 ANNUAL REPORT, at 2-3, 11 (2013) (C-21).

discoveries are reflected in Lilly's fiscal performance, which enables continuing investments in future innovation. In fiscal year 2013, Eli Lilly spent approximately \$5.5 billion on research and development.⁷

24. Canada has long been an important market for Lilly. In 1920, Lilly collaborated with two scientists at the University of Toronto to discover and produce a new treatment for diabetes, what was then a fatal disease with no effective treatment options. Lilly and the researchers produced a pancreatic extract - insulin - that had dramatic effects on diabetes patients. Lilly then devised a method to manufacture insulin in large quantities, which revolutionized the treatment of diabetes. To that point, diabetes had been a fatal prognosis; insulin enabled even those with severe diabetes to live an almost normal life, and by 1923 Lilly was producing enough to supply all of North America.⁸ This project was the first successful large-scale collaboration between a North American university and a pharmaceutical company.⁹ Lilly founded Eli Lilly Canada, Inc. 15 years later, in 1938, making it one of Lilly's longest-running foreign enterprises.¹⁰

II. PATENT PROTECTION IS THE CORNERSTONE OF LILLY'S INNOVATIVE PHARMACEUTICAL PRODUCTS.

25. Simply put, patent protection is the lifeblood of Lilly's pharmaceutical innovations. Without patents, inventors would have no

⁷ ELI LILLY & CO., 2013 ANNUAL REPORT, 2013 at 1 (2013) (C-21).

⁸ See "The Discovery of Insulin," NOBELPRIZE.ORG, <http://www.nobelprize.org/educational/medicine/insulin/discovery-insulin.html> ("[Insulin is] one of the biggest discoveries in medicine. When it came, it was like a miracle. People with severe diabetes and only days left to live were saved.") (C-22).

⁹ James H. Madison, *Manufacturing Pharmaceuticals: Eli Lilly and Company, 1876-1948*, 18 BUSINESS AND ECONOMIC HISTORY 72, 76 (1989) (C-15); John P. Swann, ACADEMIC SCIENTISTS AND THE PHARMACEUTICAL INDUSTRY: COOPERATIVE RESEARCH IN TWENTIETH-CENTURY AMERICA 73 (1988) (C-23).

¹⁰ Eli Lilly Canada, Inc., a corporation organized under the laws of Canada, 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, M1N 2E8.

protection against others copying their inventions, and there would be little incentive to undertake the costly and time-consuming process of invention.

26. Patents are the cornerstone of the innovative pharmaceutical industry because of distinctive features of the drug development lifecycle. In most industries, a product is ready to be sold in the marketplace as soon as patent protection is granted. Not so in the pharmaceutical sector. Altogether, it takes on average US\$ 1 billion and 11-14 years for a pharmaceutical company to develop a new drug and bring it to patients in the marketplace.¹¹ While the costs of discovering and developing a new drug are exceedingly high, the costs of copying the invention are very low. This asymmetry and potential for free-riding place a premium on the exclusive rights that patents provide. Without secure property rights, much investment on this scale would not take place.¹² According to one study, 60 percent of inventions in the pharmaceutical industry would not have developed without patent protection.¹³ A company's patent portfolio and the patented products it has successfully brought to market are thus fundamental drivers of the value of the innovative company.¹⁴

27. A patent, at its core, reflects a contract between the government and the inventor.¹⁵ In exchange for the government granting the inventor exclusive

¹¹ J. Mestre-Ferrandiz et al., *The R&D Cost of a New Medicine*, OFFICE OF HEALTH ECONOMICS - LONDON 6-7 (2012) (placing the cost estimate at US\$ 1.5 billion) (C-24).; *see also* Chandra Mohan et al., *Patents - An Important Tool for Pharmaceutical Industry*, RESEARCH AND REVIEWS: JOURNAL OF PHARMACEUTICS AND NANOTECHNOLOGY, April-June, 2014, at 13 (placing the figure at upwards of US\$ 800 million and 10-15 years) (C-25); U.S. CONGRESSIONAL BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (October 2006), at 19-25 (placing the figures at upwards of US\$ 800 million and 11.8 years) (C-26).

¹² Merges Report at ¶ 34.

¹³ Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MANAGEMENT SCIENCE 173, 175 (1986) (C-27). Across all fields of technology, the average percentage of inventions forgone without patent protection was only 14 percent. *Id.*

¹⁴ Armitage Statement at ¶ 4 (“A large percentage of the market capitalization of research-based biopharma companies, including Lilly, is attributable to the existence of valid and enforceable patents.”)

¹⁵ Siebrasse Report at ¶ 4.

property rights to make, construct, and use the invention, and to sell it to others to be used, during a 20-year term, the inventor must disclose its invention to the public by adequately describing it in the patent application.¹⁶ Such disclosure is designed to help generate further innovation and research, as it allows others not only to make and use the invention after the patent term, but also to build on the knowledge disclosed during the term of the patent.¹⁷ As Canadian patent expert Professor Norman Siebrasse of the University of New Brunswick explains, the purpose of this exchange is to “promote the public good by providing an incentive for the creation and disclosure of new inventions,” as “by giving an inventor exclusive rights to exploit the invention, the reward to the inventor is made commensurate with the social benefit of the invention.”¹⁸

28. Pharmaceuticals have a unique product lifecycle. They are not available to consumers shortly after the invention of a new molecule or the discovery of a new use for an existing molecule. Before a drug reaches the market, it must pass through a multi-stage process of (i) candidate identification, (ii) pre-clinical trials, (iii) clinical trials, (iv) regulatory approval, and (v) market launch.¹⁹ Patentability is a critical step, although merely one step, in an intensive research and development period to bring a drug to market. As a practical matter, patent filing usually starts early in the drug development process.²⁰ Because the creation of a finished drug generally requires a plurality of discrete inventions, discovered incrementally as the product is developed, a patentee typically files multiple

¹⁶ Siebrasse Report at ¶ 4; *see also id.* at ¶ 3 n.3 (noting that the term of a patent is 20 years from the filing date); Chandra Mohan et al., *Patents - An Important Tool for Pharmaceutical Industry*, RESEARCH AND REVIEWS: JOURNAL OF PHARMACEUTICS AND NANOTECHNOLOGY, April-June, 2014, at 13 (C-25).

¹⁷ Siebrasse Report at ¶ 11.

¹⁸ *Id.* at ¶ 3.

¹⁹ U.S. CONGRESSIONAL BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (October 2006), at 20 (C-26); Chandra Mohan et al., *Patents - An Important Tool for Pharmaceutical Industry*, RESEARCH AND REVIEWS: JOURNAL OF PHARMACEUTICS AND NANOTECHNOLOGY, April-June 2014, at 13 (C-25).

²⁰ Chandra Mohan et al., *Patents - An Important Tool for Pharmaceutical Industry*, RESEARCH AND REVIEWS: JOURNAL OF PHARMACEUTICS AND NANOTECHNOLOGY, April-June, 2014, at 13 (C-25).

applications throughout the development process. For instance, a new series of molecules may be discovered to have properties that make them useful to treat a particular condition. These compounds may be filed in a “genus” patent that sets out and claims the structure of the molecules. As one (or more) of the compounds are tested, the chemical and biological properties may give rise to further research on the structure of the molecules to improve the activity or properties. For example, the compounds originally filed in the genus patent may prove to be too toxic for human use, so medicinal chemists will investigate ways to eliminate the toxicity. The newly discovered and improved compounds may then be claimed in a second or improvement patent.²¹ Similarly, through the course of research, scientists may discover additional uses, improved methods of manufacture, or improved pharmaceutical formulations. As a result, pharmaceutical patents often represent many years of incremental research. As Professor Siebrasse explains:

In the pharmaceutical context, several types of claims are permissible. A patent may claim the pharmaceutical compound itself, or a process for making that compound, or both. A patent may claim individual compounds, or a broad class of related compounds, often referred to as a “genus.” A particular formulation of a compound may be claimed, such as a slow release formulation consisting of a compound in combination with a slow-release coating. A particular use of a known compound may also be claimed, as for example the claim to the use of AZT for the treatment of HIV / AIDS. The right to market a particular drug product may be covered by more than one type of claim, which may be found in the same patent, or in different patents. For example, a slow-release formulation of a particular drug product may be covered by a compound claim to the individual compound itself, a process claim to the method of making the compound, and a claim to the slow-release formulation.²²

29. Pre-clinical trial experiments on cell cultures in the laboratory (*in vitro* tests) or on animal subjects (*in vivo* tests) are used to determine the effects of

²¹ Patent professionals often call this improvement patent a “selection patent” as the improved compounds were “selected” through further research from the original structural class or genus.

²² Siebrasse Report at ¶ 13.

the drug and are often part of the inventive process. For good reason, human clinical trials are the final step in the drug development process and are only undertaken for a limited set of discoveries. Fewer than one percent of compounds examined in the pre-clinical period make it into the “clinical phase” involving human trials.²³ In the United States, for example, federal regulations require that an Institutional Review Board review every application for human clinical trials to assure, *inter alia*, that risks to subjects are minimized by use of procedures consistent with sound research design, that risks to subjects are reasonable in relation to anticipated benefits, that the selection of subjects is equitable, and that informed consent is obtained and documented.²⁴

30. Not surprisingly, health regulatory authorities have an extensive and thorough process of review to approve clinical trials on humans in the first instance.²⁵ In Canada, for example, Health Canada requires that clinical trial sponsors submit data sufficient to allow Health Canada to “determine that the use of the drug for the purposes of the clinical trial does not endanger the health of clinical trial subjects or other persons, the clinical trial is not contrary to the best interests of a clinical trial subject, and the objectives of the clinical trial may be achieved.”²⁶ Although clinical trials are important for Health Canada’s determination that a drug is safe and effective to market, they are not the foundation of patent protection. The patent system serves a fundamentally different function – to encourage innovation – than Health Canada’s role to

²³ Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 EMBO Reports 837 (2004) (“Of 5,000 compounds that enter pre-clinical testing, only five, on average, are tested in human trials, and only one of these five receives approval for therapeutic use.”) (C-28).

²⁴ U.S. Food and Drug Administration, *Criteria for Institutional Review Board Approval of Research*, 21 C.F.R. 56.111 (revised 1 April 2014) (C-29).

²⁵ See, e.g., Health Canada, *Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications* (29 May 2013) (C-30); Health Canada, *Protocol Safety and Efficacy Assessment Template: Clinical Trial Application* (1 April 2008) (C-31); U.S. Food and Drug Administration, *Criteria for Institutional Review Board Approval of Research*, 21 C.F.R. 56.111 (C-29).

²⁶ Health Canada, *Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications* (29 May 2013) (C-30).

protect health and safety. As such, most patent applications do not include human clinical trial data.²⁷

31. The innovation spurred by the pharmaceutical industry brings life-changing medicines to market. Lilly's drugs have helped millions with clinical depression, ADHD, and cancer, among other conditions. Lilly delivers these medicines in a highly competitive market. Lilly competes with large and small innovative pharmaceutical and biotech companies, and new inventions often displace older innovations in the same therapeutic class.²⁸ Scores of researchers across a range of institutions are often working on the same molecules to determine how to unlock their potential and build upon earlier advances. For example, researchers from Lilly and American Cynamid were conducting research on class of molecules known as "benzodiazepines" in an effort to discover a drug with the efficacy of the drug clozapine (an anti-psychotic), but without its severe toxicity. The compound patented and studied by American Cynamid never advanced.²⁹ Lilly's compound, however, became olanzapine, a breakthrough molecule, which then spurred further research. Companies and universities such as SmithKline Beecham, Janssen Pharmaceutica, Cortex Pharma, and the University of California were active in research and filing patent applications encompassing olanzapine and seeking to exploit the molecule's potential.³⁰

²⁷ Siebrasse Report, ¶ 107.

²⁸ Albert Wertheimer et al., *Too Many Drugs? The Clinical and Economic Value Of Incremental Innovations*, 14 INVESTING IN HEALTH: THE SOCIAL AND ECONOMIC BENEFITS OF HEALTH CARE INNOVATION 77 (2001) (C-32).

²⁹ U.S. Patent 3,951,981 (C-33).

³⁰ See, e.g., Canadian Patent Application No. CA19972261813 (published 5 February 1998) (SmithKline Beecham PLC, Applicant) (C-34); Canadian Patent Application No. CA19992345767 (published 27 April 2000) (Janssen Pharmaceutica NV, Applicant) (C-35); Canadian Patent Application No. CA19982306817 (published 6 May 1999) (Cortex Pharma Inc. & Univ. of California, Applicants) (C-36).

Moreover, companies like Sepracor filed patent applications on derivatives of olanzapine.³¹

32. Lilly's typical practice – like that of other pharmaceutical innovators – is to file patent applications for a new drug before it conducts any human clinical trials.³² In fact, if innovators wait to file until after clinical results become available, they can jeopardize their ability to obtain patent protection at all. Clinical trials generally lead to the publication of data regarding the new drug,³³ and if the drug is publicized before a patent application is filed, the company risks a challenge to the validity of the patent on the ground that it was not “novel” or “non-obvious” when the application was filed.³⁴

33. Patent protection is territorial, and multinational companies like Lilly need to decide in which jurisdictions to seek patent protection. Lilly generally filed its first patent application in the jurisdiction where the invention took place.³⁵ As explained by Peter Stringer, former Chair of Lilly's Foreign Patent Committee, once an initial application was filed, Lilly's Foreign Patent Committee (FPC) reviewed the initial application and decided in which other jurisdictions to

³¹ See, e.g., Canadian Patent Application No. CA19992351719 (published 2 June 2000) (Sepracor Inc., Applicant) (C-37).

³² Witness Statement of Peter George Stringer at ¶ 16.

³³ Stringer Statement at ¶ 16. See, e.g., Case T 007/07 *Bayer Pharma Aktiengesellschaft v. Hexal AG*, European Patent Office Board of Appeal (7 Jul 2011) (C-38), which invalidated the patent to the drug Yazman in Europe on the basis of clinical trials undertaken prior to filing. Further, for large scale trials, the number of people exposed to confidential technical information is so high that the risk of an inadvertent, patent-defeating disclosure is significant.

³⁴ Stringer Statement at ¶ 16. As discussed *infra*, see ¶ 266 because of this risk in waiting to file for patent protection until clinical trials are completed, the promise doctrine places companies in a “Catch-22.” Either they file for patent protection before clinical trials are completed and risk invalidation under the promise doctrine, or they wait to file for patent protection until clinical trials are completed and they risk invalidation because of publication. See also Siebrasse Report at ¶¶ 107-108.

³⁵ Stringer Statement at ¶¶ 6, 14.

file for patent protection.³⁶ For drugs with strong therapeutic potential, Lilly would file foreign patent applications in 35 to 50 countries or more. Foreign filing turned in part on Lilly's assessment of the adequacy of patent protection in each jurisdiction.³⁷ For example, in the 1980s Lilly began filing for patents in the former Czechoslovakia after a positive change to that country's patent law.³⁸

34. As a developed economy and major market with patent protection that met international standards in the 1990s, Canada was one of the core jurisdictions where patents were routinely filed. As part of its deliberations as explained by Mr. Stringer, the Foreign Patent Committee would consider any country-specific concerns about patentability and could "decide not to file in a particular foreign jurisdiction if the patent protection was not adequate."³⁹ No concerns about utility were raised about Canada when the Zyprexa and Strattera patents were filed.⁴⁰

35. As a practical matter, Lilly drafted patent applications to satisfy the requirements of every jurisdiction in which it might apply.⁴¹ This was possible for two reasons. First, the patentability requirements across jurisdictions were fairly uniform. Second, the filing process was often facilitated by the Patent Cooperation Treaty (PCT), which enables patent applicants to seek protection for their inventions in a large number of countries by filing a single international application that all PCT member states must accept as satisfying the form and content requirements of their domestic patent law.⁴²

³⁶ *Id.* at ¶¶ 5-11. In accordance with the Paris Convention, the filing date of the first, or "priority," patent application is considered to be the effective filing date of applications filed in other jurisdictions, if filed within 12 months of the priority application.

³⁷ *Id.* at ¶¶ 7-9.

³⁸ *Id.* at ¶ 9.

³⁹ *Id.* at ¶ 8.

⁴⁰ *Id.* at ¶¶ 19, 25.

⁴¹ *Id.* at ¶ 6.

⁴² *Id.* at ¶ 6; Erstling Report at ¶¶ 14, 23.

III. CANADA'S UTILITY REQUIREMENT FOR PATENTABILITY WAS CONSISTENT WITH THE INTERNATIONAL STANDARDS EMBODIED IN NAFTA CHAPTER 17 UNTIL THE FEDERAL COURTS CREATED AND APPLIED THE PROMISE UTILITY DOCTRINE.

36. The extent to which the promise utility doctrine departs from prior law and erects new and unanticipated hurdles to patentability can only be appreciated when its requirements are contrasted against the straightforward test that characterizes Canada's traditional utility standard and continues to be applied today by Canada's NAFTA partners, Mexico and the United States. Of the criteria for patentability, utility is recognized as the least demanding and operates as a low threshold requirement for some practical use – in Canada, a “mere scintilla” of utility suffices. For decades, the Canadian law of utility functioned similar to the law of its NAFTA partners, weeding out those inventions that were wholly inoperable or “fanciful” ideas not susceptible to real world use. Not unsurprisingly, under the traditional standard, pharmaceutical patents were never found to lack utility. The situation could not be more different today. Challenges to pharmaceutical patents based on lack of utility have surged, and the Federal Courts have repeatedly applied the promise utility doctrine, including in the cases of Zyprexa and Strattera, and have concluded that pharmaceuticals being prescribed by doctors every day are actually useless inventions.

A. Utility, One of Three Core Patentability Requirements in NAFTA, Requires That an Invention Have The Capacity To Be Put To a Specific, Industrial Use.

37. The core requirements for patentability developed along similar lines in many jurisdictions around the world and are reflected in international standards. In particular, NAFTA Chapter 17 codified the three core patentability requirements to establish a threshold of patent protection across NAFTA countries. Article 1709.1 of NAFTA requires that “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*.”⁴³ It is this final requirement – “capable of industrial application” (commonly referred to as “utility” or “industrial applicability”) – that is at issue in this case.

38. Among the three requirements, utility is widely understood to be the least demanding.⁴⁴ The test for utility is objective and binary: an invention has utility or it does not, and any practical, real world utility will do.⁴⁵ While the claimed invention must be capable of some practical result, utility is a low threshold.⁴⁶ Novelty, by contrast, is a test under which a single piece of identical prior art, anywhere in the world, can serve as the basis for rejection.⁴⁷ Meanwhile, the requirement that ensures that a patent is granted for innovation – non-obviousness or inventive step – is the one that “does much of the heavy lifting with respect to quality control in the patent system.”⁴⁸

39. While the precise phrasing varies somewhat across different jurisdictions, this three-part test is common to Canada and the rest of the world, as are the rationales underpinning each element. The novelty requirement ensures that exclusive rights are not granted for inventions that already exist.⁴⁹ The non-obviousness requirement ensures that patents are not granted for developments that emerge easily, and foreseeably, from the general progress of technology.⁵⁰

⁴³ NAFTA Art. 1709.1 (emphasis added) (CL-44). Both the United States and Canada apply the statutory term “useful,” whereas Mexico uses the statutory phrase “susceptible of industrial application.” The provision further clarifies that “a Party may deem the term[] . . . ‘capable of industrial application’ to be synonymous with the term[] . . . ‘useful’ . . .”

⁴⁴ Merges Report at ¶12.

⁴⁵ Merges Report at ¶ 5; Siebrasse Report at ¶¶ 20, 24.

⁴⁶ Siebrasse Report at ¶ 24; Merges Report at ¶ 6; Gonzalez Report at ¶¶ 9, 31.

⁴⁷ Merges Report at ¶ 13; Siebrasse Report at ¶ 6.

⁴⁸ Merges Report at ¶ 14; Siebrasse Report at ¶ 7.

⁴⁹ Merges Report at ¶ 13; Siebrasse Report at ¶ 6.

⁵⁰ Merges Report at ¶ 14.

40. The utility requirement ensures that a claimed invention has the capacity to be put to a specific, industrial use.⁵¹ As Professor Robert Merges, a recognized expert on patentability at University of California, Berkeley, explains, this requirement has two core dimensions:

First, this principle eliminates fanciful or incredible “technologies” from the patent system – such things as perpetual motion machines and cold fusion. Second, and more frequently . . . utility prevent[s] companies from acquiring patents “too early” on objects of research before any specific, real world use is identified.⁵²

The purpose of the utility requirement, as Professor Siebrasse notes, “is to ensure that patents are not granted for inventions where the award of the patent would stifle further research by competitors without having delivered a commensurate benefit.”⁵³

41. As Professor Merges emphasizes, utility:

does not require proof that an invention has a high degree of efficacy, or that a commercially viable version of the invention has been attained. Utility thus grants exclusivity and invites investment while there is as yet a good deal of development required to fulfill an invention’s potential.⁵⁴

42. Consistent with these underlying policy rationales, the utility requirement has traditionally operated as a low, threshold requirement of patentability in all three NAFTA countries.⁵⁵ The inquiry is binary, and does not require an assessment of degree or an analysis of comparative utility. The test is important: some capacity for industrial use is required, in the form of at least one

⁵¹ Siebrasse Report at ¶ 24; Merges Report at ¶ 21.

⁵² Merges Report at ¶ 29.

⁵³ Siebrasse Report at ¶ 22.

⁵⁴ Merges Report at ¶ 29; *see also id.* at ¶ 23 (“[A]n asserted utility is presumed to be correct and accurate, unless it appears to one skilled in the art that it manifestly defies basic principles of chemistry or physics.”).

⁵⁵ *See infra* Parts III(B) and 5.

specific and practical application. But it is not a difficult requirement to satisfy in practice.⁵⁶

43. The fact that the utility requirement is reflected in NAFTA is significant, as the NAFTA parties recognized that Chapter 17 imposed certain constraints on their domestic patent laws. Canada's Minister of Industry, The Honourable John Manley, acknowledged as much in a 1997 speech to Parliament's Standing Committee on Industry:

Canada's drug patent policy seeks to ensure we are in conformity with our international obligations.

Canada, as a trading nation, has benefited from trade agreements such as NAFTA and the WTO. They contribute to economic growth by ensuring access to global markets and promoting competition. Having an internationally competitive intellectual property regime has encouraged research and development in Canada in many sectors.

In these agreements, there are certain rules according to which we and our trading partners must live. Our ability to change our patent law is defined by these obligations. We must give all patentees, pharmaceutical or otherwise, a minimum 20 year patent term. It is not possible to return to our pre-1993 compulsory licensing regime and remain in conformity with our international obligations. Any recommendations should be looked at in the context of these international obligations.⁵⁷

B. In the 1990s, Canada's Statutory Test for Patent Utility Required That an Invention Have the Capacity For an Industrial Use.

44. In the mid-1990s, when NAFTA entered into force and Lilly's applications for the Zyprexa and Strattera patents in Canada were pending, the Canadian Patent Act (the "Patent Act") required that patents be granted and enforced for "any new and useful art, process, machine, manufacture or

⁵⁶ Merges Report at ¶ 6; Siebrasse Report at ¶ 23.

⁵⁷ Honourable John Manley, Canadian Minister of Industry, Speaking Notes for Address to the Standing Committee on Industry, Review of Bill C-91 (17 February 1997) (C-39).

composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.”⁵⁸

45. The statutory term “useful” had a well-established meaning that was applied by the Federal Courts, the Patent Office, and inventors. As explained by Professor Siebrasse, the Canadian standard is widely known as the “mere scintilla” test, because under that standard “very little will do,” and a “slight amount” of utility is sufficient.⁵⁹ Patent applications needed one asserted or apparent utility; they need not have listed all potential uses in industry, or even assert the most important or most likely use.⁶⁰ The utility test simply required that an invention be capable or susceptible of being put to a specific industrial use, and even a use without commercial value would pass this objective test.⁶¹

46. Perhaps the most notable aspect of Canada’s utility law in the 1990s is how rarely utility was questioned. From 1980 to 2004, there were a total of 28 utility challenges in Canadian trial courts.⁶² Among these 28 utility cases, four involved utility challenges to pharmaceutical patents. In one case, regarding an oral-release capsule patented by Bayer, the trial court held that the capsule for the compound nifedipine was operable for technicians skilled in the art and that, because the capsule “has been manufactured, sold and used in Canada for 14 years,” “it cannot be said that [the patent] lacks commercial utility.”⁶³ Indeed, every challenged pharmaceutical patent during this period was found to have utility. *The point bears emphasis: for a quarter of a century - from 1980 to 2004 - not a single pharmaceutical patent was found to lack utility in any Canadian court.*

⁵⁸ Patent Act (Canada), RSC, 1985, c. P-4, at § 2 (C-50).

⁵⁹ Siebrasse Report at ¶ 20.

⁶⁰ Wilson Report at ¶¶ 27, 29.

⁶¹ See, e.g., *Wandscheer et al. v. Sicard Ltd.* (1948) SCR 1, 4 (stating that the invention must be “susceptible of fulfilling its purpose”) (C-42); Siebrasse Report at ¶ 79 (discussing patentability of an unfashionable red dye).

⁶² See “Chronological List of Canadian Utility Decisions from 1980 to Present” (C-305).

⁶³ See *Bayer Aktiengesellschaft v. Apotex*, (1995) 60 CPR (3d) 58, 89-90 (Ont. Ct. Gen Div. 1995), *aff’d*, 82 CPR (3d) 526 (Ont. Ct. App. 1998) (C-40).

47. Canada's utility requirement in the early 90s was reflected in the Manual of Patent Office Practice (the "MOPOP"), guidelines relied upon by patent examiners as a practical summary of applicable patent law in Canada.⁶⁴ With particular regard to the patentability of "living matter, medical treatments, diagnostic methods, and intellectual matter," the 1990 Manual summarized Canada's mere scintilla utility requirement as follows:

12.02.01 - AN INVENTION MUST BE USEFUL:

Section 2 of the Act requires utility as an essential feature of invention. If an invention is *totally useless*, the purposes and objects of the grant would fail and such grant would consequently be void on the grounds of false suggestion, failure of consideration and having tendency to hinder progress.

12.02.02 - UTILITY MUST BE DISCLOSED:

An application for patent must not only describe the invention, but also its operation or use (Section 34(1)). The operation or use of the invention must, of course, show the purpose for which the invention was intended. *An invention may have several uses, but it must always have at least one.*

The claims must be drafted to an invention having the utility disclosed. If the claims cover only things that have utility other than that disclosed or if they included *inoperable and therefore useless* embodiments, they are bad.

12.03 - PREREQUISITES OF A PATENTABLE INVENTION:

Utility, as related to inventions, means industrial value. [I]t must be something that will impart industrial value to what is sought to be patented.

[P]rerequisites that must be satisfied are, inter alia:

- (a) whether the subject matter relates to a useful art . . . ;
- (b) *whether the subject matter is operable, controllable and reproducible by the means described by the inventor . . . ;*

⁶⁴ Wilson Report at ¶¶ 21-23.

- (c) *whether the subject matter has practical application in industry, trade or commerce;*
- (d) whether it has a licit object in view;
- (e) *whether it is more than a mere scientific principle or abstract theorem; and*
- (f) whether it is beneficial to the public.⁶⁵

48. This mere scintilla requirement, under Section 2 of the Patent Act, had a long provenance in Canadian law, and was consistently understood as imposing a low threshold for patentability, since it was not difficult to show that an invention had an industrial use.⁶⁶ As Professor Siebrasse summarizes the test in this era: “In practice, because of the low standard for utility under the mere scintilla test, inventions held to lack utility were typically wholly ‘inoperable.’”⁶⁷

49. A Federal Court assessing utility under the mere scintilla test does not ask how well an invention worked or whether it was better than a prior invention, questions poorly suited for judicial determination. Rather, the court seeks to ensure that patent applications are not filed before the practical application of the invention is discovered. By refusing to patent an invention without any practical use, Canada’s mere scintilla test prevented patents from being granted prematurely on theories, thus dissuading other inventors, pursuing the same theories, from completing their research and reducing their ideas to workable form.⁶⁸ This purpose was not unique to Canadian law. It was and is

⁶⁵ CANADIAN INTELLECTUAL PROPERTY OFFICE – PATENT OFFICE, MANUAL OF PATENT OFFICE PRACTICE §§ 12.02 & 12.03 (January 1990) (emphases added) (internal citations omitted) (C-54).

⁶⁶ Siebrasse Report at ¶¶ 20-21, citing *Prentice v. Dominion Rubber Co.* (1928) Ex CR 196, 199; *Asten-Hill Ltd. v. Ayers Ltd.*, (1939) 2 DLR 234, 246 (Ex Ct); *Otto v. Lindford* (1982), 46 LT (NS) 35, 41, quoted by Estey I in *Wandsheer* (1948) SCR 1, 24. The definition of invention under Section 2 of the Patent Act dates to 1923. See “An Act to Amend and Consolidate the Acts relating to Patents of Invention,” 1923 v. 1 at 145 (13 June 1923), at § 2 (C-43); see also Wilson Report at ¶ 27.

⁶⁷ Siebrasse Report at ¶23; see also Wilson Report at ¶ 28 (stating that patent applications that were denied for lack of utility at this time involved inventions that were inoperable or unworkable).

⁶⁸ Siebrasse Report at ¶ 22.

reflected in the utility requirements of Canada's NAFTA partners, Mexico and the United States.

50. In reviewing the stated utility, Patent Office examiners in the 1990s also applied the mere scintilla standard.⁶⁹ Any identified use would suffice; the utility inquiry thus did not consider extraneous statements as to potential benefits or advantages over the prior art.⁷⁰ Consistent with the statutory requirement ("useful"), applicants informed the patent examiner what the invention did and, if not apparent, how it worked.⁷¹ As Murray Wilson explains:

Unless the examiner had reason to doubt that the invention worked, the inquiry ended there. As a result, it was neither required nor typical for applicants to provide much, if any, data derived from real world use, whether through clinical data of pharmaceuticals, or through road testing of machines.⁷²

Patent Office rejections for lack of utility were rare and based on the simple fact that the invention either was inoperable or claimed an incredible use such as a perpetual motion machine or a death ray machine.⁷³

51. In the 1990s, utility could also be "soundly predicted," making it unnecessary for inventors to conduct duplicative or otherwise burdensome testing in order to support the utility of their inventions. In its typical application, sound prediction permitted an inventor who had tested certain chemical compounds to rely on his prediction of the behavior of structurally similar compounds that had not been tested. In the foundational 1979 case of *Monsanto Co. v. Canada (Commissioner of Patents)*,⁷⁴ the Supreme Court found that an inventor who had

⁶⁹ Wilson Report at ¶¶ 27-30 (discussing the "low threshold for establishing utility").

⁷⁰ See Wilson Report, ¶ 29 ("examiners did not consider advantages of the invention that were stated in the disclosure to be equivalent to the utility of the invention").

⁷¹ *Id.* at ¶ 27.

⁷² *Id.* at ¶ 30.

⁷³ *Id.* at ¶ 28.

⁷⁴ *Monsanto Co. v. Canada (Commissioner of Patents)* (1979) 2 SCR 1108 (C-61).

tested the properties of three related compounds, each of which inhibited the vulcanization of rubber, could soundly predict without testing that the remaining 123 compounds in the genus would also be useful in the treatment of rubber.⁷⁵ This rule was prudent because, as Professor Siebrasse explains, “[i]f the patentee were entitled to claim only the compounds that it had actually tested, competitors would be able to take advantage of the patentee’s inventive insight without infringing the patent simply by making a closely related compound that is not claimed in the patent.”⁷⁶

52. Moreover, in answering a utility challenge, an inventor could rely on testing or other evidence that had been generated *after* the date of the patent application to show that the invention, as of the filing date, was useful. Such evidence most frequently included commercial use as evidence of utility.⁷⁷ Patent utility and outcomes in the marketplace were closely linked, according to Professor Siebrasse: “While commercial success was never required to establish utility, if the invention as claimed had become a commercial success, this was considered good evidence of utility on the view that a useless invention could not be commercially successful.”⁷⁸ Every leading case that found utility on the basis of sound prediction relied on evidence that was not fully disclosed in the patent.⁷⁹ Moreover, any “use” of the invention, including infringement of the patent, was considered evidence of utility. As Professor Siebrasse explains, “the fact that the defendant had infringed the patent, and so had used the invention, was evidence that the invention was useful.”⁸⁰

53. The Federal Courts also considered post-filing testing and implementation of the invention. The admission of such evidence was a means of

⁷⁵ *Id.* See also Siebrasse Report at ¶ 27.

⁷⁶ Siebrasse Report at ¶ 28.

⁷⁷ *Id.* at ¶ 30.

⁷⁸ *Id.* at ¶ 30.

⁷⁹ *Id.* at ¶ 88.

⁸⁰ *Id.* at ¶ 31.

ensuring that claims were invalidated only when they were shown to be truly “without utility” and not simply because “they had not been tested before the patent was applied for.”⁸¹ Courts reasoned that because the laws of chemistry are invariable, the date on which they are verified is of no consequence. Their logic, according to Professor Siebrasse, was straightforward: “[I]f a process works today, it must also have worked yesterday. The fact that it was not *tested* yesterday does not mean it did not *work* yesterday.”⁸² In fact, evidence of testing done after the date of filing of the patent application could be relied on to soundly predict the utility of compounds that had never been made or tested.⁸³ Post-filing evidence was routinely considered to establish utility in chemical and pharmaceutical cases, just as for other types of inventions.⁸⁴

54. As discussed *infra*, see Part III.C.2, the Supreme Court of Canada limited the consideration of post-filing evidence in 2002, and this limitation would later become highly problematic for patentees, when combined with an elevated standard for utility based on the requirement to fulfill the “promise” of the patent.

55. The Canadian utility requirement in effect during the 1990s was understood at the time to be consistent with the intellectual property provisions of NAFTA Chapter 17. When implementing legislation for NAFTA was before the Canadian Parliament, the Assistant Deputy Attorney General explained that Canada had reviewed its domestic law, in consultation with the United States and Mexico, and where necessary amended its statutes to bring them into conformity with its treaty obligations.⁸⁵ With respect to Chapter 17, the Assistant Deputy

⁸¹ *Ciba-Geigy AG v. Canada (Commissioner of Patents)*, (1982) 65 CPR 2d 73, 78 (quoting *Monsanto* (1979) 2 SCR at 1108, 1116) (C-44).

⁸² Siebrasse Report at ¶ 34.

⁸³ Siebrasse Report at ¶ 67.

⁸⁴ Siebrasse Report at ¶ 31.

⁸⁵ See *Minutes of Proceedings and Evidence*, House of Commons Legislative Committee on Bill C-115, An Act to implement the North American Free Trade Agreement, 3rd Sess., 34th Parl. (May 1995), at 6:11 (Statement of Mr. Konrad von Finkenstein) (C-45) (“Where there are provisions in our existing legislation that conflict with the NAFTA to some extent, we have amended those provisions so that we are in conformity with the NAFTA.”).

Attorney General emphasized that “this is an entirely new part to the NAFTA,” and that “many acts on the books of Canada . . . implement the provisions of [C]hapter 17.”⁸⁶ The Patent Act was one of seven acts that had to be amended for implementation of Chapter 17, but it required only “some fine-tuning,” not major revision.⁸⁷ Significantly, no changes were made to the utility requirement in Section 2 of the Patent Act.

C. Since 2005, Canada’s Promise Utility Doctrine Has Elevated the Utility Requirement in Canada and Created Additional, Impermissible Hurdles to Patentability.

56. In the mid-2000s, after the patents for Zyprexa and Strattera had been examined and granted, but prior to their invalidation by the courts, Canada’s patent utility law underwent a dramatic transformation. The emergence of the promise utility doctrine placed the Canadian utility requirement sharply at odds not only with prior jurisprudence in Canada and Canada’s Patent Office practice, but also with the patent utility requirements of the United States and Mexico.⁸⁸

57. While the traditional mere scintilla test for utility described above still exists under Canadian law, the promise utility doctrine has created additional hurdles to patentability and has imposed a subjective utility standard on inventions that is arbitrary, unpredictable and could never have been foreseen a decade earlier. All three elements of the doctrine work together to impose a utility requirement that is well above the objective, mere scintilla standard.⁸⁹

- *First*, Canadian judges (and patent examiners) go beyond the claims of the patent and subjectively construe the patent disclosure to identify a “promise.” The promise becomes the measure to establish whether an invention has

⁸⁶ See *Minutes of Proceedings and Evidence*, House of Commons Legislative Committee on Bill C-115, An Act to implement the North American Free Trade Agreement, 3rd Sess., 34th Parl. (May 5, 1993), at 6:5 (Statement of Mr. Konrad von Finkenstein) (C-45).

⁸⁷ *Id.* (C-45).

⁸⁸ See *infra* Part V.

⁸⁹ See *supra* Part C.1; Siebrasse Report at ¶¶ 18-19.

utility. The inventor is then required to meet this elevated “promise” as of the filing date of the patent application.

- *Second*, the evidence submitted with the original patent application is subject to heightened scrutiny previously unheard of in the patent context and more akin to review by health regulators tasked with ensuring the safety and efficacy of a drug. At the same time, post-filing evidence – such as commercial use – no longer can be relied on to support the “promise” of the invention.
- *Third*, under an additional disclosure rule for “sound prediction,” pre-filing evidence is excluded from consideration to support the prediction of a promised utility unless it was referenced in the patent application itself. Both pre- and post-filing evidence of a sound prediction had previously been admissible, whether or not referenced in the patent application.

58. Canadian Federal Courts are applying the doctrine retroactively to patents that were drafted, examined, and granted at a time when these new substantive, evidentiary, and disclosure requirements did not exist and could not have been reasonably foreseen. The promise utility doctrine has now been incorporated by the Patent Office into its Manual of Patent Office Practice (the Manual of Patent Office Practice).⁹⁰

1. The Subjective Promise of the Patent

59. The first element of Canada’s promise utility doctrine is the concept of a patent’s “promise.” Whereas in the past, utility was assessed against an objective standard under which a mere scintilla of utility sufficed, the promise utility doctrine has added a distinct, elevated standard under which utility is assessed against the “promise of the patent,” as construed by the Federal Court years after the patent application was filed. As the Federal Court of Appeal has explained:

Where the specification does not promise a specific result, no particular level of utility is required; a “mere scintilla” of utility will

⁹⁰ See *infra* Part III.C.4.

suffice. However, where the specification sets out an explicit “promise”, utility will be measured against that promise.⁹¹

60. These two branches of Canadian utility law now exist side by side. Under the traditional mere scintilla test, a patent will be found valid if it meets the Patent Act’s objective standard, which “sets the bar low for utility.”⁹² However, Canadian courts now routinely ignore this traditional test, and scour the patent disclosures in search of “promises,” including, in some cases, promises that are not expressly stated in the claims or the disclosure, but are implied based on the Federal Court’s subjective reading of the patent application. Even members of Canada’s generic drug industry, the principal beneficiaries of the promise utility doctrine, recognize that the result is a “free for all” involving a “hopeless tangle of contradictory approaches.”⁹³

61. Identifying the patent’s “promise” is inherently arbitrary and unpredictable. If a court finds a promise, regardless of whether the statement at issue was ever intended as such, the patentee will be held to that higher standard of utility.⁹⁴ The Federal Court of Appeal has explained that it is free to apply an additional utility hurdle to pharmaceutical patents if the court decides that more has been “promised” in the patent application:

An inventor whose invention is described in a patent which would otherwise be valid can nonetheless promise more for his invention than required by the Act so as to render his patent invalid.⁹⁵

62. The construal of a patent’s promise is now described as “fundamental to the utility analysis” and has become a routine feature of patent

⁹¹ *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197, at ¶ 76 (C-46).

⁹² Siebrasse Report at ¶ 41 (quoting *Mylan Pharms. ULC v. AstraZeneca Canada Inc.*, 2012 FCA 109, at ¶ 7 (C-236)).

⁹³ Apotex Application for Leave to Appeal to the Supreme Court of Canada, *Apotex v. Sanofi-Aventis* (30 September 2013) at ¶ 14.

⁹⁴ Siebrasse Report at ¶ 53.

⁹⁵ *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 186, at ¶ 54 (C-47).

litigation in Canada.⁹⁶ The Federal Courts now solicit expert testimony on proper construction of a patent's promise (or promises), something unheard of before 2005 in Canada⁹⁷ and unheard of in the United States and Mexico to this day. In practice, as Professor Siebrasse explains, "the courts very often find a promise in the patent, and consequently the standard for utility is very often the elevated requirement under the promise doctrine, rather than the lower standard" of the mere scintilla test.⁹⁸

63. The promise utility doctrine abandons the notion that an invention need only have a single asserted utility. Under the promise utility doctrine, a single patent may be found to contain multiple promises, in which case *all* promises must be met. For example, in a case involving the drug esomeprazole, the Federal Court identified and addressed as many as five promises: utility was established for three promises, but the patent was invalidated because it lacked utility with respect to the two others.⁹⁹ This is in stark contrast to the traditional mere scintilla test in the 1990s, under which any one utility sufficed.¹⁰⁰

64. The Federal Courts' application of the doctrine also is arbitrary. Interpretation of a patent's promise is completely unpredictable. For example, in two cases regarding the glaucoma drug latanoprost, two panels of the Federal Court of Appeal found different promises in construing the same patent, and as a

⁹⁶ *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197, at ¶ 93 (C-46).

⁹⁷ Siebrasse Report at ¶ 78.

⁹⁸ *Id.* at ¶ 43.

⁹⁹ *Astrazeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638, at ¶¶ 214-218 (C-48). As Professor Siebrasse explains, the three main promises were (1) use as a proton pump inhibitor; (2) stability against racemization; and (3) improved therapeutic profile. *Id.*, at ¶ 133. The extension to the second considered chemical and enzyme-mediated racemization (*id.*, at ¶ 103), and the third promise included improved pharmacokinetic and metabolic properties, and a putative extension to a lower degree of interindividual variation (*id.*, at ¶ 104). The promise that the drug was useful as use as a proton pump inhibitor was met, but the promise of an improved therapeutic profile over previous drugs (including two sub-promises) was not. See Siebrasse Report at ¶ 51.

¹⁰⁰ Siebrasse Report at ¶ 77.

result reached directly opposite results.¹⁰¹ In both cases, the same trial court judge found that the promised utility of the patent was the treatment of glaucoma and upheld the patent's validity.¹⁰² In the first appeal, the Federal Court of Appeal shared the trial court's interpretation and affirmed.¹⁰³ But in the second appeal (involving exactly the same patent but a different generic challenger), the Federal Court of Appeal reversed. In that case, the court found that since glaucoma is a "chronic" condition, it was implicit that the "promise of the patent is chronic use of the compound for a chronic medical condition."¹⁰⁴ As a result of this implicit promise, the court determined that the patentee would need to have included evidence of long-term human clinical trials in its patent application to meet the utility test. Emphasizing that single dose studies on animals and healthy humans included in the patent application were no substitute for long-term human clinical trials, the Federal Court found the patent lacked utility.¹⁰⁵ The Federal Court of Appeal, construing the very same patent on two different occasions, thus reached directly opposite conclusions on this decisive legal issue.

65. This interpretive process is unpredictable in part because Federal Courts often seek to construe the promise of the patent not from the patent claims that legally define the scope of invention, but from statements in the disclosure never intended to relate to utility. As Professor Siebrasse explains:

Construction of the promise is an arbitrary and hair-splitting exercise because the statutory function of the disclosure is to disclose the invention, not to define it. It is the role of the claims to define the invention. Patentees have always been aware of the need for precision in claim drafting, but the whole purpose of claims is to isolate the definition of the invention, exactly so that patent drafters

¹⁰¹ Siebrasse Report at ¶¶ 48-50.

¹⁰² See *Pfizer Canada Inc. v. Pharmascience Inc.*, 2009 FC 1294, at ¶¶ 140-148; *Pfizer Canada Inc. v. Apotex Inc.*, 2010 FC 447, at ¶¶ 167-175 (C-49).

¹⁰³ *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 102, at ¶ 9 (reading the promised utility to be "the treatment of glaucoma or ocular hypertension without substantial ocular irritation") (C-98).

¹⁰⁴ *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, at ¶ 29 (C-99).

¹⁰⁵ *Id.* at ¶¶ 30-32, 47-50 (C-99).

need not hesitate to provide a fulsome disclosure. The effect of the promise doctrine is to take words which were intended to disclose the invention, and use them for the “antagonistic” purpose of defining the invention.¹⁰⁶

2. Heightened Evidentiary Burdens

66. The second core element of the promise utility doctrine is a heightened evidentiary burden. Under the doctrine, Canadian courts often closely scrutinize and second-guess the evidence relied upon to demonstrate or soundly predict utility in a manner usually reserved for health regulatory officials determining if a drug is safe and effective to market. In the pharmaceutical context, it is commonplace to look to *in vitro* testing or *in vivo* testing in animals to show utility, even if the asserted utility is treatment of a human condition. It was previously accepted in Canada -- and it still is accepted in the United States and Mexico -- that clinical trials are not necessary to meet the utility requirement. But under the promise utility doctrine, if a patent is found to promise utility in treating humans, nothing less than human clinical trials will suffice to demonstrate utility.¹⁰⁷ This is problematic, to say the least, given that it is quite unusual to have completed human clinical trials prior to filing for a patent.

67. Even completing human tests by the filing date is no guarantee of securing and maintaining patent rights in Canada. In several cases, positive and statistically significant results from clinical trials have been insufficient to demonstrate utility, as the Federal Courts will scrutinize the methodology and result of successful human studies,¹⁰⁸ including an examination of the design, size, and duration of the study.

68. Similarly, with regard to “sound prediction” of utility, Canadian Federal Courts have applied a heightened evidentiary burden with regard to both

¹⁰⁶ Siebrasse Report at ¶ 53.

¹⁰⁷ Siebrasse Report at ¶ 59 (discussing the implications of *Apotex Inc. v. Wellcome Found. Ltd.*, 2002 SCC 77 (C-213)).

¹⁰⁸ Siebrasse Report at ¶ 59.

the factual basis of the asserted utility and the line of reasoning from which the asserted utility can be inferred, finding in several pharmaceutical cases that even considerable scientific evidence fails to render utility soundly predicted.¹⁰⁹ In the latanoprost case discussed above, the Federal Court discounted evidence disclosed in the application of successful case studies on humans and animal testing on cats, rabbits, and monkeys. The court instead criticized the patentee for conducting only “single dose” studies on animals and healthy humans, and concluded that the implicit promise of “chronic use of the compound for a chronic medical condition” had not been soundly predicted.¹¹⁰

69. A final component of Canada’s heightened evidentiary burden is that post-filing evidence, which previously was widely-accepted as support of utility, is now prohibited.¹¹¹ It is counter-intuitive, to say the least, that a commercially-successful pharmaceutical used by thousands of patients lacks utility. In nearly every case where the validity of a pharmaceutical patent is challenged, the clinical effectiveness and commercial use of the drug are beyond dispute: indeed, the generic challenger seeks to invalidate the patent precisely so that it can sell the useful drug itself.

70. In its 2002 *AZT* decision rendered after the Zyprexa and Strattera patents were filed and granted, the Supreme Court of Canada reversed this long-standing evidentiary rule, holding for the first time that post-filing evidence of utility is inadmissible.¹¹² In that case, the trial court accepted that AZT was “a primary drug in the treatment of HIV/AIDS” and concluded that AZT’s utility had been “conclusively established . . . subsequent to the claimed date of

¹⁰⁹ See *Abbott Laboratories v. Canada (Minister of Health)*, 2005 FC 1332, at ¶¶ 78-99, *aff’d* 2007 FCA 153 (C-113); *Pfizer Canada Inc. v. Apotex Inc.*, (2007) 59 CPR (4th) 183 (FC), at ¶¶ 55-60, *aff’d* 2007 FCA 195 (C-114); *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, at ¶¶ 162-178, *aff’d*, 2009 FCA 97 (C-115).

¹¹⁰ *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, at ¶¶ 29, 31 (C-99).

¹¹¹ Siebrasse Report at ¶¶ 30-31.

¹¹² Siebrasse Report at ¶ 54.

invention.”¹¹³ The Federal Court of Appeal found that AZT met the mere scintilla test because it “is indeed useful to treat HIV.”¹¹⁴ The Supreme Court, however, ruled that evidence of scientific effectiveness and commercial use was inadmissible because it was generated after the filing date¹¹⁵

71. In the pharmaceutical sector, the impact of this doctrinal reversal excluding post-filing evidence has been substantial. As Professor Siebrasse explains:

The change in the law eliminating the ability to rely on post-filing evidence of utility has had a dramatic impact on the ability to prove that a pharmaceutical invention meets the utility requirement.

Because patents for pharmaceuticals are invariably filed long before marketing authorization is obtained, commercial use can no longer be used to establish utility. Due to the high evidentiary burden imposed by the Canadian courts, even early stage human trials, such as may be carried out prior to patenting, are often not adequate to demonstrate utility to the satisfaction of the Canadian courts, particularly when the utility of the patent is assessed against an elevated promise of clinical efficacy, or a similar standard.¹¹⁶

72. While Canada’s promise utility doctrine imposes a ban on post-filing evidence to demonstrate or soundly predict utility, post-filing evidence *remains admissible for other purposes*. Post-filing evidence can be used to demonstrate a lack of utility, for example, or to establish non-obviousness,¹¹⁷ and the Canadian Patent Office itself is authorized to conduct post-filing experiments with specimens provided by the applicant.¹¹⁸

¹¹³ *Apotex Inc. v. Wellcome Foundation Ltd.*, (1998) 79 CPR (3d) 193 (FCTD), at ¶ 100 (C-116).

¹¹⁴ *Apotex Inc. v. Wellcome Foundation Ltd.*, (2000) 10 CPR (4th) (FCA), at ¶ 53 (C-117).

¹¹⁵ *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, at ¶¶ 46, 80-85 (C-213).

¹¹⁶ Siebrasse Report at ¶¶ 56-57.

¹¹⁷ *Id.* at ¶ 55.

¹¹⁸ *Id.* at ¶ 36; Patent Act (Canada), RSC, 1985, c. P-4, at § 38 (C-50).

3. Additional Disclosure for Soundly-Predicted Utility

73. The third core element of the promise utility doctrine is an additional disclosure obligation that applies when a patentee cannot demonstrate utility as of the filing date of the patent, and therefore must rely on a sound prediction of the utility. For decades, it was well established in Canada that a patentee seeking to establish utility did not have to disclose supporting evidence in the patent.¹¹⁹ If any questions about utility arose, which was rare, additional support could be provided. That remains the rule in the United States and Mexico. But today, the Federal Courts have interpreted *AZT* to mean that where utility is based on a sound prediction, “there is a heightened obligation [on the patentee] to disclose the underlying facts and the line of reasoning for inventions that comprise the prediction” in the patent application itself.¹²⁰

74. In the Federal Court decision establishing this requirement, the invention at issue was use of the compound raloxifene for the treatment of osteoporosis. The Federal Court held that there was sufficient pre-filing evidence, in the form of a factual basis and a line of reasoning, to establish a sound prediction of utility.¹²¹ But because a key study conducted in Hong Kong before the filing date was not expressly referenced in the patent, the trial court found the patent to lack utility.¹²² The Federal Court of Appeal affirmed, holding that in sound prediction cases “there is a heightened obligation to disclose the underlying facts and the line of reasoning for inventions that comprise the prediction.”¹²³

75. Absurdly, the Federal Courts will admit and scrutinize evidence that is not disclosed in the patent to determine whether it is sufficient to “demonstrate” the utility of the invention, but if such evidence is deemed insufficient to

¹¹⁹ Siebrasse Report at ¶ 40.

¹²⁰ *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97, at ¶ 14 (C-115).

¹²¹ *Id.* at ¶¶ 156, 162 (C-115).

¹²² *Id.* at ¶¶ 163-178 (C-115).

¹²³ *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97, at ¶ 14 (C-119).

“demonstrate” utility, then it is *inadmissible* to establish that there was a sound prediction of utility. This disclosure rule has been applied retroactively to support allegations of invalidity against patents – like the raloxifene patent – for which there was sufficient evidence, before the filing date, to support a sound prediction of utility, but that evidence was not expressly referenced in the patent.¹²⁴ To be clear, the applicant would not have known to include it at the time of filing, since at that time such evidence outside the four corners of the patent application would have been accepted to answer any future questions about the utility of the invention.

4. Application of the Promise Utility Doctrine by the Patent Office

76. The promise utility doctrine has been expressly incorporated into the Canadian Patent Office’s examination manual (MOPOP).¹²⁵ Recent versions of the Manual reflect the new utility requirements created by Canada’s Federal Courts.¹²⁶ In 2005, the Patent Office inserted a section into the Manual entitled “Predicted Utility.”¹²⁷ The new section required that “[i]f utility of the subject matter which forms the basis of a claim is not apparent or the promised utility of the subject matter is in doubt, then the applicant must have established utility, at the claim date, either by demonstration (i.e. testing the invention and conclusively proving utility) or by sound prediction.”¹²⁸ The section went on to embrace the new three-part test for sound prediction articulated in [AZT].

77. In 2009, revisions to the MOPOP introduced new and lengthy subsections on utility covering “Sound Prediction” and “Sufficiency of the

¹²⁴ Siebrasse Report at ¶¶ 61, 68-70.

¹²⁵ See Wilson Report at ¶ 47.

¹²⁶ *Id.*

¹²⁷ CANADIAN INTELLECTUAL PROPERTY OFFICE – PATENT OFFICE, MANUAL OF PATENT OFFICE PRACTICE § 12.03.01 (February 2005) (C-58).

¹²⁸ *Id.* (C-58).

Description.”¹²⁹ These discussions quoted extensively from recent promise utility decisions in the Federal Court of Appeal. Moreover, a novel section entitled “Relevant Date” for the first time required that “the factual basis upon which either the demonstration or sound prediction are based must necessarily exist as of the filing date.”¹³⁰

78. A further set of changes to the MOPOP was introduced in 2010. These additions focused on the new, additional disclosure requirement for soundly-predicted utility. The text reflects the uncertainty surrounding Canadian case law on sound prediction: “The extent to which the sound line of reasoning must be described can only be evaluated on a case-by-case basis, and will depend on similar factors to those related to the factual basis.”¹³¹

5. Arbitrary Nature of the Promise Utility Doctrine

79. While the arbitrary nature of the promise utility doctrine will be discussed in detail in Part VII explaining Canada’s breaches of Chapter 11, it is worth underscoring the dramatic legal changes embodied in the doctrine and its overall effects. All three aspects of Canada’s unique promise utility doctrine – construction of a patent’s promised utility; imposition of heightened evidentiary burdens, including a ban on post-filing evidence; and creation of an additional disclosure rule for sound prediction of utility – did not exist in Canadian law when Lilly drafted and filed its Zyprexa and Strattera patents and when the Patent Office examined and granted Lilly’s applications.

80. Individually, each aspect of the promise utility doctrine makes it more difficult to establish utility, and easier to attack the validity of a patent.

¹²⁹ CANADIAN INTELLECTUAL PROPERTY OFFICE – PATENT OFFICE, MANUAL OF PATENT OFFICE PRACTICE § 12.08.04 (December 2009) (C-59); *see also* Wilson Report at ¶ 48.

¹³⁰ Wilson Report at ¶ 48 (citing CANADIAN INTELLECTUAL PROPERTY OFFICE – PATENT OFFICE, MANUAL OF PATENT OFFICE PRACTICE § 12.08.05 (2009) (C-59).

¹³¹ CANADIAN INTELLECTUAL PROPERTY OFFICE – PATENT OFFICE, MANUAL OF PATENT OFFICE PRACTICE § 9.04.01b (December 2010) (C-60).

Collectively, the different elements interact in a way that magnifies their effects. The overall result, according to Professor Siebrasse, is striking:

The elevated standard for utility imposed by the promise of the patent, and the rule against post-filing evidence, both independently make it harder to establish utility, the former by raising the bar, the latter by restricting the available evidence. . . .

Because the elevated standard for utility and the prohibition of post-filing evidence make it more difficult to establish demonstrated utility, utility based on sound prediction has become far more important than under prior law. In particular, under prior law, demonstrated utility could easily be established for any commercially valuable product by the simple fact that the product was actually being used to treat a disorder.

While sound prediction has become much more important than under prior law, the changes to the law under the Promise Utility Doctrine have also made it more difficult to establish utility based on sound prediction. In the first place, the promise of the patent and the rule against post-filing evidence both apply equally to sound prediction, thereby making sound prediction more difficult to establish for the same reasons that demonstrated utility is now more difficult to establish.

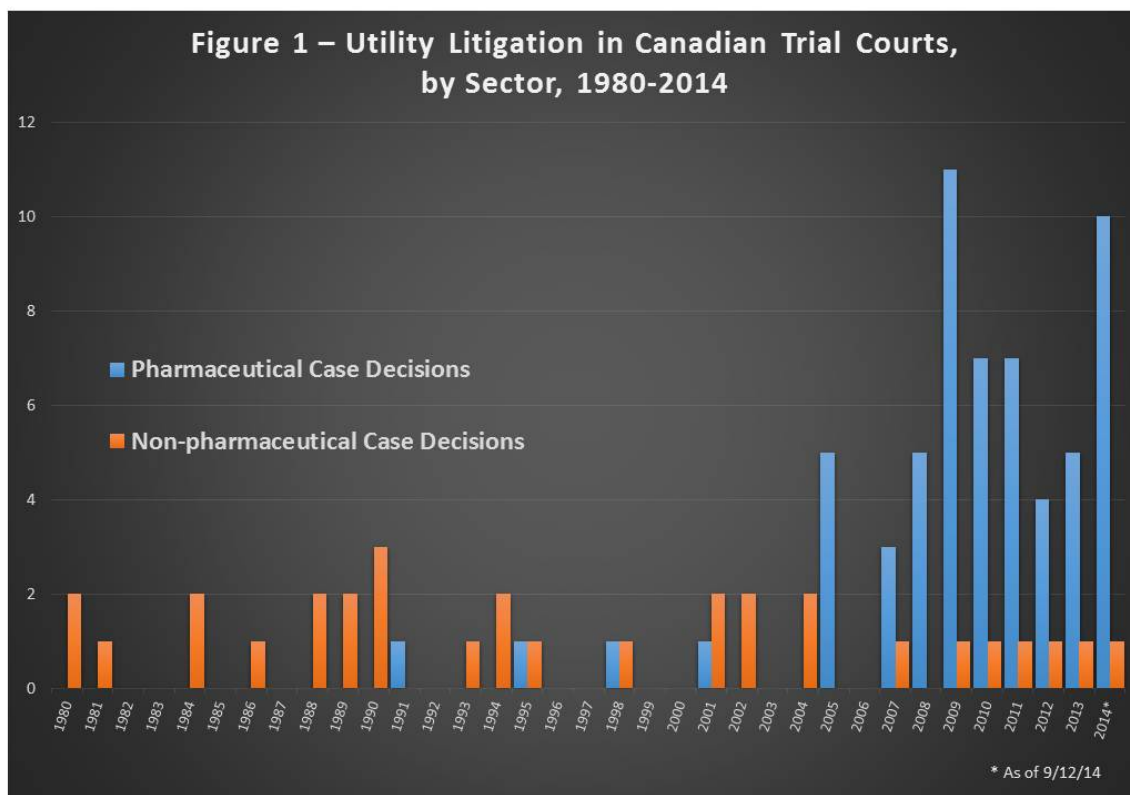
In addition, the disclosure requirement that is applicable only to sound prediction further restricts the evidence available to establish utility.¹³²

81. These dramatic developments in Canada's doctrine have invited a correspondingly dramatic rise in utility challenges since the promise utility doctrine was first applied in 2005. As the bar graph in Figure 1 shows, the surge in Federal Court decisions on utility has been almost exclusively within the pharmaceutical sector.¹³³ Since 2005, the number of utility decisions regarding pharmaceutical inventions has outpaced cases in all other sectors combined, by a

¹³² Siebrasse Report at ¶¶ 106-110.

¹³³ See "Figure 1 - Utility Litigation in Canadian Trial Courts, by Sector" (Appendix 1); "Chronological List of Canadian Utility Decisions from 1980 to Present" (C-305).

ratio of 8 to 1. This sudden interest in utility corresponds to Canada’s adoption of the promise utility doctrine.



82. Canada’s promise utility doctrine creates new and impermissible hurdles to patentability. The rise of the doctrine and the rise of utility challenges to pharmaceutical patents in the Federal Courts have gone hand-in-hand. The subjective nature of the “promise of the patent,” the heightened evidentiary burdens, and the additional disclosure for soundly-predicted utility all work together to inappropriately elevate the utility test. In the words of Professor Siebrasse, the promise utility doctrine is “frequently fatal to validity, particularly in the pharmaceutical sector, as a potential response to one element of the doctrine is blocked by another element, magnifying the cumulative impact.”¹³⁴ As

¹³⁴ Siebrasse Report at ¶ 18.

explained in detail below, this is precisely what happened when the Federal Courts applied the promise utility doctrine to Zyprexa and Strattera, leading to the wrongful revocation of those patents in a manner contrary to Canada's obligations under NAFTA Chapter 11.

IV. THE WRONGFUL REVOCATION OF THE ZYPREXA AND STRATTERA PATENTS SOLELY FOR LACK OF UTILITY.

A. Canada's Invalidation of Lilly's Patent for Zyprexa Is Wrongful.

83. *Zyprexa* (olanzapine) is a second-generation antipsychotic medicine that addressed long-standing deficiencies in the first-generation antipsychotics that were previously used to treat schizophrenia.¹³⁵ Schizophrenia patients who were prescribed first-generation antipsychotics often continued to experience feelings of apathy and social withdrawal – two common symptoms of schizophrenia.¹³⁶ Many also exhibited so-called “extra-pyramidal symptoms” (“EPS”), side effects that left them unable to initiate or control movement.¹³⁷ Zyprexa addressed these problems by treating the symptoms of schizophrenia with fewer side effects than the first generation of anti-psychotics.¹³⁸

¹³⁵ Direct Testimony of Robert Postlethwait (hereinafter Postlethwait Statement) at ¶¶ 9-16.

¹³⁶ Postlethwait Statement at ¶ 10.

¹³⁷ Postlethwait Statement at ¶ 11; *ESSENTIALS OF CLINICAL PSYCHOPHARMACOLOGY* 307 (Alan F. Schatzberg & Charles B. Nemeroff, eds., 2d ed. 2006) (describing EPS caused by first-generation antipsychotics) (C-121).

¹³⁸ Postlethwait Statement at ¶ 13; see, e.g., Nila Bhana et al., *Olanzapine: An Updated Review of its Use in the Management of Schizophrenia*, 61-1 *DRUGS* 112, 113 (2001) (“The reduced risk of adverse events and therapeutic superiority compared with haloperidol and risperidone in the treatment of negative and depressive symptoms support the choice of olanzapine as a first-line option in the management of schizophrenia in the acute phase and for the maintenance of treatment response.”) (C-122); John Kane, *Olanzapine in the Long-Term Treatment of Schizophrenia*, 174-37 *BRIT. J. PSYCHIATRY SUPPL.* 26, 28 (1999) (“The atypical drug, olanzapine, with a favourable toxicity profile and proven efficacy, offers a promising alternative to previous treatments.”) (C-123); AS Hale, *Olanzapine*, 58-9 *BRIT. J. HOSP. MED.* 442, 445 (1997) (“Olanzapine’s efficacy against positive symptoms is equivalent to [first-generation antipsychotic] haloperidol and its efficacy against negative symptoms is superior to haloperidol . . . It shows placebo level extrapyramidal side-effects at clinical doses.”) (C-124).

1. Lilly Obtained Patent Protection and Regulatory Approval for Zyprexa in Canada.

84. Lilly first synthesized Zyprexa in 1982 at its Erl Wood research campus in the United Kingdom.¹³⁹ After years of intensive pre-clinical study, Lilly progressed to human clinical trials in 1986.¹⁴⁰ In 1986 and 1987, clinical trials were carried out with healthy volunteers, and beginning in 1989 further trials were conducted in patients with schizophrenia.¹⁴¹ These trials were successful, and the company sought patent protection for olanzapine and pursued regulatory approval to bring the product to market.¹⁴²

85. Consistent with its normal practice, Lilly first filed for a patent in the jurisdiction of Zyprexa's invention, the United Kingdom, in April 1990.¹⁴³ Once this initial patent application was filed, Lilly's Foreign Patent Committee was tasked with deciding how widely to file for patent protection in other jurisdictions.¹⁴⁴ The Foreign Patent Committee considered Zyprexa to have strong potential for clinical use, and accordingly authorized filing patent applications in a long list of foreign jurisdictions, including Canada.¹⁴⁵ Lilly obtained patents in 81 jurisdictions,¹⁴⁶ including the Canada, Mexico, and the United States.¹⁴⁷

86. When Lilly's Foreign Patent Committee was considering Zyprexa in January 1991, the company had no reason to suspect that Canada would deny or

¹³⁹ Postlethwait Statement at ¶ 13.

¹⁴⁰ *Id.* at ¶ 15.

¹⁴¹ *Id.*

¹⁴² *Id.* at ¶ 16.

¹⁴³ Receipt for U.K. Patent Office Application No. 9009229/7 (25 April 1990) (C-125).

¹⁴⁴ Stringer Statement at ¶¶ 6, 10.

¹⁴⁵ *Id.* at ¶ 18.

¹⁴⁶ Armitage Statement at ¶ 11 (listing 81 jurisdictions).

¹⁴⁷ Canadian Patent Application No. 02,041,113 (published 24 April 1991) (Eli Lilly & Co., Applicant) (C-126); U.S. Patent Application No. 07/690,143 (published 23 April 1991) (Eli Lilly & Co., Applicant), superseded by U.S. Patent Application No. 07/890,348 (published 22 May 1992) (Eli Lilly & Co., Applicant) (C-128).

invalidate its Zyprexa patent for lack of utility.¹⁴⁸ Potential patentability issues were regularly evaluated as part of the Lilly's Foreign Patent Committee process, and utility was simply not raised as a potential concern for Zyprexa.¹⁴⁹ In fact, the compounds claimed within the genus patent from which Zyprexa derived (Canadian Patent No. 1,075,687) had already been found to have utility by the Patent Office,¹⁵⁰ and the utility of the genus patent was never challenged in Canada.

87. If anything, Zyprexa was unusual precisely because of the volume of clinical evidence that supported its efficacy in 1990 and 1991. Given that successful clinical trials had been completed, utility was never considered an issue.

88. Once the patent applications were filed, Lilly began to prepare to launch Zyprexa with the expectation that its patent applications would be granted. As Bob Postlethwait, the Lilly executive who oversaw the launch of Zyprexa explains: "Strong patent protection was a key factor in deciding where and when to launch any new medicine, including Zyprexa. This was particularly true for major markets like Canada and the United States, which required Lilly to devote substantial resources to launch a product."¹⁵¹

89. As the Zyprexa team prepared for market launch, they received regular updates on the status of pending patent applications.¹⁵² Mr. Postlethwait "would specifically ask [his] team if there were any patent issues about which we should be concerned."¹⁵³ No issues relating to Canada or the utility requirement

¹⁴⁸ Stringer Statement at ¶ 19.

¹⁴⁹ *Id.* at ¶ 8.

¹⁵⁰ See Canadian Patent No. 1,075,687 (C-129).

¹⁵¹ Postlethwait Statement at ¶ 21.

¹⁵² *Id.* at ¶ 22.

¹⁵³ *Id.* at ¶ 22.

were ever raised.¹⁵⁴ In fact, at the time, Canada was actively seeking U.S. investment in the pharmaceutical sector, and holding out its reliable framework for patent protection as a reason to invest in Canada.¹⁵⁵

90. An olanzapine status report reflects Lilly's expectations that it would obtain patents in Canada and other non-U.S. jurisdictions, and indicates no concern that Canadian authorities would take a different approach to Zyprexa's patentability than those of other jurisdictions.¹⁵⁶ Lilly's optimism was well founded: Zyprexa ultimately received patent protection in 81 jurisdictions, including through the European Patent Convention and the Gulf Cooperation Council regions.¹⁵⁷

91. Consistent with Lilly's expectations, the Zyprexa application was allowed by the Canadian Patent Office, and issued as a patent.¹⁵⁸ Lilly submitted its application in 1991. Under Canadian practice, an application is not examined by a patent examiner until the applicant requests examination and pays a second filing fee.¹⁵⁹ Lilly requested examination of its application on October 13, 1995, about a year before its planned launch of the drug.¹⁶⁰ The examination process in Canada was thorough.¹⁶¹ After addressing all issues raised by the examiner, none of which pertained to utility, Lilly received notice from the Patent Office that its application would be accepted on 17 March 1998.¹⁶² The patent, Canadian Patent

¹⁵⁴ *Id.* at ¶ 25.

¹⁵⁵ *Id.* at ¶ 26.

¹⁵⁶ Olanzapine Status Report (February 1995), at 1.4 (Confidential Exhibit C-130); *see also* Olanzapine Sales Forecast (February 1994), at *6 (Confidential Exhibit C-306).

¹⁵⁷ Armitage Statement at ¶ 11.

¹⁵⁸ Wilson Report at ¶ 36.

¹⁵⁹ Patent Act (Canada), RSC, 1985, c. P-4, at § 34(1) (C-50).

¹⁶⁰ Request for Examination (Canadian Patent Application 2,041,113) (Zyprexa/Olanzapine) (C-131).

¹⁶¹ Wilson Report at ¶¶ 34-37.

¹⁶² Notice of Allowance re Canadian Patent Application No. 2,041,113 (Zyprexa/Olanzapine) (5 September 1997) (C-65).

No. 2,041,113 (the '113 patent), issued on 14 July 1998.¹⁶³ According to Mr. Wilson, the decision by the Patent Office to grant the Zyprexa patent was in accordance with the MOPOP requirements for utility at that time.¹⁶⁴

92. By the time the patent issued, Zyprexa had been declared a safe and effective treatment for schizophrenia by health regulatory authorities in Canada¹⁶⁵ and dozens of other countries, including both the United States and Mexico.¹⁶⁶ Health regulators relied upon clinical studies demonstrating Zyprexa's safety and effectiveness; these studies involved more than 3,100 patients in 22 countries.¹⁶⁷ Lilly launched Zyprexa in Canada and the United States in 1996, immediately after receiving regulatory approval. Increased use by patents was rapid given the drug's dramatic benefits as an anti-psychotic,¹⁶⁸ and by 2000, nearly 4 million patients around the world had been prescribed Zyprexa for schizophrenia.¹⁶⁹

¹⁶³ Canadian Patent No. 2,041,113 (14 July 1998) (C-132).

¹⁶⁴ Wilson Report at ¶ 38.

¹⁶⁵ Notice of Compliance DIN(s) 02229250, 02229269, 02229277, 02229285 (28 October 1996) (C-133).

¹⁶⁶ See U.S. Food and Drug Administration, NDA 20-592 Approval (30 September 1996) (C-134); Mexico Secretary of Health, No. 236M97 SSA Approval (2 June 1997) (C-135); Commission of the European Communities, Commission Decision Granting the Marketing Authorization for the Medicinal Product for Human Use, "Zyprexa - Olanzapine" (27 September 1996) (C-136).

¹⁶⁷ CenterWatch, *Zyprexa*, <https://www.centerwatch.com/drug-information/fda-approved-drugs/drug/164/zyprexa> ("Lilly submitted data from extensive clinical trials involving more than 3,100 people in 22 countries.") (C-137). CenterWatch is an independent and privately owned publishing and information services provider of clinical trials information.

¹⁶⁸ Postlethwait Statement at ¶¶ 31-32; *Olanzapine may help AD-related symptoms*, 11-11 BROWN UNIVERSITY LONG-TERM CARE QUALITY ADVISOR 3 (1999) ("First introduced in 1996, the antipsychotic drug olanzapine (Zyprexa) has been prescribed for the management of symptoms of psychotic disorders in millions of schizophrenia patients worldwide.") (C-138); Shari Roan, *For Schizophrenics on Medi-Cal, a Dose of Good News*, LOS ANGELES TIMES, 6 October 1997 ("These drugs are the most miraculous I've ever seen," Rusty [Selix, executive director of the Mental Health Assn. in California] says. "The difference they make in people's lives puts them in a class by themselves.") (C-139); *Prix Galien Winners Around the Globe*, <http://prix-galien-usa.com/en/website/halloffame/prix-galien-winners-around-the-globe> (Eli Lilly UK won a Galien Award in 1997 for Zyprexa) (C-140); *Queen's Award for Lilly and Pfizer*, 264 THE PHARMACEUTICAL JOURNAL 643 (29 April 2000) (C-141).

¹⁶⁹ *Lilly's Zyprexa(R) Demonstrates Superior Clinical Benefits in Head-to-Head Comparison with Risperdal; Clinical Improvement at No Increased Cost*, PR NEWSWIRE, 12 May 2000 (C-142); Naomi Aoki, (continued...)

2. Despite a Showing of Industrial Value and Extensive Pre-Clinical and Clinical Evidence of Therapeutic Effects, Canada's Federal Courts Invalidated the Zyprexa Patent On the Sole Ground of Inutility.

93. More than a decade after Zyprexa's successful launch, and several years before the '113 patent was set to expire, the Canadian drug manufacturer Novopharm Limited in 2007 sought and obtained regulatory approval from Health Canada to market a generic version of Zyprexa.¹⁷⁰ Lilly immediately filed suit against Novopharm, which is now known as Teva Canada Limited, for infringement of the '113 patent.¹⁷¹ Lilly was confident in its patent for numerous reasons, not the least of which because Canadian drug manufacturer Apotex had challenged the patent the year before and the Federal Court had upheld the patent.

94. Among its defenses to infringement, Novopharm alleged lack of novelty, double-patenting, wrong inventorship, obviousness, misrepresentation, deemed abandonment, and that the Zyprexa patent was not a "valid selection patent."¹⁷² While rejecting Novopharm's allegations of obviousness, misrepresentation, and abandonment,¹⁷³ and while emphasizing that the court was "satisfied that olanzapine is a useful drug for the treatment of schizophrenia,"¹⁷⁴ the court nevertheless, in a decision issued on October 5, 2009, held that the '113 patent for Zyprexa is "not a valid selection patent" and dismissed Lilly's action for infringement.¹⁷⁵

Biotechnology; Drugs for Mental Ills Elusive, Causes of Diseases Poorly Understood, BOSTON GLOBE, 25 April 2001, at C4 (C-143).

¹⁷⁰ Novopharm received its Notice of Compliance ("NOC") for olanzapine on June 6, 2007, one day after the Federal Court denied Lilly's request to prohibit Health Canada from granting the NOC (C-151); see *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596 (C-144).

¹⁷¹ See *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 1018, ¶¶ 1-6 (C-145).

¹⁷² *Id.* at ¶ 10 (C-145).

¹⁷³ *Id.* at ¶¶ 149-153 (C-145).

¹⁷⁴ *Id.* at ¶ 154 (C-145).

¹⁷⁵ *Id.* (C-145).

95. Lilly sought review by the Federal Court of Appeal, which set aside the trial court's judgment on July 21, 2010.¹⁷⁶ The appeals court ruled that a selection patent, like any patent, may be challenged only on grounds set out in the Patent Act.¹⁷⁷ After finding that the '113 patent was both novel and non-obvious, the Federal Court of Appeal remanded the case to the trial court for determination of two remaining issues: utility and sufficiency of disclosure.¹⁷⁸

96. The '113 patent for Zyprexa claimed the olanzapine compound as well as the use of that compound for the short- and long-term treatment of schizophrenia and related psychotic disorders, and for the short-term treatment of manic or mixed episodes in bipolar I disorder.¹⁷⁹ In support of the compound's asserted therapeutic utility, Lilly summarized in the '113 patent the results of extensive research conducted prior to the filing date, including:

- *in vitro* lab tests showing that the compound has antipsychotic properties;
- *in vivo* animal tests, in mice and rats, showing results that are predictive of antipsychotic activity, along with a toxicity study in dogs showing lesser side effects than an analogous compound;
- four studies on small groups of healthy human volunteers showing the compound's relatively low side effects;
- a completed open-label study of the compound's therapeutic effects on schizophrenia patients, where six out of eight patients who completed at least two weeks of treatment showed between 66% and 87% improvement in their symptoms; and

¹⁷⁶ *Eli Lilly v. Novopharm Ltd.*, 2010 FCA 197, ¶ 124 (C-46).

¹⁷⁷ *Id.* at ¶ 39 (C-46).

¹⁷⁸ *Id.* at ¶¶ 109-112, 123-124 (C-46).

¹⁷⁹ Canadian Patent Application No. 02,041,113 (C-126).

- three additional clinical trials, ongoing at the time of filing, whose preliminary results confirmed high levels of efficacy, at lower dosage levels than in the prior completed study.¹⁸⁰

97. In addition to the extensive supporting evidence disclosed in the '113 patent itself, prior to the filing date in Canada Lilly had completed additional clinical trials evaluating the compound's side effects.¹⁸¹ These studies were not referenced in the patent application, and the law in Canada at the time they were filed was such that the studies could be considered whether in the application or not.

98. Moreover, the '113 patent possessed the same utility of the broader genus from which the Zyprexa compound was discovered – a utility that was never questioned when the genus patent was granted. Given that the genus patent had utility, a compound within the genus is typically presumed to retain that same utility, absent evidence to the contrary.¹⁸²

99. On remand in the Federal Court, within the context of the promise utility doctrine, Lilly noted that the Zyprexa patent expressly stated that experimental tests and clinical trials “indicate [Zyprexa’s] usefulness for the relatively safe and effective treatment of a wide range of disorders of the central nervous system.”¹⁸³

100. Based on the evidence disclosed in the '113 patent, the Federal Court accepted that Zyprexa would have qualified as useful if the asserted utility was that the compound is a relatively safe and effective anti-psychotic:

If the utility of the invention in the '113 patent relates merely to a compound with potential antipsychotic properties that might have

¹⁸⁰ See Canadian Patent No. 2,041,113, at pp. 4-6 (C-132); *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, ¶¶ 33-35, 126 (C-146) .

¹⁸¹ See Postlethwait Statement at ¶ 15-16.

¹⁸² Siebrasse Report at ¶ 97; Merges Report at ¶ 46.

¹⁸³ Canadian Patent No. 2,041,113, at p. 4 (C-132).

relatively low EPS liability [for side effects], that utility had been demonstrated by the tests conducted prior to the filing date.¹⁸⁴

101. With regard to sound prediction, the Federal Court held unequivocally that evidence in the '113 patent "does set out a rational basis for making a sound prediction that olanzapine would be useful in the treatment of schizophrenia."¹⁸⁵

102. The Federal Court, however, rejected Lilly's submissions that even under the promise utility doctrine the drug met the utility requirement in that it was shown to be a relatively safe and effective anti-psychotic. The Court refused to "accept that the '113's promise was so small."¹⁸⁶ Following guidance from the Federal Court of Appeal, the Court declined to apply what it described as "the usual requirement [that] the patent holder need only show a scintilla of utility for the patent to be valid"¹⁸⁷ – a standard that it conceded had been met. Instead, the Federal Court found "that the promise of the patent is that olanzapine treats schizophrenia patients in the clinic in a markedly superior fashion with a better side-effects profile than other known antipsychotics."¹⁸⁸

103. The '113 patent was thus construed by the Federal Court as making an elevated promise of utility, above and beyond the statutory minimum. The Court's "promise" did not focus on the claims defining the invention. Instead, its interpretation rested heavily on a general, summary statement in the disclosure regarding Zyprexa's comparative advantages over known compounds in the same field:

Overall, therefore, in clinical situations, the compound of the invention shows marked superiority and a better side effects profile

¹⁸⁴ *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, ¶ 209 (C-146).

¹⁸⁵ *Id.* at ¶ 255 (C-146).

¹⁸⁶ *Id.* at ¶ 209 (C-146).

¹⁸⁷ *Id.* at ¶ 84 (C-146).

¹⁸⁸ *Id.* at ¶ 209 (C-146).

than prior known antipsychotic agents, and has a highly advantageous activity level.¹⁸⁹

104. That statement in the disclosure of the compound's general advantages led the Federal Court to construe the patent's promised utility specifically as follows: "[O]lanzapine is substantially better ('marked superiority') in the clinical treatment of schizophrenia (and related conditions) than other known antipsychotics, with a better side-effects profile, and a high level of activity at low doses."¹⁹⁰

105. The Court did not stop there. The Federal Court also expanded its reading of the '113 patent to encompass implicit promises based on the nature of the disease. These implicit promises, again, were nowhere in the patent claims. Citing a 2011 utility decision by the Federal Court of Appeal regarding the glaucoma medication latanoprost, the Court explained that "where a patented compound is claimed to be safe and effective in the treatment of a chronic condition, utility will be demonstrated if the patent discloses studies showing that the patented compound, when administered over a long term, meets that promise."¹⁹¹ Noting that "[c]learly, schizophrenia is a chronic condition," the Court thus required that Lilly have evidence from long-term clinical trials as of the application date in April 1991 in order to meet the utility requirement.¹⁹² The Court further held that "the promise of the patent as construed" from the disclosure applies equally to all of the patent's claims.¹⁹³

106. Having adopted this expansive view of the patent's promise, the Federal Court summarily concluded that Lilly had failed to demonstrate the promised utility on the filing date. The Court emphasized that Lilly by then had

¹⁸⁹ *Id.* at ¶ 120 (C-146).

¹⁹⁰ *Id.* at ¶ 124 (C-146); *see also id.* ¶¶ 45-47, 107-110 (discussion of "overall, therefore" sentence) (C-146).

¹⁹¹ *Id.* at ¶ 210 (citing *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2011 FCA 236, ¶ 30) (C-146).

¹⁹² *Id.* (C-146).

¹⁹³ *Id.* at ¶ 225 (C-146).

completed “only one” study of Zyprexa involving schizophrenia patients, and that all of the human studies “involved a small number of subjects over a short period of time.”¹⁹⁴ While conceding that witnesses “agreed that Lilly had some early positive signals about olanzapine’s efficacy and safety,” the Court held that this evidence was “clearly insufficient to demonstrate olanzapine’s capacity to treat schizophrenia patients in the clinic in a superior fashion and with fewer side effects than other known antipsychotics.”¹⁹⁵ For guidance on what would meet Canada’s test, the Court approvingly quoted an expert who opined that “to prove the promise of the patent, you would certainly need to conduct [placebo-controlled clinical trials in sufficiently large groups of patients].”¹⁹⁶

107. The Federal Court then turned to the issue of whether Lilly had soundly predicted the promised utility of the ‘113 patent. Citing the animal studies and human clinical trials, the Federal Court of Appeal had already determined that “the ‘113 patent sets out a sufficient factual basis for a sound prediction of the patent’s promise.”¹⁹⁷ The only question for the Court, then, was “whether there was an articulable line of reasoning – that is, a *prima facie* reasonable inference – from that factual basis to the patent’s promise.”¹⁹⁸

108. For certain aspects of the promise, the Federal Court found that “the information in Lilly’s possession in April 1991 could support reasonable inferences” that Zyprexa had antipsychotic properties; had a safe range with regard to one side effects marker; and might have a lower risk of other side effects than conventional treatments.¹⁹⁹ Based on that evidence, however, “one could not

¹⁹⁴ *Id.* at ¶¶ 206, 211 (C-146).

¹⁹⁵ *Id.* at ¶¶ 212-213 (C-146).

¹⁹⁶ *Id.* at ¶ 212 (brackets in original) (C-146).

¹⁹⁷ *Id.* at ¶ 91 (C-146).

¹⁹⁸ *Id.* (C-146).

¹⁹⁹ *Id.* at ¶ 218 (C-146).

reasonably infer” that Zyprexa “would treat schizophrenia patients in the clinic in a markedly superior way,” or predict its overall side-effects liability.²⁰⁰

109. Again, the Court emphasized “the chronic nature of schizophrenia,” whose treatment “is not a short-term proposition.”²⁰¹ Again, the Court stressed that the sole clinical trial assessing therapeutic effectiveness was regarded as “preliminary, hypothesis-generating and, at best, providing early, positive signals that would warrant further study.”²⁰² The Federal Court thus concluded that “inventors could not draw a *prima facie* reasonable inference from the information available in April 1991 to the promise of the ‘113 patent that olanzapine could treat schizophrenia patients significantly better, and with fewer side effects, than other known antipsychotic drugs.”²⁰³ In the Court’s view, “Lilly scientists showed persistence, diligence and sound science” in obtaining the “early signals of safety and efficacy in a few small studies of healthy volunteers and patients,” but “[t]here must be an invention,” and the ‘113 patent was filed “before [Lilly] had a basis on which to found a sound prediction” of Zyprexa’s promised utility.²⁰⁴

110. Given Canada’s prohibition on post-filing evidence of utility, the Federal Court gave no consideration to additional studies that Lilly had conducted showing the effectiveness of the drug at the time Lilly filed for its patent. The Court’s invalidation of the ‘113 patent for Zyprexa rested on the sole ground of inutility, as the patent was held to satisfy the statutory requirement for sufficiency of disclosure.²⁰⁵

²⁰⁰ *Id.* (C-146).

²⁰¹ *Id.* at ¶ 230; *see also id.* ¶ 232 (“The chronic nature of the condition treated by a patented compound must be taken into account when determining whether the patent’s promise has been demonstrated or can be soundly predicted.”) (C-146).

²⁰² *Id.* at ¶ 237 (C-146).

²⁰³ *Id.* at ¶ 219 (C-146).

²⁰⁴ *Id.* at ¶ 265 (C-146).

²⁰⁵ *Id.* at ¶ 272 (C-146).

111. In sum, the Federal Court found that tests conducted prior to the filing date would have demonstrated (or soundly predicted) the utility of the Zyprexa patent under the mere scintilla utility test applied by Canada during the 1990s. But after finding promises of utility in statements in the disclosure of the '113 patent, and emphasizing that schizophrenia is a "chronic condition" requiring long-term clinical trials, as the promise doctrine dictates, the Court found extensive pre-filing evidence to be insufficient to demonstrate or soundly predict the "promised" utility. According to Professor Siebrasse, "the olanzapine patent would have been valid under prior law; and was invalid under the Promise Utility Doctrine because of the exclusion of post-filing evidence and the heightened utility requirement established by the promise of the patent."²⁰⁶

112. On September 10, 2012, the Federal Court of Appeal – in a one-sentence decision delivered from the bench – dismissed Lilly's appeal.²⁰⁷ Lilly's application for leave to appeal was denied by the Supreme Court of Canada on May 16, 2013.²⁰⁸ This denial exhausted all domestic appeals regarding the Zyprexa '113 patent in Canada.

113. As in Canada, the Zyprexa patent was challenged on multiple grounds in the United States. The generic manufacturers alleged anticipation, obviousness, double patenting, prior public use, and inequitable conduct. The federal district court upheld the validity of the patent on all grounds, and the court of appeals affirmed.²⁰⁹ In Mexico, there has been no litigation challenging the Zyprexa patent.²¹⁰

²⁰⁶ Siebrasse Report at ¶ 98; *see also* Merges Report at ¶¶ 44-46.

²⁰⁷ *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2012 FCA 232 (C-147).

²⁰⁸ Supreme Court of Canada, Case No. 35067.

²⁰⁹ *See Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals, Inc.*, 364 F. Supp. 2d 820 (S.D. Ind. 2005) (C-148); *Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals, Inc.*, 471 F. 3d 1369 (Fed. Cir. 2006) (C-149).

²¹⁰ Salazar Report at ¶ 35; Gonzalez Report at ¶ 31.

114. The patent for Zyprexa has been granted and upheld around the world. Lilly holds Zyprexa patents in 81 jurisdictions: Argentina, Australia, Austria, Bahrain, Bangladesh, Belarus, Belgium, Belize, Bermuda, Bolivia, Bosnia-Herzegovina, Botswana, Brazil, Brunei, Bulgaria, Burundi, Canada, the Cayman Islands, China, Cyprus, the Czech Republic, the Democratic Republic of the Congo, Denmark, the Dominican Republic, Ethiopia, the European Patent Convention region, Fiji, Finland, France, Gambia, Georgia, Germany, Great Britain, Greece, Guernsey, the Gulf Cooperation Council region, Guyana, Hong Kong, Hungary, Iran, Ireland, Israel, Italy, Jamaica, Japan, Kazakhstan, South Korea, Kosovo, Kuwait, Latvia, Luxembourg, Mexico, Montenegro, the Netherlands, New Zealand, Norway, Oman, Pakistan, Panama, Paraguay, the Philippines, Portugal, Romania, Russia, Rwanda, Saudi Arabia, Serbia, Sierra Leone, Singapore, the Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan, Trinidad & Tobago, Ukraine, the United Arab Emirates, the United States and Uruguay.²¹¹ These patents have been challenged in 24 countries, and upheld in all of them, except for Saudi Arabia and Slovenia.²¹²

115. Canada is the only jurisdiction in the world that has invalidated the Zyprexa patent on the ground of inutility.²¹³ In fact, Canada is the only jurisdiction in the world where the patent has even been challenged on the ground of inutility.²¹⁴

116. As a result of the Federal Court's invalidation of the Zyprexa patent under the promise utility doctrine, Lilly lost its patent rights. Today, generic drug

²¹¹ Armitage Statement at ¶ 11.

²¹² In Slovenia, a claim was invalidated on novelty grounds. In Saudi Arabia, where Zyprexa was protected by both a Saudi patent and a Gulf Cooperation Council patent, the Saudi patent was struck down on an issue related to the calculation of priority dates but the Gulf Cooperation Council patent remained valid and enforceable. *Id.*

²¹³ Armitage Statement at ¶ 18. The patent was challenged and upheld in Australia, Austria, Bulgaria, China, the Czech Republic, Finland, Germany, Great Britain, Greece, Hungary, South Korea, the Netherlands, Norway, Pakistan, Portugal, Romania, Russia, the Slovak Republic, Spain, Ukraine and the United States. *Id.* at ¶ 17.

²¹⁴ *Id.* at ¶ 18.

manufacturers are free to sell – and are – a version of Lilly’s “useless” drug in Canada.

B. Canada’s Invalidation of Lilly’s Patent for Strattera Is Wrongful.

117. *Strattera* (atomoxetine) was the first non-stimulant treatment for attention-deficit hyperactivity disorder (“ADHD”).²¹⁵ As its name suggests, ADHD is a condition associated with hyperactivity, impulsiveness, and an inability to focus.²¹⁶ Prior to *Strattera*’s launch, ADHD was mainly treated with stimulants.²¹⁷ Stimulants were ineffective in some patients and were associated with significant side effects, including insomnia and anxiety.²¹⁸ They were also highly addictive, and doctors were often reluctant to prescribe a drug known to have an abuse potential comparable to amphetamines.²¹⁹ Because *Strattera* was a non-stimulant, it avoided the problems associated with earlier drugs and provided a valuable treatment alternative for many adolescents and adults at risk of abusing stimulants.²²⁰

1. Lilly Obtained Patent Protection and Regulatory Approval for Strattera in Canada.

118. Lilly first began research on atomoxetine in the early 1980s, when the compound was discovered to have potential as a treatment for depression.²²¹ While Lilly researchers found that the compound had an excellent safety profile, they were not able to establish a sufficient effect on the treatment of depression to further advance the compound’s development.²²²

²¹⁵ Direct Testimony of Anne Nobles (“Nobles”) at ¶ 24.

²¹⁶ *Id.* at ¶ 5.

²¹⁷ *Id.* at ¶ 6.

²¹⁸ *Id.* at ¶ 6.

²¹⁹ *Id.* at ¶ 6.

²²⁰ *Id.* at ¶ 25.

²²¹ *Id.* at ¶ 7.

²²² *Id.* at ¶ 7.

119. Two Lilly scientists, Dr. John Heilingenstein and Dr. Gary Tollefson, then discovered that the drug could potentially be used to treat ADHD. Lilly applied for the initial patent on Strattera, a U.S. patent, on January 11, 1995.²²³ Lilly then approached doctors at the Massachusetts General Hospital (“MGH”) with a proposal for a joint human clinical trial to test the efficacy of atomoxetine in treating ADHD.²²⁴ The trial, approved by the FDA and conducted from January through April 1995, was eventually published in the *American Journal of Psychiatry*.²²⁵ Based on the successful MGH study and other research, Lilly decided to move forward with research on the drug as a candidate for regulatory approval and clinical use.²²⁶

120. Once the initial patent application was filed for Strattera, Lilly’s Foreign Patent Committee met to determine how widely to file in other jurisdictions. Like Zyprexa, Strattera was perceived as having strong potential for clinical use, and the Foreign Patent Committee accordingly decided to file widely.²²⁷ At no time during the process were any concerns raised about utility, either in Canada or elsewhere.²²⁸

121. Lilly filed its foreign patent applications for Strattera using the Patent Cooperation Treaty (PCT). Lilly filed a PCT application on January 4, 1996,²²⁹ and the company requested entry into the Canadian national phase on July 7, 1997.²³⁰ As with Zyprexa, the timing of Lilly’s patent applications for

²²³ U.S. Patent Application No. 08/371,341 (published 11 January 1995) (Eli Lilly & Co., Applicant) (C-153).

²²⁴ Nobles Statement at ¶ 8.

²²⁵ Thomas Spencer, et al., *Effectiveness and Tolerability of Tomoxetine in Adults with Attention Deficit Hyperactivity Disorder*, 155 AM. J. PSYCHIATRY 693 (May 1998) (C-152).

²²⁶ Nobles Statement at ¶ 9.

²²⁷ Stringer Statement at ¶ 24.

²²⁸ *Id.* at ¶ 25.

²²⁹ See Canadian Patent Application No. 2,209,735 (published 18 July 1996) (Eli Lilly & Co., Applicant) (C-154).

²³⁰ *Id.*; Erstling Report at ¶ 17-22.

Strattera was somewhat unusual, in that Lilly had already conducted a clinical trial before it filed its PCT application. The Foreign Patent Committee was aware of the trials and filed without further delay, given the risk of submitting a foreign patent application after the successful results of clinical testing had become public knowledge.²³¹

122. Strattera is known as a “method of use” patent.²³² A method of use patent claims (and entitles the patent-holder to exclusivity for) a particular clinical use for a particular compound. In the case of Strattera, the patent claimed the compound atomoxetine for a specific use of the treatment of ADHD.²³³

123. Lilly expected that Strattera would be eligible for patent protection under Canadian law.²³⁴ Anne Nobles, who led Lilly’s Strattera global launch, explains that “[p]atent protection was an extremely important consideration in determining whether and how to launch Strattera in a particular market.”²³⁵ Consistent with Ms. Nobles’ recollections, Lilly’s “Launch Guidelines” for Strattera required that patents be “filed or granted by local authorities” prior to launch.²³⁶

124. Because of the importance of patent protection to the successful launch of Strattera, Ms. Nobles received regular updates on the prosecution of Strattera patents across all major jurisdictions, but she recalls no issues related to the validity of Lilly’s Canadian patent application.²³⁷ Specifically, Ms. Nobles recalls no discussion at all of the utility requirement for Strattera.²³⁸ Lilly’s risk

²³¹ Stringer Statement at ¶ 23.

²³² Nobles Statement at ¶ 15.

²³³ Stringer Statement at ¶ 15.

²³⁴ Nobles Statement at ¶ 23.

²³⁵ *Id.* at ¶ 14.

²³⁶ Strattera - Launch Guidelines v. 1.2 (14 June 2002), at 3 (Confidential Exhibit C-155).

²³⁷ Nobles Statement at ¶¶ 14, 23.

²³⁸ Nobles Statement at ¶ 17.

management plans for the Strattera launch likewise revealed no cause for concern.²³⁹ As with Zyprexa, Lilly's expectations regarding patentability were borne out. Lilly requested examination on February 27, 2001,²⁴⁰ and filed a request to expedite examination in January 2002.²⁴¹ The Canadian Patent Office conducted a thorough examination and did not note any objections on Lilly's application.²⁴² Lilly received its notice of allowance just over a month after its request to expedite, on March 4, 2002.²⁴³ The patent, Canadian Patent No. 2,209,735 (the '735 patent), was issued on October 1, 2002.²⁴⁴ According to Mr. Wilson, the Patent Office's decision to grant the Strattera patent was consistent with the MOPOP's utility requirements at that time.²⁴⁵ Lilly also received patent protection for Strattera in dozens of other jurisdictions in which it applied.²⁴⁶

125. With its safety and efficacy evidenced by six randomized, double-blind, placebo-controlled studies in children, adolescents, and adults,²⁴⁷ Strattera was approved for sale by the U.S. Food and Drug Administration a few days before the publication of the Canadian patent.²⁴⁸ Mexican regulatory approval was secured on May 29, 2003,²⁴⁹ and Health Canada's approval was received on

²³⁹ For example, Lilly developed a risk management plan relating to the global launch of Strattera, and patent protection in Canada was not identified as a risk. See Summary of Risk Management Plan (Confidential Exhibit C-156).

²⁴⁰ Request for Examination re Canadian Patent Application 2,209,735 (Strattera/Atomoxetine) (C-66).

²⁴¹ Request to Advance Examination (Canadian Patent Application 2,209,735) (Strattera) (C-157).

²⁴² Wilson Report at ¶¶ 43-44.

²⁴³ Notice of Allowance re Canadian Patent Application 2,209,735 (Strattera/Atomoxetine) (21 March 2002) (C-69).

²⁴⁴ Canadian Patent No. 2,209,735 (1 December 2002) (Strattera) (C-67).

²⁴⁵ Wilson Report at ¶ 45.

²⁴⁶ Armitage Statement at ¶ 19 and Appendix B.

²⁴⁷ CENTERWATCH, *Strattera*, <https://www.centerwatch.com/drug-information/fda-approved-drugs/drug/164/strattera> (C-158).

²⁴⁸ See *id.*

²⁴⁹ Mexican Secretariat of Health, No. 220M2003 SSA Approval (29 May 2003) (Strattera) (C-164).

December 24, 2004.²⁵⁰ Lilly launched in all three markets immediately after receiving regulatory approval. As with Zyprexa, use by patients was rapid; while Strattera has not replaced stimulants, it has provided doctors with a valuable treatment option, particularly for patients affected by anxiety or at risk for substance abuse.²⁵¹

2. Despite Clear Industrial Value and Clinical Trial Results Published in a Peer-Reviewed Journal, Canada’s Federal Courts Invalidated the Strattera Patent on the Sole Ground of Inutility.

126. A few years after Strattera’s successful launch, Canadian drug manufacturer Novopharm (now known as Teva Canada Limited) filed suit to invalidate the ‘735 patent and thereby obtain regulatory approval to market a generic version of atomoxetine in Canada.

127. Novopharm alleged that the ‘735 patent for Strattera was invalid on the grounds of obviousness, anticipation, incomplete disclosure of the compound’s selection, and inutility.²⁵² The Federal Court held that the ‘735 patent was both non-obvious and new, and that it was not a selection patent.²⁵³

128. With regard to utility, Lilly principally supported the drug’s utility through the MGH study of the compound’s therapeutic effects. This research involved a seven-week, placebo-controlled, double-blind, crossover study of the compound in 22 adult patients with ADHD. The results of the study, obtained

²⁵⁰ Notice of Compliance DIN(s) 02262827, 02262835, 02262843, 02262800, 02262819 (24 December 2004) (C-159).

²⁵¹ Nobles Statement at ¶ 25.

²⁵² *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, ¶ 3 (C-160). One of Novopharm’s allegations was that the patent was invalid because anticipatory disclosure had taken place in connection with the MGH study. *See id.* at ¶ 81 (“The second of these [alleged instances of anticipatory disclosure] was a conversation between Dr. Heiligenstein and Dr. Spencer in 1993 or 1994 when they discussed the possibility of MGH conducting research into compounds to treat ADHD on behalf of Lilly.”). As discussed *infra* at ¶ 266, this allegation reveals the “Catch-22” risk that pharmaceutical companies face when they conduct human clinical trials before filing for patent protection.

²⁵³ *Id.* at ¶¶ 77, 79, 87-88 (C-160).

prior to the filing of Canada's international PCT application (and, *inter alia*, prior to the Canadian filing date as well), showed a positive and statistically significant response for atomoxetine over a placebo. Eleven of the 21 patients who completed the study showed a 30 percent or greater reduction in ADHD symptoms.²⁵⁴

129. These results were published in the *American Journal of Psychiatry*, a prestigious peer-reviewed journal.²⁵⁵ Although not disclosed in the patent application, the results were submitted to Health Canada and included with other clinical research findings in the dossier leading to the approval of Strattera. The study, moreover, was cited in a 2003 Canadian government publication on atomoxetine as one of "three randomized, double blind, placebo controlled trials... conducted in adults with ADHD," and summarized as having "demonstrated a statistically significant decrease in ADHD [symptoms] in the [atomoxetine] group compared to placebo."²⁵⁶

130. The trial court accepted that Strattera met the mere scintilla utility test, as the compound had been "shown to be somewhat useful to treat ADHD."²⁵⁷ Citing the Federal Court of Appeal decision on Zyprexa, the trial court nonetheless insisted that "utility is assessed against the inventive promises of the patent," and that "[a]n invention is only useful if it does what the inventor claims it will do."²⁵⁸

131. According to the trial court, the promise of the '735 patent was as follows:

²⁵⁴ *Id.* at ¶¶ 96-97 (C-160).

²⁵⁵ T. Spencer, et al., *Effectiveness and Tolerability of Tomoxetine in Adults with Attention Deficit Hyperactivity Disorder*, 155 AM. J. PSYCHIATRY 693 (May 1998) (C-152).

²⁵⁶ *Issues in Emerging Health Technologies: Atomoxetine for Attention Deficit / Hyperactivity Disorder*, CANADIAN COORDINATING OFFICE FOR HEALTH TECH. ASSESSMENT, Issue 46 (May 2003), at 3 & n.13 (C-162).

²⁵⁷ *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, ¶ 93 (C-160).

²⁵⁸ *Id.* (citing *Eli Lilly v. Novopharm*, 2010 FCA 197, ¶ 76) (C-160).

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.²⁵⁹

132. Emphasizing that “ADHD is a chronic disorder requiring sustained treatment,” and questioning the evidentiary weight to be assigned to experimental results, the Federal Court then identified in the '735 patent an additional *implicit* promise of long-term effectiveness:

Only where experimental results are sufficiently compelling to independently support the inventive promise (or to support a sound prediction) is utility established. In the case of the '735 Patent, the inventors claimed a new use for atomoxetine to effectively treat humans with ADHD. What is implicit in this promise is that atomoxetine will work in the longer term.²⁶⁰

133. Based on this implicit promise, the trial court required that Lilly – as of the filing date in 1996 – have affirmative evidence of Strattera’s long-term clinical effectiveness in order to satisfy Canada’s elevated utility requirement. This implied promise of long-term effectiveness was construed from the '735 patent even though Strattera is approved for short-term treatment of acute ADHD, in addition to long-term treatment of the disorder.²⁶¹

134. In evaluating demonstrated utility, the Federal Court closely scrutinized the methodology of the MGH study on which Lilly relied. For example, the Court seized upon statements by authors of the study that the results were “preliminary” and “promising,” that the trial had certain “limitations,” and that their “findings should be confirmed in a larger study with a parallel design.”²⁶² The Court even accepted testimony speculating that the study might

²⁵⁹ *Id.* (C-160).

²⁶⁰ *Id.* at ¶ 112 (C-160).

²⁶¹ This fact was presented to the court. See *Eli Lilly & Co. v. Teva Canada Ltd.*, 2011 FCA 220, at ¶ 28 (C-163).

²⁶² *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, at ¶¶ 98, 101, 113 (C-160).

have been “compromised” if patients, after experiencing side effects of atomoxetine, “may have been able to effectively break the blind” by detecting when they received active compound as opposed to placebo.²⁶³

135. On the basis of “evidence about the limitations of the MGH Study,” the Federal Court held that “its reported results do not demonstrate the clinical utility of atomoxetine to treat ADHD in adults.”²⁶⁴ The Court explained: “This was a clinical trial that was too small in size and too short in duration to provide anything more than interesting but inconclusive data.”²⁶⁵

136. With regard to sound prediction, the Federal Court conceded that “an initial study of this sort might provide a basis for a sound prediction of utility.”²⁶⁶ However, citing the 2002 *AZT* decision of the Supreme Court of Canada, the Court stated that for sound prediction, it is “beyond debate that an additional disclosure obligation arises” and that “this obligation is met by disclosing in the patent both the factual data on which the prediction is based and the line of reasoning followed to enable the prediction to be made.”²⁶⁷

137. Because the completed MGH study was not explicitly referred to in the ‘735 patent, the trial court held that “the patent fails for want of disclosure because some reference to those findings was required to be set out in the patent.”²⁶⁸ In sum, having found an implicit promise of long-term effectiveness, the Federal Court closely scrutinized and found insufficient for purposes of demonstrated utility the statistically significant, positive results of a placebo-controlled, double-blind, crossover human trial that merited publication in the *American Journal of Psychiatry*. Then, as a basis for rejecting a sound prediction of

²⁶³ *Id.* at ¶ 102 (C-160).

²⁶⁴ *Id.* at ¶ 113 (C-160).

²⁶⁵ *Id.* (C-160).

²⁶⁶ *Id.* (C-160)

²⁶⁷ *Id.* at ¶ 117 (emphasis in original) (C-160).

²⁶⁸ *Id.* at ¶ 120 (C-160).

utility, the Court applied a disclosure rule that did not exist when the patent application was filed and granted by the Patent Office, and held that Lilly's failure to refer to that study in the patent was fatal to the patent's validity.

138. Effectively acknowledging that this result was unfair, the Federal Court noted Lilly's point "that the validity of the '735 Patent is now being assessed against the backdrop of a more rigorous disclosure obligation than may have been apparent at the time of its filing in 1996."²⁶⁹ The Court nonetheless emphasized that the disclosure rule is binding precedent, "and to the extent that it may be amenable to reconsideration, it must be examined elsewhere."²⁷⁰

139. In a decision rendered on July 5, 2011, the Federal Court of Appeal found no reversible error and dismissed Lilly's appeal.²⁷¹ The appeal court affirmed the trial court's interpretation of the '735 patent's promise, and found no error in the reference to an "implicit" promise for long-term treatment.²⁷² The appeal court declined to address a different case where a study of similar size, with results that did not reach statistical significance, was held to demonstrate utility.²⁷³ Lilly then sought leave to appeal from the Supreme Court of Canada. That Leave Application was denied on December 8, 2011, exhausting all domestic appeals regarding the '735 patent for Strattera.²⁷⁴

140. Canada's invalidation of the Strattera patent rested squarely and exclusively on the promise utility doctrine. As Professor Siebrasse concludes:

Under the mere scintilla standard, the patent would have been held to have utility, because utility would have been measured by the "scintilla" required under the [Patent] Act, rather than by the construed promise of clinical utility. . . .

²⁶⁹ *Id.* at ¶ 121 (C-160).

²⁷⁰ *Id.* (C-160).

²⁷¹ *Eli Lilly & Co. v. Teva Canada Ltd.*, 2011 FCA 220, ¶ 56 (C-163).

²⁷² *Id.* at ¶¶ 19-21, 27-30 (C-160).

²⁷³ *Id.* at ¶¶ 41-43 (C-160).

²⁷⁴ Supreme Court of Canada Docket No. 34396.

In summary, the atomoxetine patent would have been valid under prior law. The invalidity of the patent turned on three novel rules of Canadian law, namely the heightened standard for utility under the promise doctrine; the exclusion of post-filing evidence; and the requirement that evidence of sound prediction must be disclosed in the patent.²⁷⁵

141. As with Zyprexa, the Strattera patent was challenged in the United States, and was upheld as valid. The U.S. patent application for Strattera contained identical disclosures to the Canadian patent, though when the U.S. patent was filed, the MGH study had been initiated, but not completed. A district court judge in New Jersey initially held that the Strattera patent was invalid for failing to properly enable the invention as required by Section 112 of the U.S. Patent Act.²⁷⁶ On appeal, the Federal Circuit noted that the generic firms seeking to invalidate the patent “do not dispute that the ‘590 patent described the utility of [atomoxetine] for treatment of ADHD, and the utility is correctly described.”²⁷⁷ The Federal Court, in an unpublished opinion that broke no new legal ground, went on to reverse the trial court and conclude that Lilly had met the Section 112 enablement requirement.²⁷⁸ There has been no litigation challenge to the Strattera patent in Mexico.²⁷⁹

142. Lilly held Strattera patents in a total of 36 jurisdictions: Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, the European Patent Convention region, Finland, France, Germany, Great Britain, Greece, Hungary, Ireland, Italy, Jamaica, Latvia, Liechtenstein, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Russia, Singapore, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United States. Aside from Canada and the United States, the only other jurisdiction in

²⁷⁵ Siebrasse Report at ¶¶ 102-103.

²⁷⁶ See *Eli Lilly & Co. v. Actavis Elizabeth LLC*, No. 2010-1500 (Fed. Cir., July 29, 2011) (C-83), reversing 676 F. Supp. 2d 352 (D.N.J. 2009) and 731 F. Supp. 2d 348 (D.N.J. 2010).

²⁷⁷ *Id.* at 12.

²⁷⁸ *Id.*

²⁷⁹ See Armitage Statement ¶ 21 and Attachment B.

which the Strattera patent has been challenged is Denmark, on grounds of obviousness and insufficiency of disclosure, not utility.²⁸⁰ The patent was found valid, and the decision was not appealed.²⁸¹

143. Canada is the only jurisdiction in the world that has invalidated the Strattera patent for lack of utility. Canada is the only jurisdiction in the world even to entertain such a challenge.²⁸²

144. As a result of the Federal Court's invalidation of the Strattera patent under the promise utility doctrine, Lilly lost its patent rights, and generic drug manufacturers are selling versions of Lilly's "useless" Strattera drug in Canada today.²⁸³

V. THE UTILITY STANDARD IN OTHER NAFTA JURISDICTIONS CONTRASTS SHARPLY WITH CANADA'S PROMISE UTILITY DOCTRINE.

145. Canada's application of an elevated utility requirement to the Zyprexa and Strattera patents bears no resemblance to the longstanding patent utility standards of its NAFTA partners, the United States and Mexico. Both during the 1990s and today, for an invention to qualify as useful or industrially applicable in the United States and Mexico, it must simply have the capacity to be put to an industrial use. This threshold is low, and unlike in Canada, the utility test in the United States and Mexico has been consistently applied since NAFTA entered into force.

²⁸⁰ See Danish Patent and Trademark Office, Decisions re Administrative Revocation Filed Against DK/EP Patent No. 0,721,777 (6 June 2012) (English Translation) (C-298). Paragraph 56 of the Notice of Arbitration and Statement of Claim incorrectly states that the Strattera patent had been challenged on the ground of utility in Denmark.

²⁸¹ *Id.* See Armitage Statement at ¶ 21 and Attachment B.

²⁸² *Id.* at ¶ 26.

²⁸³ *Id.*

1. United States

146. The United States extends patent protection to “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”²⁸⁴ In the words of the U.S. Court of Appeal for the Federal Circuit, the appellate court with special jurisdiction over patent cases, “[t]he threshold of utility is not high.”²⁸⁵ As Professor Merges explains:

In the United States, an asserted utility is generally presumed to satisfy the utility requirement. Once an inventor presents a specific, credible, and substantial use, the inventor has met his burden. Patent law in the United States does not require the inventor to establish any particular *degree* of usefulness. The invention just has to work – a simple yes/no inquiry. As the Federal Circuit put it, “[t]o violate § 101 the claimed device must be totally incapable of achieving a useful result.”²⁸⁶

147. This basic, binary standard has not varied over the years.²⁸⁷ In practice, an asserted utility is credible unless it is unbelievable on its face or wholly inoperative.²⁸⁸ The burden, it follows, is on the examiner to establish that an invention lacks utility, but even then the applicant has an opportunity to submit additional evidence, including post-filing evidence, to establish the credibility of the asserted use.²⁸⁹ As explained by Stephen Kunin, former Deputy Commissioner of the U.S. Patent and Trademark Office, inventions were found to lack credible utility only when it was “clear on the factual record ‘that the invention could not and did not work as the inventor claimed it did.’”²⁹⁰

²⁸⁴ See 35 U.S.C. § 101 (C-73).

²⁸⁵ *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999) (C-165).

²⁸⁶ Merges Report at ¶ 5 (emphasis in original) (quoting *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) (C-166)).

²⁸⁷ Merges Report at ¶ 7.

²⁸⁸ Kunin Report at ¶¶ 25, 34.

²⁸⁹ Merges Report at ¶¶ 18-19; see also Kunin Report at ¶¶ 25, 46, 51.

²⁹⁰ Kunin Report at ¶ 34 (citing United States Patent and Trademark Office, Manual of Patent Examination Procedure, § 2107.01(b) (1 September 1995)).

Examples include inventions that conflict with the laws of science, such as a perpetual motion machine.²⁹¹

148. Moreover, a patent applicant “need only make one credible assertion of specific utility.”²⁹² Any “additional statements of utility, even if not ‘credible,’ do not render the claimed invention lacking in utility.”²⁹³ Patent examiners in the United States do not reject applications based on a lack of utility if the invention is “useful for *any* particular practical purpose.”²⁹⁴

149. Only inventions that can work for a specific, real world purpose have patentable utility in the United States.²⁹⁵ Inventions with no definite and identifiable use, or with a nominal use of no practical significance, do not have specific and substantial utility.²⁹⁶ Examples that fail this test include inventions that produce basic research of no known use or that claim to treat an unspecified disease.²⁹⁷

150. Because the threshold for utility is low, patent challenges based on utility are rare in U.S. courts. According to one study, an academic analysis of U.S. patent validity cases from 1989 to 1996, only five cases in the full set of 300 included an allegation of inutility, and only one of these five utility challenges was successful.²⁹⁸

²⁹¹ *Id.* (citing *Newman v. Quigg*, 877 F.3d 1575, 11 USPQ2d 1350 (Fed. Cir. 1989)).

²⁹² United States Patent and Trademark Office, Manual of Patent Examination Procedure, § 2107.01(a) (1 September 1995); Kunin Report at ¶ 35.

²⁹³ *Id.*

²⁹⁴ Kunin Report at ¶ 42 (quoting United States Patent and Trademark Office, Manual of Patent Examining Procedure § 2107(II)(B) (August 2001)) (emphasis added).

²⁹⁵ Merges Report at ¶ 21; *see also* Kunin Report at ¶ 26.

²⁹⁶ Merges Report at ¶¶ 21-22.

²⁹⁷ Kunin Report at ¶ 44.

²⁹⁸ John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-209 (1998) (C-167).

151. In the pharmaceutical sector, the utility of an innovative drug is presumptively established when the specification states the condition to be treated by the invention. The Manual of Patent Examination Procedure (the “MPEP”), which is treated as authoritative by examiners at the U.S. Patent and Trademark Office, makes clear that “[i]nventions asserted to have utility in the treatment of human or animal disorders are subject to the same legal requirements for utility as inventions in any other field of technology.”²⁹⁹ The MPEP provides specific guidance on pharmaceutical inventions, emphasizing that “[c]ourts have repeatedly found that the mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides an ‘immediate benefit to the public’ and thus satisfies the utility requirement.”³⁰⁰ The MPEP further notes that “courts have found utility for therapeutic inventions despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition.”³⁰¹

152. As a result, the utility of a pharmaceutical compound is established well before it is ready for later-stage clinical testing, let alone public sale. As the United States Court of Appeals for Federal Circuit has explained:

FDA approval . . . is not a prerequisite for finding a compound useful within the meaning of the patent laws. 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

²⁹⁹ United States Patent and Trademark Office, Manual of Patent Examination Procedure, § 2107.01 (March 2014) (C-72).

³⁰⁰ *Id.* (emphasis in original) (C-72).

³⁰¹ *Id.* (C-72).

incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.³⁰²

153. In fact, if a drug has simply been approved for clinical study, U.S. examiners apply a strong presumption of utility in its favor. This rule is reflected in the MPEP, which explains:

Before a drug can enter human clinical trials, the sponsor, often the applicant, must provide a convincing rationale to those especially skilled in the art (e.g., the Food and Drug Administration) that the investigation may be successful. Such a rationale would provide a basis for the sponsor's expectation that the investigation may be successful. In order to determine a protocol for phase I testing, the first phase of clinical investigation, some credible rationale of how the drug might be effective or could be effective would be necessary. Thus, 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.³⁰³

154. Applying these guidelines from 1994 to present, U.S. examiners have consistently found that pharmaceutical patent applications have utility without any requirement that the underlying invention first be tested in human trials.³⁰⁴

2. Mexico

155. Mexican patent law requires that inventions have utility, and extends patent protection only to inventions that are "susceptible of industrial application."³⁰⁵ As explained by Gilda Gonzalez, former Deputy Director General of the Mexican Institute of Industrial Property ("IMPI"), "the requirement in

³⁰² *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) (C-168).

³⁰³ United States Patent and Trademark Office, Manual of Patent Examination Procedure, § 2107.03 (March 2014) (C-72) (emphasis in original); *see also* Kunin Report at ¶ 39.

³⁰⁴ Kunin Report at ¶¶ 39-40.

³⁰⁵ Industrial Property Law (IPL), Art. 16 (C-90).

Mexico is that the industrial application of an invention must be plausible, as opposed to certain.”³⁰⁶

156. As codified in Mexico’s Industrial Property Law (IPL), “industrial application” is defined as “the *possibility* of an invention having a practical utility or being produced or used in any branch of economic activity, for the purposes described in the application.”³⁰⁷ According to Ms. Gonzalez, this emphasis on the “possibility” of production or use means that “applicants are not obliged to submit proof that establishes the industrial application of the claimed invention; all that is required is a possibility.”³⁰⁸

157. The legal standard for industrial application in Mexico is uniform across the different technological fields in which innovation occurs. As explained by Ms. Gonzalez:

The information required to establish industrial applicability of pharmaceutical patents is the same as what would be required, for instance, in the case of a mechanical patent. Both applicants would have to expressly indicate that the invention can be produced or used in any branch of economic activity, unless this is apparent from the description of the patent application or the nature of the invention, in which case the applicant does not need to “expressly indicate” the possible industrial application.³⁰⁹

158. According to Fabian Salazar, former Director of the Patent Division at IMPI, examiners in Mexico analyze the industrial application requirement as follows:

³⁰⁶ Gonzalez Report at ¶ 18.

³⁰⁷ Industrial Property Law (IPL), Art. 12(IV) (emphasis added) (C-90). This definition dates to 2010, when existing practice at IMPI was codified in certain amendments. As adopted initially in 1994, the definition stated that “‘industrial application’ means the possibility of an invention being produced or used in any branch of economic activity.” See 1994 Industrial Property Law, Art. 12(IV) (C-91).

³⁰⁸ Gonzalez Report at ¶ 9.

³⁰⁹ Gonzalez Report at ¶ 17.

In practice, analysis of the industrial application requirement focuses on verification by the patent examiner that one of the two conditions considered in the definition of industrial application has been met, namely:

1. that the invention can be produced in any branch of economic activity, with this being defined as broadly as possible, or
2. that the invention can be used in any branch of economic activity, with this being defined as broadly as possible.

It should be pointed out that the IPL and its Regulations do not require the presentation of evidence in the patent application to prove that the patentability requirements have been met. It will, therefore, suffice that the applicant indicate or submit documents that on an indicative basis (through preliminary tests, comparative tables, etc.) suggest that the invention can possibly be produced or used in any branch of economic activity.³¹⁰

159. If an examiner were to question an invention's industrial application, the applicant would have the right to submit post-filing information or documentation to resolve any doubt. For example, according to Mr. Salazar, the applicant "may submit all kinds information or documents (such as *in vivo* or *in vitro* tests for pharmaceutical inventions) after the filing date, to address any objection issued during the substantive review."³¹¹

160. Given the low threshold established by statutory terms such as "susceptible" and "possibility," it is exceedingly rare for a patent to be denied or challenged for failure to satisfy the industrial application requirement. During his years of service at IMPI as head of the Patent Division, Mr. Salazar is not aware of a single case in which "any patent (including pharmaceutical patents) was denied for lack of industrial application."³¹² Similarly, throughout her term at IMPI, Ms.

³¹⁰ Salazar Report at ¶¶ 21-22.

³¹¹ Salazar Report at ¶ 24.

³¹² Salazar Report at ¶ 34.

Gonzalez does not recall a patent ever being “declared null for lack of industrial applicability,” nor does she “recall the ‘susceptible of industrial application’ requirement ever being an issue in litigation before IMPI or before the Federal Courts where IMPI was a defendant.”³¹³

VI. THE TRIBUNAL HAS JURISDICTION OVER CLAIMANT’S CLAIMS BROUGHT PURSUANT TO NAFTA CHAPTER 11.

161. It is uncontested that the dispute submitted in this proceeding is within the competence of the Tribunal pursuant to NAFTA Chapter 11.³¹⁴ All requirements for jurisdiction under NAFTA have been met. In brief:

162. *Lilly is a protected investor.* Article 1116 of NAFTA authorizes an “investor of a Party” to submit to arbitration a claim that another Party has breached its obligations under Chapter 11. An “investor of a Party” is defined in Article 1139 to mean “a Party or state enterprise thereof, or a national or an enterprise of such Party, that seeks to make, is making or has made an investment.”³¹⁵ An “enterprise of a Party,” in turn, is defined to mean “an enterprise constituted or organized under the law of a Party, and a branch located in the territory of a Party and carrying out business activities there.”³¹⁶ Lilly is an “enterprise of a Party” – and therefore has standing in this proceeding – because

³¹³ Gonzalez Report at ¶ 31.

³¹⁴ Under Article 21(3) of the UNCITRAL Rules, “[a] plea that the arbitral tribunal does not have jurisdiction shall be raised not later than in the statement of defence or, with respect to a counter-claim, in the reply to the counter-claim.” Respondent filed its Statement of Defence on 30 June 2014 and did not challenge this Tribunal’s jurisdiction, except to make the argument that the Tribunal “lacks jurisdiction to rule on alleged violations of any of TRIPS, PCT, or NAFTA Chapter Seventeen.” See Statement of Defence, ¶ 83. As Canada acknowledged during the procedural hearing, however, Respondent’s submissions on this issue are properly conceived as going to the merits, not jurisdiction. See Audio Recording of the First Procedural Hearing (10 May 2014) at 3:13-3:15.

³¹⁵ NAFTA art. 1139.

³¹⁶ *Id.* The term “enterprise” is further defined in Article 201 of NAFTA to mean “any entity constituted or organized under applicable law, whether or not for profit, and whether privately-owned or governmentally-owned, including any corporation, trust, partnership, sole proprietorship, joint venture or other association.”

it is a United States company duly incorporated under the laws of the state of Indiana with its principal place of business in Indianapolis, Indiana.³¹⁷

163. *Lilly's claims concern its protected investments in Canada.* Tribunals constituted under Chapter 11 have jurisdiction to consider measures in respect of covered "investments." Article 1139 of NAFTA defines "investment" to include, *inter alia*, "enterprise[s]" and "real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes." Lilly's Zyprexa and Strattera patents – which each encompass a bundle of exclusive property rights and the ability to enforce those rights – qualify as "investments" under Article 1139 because they are intangible property acquired in the expectation, or used for the purpose, of economic benefit or other business purposes.³¹⁸

164. *Lilly and Canada have each consented to arbitration of this dispute.* Lilly has previously consented to arbitration of this dispute in its Notice of Intent to Submit a Claim to Arbitration dated 13 June 2013 and its Notice of Arbitration dated 12 September 2013.³¹⁹ Canada has expressed its consent to arbitrate this dispute in Article 1122(1) of NAFTA, which provides that "[e]ach Party consents

³¹⁷ Office of the Secretary of State for the State of Indiana, Indiana Business Entity Report No. 183025-143 (Eli Lilly & Co.) (30 January 2013) (C-14). Pursuant to NAFTA Article 1117, the Tribunal also has jurisdiction to consider Lilly's claim brought on behalf of its wholly-owned subsidiary, Eli Lilly Canada Inc. See Affidavit of Jamie Haney (16 September 2014) (C-170).

³¹⁸ See Canadian Patent No. 2,041,113 (C-132); Canadian Patent No. 2,209,735 (C-67) (both showing the applicant and owner at page 1, line 73).

³¹⁹ Lilly's Notice of Intent to Submit a Claim to Arbitration satisfies the requirements of Article 1119 of NAFTA, which requires that "[t]he disputing investor shall deliver to the disputing Party written notice of its intention to submit a claim to arbitration at least 90 days before the claim is submitted." As noted in Lilly's Notice of Arbitration, Claimant initially delivered a Notice of Intent to Submit a Claim to Arbitration to Canada with regard to the Strattera patent on 7 November 2012. Claimant delivered a second Notice of Intent to Submit a Claim to Arbitration with regard to both the Strattera and Zyprexa patents on 13 June 2013. Both Notices of Intent raised identical claims, but the second Notice of Intent added the Zyprexa patent. Lilly withdrew its Strattera-only Notice of Intent in reliance on Canada's representation that it would not raise any jurisdictional or other preliminary objections specifically relating to the withdrawal. See Notice of Arbitration ¶ 19.

to the submission of a claim to arbitration in accordance with the procedures set out in this Agreement.”

165. *Lilly’s claims are timely.* Under NAFTA Article 1116(2) and 1117(2), “an investor may not make a claim if more than three years have elapsed from the date on which the investor first acquired, or should have first acquired, knowledge of the alleged breach and knowledge that the investor has incurred loss or damage.” In addition, pursuant to Article 1120, six months must elapse after the “events giving rise to a claim,” before an investor may submit the claim to arbitration. Lilly’s claims are timely under these standards. As discussed above, the Federal Court trial judge invalidated the Strattera patents on the sole ground of inutility on 14 September 2010. The Zyprexa patent was invalidated on the sole ground of inutility on 10 November 2011. Lilly’s Notice of Arbitration was filed on 12 September 2013, which is more than six months but less than three years after these dates.

VII. CANADA’S TERMINATION OF LILLY’S PATENT RIGHTS WITH REGARD TO ZYPREXA AND STRATTERA IS INCONSISTENT WITH NAFTA CHAPTER 11.

166. Lilly asserts two claims to relief under NAFTA Chapter 11. The first claim is that Canada wrongfully expropriated Lilly’s patent rights in Zyprexa and Strattera in violation of Article 1110 of NAFTA. The second claim is that Canada violated Article 1105(1) of NAFTA by failing to afford Lilly’s investments “fair and equitable treatment.” Each claim is predicated on multiple legal grounds, some cumulative and others in the alternative, as set forth below.

A. Canada Wrongfully Expropriated Claimant’s Patent Rights In Zyprexa and Strattera.

1. Article 1110 of NAFTA Prohibits Uncompensated Direct and Indirect Expropriations, Including Measures That Substantially Deprive Investments of Value While Violating a Rule of International Law.

167. NAFTA prohibits Canada from expropriating the investments of United States investors without fulfilling prescribed conditions, including, *inter*

alia, non-discrimination and payment of compensation in accordance with NAFTA. Article 1110(1) of NAFTA provides:

No Party may directly or indirectly nationalize or expropriate an investment of an investor of another Party in its territory or take a measure tantamount to nationalization or expropriation of such an investment (“expropriation”), except:

(a) for a public purpose;

(b) on a non-discriminatory basis;

(c) in accordance with due process of law and Article 1105(1) [setting forth the minimum standard of treatment under international law]; and

(d) on payment of compensation in accordance with paragraphs 2-6.³²⁰

168. Article 1110 of NAFTA applies equally to measures of direct expropriation and indirect expropriation. Article 1110(1) states that “[n]o Party may *directly or indirectly* nationalize or expropriate an investment of an investor of another Party” without fulfilling prescribed conditions.³²¹ In addition, Article 1110(1) provides that Parties may not “take a measure *tantamount to nationalization or expropriation* of such an investment” without satisfying the same conditions.³²² Tribunals have interpreted the phrase “tantamount to nationalization or expropriation” in Article 1110(1) as a further basis for concluding that the Article 1110 encompasses indirect expropriation.³²³

³²⁰ NAFTA, Art. 1110(1).

³²¹ *Id.* (emphasis added).

³²² *Id.* (emphasis added).

³²³ See *Fireman’s Fund Insurance Company v. The United Mexican States*, ICSID Case No. ARB(AF)/02/01, Award (17 July 2006), at ¶ 176(h) & n.159 [hereinafter *Fireman’s Fund v. Mexico*] (“Indirect expropriation is contemplated by Article 1110(1) of the NAFTA: ‘No Party may directly or *indirectly* nationalize or expropriate ... or take a *measure tantamount to* nationalization or expropriation ...’ (emphasis added).”) (CL-45). See also Campbell McLachlan et al., *INTERNATIONAL INVESTMENT ARBITRATION*, § 8.75 (2008) (“Several terms, in addition to ‘indirect’, are used [by arbitral tribunals] to describe indirect expropriation, for example ‘de facto, ‘creeping’ (continued...)”).

169. In analyzing the standards for direct and indirect expropriation embodied in Article 1110(1), NAFTA tribunals have considered a range of sources of international law, including arbitral decisions from outside of the NAFTA context.³²⁴ As the tribunal explained in *Fireman's Fund v. Mexico*:

[T]he parties to the present case have debated the relevance of international case law relating to expropriation. It is true that arbitral awards do not constitute binding precedent. It is also true that a number of cases are fact-driven and that the findings in those cases cannot be transposed in and out of themselves to other cases. It is further true that a number of cases are based on treaties that differ from the NAFTA in certain respects. *However, cautious reliance on certain principles developed in a number of those cases, as persuasive authority, to the extent they cover the same matters as the NAFTA, may advance the body of law, which in turn may serve predictability in the interest of both investors and host States.*³²⁵

170. Direct expropriation, as the tribunal observed in *Metalclad v. Mexico*, involves the “open, deliberate, and acknowledged taking[] of property.”³²⁶ According to Professor McLachlan, “[a]rbitral tribunals have considered direct expropriation as being relatively easy to recognize In fact, the central element

expropriation, or measures ‘tantamount to’ or ‘equivalent to’ expropriation) (CL-46); *Técnicas Medioambientales Tecmed S.A. v. The United Mexican States*, ICSID Case No. ARB(AF) 00/2, Award (English Language) (29 May 2003), at ¶ 114 [hereinafter *Tecmed v. Mexico*] (“Generally, it is understood that the term ‘...equivalent to expropriation ...’ or ‘tantamount to expropriation’ included in the Agreement and in other international treaties related to the protection of foreign investors refers to the so-called ‘indirect expropriation’ or ‘creeping expropriation . . .’”) (CL-47).

³²⁴ See, e.g., *Glamis Gold, Ltd. v. United States of America*, NAFTA/UNCITRAL, Award (14 May 2009), at ¶ 357 & n. 708 (CL-116) [hereinafter *Glamis Gold v. United States*] (quoting *Tecmed v. Mexico*); *Fireman's Fund v. Mexico*, at ¶ 176 & nn. 158, 161 (CL-45) (quoting *Tippets, Abbott, McCarthy, Stratton v. TAMS-AFFA Consulting Engineers of Iran*, Award No. 141-7-2, reprinted in 6 Iran-United States Cl. Trib. 219 (1984), and *Tecmed v. Mexico*); *Methanex Corporation v. United States of America*, NAFTA/UNCITRAL, Award (3 August 2005), at Part IV, Ch. D, ¶ 8 (quoting *Revere Copper & Brass, Inc. v. Overseas Private Invest. Corp.*, AAA Award (24 August 1978) (CL-48), 56 ILR 258 (1978)); *Metalclad Corporation v. United Mexican States*, Case No. ARB(AF)/97/1, Award (30 August 2000), at ¶ 108 [hereinafter *Metalclad v. Mexico*] (citing *Biloune, et al. v. Ghana Investment Centre, et al.*, Award on Jurisdiction and Liability (27 October 1989) and Award on Damages and Costs (30 June 1990), 95 ILR 183, 207-10 (1993)) (CL-49).

³²⁵ *Fireman's Fund v. Mexico*, at ¶ 172 (CL-45) (emphasis added).

³²⁶ *Metalclad v. Mexico*, at ¶ 103 (CL-49).

is that property must be 'taken' by State authorities or the investor must be deprived of it by State authorities."³²⁷

171. An investment may be overtly "taken" – and thus directly expropriated – by the State in different ways. "[F]or example, governmental authorities [could] take over a mine or factory, depriving the investor of all meaningful benefits of ownership and control, or there [could be] a compulsory transfer of property rights."³²⁸ Alternatively, a direct expropriation could involve the outright destruction of the investment.³²⁹ Both of these scenarios qualify as direct expropriations because the "legal title of the owner is affected by the measure in question."³³⁰

172. Indirect expropriation, by contrast, encompasses a broad range of actions or conduct that "do not explicitly express the purpose of depriving [an investor of its] rights or assets, but actually have that effect."³³¹ For example, in *Metalclad v. Mexico*, the tribunal held that indirect expropriation encompasses "covert or incidental interference with the use of property which has the effect of depriving the owner, in whole or in significant part, of the use or reasonably-to-be expected economic benefit of property even if not necessarily to the obvious benefit of the host State."³³²

³²⁷ Campbell McLachlan et al., *INTERNATIONAL INVESTMENT ARBITRATION*, § 8.69 (2008) (CL-46).

³²⁸ *Id.* (internal quotation marks omitted).

³²⁹ See *Fireman's Fund v. Mexico*, at ¶ 176(a) ("Expropriation requires a taking (*which may include destruction*) by a government-type authority of an investment by an investor covered by the NAFTA.") (emphasis added) (CL-45); see also *id.*, at ¶ 176(e) ("The taking usually involves a transfer of ownership to another person (frequently the government authority concerned), but that need not necessarily be so in certain cases (e.g., *total destruction of an investment due to measures by a government authority without transfer of rights*.)") (emphasis added) (CL-45).

³³⁰ Rudolf Dolzer & Christoph Schreuer, *PRINCIPLES OF INTERNATIONAL INVESTMENT LAW*, at 101 (2d ed. 2012) (CL-50) ("The difference between a direct or formal expropriation and an indirect expropriation turns on whether the legal title of the owner is affected by the measure in question.").

³³¹ *Tecmed v. Mexico*, at ¶ 114 (Ex. CL-47).

³³² *Metalclad v. Mexico*, at ¶ 103 (Ex CL-49).

173. To qualify as an indirect expropriation the extent of the deprivation suffered by the investor in respect of its investment must be “substantial.” In an early NAFTA decision, *Pope & Talbot v. Canada*, the tribunal concluded that, under international law, indirect expropriation “requires a *substantial deprivation*.”³³³ Since then, NAFTA tribunals have consistently applied this “substantial deprivation” standard. As the tribunal explained in *Merrill & Ring v. Canada*, “[t]he standard of substantial deprivation identified in *Pope & Talbot*, and followed by many other decisions, both in the context of NAFTA and other investment protection agreements, is the appropriate measurement of the requisite degree of interference” for purposes of analyzing a claim of indirect expropriation.³³⁴

174. The corollary of the “substantial deprivation” test is that “[t]he *effects* of the host State’s measures are dispositive, *not the underlying intent*, for determining whether there is expropriation.”³³⁵ In other words, claimants are not required to demonstrate that the State *intended* to expropriate the claimant’s

³³³ *Pope & Talbot v. Canada*, NAFTA/UNCITRAL, Interim Award (26 June 2000), at ¶ 102 [hereinafter *Pope & Talbot v. Canada*] (emphasis added and internal quotation marks omitted) (CL-120).

³³⁴ *Merrill & Ring Forestry L.P. v. Canada*, NAFTA/UNCITRAL, Award (31 March 2010), at ¶ 145 [hereinafter *Merrill & Ring v. Canada*] (CL-51); see also *Fireman’s Fund v. Mexico*, at ¶ 176(c) (“The taking must be a substantially complete deprivation of the economic use and enjoyment of the rights to the property, or of identifiable distinct parts thereof (i.e., it approaches total impairment”) (CL-45). The question whether a particular state measure results in a sufficiently “substantial” deprivation has been the dispositive issue in most NAFTA cases involving claims of indirect expropriation. Where NAFTA tribunals have rejected the claim, it has generally been because the extent of deprivation was found to be insufficient. See, e.g., *Merrill & Ring v. Canada*, at ¶ 135; *Glamis Gold, Ltd. v. United States*, at ¶ 536 (CL-116); *Corn Products International, Inc. v. United Mexican States*, ICSID Case No. ARB (AF)/04/1, Decision on Responsibility (15 January 2008), at ¶ 92 (CL-121); *S.D. Myers, Inc. v. Government of Canada*, NAFTA/UNCITRAL, Partial Award (13 November 2000), at ¶ 284 (CL-006); *Pope & Talbot v. Canada*, at ¶ 101 (CL-120). Here, as discussed below, this issue is not fairly in dispute. There is no question that Canada’s invalidation of the Zyprexa and Strattera patents deprived these investments of substantially all value.

³³⁵ *Fireman’s Fund v. Mexico*, at ¶ 176(f) (emphasis added) (CL-45); see also *Biwater Gauff (Tanzania) Ltd. v. United Republic of Tanzania*, ICSID Case No. ARB/05/22 (24 July 2008), at ¶ 463 (concluding that expropriation is generally measured ‘by reference to the *effect* of the relevant acts, rather than the intention behind them.’) (emphasis in original) (CL-52).

investment, or that the State subjectively considered its measures to be an expropriation.³³⁶

175. The doctrine of indirect expropriation protects investors from exercises of state authority that are expropriatory in their effects.³³⁷ In *Pope & Talbot*, for example, Canada argued that its measures could not engage Article 1110 because they were exercises of a recognized sovereign power – in that case, the power to impose export duties. The tribunal rejected the argument, noting that it “would create a gaping loophole in international protections against expropriation”:

Canada appears to claim that, because the measures under consideration are cast in the form of regulations, they constitute an exercise of ‘police powers,’ which, if nondiscriminatory, are supposedly beyond the reach of the NAFTA rules regarding expropriations. While the exercise of police powers must be analyzed with special care, the Tribunal believes that Canada’s formulation goes too far. Regulations can indeed be exercised in a way that would constitute creeping expropriation.³³⁸

176. To discern between a compensable expropriation and a non-compensable state action, NAFTA tribunals have considered a range of factors,

³³⁶ *Biloune et al. v. Ghana Investment Centre, et al.*, Award on Jurisdiction and Liability (27 October 1989), 95 ILR 183, 209 (1993) (“[T]he Tribunal need not establish [the government’s] motivations to come to a conclusion” that expropriation has occurred.) (CL-53); *Generation Ukraine, Inc. v. Ukraine*, ICSID Case No. ARB/00/9, Award (16 September 2003), at ¶ 20.28 (CL-54) (proceeding to conduct an expropriation inquiry despite the tribunal’s finding that the government’s challenged omissions “did not have the express intention of depriving the Claimant of the legal basis of [his] right to proceed to construction”); *Phelps Dodge Corp. et al v. Iran*, 10 Iran-US CTR 121, 130 (1986-1) (“[T]he Tribunal understands the financial, economic and social concerns that inspired the law pursuant to which it acted, but those reasons and concerns cannot relieve the Respondent of the obligation to compensate Phelps Dodge for its loss.”) (CL-55); United Nations Conference on Trade and Development, *Bilateral Investment Treaties in the Mid-1990s* (New York and Geneva, United Nations, 1998) at 66 (“[I]ndirect expropriation may occur even though the host country disavows any intent to expropriate the investment and characterizes its actions as something other than expropriation.”) (CL-56).

³³⁷ Tribunals often refer to such government actions as “regulations” or “exercises of the police power.”

³³⁸ *Pope & Talbot v. Canada*, at ¶ 99 (CL-120).

including: “[i] whether the measure is within the recognized police powers of the host State; [ii] the (public) purpose and effect of the measure; [iii] whether the measure is discriminatory; [iv] the proportionality between the means employed and the aim sought to be realized; [v] and the bona fide nature of the measure.”³³⁹ In addition, “[vi] [t]he investor’s reasonable ‘investment-backed expectations’ may be a relevant factor whether (indirect) expropriation has occurred.”³⁴⁰

177. This multi-factor analysis applies regardless of whether the challenged measure is an act of the executive, legislative, or judicial instrumentality of the State. Article 4 of the ILC Draft Articles on State Responsibility makes clear that “[t]he conduct of any State organ shall be considered an act of that State under international law, whether the organ exercises legislative, executive, judicial or any other functions, whatever position it holds in the organization of the State, and whatever its character as an organ of the central Government or of a territorial unit of the State.”³⁴¹

178. This fundamental principle was also embraced by the NAFTA tribunal in *Azinian v. Mexico*, which approvingly quoted former ICJ President Eduardo Jiménez de Aréchaga’s observation that:

Although independent of the Government, the judiciary is not independent of the State: *the judgment given by a judicial authority*

³³⁹ *Fireman’s Fund v. Mexico*, at ¶ 176(j) (CL-45).

³⁴⁰ *Id.*, at ¶ 176(k).

³⁴¹ Responsibility of States for Internationally Wrongful Acts, art. 4(1) (as reproduced in the annex to United Nations General Assembly Resolution 56/83 of 12 December 2001 and corrected through U.N. Doc. A/56/49(Vol. I)/Corr.4) (CL-57); *EDF (Services) Limited v. Republic of Romania*, ICSID Case No. ARB/05/13, Award (8 Oct. 2009), at ¶ 188 (CL-101) (citing *id.*), *Rumeli Telekom A.S., Telsim Mobil Telekomikasyon Hizmetleri A.S. v. Republic of Kazakhstan*, ICSID Case No. ARB/05/16, Award (29 July 2008), at ¶ 702 (“Whereas most cases of expropriation result from action by the executive or legislative arm of a State, a taking by the judicial arm of the State may also amount to an expropriation.”) (CL-58); *Oil Field of Texas, Inc. v. Iran*, 12 Iran-U.S. C.T.R. 308, 318 (1986) (“It is well established in international law that the decision of a court in fact depriving an owner of the use and benefit of his property may amount to an expropriation of such property that is attributable to the state of that court.”) (CL-59); Ian Brownlie, PRINCIPLES OF PUBLIC INTERNATIONAL LAW 531 (7th ed. 2008) (“The essence of [expropriation] is the deprivation *by state organs* of a right of property”) (emphasis added) (CL-60).

emanates from an organ of the State in just the same way as a law promulgated by the legislature or a decision taken by the executive.

The responsibility of the State for acts of judicial authorities may result from three different types of judicial decision. The first is a decision of a municipal court *clearly incompatible with a rule of international law*. The second is what is known traditionally as a ‘denial of justice.’ The third occurs when, in certain exceptional and well-defined circumstances, a State is responsible for a judicial decision contrary to municipal law.”³⁴²

179. In other words, no special rules attach to claims of expropriation based on judicial measures. It is not necessary, for example, that the claimant establish a “denial of justice” or otherwise demonstrate any deficiency in the process afforded by the national courts.³⁴³ What is necessary is to show that the judicial measure (i) resulted in a “substantial deprivation” and; (ii) qualifies as a compensable taking as opposed to a non-compensable exercise of state authority. In respect of the latter criterion, as Judge Aréchaga noted, one way an expropriatory judicial measure may be distinguished from a non-compensable

³⁴² *Robert Azinian et al. v. The United Mexican States*, Case No. ARB(AF)/97/2, Award (1 November 1999), at ¶ 98 [hereinafter *Azinian v. Mexico*] (quoting Eduardo Jiménez de Aréchaga, *International Law in the past Third of a Century*, 159-1 Recueil des cours (General Course in Public International Law, The Hague, 1978) (emphasis added in *Azinian*) (CL-61). *Azinian v. Mexico* involved the cancellation of a concession contract by the Mexican courts. The tribunal rejected the claimants’ claim of expropriation because they “raised no complaints against the Mexican courts” and, even if they had, there was no colorable argument that “the Mexican court decisions [themselves were] violations of NAFTA.” *Id.* at ¶¶ 100-101. In other words, Judge Jiménez de Aréchaga’s first basis for State responsibility arising out of judicial measures – when “a decision of a municipal court [is] clearly incompatible with a rule of international law” – was not at issue in the case.

³⁴³ See *Biwater Gauff (Tanzania) Ltd. v. United Republic of Tanzania*, ICSID Case No. ARB/05/22 (24 July 2008), at ¶¶ 457-458 (“Hence the Republic argues that the availability of UNCITRAL arbitration to resolve any complaints about DAWASA’s contractual performance means that there can be no allegation of denial of justice in this case. Whatever the force of this analysis in the context of a claim under the ‘Fair and Equitable Treatment standard,’ and specifically in relation to a denial of justice claim, it is unnecessary in the context of an expropriation claim. A denial of justice (including, for example, the absence of any other remedy) need not be established before a breach of contract by a State party can amount to an expropriation.”) (CL-52).

exercise of judicial authority is if the measure is “clearly incompatible with a rule of international law.”³⁴⁴

180. Consistent with this framework, tribunals have concluded that judicial measures qualify as indirect expropriations when they result in a substantial deprivation and violate a rule of international law. In *Saipem v. Bangladesh*, for example, the claimant alleged that annulment of a commercial arbitration award by the Bangladeshi courts constituted an indirect expropriation under the Italy-Bangladesh BIT.³⁴⁵ The tribunal noted at the outset that “the most significant criterion to determine whether the disputed actions amount to indirect expropriation or are tantamount to expropriation is the impact of the measure.”³⁴⁶ The tribunal explained, however, that in the context of the judicial measure at issue,

the substantial deprivation of Saipem’s ability to enjoy the benefits of the ICC Award is not sufficient to conclude that the Bangladeshi courts’ intervention is tantamount to an expropriation. If this were true, any setting aside of an award could then found a claim for expropriation, even if the setting aside were ordered by the competent state court upon legitimate grounds.³⁴⁷

181. Accordingly, the tribunal concluded that – in addition to a substantial deprivation – “the *unlawful character of the actions* was a necessary condition” for finding an indirect expropriation.³⁴⁸ The tribunal then determined that this condition was met through two independent violations of international law, one of which was a violation of Bangladesh’s treaty obligations under the

³⁴⁴ *Azinian v. Mexico*, at ¶ 98 (CL-61).

³⁴⁵ *Saipem S.p.A. v. The People’s Republic of Bangladesh*, ICSID Case No. ARB/05/7, Award (30 June 2009), at ¶ 133 [hereinafter *Saipem v. Bangladesh*] (CL-62).

³⁴⁶ *Id.* at ¶ 133 (CL-62).

³⁴⁷ *Id.* (CL-62).

³⁴⁸ *Id.* at ¶ 134 (emphasis added) (CL-62).

New York Convention.³⁴⁹ Based on these findings, the tribunal concluded that Bangladesh's measures constituted an indirect expropriation.³⁵⁰

182. In reaching this conclusion, the tribunal in *Saipem* was explicit that a claimant need not prove a denial of justice (or procedural unfairness more generally) to establish that a judicial measure is "unlawful" under international law. The tribunal held that "[w]hile the Tribunal concurs with the parties that expropriation by the courts presupposes that the courts' intervention was illegal, *this does not mean that expropriation by a court necessarily presupposes a denial of justice.*"³⁵¹

183. In the specific context of intellectual property rights, NAFTA itself provides guidance on the dividing line between a compensable taking and a non-compensable state action. Article 1110(7) states:

This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, *to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property).*³⁵²

³⁴⁹ See *id.* at ¶ 170 ("[T]he Tribunal concludes that the revocation of the arbitrators' authority was contrary to international law, in particular to the principle of abuse of rights and the New York Convention.") (CL-62). The international law violation relevant here is Bangladesh's violation of the New York Convention, which is analogous to Canada's violation of Chapter 17 of NAFTA. The other independent ground for the *Saipem* tribunal's decision was its finding of an "abuse of rights," which occurs when a "State exercis[es] a right for a purpose that is different from that for which that right was created." *Id.* at ¶ 160 (CL-62).

³⁵⁰ *Id.* at ¶ 216. See also *ATA Construction, Industrial and Trading Co. v. Hashemite Kingdom of Jordan*, ICSID Case No. ARB/08/2, Award (18 May 2010), at ¶¶ 125-128 (CL-63).

³⁵¹ *Id.* at ¶ 181. See also *Rumeli Telekom A.S., Telsim Mobil Telekomikasyon Hizmetleri A.S. v. Republic of Kazakhstan*, ICSID Case No. ARB/05/16, Award (29 July 2008), at ¶¶ 705-706 (observing that "the final act of 'taking' ... was the decision of the Presidium of the Supreme Court, noting that "the decision was made 'for a public purpose'" and "there was no evidence that it was not made 'in accordance with due process of law,'" but finding the decision nonetheless constituted an unlawful expropriation) (CL-58).

³⁵² NAFTA Art. 1110(7) (emphasis added).

184. In other words, if Canada's revocation of a foreign investor's IP rights is *consistent* with Chapter 17 of NAFTA, then Canada's obligations under Article 1110 are not engaged. But if the revocation of IP rights is *inconsistent* with Chapter 17, then those measures qualify as compensable expropriations under Article 1110.³⁵³ Indeed, if a revocation of IP rights could not otherwise amount to a compensable expropriation, there would be no need for the express carve-out contained in Article 1110(7).³⁵⁴

2. Canada's Revocations of Lilly's Zyprexa and Strattera Patents Violate Its Obligations to Protect Intellectual Property Under NAFTA Chapter 17.

185. NAFTA Chapter 17 sets forth specific obligations to ensure the adequate and effective protection of intellectual property rights. Specifically, Article 1709, "Patents," establishes an important baseline for patent protection among the NAFTA parties. Chapter 17 explicitly contemplates that a Party "may implement in its domestic law *more* extensive protection of intellectual property rights than is required" under Chapter 17,³⁵⁵ but *less* extensive protection is plainly

³⁵³ The same point has been made in the context of TRIPS. See Anthony Taubman, *Rethinking TRIPS: Adequate Remuneration for Non-Voluntary Patent Licensing*, 11 J. INT'L ECON. L. 927, 964 (2008) (analyzing "recent BITs [that] explicitly exclude TRIPS-compatible compulsory licenses from provisions on expropriation" and concluding that "this implies that TRIPS-incompatible compulsory licenses may be considered expropriation".) (CL-64). Cf. *Waste Management, Inc. v. Mexico (II)*, NAFTA/ICSID(AF) No. 00/3, Award (30 April 2004), at ¶ 144 [hereinafter *Waste Management v. Mexico*] ("Indeed there is some indication that [the phrase 'take a measure tantamount to nationalization or expropriation of such an investment' in Article 1110(1)] was intended to have a broad meaning, otherwise it is difficult to see why Article 1110(8) was necessary. As a matter of international law a 'non-discriminatory measure of general application' in relation to a debt security or loan which imposed costs on the debtor causing it to default would not be considered expropriatory or even potentially so. It is true that paragraph (8) is stated to be 'for greater certainty,' but if it was necessary for certainty's sake to deal with such a case this suggests that the drafters entertained a broad view of what might be 'tantamount to an expropriation.'") (CL-65).

³⁵⁴ Cf. *Waste Management v. Mexico*, at ¶ 144 (CL-65) (considering the statement in Article 1110(8) that "a non-discriminatory measure of general application shall not be considered a measure tantamount to an expropriation of a debt security or loan," and concluding that it suggests the phrase "measure tantamount to an expropriation" "was intended to have a broad meaning, otherwise it is difficult to see why Article 1110(8) was necessary").

³⁵⁵ See NAFTA, art. 1702 (emphasis added) (CL-44).

barred. By creating an additional hurdle to patentability for the Zyprexa and Strattera patents under the rubric of the promise utility doctrine, by applying the promise utility doctrine in a way that discriminates against the pharmaceutical sector, and by revoking the Zyprexa and Strattera patents *ex post* on the basis of a new criterion that could not have justified denial of the patent in the first instance since it did not exist at the time the patents were granted, Canada has acted inconsistently with its obligations under Chapter 17.

186. Specifically, Canada acted inconsistently with its obligations under Chapter 17 in at least four respects:

- *First*, Canada revoked patent protection for Zyprexa and Strattera for lack of utility, despite the fact that those inventions met the “capable of industrial application” criterion set forth in Article 1709(1).
- *Second*, Canada’s promise utility doctrine discriminates against pharmaceutical inventions – including Zyprexa and Strattera, among others – as compared to other fields of technology, which Article 1709(7) prohibits.
- *Third*, contrary to Article 1709(8), Canada applied the promise utility doctrine, rather than the statutory “mere scintilla” test, to revoke the Zyprexa and Strattera patents on a legal ground that did not exist when those patents were granted and thus could not have justified an initial denial of Lilly’s applications.
- *Fourth*, by invalidating Lilly’s patents for Zyprexa and Strattera, Canada has failed to provide adequate and effective protection and enforcement of intellectual property rights, which it committed to do in Article 1701(1).

a) **The Revocations of the Zyprexa and Strattera Patents Based On The Promise Utility Doctrine Are Inconsistent with Canada’s Obligation Under NAFTA Article 1709(1) to Provide and Maintain Patents for Inventions that are “Capable of Industrial Application”**

187. As discussed in Parts III(B) and V, *supra*, both at the time NAFTA was negotiated and after it entered into force, the utility requirement was a well-understood, threshold inquiry about industrial value. In terms of both doctrine and outcomes, the NAFTA parties marched in lockstep throughout the 1990s.

Canada alone changed course in the mid-2000s, unilaterally adopting and applying the promise utility doctrine with significant adverse consequences for many pharmaceutical patents, including Zyprexa and Strattera, while at the same time maintaining a traditional utility test. NAFTA does not permit Canada to apply an additional hurdle to patentability in this manner.

188. Under Article 1709(1), each NAFTA 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.³⁵⁶

189. As described more fully below, the core patentability criteria in Article 1709(1) establish an obligatory standard of patent protection. To determine the nature of Canada’s obligations under Chapter 17, the Tribunal must interpret the meaning of the relevant treaty provisions “in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”³⁵⁷ In the first instance, “shall make patents available” is an obligation to grant and maintain patents as long as the three enumerated criteria are met. For this floor of protection to be meaningful, these patentability criteria – “new,” “inventive step,” and “capable of industrial application” – must be interpreted as having substantive content and given effect.³⁵⁸ As explained in detail below, “capable of industrial application” is well

³⁵⁶ NAFTA Art. 1709(1) (emphases added) (CL-44). This obligation is subject to two exceptions not relevant here. First, Article 1709(2) allows a Party to exclude inventions from patentability if “necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment.” Second, Article 1709(3) permits certain subject matter exclusions. *Id.*, at Arts. 1709(2) & (3) (CL-44).

³⁵⁷ Vienna Convention on the Law of Treaties, Art. 31(1) (CL-66).

³⁵⁸ See *ConocoPhillips Petrozuata B.V. v. Venezuela*, ICSID Case No. ARB/07/30, [effet utile] Decision on Jurisdiction and the Merits (3 September 2013), ¶ 309 (noting “well-established principle” that treaty terms should “be interpreted so that they do not become devoid of effect”) (CL-67); (continued...)

understood in the patent context, and it is not a high threshold. It requires that an invention have the *capacity* to be put to a specific use in industry. Canada's promise utility doctrine is at odds with this utility test enshrined in NAFTA, and the doctrine's application to the Zyprexa and Strattera patents is inconsistent with Canada's NAFTA obligations.³⁵⁹

**(1) "Capable of Industrial Application" in the
NAFTA Article on Patent Protection Is a Legal
Term Meaning the Capacity To Be Put to a
Specific Use in Industry.**

190. While traditionally one turns first to the dictionary to discern ordinary meaning, discerning the meaning of "capable of industrial application" requires an approach that focuses on the definition of the treaty's terms in context. Chapter 17 is titled "Intellectual Property," and it has a specific article dedicated to each area of intellectual property rights: Copyright (1705), Trademarks (1708), Patents (1709), Trade Secrets (1711), and so on. Canada's obligation to grant patents that meet the "capable of industrial application" standard must be interpreted in that context, and in light of the purpose of NAFTA to "ensure a predictable commercial framework for business planning and investment,"³⁶⁰ to "foster creativity and innovation, and promote trade in goods that are the subject of intellectual property rights,"³⁶¹ and to "provide adequate and effective protection and enforcement of intellectual property rights in each Party's territory[.]"³⁶² Further, together with the context, subsequent practice of the

Appellate Body Report, *Canada – Measures Affecting the Importation of Milk and the Exportation of Dairy Products*, WTO Doc. No. WT/DS103/AB/R (13 October 1999), ¶ 133 (noting that the "task of the treaty interpreter is to ascertain and give effect to a legally operative meaning for the terms of the treaty" and not to "adopt a meaning that would reduce parts of a treaty to redundancy or inutility") (CL-68).

³⁵⁹ Whether framed as a challenge to the promise utility doctrine or as an as-applied challenge to the Canadian Patent Act, the inconsistency is the same: Canada is failing to make patents available for inventions that satisfy the utility requirement set forth in NAFTA Article 1709(1).

³⁶⁰ NAFTA Preamble (CL-44).

³⁶¹ NAFTA Preamble (CL-44).

³⁶² NAFTA Art. 102(1)(d) ("Objectives") (CL-44).

parties, and relevant rules of international law applicable among the parties, “shall be taken into account”³⁶³ when interpreting Article 1709(1). Applying these rules of treaty interpretation to Article 1709(1), Canada must grant and maintain patent protection for inventions that have the capacity to be put to specific use in industry, assuming the other two core patentability requirements also have been met. Canada failed to do so in this case.

191. Article 1709(1) itself treats the concepts “capable of industrial application,” “new,” and “inventive step” as terms of art in the patent context, explicitly noting that “inventive step” may be deemed synonymous with “non-obvious,” while “capable of industrial application” may be deemed synonymous with “useful.”³⁶⁴ This language recognizes the fact that some jurisdictions, like Canada and the United States, use the term “useful” to describe the utility requirement enshrined in Article 1709(1). Given this guidance provided by Article 1709(1) itself, it is important to identify the meaning shared by both terms.³⁶⁵

192. Given that “capable of industrial application” and “useful” are terms of art in patent law and are used in NAFTA to define the parties’ substantive patent obligations, the effect of additional tools of treaty interpretation such as subsequent party practice and relevant rules of international law applicable to the parties (in particular the Patent Cooperation Treaty, which defines industrial applicability)³⁶⁶ are addressed in detail, below. That said, a good faith interpretation of “capable of industrial application” and “useful” in accordance with the ordinary meaning of those terms leads to a straightforward conclusion:

³⁶³ Vienna Convention on the Law of Treaties, Art. 31(3)(b) and (c) (CL-66).

³⁶⁴ NAFTA, art. 1709(1) (CL-44).

³⁶⁵ This is also consistent with Article 31(4), of the Vienna Convention (CL-66) which states that “[a] special meaning shall be given to a term if it is established that the parties so intended.” As a WTO dispute settlement panel noted in a case involving Mexico and the United States, “Article 31(4) includes cases in which the term at issue is a technical one that is in common use in its field, and which the parties can be presumed to have been aware of.” *See* Panel Report, *Mexico – Measures Affecting Telecommunications Services*, WTO Doc. WT/DS204/R (April 2, 2004), ¶ 7.169 (CL-69).

³⁶⁶ *See infra* ¶¶ Part VII.A.2.

an invention with the capacity to be put to specific use in industry meets the standard articulated in NAFTA Article 1709(1).

193. According to the Oxford English Dictionary, the term “capable” is defined as “[a]ble to be affected by; of a nature, or in a condition, to allow or admit of; admitting; *susceptible*.”³⁶⁷ An alternative definition is “[h]aving the needful *capacity*, power, or fitness for (some specified purpose or activity).”³⁶⁸ Both variants emphasize susceptibility or capacity. The adjective “industrial” means “[p]ertaining to, or of the nature of, industry or productive labour.”³⁶⁹ The term “application” is defined as the “action of bringing something to bear upon a person or thing with practical results,” or the “action or fact of putting something to a use or purpose; employment, specific use.”³⁷⁰ Read together, the words thus imply a susceptibility or capacity to be put to a specific or practical use in industry.

194. The definition of “useful” is similar. The Oxford English Dictionary defines “useful” as “*capable* of being put to good use; *suitable* for use; advantageous, profitable, beneficial.”³⁷¹ As with “capable of industrial application,” the ordinary meaning of “useful” emphasizes capability or suitability for use. Black’s Law Dictionary sheds additional light on the concept of “useful” in a legal context. In a technical field such as patent law, specialized legal definitions are especially relevant to any assessment of a treaty’s ordinary meaning.³⁷² Particularly when one considers that the NAFTA negotiating teams

³⁶⁷ OED Online, Oxford University Press (September 2014); <http://www.oed.com/view/Entry/27354?redirectedFrom=capable> (emphases added) (CL-70).

³⁶⁸ “Capable,” OED Online, Oxford University Press (September 2014) (emphasis added) (CL-70).

³⁶⁹ “Industrial,” OED Online, Oxford University Press (September 2014) (CL-70).

³⁷⁰ “Application,” OED Online, Oxford University Press (September 2014) (CL-70).

³⁷¹ “Useful,” OED Online, Oxford University Press (September 2014) (emphases added) (CL-70).

³⁷² Under international law, a term’s ordinary meaning may encompass its legal or technical meaning. Observing that the negotiators of the applicable treaty “likely possessed a sophisticated knowledge of business and law,” the tribunal in *Agua del Tunari v. Republic of Bolivia* concluded that “[f]or such persons, the ordinary meaning of a word or phrase also includes the legal meanings given to such words or phrases.” In *Agua del Tunari, S.A., v. Republic of Bolivia*, for example, an (continued...)

included intellectual property experts familiar with the legal meaning of the core patentability requirements under discussion, an examination of legal dictionary definitions is appropriate. Given that one of NAFTA's objectives is to "ensure a predictable commercial framework for business planning and investment,"³⁷³ one also would expect well-established legal and business terms in NAFTA to conform to widely accepted definitions.

195. According to Black's Law Dictionary, the term "useful" has the following definition in the specific context of patent law: "(Of an invention) having a *practical application*."³⁷⁴ The phrase "new and useful" is defined as follows: "Two of the requirements for an invention to be patentable - namely, that the invention be novel and that it have *practical utility*."³⁷⁵ The related term "utility," not surprisingly, also has a specific meaning in the patent law setting: "*Capacity to perform a function or attain a result for which the patent applicant or holder claims protection as intellectual property*."³⁷⁶ These legal dictionary definitions corroborate the Oxford English Dictionary's general definition of "useful." In particular, they confirm that in patent law, the utility requirement focuses on capacity to perform and that a single use - "*a practical application, " a function, " a result*" - meets the utility standard. Together, the ordinary meaning of "capable of industrial application" and "useful" in Article 1709(1) reflects a utility standard that requires an invention to have the capacity to attain a practical

ICSID tribunal construed the term "controlled" with reference not only to its common meaning, but also to its specialized legal meaning. In particular, the tribunal relied in part on Black's Law Dictionary in holding that "controlled" means the "power" or "legal *capacity to control*," and does not require "actual exercise" of control. See *Aguas del Tunari, S.A. v. Republic of Bolivia*, ICSID Case NO. ARB/02/3, Decision on Respondent's Objections to Jurisdiction (21 October 2005), ¶¶ 228-232 (emphasis added) (CL-117). See also Panel Report, *Mexico - Measures Affecting Telecommunications Services*, WTO Doc. WT/DS204/R (April 2, 2004), ¶¶ 7.108-117 (analyzing legal and technical meaning of "interconnection" as a "special meaning") (CL-69).

³⁷³ NAFTA Preamble (CL-44).

³⁷⁴ "Useful," Black's Law Dictionary (9th ed. 2009) (emphasis added) (CL-71).

³⁷⁵ "New and Useful," Black's Law Dictionary (9th ed. 2009) (emphasis added) (CL-71).

³⁷⁶ "Utility," Black's Law Dictionary (9th ed. 2009) (emphasis added) (CL-71).

use in industry. As described elsewhere, this is a standard that is easily met by most pharmaceutical patents, as they claim the capacity to treat a specific disease.

(a) Subsequent Practice of the NAFTA Parties Reinforces the Ordinary Meaning of “Capable of Industrial Application” as a Low Threshold Requiring Patentable Inventions To Have the Capacity To Be Put to a Specific Use in Industry.

196. Together with context, “any subsequent practice of the parties in the application of the treaty which establishes the agreement of the parties regarding its interpretation” also informs a treaty’s meaning, pursuant to Article 31(3)(b) of the Vienna Convention.³⁷⁷ The consistent practice of NAFTA parties, both at the time NAFTA was signed and during the ten years after NAFTA entered into force in 1994, confirms that “capable of industrial application” is a uniform standard requiring a simple threshold showing that an invention is capable of a specific use in industry. In the United States, Mexico, and also in Canada, the utility requirement uniformly and consistently applied was a simple and straightforward test. Throughout the 1990s and into the early 2000s, in all three jurisdictions an invention qualified as industrially applicable or useful if it was operable and could be made or used in any industrial activity. The utility test in Canada, the United States, and Mexico has been discussed at length above.³⁷⁸ Nevertheless, it is worth reiterating the convergence here, as it provides additional support for the ordinary meaning of the terms “capable of industrial application” and “useful” as they are used in the “Patents” Article of NAFTA.

³⁷⁷ Vienna Convention on the Law of Treaties, art. 31(3)(b) (CL-66). See Ian Sinclair, *THE VIENNA CONVENTION ON THE LAW OF TREATIES* 137 (2d ed. 1984) (“The value and significance of subsequent practice will naturally depend on the extent to which it is concordant, common and consistent.”) (CL-72); *The Canadian Cattlemen for Fair Trade v. United States*, UNCITRAL, Award on Jurisdiction (28 Jan. 2008), ¶ 182-83 (“[T]he tribunal is of the view that, in interpreting a treaty, ‘reference may be made to ‘subsequent practice that clearly establishes the understanding of all parties regarding its interpretation.’”) (quoting Ian Brownlie, *PRINCIPLES OF PUBLIC INTERNATIONAL LAW* 635 (5th ed. 1998)) (CL-60).

³⁷⁸ See *supra* Parts III and V.

(i) Canada

197. In Canada after NAFTA entered into force, the statutory term “useful” established an objective standard requiring that the claimed invention be capable of some practical result.³⁷⁹ While an invention might have multiple uses, Canadian patent law required only that it have some practical application in industry, trade, or commerce. As Professor Siebrasse explains, “[t]raditionally it was said that a ‘slight amount’ of utility is sufficient, or ‘very little will do,’ while more recently it has become standard to say that a ‘mere scintilla’ of utility is sufficient.”³⁸⁰ As long as an invention was neither inoperable nor purely abstract, it typically passed Canada’s objective test.³⁸¹ When questions arose related to utility, post-filing evidence was admissible to establish utility. This evidentiary rule had a major impact, as Professor Siebrasse explains: “[I]f a pharmaceutical was actually being used to treat a particular disease at the time of litigation, the courts would accept that as conclusive evidence that it would have been useful in treating that disease at the time of filing.”³⁸² Under Canada’s statutory test as it was then applied, not a single pharmaceutical patent was successfully challenged in the Federal Courts for lack of utility between 1994 and 2004. As explained above,³⁸³ this mere scintilla test still exists under Canadian law, even though it was not given force with regard to the Zyprexa and Strattera patents.

(ii) The United States

198. Under U.S. law, both before and after NAFTA entered into force in 1994, the utility requirement, like Canada’s “mere scintilla” test, mandated simply that an invention have a specific and practical industrial use. Professor Merges summarizes the U.S. “useful” standard as follows:

³⁷⁹ Siebrasse Report at ¶ 24.

³⁸⁰ Siebrasse Report at ¶ 20.

³⁸¹ Siebrasse Report at ¶ 23; Wilson Report at ¶ 27-28.

³⁸² Siebrasse Report at ¶ 16.

³⁸³ See *supra* ¶ 57.

The utility requirement under U.S. patent law is very easy to meet, except in a few rare cases involving facially incredible inventions (such as perpetual motion machines) . . . Patent law in the United States does not require the inventor to establish any particular *degree* of usefulness. The invention just has to work – a simple yes/no inquiry. As the Federal Circuit put it, “[t]o violate § 101 the claimed device must be totally incapable of achieving a useful result.”³⁸⁴

199. The utility of a pharmaceutical invention is presumptively established when the specification states the condition treated by the invention. This presumption is rebutted only with “evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility,” such that the asserted utility is not credible.³⁸⁵ U.S. courts have also long accepted post-filing evidence to establish utility in patent litigation.³⁸⁶ Utility challenges are a rarity in the United States. An academic analysis of 300 U.S. patent validity cases from 1989 to 1996 found that only five – *i.e.*, less than two percent – involved a challenge to utility, and that only one was successful.³⁸⁷

(iii) Mexico

200. In Mexico, as in Canada and the United States, the industrial applicability requirement is a low threshold. Mexican patent law requires that inventions are “susceptible of industrial application.”³⁸⁸ As codified in Mexico’s 1994 Industrial Property Law (IPL),³⁸⁹ “[i]ndustrial application means the *possibility* of an invention being produced or used in any branch of economic

³⁸⁴ Merges Report at ¶ 5 (emphasis in original).

³⁸⁵ *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (C-168). See Merges Report at ¶¶ 18-19.

³⁸⁶ Merges Report at ¶¶ 5, 19. Compare Siebrasse Report at ¶¶ 54-60.

³⁸⁷ John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 208-209 (1998) (C-167).

³⁸⁸ 1994 Industrial Property Law (IPL), Art. 16 (C-91).

³⁸⁹ This 1994 statute, which implemented the provisions of NAFTA Chapter 17, continued patent law reforms that began in 1991, when Mexico extended patentability for the first time to pharmaceutical products. See 1991 Law to Promote and Protect Industrial Property, Art. 20.II (C-92).

activity.”³⁹⁰ As Ms. Gonzalez explains, “applicants are not obliged to submit proof that establishes the industrial application of the claimed invention; all that is required is a possibility.”³⁹¹

201. Since NAFTA entered into force, pharmaceutical patents in Mexico have routinely satisfied the “susceptible of industrial application” requirement during examinations by IMPI.³⁹² Across all technical fields, moreover, patent litigation regarding industrial applicability has been extraordinarily uncommon.³⁹³

(b) The Patent Cooperation Treaty Is a Relevant Rule of International Law Applicable Among the NAFTA Parties Under Vienna Convention Article 31(3)(c), and It Reiterates that Industrial Applicability Is a Basic Inquiry Focused on Any Industrial Use.

202. The Patent Cooperation Treaty (PCT) is a procedural treaty that has applied among the NAFTA parties since Mexico joined in 1995,³⁹⁴ and includes a definition of industrial applicability. This broader international legal framework is relevant to the analysis of this same industrial applicability concept in NAFTA Article 1709(1), particularly in light of the broad principle of systemic integration

³⁹⁰ 1994 Industrial Property Law (IPL), Art. 12(IV) (emphasis added) (C-91). In June 2010, the Mexican Congress incorporated the concept of “practical utility” by amending Article 12(IV) to define “industrial application” as “the possibility of an invention *having a practical utility or* being produced or used in any branch of economic activity, for the purposes described in the application.” *Id.* (C-172). This amendment simply codified existing practice. See Gonzalez Report at ¶¶ 22–23; Salazar Report at ¶¶ 29–30.

³⁹¹ Gonzalez Report at ¶ 9.

³⁹² Salazar Report at ¶ 28.

³⁹³ Gonzalez Report at ¶ 31.

³⁹⁴ See Patent Cooperation Treaty, 28 U.S.T. 7645 (1976-77) (CL-73); PCT Contracting States www.wipo.int/pct/en/pct_contracting_states.html (CL-78). The PCT definition also might be viewed as subsequent state practice under Article 31(3)(b) of the Vienna Convention (CL-66).

in international law, which favors consistent interpretations of treaties where possible.³⁹⁵

203. For purposes of facilitating common standards in international preliminary patent examinations, the PCT includes definitions of all three core patentability criteria: novelty, inventive step, and industrial applicability. In defining industrial applicability, Article 33(4) of the PCT states: “a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry. ‘Industry’ shall be understood in its broadest sense, as in the Paris Convention for the Protection of Industrial Property.”³⁹⁶ The PCT thus defines industrial applicability as a requirement narrowly focused on whether an invention can be made or used – or is at all capable of exploitation – in any kind of industry, with industry very broadly defined. This PCT definition is entirely consistent with the ordinary meaning of “capable of industrial application” in NAFTA Article 1709(1), a standard that is focused on plausible industrial applicability, not demonstrated usefulness.

³⁹⁵ As the International Law Commission has explained, “although a tribunal may only have jurisdiction in regard to a particular instrument, it must always *interpret* and *apply* that instrument in its relationship to its normative environment - that is to say ‘other’ international law. This is the principle of systemic integration to which article 31(3)(c) [of the Vienna Convention] gives expression.” International Law Commission, *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law*, UN Doc. A/CN.4/L.682, ¶ 423 (13 April 2006) (internal citation omitted) (CL-75). See also Campbell McLachlan, *The Principle of Systemic Integration and Article 31(3)(c) of the Vienna Convention*, 54 INT’L & COMP. L.Q. 279, 318-19 (2005) (CL-76); Borzu Sabahi & Kabir Duggal, *International Decision: Philip Morris Brands Sàrl v. Oriental Republic of Uruguay*, 108 AM. J. INT’L LAW 67, 71 (2014) (CL-77).

³⁹⁶ Patent Cooperation Treaty, 28 U.S.T. 7645, 7679 (1976-77), art. 33(4) (CL-73). The Paris Convention states that “[i]ndustrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.” Paris Convention on the Protection of Industrial Property, art. 1(3) (CL-74).

(c) The Circumstances Surrounding the Conclusion of NAFTA Confirm that “Capable of Industrial Application” in Article 1709(1) Is a Threshold Industrial Applicability Requirement Akin to the Standard in the PCT.

204. NAFTA Chapter 17 was not negotiated in a vacuum. The World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was being negotiated in parallel as part of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT).³⁹⁷ The language in NAFTA Article 1709(1) and TRIPS Article 27.1 is nearly identical.³⁹⁸ The TRIPS negotiations guided NAFTA’s working group on intellectual property,³⁹⁹ and according to one commentator, throughout the NAFTA negotiations, “Canadian negotiators argued that they wanted the same intellectual property provisions that were negotiated in the GATT.”⁴⁰⁰ The official negotiating documents of the TRIPS

³⁹⁷ For the avoidance of doubt, the TRIPS Agreement and its negotiating documents are not “preparatory work” or *travaux préparatoires* of NAFTA. Nevertheless, the parallel TRIPS negotiations are a relevant circumstance related to the conclusion of NAFTA Chapter 17, particularly as the two treaties resulted in almost identically worded obligations. See Vienna Convention, art. 32 (CL-66) (“Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty *and the circumstances of its conclusion*”);

³⁹⁸ Compare NAFTA Art. 1709(1) (CL-44) (“Subject to paragraphs 2 and 3, 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.”) with TRIPS Art. 27(1) & n.5 (CL-122) (“Subject to the provisions of paragraphs 2 and 3, 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.”)

³⁹⁹ According to several commentators, “the NAFTA text was imported directly from the Dunkel Text of the Uruguay Round.” Maxwell A. Cameron & Brian W. Tomlin, *The Making of NAFTA: How the Deal was Done* (2000), at 140 (C-172). See also Maryse Robert, *Negotiating NAFTA: Explaining the Outcome in Culture, Textiles, Autos, and Pharmaceuticals* (University of Toronto Press 2000), at 240-41 (“The Canadians had found their formula, the Dunkel Text.”) (C-173).

⁴⁰⁰ Maxwell A. Cameron & Brian W. Tomlin, *The Making of NAFTA: How the Deal was Done*, at 140 (C-172).

negotiations in the Uruguay Round⁴⁰¹ are thus useful in confirming the meaning of NAFTA Article 1709(1).

205. Of interest, the TRIPS negotiators in Geneva were aware of and relied on the special meaning of industrial applicability set forth in PCT Article 33(4), under which any invention that “can be made or used . . . in any kind of industry” meets the standard.

- In March 1988, during the early stages of the Uruguay Round, TRIPS negotiators invited the International Bureau of the World Intellectual Property Organization (WIPO) “to prepare a factual document to facilitate an understanding of the existence, scope and form of generally internationally accepted and applied standards/norms for the protection of intellectual property.”⁴⁰² Emphasizing the convergence of patent standards across domestic intellectual property regimes, WIPO reported to TRIPS negotiators that “[n]ovelty, inventive step (or non-obviousness) and industrial applicability are patentability criteria commonly applied throughout the world.”⁴⁰³
- WIPO further noted that in terms of international law, the PCT “contains definitions of novelty, inventive step (or non-obviousness) and industrial applicability.”⁴⁰⁴ The PCT’s definition of the utility criterion – that “a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry” – was thus recognized by WIPO at the time NAFTA was concluded as a relevant, governing international standard.
- In May 1989, TRIPS negotiators asked the GATT Secretariat “to prepare synoptic tables setting out in a comparative manner the proposals tabled in the

⁴⁰¹ See “History: derestricted Uruguay Round negotiating documents on TRIPS” at http://www.wto.org/english/tratop_e/trips_e/trips_e.htm (“On 15 May 2006, the [WTO] General Council decided to make public all official documents issued under the General Agreement on Tariffs and Trade (GATT). The includes all official documents on TRIPS and other areas of the Uruguay Round negotiations.”) (C-174).

⁴⁰² *Meeting of the Negotiating Group of 29 Feb.–3 Mar. 1988: Note by the Secretariat*, WTO Doc. MTN.GNG/NG11/6 (April 8, 1988), at 15, 17 (C-175).

⁴⁰³ *Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property: Note prepared by the International Bureau of WIPO*, Doc. MTN.GNG/NG11/W/24 (May 5, 1988), at 3 (C-176).

⁴⁰⁴ *Id.*

Group on standards and enforcement and corresponding provisions of existing international treaties.”⁴⁰⁵ The GATT Secretariat emphasized that in terms of the basic “[c]onditions for patentability,” the PCT “contains definitions of novelty, inventive step (or non-obviousness) and industrial applicability (Article 33).”⁴⁰⁶

206. These circumstances confirm that there was a common understanding of “capable of industrial application” that was reflected in the PCT. As described above, that PCT definition focuses on a showing that something “can be made or used” in any kind of industry. This is consistent with the ordinary meaning of “capable of industrial application,” namely the capacity to be put to a specific, industrial use.

(2) Canada’s Promise Utility Doctrine Is Inconsistent with Article 1709(1)’s “Capable of Industrial Application” Standard and Has Stripped Zyprexa and Strattera of Patent Protection in Violation of NAFTA Chapter 17.

207. As discussed above,⁴⁰⁷ Canada maintains a “mere scintilla” test for utility that existed when NAFTA entered into force. Since 2005, however, Canadian courts also have applied a second utility test, the promise utility doctrine. The promise utility doctrine described at Part III.C, *supra*, impermissibly places additional utility hurdles on patents in a manner fundamentally at odds with Canada’s obligations under NAFTA Article 1709(1).

208. The revocations of the Zyprexa and Strattera patents, described at Parts IV.A.2 and IV.B.2 *supra*, are the product of what Professor Siebrasse describes as a “sea change in the Canadian law of utility,”⁴⁰⁸ whereby distinct doctrinal changes interact to impose a burdensome new test:

⁴⁰⁵ *Synoptic Tables Setting Out Existing International Standards and Proposed Standards and Principles*, Doc. MTN.GNG/NG11/W/32 (June 2, 1989), at 1 (C-177).

⁴⁰⁶ *Id.*

⁴⁰⁷ *See supra* at ¶ 57.

⁴⁰⁸ Siebrasse Report at ¶ 105.

[A]ssessing utility by reference to the “promise” has substantively raised the standard for utility while at the same time, the elimination of the ability to rely on post-filing evidence has made it substantially more difficult to establish utility, based on any standard. Canadian courts now impose a high evidentiary burden to show that utility was demonstrated at the date of filing, making it necessary for patentees to assert that utility was “soundly predicted.” However, under the current law, evidence to establish that utility was soundly predicted must be disclosed in the patent itself, notwithstanding that this requirement did not exist and could not have been anticipated at the date the patent was filed.⁴⁰⁹

209. Under the promise utility doctrine, Canada’s Federal Courts depart significantly from the “capable of industrial application” test in NAFTA. The NAFTA test simply requires that an invention have the capacity to be put to a specific, industrial use. Under the promise utility doctrine, by contrast, instead of determining whether a claimed invention has any specific, industrial use, the Federal Courts scour the patent’s disclosure to construe any and all “promises” of utility, express or implied, all of which must be “demonstrated” or “soundly predicted” as of the patent filing date. Then, the courts exclude all post-filing evidence, including commercial use, and scrutinize all pre-filing evidence in a heightened manner akin to a safety and efficacy review. Pharmaceuticals found to “promise” use in humans are almost certain to fail the “demonstrated” utility test, in which case only evidence in the patent itself can support a “sound prediction” of utility. This exercise, unprecedented in Canada before 2005 and unparalleled in the United States and Mexico, is inconsistent with Canada’s obligation under NAFTA Article 1709(1), which requires Canada to grant and maintain patents as long as the traditional industrial applicability test is met.

210. Under the traditional test for utility in Canada, commercial use is typically dispositive of any utility challenge. Where even a “mere scintilla” of utility suffices, evidence of widespread use far surpasses that low threshold.⁴¹⁰ As

⁴⁰⁹ Siebrasse Report at ¶ 19.

⁴¹⁰ Siebrasse Report at ¶ 16.

Professor Siebrasse explains the traditional test, “if the invention as claimed had become a commercial success, this was considered good evidence of utility on the view that a useless invention could not be commercially successful.”⁴¹¹ By contrast, under Canada’s promise utility doctrine, despite clear and undisputed evidence of commercial use, the Zyprexa and Strattera patents have been found to lack utility not only because of their failure as of the filing date to meet promises of elevated utility construed by the courts, but also because of the exclusion of post-filing evidence.

211. The test in Mexico and the United States reflect the traditional standard embedded in NAFTA. As explained by Ms. Gonzalez: “The industrial applicability standard in Mexico has always been that inventions must be ‘**susceptible** of industrial application.’ . . . In addition, under [Mexican Law], as amended in 1994, industrial application was defined as ‘the possibility of an invention being produced or used in any branch of economic activity.’”⁴¹² Similarly, according to Professor Merges, “[p]atent law in the United States does not require the inventor to establish any particular degree of usefulness. The invention just has to work – a simple yes/no inquiry. As the Federal Circuit put it, ‘[t]o violate § 101 the claimed device must be totally *incapable* of achieving a useful result.’”⁴¹³ While Canada’s traditional utility test also mirrors the NAFTA standard, the promise utility doctrine impermissibly departs from it.

212. By unilaterally redefining the term “capable of industrial application” and imposing burdensome new requirements on patentees under the promise utility doctrine, Canada has run afoul of NAFTA Article 1709(1). In applying the flawed promise utility doctrine, Canada invalidated the Zyprexa and Strattera patents even though there was ample evidence at the date of filing that these drugs had the capacity to be put to a specific, industrial use – and did so

⁴¹¹ Siebrasse Report at ¶ 30.

⁴¹² Gonzalez Report at ¶ 18.

⁴¹³ Merges Report at ¶ 5 (citing *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) (C-166) (emphasis added)).

despite the fact that generic manufacturers sought to make and sell the drugs because of their widespread use. Put another way, Canada has failed to make patents available for inventions that are “capable of industrial application,” a violation of Article 1709(1).

b) Canada’s Promise Utility Doctrine Discriminates Against Pharmaceuticals as a Field of Technology in Contravention of NAFTA Article 1709(7)

213. Canada’s promise utility doctrine also has had unique, adverse effects on inventions in the pharmaceutical sector. NAFTA Article 1709(7) requires that Canada make patent rights available and enjoyable for inventions in all fields of technology, without discrimination:

[P]atents shall be available and patent rights enjoyable *without discrimination as to the field of technology*, the territory of the Party where the invention was made and whether products are imported or locally produced.⁴¹⁴

214. The ordinary meaning of 1709(7) is straightforward. This provision requires NAFTA governments to apply their domestic patent laws in a manner that does not impose discriminatory burdens on inventions within a certain technical field. In theory, Canada’s unique requirements for patent utility apply to inventions in all technical fields. In practice, however, Canada’s promise utility doctrine has had adverse effects exclusively within the pharmaceutical sector.⁴¹⁵ Canada’s doctrine thus constitutes *de facto* discrimination against a specific field of technology, which Chapter 17 prohibits.

⁴¹⁴ NAFTA Art. 1709(7) (CL-44) (emphasis added) (subject to the same two exceptions as Art. 1709(1)).

⁴¹⁵ As noted elsewhere, in only one case outside the pharmaceutical sector have any challenged *claims* been found to lack utility. See *infra* ¶ 221; *Eurocopter v. Bell Helicopter Textron Canada Ltd.*, (2012) F.C. 113 (C-120). In *Eurocopter*, claims relating to an untested design for helicopter landing gear lacked utility, but the claim relating to the tested and commercially produced design was found to be useful, the patent remained valid, and there was a finding of infringement.

215. The Federal Court itself recognized in 2000 that Canada's obligations under NAFTA prohibit it from imposing a more burdensome test on pharmaceuticals, concluding that "this Court may not hold pharmaceutical inventions to a higher standard of utility than it does other classes of inventions."⁴¹⁶ Yet, in practice, that is precisely what the Canadian courts have done. Canada's Federal Courts have applied the promise utility doctrine in a manner that has had disproportionate effects on pharmaceutical inventions, as compared with inventions in other technological fields.

(1) The nondiscrimination rule in NAFTA Article 1709(7) bars *de facto* field of technology discrimination.

216. Article 1709(7) prohibits NAFTA parties from imposing discriminatory limits on the availability or enjoyment of patent protection in any specific field of technology. If inventions within a given technological field meet the patentability criteria, Canada has an obligation to ensure that patent protection is available and enjoyable for all inventions in that sector, as in other fields of technology. A WTO tribunal has examined an identical obligation not to discriminate as to field of technology under the TRIPS Agreement. In that previous WTO challenge regarding Canada's treatment of pharmaceutical patents, the pharmaceutical sector was appropriately recognized as a distinct "field of technology."⁴¹⁷

⁴¹⁶ See *Apotex Inc. v. Wellcome Found. Ltd.*, (2000) 10 CPR 4th 65, at 84 (C-179). Apotex argued that Wellcome's patent on AZT for the treatment or prophylaxis of HIV was invalid because its claims had not been tested in humans and that "absent such testing, there can be no 'sound prediction' sufficient to establish invention." The Federal Court of Appeal rejected this argument and upheld Wellcome's patent, holding that after NAFTA and TRIPS, "this Court may not hold pharmaceutical inventions to a higher standard of utility than it does other classes of inventions." In its landmark AZT decision, the Supreme Court of Canada did not review the Federal Court of Appeal's holding related to Canada's international obligations.

⁴¹⁷ Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, Doc. WT/DS114/R (17 March 2000) ("*Canada-Pharmaceuticals*"), ¶¶ 7.94-7.105 (CL-79). Canada's "stockpiling provision" was found to violate the TRIPS Agreement. Its "regulatory review" provision also violated the TRIPS Agreement, but qualified as a limited exception. With regard to a claim of discrimination against the pharmaceutical sector, the WTO tribunal concluded that the European Communities had not (continued...)

217. As recognized by the WTO tribunal in *Canada-Pharmaceuticals*, the non-discrimination obligations of NAFTA Article 1709(7) apply not only to facially discriminatory measures, but also to facially neutral measures that discriminate in practice. The scope of protection would be severely narrowed if only explicit, facially transparent *de jure* discrimination were barred. In *Canada-Pharmaceuticals*, the WTO tribunal interpreted an identically-worded field of technology discrimination clause in the TRIPS Agreement and concluded that the provision prohibits both *de jure* and *de facto* discrimination: “Discrimination may arise from explicitly different treatment, sometimes called ‘*de jure* discrimination,’ but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called ‘*de facto* discrimination.’”⁴¹⁸

218. The WTO tribunal that assessed Canada’s practices emphasized that “the question of *de facto* discriminatory effect – whether the actual effect of the measure is to impose *differentially disadvantageous consequences* on certain parties” in a specific field of technology – is central.⁴¹⁹ Under this standard, as explained below, the Federal Courts’ application of the promise utility doctrine results in *de facto* discrimination prohibited under Article 1709(7).

put forward enough evidence to prove a discrimination claim. Canada did not contest, however, that the pharmaceutical sector was a distinct “field of technology.”

⁴¹⁸ Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, Doc. WT/DS114/R (17 March 2000) (“*Canada-Pharmaceuticals*”), ¶ 7.94 (CL-79). As a third party in that WTO case, the United States – a NAFTA signatory – took the same view, explaining to the panel that the non-discrimination obligation “requires consideration not only of the *de jure* exclusive rights provided under the law, but also the effective protection provided to the patent holder as a result of the patent.” The United States thus encouraged the panel to “assess whether the aspects of the Canadian regime that apply differentially to pharmaceuticals effectively and consistently accord less-favorable treatment in the enjoyment of rights to pharmaceutical inventions, as compared to inventions in other fields of technology.” See *id.* at 144 (quoting Third Party Oral Statement of the United States, *Canada-Pharmaceuticals* (June 10, 1999)) (CL-79).

⁴¹⁹ *Id.* at ¶ 7.101 (emphasis added) (CL-79). See, e.g., Panel Report, *European Communities-Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, Doc. WT/DS174/R (15 March 2005), ¶¶ 7.177-7.204 (CL-80).

(2) The promise utility doctrine has had significant and disproportionate adverse effects in the pharmaceutical sector.

219. From 2005, when Canada's Federal Courts first applied the promise utility doctrine, to present, the record is unambiguous: the doctrine has had disproportionate consequences on innovative pharmaceutical companies, as compared with patent holders in other fields of technology.

220. To evaluate a claim of field of technology discrimination, it is helpful to have information on a range of industries affected by the challenged measure.⁴²⁰ A review of all patent utility decisions by the Federal Courts shows the striking, disparate impact of the promise utility doctrine across different fields of technology. Not only is Canada applying an elevated utility requirement, distinct from the industrial applicability standard of NAFTA Article 1709(1); it is applying this improper test *solely* to the detriment of inventions in the pharmaceutical sector.

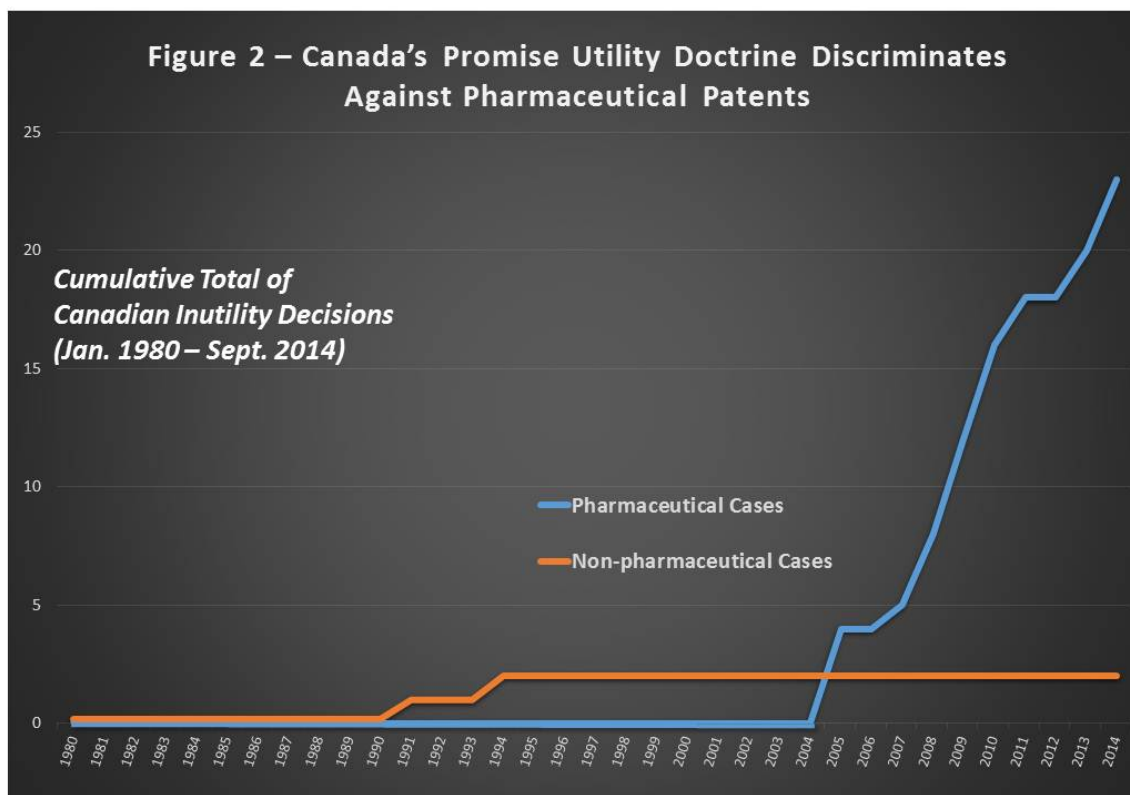
221. As Figure 2 indicates,⁴²¹ since 2005, Federal Courts have made inutility findings in 23 separate invalidity decisions involving pharmaceutical inventions.⁴²² Thirteen of these invalidity decisions rested solely on the basis of inutility. In the same time period, not a single patent in any other field of technology has been found to lack utility. In one non-pharmaceutical case, involving helicopter landing gear, certain *claims* were found to lack utility, but the

⁴²⁰ Panel Report, *Canada–Patent Protection of Pharmaceutical Products*, Doc. WT/DS114/R (Mar. 17, 2000) (“*Canada–Pharmaceuticals*”), ¶ 7.102 (CL-79) (noting that panel received no such information, but that such information would have assisted the tribunal with its analysis).

⁴²¹ See “Figure 2 – Canada’s Promise Utility Doctrine Discriminates Against Pharmaceutical Patents” (Appendix 2); “Chronological List of Canadian Utility Decisions from 1980 to Present” (C-305).

⁴²² Pharmaceutical patents in Canada are challenged both in infringement proceedings, and in court proceedings seeking a finding of invalidity so that Health Canada can issue a marketing approval to a generic company wishing to sell the patented medicine. (These latter proceedings are under the Patented Medicines (Notice of Compliance) Regulations.) In both instances, the court issues a finding on the validity of the patent, and the law applied – including the law on utility -- is the same. Here, we refer to both type of proceedings as decisions on validity.

commercially significant claim remained valid, such that punitive damages for infringement were awarded to the patentee.⁴²³



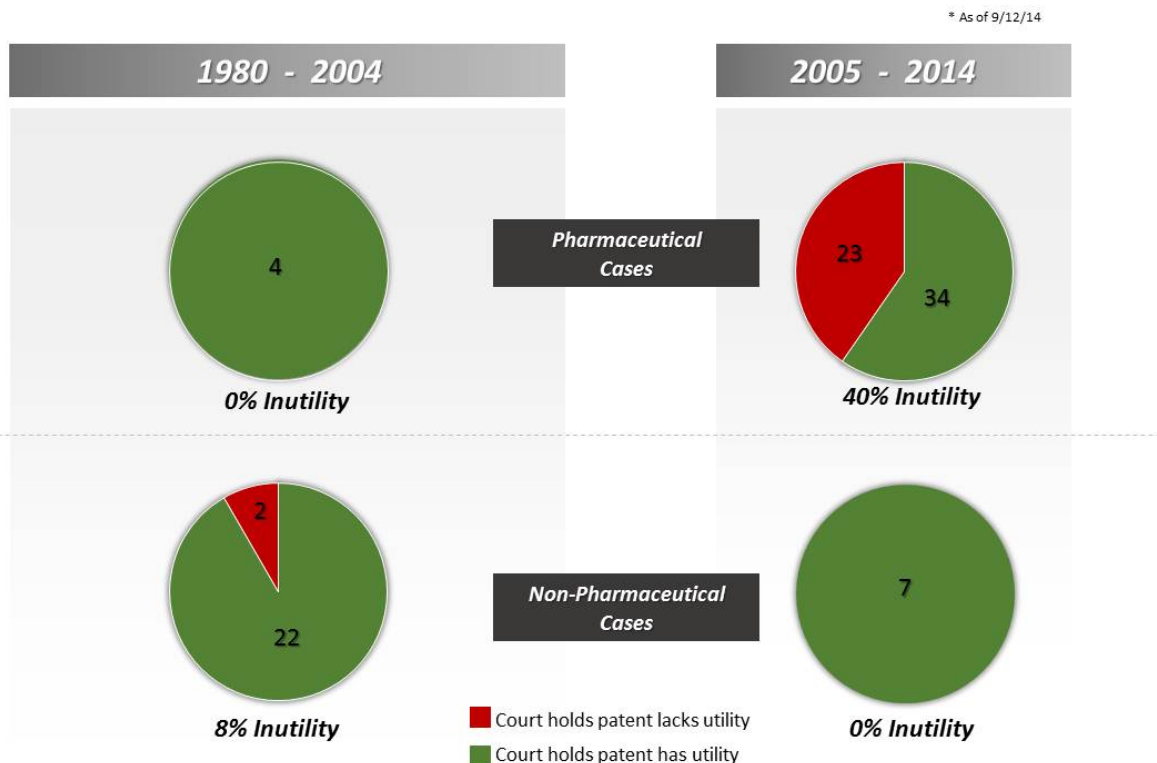
222. Moreover, as Figure 3 indicates, since the Federal Courts’ application of the promise utility doctrine began in 2005, inutility findings have jumped from zero to 40 percent for pharmaceutical patents, while inutility findings for non-pharmaceutical patents have actually declined, from eight to zero percent.⁴²⁴ These disparate effects speak for themselves. Under the traditional mere scintilla test from 1980 to 2004, inutility decisions were rare across all sectors. Since 2005, the rate of inutility decisions has spiked, but only for the pharmaceutical sector.

⁴²³ In that 2012 decision, claims relating to an untested design for helicopter landing gear lacked utility, but the claim relating to the tested and commercially produced design was found to be useful, the patent remained valid, and there was a finding of infringement. See *Eurocopter v. Bell Helicopter Textron Canada Ltd.*, 2012 FC 113 (C-120).

⁴²⁴ See “Figure 3 - Utility Outcomes by Sector in Canadian Courts” (Appendix 3).

Among NAFTA countries, this dramatic increase in inutility findings is also unique to Canada.⁴²⁵

Figure 3 – Utility Outcomes by Sector in Canadian Courts



(3) Discriminatory intent, a secondary consideration, can be inferred from the characteristics of Canada’s promise utility doctrine.

223. In this case, it is not necessary to look to discriminatory intent, given that the consequences of the doctrine are clear.⁴²⁶ That said, it is worth

⁴²⁵ In the United States, for example, the rate of invalidations for lack of utility across all sectors was 0.7% between 1989 and 1996. John R. Allison and Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 *AIPLA Q.J.* 185, 205-208 (1998) (C-167). See also Gonzalez Report at ¶ 31 (“During my almost 10 year career with IMPI . . . I do not recall a case in which a patent was declared null based on lack of industrial applicability.”)

commenting on intent, which can be inferred from the from the objective characteristics of the promise utility doctrine. As framed by the WTO tribunal that previously reviewed Canada's Patent Act in light of Canada's obligation not to discriminate by field of technology, this is "not an inquiry into the subjective purposes of the officials responsible for the measure, but an inquiry into the objective characteristics of the measure from which one can infer the existence or nonexistence of discriminatory objectives."⁴²⁷ Given the clear record of disproportionate effects of the promise utility doctrine on pharmaceuticals as a field of technology in Canada, it is not necessary to evaluate or find evidence of discriminatory intent in the design and operation of Canada's promise utility doctrine. Nonetheless, it is possible to infer the existence of discriminatory intent from the objective characteristics of Canada's doctrine.

224. As an initial matter, the promise utility doctrine came into being and took shape exclusively in the context of litigation regarding pharmaceutical patents. Significantly, the Federal Court has expressly recognized the differential impact of the promise utility doctrine on pharmaceutical inventions. The Federal Court, distinguishing the result in *Consolboard* (which related to machinery for making waferboards), has held that the "basis for sound prediction, *at least in respect of a pharmaceutical*, must be disclosed in the descriptive part of the patent."⁴²⁸ In addition, as noted by Professor Siebrasse, the evidentiary standard to demonstrate utility seems to be higher for pharmaceutical inventions. If the patent is construed as promising utility in treating humans, human testing is

⁴²⁶ See *Marion Unglaube and Reinhard Unglaube v. Republic of Costa Rica*, ICSID Case Nos. ARB/09/20 and ARB/09/20, Award (16 May 2012), at ¶ 263 ("While evidence of discriminatory intent may be relevant . . . it is the fact of unequal treatment which is key.") (CL-114).

⁴²⁷ Panel Report, *Canada–Patent Protection of Pharmaceutical Products*, Doc. Int/DS 114/R (17 March 2000) ¶ 7.101 (CL-79).

⁴²⁸ *Pfizer Canada Inc. v. Pharmascience Inc.*, [2013] F.C. 120 (Can. Fed. Ct.), ¶¶ 157-58 (emphasis added) (C-180).

required, whereas in the mechanical context, utility can be demonstrated based on a sufficiently precise model without any testing.⁴²⁹

225. The unique features of the sector are widely known. As compared with the typical mechanical invention, the development lifecycle for a pharmaceutical invention is extremely lengthy and very costly. Clinical safety and efficacy data often take a decade or more to compile. The characteristics of the promise utility doctrine thus conflict, and would objectively be known to conflict, with the reality of innovative drug development. For example, Canada's restrictions on post-filing evidence of utility – which did not exist before the *AZT* ruling, and are not applied to evidence of *inutility* introduced by generics – appear designed to have maximum impact on pharmaceutical innovators, given the extended timeline of the drug development cycle.

226. Another, less prominent aspect of discrimination, relating to nationality, is also present in the application of the promise utility doctrine by Canadian courts. In all 23 inutility decisions under the promise utility doctrine, the patents at issue were initially granted to innovative pharmaceutical companies headquartered outside of Canada, typically in either the United States or Europe. The principal beneficiaries of such rulings are generic drug makers operating in Canada.

c) Canada's Promise Utility Doctrine is Inconsistent with NAFTA Article 1709(8) Because it Adds an Additional Requirement that Did Not Exist at the Time Lilly's Zyprexa and Strattera Patents Were Granted

227. Under NAFTA Article 1709(8), the grounds for revocations are expressly limited to those that existed at the time of grant:

A Party may revoke a patent *only* when:

⁴²⁹ Siebrasse Report at ¶ 59.

(a) *grounds exist that would have justified a refusal to grant the patent; or*

(b) the grant of a compulsory license has not remedied the lack of exploitation of the patent.⁴³⁰

228. This provision precludes Canada from revoking Lilly’s Strattera and Zyprexa patents under the promise utility doctrine, a wholly new requirement that did not exist at the time those patents were granted by the Patent Office. Given its explicit use of the adverb “only,” Article 1709(8) operates to protect patent holders from being subject to invalidity attacks on the basis of patentability requirements that could not have been relied upon when their patent applications were initially filed and granted.

229. As Professor Siebrasse has explained:

under the current law, the standard for utility now has two branches: the mere scintilla test and the “promise” branch. The “promise” branch is an extra-statutory requirement in addition to the utility required by the Act, in the sense that a mere scintilla of utility will not suffice if the patent is held to promise more.⁴³¹

230. There is a material difference between nuanced developments in common law relating to existing patentability requirements and the creation of entirely new and additional grounds for revocation that did not exist when the Zyprexa and Strattera patents were granted. Mr. Wilson confirms in his expert opinion that Lilly’s applications for Zyprexa and Strattera fulfilled the Patent Office’s requirements for utility at the time the patents were granted, as set forth in the relevant guidelines for examiners⁴³², and those guidelines made no mention of the promise utility doctrine.⁴³³

⁴³⁰ NAFTA Art. 1709(8) (emphases added) (CL-44).

⁴³¹ Siebrasse Report at ¶ 17.

⁴³² Wilson Report at ¶¶ 38, 45.

⁴³³ *Id.* at ¶ 29.

231. While the Canadian courts may reconsider and, as appropriate, reverse decisions of examiners with regard to existing patentability requirements, Chapter 17 does not permit them to revoke patent protection based on an entirely new legal requirement that the Patent Office could not have used in an initial refusal to grant the patent. In the cases of Zyprexa and Strattera, the Federal Court acted inconsistently with Article 1709(8) by revoking patents based on an entirely new extra-statutory requirement not in existence when the patents for Zyprexa and Strattera issued.

d) Canada's Promise Utility Doctrine Is Inconsistent With The Commitment In NAFTA Article 1701(1) To Provide Adequate and Effective Protection and Enforcement of Patent Rights

232. Reinforcing the nature and scope of the obligations undertaken in NAFTA Chapter 17, Article 1701(1) states that Canada "shall provide in its territory to the nationals of another Party adequate and effective protection and enforcement of intellectual property rights," including patent rights.⁴³⁴ Canada's retroactive and discriminatory application of a heightened utility requirement to revoke Lilly's patents for Zyprexa and Strattera constitutes a failure *per se* to provide adequate and effective protection of intellectual property rights.

233. The principle of "adequate and effective protection and enforcement" underscores Canada's obligations to protect intellectual property, and to provide rights holders reliable means to enforce their legal rights. The Oxford English Dictionary defines adequate as "[f]ully satisfying what is required; quite sufficient, suitable, or acceptable in quality or quantity."⁴³⁵ Effective, meanwhile, is defined as "[p]owerful in effect; producing a notable effect; effectual."⁴³⁶ The definitions of both terms point to a commitment to provide

⁴³⁴ NAFTA Art. 1701(1) (CL-44).

⁴³⁵ "Adequate," OED Online. Oxford University Press (CL-70).

⁴³⁶ "Effective," OED Online. Oxford University Press (CL-70).

“fully satisfying” and “powerful” protection and enforcement of patent rights, through a system that is “quite sufficient” and that “produc[es] a notable effect.”

234. As applied by the judiciary to the Zyprexa and Strattera patents, Canada’s utility requirement has produced a notable effect, but one directly at odds with NAFTA Article 1701(1). The promise utility doctrine has impermissibly lowered the level of protection for inventions, making it far more difficult for pharmaceutical innovators to obtain and enforce patent rights in Canada. The doctrine has created an additional, unforeseen, and burdensome requirement that operates as a bar to defending otherwise valid patents, including the Zyprexa and Strattera patents. The doctrine also impairs the ability of patentees to enforce their rights effectively against infringers. As a direct consequence of the promise utility doctrine, Canada has failed to provide adequate protection and enforcement of Lilly’s otherwise valid patent rights.

e) Since Canada’s Revocations of Lilly’s Patents for Zyprexa and Strattera Are Inconsistent With Chapter 17, They Are Subject to NAFTA’s Expropriation Clause Pursuant to The Express Terms of Article 1110(7)

235. The revocations of the Zyprexa and Strattera patents directly resulted from the Federal Courts’ application of a utility requirement that is plainly inconsistent with Chapter 17. Inutility was the sole ground for finding invalidity in both cases. Put another way, but for the judiciary’s interpretation of the Patent Act to include the promise utility doctrine, both patents would have been valid and enforced, and no expropriation of Lilly’s investments would have occurred.⁴³⁷

236. In the Zyprexa case, the trial court conceded that the utility of the ‘113 patent as a compound with potential antipsychotic properties and low side effects “had been demonstrated by the tests conducted prior to the filing date.”⁴³⁸

⁴³⁷ Siebrasse Report at ¶ 89.

⁴³⁸ *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, ¶ 209 (C-146).

Similarly, in the Strattera case, the trial court noted that the '735 patent had utility, as the compound had been "shown to be somewhat useful to treat ADHD," and also admitted "that the validity of the '735 Patent is now being assessed against the backdrop of a more rigorous disclosure obligation than may have been apparent at the time of its filing in 1996."⁴³⁹

237. Accordingly, Canada's promise utility doctrine – which retroactively and with discriminatory effects in the pharmaceutical sector imposed a new, heightened utility test that is inconsistent with the international standard embodied in NAFTA – led to the improper revocation of patent protection for Lilly, in contravention of the intellectual property commitments assumed by Canada in NAFTA Chapter 17.

238. Given that Canada's revocations of Lilly's patents are inconsistent with Chapter 17, these challenged measures fall squarely within the scope of NAFTA's expropriation clause pursuant to Article 1110(7). That provision exempts from Article 1110 any revocation of patent rights that is consistent with Chapter 17, and thereby *applies* Article 1110 to any patent invalidation that falls short of the standards established in Chapter 17. Canada's improper and discriminatory revocations of the Zyprexa and Strattera patents, conducted in breach of Chapter 17, represent takings prohibited by Article 1110.

3. Canada's Revocations of the Zyprexa and Strattera Patents Constitute Both a Direct and Indirect Expropriation Under Article 1110.

239. The Tribunal might ask whether Respondent's measures against Lilly are best characterized as a *direct* or *indirect* expropriation. Canada's revocations of the Zyprexa and Strattera patents bear the hallmarks of both. Respondent's measures constitute "open, deliberate, and acknowledged takings of property" – the classic definition of a direct expropriation.⁴⁴⁰ They also satisfy the

⁴³⁹ *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, ¶¶ 93, 121 (C-160).

⁴⁴⁰ See *Metalclad v. Mexico*, at ¶ 103 (CL-49).

definition of indirect expropriation because they have the “effect of depriving [Lilly], in whole or significant part, of the use or reasonably-to-be expected economic benefit of property even if not necessarily to the obvious benefit of the host State.”⁴⁴¹ There is no dispute that the Canadian Federal Courts’ application of the Patent Act deprived Lilly’s investments – the Zyprexa and Strattera patents – of substantially all value.

240. However the Tribunal chooses to characterize Canada’s measures, it is clear that they cannot be defended as non-compensable exercises of State power. As discussed above, the invalidation of the Zyprexa and Strattera patents violates Canada’s obligations under Chapter 17 of NAFTA. This breach of Chapter 17 provides the Tribunal with two fully independent and alternative grounds for concluding that Canada’s measures are a compensable taking.

241. First, as discussed above, Article 1110(7) of NAFTA states that Article 1110 does not apply to a revocation of intellectual property rights “to the extent that such ... revocation ... is consistent with Chapter Seventeen (Intellectual Property).” By its plain implication, Article 1110(7) provides that revocations of intellectual property rights that *violate* Chapter 17 qualify as expropriations. In so doing, Article 1110(7) provides this Tribunal with a fully sufficient and Treaty-specific basis for recognizing Canada’s invalidations of the Zyprexa and Strattera patents as an expropriation under Article 1110, rather than as non-compensable exercises of state authority.

242. Second, even if Article 1110(7) did not exist, cases such as *Saipem* stand for the proposition that Canada’s breach of its patent obligations under Chapter 17 means that its measures are not “non-compensable regulation[s].”⁴⁴² As demonstrated above, it is well-established that one way to discern a compensable taking from a non-compensable exercise of state authority is when

⁴⁴¹ *Tecmed v. Mexico*, at ¶ 113 n. 125 (quoting *Metalclad v. Mexico*, at ¶ 103) (CL-47).

⁴⁴² *Fireman’s Fund v. Mexico*, at ¶ 176(j) (CL-45). See also *Saipem v. Bangladesh*, at ¶ 170 (CL-62).

the measure violates a rule of international law.⁴⁴³ Here, that violation is Canada's breach of Chapter 17. When such a violation is accompanied by a substantial deprivation in the value of the investment – as is the case here – the result is an expropriation.⁴⁴⁴

243. Finally, Canada's breach of Chapter 17 is not the only basis upon which the Tribunal can conclude that the revocation of the Zyprexa and Strattera patents constitutes a compensable expropriation. As discussed below in respect of Lilly's claim under Article 1105 of NAFTA, Canada's application of its unique promise utility doctrine to Claimant's investments also is arbitrary and in conflict with Lilly's reasonable investment-backed expectations. Specifically:

- When Lilly made its investments in Canada in the 1990s, it did so in reliance on Canada's patent law at the time, including its utility requirement. Canada's utility standard at the time of Lilly's investment reflected long-settled law and was consistent with the standards in other countries around the world. The revocation of Zyprexa and Strattera under the novel promise utility doctrine contravened Lilly's expectations.⁴⁴⁵
- Even if Lilly could have reasonably expected the advent of the promise utility doctrine (it could not), the application of the doctrine to Lilly's investments would still engage Article 1110 because it is arbitrary. As set forth below in detail, the promise utility doctrine is arbitrary because it is completely unpredictable and leads to absurd and illogical results.⁴⁴⁶

As the tribunal recognized in *Fireman's Fund v. Mexico*, both of these factors support the conclusion that Canada's measures constitute an expropriation under Article 1110.⁴⁴⁷

⁴⁴³ See *supra* Part VII.A.1.

⁴⁴⁴ See *id.*

⁴⁴⁵ See *supra* Part VII.B.3.

⁴⁴⁶ See *supra* Part VII.B.2.

⁴⁴⁷ *Fireman's Fund v. Mexico*, at ¶ 176(k) and n. 163 (CL-45).

4. Respondent's Expropriation is Wrongful.

244. Canada's expropriation measures are in breach of Article 1110 of NAFTA in at least four independent different ways: (i) they were taken without any compensation, let alone the compensation required by NAFTA; (ii) they were discriminatory; (iii) they lacked a public purpose; and (iv) they violated Article 1105(1) of NAFTA. For any and all of these reasons, Canada's expropriation of the Zyprexa and Strattera patents is wrongful under NAFTA.

a) The Expropriation Lacked Compensation

245. Article 1110(1) of NAFTA requires that expropriatory measures be taken "on payment of compensation in accordance with paragraphs 2 through 6." These paragraphs, in turn, require:

2. Compensation shall be equivalent to the fair market value of the expropriated investment immediately before the expropriation took place ("date of expropriation"), and shall not reflect any change in value occurring because the intended expropriation had become known earlier. Valuation criteria shall include going concern value, asset value including declared tax value of tangible property, and other criteria, as appropriate, to determine fair market value.
3. Compensation shall be paid without delay and be fully realizable.
4. If payment is made in a G7 currency, compensation shall include interest at a commercially reasonable rate for that currency from the date of expropriation until the date of actual payment.
5. If a Party elects to pay in a currency other than a G7 currency, the amount paid on the date of payment, if converted into a G7 currency at the market rate of exchange prevailing on that date, shall be no less than if the amount of compensation owed on the date of expropriation had been converted into that G7 currency at the market rate of exchange prevailing on that date, and interest had accrued at a commercially reasonable rate for that G7 currency from the date of expropriation until the date of payment.
6. On payment, compensation shall be freely transferable as provided in Article 1109.

246. Contrary to its obligations under these provisions, Canada has not tendered any compensation to Lilly for its expropriatory measures. As numerous decisions hold, the mere failure to pay the compensation required under an investment treaty makes the expropriation wrongful.⁴⁴⁸

b) The Expropriation Was Discriminatory

247. To be consistent with NAFTA, an expropriation must be carried out “on a non-discriminatory basis.”⁴⁴⁹ An expropriation measure that is discriminatory is therefore wrongful under the Agreement.

248. Under international law, state conduct is discriminatory if “(i) similar cases are (ii) treated differently (iii) and without reasonable justification.”⁴⁵⁰ Here, as discussed above, NAFTA expressly prohibits

⁴⁴⁸ See, e.g., *Burlington Resources v. Republic of Ecuador*, ICSID Case No. ARB/08/5, Decision on Liability (14 December 2012) at ¶¶ 543-44 (noting that “[m]any tribunals have held that the lack of payment is sufficient for the expropriation to be deemed unlawful” and concluding that an expropriation was unlawful because Ecuador made no “prompt, adequate and effective payment” to compensate for the expropriation of the claimant’s investment) (CL-81); *Compañía de Aguas del Aconquija S.A. and Vivendi Universal S.A. v. Argentine Republic*, ICSID Case No. ARB/97/3 (Resub.), Award (20 August 2007), at ¶ 7.5.21 (CL-82); *Bernardus Henricus Funnekotter and ors. v. Zimbabwe*, ICSID Case No. ARB/05/6, Award (22 April 2009), at ¶ 98 (CL-83); *Rumeli Telekom A.S. and Telsim Mobil Telekomikasyon Hizmetleri AS v. Kazakhstan*, ICSID Case No. ARB/05/16, Award (29 July 2008), at ¶ 706 (“Nevertheless [...] the valuation placed on Claimants’ shares was manifestly and grossly inadequate compared to the compensation which the Tribunal there holds to be necessary in order to afford adequate compensation under the BIT [...]. The Tribunal accordingly holds that the expropriation by the Presidium was unlawful.”) (CL-58); *Wena Hotels Ltd. v. Egypt*, ICSID Case No. ARB/98/4, Award (8 December 2000), at ¶ 101 (“[T]he Tribunal concludes that Egypt violated its obligation under Article 5 of the IPPA, by failing to provide Wena with ‘prompt, adequate and effective compensation’ for the losses it suffered as a result of the seizures of the Luxor and Nile Hotel.”) (CL-84).

⁴⁴⁹ NAFTA, Art. 1110(1)(b).

⁴⁵⁰ *Saluka Investments BV v. Czech Republic*, PCA/UNCITRAL, Partial Award (17 March 2006), at ¶ 313 [hereinafter *Saluka v. Czech Republic*] (CL-85); *Tulip Real Estate Investment; Development Netherlands B.V. v. Republic of Turkey*, ICSID Case No. ARB/11/28, Award (10 March 2014), at ¶ 398 (noting the parties’ agreement as to the *Saluka* standard) (CL-86); *El Paso Energy International Company v. Argentine Republic*, ICSID Case No. ARB/03/15, Award (31 October 2011), at ¶ 305 (“[F]or a measure to be discriminatory . . . [i]t is sufficient that, objectively, two similar situations are not treated similarly.”) (CL-87); *Antoine Goetz & Others v. Republic of Burundi*, ICSID Case No. ARB/95/3, Award, (10 February 1999), at Part VII.C ¶ 121 (“discrimination supposes a differential treatment applied to people who are in similar situations.”) (translation by Claimant) (CL-88).

discrimination on the basis of field of technology. In so doing, the NAFTA Parties made clear that *all* patent-holders are entitled to similar treatment, and that distinctions based on field of technology are not supported by reasonable justification. Because Canada's measures afford treatment less favorable to pharmaceutical patents (including the specific patents for Zyprexa and Strattera) than to patents in other fields of technology, Respondent's expropriation was not taken "on a non-discriminatory basis." It is accordingly wrongful under Article 1110.

c) The Expropriation Lacked a Public Purpose

249. Article 1110(1)(a) requires that expropriations be conducted "for a public purpose." Any expropriation that lacks a public purpose is accordingly wrongful. As discussed below in respect of the Minimum Standard of Treatment, Canada's promise utility doctrine is arbitrary and leads to absurd and illogical results.⁴⁵¹ Because the promise doctrine serves no rational policy, it accordingly lacks a public purpose.⁴⁵²

d) The Expropriation Was Not Carried Out in Accordance With Article 1105(1) of NAFTA.

250. Finally, Respondent's expropriation was wrongful because it violated Article 1110(1)(c), which provides that any expropriation be "in accordance with ... Article 1105(1)." Article 1105(1), in turn, provides that "[e]ach Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security." As discussed in the following section, Respondent's

⁴⁵¹ See *infra* Part VII.B.2.

⁴⁵² See *Saluka v. Czech Republic*, at ¶ 309 (defining unreasonable government action as action that is "unrelated to some rational policy") (CL-85); *ADC Affiliate Ltd. v. Republic of Hungary*, ICSID Case No. ARB/03/16, Award (2 October 2006), at ¶ 432 ("In the Tribunal's opinion, a treaty requirement for 'public interest' requires some genuine interest of the public. If mere reference to 'public interest' can magically put such interest into existence and therefore satisfy this requirement, then this requirement would be rendered meaningless since the Tribunal can imagine no situation where this requirement would not have been met.") (CL-89).

measures violate this provision because they did not afford Lilly fair and equitable treatment. In addition to constituting a free-standing breach of NAFTA Article 1105, this violation also renders Respondent's expropriation wrongful under Article 1110(1)(c).

B. Canada Failed to Accord Fair and Equitable Treatment to Claimant's Investments in Violation of NAFTA Article 1105.

1. Article 1105's Guarantee of "Fair and Equitable Treatment" Protects Against Arbitrary and Unreasonable Measures and Safeguards Investors' Legitimate Expectations.

251. Article 1105 of NAFTA requires that covered investments must be afforded "fair and equitable treatment" by each State Party. Article 1105 states:

Article 1105: Minimum Standard of Treatment

1. Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security.

252. The guarantee of "fair and equitable treatment" in Article 1105(1) has received close attention in NAFTA arbitrations. Tribunals have analyzed Article 1105(1) in light of the background principle of international law that foreign investors are entitled to a certain level of treatment from the state in which they invest. This fundamental principle of international law has been expressed using two different rubrics: (i) as the minimum standard of treatment of aliens under customary international law (Minimum Standard of Treatment); and (ii) as the standard of Fair and Equitable Treatment that has been adopted by most international investment treaties in force today and that has been interpreted and applied in numerous decisions of international tribunals.

253. In 2001, the Trade Ministers for the NAFTA Parties, acting through the NAFTA Free Trade Commission, issued Notes of Interpretation regarding

Article 1105 (“FTC Notes”).⁴⁵³ The Commission is authorized by NAFTA Article 2001(2) to issue such interpretative notes.⁴⁵⁴ The FTC Notes state that “Article 1105(1) prescribes the customary international law minimum standard of treatment of aliens as the minimum standard of treatment to be afforded to investments of investors of another Party.”⁴⁵⁵ The FTC Notes further provide that “[t]he concepts of ‘fair and equitable treatment’ and ‘full protection and security’ do not require treatment in addition to or beyond that which is required by the customary international law minimum standard of treatment of aliens.”⁴⁵⁶

254. The FTC Notes thus link the “fair and equitable treatment” standard under Article 1105(1) to the Minimum Standard of Treatment. The FTC Notes do not, however, stand for the proposition that the treaty-based Fair and Equitable Treatment standard is irrelevant to the Article 1105(1) analysis. To the contrary, as a product of customary international law, the Minimum Standard of Treatment has continually evolved and been shaped by the more than 3,000 bilateral investment treaties and regional investment agreements that have been signed

⁴⁵³ Article 1131(2) of NAFTA provides that “an interpretation by the Commission of a provision of this Agreement shall be binding on a Tribunal established under this Section.”

⁴⁵⁴ Article 2001(2) provides that “The Commission shall: (a) supervise the implementation of this Agreement; (b) oversee its further elaboration; (c) resolve disputes that may arise regarding its interpretation or application; (d) supervise the work of all committees and working groups established under this Agreement, referred to in Annex 2001.2; and (e) consider any other matter that may affect the operation of this Agreement” (CL-44). At the same time, the Commission is not authorized to amend NAFTA. Pursuant to Article 2202 of the Treaty, only “[t]he Parties may agree on any modification of or addition to this Agreement.” Tribunals have weighed whether the FTC Notes were a valid exercise of the Commission’s authority under Article 2001(2), or, alternatively, an impermissible attempt to amend NAFTA without following the procedures of Article 2202. *See, e.g., Pope & Talbot v. Government of Canada*, NAFTA/UNCITRAL, Award in Respect of Damages (31 May 2002), at ¶ 47 (“[W]ere the Tribunal required to make a determination whether the Commission’s action is an interpretation or an amendment, it would choose the latter.”) (CL-90). Here, it is not necessary for the Tribunal to reach the question whether the FTC Notes were a valid exercise of the Commission’s authority, because, as demonstrated below, Canada’s measures violate Article 1105 even under the interpretation articulated by the FTC Notes.

⁴⁵⁵ NAFTA Free Trade Commission, *Notes of Interpretation of Certain Chapter 11 Provisions*, § B(1) (31 July 2001) (CL-41).

⁴⁵⁶ *Id.* § 2(2) (CL-41).

since 1962, when the first BIT entered into force.⁴⁵⁷ The vast majority of these treaties contain a guarantee of fair and equitable treatment.⁴⁵⁸ As the tribunal observed in *Pope & Talbot*, “applying the ordinary rules for determining the content of custom in international law, one must conclude that the practice of states is now represented by those treaties.”⁴⁵⁹ More recently, the tribunal in *Chemtura v. Canada* reached a similar conclusion, noting that “in determining the standard of treatment set by Article 1105 of NAFTA, the Tribunal has taken into account the evolution of international customary law as a result *inter alia* of the conclusion of numerous BITs providing for fair and equitable treatment.”⁴⁶⁰ In other words, while expressed using different labels, both the Minimum Standard of Treatment and the Fair and Equitable Treatment standard are shaped by the

⁴⁵⁷ United Nations Conference on Trade and Development, *World Investment Report 2012: Overview* (2012), at 18 (C-181). See also United Nations Conference on Trade and Development, *The Entry Into Force of Bilateral Investment Treaties (BITs)* (2006), at 2–3 (C-182). The fair and equitable treatment treaty standard has its origin in late eighteenth century practice under treaties of friendship, commerce and navigation, and thus reflects over a century of evolving state practice. See Stephan W. Schill, *THE MULTILATERALIZATION OF INTERNATIONAL INVESTMENT LAW* 29 (2009) (C-105).

⁴⁵⁸ See Ioana Tudor, *THE FAIR AND EQUITABLE TREATMENT STANDARD IN INTERNATIONAL FOREIGN INVESTMENT LAW* 23 (2008) (analyzing a sample of 365 BITs and finding that only 19 (5%) did not refer to fair and equitable treatment in the body of the treaty (the analysis excluded references in the preamble)) (CL-109). The fact that a few BITs do not contain a guarantee of Fair and Equitable treatment (or that some countries have not entered into BITs or analogous agreements) does not detract from the influence of these instruments in shaping the Minimum Standard of Treatment. It is well-established that State practice need not be unanimous for a rule to become a customary norm. See *Case Concerning the Military and Paramilitary Activities in and Against Nicaragua*, I.C.J. Reports 1986, Judgment of 27 June 1986, at ¶ 186 (holding that it “does not consider that, for a rule to be established as customary, the corresponding practice must be in absolutely rigorous conformity with the rule.”) (CL-91).

⁴⁵⁹ *Pope & Talbot v. Government of Canada*, NAFTA/UNCITRAL, Award in Respect of Damages (31 May 2002), at ¶ 62 (internal citations omitted) (CL-90). See also *Mondev International Ltd. v. United States of America*, NAFTA/ICSID Case No. ARB(AF)/99/2, Award (11 October 2002), at ¶ 125 [hereinafter *Mondev v. United States*] (“[T]he FTC interpretations incorporate current international law, whose content is shaped by the conclusion of more than two thousand bilateral investment treaties and many treaties of friendship and commerce. Those treaties largely and concordantly provide for ‘fair and equitable’ treatment of, and for ‘full protection and security’ for, the foreign investor and his investments.”) (CL-7).

⁴⁶⁰ *Chemtura Corp. v. Government of Canada*, NAFTA/UNCITRAL, Award (2 August 2010), at ¶ 236 (CL-92).

same source of law: state practice as reflected through the extensive network of bilateral investment treaties.

255. Indeed, since the FTC Notes, NAFTA and non-NAFTA tribunals have recognized that the Minimum Standard of Treatment has evolved to the point that it now affords foreign investors the same level of protection as the autonomous Fair and Equitable Treatment standard.⁴⁶¹ In *Merrill & Ring v. Canada*, for example, having expressly considered the FTC Notes, the tribunal noted that the “requirement that aliens be treated fairly and equitably in relation to business, trade and investment is the outcome of this changing reality and as such it has become sufficiently part of widespread and consistent practice so as to demonstrate that it is reflected today in customary international law as *opinio juris*.”⁴⁶² And in *Biwater Gauff v. Tanzania*, the tribunal similarly concluded that “as found by a number of previous arbitral tribunals and commentators, ... the actual content of the treaty standard of fair and equitable treatment is not materially different from the content of the minimum standard of treatment in customary international law.”⁴⁶³ These decisions both reflect customary international law

⁴⁶¹ See *Merrill & Ring v. Canada*, at ¶ 210 (CL-51); *Deutsche Bank v. Sri Lanka*, ICSID Case No. ARB/09/2, Award (31 October 2012), at ¶¶ 418-419 (CL-93); *Rumeli Telekom A.S., Telsim Mobil Telekomikasyon Hizmetleri A.S. v. Republic of Kazakhstan*, ICSID Case No. ARB/05/16, Award (29 July 2008), at ¶ 611 (CL-58); *Duke Energy v. Ecuador*, ICSID Case No. ARB/04/19, Award (12 August 2008), at ¶ 337 (CL-94); *Azurix Corp. v. Argentina*, ICSID Case No. ARB/01/12, Award (23 June 2006), at ¶ 361 (CL-95); *Saluka v. Czech Republic*, at ¶ 291 (CL-85); *CMS Gas Transmission Company v. Argentina*, ICSID Case No. ARB/01/8, Award (12 May 2005), at ¶¶ 282-284 (CL-96); *Occidental Exploration and Production Co. v. Republic of Ecuador*, Award (1 July 2004), at ¶ 70 (CL-97); Hon. Stephen Schwebel, *The Influence of Bilateral Investment Treaties on Customary International Law*, 2004 ASIL PROCEEDINGS 27, 29-30 (“[W]hen BITs prescribe treating the foreign investor in accordance with customary international law, they should be understood to mean the standard of international law embodied in the terms of some two thousand concordant BITs”) (CL-98).

⁴⁶² *Merrill & Ring v. Canada*, at ¶ 210 (CL-51).

⁴⁶³ *Biwater Gauff Ltd. v. Tanzania*, ICSID Case No. ARB/05/22, Award and Separate Opinion (18 July 2008), at ¶ 592 (CL-52); see also *Deutsche Bank v. Sri Lanka*, ICSID Case No. ARB/09/2, Award (31 October 2012), at ¶¶ 418-419 (“[T]he actual content of the Treaty standard of fair and equitable treatment is not materially different from the content of the minimum standard of treatment in customary international law, as recognized by numerous arbitral tribunals and commentators.”) (CL-93).

and contribute to its formation by adding texture to the Minimum Standard of Treatment as it has been applied on the facts of particular cases.⁴⁶⁴

256. A minority of decisions, such as *Glamis Gold v. United States*, have concluded the Minimum Standard of Treatment requires a different (and lesser) level of protection than the treaty-based Fair and Equitable Treatment standard.⁴⁶⁵ These cases have been heavily criticized for their over-reliance on customary principles from the 1920s from outside the investor protection context.⁴⁶⁶ As the

⁴⁶⁴ It is well-established that even though arbitral tribunals are not bound by previous decisions of other international tribunals, such decisions are nevertheless persuasive authority that should be taken into account. See, e.g., *Railroad Development Corporation v. Guatemala*, ICSID Case No. ARB/07/23, Award (29 June 2012), at ¶ 217 (explaining in the context of a fair and equitable treatment claim that while “arbitral awards do not constitute State practice” they are “an efficient manner for a party in a judicial process to show what it believes to be the law”) (CL-100); *EDF v. Argentina*, ICSID Case No. ARB/03/23, Award (11 June 2012), at ¶ 897 (“Although not bound by previous decisions of other international tribunals, the Tribunal has given them due consideration with the aim of enhancing consistent interpretation of comparable treaty language as applied to similar fact patterns, thereby promoting the legitimate expectations of both host states and foreign investors.”) (CL-101).

⁴⁶⁵ See *Glamis Gold v. United States*, at ¶¶ 601-607; see also *Cargill Incorporated v. Mexico*, ICSID Case No. ARB(AF)/05/2, Award (18 September 2009) at ¶ 276 (“It is the Tribunal’s view that significant evidentiary weight should not be afforded to autonomous [Fair and Equitable Treatment] clauses inasmuch as it could be assumed that such clauses were adopted precisely because they set a standard other than that required by custom.”) (CL-107).

⁴⁶⁶ The tribunal in *Glamis Gold* principally relied on the *Neer* case, a decision by the Mexican Claims Commission from 1926 involving claims arising from the murder of a foreign national. The tribunal held in that case that “the treatment of an alien . . . should amount to an outrage, bad faith, to wilful neglect of duty, or to an insufficiency of governmental action so far short of international standards that every reasonable and impartial man would readily recognize its insufficiency.” *Glamis Gold v. United States*, at ¶ 547 n.1097 (quoting *Neer v. Mexico*, 4 R. Int’l Arb. Awards, 60-62 (15 October 1926)). The *Glamis Gold* tribunal has been heavily criticized for its reliance on *Neer*. See, e.g., Hon. Stephen Schwebel, *Is Neer Far from Fair and Equitable?*, 27(4) ARB. INT’L 4-555, 559 (2011) (“It may indeed be asked why the *Neer* award [was] invoked [by the *Glamis Gold* tribunal] at all. It had nothing to do with the treatment of foreign investors or investments. It did not address what is fair and equitable. Rather, it only examined whether Mexico had committed a denial of justice in failing adequately to investigate and prosecute the murderers of an alien. It considered whether proper investigatory and judicial procedures were observed. It held that Mexico could not be held liable for sufficiently egregious failure to follow those procedures. What in another case may or may not be fair and equitable treatment by a State of foreign investment may involve procedural matters, or matters of substance, or both, far removed from the confines and criteria of a denial of justice.”) (CL-103); Stephan Schill, *Note on the Award in Glamis Gold, Ltd. v. United States Award*, 104 AM. L. J. INT’L L. 253, 258 (2010) (CL-118). See also *Waste Management v. Mexico*, at ¶ 98 (“Both the *Mondev* and *ADF* tribunals rejected any suggestion that (continued...)”) (CL-101).

tribunal in *Mondev v. Canada* observed, “[t]he content of the minimum standard today cannot be limited to the content of customary international law as recognized in arbitral decisions in the 1920s.”⁴⁶⁷ And even in *Glamis Gold* itself, the tribunal acknowledged that the Minimum Standard of Treatment has evolved in the past hundred years.⁴⁶⁸ Apart from these outlier cases, most authorities recognize that the end result of this evolution, as the tribunal noted in *Pope & Talbot*, is a “broadened” Minimum Standard of Treatment that “include[s] the concept of fair and equitable treatment.”⁴⁶⁹

257. While the weight of authority thus supports the proposition that the Minimum Standard of Treatment affords investors the same level of protection as the treaty-based Fair and Equitable Treatment Standard, it is not necessary for the

the standard of treatment of a foreign investment set by NAFTA is confined to the kind of outrageous treatment referred to in the *Neer* case.”) (CL-65).

⁴⁶⁷ *Mondev v. United States*, at ¶ 123 (CL-7). In *Mondev*, the tribunal rejected the argument that the International Minimum Standard should be governed by reference to the *Neer* case.

⁴⁶⁸ *Glamis Gold v. United States*, at ¶ 616 (applying the “fundamentals of the *Neer* standard” but recognizing that “as an international community, we may be shocked by State actions now that did not offend us previously.”) (CL-116); see also *Cargill v. Mexico*, at ¶ 282 (“As stated above, the Parties in this proceeding and this Tribunal agree with the view that the customary international law minimum standard of treatment may evolve in accordance with changing State practice manifesting to some degree expectations within the international community. As the world and, in particular, the international business community become ever more intertwined and interdependent with global trade, foreign investment, BITs and free trade agreements, the idea of what is the minimum treatment a country must afford to aliens is arising in new situations simply not present at the time of the *Neer* award which dealt with the alleged failure to properly investigate the murder of a foreigner.”) (CL-102).

⁴⁶⁹ See *Pope & Talbot v. Government of Canada*, NAFTA/UNCITRAL, Award in Respect of Damages (31 May 2002), at ¶¶ 58-60 (rejecting the Respondent’s “static conception of customary international law,” reasoning that, *inter alia*, “there has been evolution in customary law concepts since the 1920s” and “since the 1920’s, the range of actions subject to international concern has broadened beyond the international delinquencies considered in *Neer* to include the concept of fair and equitable treatment.”) (CL-90); see also *Merrill & Ring v. Canada*, at ¶ 213 (“In conclusion, the Tribunal finds that the applicable minimum standard of treatment of investors is found in customary international law and that, except for cases of safety and due process, today’s minimum standard is broader than that defined in the *Neer* case and its progeny. Specifically, this standard provides for the fair and equitable treatment of alien investors within the confines of reasonableness. The protection does not go beyond that required by customary law, as the FTC has emphasized. Nor, however, should protected treatment fall short of the customary law standard.”) (CL-51).

Tribunal to decide this issue. Even if the Tribunal were to conclude that the Minimum Standard of Treatment *is* materially different from the Fair and Equitable Treatment standard, the result in this case would be the same because Canada's measures violate at least three well-established aspects of the Minimum Standard of Treatment.

258. *Protection against arbitrary treatment.* The Minimum Standard of Treatment protects investors against treatment that is arbitrary or unreasonable. In *Waste Management v. Mexico*, the tribunal reviewed prior NAFTA decisions and concluded that "the minimum standard of fair and equitable treatment is infringed by conduct attributable to the State and harmful to the claimant if the conduct is [*inter alia*] arbitrary ... unjust or idiosyncratic."⁴⁷⁰ Canada's promise utility doctrine is arbitrary and unreasonable because it is unpredictable and leads to illogical and absurd results.

259. *Protection of legitimate, investment-backed expectations.* As the tribunal recognized in *Thunderbird Gaming Corp. v. Mexico*, the Minimum Standard of Treatment is engaged "where a Contracting Party's conduct creates reasonable and justifiable expectations on the part of the investor (or investment) to act in reliance on said conduct, such that a failure by the NAFTA party to honour these expectations would cause the investor (or investment) to suffer damages."⁴⁷¹ This standard is satisfied here. When Lilly patented and launched Zyprexa and Strattera, it legitimately expected that Canada's patent utility requirement would not be changed in an arbitrary and unreasonable manner.

⁴⁷⁰ *Waste Management v. Mexico v. Mexico*, at ¶ 98 (CL-64).

⁴⁷¹ *International Thunderbird Gaming Corporation v. Mexico*, NAFTA/UNCITRAL, Award (26 January 2006), at ¶ 147 (CL-104). See also *id.*, *Separate Opinion of Professor Thomas Wälde* at ¶ 34 ("[I]f '**fair competition**' aimed at (Art. 101(1)(b) NAFTA) and an '**increase of substantial investment opportunities**' (Art. 101(1)(c) NAFTA) is to be achieved, there must be an extra attention to '**clarity**' and '**predictability**' for '**business planning and investment**' (NAFTA Preamble). The protection of legitimate expectations standard thus says that such competitive opportunities as are protected under Art. 101(1)(b) NAFTA shall not be offset by measures which are in effect detrimental to the '**business planning and investment**' of the investor.") (emphasis in original) (CL-44).

260. *Protection against discriminatory treatment.* Finally, the Minimum Standard of Treatment shields investors from discriminatory measures.⁴⁷² As discussed above, Canada's promise utility doctrine results in unjustified discrimination against the innovative pharmaceutical industry, including Lilly's patents for Zyprexa and Strattera.

2. Respondent's Measures Violate Article 1105 Because They are Arbitrary, Unjust, and Idiosyncratic.

261. As already noted, the Minimum Standard of Treatment protects investors against "conduct [that] is arbitrary, . . . unjust or idiosyncratic."⁴⁷³ A State acts arbitrarily when it changes municipal law such that the new rule is unclear and the investor cannot reasonably plan for and comply with it. In *Occidental v. Ecuador (VAT Dispute)*, for example, the tribunal determined that Ecuador acted arbitrarily when it changed its VAT tax law "without providing any clarity about its meaning and extent," noting that "the practice and regulations were also inconsistent with such changes."⁴⁷⁴ The tribunal reached this conclusion despite finding that Ecuador's tax authority was not acting in bad faith. As the tribunal explained:

In the context of the present dispute, the decisions taken by SRI do not appear to have been founded on prejudice or preference rather than on reason or fact. As was convincingly explained in the hearing by the Director of SRI [Ecuador's tax service], the SRI was confronted with a variety of practices, regulations, and rules dealing with the question of VAT. It has been explained above that this resulted in a

⁴⁷² *Glamis Gold v. United States*, at ¶ 616 (concluding that "evident discrimination" violates the customary international law minimum standard of treatment codified in Article 1105 of the NAFTA) (CL-116).

⁴⁷³ *Waste Management v. Mexico*, at ¶ 98 (CL-64). See also *International Thunderbird Gaming Corporation v. Mexico*, NAFTA/UNCITRAL, Award (26 January 2006), at ¶ 194 ("For the purposes of the present case, the Tribunal views acts that would give rise to a breach of the minimum standard of treatment prescribed by the NAFTA and customary international law as those that, weighed against the given factual context, amount to a gross denial of justice or manifest arbitrariness falling below acceptable international standards.") (emphasis added) (CL-104).

⁴⁷⁴ *Occidental Exploration and Production Co. v. Republic of Ecuador*, UNCITRAL/LCIA Case No. UN 3467, Award (1 July 2004), at ¶ 163 (CL-97).

confusing situation into which the SRI had the task of bringing some resemblance of order. However, it is that very confusion and lack of clarity that resulted in some form of arbitrariness, even if not intended by the SRI.⁴⁷⁵

262. Canada's promise utility doctrine is arbitrary, unjust, and idiosyncratic. Its elements – the promise, the heightened evidentiary burden, and the additional disclosure obligation – taken together, have a multiplier effect that grossly distorts the traditional test for utility, under which the invention need only have a mere scintilla of utility. The end result is that foreign investors are confronted with a completely unpredictable doctrine that is unreasonably difficult to satisfy.

263. *First*, as discussed above, the promise utility doctrine requires judges to undertake the inherently unpredictable task of identifying the “promises” contained in a patent.⁴⁷⁶ The construal of a patent's promised utility is critical to whether the patent will ultimately pass muster under the doctrine, yet the Canadian courts take widely divergent approaches to determining the number and content of a patent's “promises.”⁴⁷⁷ One court may look at a patent for a drug that treats a condition and conclude that its “promise” is simply that it treats the condition. Another court may look at the same patent and conclude (as the court did in the *Strattera* and *Zyprexa* cases) that it contains an *implicit* promise to treat the condition according to the Judge's own additional criteria, such as whether the drug is effective over the long term.⁴⁷⁸ As discussed above, the subjectivity of the

⁴⁷⁵ *Id.* at ¶ 163 (CL-97). The tribunal made clear that the treaty-based Fair and Equitable treatment standard it was applying was “not different from that required under international law concerning both the stability and predictability of the legal and business framework of the investment.” *Id.* at ¶ 190 (CL-97).

⁴⁷⁶ *See supra* Parts III.C.1 & III.C.5.

⁴⁷⁷ *See supra* Part III.C.

⁴⁷⁸ As discussed in detail above, in the case of *Zyprexa*, the claimed utility of the patent was simply that it was useful as an anti-psychotic. The Federal Court, however, concluded that “the promise of the patent is that olanzapine treats schizophrenia patients in the clinic in a markedly superior fashion and with a better-side effects profile than other known antipsychotics.” *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, ¶ 209 (C-146). Similarly, in the case of *Strattera*, the claimed utility (continued...)

process is such that *the very same court* can look at the *very same patent* in two different cases and conclude that its promised utility is different.⁴⁷⁹

264. This unpredictable interpretation of a patent's "promise" would be problematic enough if courts limited their scrutiny to the patent's carefully-drafted claims, which as Professor Siebrasse explains, are intended to precisely define the invention.⁴⁸⁰ But Canadian judges often construe a patent's promise by scouring statements in the patent's disclosure: the more fulsome explanatory statement that allows others to make and use the invention at the end of the patent term.⁴⁸¹ As Professor Siebrasse explains, a patent's disclosure was never intended to be parsed like a patent's claims, and the fact that Canadian judges have scrutinized the disclosure in applying the promise doctrine is part of the reason why its results have been so confused and unpredictable: "[C]onstruction of the promise is an arbitrary and hair splitting exercise because the statutory function of the disclosure is to disclose the invention, not to define it."⁴⁸² This unpredictability is magnified when the court not only looks to the disclosure, but also discerns an implicit promise within that description.

265. *Second*, the promise utility doctrine is arbitrary and unpredictable because of its heightened evidentiary burden, pursuant to which judges second guess the scientific evidence submitted in support of a patent's utility. Patent applicants have no way of knowing at the time of drafting how much (and what type of) evidence a judge will require to demonstrate or soundly predict a patent's utility. Under the promise utility doctrine, Canadian judges sometimes require

was that the drug treated humans with ADHD. But the court concluded that "[w]hat is implicit in this promise is that atomoxetine will work in the longer term." *See supra* ¶ 132.

⁴⁷⁹ As discussed above, in two decisions issued just months apart, the Federal Court of Appeal first upheld the utility of a patent on the drug latanoprost after finding it had a particular promise, and then invalidated the very same patent on the sole ground of inutility after concluding that it had an entirely different promise. *See supra* ¶ 64.

⁴⁸⁰ *See supra* ¶ 209; *see also* Siebrasse Report at ¶¶ 10-12.

⁴⁸¹ Siebrasse Report at ¶¶ 9, 15.

⁴⁸² Siebrasse Report at ¶¶ 52-53.

human clinical trial data to demonstrate utility as of the filing date, and may even find human clinical trials insufficient to soundly predict utility. In some cases – as in the case of Zyprexa and Strattera – they conclude that even successful, published, and statistically significant clinical trial results fail to satisfy the judges’ standards of design, size, or duration.⁴⁸³ An inventor has no way of knowing how much is enough.

266. Nor is it any answer to say that patent applicants could satisfy this heightened evidentiary burden by always including comprehensive human clinical trial data in their applications. It is difficult and in many cases impossible to conduct clinical trials without making them public, since many governments require publication to ensure adequate review of the safety of the trial for its participants.⁴⁸⁴ If clinical trial information becomes public before a company files its patent applications, then the company runs the risk of the patent being invalidated on the ground that is not novel or non-obvious.⁴⁸⁵ Companies thus face a “Catch-22” under the promise utility doctrine. Either they file without clinical trial data and risk invalidation under the promise utility doctrine, or they wait for significant clinical trial data and, because such data are often published, they risk losing their patent to a determination that their invention is no longer patentable for lack of novelty or anticipation.

267. This is more than a theoretical concern – it manifested itself on the facts of this case. As discussed above, the Zyprexa and Strattera patents were unusual in that Lilly had developed clinical trial data for both drugs before they

⁴⁸³ See *supra* Parts IV.A.2 and IV.B.2.

⁴⁸⁴ See Stringer Statement at ¶ 16. Thus, for example, Canadian law requires that a trial be disclosed to a number of persons, such as (i) an independent review committee, (ii) medical representatives of the subjects, such as their personal physicians, and of course (iii) the patients themselves. As the number of people increase, the risk of inadvertent or intentional disclosure increases dramatically. See Siebrasse Report at ¶ 107. Once a clinical study becomes public, it is easily accessible on a number of comprehensive websites. For example, the website clinicaltrials.gov, which is operated by the U.S. National Institute of Health, currently lists 175,432 studies from 187 countries.

⁴⁸⁵ Stringer Statement at ¶ 16; Siebrasse Report at ¶¶ 107-108.

filed for patent protection in Canada.⁴⁸⁶ As Mr. Stringer explains, during the Foreign Patent Committee process, Lilly recognized that this clinical trial data was placing the patentability of their inventions at “major risk,” which was why it was important not to delay in submitting foreign patent applications.⁴⁸⁷ In other words, if Lilly had waited to file for patent protection in Canada with respect to Zyprexa and Strattera until comprehensive clinical testing had been completed, it could easily have missed its chance. Indeed, as noted above, one of the reasons that Novopharm alleged the Strattera patent was invalid was because of a disclosure made during the MGH clinical trial.⁴⁸⁸

268. The heightened evidentiary burden of the promise utility doctrine is also arbitrary because it bars consideration of post-filing evidence to *support* utility while continuing to allow post-filing evidence to establish a *lack* of utility.⁴⁸⁹ Post-filing evidence also continues to be admissible and regularly used to establish non-obviousness.⁴⁹⁰ Professor Siebrasse notes that this selective bar on post-filing evidence “has had a dramatic impact on the ability to prove that a pharmaceutical invention satisfies the utility requirement.”⁴⁹¹

269. *Third*, the utility doctrine is arbitrary because of its third core element – the disclosure obligation that requires that evidence in support of a sound prediction of utility must have been disclosed in the patent application itself.⁴⁹² As Professor Siebrasse explains, this requirement introduces an additional dimension of unpredictability to the promise utility doctrine because

⁴⁸⁶ See *supra* ¶ 121.

⁴⁸⁷ Stringer Statement at ¶¶ 16-17, 23.

⁴⁸⁸ See *supra* ¶¶ 134-35 ; see also *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, at ¶ 3 (C-160). Notably, a similar argument was raised in the United States with respect to Zyprexa. *Eli Lilly and Co. v. Zenith Goldine Pharm.*, 471 F.3d 1369, 1381 (Fed. Cir. 2006) (C-149).

⁴⁸⁹ Siebrasse Report at ¶ 55.

⁴⁹⁰ Siebrasse Report at ¶ 55.

⁴⁹¹ Siebrasse Report at ¶ 56.

⁴⁹² See *supra* ¶¶ 73-75, 79-82.

the distinction between demonstrated utility and sound prediction is “conceptually arbitrary and unclear in practice.”⁴⁹³ Properly understood, “the concept of ‘sound prediction’ is nothing more than an acknowledgment that utility need not be established by actual testing.”⁴⁹⁴ In practice, because inventors cannot know how the court will construe the promise, they have no way of knowing if it will be necessary to evaluate utility on the basis of a sound prediction, in which case the record is limited solely to evidence disclosed in the patent itself.⁴⁹⁵

270. In other words, the court can rely on evidence that was not included in the patent application to conclude that the promised utility was “demonstrated” as of the date of filing. But if the court finds that the evidence falls short of “demonstrating” utility, it cannot then rely on the very same evidence to assess whether the promise was nonetheless soundly predicted.⁴⁹⁶ Given that there is only one standard of utility under Canadian law that applies regardless of whether utility is demonstrated or soundly predicted,⁴⁹⁷ this distinction is arbitrary and devoid of any rationale.

271. Under this highly subjective and unpredictable framework, it does not require bad faith for the process to produce arbitrary results.⁴⁹⁸ Just as in *Occidental*, “it is that very confusion and lack of clarity that resulted in some form of arbitrariness, even if not intended by the [Canadian courts].”⁴⁹⁹

⁴⁹³ Siebrasse Report at ¶ 67.

⁴⁹⁴ Siebrasse Report at ¶ 67.

⁴⁹⁵ See *supra* ¶¶73-75; Siebrasse Report at ¶¶ 67-68.

⁴⁹⁶ Siebrasse Report at ¶¶ 69-70.

⁴⁹⁷ Siebrasse Report at ¶ 67.

⁴⁹⁸ See *Waste Management, Inc. v. Mexico*, at ¶ 97 (CL-64). The principle “that a breach of fair and equitable treatment does not presuppose bad faith on the part of the State” has been confirmed in “a consistent line of cases” decided both under NAFTA and under other investment treaties. *Duke Energy Electroquil Partners v. Ecuador*, ICSID Case No. ARB/04/19, Award (18 August 2008), ¶ 341 (CL-94).

⁴⁹⁹ *Occidental Exploration and Production Co. v. Republic of Ecuador*, UNCITRAL/LCIA Case No. UN 3467, Award (1 July 2004), at ¶ 163 (CL-97). The arbitrariness of the promise utility doctrine is also supported by the fact that, as demonstrated above, the doctrine violates Chapter 17 of NAFTA and (continued...)

3. Respondent's Measures Violated Claimant's Legitimate Expectations Rooted in Canada's Patent Law, Its International Commitments Under NAFTA and the PCT, and Its Grant of the Zyprexa and Strattera Patents.

272. The Minimum Standard of Treatment also protects an investor's legitimate expectations in making its investment decisions. In both NAFTA and non-NAFTA cases, tribunals have recognized that an investor's legitimate expectations may be grounded in the "basic principles" of law governing the investment, "even in the absence of specific promises by the government."⁵⁰⁰ In *Grand River Enterprises v. United States*, for example, the tribunal interpreted "the concept of reasonable or legitimate expectations in the NAFTA context to correspond with those expectations upon which an investor is entitled to rely as a result of representations *or conduct* by a state party."⁵⁰¹

is therefore opposed to Canada's legal commitments and its expressed policy objectives in respect of the protection of intellectual property. The FTC Notes are not to the contrary. The FTC Notes provide that a "determination that there has been a breach of another provision of NAFTA, or of a separate international agreement, does not establish that there has been a breach of Article 1105(1)." NAFTA Free Trade Commission, *Notes of Interpretation of Certain Chapter 11 Provisions*, § 2(3) (31 July 2011) (CL-41). But the FTC Notes do not preclude Tribunals from taking notice of a breach of NAFTA or another international agreement as one factor among others in determining whether the state measure is arbitrary and thus, in turn, a violation of Article 1105. *Id.* (C-41).

⁵⁰⁰ *Total S.A. v. Argentine Republic*, ICSID Case No. ARB/04/01, Award, (27 December 2010), at ¶ 333 ("A foreign investor is entitled to expect that a host state will follow those basic principles (which it has freely established by law) in administering a public interest sector that it has opened to long term foreign investments. Expectations based on such principles are reasonable and hence legitimate, even in the absence of specific promises by the government.") (CL-106); *see also Tecmed v. Mexico*, at ¶ 154 ("The foreign investor expects the host State to act in a consistent manner, free from ambiguity and totally transparently in its relations with the foreign investor, so that it may know beforehand *any and all rules and regulations that will govern its investments, as well as the goals of the relevant policies and administrative practices or directives, to be able to plan its investment and comply with such regulations.*") (emphasis added) (CL-47).

⁵⁰¹ *Grand River Enterprises Six Nations, Ltd. v. United States of America*, NAFTA/UNCITRAL, Award (12 January 2011), at ¶ 136 (emphasis added) (CL-107) (quoting *Thunderbird Gaming v. Mexico*, at ¶ 147); *see also Fireman's Fund v. Mexico*, at ¶ 176(k) n. 163 ("Under a common view of international investment law, the foreign investor and host State are entitled to have the governmental interference with the investor's enterprise considered in light of the investor's chosen business model, the nature of the enterprise, the regulatory regime in place at the time of investment, and associated expectations.") (CL-45) (quoting Jack Coe, Jr. and Noah Rubins, *Regulatory Expropriation and the Tecmed Case: Context and Contributions*, in INTERNATIONAL INVESTMENT LAW AND (continued...)

273. In applying Article 1105, “[t]ribunals have emphasized that the legitimate expectations of the investor *will be grounded in the legal order of the host state as it stands at the time the investor acquires the investment.*”⁵⁰² This is not to say, of course, that municipal law must remain frozen and cannot evolve in light of changing circumstances. As Professors Dolzer and Schreuer have observed:

[Arbitral] decisions are consistent with the right of the host state to determine its own legal and economic order, subject to the international minimum standard. At the same time, they recognize the investor’s concern for planning and stability based on that order at the time of the investment. Whereas the prudent investor will, in light of these rulings, carefully examine the laws before investing, *the host state must at all times be aware that its legal order forms the basis of legitimate expectations which must be taken into account in future reforms.*⁵⁰³

274. Here, Lilly was entitled to – and did in fact – rely on Canada’s patent utility requirement at the time of making its investment. This requirement, like the other patentability standards contained in Canada’s Patent Act, were technical regulations designed and addressed specifically to inventors like Lilly that were seeking to protect their inventions with a patent in Canada. As discussed above, a patent is a bundle of exclusive rights granted by the Government which are exercised in the marketplace, including the right to be the exclusive seller of

ARBITRATION: LEADING CASES FROM THE ICSID, NAFTA, BILATERAL TREATIES AND CUSTOMARY INTERNATIONAL LAW 597, 632-643 (Todd Weiler ed., 2005)).

⁵⁰² RUDOLF DOLZER & CHRISTOPH SCHREUER, *PRINCIPLES OF INTERNATIONAL INVESTMENT LAW* 145-146 (2d ed. 2012) (emphasis added) (CL-50) (citing, *inter alia*, the NAFTA cases *GAMI Investments Inc. v. United Mexican States*, NAFTA/UNCITRAL, Award (15 November 2004), at ¶ 93 (CL-108), *Marvin Feldman v. Mexico*, NAFTA/ICSID No. ARB(AF)/99/1, Award (16 December 2002), at ¶ 128 (CL-109), *Mondev v. United States*, at ¶ 156 (CL-7), and *Azinian v. Mexico*, ¶¶ 95-97 (CL-61)). The principle is equally well established outside the NAFTA context. *See, e.g.*, *LG&E Energy Corp. v. Argentina*, ICSID Case No. ARB/02/1, Decision on Liability (3 October 2006), at ¶ 130 (CL-110); *BG Group v. Argentina*, UNCITRAL, Final Award (24 December 2007), at ¶ 298 (“The duties of the host State must be examined in the light of the legal and business framework as represented to the investor at the time that it decides to invest.”) (CL-111).

⁵⁰³ RUDOLF DOLZER & CHRISTOPH SCHREUER, *PRINCIPLES OF INTERNATIONAL INVESTMENT LAW* 146 (2d ed. 2012) (emphasis added) (CL-50).

products protected by the patent.⁵⁰⁴ A patent-holder further invests in the value of its patent by bringing patent-protected products to market during the period of exclusivity secured by the patent.

275. Lilly relied on Canada's patent laws throughout the process of developing Zyprexa and Strattera, including early in the product lifecycle when Lilly was deciding whether to file for patent protection in Canada. As Mr. Stringer explains, Lilly's Foreign Patent Committee would weigh "country-specific concerns about patentability or enforceability of pharmaceutical patents," when deciding how widely to file foreign patent applications.⁵⁰⁵ When the Committee considered Zyprexa and Strattera, Lilly "had no reason to suspect that any foreign filing, including in Canada, could be invalidated for lack of utility."⁵⁰⁶ As Mr. Stringer explains, if utility had been a concern, Lilly would have addressed that concern prior to filing.⁵⁰⁷

276. It was not surprising that Canada's utility requirement was not flagged as a concern during the Foreign Patent Committee process. As Robert Armitage, Lilly's former General Counsel, explains, the utility requirement is "substantially harmonized across jurisdictions," and as a practical matter it "never arises with respect to a marketed biopharmaceutical product," as the utility of a drug approved for clinical use is self-evident.⁵⁰⁸ This "was true even in Canada until relatively recently."⁵⁰⁹ Accordingly, Lilly "expected that the utility requirement could not possibly pose an issue for the Strattera and Zyprexa patents."⁵¹⁰ Mr. Armitage's recollections are consistent with Lilly's internal launch

⁵⁰⁴ See *supra* ¶¶ 25-27, 163.

⁵⁰⁵ Stringer Statement at ¶ 8.

⁵⁰⁶ *Id.* at ¶¶ 19-25.

⁵⁰⁷ *Id.*

⁵⁰⁸ Armitage Statement at ¶ 7.

⁵⁰⁹ *Id.*

⁵¹⁰ *Id.* at ¶ 8.

check lists and other planning documents, which reflect optimism that Lilly's patents would be granted in Canada and no concerns regarding utility.⁵¹¹

277. Lilly continued to rely on Canada's patent laws as it brought Zyprexa and Strattera to market. According to Robert Postlethwait and Anne Nobles – the executives who oversaw the launch of the two products – Lilly closely monitored the prosecution of the Zyprexa and Strattera patents while the company prepared to launch in Canada. Given the importance of patent rights for the success of Lilly's products in major markets like Canada, any issues regarding patentability in Canada would have been flagged for these executives.⁵¹² None was.⁵¹³ As Ms. Nobles recalls with respect to Strattera, “[w]e certainly did not have any concern that the Strattera patent would be invalidated because it was not ‘useful.’ In fact, I do not recall any discussions about the ‘utility’ criterion for patentability at all.”⁵¹⁴

278. The ability to secure patent protection for Zyprexa was also critical to the launch of that medicine. When Lilly requested examination in Canada in October 1995, it already had patent protection for Zyprexa in the United States (20 July 1993), the United Kingdom (13 September 1995), and Mexico (25 March 1994), among other jurisdictions.⁵¹⁵ Patent protection was expected in Canada as well. According to Mr. Postlethwait,

[W]e did not see any realistic prospect that the patent application would be rejected, particularly when Health Canada had approved Zyprexa as safe and effective we were very focused on patent protection, and our patent attorneys had not flagged any issues with our Canadian patent application. The fact that no issues were raised gave us confidence that we would receive a patent, which in turn

⁵¹¹ See *supra* at ¶ 90.

⁵¹² Postlethwait Statement at ¶ 22; Nobles Statement at ¶ 17.

⁵¹³ Postlethwait Statement at ¶ 25; Nobles Statement at ¶ 23.

⁵¹⁴ Nobles Statement at ¶ 17.

⁵¹⁵ See *supra* at ¶¶ 85-90.

was a key consideration in our decision to proceed with the Canadian launch.⁵¹⁶

279. Lilly's expectations regarding patent protection for Zyprexa and Strattera in Canada were objectively reasonable. Lilly could not reasonably have expected that Canada would promulgate the unique promise utility doctrine, which has no basis in Canada's statutory patent law and adds a second utility hurdle distinct from the mere scintilla test embodied in the Patent Act. Nor could any reasonable investor have expected that Canada would develop a utility doctrine that was inconsistent with Canada's international obligations under Chapter 17 of NAFTA – particularly when Canada had enacted implementing legislation that expressly required that all federal laws must be interpreted in a manner consistent with the treaty and its own Minister of Industry had acknowledged on the floor of Parliament that Canada's "ability to change [its] patent law [was] defined by [the] obligations" in Chapter 17.⁵¹⁷ This dramatic and internationally wrongful departure in Canada's patent law was plainly outside the "acceptable margin of change" that investors must reasonably anticipate.⁵¹⁸

280. In the case of Strattera, moreover, Lilly expected that its PCT application, the basis for the Canadian patent filing, would be sufficient to meet Canadian requirements relating to disclosure of utility, and that Canada would not retroactively impose additional utility disclosure requirements to invalidate the Strattera Patent. Canada ratified the PCT on October 2, 1989 and became

⁵¹⁶ Postlethwait Statement at ¶ 29.

⁵¹⁷ See The North American Free Trade Implementation Act, S.C. 1993, c. 44, § 3 ("For greater certainty, this Act, any provision of an Act of Parliament enacted by Part II and any other federal law that implements a provision of the Agreement or fulfils an obligation of the Government of Canada under the Agreement shall be interpreted in a manner consistent with the Agreement.") (C-184); Honourable John Manley, Canadian Minister of Industry, Speaking Notes for Address to the Standing Committee on Industry, Review of Bill C-91 (17 February 1997) (C-39). See also *supra* Part VII.A.2.

⁵¹⁸ RUDOLF DOLZER & CHRISTOPH SCHREUER, *PRINCIPLES OF INTERNATIONAL INVESTMENT LAW* 148 (2d ed. 2012) (CL-50) ("What matters is whether measures exceed normal regulatory powers and fundamentally modify the regulatory framework for the investment beyond an acceptable margin of change.")

bound by its terms on January 2, 1990.⁵¹⁹ Prior to ratification, Canada amended its Patent Act to conform with the PCT, and issued regulations making clear that Canada would “adhere to the PCT in its entirety.”⁵²⁰

281. The fundamental purpose of the PCT is to permit a patent applicant to file a single international patent application that will meet the form and content requirements of every PCT member country, including what must be disclosed by the patentee within the specification.⁵²¹ The PCT prohibits member countries from imposing additional or different form and content requirements from those set out in the PCT and PCT Regulations, otherwise the fundamental objective of the treaty would be undermined.⁵²²

282. As Mr. Erstling explains, the PCT does not require a patent applicant to disclose evidence of the utility of an invention within the patent specification itself.⁵²³ In fact, there is no requirement to disclose anything regarding the utility of the invention in the patent specification unless the utility of the invention is not obvious from the description or nature of the invention, in which case the specification must simply “indicate, explicitly . . . the way in which the invention

⁵¹⁹ World Intellectual Property Organization, PCT Notification No. 56; Ratification by Canada (2 October 1989) (C-185).

⁵²⁰ An Act to Amend the Patent Act and To Provide For Certain Matters in Relation Thereto, Ch. 41, 1987 Can. Stat. (C-186); *Regulations For Carrying Into Effect the Terms of the Patent Cooperation Treaty Done at Washington on June 19, 1970*, SOR/89-453 (21 September 1989) and accompanying Regulatory Impact Analysis Statement (C-187). In 1996, Canada repealed the Patent Cooperation Treaty Regulations and combined them with the Patent Rules, which were amended to incorporate by reference the provisions of the PCT into domestic law: Patent Rules, SOR/96-423 (including Regulatory Impact Analysis Statement) C Gaz II, 2742 (C-51).

⁵²¹ Erstling Report at ¶¶ 16, 24-26.

⁵²² Erstling Report at ¶ 28; Patent Cooperation Treaty, Art. 27(1) (C-106).

⁵²³ Erstling Report at ¶ 34. The form and content requirements of an international application are in Article 5 of the Patent Cooperation Treaty (C-106) and Rule 5.1 of the PCT Regulations (C-188). These provisions require that the description “disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.”

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.”⁵²⁴

283. The Strattera patent application claimed atomoxetine for the treatment of ADHD. Its utility was obvious from the subject matter of the invention. Accordingly, under the PCT, no further information regarding utility was required to be disclosed in the patent application. Yet Canada invalidated the Strattera patent by applying the promise doctrine’s disclosure rule – the retroactive requirement that evidence of utility must be disclosed within the patent application itself. This invalidation contravened Lilly’s legitimate expectation that if it submitted a valid PCT application, Canada would adhere to its treaty obligations (and domestic legislation) and not impose additional disclosure obligations beyond those contained in the PCT.⁵²⁵

284. Some NAFTA tribunals have concluded that in order to violate an investor’s legitimate expectations under the Minimum Standard of Treatment, the State must make specific commitments to the particular investor.⁵²⁶ This narrow standard imposes additional restrictions not found in customary international law.⁵²⁷ This more narrow standard is also met by Lilly’s reliance on Canada’s

⁵²⁴ Erstling Report at ¶ 33; Regulations under the Patent Cooperation Treaty, Rule 5.1(a)(vi) (C-188).

⁵²⁵ Both the PCT itself and Contracting States restrict the introduction of “new matter” into a patent application. See, e.g., Patent Act (Canada), RSC, 1985, c. P-4, at § 38.2(2) (C-50). If new matter is added that goes beyond the disclosure, the priority date for claims relying on such subject matter can be lost, which can be fatal to a patent application. As a result, if national laws impose additional form and content requirements, applicants who use the PCT process can be denied a patent. See Erstling Report, ¶¶ 27-28. By ratifying and implementing the PCT into domestic law, Canada gave assurances that it would not defeat this fundamental purpose of the PCT.

⁵²⁶ See *Mobil Investments Canada Inc. v. Canada*, NAFTA/ICSID Case No. ARB(AF)/07/4, Award (22 May 2012), at ¶ 152 (CL-112); see also *Glamis Gold v. United States*, at ¶ 620 (CL-116) (“Article 1105(1) requires the evaluation of whether the State made any specific assurance or commitment to the investor so as to induce its expectations.”).

⁵²⁷ *International Thunderbird Gaming Corp. v. Mexico*, NAFTA/UNCITRAL, Separate Opinion of Walde (1 December 2005), at ¶ 32 (“A review of these cases suggests that conduct, informal, oral or general assurances can give rise to or support the existence of a legitimate expectation.”) (CL-113); *Duke Energy Electroquil Partners v. Ecuador*, ICSID Case No. ARB/04/19, Award (18 August 2008), ¶ 340 (“The stability of the legal and business environment is directly linked to the investor’s justified expectations.”) (CL-94); *Occidental Exploration and Production Co. v. Ecuador*, (continued...)

utility requirement because that standard *was* a specific commitment to prospective inventors like Lilly. Unlike a law of general applicability, Canada's patentability standards, including its utility requirement, were technical regulations aimed, and relied upon, by a discrete and identifiable group.

285. But even if the Tribunal were to conclude that legitimate expectations under Article 1105 can be formed only through a commitment targeted at the *specific investor*, then Canada's measures would *still* violate Claimant's legitimate expectations because Canada made a specific commitment to Lilly in the form of the grant of the Zyprexa and Strattera patents themselves.

286. A patent constitutes a commitment to the patentee that it will have exclusive rights to make, use, and sell its invention until the expiry of the patent.⁵²⁸ By granting exclusivity to Lilly, Canada was upholding its end of the bargain between the inventor and the State that undergirds the entire Canadian Patent Act.⁵²⁹ As discussed in greater detail above, Respondent granted patents to Lilly on 14 July 1998 for Zyprexa and on 1 December 2002 for Strattera in exchange for Lilly disclosing its inventions to the public. Both patents were granted only after being carefully and thoroughly examined by CIPO's specialist patent examiners in accordance with the Manual of Patent Office Practice and Canadian law.⁵³⁰ Lilly's patents were legally enforceable the moment they were issued by the Canadian Intellectual Property Office.⁵³¹ In other words, the Zyprexa and Strattera patents were *more* than a mere representation to Lilly from the government of Canada; they were a bundle of legally enforceable rights.

UNCITRAL/LICA Case No. UN 3467, Final Award (1 July 2004), ¶¶ 183, 185 (CL-97) (citing *Tecmed v. Mexico*, at ¶ 154 (defining the "rules and regulations that will govern [the relevant] investments" as part of the "basic expectations . . . taken into account by the foreign investor")) (CL-47).

⁵²⁸ See *supra* ¶ 27.

⁵²⁹ *Free World Trust v. Électro Santé Inc.*, (2000) 2 SCC 66, at ¶ 13 (C-189); *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, at ¶ 133 (C-190).

⁵³⁰ Wilson Report at ¶¶ 9, 35-37, 43-44.

⁵³¹ Wilson Report at ¶ 18. See also Patent Act (Canada), RSC, 1985, c. P-4, at § 43(2) (C-50).

287. Lilly relied on these specific patent grants when it made further investment decisions in relation to both Zyprexa and Strattera. In the case of Zyprexa, Respondent granted Lilly's patent application on 14 July 1998 after expedited approval was requested on 13 October 1995. The British, American and Mexican patents on Zyprexa had already issued (along with several others),⁵³² and particularly given Health Canada's approval of the drug on October 28, 1996, no issues related to utility were anticipated. Once the patent was granted, Lilly's confidence that it would have patent protection in the Canadian market was affirmed. As Robert Postlethwait explains, "[a]s we had predicted, our Canadian patent application was granted in the summer of 1998. Although we had already launched Zyprexa, the granting of the patent application was still an important step. The market exclusivity provided by the patent was critical to succeeding in the market."⁵³³

288. In the case of Strattera, Respondent granted Lilly's patent application on 1 December 2002. As Ms. Nobles explains, because of a lack of any concerns that had been raised in Canada or elsewhere, Lilly was already confident that Respondent would grant the Strattera patent.⁵³⁴ Once the patent was granted, Lilly's confidence was validated with an enforceable bundle of exclusive property rights to make, use, and sell its invention until the expiry of the patent. As Ms. Nobles recounts, "[o]nce we received the Strattera patent . . . we had a legal entitlement to exclusivity, which provided us with additional confidence in planning for bringing the drug to market in Canada."⁵³⁵

289. Canada's arbitrary and unreasonable change in the law governing the utility of the Zyprexa and Strattera patents breached these representations. To

⁵³² See *supra* ¶ 278 (discussing grant of British, American and Mexican patent). See generally Armitage Statement at ¶ 11 (listing the 81 jurisdictions in which Zyprexa patents were ultimately granted).

⁵³³ Postlethwait Statement at ¶ 30.

⁵³⁴ Nobles Statement at ¶ 23.

⁵³⁵ Nobles Statement at ¶ 23.

be clear, it is not the fact of invalidation in and of itself that violates NAFTA Article 1105. To be sure, in most cases, the judicial invalidation of a patent would not constitute a breach of Canada's NAFTA Chapter 11 obligations. But here, a fundamental doctrinal transformation took place in Canada with regard to utility. Canada did not simply call the ball "out of bounds" under a core patentability requirement; it ordered that the game be played on an entirely different field, using completely different rules. Lilly's patents were not invalidated because they lacked a mere scintilla of utility, *i.e.*, because they fell short of the standard embodied in NAFTA Article 1709(1). Lilly's patents were invalidated under an entirely new standard that was layered on top of the existing mere scintilla standard, and that was not part of Canadian patent law when Lilly invested in Canada.

4. Respondent's Measures Violate Article 1105 Because They Are Discriminatory.

290. The Minimum Standard of Treatment protects investors against discriminatory conduct. A State measure is discriminatory when it subjects an investment to differential treatment and is "based on unjustifiable distinctions."⁵³⁶ A measure qualifies as discriminatory under international law so long as it has a discriminatory effect, irrespective of whether it was adopted with discriminatory intent.⁵³⁷

291. The promise utility doctrine is plainly discriminatory under this standard. As discussed at length above, the unmistakable effect of the promise

⁵³⁶ *Saluka v. Czech Republic*, at ¶ 309 (CL-85). Indeed, this follows from the plain meaning of the word. See "Discrimination," Black's Law Dictionary (9th ed. 2009) (defining discrimination as, *inter alia*, "a failure to treat all persons equally when no reasonable distinction can be found between those favored and those not favored") (CL-71).

⁵³⁷ *Marion Unglaube and Reinhard Unglaube v. Republic of Costa Rica*, ICSID Case Nos. ARB/09/20 and ARB/09/20, Award (16 May 2012), at ¶ 262-63 (CL-114) ("While evidence of discriminatory intent may be relevant . . . it is the fact of unequal treatment which is key.") (citing, *inter alia*, *LG&E Energy Corp. v. Argentina*, ICSID Case No. ARB/02/1, Decision on Liability (3 October 2006), at ¶ 146 (CL-110)). See Jeswald W. Salacuse, *THE LAW OF INVESTMENT TREATIES* 241 (2010) (citing K Vandeveld, *UNITED STATES INVESTMENT TREATIES: POLICY AND PRACTICE* 77 (1992)) (CL-115).

utility doctrine is to discriminate against pharmaceutical inventions in violation of Chapter 17 of NAFTA.⁵³⁸ The promise utility doctrine has been applied by the Federal Courts and resulted in 23 inutility decisions in the pharmaceutical sector, as opposed to zero in any other field of technology. Zyprexa and Strattera were among these 23 adverse decisions. The principal beneficiaries of these rulings are mainly generic drug makers, and those harmed are innovative foreign firms.⁵³⁹ Thus, whether discrimination is analyzed on the basis of field of technology or nationality, the promise utility doctrine subjected Lilly to treatment less favorable than that afforded to similarly-situated companies, without reasonable justification.

VIII. CONCLUSION

292. In this Memorial, Lilly has demonstrated that the promise utility doctrine is arbitrary in its application, discriminatory in its effects, and in conflict with Canada's commitments in Chapter 17 of NAFTA. Lilly has also demonstrated that the advent of the doctrine violated the company's legitimate, investment-backed expectations. This evidence provides the Tribunal with multiple independent bases for rendering an award in favor of Lilly on both of its asserted claims.

293. On Lilly's claim of expropriation, the only genuine issue for the Tribunal is whether to regard Canada's measures as uncompensated

⁵³⁸ See *supra* Part VII.A.2.

⁵³⁹ The groups affected are: Merck; Abbott Laboratories; Sanofi AG (through Sanofi-Aventis and Aventis Pharma Inc.); Pfizer; Eli Lilly and Company; Shire Biochem.; GlaxoSmithKline; Lundbeck; AstraZeneca; and Novartis (including through its affiliate Alcon). None of these groups is Canadian. See *The World's Biggest Public Companies*, FORBES, 2014 (C-191) (filtered for pharmaceutical industry); Bloomberg, Company Description: H Lundbeck A/S (retrieved September 21, 2014) (C-192).

Canada itself acknowledges that "[m]ost major branded pharmaceutical companies are foreign multinationals with subsidiaries in Canada. Valeant is the only Canadian-headquartered branded MNE. The generic segment is a mix of Canadian-based and foreign MNEs and smaller companies Canada's larger pharmaceutical companies include Apotex and Pharmascience." Industry Canada, *Canada's Pharmaceutical Industry and Prospects* (2013), at 11 (C-307). Both Apotex and Pharmascience are generic drug companies. *Id.*

expropriations, rather than as non-compensable exercises of state authority. The fact that the promise utility doctrine is inconsistent with Chapter 17 of NAFTA is a clear-cut and fully sufficient basis for ruling in favor of Lilly on this issue. But it is not the only ground for concluding that Canada's measures engage Article 1110. The arbitrariness of the promise utility doctrine and its violation of Lilly's legitimate expectations are additional bases for recognizing Canada's measures as expropriations.

294. The same underlying evidence supports Lilly's claim for breach of Article 1105. Each category of proof - of arbitrariness, violation of legitimate expectations, and discrimination - affords the tribunal with an independent basis for concluding that Canada's measures were neither fair nor equitable within the meaning of Article 1105.

295. Ultimately, each analysis arrives at the same conclusion: Canada's revocation of the Zyprexa and Strattera patents under the promise utility doctrine violates Chapter 11 of NAFTA. Accordingly, Lilly respectfully requests that the Tribunal render an award in favor of the Claimant and grant the relief set forth in its Statement of Claim.

Respectfully submitted,

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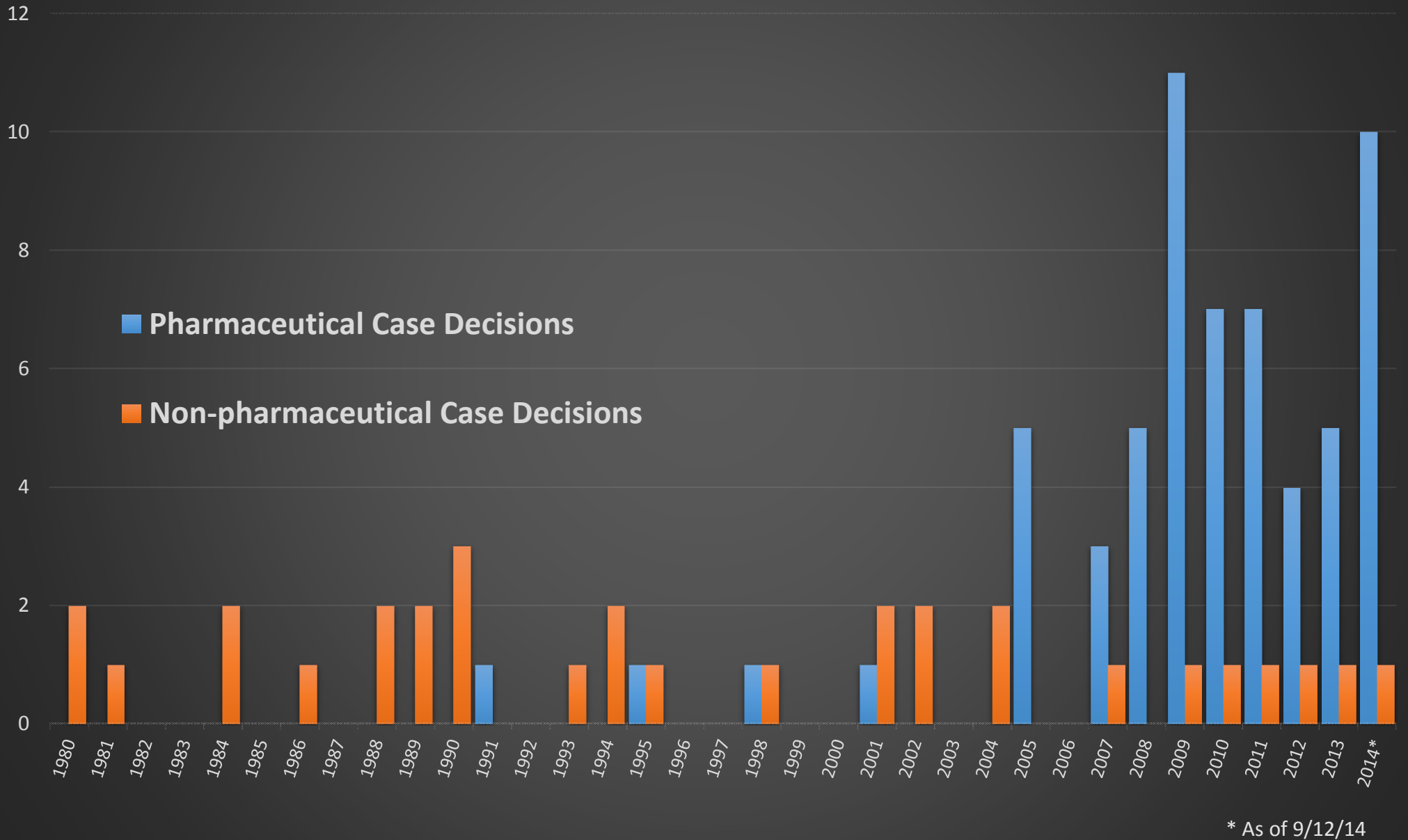
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Appendix 1

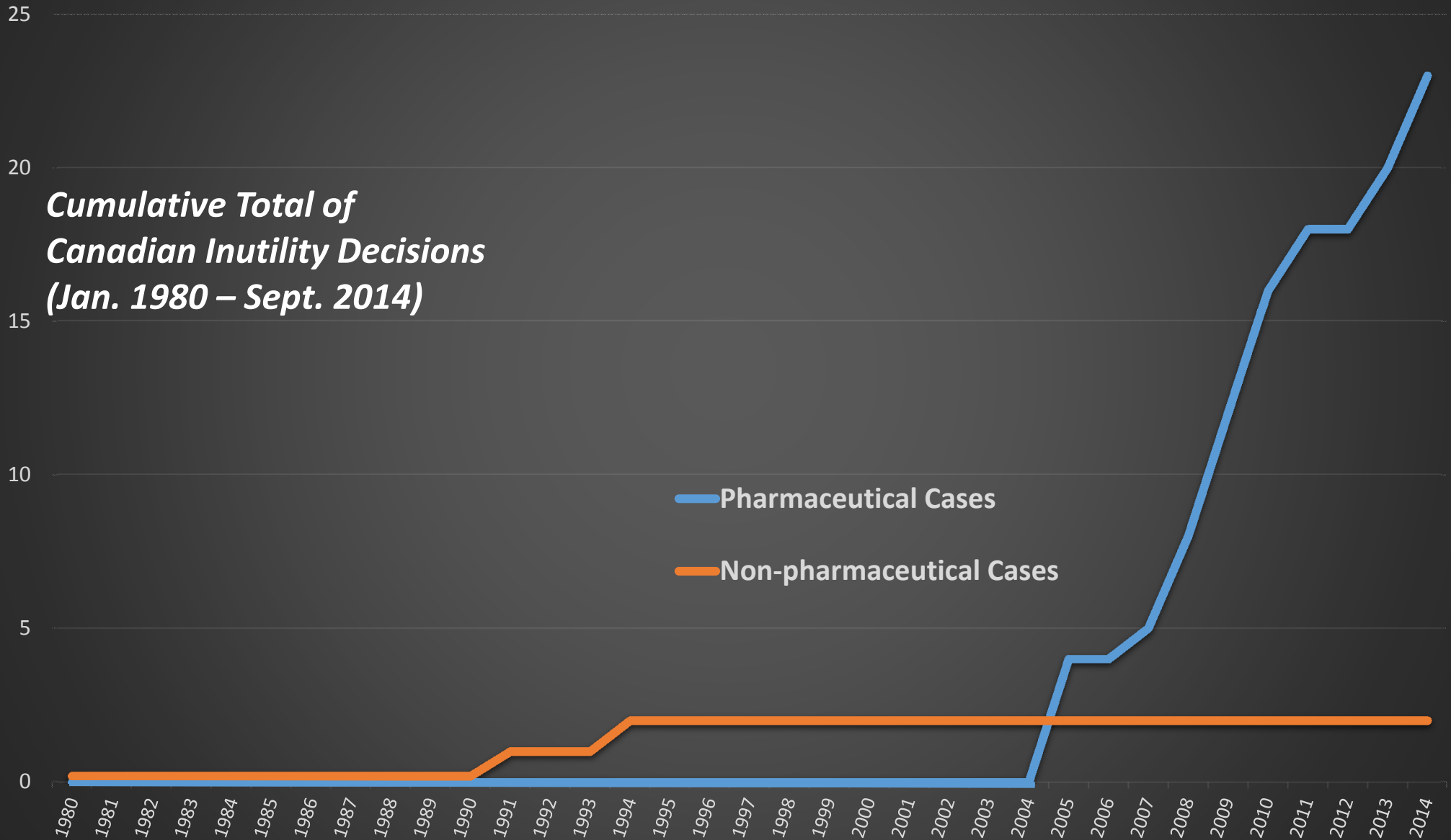
Figure 1 – Utility Litigation in Canadian Trial Courts, by Sector, 1980-2014



* As of 9/12/14

Appendix 2

Figure 2 – Canada’s Promise Utility Doctrine Discriminates Against Pharmaceutical Patents



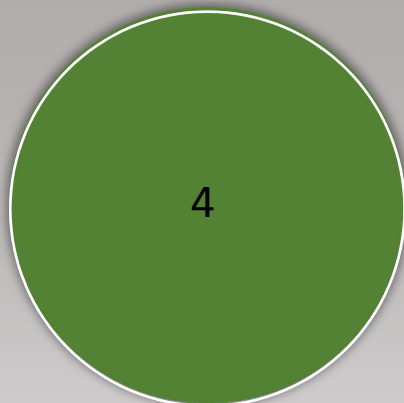
Appendix 3

Figure 3 – Utility Outcomes by Sector in Canadian Courts

* As of 9/12/14

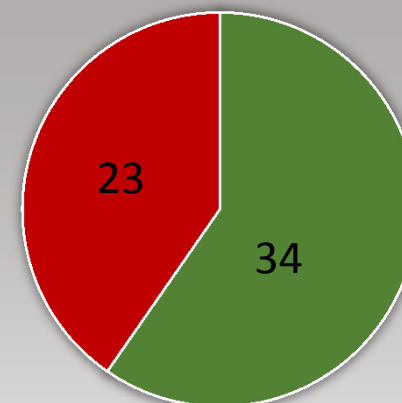
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2005 - 2014

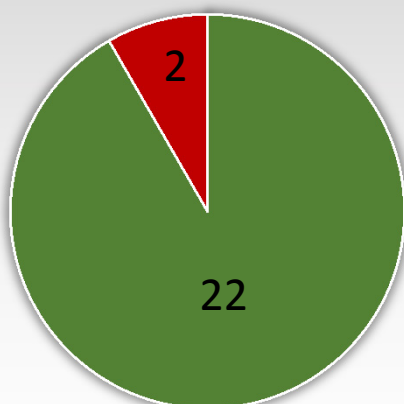


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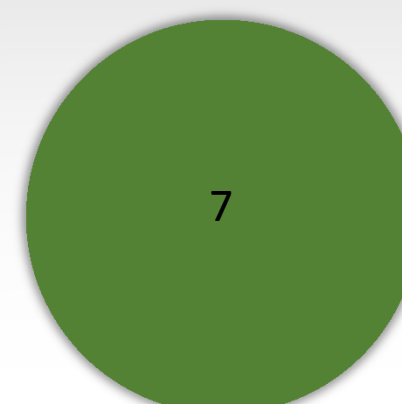


40% Inutility





8% Inutility

**Non-Pharmaceutical
Cases**



0% Inutility

-  Court holds patent lacks utility
-  Court holds patent has utility