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*

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# CLAIMANT'S REPLY MEMORIAL

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## INTRODUCTION

1. Since Lilly filed its Memorial on 29 September 2014, Canada has continued its pattern of finding that pharmaceutical patents lack utility under its unique promise utility doctrine. From 1980 to 2005, not a single pharmaceutical patent was found to lack utility by the Canadian Federal Courts. Between 2005 and today, the Federal Courts have decided 25 times that a pharmaceutical patent lacked utility, including in the cases of Zyprexa and Strattera — Lilly's patents at issue in this arbitration.

2. This striking pattern is all the more remarkable when it is considered in light of how Lilly's patents for Zyprexa and Strattera have fared in other jurisdictions. Lilly held Zyprexa patents in 80 other jurisdictions and was challenged in 23 — never on the ground of utility. Lilly held Strattera patents in 35 other jurisdictions and was challenged in two — again, never on the ground of utility. Canada is the *only* country to invalidate these patents for lack of utility.

3. Something is clearly happening in Canada. In its Memorial, Lilly demonstrated that Canada's unique pattern of utility invalidations is attributable to a new utility requirement, the promise utility doctrine. Lilly established that this doctrine represented a radical departure from Canada's traditional utility requirement and constituted a violation of Canada's obligations under Chapter 17 of NAFTA — both because it is an impermissible additional requirement for patentability, and because it discriminates against the pharmaceutical sector. When Canada applied this doctrine to revoke Lilly's Zyprexa and Strattera patents, it effected an uncompensated expropriation in violation of Article 1110 of NAFTA and a violation of Canada's obligation to afford "fair and equitable treatment" to Lilly's investments under Article 1105 of NAFTA.

4. Canada's Counter-Memorial fails to rebut Lilly's showing that Canada's measures violate Articles 1110 and 1105 of NAFTA. Canada cannot explain its dramatic increase of inutility determinations, or the discriminatory impact of those determinations on the pharmaceutical sector. It cannot explain why its utility requirement and its pattern of invalidations are in such contrast

with the practice of its NAFTA partners. It cannot defend a doctrine that even Canada's generic pharmaceutical industry — the prime beneficiary of the promise utility doctrine — has criticized as resulting in a "free for all" and a "hopeless tangle of contradictory approaches."

5. Unable to confront this evidence, Canada responds with a series of arguments that rest on mischaracterizations of Lilly's contentions and the record in this case. Central to Canada's Counter-Memorial are several fallacies, which together reflect Canada's inability to address the substance of Lilly's claims.

6. ***The "there is no promise utility doctrine" fallacy***. Canada argues that what Lilly has referred to as the "promise utility doctrine" is in fact several completely distinct patent law rules. Canada's semantic objection ignores the fact that, whatever it is called, the promise utility doctrine operates as a unitary patentability requirement that has resulted in the repeated and disproportionate invalidation of pharmaceutical patents, including the Zyprexa and Strattera patents, for lacking utility. The Federal Courts routinely analyze the three elements of the promise utility doctrine — (i) the construal of the promise(s); (ii) the heightened evidentiary scrutiny and prohibition on post-filing evidence; and (iii) the additional disclosure rule for sound prediction — as part of a unitary utility analysis.

7. ***The "nothing has changed" fallacy***. Canada devotes the bulk of its factual submission to the argument that the promise utility doctrine is not new and was part of Canadian patent law when Lilly filed its applications for the Zyprexa and Strattera patents. Yet Canada cannot identify *a single case* prior to the 2000s in which a Canadian court applied *any aspect* of the promise utility doctrine to invalidate a patent. Nor does Canada have any answer to the significant overhaul of Canada's Manual of Patent Office Practice ("MOPOP") in 2009 and 2010 that took account of the change in utility law in Canada after the advent of the promise utility doctrine.

8. ***The "MOPOP is not the law" fallacy***. Lacking an answer to the self-evident change in Canada's utility law reflected in the 2009 and 2010 MOPOP

amendments, Canada seeks to minimize the MOPOP by arguing that it is not binding and was not used by the examiners of Canada's Patent Office. But the fact that the MOPOP does not have the *force* of law does not mean that it is not a *reliable restatement* of the law. The MOPOP is the authoritative and comprehensive reference guide used by Patent Office examiners. Canada's notion that each of its 400 patent examiners ignored the MOPOP and independently interpreted Canada's utility jurisprudence is plainly absurd on its face.

9. ***The "United States and Mexico are doing it too" fallacy***. Canada does not dispute that the utility and industrial applicability requirements of the United States and Mexico are strikingly different from its promise utility doctrine. Instead, Canada argues that the United States and Mexico pursue similar policy objectives as Canada through other patentability requirements. Yet Canada cannot identify *any* analogue for its promise utility doctrine in Mexican or U.S. law. Even if Canada could identify a theoretical analogue (it cannot), it would provide no answer to Canada's unique practice of revoking pharmaceutical patents under its utility requirement.

10. ***The "patents are not property" fallacy***. Canada strains to minimize Lilly's investments — the Zyprexa and Strattera patents — by arguing that Lilly's patent rights were only "conditional" when granted by the Canadian Intellectual Property Office. But there is nothing "conditional" about the legally enforceable rights that a patent conveys immediately upon issuance. As Canada's own Patent Office has recognized, a "granted patent . . . *is an asset like a deed to a physical property such as a house*. It can become very valuable and can be sold, licensed or used to negotiate funding, venture capital or other forms of financing."

11. ***The "some patents survive" fallacy***. In its Memorial, Lilly demonstrated that the promise utility doctrine places pharmaceutical companies in a Catch-22. If they wait to file a Canadian patent application until they amass significant clinical trial data, they risk destroying the patentability of their invention for lack of novelty. But if they file a Canadian patent application without significant clinical trial data, they risk invalidation under Canada's

heightened utility requirement. Canada barely addresses this Catch-22, except to assert that some patents have been upheld without significant clinical trial data. But this does not refute Lilly's evidence that the promise utility doctrine creates a substantial risk of invalidation for applications without significant clinical trial data — and even for applications supported by positive trial results. The fact that some patent holders clear Canada's additional utility bar does not mean that Canada's utility standard is workable or that it complies with Canada's NAFTA obligations.

12. ***The "3 not 23" fallacy.*** Lilly's Memorial established that the promise utility doctrine discriminates against pharmaceutical patents. Not a single pharmaceutical patent was found to lack utility in Canada from 1980-2004, but since 2005 courts have held 23 times (plus two more since Lilly filed its Memorial) that a pharmaceutical patent lacks utility. Meanwhile, not a single non-pharmaceutical patent was invalidated on the ground of inutility in the last two decades. Canada tries to downplay this evidence by arguing that only three cases involved "true" invalidations, and the remaining 20 determinations were in regulatory *PM(NOC)* proceedings, rather than infringement proceedings. But *PM(NOC)* proceedings apply the exact same utility law as infringement proceedings, follow the same analysis, involve the same Federal Court judges, and result in statements of law that are equally precedential. Canada's attempt to disavow 20 findings of inutility simply because they arise in *PM(NOC)* proceedings is a textbook example of elevating form over substance.

13. ***The "standard process of adjudication" fallacy***. Canada denies that the promise utility doctrine is arbitrary in its application. Rather, Canada asserts, the Federal Courts are simply engaged in the standard process of adjudication, including by applying settled rules of construction and weighing evidence with the assistance of expert testimony. This might be a relevant response if Lilly were claiming a lack of procedural fairness, but it is not. Canada has put forward no explanation for the dramatic change in litigation *outcomes* since the advent of the promise utility doctrine, including the substantial increase in findings of inutility and a string of facially inconsistent rulings.

14. ***The "speculative patenting" fallacy***. Unable to refute the multiple ways in which the promise utility doctrine is arbitrary, Canada asserts that it is necessary to address "speculative patenting." Yet Canada does not (and cannot) establish that the promise utility doctrine actually deters "speculative patenting." So, instead, Canada substitutes an attack on Lilly's overall patenting practices and simply labels those practices as "speculative." These attacks are entirely unfounded: Lilly files patent applications that it determines meet all patentability criteria and are justified by the underlying science. Canada's attack on Lilly also reflects a fundamental misunderstanding of the drug development process generally. Canada's "speculative patenting" argument is thus a red herring.

15. ***The "harmonization" fallacy***. Lilly's Memorial established that when Canada signed NAFTA, it assumed specific obligations to ensure the adequate and effective protection of IP rights. Canada's Counter-Memorial seeks to minimize these obligations by arguing that Chapter 17 of NAFTA did not "harmonize" substantive patentability requirements. Yet Lilly never argued that such requirements were harmonized across jurisdictions. Rather, Lilly has established that Chapter 17 requires the NAFTA parties to provide a *baseline* level of patent protection. This proposition is unassailable. Chapter 17 expressly provides that countries may provide *more* protection for intellectual property than is required by the Treaty, but not less — which is why Canada attacks its "harmonization" straw man instead.

16. These fallacies permeate Canada's factual statements in its Counter-Memorial. They also compromise Canada's legal arguments. With respect to both Lilly's expropriation claim under Article 1110 and its claim for violation of the "fair and equitable treatment" standard in Article 1105, Canada's response rests on mischaracterizations of Lilly's arguments, unfounded formalistic objections, and alarmist rhetoric.

17. Central to Canada's legal argument is the notion that because the Zyprexa and Strattera patents were revoked by the Canadian courts, the only way Lilly can prevail is by proving a procedural "denial of justice." Canada then

proceeds to litigate a denial of justice claim by reciting — at length — the procedural history of the Zyprexa and Strattera cases. This may be the case that Canada prefers to defend, but it is not the case that Lilly has brought. Lilly's claims do not rest on denial of justice, but rather on a completely separate and equally well-established basis for liability: the Canadian judiciary's *substantive* violations of international law.

18. In the context of expropriation, tribunals have repeatedly embraced the principle that a judicial measure may be expropriatory when it violates a substantive rule of international law, and Canada fails to cite any decisions to the contrary. Even if Canada's position had merit as a matter of general principles of international law (it does not), Article 1110(7) of NAFTA provides a fully independent and NAFTA-specific basis for concluding that patent revocations in violation of Chapter 17 qualify as compensable expropriations. Canada hardly addresses Article 1110(7) in its Counter-Memorial, and the one argument that it does make — that Article 1110(7) is merely an "additional hurdle" to liability — was rejected by the one NAFTA tribunal to consider it in an analogous context.

19. Here, Canada's violations of Chapter 17 are plain. Canada fails to refute that Article 1709(1) embodies a baseline obligation to make patents available for inventions that meet the Treaty's "capable of industrial application" requirement. This commonly understood criterion is *consistent* with Canada's traditional "mere scintilla" utility standard (which the Zyprexa and Strattera patents indisputably met), but is *inconsistent* with the additional promise utility doctrine requirement now part of Canadian law. Canada also fails to refute its other violations of Chapter 17, including in particular its discrimination against pharmaceutical patents as a field of technology.

20. Canada fares no better in its response to Lilly's claim that Canada's measures violate Article 1105 because they are arbitrary, discriminatory, and in conflict with Lilly's legitimate, investment-backed expectations. For each component of Article 1105, Canada strains to narrow the scope of protection afforded by NAFTA. It argues that to be arbitrary under NAFTA, a measure must

have "no legitimate purpose"; that Article 1105 protects (at most) only those expectations that are grounded in specific assurances from the host State; and that Article 1105 protects only against discrimination on the basis of nationality.

21. Canada's restrictive interpretations do not withstand scrutiny, but even if they were accepted, Canada's measures would *still* violate Article 1105. The promise utility doctrine is unpredictable and incoherent and, as such, cannot possibly serve any "legitimate purpose." With respect to legitimate expectations, Canada *did* provide Lilly with specific assurances in the form of the grant of the Zyprexa and Strattera patents. As for discrimination, the promise utility doctrine discriminates not just against innovative pharmaceutical companies as a field of technology, it also has the effect of favoring a prominent domestic industry (generic manufacturers) at the expense of foreign patent holders.

22. Throughout its Counter-Memorial, Canada warns that Lilly is asking this Tribunal to act inappropriately as a supranational "court of *de novo* review." There is no foundation for this alarmist rhetoric in Lilly's actual submissions. Lilly is *not* seeking *de novo* review of the Zyprexa and Strattera court decisions; in fact, Lilly is not asking this Tribunal to assess *at all* whether the court decisions were correctly decided under *Canadian* law. Rather, what Lilly seeks — and, indeed, has proven — is a finding that Canada's measures violate its commitments under *international* law, and that those violations engage Canada's obligations under Chapter 11 to provide full reparations. Stripped of its rhetoric, what Canada is *really* seeking is a ruling that would immunize its judiciary from the substantive obligation to comply with Canada's treaty commitments. NAFTA provides no basis for such an immunity, neither does customary international law, and nor should this Tribunal.

## I. LILLY WAS GRANTED PATENT RIGHTS IN CANADA FOR ITS ZYPREXA AND STRATTERA INVENTIONS AFTER REVIEW BY THE PATENT OFFICE UNDER CANADA'S TRADITIONAL UTILITY REQUIREMENT.

### A. Lilly Filed its Patent Applications on Zyprexa and Strattera to Secure the Economic Foundation Necessary to Bring the Drugs to Market.

23. Lilly filed the patent applications resulting in the Zyprexa and Strattera patents based on thorough research and sound science. Lilly's Zyprexa patent was supported by *in vitro* lab tests, *in vivo* animal tests, and five different small-group studies on healthy volunteers and patients.[1] Similarly, Lilly's Strattera patent was supported by years of research, including a clinical trial that was conducted by doctors at Massachusetts General Hospital and that was ultimately published in the *American Journal of Psychiatry*.[2]

24. This scientific research was more than sufficient to support Lilly's patents, both in Canada and around the world. Nonetheless, Canada criticizes Lilly for filing patent applications "extremely early in the research process" when claimed uses of patented compounds were, in Canada's view, "at best speculation."[3] This criticism is unsupported by the facts. It also reflects Canada's failure to engage with the fundamental economic realities of the innovative pharmaceutical industry — realities that Canada does not even challenge, but rather simply ignores.

25. In contrast to products in many other industries that can be commercialized soon after they are conceived, a pharmaceutical product must pass through a battery of tests and regulatory reviews before it reaches patients.[4]

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[1] Claimant's Memorial ("Cl. Mem.") at ¶ 96; *see* First Witness Statement of Robert A. Postlethwait ("Postlethwait Statement") at ¶¶ 15-16.

[2] Cl. Mem. at ¶ 119; *see* First Witness Statement of Anne Nobles ("Nobles Statement") at ¶¶ 7-8.

[3] Respondent's Counter-Memorial ("Resp. CM") at ¶ 163.

[4] *See* Cl. Mem. at ¶¶ 26-33; Chandra Mohan et al., "Patents - An Important Tool for Pharmaceutical Industry," RES. & REV.: J. OF PHARM. & NANOTECHNOLOGY, Apr.-June 2014, at 13 (C-25).

Bringing a drug through preclinical trials, clinical trials, regulatory approval, and ultimately to market is an immensely uncertain and expensive undertaking. Moreover, as one industry expert emphasizes,

> unlike industries which produce products requiring expensive and complex manufacturing infrastructures, the patented products of pharmaceutical companies can be easily and cheaply replicated by copiers with little capital investment. Since capital investment in the pharmaceutical industry disproportionately is directed to laboratory research and clinical trials rather than the manufacture of the final product, patent exclusivity is the only effective way to protect and receive a return on that investment.[5]

26. As explained by Robert Armitage, Lilly's former General Counsel, patents provide the "economic rationale" that makes it feasible for firms like Lilly to invest hundreds of millions of dollars in developing a single medicine and bringing it to market. [6] Without a reliable expectation that such investment may be recouped, firms simply could not justify their research and development ("R&D") budgets to investors, creditors, and other stakeholders.

27. For patents to play their vital economic role, they must generally be sought before the innovator undertakes large-scale human clinical trials.[7] For a

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[5] Bruce Lehman, "The Pharmaceutical Industry and the Patent System," INT'L INTELL. PROP. INST., (2003) (C-308).

[6] *See* Second Witness Statement of Robert A. Armitage ("Armitage Second Statement") at ¶ 15. The Strattera patent is illustrative in this regard. Atomoxetine (Strattera) was initially conceived as an anti-depressant, and extensive research was conducted on this use. Atomoxetine was only considered as an ADHD treatment late in the development process, when the compound patent was approaching expiry. The availability of a patent claiming atomoxetine in the treatment of ADHD (*i.e.*, the Strattera patent), provided the "economic force" that allowed Lilly to invest in establishing the safety and effectiveness of Strattera as a treatment for ADHD. *See* Armitage Second Statement at ¶¶ 15-16.

[7] Such trials are a prerequisite of regulatory approval. *See, e.g.*, HEALTH CANADA, *How Drugs Reviewed in Canada*, http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/reviewfs_examenfd-eng.php ("What is done with the results from clinical trial? If clinical trial studies prove that the drug has potential therapeutic value that outweighs the risks associated with its use (e.g. adverse effects, toxicity), the sponsor may choose to file a New Drug Submission with HPFB.") (C-309).

variety of practical and legal reasons, such trials cannot reliably be kept private.[8] At the same time, any disclosure of a clinical trial prior to the filing of a patent application risks revealing the essence of the invention, thereby destroying the novelty or non-obviousness of any subsequent application.[9] For these reasons, deferring a patent filing until after substantial human clinical testing takes place creates a commercially unacceptable risk that the invention will be rendered un-patentable.[10]

28. The timing of Lilly's patent applications on Zyprexa and Strattera was consistent with and driven by these immutable features of the innovative pharmaceutical industry.[11]

### B. CIPO Conducted a Thorough Review of the Zyprexa and Strattera Patents Under Existing Law.

29. After Lilly applied for patent protection in Canada, CIPO conducted a thorough review of Lilly's applications and granted both the Zyprexa and Strattera patents. In an obvious attempt to diminish the significance of the fact that its own Patent Office concluded that both the Strattera and Zyprexa applications satisfied all requirements of patentability, including utility, Canada argues that the review was superficial because CIPO's "patent examiners operate

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[8] *See* Armitage Second Statement at ¶¶ 37-38 (providing reasons why "without patent applications already in place, Lilly simply could not risk conducting the clinical research necessary to demonstrate that its medicines can safely be prescribed and used by patients"). Among other things, Mr. Armitage points out that the existence of clinical trials must be reported in public databases in many countries (including the United States and Canada) and that extensive disclosures must be made to trial patients and their individual doctors, generating a risk of leaks.

[9] *See* First Expert Report of Norman V. Siebrasse ("Siebrasse First Report") at ¶¶ 107-108.

[10] *See* Cl. Mem. at ¶¶ 32, 266; First Witness Statement of Peter Stringer ("Stringer Statement") at ¶ 16; Siebrasse First Report at ¶¶ 107-108. Notably, if pharmaceutical companies could safely delay filing, they would have a strong incentive to do so. A consequence of filing before large-scale clinical trials is that much of a patent's term will have run by the time the relevant patented medicine reaches the market. If filing could be delayed without undue risks, firms could routinely enjoy a full 20-year term of market exclusivity rather than the much shorter period that is typical. *See* Armitage Second Statement at ¶ 39.

[11] Cl. Mem. at ¶ 26 *et seq*.

under time and informational limitations."[12] Canada's characterization of Patent Office examinations of patent applications as cursory, non-substantive reviews is also aimed at making Lilly appear unreasonable in relying on the grant of its patents.[13] This is part of a broader campaign by Canada to diminish and impugn the work of examiners.[14] Canada's attempt to undermine its own Patent Office is not only surprising, it lacks merit.

30. Examiners at CIPO are skilled and well-trained. All CIPO examiners must have scientific degrees, such as engineering, chemistry, physics, or biotechnology.[15] Examiners receive training in the classroom for three months and are then assigned to work under the direct supervision of a senior examiner for at least nine months.[16] Examiners return to the classroom for an additional month of coursework and then must successfully pass exams related to patent prosecution practice and patent jurisprudence.[17] Examiners continue under the supervision of a trainer until they are deemed to be capable of working independently.[18] Examiners are also assigned patent applications related to their field of expertise, and many examiners review applications in the same field of technology for a long period of time.[19]

31. Given an examiner's extensive training and experience, it would not have been difficult or time-intensive for him or her to assess the utility of an

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[12] Resp. CM at ¶ 70; *see also* Statement of Dr. Michael Gillen ("Gillen Statement") at ¶¶ 12-13.

[13] *See* Resp. CM at ¶ 66.

[14] Canada attacks Mexico's patent examiners as well. *See* Resp. CM at ¶¶ 38, 180 (emphasizing the "inherent weakness of the patent grant" in Mexico and alleging that Mexican examiners issue "intrinsically flawed" patents). *See also infra* Part II.C.2.

[15] Second Expert Report of Murray Wilson ("Wilson Second Report") at ¶ 3.

[16] Wilson Second Report at ¶¶ 4-5; *see also* Wilson First Report at ¶ 14; CIPO, *Patent examiner recruitment – Frequently Asked Questions*, http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00135.html#pt_exmn_recrt_train01 (C-310).

[17] CIPO, *Patent examiner recruitment – Frequently Asked Questions*, http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00135.html#pt_exmn_recrt_train01 (C-310).

[18] Wilson Second Report at ¶ 5.

[19] *Id.* at ¶ 6.

invention during an examination.[20] An examiner would not accept incredible statements of utility or grant a patent where there was no indication of the invention's use.[21] The fact that examiners could efficiently review patent applications for compliance with the utility requirement does not mean that such reviews were perfunctory.

32. Canada also seeks to impugn CIPO examinations by asserting that they are based on a "limited record."[22] But examiners could request additional information from the applicant if necessary.[23] For example, an examiner could ask for working model or additional data if it doubted the operability of an invention.[24] Had Lilly's patents raised any concerns with respect to the utility requirement as it existed at the time of grant, the examiner would have issued a rejection on that basis in a formal letter known as an Office Action.[25] This did not happen, in part because at the time the Zyprexa and Strattera patents were examined, the Canadian utility test was simple, and Lilly's patents easily satisfied that requirement.

33. In a similar vein, Canada misleadingly asserts that CIPO examiners apply special "assumptions" in favor of the applicant that are not afforded in any post-grant judicial proceedings.[26] In reality, CIPO's examiners have to follow the law, and it is the same law that is applied by Canadian courts.[27] Certain presumptions may be applied in favor of the applicant during the review process, but such presumptions are grounded in the law and do not simply reflect a lack of

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[20] *Id.* at ¶¶ 6-8.

[21] First Expert Report of Murray Wilson ("Wilson First Report") at ¶ 29.

[22] Resp. CM at ¶¶ 70-71.

[23] Wilson First Report at ¶¶ 16-17.

[24] *Id.* at ¶ 27.

[25] *See* Wilson Second Report at ¶ 39.

[26] Resp. CM at ¶ 72

[27] Wilson First Report at ¶ 15.

resources at CIPO, as Canada suggests.[28] Moreover, an examiner may grant a patent only if it meets all the requirements of the *Patent Act*, including utility.[29]

34. In short, Canada fails to discredit the significance of the fact that its own Patent Office — the specialized administrative body tasked with reviewing patent applications according to Canadian law — thoroughly reviewed Lilly's applications and granted the Zyprexa and Strattera patents. No Office Actions were issued regarding utility because Lilly's applications fulfilled the traditional requirement in Canadian law at that time. As discussed below, the reason these patents were later invalidated for lack of utility was not because CIPO got it wrong, but rather because Canada's law dramatically changed. *See infra* Part II.

### C. When CIPO Granted Lilly's Patent Applications, It Vested Lilly with Economically Valuable and Immediately Enforceable Legal Rights.

35. Consistent with the considered judgment of its patent examiners, the Canadian government issued Lilly its patent in respect of Zyprexa.[30] Then, four years later, the Canadian government issued Lilly its patent in respect of Strattera.[31] Canada suggests that the rights accorded by these patents were conditional. Specifically, Canada argues that the patents were granted on the condition that they were "subject to subsequent review and invalidation *ab initio* by the Federal Court."[32]

36. It is absurd for Canada to suggest that an issued patent is somehow a conditional or incomplete property right.[33] In other contexts, the Canadian government has repeatedly recognized that issued patents constitute a form of

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[28] Wilson Second Report at ¶ 9. *See* Resp. CM at ¶ 72.

[29] Wilson First Report at ¶ 16.

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

[31] Canadian Patent No. 2,209,735 (October 1, 2002) (C-67).

[32] Resp. CM at ¶ 329.

[33] As explained *infra* at ¶ 230, Canada's jurisdictional argument based on this factual assertion is untimely and thus waived.

property just like any other. Canada's position in this case that patents are not property thus appears to be a matter of arbitration-driven expediency. Even today, outside this arbitration, CIPO describes Canadian patents as "very valuable" assets that may be "sold, licensed or used to negotiate . . . financing."[34] It explains that patents provide "*proof of ownership*" over the claimed intellectual property.[35] It even analogizes patents to "a deed to physical property such as a house."[36]

37. Such clear and repeated acknowledgements by Canada that issued patents confer "ownership and exclusive rights"[37] are alone sufficient to rebut Canada's argument that the property rights accorded by patents are contingent. But even without these statements, the nature of a patent as a bundle of property rights is clear from the plain language of Canadian law.

38. Canadian law expressly vested Lilly with the rights to exclude others from "making, constructing and using" or "selling" Zyprexa and Strattera.[38] As

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[34] *See* CIPO, *Protect your innovation*, http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03586.html ("A granted patent . . . can become very valuable and can be sold, licensed or used to negotiate funding, venture capital or other forms of financing.") (C-312). *See also* CIPO, *Stand out from your competitors*, http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00818.html#no1 ("Like physical assets, IP assets must be acquired and maintained, accounted for, valued, monitored closely, and properly managed in order to extract their full value.") (C-311).

[35] CIPO, *Protect your innovation*, http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03586.html (emphasis added) (C-312).

[36] *Id.*

[37] *Id.*

[38] *Patent Act* (Canada), R.S.C., 1985, c. P-4, at § 42 (C-50). Canada emphasizes that, under Section 42, the rights conferred by a patent are "subject to [the Patent Act]" and "to adjudication . . . before any court of competent jurisdiction." *See* Resp. CM at ¶¶ 68, 329 (quoting Canadian Patent Act at § 42). But this is unexceptional, and necessarily true of any property right established or conditioned by statute and enforced by the courts. Canadian Federal and provincial legislation is littered with references to property rights that are "subject to" legislation and judicial process. *See, e.g.*, Civil Code of Quebec at § 947 (defining ownership of property as "the right to use, enjoy and dispose of property fully and freely, subject to the limits and conditions for doing so determined by law") (C-313); Mines and Minerals Act (Alberta), RSA 2000, c. M-17, at § 3 (making all mineral grants in Canada's largest oil-producing state "subject to [the] Act") (C-314); Planning Act (Ontario) at § 34(1)(1) (permitting "zoning by-laws . . . for prohibiting the use of land, for or except for such (continued…)

explained by Canadian patent law expert and practitioner Andrew Reddon, these rights were "legally enforceable immediately upon issuance" of Lilly's patents.[39] Indeed, these property rights are recognized in multiple distinct provisions of Canadian statutes, regulations, and case law, which accorded Lilly each of the powers and benefits normally accruing to an owner of property: those of use and exclusion, benefit, and encumbrance and transfer.[40]

39. Under the *Patented Medicines (Notice of Compliance) Regulations* ("*PM(NOC) Regulations*"), for example, the grant of patents on Zyprexa and Strattera established Lilly's right to list those drugs as patented medicines with Health Canada.[41] The effect of Lilly's listings was to automatically preclude any other person from marketing either Lilly drug.[42] Lilly was also empowered upon issuance of the patents to exploit the value of the patents by licensing or transferring them to third parties, if it saw fit to do so.[43] These and other rights were not contingent in any way on litigation confirming the validity of the patents. Thus, as Mr. Reddon explains, the issuance of the Zyprexa and Strattera

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purposes as may be set out in the by-law") (C-315). The fact that that the scope of a patent right is defined by statute and is adjudicated by the courts does not, therefore, differentiate it from other forms of property or undermine the fact that a patent confers immediate "exclusive rights [that] give [patent holders] an effective means to stop others from making, using, selling or importing" the patented invention. *See* CIPO, *Protect your innovation, http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03586.html* ("Exclusive rights give you an effective means to stop others from making, using, selling or importing your product or process. You can even use exclusive rights to stop someone who might later independently invent your claimed invention. In many cases a patent is the only way to ensure exclusivity – and hence a competitive edge – in the marketplace.") (C-312).

[39] First Expert Report of Andrew J. Reddon ("Reddon Report") at ¶ 27.

[40] *See* Ilya Segal & Michael D. Whinston, "Property Rights," in HANDBOOK OF ORGANIZATIONAL ECONOMICS 100-01 (2013) (C-316); Bruce Ziff, PRINCIPLES OF PROPERTY LAW 6 (6th ed. 2014) (defining the rights typically associated with property as those of "exclusion . . . use, transfer [and] income") (C-317).

[41] Patented Medicines (Notice of Compliance) Regulations, (Canada), SOR/93-133 at § 4 (R-31).

[42] *Id.* at § 5.

[43] Reddon Report at ¶¶ 26-28 (noting also that "[l]icensors and licensees do not wait until a patent has been adjudicated before a court (which may never occur) prior to entering a licensing agreement").

patents provided Lilly with an immediate, effective, and well understood property right under Canadian law.[44]

40. Further, as a practical matter, patent rights form a substantial part of the value of biopharmaceutical research companies such as Lilly.[45] As Mr. Armitage notes, patents are routinely valued and sold regardless of whether they have been the subject of litigation, and patents are often among the most significant assets driving corporate transactions in the pharmaceutical industry.[46] "In other words," he explains, "the marketplace treats a patent as a property right,"[47] consistent with its treatment at law.

41. The rights conferred by the Zyprexa and Strattera patents were subject to a risk of litigation, but that is true of all property rights.[48] Thus, while the Zyprexa and Strattera patents were subject to possible later invalidation by a court, this does not set them apart from other property.

42. Nor is it relevant that the invalidation of a patent is said to be "*ab initio*." Canada's argument on this point is circular: to defend the improper revocation of Lilly's patents, Canada argues that those invalidations cannot be challenged because the courts held that the underlying patents ceased to exist.[49] The reason why a patent is invalidated *ab initio* is to preclude the patent holder from later bringing a claim against third parties who infringed the patent prior to its invalidation.[50] The rule reflects the uncontroversial idea that a patent holder

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[44] *See id.* at ¶¶ 26-28.

[45] Armitage Second Statement at ¶¶ 40-41.

[46] *Id.* at ¶¶ 43-44.

[47] *Id.* at ¶ 43.

[48] Reddon Report at ¶ 28 ("That patent rights are subject to adjudication by the courts is no different from any other form of property, title to which may be challenged in later litigation.").

[49] *See* Resp. CM at ¶ 327; *see also infra* Part IV.A.

[50] Reddon Report at ¶ 29 ("The fact that a patent is void *ab initio* as a matter of law does not meant that it is treated as if it never existed in practice, or that, upon issuance, valuable property rights were not conferred.").

who loses that right should not rely on the prior existence of the right to obtain damages for past conduct.

43. Invalidation "*ab initio*" does not retroactively revise the factual record. It does not mean that the patent never existed or that the patent holder never enjoyed the benefits of the patent. While invalidation has prospective effects on existing business arrangements, it does not compel a retroactive unwinding of actions performed prior to invalidation. Thus, for example, it does not automatically require that a patent holder refund fees paid by third parties to license the patent. Indeed, as Mr. Reddon explains, "[e]ven after the invalidation, patentees may still enjoy rights . . . such as payments made pursuant to licenses."[51] Invalidation *ab initio* certainly does not change the fact that previously enforceable patent rights were revoked.

44. In other words, the phrase "*ab initio*" conveys a legal fiction; it does not re-write the facts. The Zyprexa and Strattera patents were granted by Canada's government. Then, years later, they were taken away by a different branch of that same government based on the novel, unforeseeable, and retroactive promise utility doctrine.

### D. When CIPO Granted the Zyprexa and Strattera Patents, Canada's Traditional Utility Requirement Was Consistent with the Baseline of Protection Required by NAFTA.

45. Lilly received patents for Zyprexa and Strattera in Canada only after CIPO confirmed that Lilly's inventions satisfied Canada's traditional utility requirement. As discussed below, that "mere scintilla" requirement was (and is) consistent with the baseline of patent protection Canada agreed to provide in NAFTA Chapter 17.

[51] Reddon Report at ¶ 29.

### 1. In Implementing NAFTA, Canada Recognized that the Treaty Requires a Baseline Level of Substantive Patent Protection and Reformed its Domestic Patent Law to Meet Those Requirements.

46. Canada argues that "nothing in NAFTA prohibits the domestic law of the Parties from changing over time, including with respect to intellectual property."[52] It argues further (incorrectly[53]) that similar changes in law have occurred in the United States and Mexico.[54] But Canada cannot explain why, if NAFTA does not constrain domestic intellectual property law, it significantly amended its Patent Act in the early 1990s (with respect to issues other than utility) so as to bring the act, in the words of Canada's Parliament, into "conformity with the NAFTA."[55]

47. Prior to ratifying NAFTA, Canada had historically been openly hostile to pharmaceutical innovation.[56] For most of the 20th century, Canada imposed a compulsory licensing system with respect to pharmaceutical patents.[57] This system allowed generic companies to compete with patented pharmaceutical

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[52] Resp. CM at ¶ 81.

[53] *See infra* Part II.C.

[54] Resp. CM at ¶¶ 170-180.

[55] *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).

[56] *See* Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, Doc. WT/DS114/R, ¶ 7.36 (17 March 2000) ("*Canada-Pharmaceuticals*") (finding "stockpiling exception" in Canadian *Patent Act* curtailed the rights of pharmaceutical patent holders to a degree inconsistent with Canada's obligations under TRIPS) (CL-79); Paul L.C. Torremans, "Compulsory licensing of pharmaceutical products in Canada," 27 INT'L REV. OF INTELL. PROP. & COMPETITION L. 3, 316 (1996) ("…[P]harmaceutical products were always singled out for special treatment under Canadian patent law.") (C-320); Comm'n on Pharm. Servs., Canadian Pharm. Ass'n, PHARMACY IN A NEW AGE: REPORT OF THE COMMISSION ON PHARMACEUTICAL SERVICES 25 (1971) (recognizing that Canadian patent law regime effectively denies market exclusivity to pharmaceuticals) (C-321); *Celotex Corp. v. Donnacona Paper Co.*, (1939) 2 C.P.R. 26, at 41 (Ex. Ct.) (recognizing pharmaceutical patent regime as impractical and oppressive) (C-322).

[57] Patent Act (Canada), S.C. 1923, c. 23, § 17 (C-323).

inventions during the period of patent protection as a matter of right, subject only to a statutory fee.[58]

48. As Canada's own expert recognizes, Canada's compulsory license system disfavored pharmaceutical inventors' rights and "hardly considered" the interests of patentees.[59] Yet Canada maintained and even expanded its compulsory licensing system over much of the 20th century; as a prominent professor and consultant for the World Intellectual Property Organization put it, pharmaceuticals "were always singled out for special treatment under Canadian patent law."[60] Indeed, for a period of time, Canada maintained a complete prohibition on pharmaceutical compound patents.[61]

49. Canada was able to maintain this legal framework — which discriminated on its face against pharmaceuticals as a field of technology — only because it was not yet subject to any substantive international obligations with respect to its patent laws.[62] However, this changed with NAFTA.[63] Specifically,

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[58] *Canada-Pharmaceuticals*, at ¶ 4.6 (CL-79).

[59] Dimock Report at ¶ 39.

[60] Paul L.C. Torremans, "Compulsory licensing of pharmaceutical products in Canada," 27 INT'L REV. OF INTELL. PROP. & COMPETITION L. 3, 316 (1996) ("…[P]harmaceutical products were always singled out for special treatment under Canadian patent law.") (C-320); Jean-Frederic Morin & Mélanie Bourassa Forcier, "Pharmaceutical Patent Policy in Developing Countries: Learning from the Canadian Experience," in INTELL. PROP., PHARMACEUTICALS AND PUB. HEALTH 2 (2011) (noting 1969 expansion of the compulsory license system that allowed generic companies to import medicines produced with patented processes and requiring the Patents Commissioner to grant the license absent a showing of good cause, and 1987 amendment that, *inter alia*, varied a patent's deferral period depending on whether drugs were imported or manufactured in Canada and excluded Canadian-developed drugs from the compulsory license regime application) (C-324).

[61] *See* Margaret Smith, Law & Gov't Div., Gov't of Canada, "Patent Protection for Pharmaceutical Products," Library of Parliament Background Paper BP 354E at 6 (Nov. 1993) (C-325). Note that process patents, a relatively weak form of patent protection, were permitted. *Id.*

[62] *See Canada-Pharmaceuticals*, ¶ 4.21(a) (stating that prior to TRIPS, Canada was bound only by the Paris Convention on the Protection of Industrial Property of 1934, which did not provide minimum standards for substantive patent protection) (CL-79).

[63] *See infra* Part I.D.2(a) (showing that NAFTA Chapter 17 establishes a baseline of substantive patent protection). Around the time of NAFTA, Canada also made substantive commitments to provide a similar baseline of patent protection in the TRIPS Agreement.

through NAFTA, Canada committed to make patents available for *all* inventions in *all* fields of technology.[64] Canada also agreed to limits on its ability to grant compulsory licenses.[65] Recognizing that aspects of its law were inconsistent with these commitments, Canada enacted multiple amendments to its *Patent Act* and other statutes.[66]

50. Among other things, Canada repealed its prohibition on compound patents and dismantled its pharmaceutical-specific compulsory license system.[67] While no conforming changes were made to Canada's utility requirement,[68] this is

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[64] NAFTA Art. 1709(1) (CL-44); TRIPS Art. 27.1 (CL-122).

[65] *See* NAFTA Art. 1709(6-7) (CL-44); *see also* Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, Doc. WT/DS114/R (Mar. 17, 2000) ("*Canada-Pharmaceuticals*") ¶ 4.21(a) ("…[A] major objective of many participants [in the Uruguay Round of the TRIPS negotiation] had been the elimination of the compulsory licensing provisions respecting patented foods and medicines in national intellectual property laws.") (CL-79).

[66] Patent Act (Canada), R.S., 1985, c. P-4 (C-50); The North American Free Trade Implementation Act, S.C. 1993, c. 44 (C-184). The principal amendments to the *Patent Act* were the elimination of compulsory licensing, the introduction of exceptions to patent infringement for regulatory approval and for stockpiling, the introduction of the PM(NOC) regulations, and the strengthening of the powers accorded to the Patented Medicine Prices Review Board. *See* 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).

[67] *See* Roger Hughes, Dino Clarizio, and John Woodley, HUGHES AND WOODLEY ON PATENTS 201 (1996) ("In the place of compulsory licenses there was introduced a system, derived in part from somewhat similar provisions in the United States…") (C-328). Canada suggests that at the time it repealed its pharmaceutical patent prohibition, "many other countries" had similar prohibitions. *See* Dimock Report at ¶ 35. This statement is misleading in that the vast majority of other countries that failed to grant such patent protection were developing countries with overall weaker intellectual property protections. INTELL. PROP. AND INT'L TRADE: THE TRIPS AGREEMENT 191 (Carlos M. Correa & Yusef A. Abdulqawi eds., 1998) (characterizing the requirement in TRIPS that pharmaceutical products be patentable as "perhaps the greatest concession made by developing countries during the negotiations" and listing the policy reasons developing countries maintained the prohibition) (C-327). By obscuring the fact that Canada was one of few developed countries to maintain this prohibition, Canada downplays the traditional hostility of its patent system toward pharmaceuticals.

[68] *Compare 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) (explaining that "[w]here there are provisions in our existing legislation that conflict with the NAFTA . . . we have amended those provisions") (C-45) *with* North American Free Trade Agreement Implementation Act, S.C. 1993, (continued…)

only because Canada's utility requirement was already in conformance with the treaty.[69]

51. Canada expressly recognized that the reform of its patent system was required by NAFTA. In 1995, just after NAFTA came into effect, Canada's then Assistant Deputy Attorney General reported to Parliament that: "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."[70] Similarly, Canada's then Minister of Industry stated that Canada's obligations under NAFTA "defined" its ability to change its patent laws, and that it was "not possible to return to our pre-1993 compulsory licensing regime and remain in conformity with our international obligations."[71]

52. Canada's suggestion that NAFTA does not constrain its substantive patent law is thus undermined by its own actions. It is also undercut by the fact that since NAFTA was enacted, other governments have called attention to Canadian noncompliance with its international obligations. Canada has lost two separate WTO cases relating to different aspects of its patent law and, as a result, made changes to its patent laws to bring them into compliance with Canada's international obligations.[72] Significant concerns relating to Canada's intellectual

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c. 44 (reflecting no changes to Section 2 of the Patent Act, which requires that patentable inventions be "useful") (C-184).

[69] *See infra* Part IV.B.3.

[70] *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 (C-45).

[71] 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), at 5-6 (C-39).

[72] *See* Panel Report, *Canada–Patent Protection of Pharmaceutical Products*, Doc. WT/DS114/R (Mar. 17, 2000) (EU) (CL-79); Panel Report, *Canada–Term of Patent Protection*, Doc. WT/DS170/R (May 5, 2000) (U.S.) (CL-165); Margaret Smith, Law & Gov't Division, Gov't of Canada, "Legislative Summary of Bill S-17: An Act to Amend the Patent Act," Libr. of Parliament Doc. LS-390E at 1 (1 March 2001) (bill introduced to implement the "two recent decisions of the World Trade Organization (WTO)" regarding the WTO challenges brought by the U.S. and the EU) (C-325). International surveys have also ranked Canada's intellectual property environment as the weakest among developed economies, particularly in the life sciences sector. *See* GLOBAL INTELL. PROP. (continued…)

property regime also have been repeatedly flagged in the annual "Special 301" report published by the Office of the U.S. Trade Representative (USTR), and starting in 2013 USTR began expressing "serious concerns" regarding Canada's adoption of heightened patent utility standards.[73]

### 2. Canada's International Patent Law Harmonization Straw Man Distracts From the Unassailable Proposition that Chapter 17 Includes Substantive Patent Commitments.

53. Canada spends page after page of its Counter-Memorial arguing that "substantive international patent law is not harmonized."[74] Through Professor Daniel Gervais — who did not appear to be an active participant in any of the patent discussions in the WIPO Standing Committee on the Law of Patents — Canada describes various unsuccessful attempts by member states of the World Intellectual Property Organization (WIPO) to "harmonize" their domestic patent laws.

54. This extended argument and evidence has little apparent purpose other than atmospherics. It is uncontroversial that neither NAFTA (nor any other treaty) has harmonized substantive patent law,[75] and Lilly has not argued that

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CTR., U.S. CHAMBER OF COM., UNLIMITED POTENTIAL: GIPC INTERNATIONAL IP INDEX 21 (3d ed. Feb. 2015) (C-334); PUGATCH CONSILIUM, MEASURING THE GLOBAL BIOMEDICAL PULSE: THE BIOPHARMACEUTICAL INVESTMENT & COMPETITIVENESS (BCI) SURVEY – 2015, 8 (2015) (C-335).

[73] Canada's intellectual property regime (both copyright and patent) has been flagged in all but two years since the report's inception in 1989. The only two years Canada was not listed on a Special 301 watch list were 1993 and 1994, when it brought its laws into compliance with NAFTA. *See* INT'L INTELL. PROP. ALLIANCE, CHART OF COUNTRIES' SPECIAL 301 PLACEMENT (1989-2014) AND IIPA 2015 SPECIAL 301 RECOMMENDATIONS (Feb. 6, 2015) (C-330); OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2015 Special 301 Report 66-67 (Apr. 2015) (C-332); OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2014 Special 301 Report 49-50 (Apr. 2014) (C-331).

[74] *See* Resp. CM at Part II.I.

[75] *See, e.g.*, Daniel Gervais, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 174 (4th ed. 2012) (acknowledging that harmonization was not achieved in TRIPS and noting that TRIPS instead "sets minimum standards") (C-336). For this reason, Canada's statement that "Claimant's own legal counsel recognized in a peer-reviewed article that 'the TRIPs Agreement is not intended to be a harmonization agreement'" is at once unsurprising and unavailing. *See* Resp. CM at ¶ 186. Canada neglects to present the full context for Ms. Cheek's statement, which emphasizes that the TRIPS Agreement establishes a common baseline of protection. *See* Marney L. Cheek, "The Limits (continued…)

patent law is internationally harmonized.[76] Rather, Lilly has argued that NAFTA establishes a *baseline* or minimum level of patent protection:

> 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.*[77]

### a) NAFTA Chapter 17 Does not "Harmonize" Patent Law, but Establishes a Baseline of Substantive Protection.

55. Lilly's Memorial showed that during the negotiation of NAFTA (and also today, at least outside Canada) utility was understood by all three NAFTA parties simply to require that an invention have the capacity to be put to a specific, industrial use.[78] While there are differences in nomenclature among jurisdictions (*i.e.*, the use of "industrial applicability," "useful" or "utility"), these variations do not detract from the common substantive core of the requirement.[79]

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of Informal Regulatory Cooperation in International Affairs: A review of the Global Intellectual Property Regime," 33 GEO. WASH. INT'L L. REV. 277, 292-93 ("*The TRIPs Agreement goes beyond the voluntary alignment of domestic laws and mandates the mutual recognition of domestic laws that provide minimum levels of substantive intellectual property protection.* At the same time, the TRIPs Agreement 'is not intended to be a harmonization agreement,' meaning that countries are not required to create identical regimes.") (emphasis added) (R-314).

[76] Notably, *the sole reference to harmonization* in the hundreds of pages of argument, witness statements, and expert testimony submitted by Lilly comes from a comment by a fact witness, Mr. Armitage, that in his experience the utility requirement, as applied, is "'*substantially* harmonized across jurisdictions,' and *as a practical matter* it 'never arises with respect to a marketed biopharmaceutical product.'" *See* Cl. Mem. at ¶ 276 (quoting Armitage First Statement at ¶ 7) (emphasis added). This statement was quoted and relied on in connection with discussing Lilly's actual expectations of how Canadian law would operate, and it was plainly not offered as an expert interpretation of NAFTA Chapter 17 or any other treaty.

[77] Cl. Mem. at ¶ 185 (emphasis added).

[78] *Id.* at ¶ 206.

[79] *See* Cl. Mem. at ¶¶ 146-160, 196-201 (discussing the similar requirements of the United States, Mexico, and — before 2005 — Canada); *see also infra* Parts II.C and IV.B.3.

56. In response, rather than focusing on NAFTA alone, Canada quotes selectively from Article 1(1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"):[80]

> Members shall be free to determine the appropriate method of implementing the provisions of [TRIPS] within their own legal system and practice.

57. In the first instance, NAFTA needs to be interpreted on its own terms.[81] But it is worth looking at TRIPS Article 1(1) in its entirety, as Canada has selectively quoted the TRIPS Agreement and ignored its language affirming WTO members' substantive commitments.[82] Canada omits the first two sentences of TRIPS Article 1(1), which states in full:

> *Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.* Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

58. NAFTA — the Treaty at issue in this proceeding — includes similar language affirming the right of the NAFTA parties to provide *greater* substantive protection, but not less.[83] NAFTA Article 1702, titled "More Extensive

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[80] Resp. CM at ¶ 185.

[81] The TRIPS Agreement is only relevant as a supplementary means of interpretation relating to the circumstances of NAFTA's conclusion. See *infra* Part IV.B.3.

[82] Canada's expert, Professor Gervais, also discusses TRIPS at length. Again, TRIPS is not of primary relevance to the interpretation of NAFTA obligations. But in any case, his arguments are unsupported. Professor Gervais suggests that the absence of a definition for "capable of industrial application" or "useful" in the TRIPS Agreement indicates that "TRIPS left ample room for national variations" and "broad flexibilities." Gervais Report at ¶ 25. This leap of logic finds no support in the treaty text. *See infra* Part IV.B.3.

[83] The NAFTA text does not have an additional sentence related to implementation under domestic law.

Protection," reinforces that Chapter 17 establishes a substantive baseline of protection:

> A Party may implement in its domestic law *more* extensive protection of intellectual property rights than is required under this Agreement, provided that such protection is not inconsistent with this Agreement.[84]

NAFTA Article 1702 (like TRIPS Article 1(1)) is fully consistent with Lilly's position that NAFTA creates a minimum set of requirements that the NAFTA parties may exceed, but not contravene.[85]

**b) To the Extent Negotiations of Other International Treaties are Relevant to the Interpretation of NAFTA, They Reflect that Utility is an Uncontroversial Requirement That is Consistently Applied in Practice.**

59. Not only has Canada misrepresented Lilly's argument, it has also overstated the evidence that purportedly supports its "harmonization" straw man. Canada points to a series of international negotiations in the World Intellectual Property Organization (WIPO) to argue not only that the utility requirement remains un-"harmonized" (a point that is not in contention) but also that the requirement "continued to be applied differently across jurisdictions" both before and after the conclusion of NAFTA.[86] The actual records of those negotiations, however, do not support Canada's argument.

60. Canada raises WIPO negotiations related to the Treaty Supplementing the Paris Convention as far as Patents are Concerned (known as

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[84] *See* NAFTA, Art. 1702 (emphasis added) (CL-44).

[85] Canada has been held to this substantive baseline of patent protection in the past in the context of the TRIPS Agreement. *See, e.g.*, Panel Report, *Canada–Term of Patent Protection*, Doc. WT/DS170/R (May 5, 2000) (U.S.) (finding that Canada is obligated to provide for a term of patent protection of at least 20 years from the date of the filing of the patent application, and its failure to do so is inconsistent with TRIPS Article 33) (CL-165).

[86] Resp. CM at ¶ 192.

the "Basic Proposal") (1983-1991)[87] and the proposed Substantive Patent Law Treaty ("SPLT") (from 2000-2004), as well as recent negotiations among the so-called Tegernsee Group (consisting of the United States, Japan, and several European countries). Professor Gervais's account of these negotiations cannot be reconciled with the documentary record. Nor can his account be reconciled with the recollections of Lilly's WIPO expert, Mr. Philip Thomas, who attended substantive patent law negotiations as a senior member of the WIPO secretariat with responsibility for international patent policy.[88] As Mr. Thomas explains:

> Given the substantial consistency of practice with regard to the core industrial applicability (utility) requirement among WIPO member states, the issue was not considered to be a priority for harmonization.[89]

61. In his attempt to show otherwise, Professor Gervais first asserts that, prior to the negotiation of the TRIPS Agreement, utility had been a controversial topic among WIPO members and that the TRIPS Agreement left "ample room for national variations in this regard" by not including a definition of utility or industrial applicability.[90] Professor Gervais goes on to imply that utility continued to attract controversy in the post-TRIPS and NAFTA period, particularly in the course of the SPLT negotiations from 2000 to 2004. He suggests that the controversial nature of the utility standard is further illustrated by the fact that in 2004 utility was "***not*** *included in [a joint U.S., Japanese and European] list of issues suggested to be ripe for possible international harmonization or even discussion*."[91]

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[87] The "Basic Proposal" is more formally known as the proposed Treaty Supplementing the Paris Convention as far as Patents are Concerned.

[88] First Expert Report of Philip Thomas ("Thomas Report") at ¶ 4.

[89] Thomas Report at ¶ 12.

[90] Resp. CM at ¶ 185 (citing Gervais Report at ¶ 25 ("The negotiating history of TRIPS shows no serious attempt to agree on a definition of utility or industrial applicability. Rather, TRIPS left ample room for national variations in this regard.")).

[91] Resp. CM at ¶ 194 (quoting Gervais Report at ¶¶ 46-47) (emphasis in original).

62. These bald assertions and unsupported inferences are in conflict with what was actually transpiring in the WIPO negotiations, where the core patentability requirement of utility was not a focus of discussions. The WIPO talks addressed areas of divergent patent office practice across jurisdictions, in an attempt to bridge gaps in international patent prosecution practice. As Mr. Thomas explains:

> Industrial applicability (utility) and the other main substantive patentability requirements can be likened to the planks of a hardwood floor. Consistency in international practice creates a floor of secure rights that people and companies rely on every day to make decisions. Debates in WIPO focused on gaps between these planks.[92]

The focus of these talks, in other words, was on technical issues that were meaningful to resolve in light of the overall goal of streamlining international patent prosecution.[93] The substantive utility requirement was not a source of controversy or divergence, and therefore not a focal point.

63. In fact, as early as 1989, several WIPO members involved in Basic Proposal negotiations suggested deleting utility as a patentability requirement altogether.[94] While other delegations objected to this proposal, their objections were not on substance. There was no controversy over the substantive utility requirement, but rather a consensus view that "it serve[s] to exclude from

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[92] Thomas Report at ¶¶ 12-13 (noting that "commonalities in practice," like the utility requirement, "were generally not a focal point of discussion").

[93] *See id.* at ¶¶ 13-16, 26. For example, as Mr. Thomas explains, during discussions leading up to the 1991 Basic Proposal, key disputes involved "whether patent ownership should automatically attach to the 'first to file' for a patent (as in Europe), or whether states could continue to prefer a more fact-intensive inquiry of identifying the person who was 'first to invent' (as in the United States)." *See id.* at ¶¶ 15, 21.

[94] "Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions, Sixth Session (Geneva, April 24-28, 1989)," INDUSTRIAL PROP. 269, 278 (C-339). Further, utility is not included in a WIPO document listing "important issues in the field of patents upon which there is great divergence in treatment among national and regional laws, but for which harmonization [was] desired" through the Basic Proposal. WIPO Document PLT/DC/5, at 100 (Dec. 21, 1990) (History of the Preparations of the Patent Law Treaty) (C-338).

patentability such inventions as chemical compounds *for which no use was disclosed*, perpetual motion machines, and the like."[95] That is to say, utility as conceived in the Basic Proposal was expected to exclude from patentability inventions with no *identified,* real world use and inventions that were plainly fanciful or inoperable.

64. The 1991 Basic Proposal eventually formed the basis of a procedural harmonization treaty known as the Patent Law Treaty, which was adopted in 2000. It was only after this consensus was reached on procedural harmonization (and eight years after NAFTA was signed), that the WIPO member states once again began to tackle substantive harmonization in earnest. During these SPLT negotiations, the contentious issues included a debate over "first to file" versus "first to invent," patent protection for business methods, and whether special disclosure obligations should attach to patents involving genetic resources.[96]

65. With many contentious topics on the table, WIPO member states were looking for a way forward. Professor Gervais refers to a priority list of issues for SPLT negotiators to address that was circulated by the United States, Japan, and the European Patent Office in 2004 (the "Joint Proposal") to try to focus the talks and spur progress. Professor Gervais makes much of the fact that utility was not on the list of priority topics to be addressed. But as Mr. Thomas explains, the topics on the list were chosen in part because they were thought to be resolvable, but also because they were thought to be *important*.[97] As the face of the Joint

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[95] Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions, Sixth Session, April 24 to 28, 1989, at 278 (emphasis added) (C-339). *See also* Thomas Report at ¶ 21 (explaining that "the Basic Proposal failed largely because a dispute over whether to make mandatory the 'first-to-file' principle for establishing the right to a patent, requiring countries (in particular, the U.S.) to forgo the 'first-to-invent' system").

[96] Thomas Report at ¶¶ 15-16.

[97] The document provides three rationales for the priority list: "First, a limited number of provisions will permit more comprehensive discussions. Second, by reducing the number of issues to be addressed, progress may be achieved more rapidly. *Third, an appropriately selected first package of provisions can serve to facilitate the objectives of enhancing patent quality and producing beneficial results for users of the patent system*." WIPO Doc. SCP/10/9, at 2 (22 Apr. 2004) (proposal from the United States of America, Japan and the European Patent Office regarding the substantive patent law treaty ) (emphasis added) (R-235). Because of these three priorities, the "initial package of priority items" focused on "prior-art related issues." *Id.* The member states that drafted the priority list (continued…)

Proposal makes clear, the Joint Proposal was "driven by the desire for a 'near-term agreement' that 'would result in consistent examination standards throughout the world, improve patent quality, and reduce the duplication of work performed by patent offices.'"[98] Given common practice on utility, it simply did not rank as a priority.[99]

66. In its strained effort to find contention where there was none, Canada points to a study conducted by the WIPO secretariat in the course of SPLT negotiations that surveyed domestic utility requirements. Canada states that this report "confirmed that the notions of 'industrial applicability' and 'utility' as of 2003 continued to be applied differently across jurisdictions."[100] Canada argues that the same WIPO report specifically recognized the promise utility doctrine as "in line with international norms and practices."[101]

67. Reflecting the limited attention given to the utility requirement, there is no record of the WIPO report that Canada cites ever being discussed at a WIPO negotiating session.[102] But more to the point, while the report does (and

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believed that a focus on prior art would have immediate and tangible benefits. *Id.* ("Agreement on these issues would result in consistent examination standards throughout the world, improve patent quality, and reduce the duplication of work performed by patent offices.").

[98] Thomas Report at ¶ 37 (quoting WIPO Document SCP/10/9, at 2 (22 April 2004) (proposal from the United States of America, Japan and the European Patent Office regarding the substantive patent law treaty)).

[99] As in the earlier discussions, one alternative suggested by the WIPO secretariat was to delete the utility requirement altogether. *See* Thomas Report at ¶ 26. To the extent utility was debated at all, negotiators were focused on the implications that particular language on utility might have for issues that were of greater significance, such as the scope of subject matter exclusions from patentability. *See* Thomas Report at ¶ 17 (noting that political debates such as subject matter exclusions sometimes "spilled over" into other areas but that such debates "did not undermine or call into question the substantial commonalities in patent practice among WIPO member states").

[100] Resp. CM at ¶ 192.

[101] *Id.* at ¶ 193 (quoting Gervais Report at ¶ 41).

[102] Thomas Report at ¶ 31. As Mr. Thomas notes, Professor Gervais was not present at meetings of the WIPO Standing Committee on Patents (the principal body responsible for the negotiation of draft text for inclusion in the proposed Substantive Patent Law Treaty). Thomas Report at ¶ 4. For this reason, Professor Gervais is constrained to rely on the plain text of formal WIPO documents without the benefit of the surrounding political context and negotiating dynamics.

was intended to) survey and catalogue how WIPO member states may use different terminology to express very similar substantive patentability requirements,[103] it also makes clear that variations in national nomenclature did not result in variations in national practice. The report specifically notes that "decisions based on the lack of industrial application are, in general, very rare."[104] Further, and contrary to Canada's assertions, the report simply does not address the promise utility doctrine under Canadian law.[105]

68. Professor Gervais's treatment of the 2003 WIPO report on utility is just one of the many mischaracterizations contained in his statement.[106] Simply

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[103] Canada and Mr. Gervais place great emphasis on these linguistic differences and assert that WIPO documents reflect that "'utility' and 'industrial applicability do not have the same meaning.'" Gervais Report at ¶ 31. But the support for this point comes from documents that make a more nuanced point: that utility and industrial applicability "do not have *exactly* the same meaning." *See id.* (quoting WIPO Doc. SCP/4/2, at 25 (Sep. 25, 2000)) (emphasis added). Canada does not and cannot argue that any of the identified differences were thought to be of practical importance. To the contrary, as discussed below, the differences were understood as marginal and largely theoretical.

[104] "WIPO Doc. SCP/9/5, at 5-6 (17 March 2003) ("Industrial applicability" and "Utility" Requirements: Commonalities and Difference) (R-230).

[105] Thomas Report at ¶ 34 ("Nothing similar to the utility test articulated in [the Zyprexa and Strattera] cases was ever, to my recollection, discussed in WIPO meetings that I attended.").

[106] Professor Gervais's treatment of WIPO's 2009 Report on the International Patent System is a second example. At paragraph 48 of his report, Professor Gervais uses this WIPO document as follows (emphasis added):

> Since the failure of the SPLT negotiations, WIPO has prepared and keeps updating a "Report on the International Patent System." This report discusses patentability criteria but it leaves utility aside. If the criteria of utility (and industrial applicability) were the object of an emerging consensus of some sort, it is logical to assume that WIPO would at least report on it or mention it. *Rarely does one see such a convincing acknowledgement of the lack of uniformity of views, both among countries and within them.*

Professor Gervais thus takes the simple fact that a particular series of WIPO reports does not discuss utility and converts it into "a convincing acknowledgement" of disagreement on the utility standard. He does this without any meaningful analysis, and without even pausing to consider the possibility that utility is not discussed because it was not viewed as worth discussing.

Professor Gervais's treatment of a recent joint WIPO, WTO, and World Health Organization study on access to medical technologies and innovation is similarly selective. Gervais Report at ¶ 50. He and Canada emphasize a sentence stating that "even though the same essential patentability criteria are found in the vast majority of countries . . . *some* policy space regarding the[] (continued…)

put, there was no controversy over the meaning and application of the substantive utility requirement in WIPO.[107] Rather, as Mr. Thomas explains, "The terms 'utility' and 'industrial applicability' are treated as equally acceptable terms that lead to the same practical outcomes."[108] Commercially valuable patents are rarely (if ever) invalidated on grounds of utility[109] — a point that Canada has not contested. It is thus unsurprising that when national authorities in the Tegernsee Group countries asked their domestic stakeholders (including patent professionals, patent lawyers, corporations, and university research institutes) in 2012 and 2013 to identify "any issue that has caused problems due to differences in laws practiced in each country," *no stakeholder identified utility* as such an issue.[110]

## II. CANADA'S PROMISE UTILITY DOCTRINE REPRESENTED A DRAMATIC AND FUNDAMENTAL CHANGE IN CANADIAN PATENT LAW THAT CREATED UNREASONABLE AND ARBITRARY HURDLES TO PATENTABILITY.

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establishment" of substantive patent concepts is reserved to national law. *Id.*; Resp. CM at ¶ 197 (emphasis added). Yet, he omits the report's clear position that the "application of [the utility requirement] does not pose practical problems" except on the margins (in connection with "patent applications claiming gene-related inventions that would block the use of the claimed gene sequences for uses that were not yet known by the applicant"). WTO, WIPO & WHO, PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION, INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE 59 (2013) (emphasis added) (R-220). Canada also emphasizes the report's statement that some nations (such as the Andean Community states) disallow patents on second medical uses of known compounds. Resp. CM at ¶ 198. But this is a categorically distinct issue. TRIPS specifically permits parties to exclude therapeutic methods from patentability. *See* TRIPS Art. 27(3)(a) (CL-122). However, such exclusions operate as standalone statutory exclusions from national patent laws. In other words, such exclusions do not follow from the core patentability concepts of novelty, inventiveness, and utility.

[107] Thomas Report at ¶¶ 20, 24, 39 (noting the lack of controversy over the industrial applicability (utility) requirement in negotiations over the 1991 Basic Proposal and the SPLT).

[108] *Id.* at ¶ 20 (discussing, in particular, the 1991 Basic Proposal).

[109] Armitage First Statement at ¶ 4.

[110] *See, e.g.*, Japan Patent Office, REPORT ON CONSULTATIONS WITH USERS 21 (2013) (listing five "main issues . . . raised" without mention of utility) (C-340); European Patent Office, EVALUATION OF THE TEGERNSEE QUESTIONNAIRES FOR GERMANY 2 (2013) ("there are no other obvious topics deemed to be similarly important") (C-483).

69. Canada states that Canadian law on utility "has not changed since Claimant filed its patents"[111] and that the promise utility doctrine is "merely an articulation of the long-standing utility requirement."[112] The record, however, decisively contradicts Canada's defense. Whether one looks at the relevant case law before and after the Zyprexa and Strattera patents were granted or at the significant overhaul of MOPOP in 2009 and 2010, there can be no doubt: the promise utility doctrine is new, and constitutes a radical shift in Canadian patent law.

### A. The Promise Utility Doctrine Is Made Up of Three Component Parts, All New, Which Interact to Impose an Elevated and Additional Utility Requirement Without Precedent in Canadian Law Until the 2000s.

70. Canada's promise utility doctrine comprises three novel and interlocking parts: (i) the subjective promise of the patent; (ii) heightened evidentiary burdens, including the exclusion of post-filing evidence; and (iii) an additional disclosure requirement for evidence of soundly predicted utility. Canada contends that these are "a series of distinct patent law rules,"[113] but in fact they are elements of a unitary and cohesive doctrine of utility. The integral nature of Canada's promise utility doctrine is reflected not only in the reasoning of Federal Court decisions, but even in the tables of contents of their Reasons For Decision, which demonstrate that judges address the promise of the patent, scrutinize pre-filing evidence of utility, and compel disclosure of the factual basis for sound prediction all under the unambiguous heading of "Utility."[114]

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[111] Resp. CM at ¶ 83.

[112] *Id.* at ¶ 292.

[113] *Id.* at ¶ 86.

[114] *See, e.g.*, *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2009 FC 676, at Table of Contents, ¶¶ 142-231 (Snider, J.) (C-248); *Pfizer Canada Inc. v. Pharmascience Inc.*, 2013 FC 120, at Index of Decision, ¶¶ 96-168 (Hughes, J.) (C-180); *Astrazeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638, at Table of Contents, ¶¶ 83-218 (Rennie, J.) (C-48).

71. Canada's contention that these rules "were all part of Canadian patent law when [Lilly] filed its patent applications"[115] is plainly incorrect, as the cases cited by Canada reveal. If such rules were "longstanding," as Canada asserts,[116] one would expect to find support in the published opinions of the Federal Courts. Yet Canada and its expert witnesses have failed to identify *a single case* prior to the 2000s in which a Canadian court applied *any aspect* of the promise utility doctrine to the detriment of a patent holder. The fundamental shift in Canada's utility standard is apparent not only in the case law, but also in the work of the patent bar. Mr. Reddon, for example, explains that before 2005, "utility rarely arose" in his practice, but "[t]oday, it is challenged in most pharmaceutical patent cases that I litigate, with thousands of pages of evidence and days of testimony submitted to the court on this one issue."[117] This transformation in litigation tactics reflects the fact that Canada's additional promise utility doctrine requirement is new, unprecedented, and unforeseeable.

### 1. The Subjective, Elevated "Promise of the Patent"

72. According to the traditional utility requirement under which Lilly's patents were granted, inventions must have a "mere scintilla" of utility. This traditional test is objective, and the quantum of utility it requires is both uniform and modest.[118] As Professor Siebrasse explains: "Under the mere scintilla test, the standard for utility does not vary based on particular statements about the usefulness of the invention made in (or implied from) the patent. The requisite degree of utility is always the same: a 'mere scintilla' will do."[119]

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[115] Resp. CM at ¶ 87.

[116] *Id.* at ¶ 83.

[117] Reddon Report at ¶ 13; *see also id.* at ¶ 5 (noting that in a "new approach," counsel for generic companies now use the promise utility doctrine as "a tactical tripwire . . . to invalidate claims even where those claims have unquestioned utility and even when the patented invention delivers on the 'promise' in full measure").

[118] Cl. Mem. at ¶¶ 44-55.

[119] Second Expert Report of Norman V. Siebrasse ("Siebrasse Second Report") at ¶ 14.

73. For decades, the mere scintilla standard was applied to *all* patents, and findings of inutility were exceedingly rare,[120] but in the mid-2000s Canada's Federal Courts began to impose an elevated standard under which utility is assessed against the "promise of the patent."[121] Under this alternative test, the quantum of required utility is not objective and uniform, nor is it modest. Rather, as Professor Siebrasse emphasizes, "the standard for utility depends on the particular statements made in the disclosure (regardless of what is claimed), and may be much higher than the scintilla that would otherwise be required to support a patent."[122] The contrast with the mere scintilla test is stark, as Professor Siebrasse explains: "[A]pplying the promise of the patent, the courts will scour the disclosure to determine what specific 'promises' have been made about the usefulness or performance of the invention, and these 'promises' then determine the degree of utility that is required."[123] Moreover, where a court finds multiple promises of utility, the patent must fulfill *all* of them, even though a single use will suffice under the traditional mere scintilla test.[124]

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[120] For example, as Figure 1 indicates, from 1980 to 2004 only two patents were ruled to lack utility in the Federal Courts, and both cases involved non-pharmaceutical inventions. *See* Figure 1, "Annual Number of Canadian Inutility Decisions, 1980 – present" (C-342).

[121] Canadian courts themselves refer to this elevated standard as "the promise doctrine." *See, e.g.*, *Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC*, 2015 FC 17, at ¶ 88 (C-343); *Apotex Inc. v. Pfizer Canada Inc.*, 2014 FCA 250, at ¶¶ 65-66 (C-344).

[122] Siebrasse Second Report at ¶ 14.

[123] *Id.* at ¶ 16.

[124] Siebrasse First Report at ¶ 77. For example, in a recent case regarding AstraZeneca's drug Nexium, the trial court ruled that the claimed compound fulfilled several promises, including its principal use as a proton pump inhibitor, but nonetheless invalidated the patent for lack of utility because a single promise of an "improved therapeutic profile" was not soundly predicted. *See AstraZeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638, at ¶¶ 162-217 (C-48). In another case involving Pfizer's drug Revatio, the trial court held that the claimed compound promised treatment for multiple types of pulmonary hypertension based on an explanation of pulmonary hypertension in the written description. Even though the court accepted that the disclosed human clinical trial soundly predicted the drug's effectiveness in treating pulmonary arterial hypertension, it nonetheless found the patent to lack utility because the clinical trials did not test two additional classes of patients. *Pfizer Canada v. Ratiopharm Inc.*, 2010 FC 612, at ¶¶ 91-113 (C-345).

74. Canada cannot, and does not, dispute that its utility requirement has two distinct branches. Where a court finds no promise, a scintilla of utility will do; the promise utility doctrine is an additional requirement, layered on top of that traditional test. Indeed, Canada acknowledges that its current law requires no more than a "scintilla of utility" for patents that are "silent on the issue," that statements in the disclosure often set an elevated standard for utility, and that a patent promising what it describes as "*levels* of utility" will be "held to those promises" at the risk of invalidation.[125]

75. Canada's defense, in other words, is that its utility law has *always* had two branches, and that the "promise of the patent" has long been "recognized as an integral part of Canadian law."[126] However, the authorities on which Canada relies provide no support for its reinterpretation of the relevant jurisprudence.

### a) The *Consolboard* Ruling of the Supreme Court of Canada Has No Connection to the Promise Utility Doctrine

76. *Consolboard*, the only case Canada cites in its Counter-Memorial for its argument that the "promise of the patent" has always played a role,[127] has nothing to do with the promise utility doctrine, and Canada does not even attempt to argue that the Supreme Court of Canada applied the promise utility doctrine in *Consolboard*. The principal holding in *Consolboard* was that the utility of an invention need not be disclosed in the patent itself.[128] Whether the invention possessed utility was not even contested in the case.[129]

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[125] Resp. CM at ¶ 90 (emphasis added).

[126] *Id.* at ¶ 93.

[127] *See* Resp. CM at ¶¶ 88-100.

[128] *See* Siebrasse First Report at ¶ 73.

[129] *See* Siebrasse Second Report at ¶ 21.

77. Canada's claim that *Consolboard* embodies the promise doctrine rests on a single sentence, quoted from *Halsbury's Laws of England* (an encyclopedia of English law), stating that "not useful" means "'that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises it will do.'"[130] As Professor Siebrasse explains, any attempt to resurrect this language as authority for the contemporary promise utility doctrine "is a *post hoc* interpretation that is not supported by the decision itself."[131]

78. To understand the passage from *Consolboard*, one must understand both the context in which that sentence appears in the decision and the way in which the Supreme Court's ruling was understood for more than two decades afterwards.

79. As an initial matter, the word "promise" in *Consolboard* and other older cases refers simply to the stated utility of the invention.[132] As the quoted sentence itself indicates, the phrase "will not do what the specification promises it will do" is merely another way of saying "will not work" — *i.e.*, will not fulfill its purpose. The term "promise" is thus shorthand for the invention's intended use; in no way does it relate to an exercise whereby the court scours the disclosure to identify and assess every performance characteristic of the invention.

80. As to context, the quoted sentence appears in a passage in which the Supreme Court of Canada emphasizes that utility is a relatively low standard, noting that "it is sufficient utility to support a patent that the invention . . . affords the public a useful choice."[133] This passage rejects a comparative utility requirement, under which an invention must be more useful than the prior art, or must achieve commercial success. So long as an invention can work and do what

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[130] *Consolboard*, at 525 (C-118).

[131] Siebrasse Second Report at ¶ 20.

[132] *See* Siebrasse First Report at ¶ 75.

[133] *See id.* at ¶ 74.

its inventor intends, affording the public a useful choice, it has patentable utility even if other inventions perform better or are preferred by the market.

81. The original source, *Halsbury's Laws of England*, included footnotes that covered three categories or lines of English case law. The first relates to an antiquated and distinct "false promise" doctrine that was no longer part of English law when *Consolboard* was decided, and that revoked a patent only if a statement of utility was proven to be *false*.[134] The second rejects a comparative utility standard, while the third makes clear that wholly inoperable inventions lack utility.[135] None of these lines of precedent provides authority for the promise analysis because none resembles Canada's current doctrine — under which a patent can be invalidated even if the invention is obviously useful, and even if every statement made in the disclosure is true.[136]

82. Based on the context in which the quoted sentence from *Halsbury's* appears, Professor Siebrasse concludes there is simply no way to read *Consolboard* as establishing the contemporary promise analysis of the promise utility doctrine:

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[134] England's historical "false promise" doctrine was abolished in 1977 by the U.K. *Patents Act*. *See* Siebrasse Second Report at ¶¶ 25-26.

[135] *See* Siebrasse Second Report at ¶ 22.

[136] Just after the quotation from *Halsbury's*, the Supreme Court of Canada proceeded to cite two cases. Again, neither decision supports the promise utility doctrine. The first is the ruling of the Quebec Court of Appeal in *Metalliflex*, where the court held the patent valid even though the claims did not specify how the component parts of the invention, a watch band, were to be held together. *See Rodi & Wienenberger A.G. v. Metalliflex Ltd.* (1959) 32 C.P.R. 102 (Que CA) (R-8). The court held that the disclosure may be used to "explain the obvious," *i.e.*, that the parts must somehow be held together for the invention to be useful. The words "promised results" appear, but have nothing to do with the promise doctrine. *See* Siebrasse Second Report at ¶ 28. The second is the English case *Unifloc*, in which the patent stated that the membranes of a flocculating gel were cellulose, but the challenger claimed they were starch. The court held that the challenger was likely correct, but that the patent's erroneous description did not "affect the utility of the invention," which still worked as "an efficient flocculating agent." *See Unifloc Reagents, Ld. v. Newstead Colliery, Ld.* (1943) 60 R.P.C. 165, at 184 (C-255). As Professor Siebrasse explains, the point of *Unifloc* is that "even erroneous statements in the disclosure as to why the invention works will be considered irrelevant so long as the invention is in fact useful." *See* Siebrasse Second Report at ¶ 30; *Unifloc*, at 178 (C-255).

> [F]ar from dealing with the promise of the patent, the disputed issue in *Consolboard* was not even about utility; it was about disclosure. The discussion of utility makes the point that the utility requirement is not onerous, and is satisfied if the invention in fact has utility, regardless of what may or may not be said about it in the disclosure.[137]

83. Also highly relevant is the way in which *Consolboard* was understood and applied by Canadian judges after the Supreme Court's ruling in 1981. As noted, the holding in *Consolboard* related to the disclosure requirement, and the case was cited primarily on that point, but also on the proper approach to claim construction, as well as certain ancillary issues.[138] In his first report, Professor Siebrasse concluded: "*Consolboard* was often cited in the 25 years from the time it was decided until 2005, but never in support of the exercise by which the court construes a 'promise,' against which utility is assessed."[139] Canada identified no such case in its Counter-Memorial.

84. Mr. Dimock, Canada's expert witness, identifies a single Canadian case, *Mobil Oil*, that cites *Consolboard* and that in his view illustrates the promise of the patent. The ruling in *Mobil Oil* is decidedly not an example of the promise analysis. In the passage emphasized by Mr. Dimock, the trial court in *Mobil Oil* utilized the word "promise," but only to indicate the invention's intended utility, as is customary in older decisions.[140] Moreover, as Professor Siebrasse explains, the holding in *Mobil Oil* is at odds with the promise utility doctrine on the weight to be assigned to statements made in the disclosure about specific performance characteristics of the invention.[141] The invention in *Mobil Oil* related to an

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[137] Siebrasse Second Report at ¶ 32.

[138] *See* Siebrasse First Report at ¶ 73 & n.100 (summarizing citations to *Consolboard*).

[139] *Id.* at ¶ 73.

[140] The excerpt noted by Mr. Dimock states: "The patent specification promises an oriented polypropylene film substrate having enhanced adhesion to a metallized coating. The evidence indicates that this was indeed achieved . . . Therefore, the patent is not invalid for inutility." *See* Dimock Report at ¶ 71 (Mr. Dimock's emphasis omitted).

[141] Siebrasse Second Report at ¶ 32.

adhesive, and the challenger argued that data in the disclosure required the adhesive to achieve a specified strength. The court, however, concluded that data in the patent "is merely provided as an example" and "does not define the promise of the patent" unless the specified strength is *claimed*.[142] Professor Siebrasse emphasizes that this result "is inconsistent on its face with the 'promise of the patent', according to which it is acceptable to hold the patentee to a statement made in the disclosure regardless of what is claimed."[143]

**b) Other Authorities Identified by Canada Provide No Support for the Promise Utility Doctrine**

85. The only other Canadian case cited by Mr. Dimock as purportedly applying the promise of the patent is *New Process Screw*, a decision that predated *Consolboard* by twenty years and that involved a straightforward assessment of the operability of the claimed invention. In *New Process Screw*, the claim at issue was specific to the production of a certain type of screws: "1. A pair of relatively movable screw thread rolling dies capable of only rolling double threads . . . ."[144] As it happens, dies with the pitch angles specified in the claims would produce only single- and triple-threaded screws, not double-threaded screws, and the court concluded that this failure was fatal to the patent. While the decision used the phrase "promise of the patent," the court — as Professor Siebrasse explains — "did not examine the disclosure to find promises of utility in a manner similar to the promise of the patent, but rather simply found that the claimed invention (a specific technique for producing double threaded screws) did not work."[145] In sum, the claimed invention in *New Process Screw* was ruled inoperable. As a result, *New Process Screw* is not a precedent for the promise of the patent.

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[142] *Mobil Oil Corp. v. Hercules Canada Inc.*, (1994), 57 C.P.R. (3d) 488 (FC), at 31 (C-347).

[143] Siebrasse Second Report at ¶ 32.

[144] *New Process Screw Corp. v. PL Robertson Mfg Co. Ltd.*, (1961) 39 C.P.R. 31 (Ex Ct), at 32 (emphasis added) (R-162).

[145] Siebrasse Second Report at ¶ 36.

86. Finding no defensible examples of the promise prong of the promise utility doctrine in Canada's pre-2005 utility jurisprudence, Mr. Dimock strays beyond utility to analyze cases regarding the distinct and separate doctrine of overbreadth. To justify this broadening of his search, Mr. Dimock contends that "[t]he principles underlying promised utility also arise in overbreadth," but these patentability requirements are independent of one another and serve quite different purposes. As Professor Siebrasse explains, overbreadth is "a ground of objection to a patent [that] is quite distinct from utility."[146] A patent that is overbroad claims subject matter that is useful, but claims *more* subject matter than has actually been invented.

87. The *Amfac* case cited by Mr. Dimock illustrates this distinction, as the court invalidated the patent for overbreadth, and utility was never at issue.[147] The other overbreadth case cited by Mr. Dimock, *Unilever*, actually rejected an argument resembling the promise analysis. As Professor Siebrasse explains, in *Unilever* the Federal Court of Appeal "refused to accept the defendants' assertion that statements in the disclosure could amount to a 'promise,' on the basis that utility was to be assessed by reference to the claimed invention."[148]

88. Given that decades of Canadian case law provide no support for the allegedly "longstanding" promise of the patent analysis, Canada and Mr. Dimock turn to the writings of selected commentators in the 1960s.[149] But the only case law cited by these commentators is the English "false promise" doctrine, which the U.K. *Patents Act* abolished in 1977 and which never became part of Canadian law.[150] This historical English rule was in any event distinct from Canada's

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[146] *Id*. at ¶ 37.

[147] *See id*. at ¶ 38; *Amfac Foods Inc. v. Irving Pulp & Paper, Ltd*., (1986) 12 C.P.R. (3d) 193 (FCA), at 200 (R-168).

[148] *See* Siebrasse Second Report at ¶ 39; *Unilever PLC. v. Procter & Gamble Inc*., (1995) 61 C.P.R. (3d) 499 (FCA), at 512 (R-172).

[149] *See* Resp. CM at ¶¶ 95-96; Dimock Report at ¶¶ 62, 65-66.

[150] *See* Siebrasse Second Report at ¶¶ 25-26, 40 & n.53.

promise utility doctrine in fundamental respects. Under the old English test, a promise had to be proven *false* for a court to revoke the patent. In Canada, by contrast, courts applying the promise utility doctrine invalidate patents for statements that are undisputed and accepted as true at the time of the litigation, but for which the courts find insufficient factual support at the time of filing. As a result, many pharmaceutical patents found by the Federal Courts to lack utility under the promise utility doctrine — including Lilly's patents for Zyprexa and Strattera — would have remained valid under the English "false promise" doctrine because their clinical effectiveness and promised advantages were beyond dispute. Canadian law incorporates a version of the old English test in Section 53 of the *Patent Act*, which prohibits misrepresentation — a ground of challenge that the court expressly rejected in the Zyprexa litigation and that was not even alleged in the Strattera litigation.[151]

89. Finally, conflating the utility requirement with other distinct doctrines, Canada argues that a promise has long been required to support "new use" and "selection" patents.[152] But the need to establish a use as "new" relates to the novelty requirement, and the need to identify an "advantage" for a compound selected from a known genus relates to the non-obviousness requirement. As Professor Siebrasse explains, these are entirely separate patent requirements from the requirement in Section 2 of the *Patent Act* that an invention have utility.[153] In

[151] *See Eli Lilly Canada Inc. v. Novopharm Limited*, 2009 FC 1018, at ¶ 153 ("As I have found above, some of the assertions in the '113 were hopeful. They were based on too little evidence to be factual contentions or even sound predictions of olanzapine's alleged advantages. But, to my mind, that does not mean that they were misleading or made in bad faith. I find no basis under s. 53 or s. 73 to invalidate the '113 patent, or any part of it.") (C-145).

[152] Resp. CM at ¶¶ 97-98; *see also* Dimock Report at ¶ 73.

[153] *See* Siebrasse Second Report at ¶¶ 46-50. Professor Siebrasse further explains that insofar as Canadian law *today* requires that a selection patent assert an enhanced utility over the genus, that requirement "is a consequence of the promise of the patent, not a cause." *Id.* at ¶ 50.

any event, Canada cites *no case prior to 2005* in which the promise utility doctrine was applied to a new use or selection patent.[154]

90. In sum, Canada's contention that the promise prong of the promise utility doctrine is a longstanding component of its utility standard is wholly unsubstantiated. Canada and its witnesses have not identified a single case in which a Canadian court applied the promise utility doctrine prior to 2005. Instead, Canada has called attention to a handful of cases in which the word "promise" is used in an entirely different and uncontroversial manner, with reference to the invention's stated use. Canada has also cited cases that deal with entirely distinct patentability requirements, such as overbreadth or sufficiency of disclosure, as well as to commentators citing antiquated and distinct English law. The authorities relied upon in the Counter-Memorial and by Mr. Dimock do not, and cannot, contradict the fact that the promise utility doctrine has emerged as a core aspect of Canada's newly elevated utility standard only since 2005.

### 2. Heightened Evidentiary Burdens

91. The second element of the promise utility doctrine is a heightened evidentiary standard. As explained in the Memorial, the evidentiary burdens associated with Canada's elevated utility requirement are twofold — and, contrary to Canada's allegations, both facets were entirely unprecedented when Lilly filed the patent applications for Zyprexa and Strattera.[155]

92. First, Canadian courts have begun to second-guess evidence relied upon to demonstrate or soundly predict utility, scrutinizing even the design, size, and duration of human clinical trials.[156] The contrast between this close

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[154] Nor does Canada argue that the promise utility doctrine has applied *only* to new use and selection patents since 2005. The record is clear that the doctrine has been applied to a wide range of patents types. *See* Brisebois Statement at ¶¶ 41, 43 (acknowledging that patent types successfully challenged for lack of utility include compound, formulation, dosage, and others).

[155] *See* Cl. Mem. at ¶¶ 66-72; Siebrasse First Report at ¶¶ 54-58.

[156] *See, e.g., Novartis Pharmaceuticals Canada Inc v. Teva Canada Limited*, 2013 FC 283 (finding patent to lack utility because applicant should have tested more compounds within the genus to establish a basis for sound prediction) (C-244); *Glaxosmithkline Inc. v. Pharmascience Inc.*, 2008 FC 593 (finding (continued…)

evidentiary scrutiny and the traditional mere scintilla test is stark. In an example of the traditional test, a Canadian generic company in 2001 challenged the utility of a formulation patent claiming a process "much less likely to develop a pink hue."[157] The trial court disposed of this utility challenge based on testimony that pink hue in fact posed a significant problem that delayed launch, and therefore that the invention had a practical use in resolving that problem.[158] On that basis alone, with no inquiry as to whether or how effectively the new formulation worked, the court was satisfied that the innovator had "met the burden on it to establish that the allegation of lack of utility [was] not justified."[159]

93. Second, since the *AZT* ruling of the Supreme Court in 2002, Canadian judges no longer admit evidence of utility that post-dates the patent application. This new evidentiary exclusion overturned decades of settled law allowing patentees to offer post-filing evidence of the fact that an invention had utility as of the filing date.

94. Canada does not, and cannot, dispute that Canadian courts now routinely scrutinize evidence offered to demonstrate or soundly predict utility, second-guessing not only *in vitro* and animal tests but even the results of human clinical trials.

95. Canada also does not contest (nor can it) that in some cases, including the Strattera litigation at issue in this proceeding, the Federal Courts

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patent to lack utility because applicant did not test enough compounds to satisfy promise that the selected compound works "surprisingly" better than the genus) (C-348); *Pfizer Canada Inc. v. Ratiopharm Inc.*, 2010 FC 612, at ¶¶ 101, 109 (questioning the length of the time for which patients were tested in the clinical trial, the number of patients, and whether the test was double-blind in deciding that there was insufficient support to soundly predict the promised utility) (C-345).

[157] *SmithKline Beecham Pharma Inc. v. Apotex Inc.* (2001) 14 C.P.R. (4th) 76, at ¶ 54 (C-349).

[158] *Id.* at ¶¶ 55-56.

[159] *Id.* at ¶ 57. The generic did not bother to appeal this traditional utility ruling. *See SmithKline Beecham Pharma Inc. et al. v. Apotex Inc. et al.*, 2002 FCA 216, at ¶¶ 9-10 (C-350).

have concluded that even statistically significant clinical trial data are insufficient to establish utility.[160]

96. Attempting to avoid the issue, Canada contends that these evidentiary burdens "ha[ve] nothing to do with" and "do not relate to" the meaning of utility under the *Patent Act* and NAFTA Article 1709(1). Yet evidentiary burdens are intrinsically tied to substantive law doctrines, and since the *AZT* ruling,[161] Canadian courts have routinely recognized and applied the bar on post-filing evidence as an integral part of the substantive utility requirement.[162] Indeed, the post-filing evidence prohibition in many cases is a dispositive component of the promise utility doctrine, given the unquestioned utility of pharmaceuticals that achieve commercial success after obtaining regulatory approval from Health Canada.

97. As with the other components of the promise utility doctrine, Canada's principal point of contention with regard to heightened evidentiary burdens is that the Supreme Court's "ruling in *AZT* did not change the law on post-filing evidence of utility."[163] This assertion is squarely contradicted by decades of pre-*AZT* case law, as well as by uncertainty in the lower courts regarding how to apply the new rule set forth in *AZT*.

98. Prior to *AZT*, there was a clear and consistent record of Canadian courts admitting post-filing evidence to show that an invention possessed utility on the date of filing. It is common ground that the date on which utility is

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[160] *See* Cl. Mem. at ¶¶ 128-129, 134-135 (discussing trial court's finding that the statistically significant, positive results of the MGH Study failed to demonstrate the utility of atomoxetine to treat ADHD).

[161] *Apotex Inc. v. Wellcome Foundation Ltd. (AZT)*, 2002 SCC 77, at ¶ 52 (C-213) [hereinafter "*AZT*"].

[162] *See, e.g.*, *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283, at ¶ 157 ("There is no question that the '206 patent turned out to be a very useful invention. However, this sort of 'after the fact validation' was specifically rejected by the Supreme Court of Canada in *[AZT]*.") (C-209); *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 26, at ¶ 68 ("It is clear . . . that after-the-fact confirmation of the utility of a purported invention is not enough to uphold a patent.") (C-352).

[163] Resp. CM at ¶ 113.

assessed is the date of the patent application, but Canadian courts traditionally allowed patentees to offer post-filing evidence that the claimed invention possessed utility.[164] In *McPhar Engineering*, for example, the court found the invention useful as of the filing date based on post-filing evidence of commercial success.[165] Similarly, in *Cochlear Corp.*, the court relied on post-filing evidence of commercial success, including testimony from an individual who had used the patented invention, to find utility.[166] As Professor Siebrasse observes, the court expressly stated that "utility is to be judged at the date of the invention," and also that "[t]he utility of a patent may be proven by the reception received from the public, *i.e.*, its commercial success."[167] The rule for pharmaceutical inventions was no different: in *Hoechst Pharmaceuticals*, the court accepted evidence of a compound's use, after issuance of the patent, to assess utility.[168]

99. Neither Canada nor Mr. Dimock has identified a single case prior to *AZT* in which post-filing evidence of utility was excluded. Mr. Dimock asserts that "it has long been understood in Canadian patent law that post-filing evidence is not available" with respect to utility at the time of filing, yet the only precedent he cites for this proposition is *AZT* itself, the 2002 decision that established the new rule barring post-filing evidence.[169] Indeed, the only pre-*AZT* case that Mr.

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[164] As Professor Siebrasse explains, the rule requiring utility as of the filing date ensures that the claimed invention – and not a subsequently improved version – is the focus of the utility inquiry. That rule is independent of whether post-filing evidence of utility may be offered. *See* Siebrasse Second Report at ¶¶ 51-52.

[165] *McPhar Engineering Co. of Canada v. Sharpe Instruments Ltd.* (1960) 35 C.P.R. 105, at 147-48 (C-220).

[166] *Cochlear Corp. v. Cosem Neurostim Ltée* (1995) 64 C.P.R. (3d) 10, at 16, 35 (C-228).

[167] *See* Siebrasse Second Report at ¶ 58.

[168] *See* Siebrasse Second Report at ¶ 58 & n.90 (discussing *Hoechst Pharmaceuticals of Canada Ltd. v. Gilbert & Co.* [1965] 1 ExCR 710, at 714). Canada and Mr. Dimock attempt to explain away such cases by drawing a distinction between "utility at the filing date" and "the *operability* (or utility-in-fact) of the invention." Resp. CM at ¶ 115 (emphasis in original); *see also* Dimock Report at ¶ 105. Even if there are circumstances in which post-filing evidence of utility remains admissible regarding "operability," Canada has presented no evidence that post-filing evidence was ever barred until *AZT*.

[169] Dimock Report at ¶ 102.

Dimock identifies as relevant is *Ciba-Geigy*, in which — as he acknowledges — the Federal Court of Appeal *reversed* a decision of the Patent Office rejecting post-filing evidence.[170]

100. The lack of authority for Canada's position is striking. As Professor Siebrasse notes: "If the rule in *AZT* were long-established, . . . then we should expect to find at least one case in the previous 100 years of patent litigation in which the rule was actually applied. Mr. Dimock does not cite any, and to my knowledge there are no such cases."[171]

101. Moreover, if the rule in *AZT* were longstanding, it should not have been necessary for the Supreme Court of Canada to reverse lower courts on this very issue. But the Federal Court of Appeal in *AZT* conclusively rejected the generic challenger's argument that post-filing evidence of utility should be prohibited — indeed, it described such as position as illogical and unsound:

> To conclude that evidence of actual utility subsequent to a patent's priority date may not be introduced to demonstrate that an invention meets the requirements of the *Patent Act* would produce illogical results. For instance, suppose that on December 10, 1903, Wilbur and Orville Wright obtained a patent for an airplane, and that by that date, neither brother had successfully flown the plane or could be said to have a "sound prediction" that a machine heavier than air could fly. Suppose further that one week later, the Wright brothers managed to successfully fly their plane. If the Wright brothers' patent was later attacked, and if uncontradicted expert testimony was provided by the attackers to demonstrate that by December 10, 1903, machines heavier than air could not fly, would their patent be invalid even though all would concede that by the time the attack was brought, such machines could fly? In my view, to so conclude would require a Court to close its eyes to continuing

[170] *Id.* at ¶ 106. Canada suggests that Claimant "over-reads" *Ciba-Geigy*, but its arguments rest on the Supreme Court's entirely understandable, yet unpersuasive, attempts to distinguish *Ciba-Geigy* in the *AZT* decision itself. *See* Resp. CM at ¶¶ 116-118.

[171] Siebrasse Second Report at ¶ 55.

> scientific advancements, and would disentitle patentees to rely on the instinctive sparks that so often engender great discoveries.[172]

102. A final indication that the rule announced by the Supreme Court of Canada in *AZT* was a departure from past practice is that lower courts initially did not know how to implement it. In particular, there were disputes regarding which filing date — the priority date on which the first application in any jurisdiction was filed, or the filing date of the Canadian application — was the cut-off for evidence of utility.[173] As Professor Siebrasse observes, "[i]f the rule against post-filing evidence were long-established, then there would have been no confusion as to the cut-off date."[174]

103. In sum, though Canada claims its courts have treated post-filing evidence consistently, the case law before and after *AZT* reveals an unambiguous shift. Prior to *AZT*, post-filing evidence, such as commercial success, was commonly accepted to establish the utility of an invention on the filing date. Canada has not identified a single pre-*AZT* case in which post-filing evidence was excluded. After *AZT*, by contrast, post-filing evidence of utility as of the filing date has been squarely barred, again without exception. For Canada to contend that Canadian law did not change in this respect strains credulity. Not only was there a fundamental shift in the law, but that shift has had a dramatic, adverse effect on the ability of pharmaceutical innovators to establish the utility of their inventions.[175]

### 3. Additional Disclosure for Soundly Predicted Utility

104. The third element of the promise utility doctrine is an additional disclosure rule that applies when an innovator cannot demonstrate utility with

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[172] *Apotex Inc. v. Wellcome Foundation Ltd.*, (2000) 10 C.P.R. (4th) (FCA), at ¶ 52 (C-117).

[173] As Professor Siebrasse notes, the lead case resolving this uncertainty in favor of the Canadian filing date was *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283, at ¶¶ 91-96, *aff'd* 2006 FCA 64, at ¶ 30 (C-209). *See* Siebrasse Second Report at ¶ 62 & n.95.

[174] Siebrasse Second Report at ¶ 62.

[175] *See* Siebrasse First Report at ¶¶ 56-57.

evidence available at the filing date and therefore must assert that utility was soundly predicted.[176] While Canada asserts that this heightened disclosure obligation has been in place for decades, in fact the rule was articulated and applied for the first time only in 2008, long after Lilly received patent protection for Zyprexa and Strattera.

105. Under this rule, Canadian courts assessing whether a promise of utility is soundly predicted will refuse to consider any evidence that does not appear in the patent application.[177] As a result, when utility is based on a sound prediction, the factual basis for that prediction — including the evidence and line of reasoning that supports the prediction — must be in the patent itself.

106. As an initial matter, Canada asserts that this rule relates to sufficiency of disclosure, rather than utility.[178] This is incorrect. Sufficiency of disclosure is a distinct patentability requirement, independent of utility, that is set forth in Section 27(3) of the *Patent Act*. This requirement obligates an inventor to describe in the patent how to make and use the claimed invention. Sufficiency thus has nothing to do with proof of utility, as Professor Siebrasse explains:

> The traditional requirement for sufficient disclosure does not require disclosure of the evidence of utility, any more than it requires disclosure of evidence establishing novelty or non-obviousness. If a patentee invents a new compound that cures the common cold, and discloses how to make that compound, and how much should be administered, and the compound does cure the common cold, then the requirement for sufficient disclosure is met. That is true whether or not data predicting that the compound will cure the common cold is found in the patent itself — the distinct requirement that is at issue here.[179]

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[176] *See id.* at ¶¶ 64-65 (discussing origins of requirement).

[177] *See* Cl. Mem. at ¶¶ 73-75.

[178] *See* Resp. CM at ¶ 125.

[179] *See* Siebrasse Second Report at ¶ 64.

107. The distinction between the traditional sufficiency requirement and the separate disclosure rule for soundly predicted utility is clear on the face of recent Canadian court decisions. Federal Court judges now routinely refer to the rule for soundly predicted utility as an "additional," "heightened," or "enhanced" disclosure requirement that arises and is examined exclusively in the context of the utility requirement.[180] Moreover, Canadian courts routinely reach independent, divergent results on utility and sufficiency. As one of many examples, Lilly's patent for Zyprexa was ruled to have met the sufficiency requirement, but to have failed Canada's elevated utility standard.[181]

108. While unable to blur the line with sufficiency of disclosure, Canada argues that the requirement to disclose the factual basis for a sound prediction in the patent "has been recognized in Canadian patent law since at least the 1970s."[182] But as Professor Siebrasse explains, none of the authorities cited by Canada indicates that this requirement existed at any time before 2008.

109. The case on which Canada and Mr. Dimock principally rely is *Monsanto*, a 1977 decision of the Supreme Court of Canada. Notably, however, the Supreme Court in *Monsanto* reversed a decision of the CIPO Patent Appeal Board that effectively required disclosure of the factual basis for sound prediction. The Supreme Court held that the Board had erred when it decided, "in spite of a complete absence of any evidence of unsoundness of the prediction, [to] deny the claims and . . . in the end limit them to the area of *proved utility* instead of allowing them to the extent of *predicted utility*."[183] The Supreme Court clarified that the burden is on the challenger, explaining: "If the inventors have claimed more than what they have invented and included substances which are devoid of utility,

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[180] *See* Siebrasse First Report at ¶ 66 & n.91 (quoting cases).

[181] *See Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, at ¶¶ 268, 272 (C-146). *See e.g., Alcon Canada Inc. v. Cobalt Pharmaceuticals Co,* 2014 FC 149, at ¶¶ 222, 240 (C-353).

[182] Resp. CM at ¶ 128.

[183] *Monsanto Co. v. Canada*, [1979] 2 S.C.R. 1108 (SCC), at ¶ 24 (emphases in original) (R-23) [hereinafter *Monsanto*].

their claims will be open to attack. But in order to succeed, such attack will have to be supported by evidence of lack of utility. At present there is no such evidence."[184] As Professor Siebrasse explains, "*Monsanto* holds that "the burden is on the patent office to disprove utility, not on the patent applicant to prove it."[185] Nothing in *Monsanto* implies, let alone holds, that the factual basis for a sound prediction must be disclosed in the patent.[186]

110. As Canada emphasizes,[187] *Monsanto* draws upon a 1969 English decision, *Olin Mathieson*, that Mr. Dimock describes as establishing "an obligation to properly support a sound prediction within the patent specification."[188] However, as Professor Siebrasse explains, *Olin Mathieson* actually "stands for the contrary proposition" — that evidence in support of a sound prediction need *not* be in the patent.[189] The patent in *Olin Mathieson* identified the use of the claimed compounds, but provided no evidence to support that utility. The court drew upon various evidentiary sources, none of them disclosed in the patent, in affirming the utility of the patent. The evidence included test results showing that the claimed compounds had therapeutic activity, a fact to which the court attached "great importance" even though it was not referenced in the patent.[190] So *Olin*

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[184] *Id.* at ¶ 25 (R-23).

[185] Siebrasse Second Report at ¶ 69.

[186] Canada calls attention to language quoted in *Monsanto* that states: "If it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so." Resp. CM at ¶ 131. However, as Professor Siebrasse notes, this quotation "simply says that the prediction must in fact be sound," not that its factual basis must be disclosed. Siebrasse Second Report at ¶ 70. Canada also emphasizes language quoted in *Monsanto* stating that in a valid patent, "[the] claim does not go beyond the consideration given by [the] disclosure." Resp. CM at ¶ 131. But this quotation refers to the traditional sufficiency requirement, which – as Professor Siebrasse explains – "can be satisfied without disclosing any evidence of utility in the patent itself." Siebrasse Second Report at ¶ 71.

[187] *See* Resp. CM at ¶ 131.

[188] Dimock Report at ¶ 149 (emphasis in original).

[189] Siebrasse Second Report at ¶ 67.

[190] *Id.*

*Mathieson*, which the Supreme Court of Canada cited approvingly in both *Monsanto* and *AZT*, thus provides no basis for — and actually contradicts — Canada's new disclosure rule.[191]

111. Among more recent cases, Canada points to the Supreme Court's ruling in *AZT* as "reaffirming that a sound prediction must be adequately supported by the disclosure."[192] This is incorrect. It bears emphasis that *AZT* did not establish or endorse a heightened disclosure rule for sound prediction. To the contrary, in *AZT* — as in *Olin Mathieson* — *the court determined that utility was soundly predicted after considering and relying upon evidence that was not disclosed in the patent*.[193] The *AZT* decision restated the requirements for sound prediction, identifying "proper disclosure" as an element.[194] But as Mr. Dimock acknowledges, *AZT* is silent on what constitutes "proper disclosure" in the context of sound prediction because, as the decision states, "disclosure in this respect did not become an issue between the parties."[195] Accordingly, *AZT* does not suggest, much less hold, that courts must disregard evidence of soundly predicted utility that is not disclosed in the patent.

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[191] Finding no support in the case law, Canada points to a patent tutorial published in 1971 advising that patent applicants "must include sufficient examples to justify a sound prediction that everything falling within the scope of the claims will have the promised utility." Resp. CM at ¶ 128 (quoting W.L. Hayhurst, "Disclosure Drafting" (1971), pp. 77-78). This may be prudent advice for applicants who prefer not to face an initial rejection, even if such a rejection can be cured during examination. However, as Professor Siebrasse explains, this tutorial is not, and cannot be, intended as a statement of Canadian utility law, because the only case cited in support of the advice is *Olin Mathieson* – a decision that relied upon evidence of sound prediction that was *not* disclosed in the patent. Siebrasse Second Report at ¶¶ 66-67.

[192] Resp. CM at ¶ 132.

[193] As Professor Siebrasse notes, in *AZT* the trial court discussed undisclosed evidence, and the Supreme Court summarized evidence relied upon by the trial judge that were either not disclosed or disclosed only in part. Additional evidence of utility was disclosed and considered, but nothing in *AZT* indicates that the finding of sound prediction rested on disclosed facts alone, or that non-disclosed evidence was disregarded. *See* Siebrasse Second Report at ¶¶ 72-73 & nn. 118-19.

[194] *AZT* at ¶ 70 (C-213).

[195] Dimock Report at ¶ 125; *AZT* at ¶ 70 (C-213).

112. As Professor Siebrasse explains, the controversy surrounding the cut-off date for post-filing evidence after *AZT* is another clear sign that *AZT* did not impose, or affirm, a rule requiring the disclosure of all evidence for sound prediction. In two cases where the cut-off date was contested, the issue mattered only because there was evidence of sound prediction that came after the priority date, but before the Canadian filing date.[196] Crucially, this evidence was not disclosed in the patent. If *AZT* barred reliance on undisclosed evidence for sound prediction, the cut-off date would have been moot in those cases, because the undisclosed evidence at issue would have been excluded regardless. But in both cases, after ruling that the Canadian filing date provided the cut-off, the court evaluated evidence of soundly predicted utility that came after the priority date and that was not disclosed in the patent.[197] The issues addressed in these cases, which were decided between 2005 and 2007, would never have arisen if Canada's historical account were remotely accurate.

113. The case law is unambiguous. No court cited *AZT* in support of a heightened disclosure rule for sound prediction, and no such rule existed, until 2008. When the Federal Court imposed this new rule against Lilly in the *Raloxifene* case, the result — as Mr. Dimock concedes — was controversial.[198] Mr. Dimock asserts that *Raloxifene* "follows the same principles applied more than 25 years prior in *Monsanto*,"[199] yet the decisions include no citations to *Monsanto*.[200] Canada contends that this additional disclosure obligation for sound prediction was well established for decades, but neither the trial court nor the Federal Court

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[196] *See* Siebrasse Second Report at ¶ 74 & n.121 (discussing *Aventis Pharma. Inc. v. Apotex Inc.*, 2005 FC 1283, *aff'd* 2006 FCA 64, and *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FCA 209, *rev'g* 2005 FC 1205).

[197] *See id.*

[198] *See* Dimock Report at ¶ 140 (admitting the *Raloxifene* decision "appears to be somewhat controversial").

[199] *Id.* at ¶ 140.

[200] *See Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142 (C-115); 2009 FCA 97 (C-119).

of Appeal cited any authority before *AZT* — the sole precedent on which both *Raloxifene* decisions claim to rest.[201]

114. The unprecedented nature of the heightened disclosure rule set forth in *Raloxifene* is apparent not only on the face of the decisions, but also in the reactions of experienced patent litigators, who immediately identified the rule as unprecedented.[202] Even other Canadian judges have recognized and debated the scope of the change. In the *Plavix* case, a concurring judge on the Federal Court of Appeal questioned whether *AZT* is a proper basis for "the heightened level of disclosure applied in recent case law," and proposed to limit the rule to new use patents.[203] Similarly, the trial judge in *Nexium*, recently elevated to the Federal Court of Appeal, traced the new rule to *AZT* and concluded that it should apply only to new use patents.[204] This ongoing public debate, within the judiciary itself, is telling. As Professor Siebrasse concludes: "If the obligation to disclose the evidence of sound prediction in the patent itself were long-standing, surely the scope of the requirement would already have been addressed and would not need to be extensively discussed within the jurisprudence."[205]

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[201] *See Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142 (C-115); 2009 FCA 97 (C-119).

[202] Mr. Reddon, for example, notes that he had "never considered that there was any need to establish that an inventor had met a 'heightened' obligation to disclose facts supporting a prediction in the patent," and that he and his colleagues gave presentations to clients in 2009 advising them of the new rule — a rule that "has been difficult for patentees in practice." *See* Reddon Report at ¶¶ 10-11; *see also* Steven Mason and David Tait, McCarthy Tetrault Case Alert (*Eli Lilly v. Apotex Inc.*) (September 17, 2009) (describing *Raloxifene* as a "watershed decision" that "requires, for the first time, that all data and studies that constitute the factual basis upon which the prediction is made should be disclosed clearly in the patent specification itself') (C-499).

[203] *See Sanofi-aventis et al. v. Apotex Inc.*, 2013 FCA 186, at ¶ 132 (C-47) (citing Norman Siebrasse, *Must the Factual Basis for Sound Prediction be Disclosed in the Patent?*, 28(1) CAN. I.P. REV. 39, 75 (2012) (C-206)).

[204] *See AstraZeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638, ¶¶ 139-161 (Rennie, J.) (C-48).

[205] Siebrasse Second Report at ¶ 77.

115. In short, each element of Canada's promise utility doctrine is demonstrably new. *Canada has failed to identify a single case applying any aspect of the promise utility doctrine at any time before Lilly sought patent protection for Zyprexa and Strattera*. When Lilly drafted and submitted its applications, the traditional utility standard in Canada required no more than a mere scintilla of utility; accepted post-filing evidence of utility, including commercial success; and admitted evidence of sound prediction that was not disclosed in the patent. Lilly did not, and could not, anticipate that these core features of Canada's traditional utility test would all be displaced. Nor did Lilly expect that an additional, elevated and improper utility requirement would be applied to invalidate its rights. Yet that is what happened in Canada.

### B. The Advent of the Promise Utility Doctrine Transformed How Canada's Patent Office Analyzed and Applied the Utility Requirement in Deciding Whether to Grant a Patent.

116. Another clear and unassailable manifestation of the change in Canada's utility standard was the dramatic shift in Patent Office practice as evidenced by the substantial amendments to the Patent Office's Manual of Patent Office Practice (MOPOP) in 2009 and 2010.

#### 1. The Change in MOPOP Is Evidence of a Shift in Canada's Law on Utility.

117. The advent of the promise utility doctrine caused a transformational change in how CIPO analyzed and applied the utility requirement in the patent examination process. Prior to 2005, the utility test in MOPOP was simple and straightforward. As articulated in the 1990s versions of MOPOP, the Canadian "utility" requirement was a simple requirement to show that the invention was not "totally useless." As former acting chair of Canada's Patent Appeal Board Mr. Murray Wilson explains, "[a]s soon as an examiner found that the invention had a single utility, that was enough to meet the utility requirement."[206]

[206] Wilson Second Report at ¶ 19.

118. Canada's traditional utility requirement was described by Canada's Patent Office in the 1990 MOPOP 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.[207]

The 1990 MOPOP further explained that "utility, as related to inventions, means industrial value."[208]

119. Despite the MOPOP's plain and unequivocal language, Canada argues that "Claimant is incorrect that in the 1990s patent examiners looked only for 'any utility'" and instead that patent examiners "have long assessed utility based on what was asserted in the patent application."[209] Canada claims that the promise utility doctrine existed at the time Lilly's patents were granted and has existed in Canadian law for the past sixty years.[210] But nothing in the MOPOP at the time Lilly's patents were granted supports Canada's assertions. The 1990 MOPOP is clear that utility is a low threshold requiring that an invention not be "totally useless." Canada has failed to produce any documentation that would support its interpretation.[211]

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[207] Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 12.02.01 (January 1990) (emphasis added) (C-53).

[208] *Id.* at § 12.03.

[209] Resp. CM at ¶ 98.

[210] *Id.* at ¶ 91 ("As Mr. Ronald Dimock explains, 'the well-established rule in Canadian jurisprudence and legal literature for at least the past sixty years is that if a patent promises a certain utility then such utility must be attainable by the claimed invention.'").

[211] Mr. Wilson also states that he is "not aware of any written or oral instruction that examiners would have followed to hold applicants to a more stringent utility test other than the test articulated in the MOPOP." Wilson Second Report at ¶ 17.

120. Canada next argues that patent examiners combed through applications for multiple promises and considered advantages of inventions — such as fewer side effects or improved efficacy — as "utility."[212] But the 1990 MOPOP was clear that a single utility was enough.[213] At the time of grant of Lilly's patents, statements of advantage were irrelevant to utility in all patents, including new use or selection patents.[214]

121. Canada also argues that examiners would have required substantial evidence, including clinical trials, to prove utility.[215] This argument contradicts Canada's claim that CIPO examiners conducted only a cursory review, and is incorrect in any event. Examiners did not require clinical trial evidence because utility was a very low bar at the relevant time. As Mr. Wilson explains, "[b]ecause the bar to establish utility was low and the utility requirement easily satisfied, clinical data were not required" and "[e]xaminers would therefore not have expected human and clinical data to be included in the patent application to prove utility."[216]

122. Following the Supreme Court of Canada's 2002 decision in *AZT* and subsequent Federal Courts decisions, CIPO undertook efforts to revise and restate the utility test in MOPOP.[217] Since MOPOP is updated to reflect the current case law, the difference between the simple utility test in the 1990s versions of MOPOP and the heightened utility standard in the 2009 and 2010 versions of MOPOP demonstrates the fundamental change in the law and Patent Office practice that resulted from the advent of the promise utility doctrine.

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[212] Resp. CM at ¶ 98.

[213] Wilson Second Report at ¶ 19; Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 12.02.01 (January 1990) (C-53).

[214] Wilson Second Report at ¶¶ 20-21.

[215] *See* Resp. CM at ¶ 162.

[216] Wilson Second Report at ¶ 22.

[217] Wilson First Report at ¶ 46.

123. The 2009 and 2010 amendments to the MOPOP incorporated dramatically different language on the test for utility. As Mr. Wilson explains, "[t]he changes made in 2009 and 2010 contained extensive requirements for utility that did not exist when Eli Lilly applied for its olanzapine (Zyprexa) and atomoxetine (Strattera) patents."[218]

124. For example, Chapter 12 of MOPOP was revised in 2009 to include for the first time a utility requirement that an inventor had to meet every "promise" made in the patent application:

> 12.08.01 – OPERABILITY
>
> . . .Where, however, the inventors promise that their invention will provide particular advantages (e.g. will do something better or more efficiently or will be useful for a previously unrecognized purpose) it is this utility that the invention must in fact have.
>
> *Although an invention need only have one use in order to be patentable, where several uses are promised the applicant must be in a position to establish each of them*. For example, if a composition is promised to be useful as a drug, the applicant must be in a position to show that it is useful in the therapy of at least one disease. If, however, it is promised to be useful as a drug for treating many diseases, the applicant must be in a position to establish its utility . . . in treating each of the diseases.[219]

125. This new section added to Chapter 12 in 2009 stands in stark contrast to the 1990 version of MOPOP that merely required an invention to show a single utility (*i.e.*, that the invention was not "totally useless").[220] The 2009 MOPOP also

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[218] *Id.* at ¶ 48.

[219] Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 12.08.01 (December 2009) (emphasis added) (C-59); s*ee also* Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 17.03 (January 2009) (similar language on promised utility was also included in Chapter 17, the chapter pertaining to biotechnology) (C-351).

[220] Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice § 12.02.01 (January 1990) (C-54). Section 12.02.02 also noted that "an invention *may* have several uses, but it must always have at least one." *Id.* Even if an invention had multiple utilities, the application need only provide one utility to satisfy the utility test. Wilson Second Report at ¶ 20.

added a section on "Office Actions on Utility,"[221] because Office Actions rejecting applications on the basis of utility were rare prior to 2005.[222]

126. Lastly, in 2010, CIPO issued an amended Chapter 9, the chapter addressing description. These amendments included a new requirement that the factual basis for a sound prediction of utility "must be included in the description."[223] While this provision made clear that evidence for utility must be included in the patent application at the time of filing, the 2010 MOPOP also provided that "evidence of inutility can be provided at any time."[224]

### 2. Amendments to MOPOP Were in Response to New Jurisprudence.

127. Canada does not and cannot dispute these post-2005 changes to the MOPOP, so instead it tries to rewrite history to suit its narrative. Canada argues that even though the text of MOPOP changed, those changes reflected "longstanding practice" within CIPO, rather than an update to reflect a change in the law.

128. Unfortunately for Canada, there is no evidence that, prior to 2005, CIPO applied a more onerous utility test than the simple one articulated in the 1990 MOPOP. Canada fails to point to any documentation that would support this alleged long-standing practice.[225]

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[221] Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 12.09. (December 2009) (C-59).

[222] *See* Wilson First Report at ¶ 30.

[223] Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 9.04.01a (December 2010) (C-60); *see also id.* at § 9.04.01b ("Here again, the description must provide whatever explanation is necessary to supplement the common general knowledge of the person skilled in the art so as to permit them, in view of the factual basis provided, to soundly predict that the invention will have the utility proposed.").

[224] Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 12.09. (December 2009) (C-59).

[225] Wilson Second Report at ¶¶ 17, 30 (stating that there was no "long standing practice" of the Patent Office in the 1990s applying a more onerous utility test than the simple test set forth in the (continued…)

129. Second, contemporaneous CIPO documents produced by Canada in this proceeding demonstrate that the 2009 and 2010 amendments to MOPOP reflected a significant and fundamental change in Patent Office practice.

130. Several documents note, for example, that the 2009 amendments to MOPOP's section on utility and sound prediction were drafted in response to recent court decisions issued well after Lilly's patents were granted. For example, a document titled "MOPOP Update Priority List" dated 9 December, 2005, describes the updates to utility planned for Chapter 17 (and Chapter 12) as "sound prediction (interpretation and guidelines *resulting from recent decisions*)."[226]

131. As part of the amendment process, examiners within different fields of technology in CIPO had the opportunity to comment on draft amendments. With respect to the changes to the utility sections in Chapters 9, 12, and 17, examiners expressed significant confusion regarding the new "promised utility" test. This confusion demonstrates that the amendments were a significant departure from past practice.

132. For example, an email from January 2009 relays concerns from examiners regarding the utility section on Chapter 17 of MOPOP:

> There were a number of questions about applying subsection 27(3) when an assertion is made in the description that lacks utility (17.03). Questions varied from "Is this based on a court case?" to "Should such a case be brought to a Final Action if they do not amend?" "How will the applicant be able to amend the description without adding new matter?" (i.e. would changing compound X is useful" to "compound X may be useful" be considered new matter"). There was also some concern as to why this part of the PA [Patent Act] is being used for this objection."[227]

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MOPOP and that he is unaware of any documents that would have instructed examiners to apply such a test).

[226] "MOPOP Update Priority List" (9 September 2005), [Canada Doc. No. 1119, at 067254] (emphasis added) (C-355).

[227] Email "RE: Chapter 17 questions" (16 January 2009), [Canada Doc. No. 794, at 063529] (C-356).

In another commentary on Chapter 17 of MOPOP from July 2007, one Patent Office examiner noted confusion with the new utility standard, asking "[w]ould a clear statement of utility [be] enough? e.g. I tested it (medication x) and it cured my skin cancer" and "Does factual support need to be in their examples?"[228] The examiner also noted that the new section was in part a response to *Pfizer v. Apotex* and stated: "*Pfizer v. Apotex*, this case is really new. Has the office completed their study of this case?"[229]

133. Similarly, in comments on amendments to MOPOP Chapter 12 from January 2008, one examiner wrote: "the draft of Chapter 12 contains information *that is not our current examination practice*."[230] Another examiner asked: "Chapter 12 underwent a major revision, which included discussion and consultation, resulting in the version of February 2005. Why, three years later is the entire chapter being revised again?"[231] The reason for the changes was, of course, the emergence of the promise utility doctrine starting in 2005.

134. In another comment on the amendments to Chapter 12 of MOPOP, a Patent Office examiner noted that section 12.8.01 "*does not appear to be in line with our practice*."[232] That examiner explained:

> The expression 'is promised to be useful as a drug,' in this passage seems unclear. Specifically it is unclear if the expression related to the application in general or to a claim simply defining the use of the composition as a drug. If the applicant shows that the composition

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[228] "Chapter 17 Working draft (July 2007) comments from C9," Comments from Daniel Begin, [Canada Doc. No. 1065, at 066681] (C-357). Another examiner was driven to self-doubt, writing, "[t]he inconsistency may lie with me and what I interpret from this chapter and what I believe may be current practice . . . maybe either I or the chapter may need some clarification." *See* "Comments on MOPOP Chapter 12 Compiled from Section C5 Biotech," Comments from Tony Candeliere, (17 March 2008) [Canada Doc. No. 910, at 065397] (C-358).

[229] *Id.* *Pfizer v. Apotex*, 2007 FC 26 was a case decided only in 2007.

[230] "Comments on MOPOP Chapter 12 Compiled from Section C5 Biotech," Comments from Rob Rymerson, (17 March 2008) [Canada Doc. No. 910, at 065383] (emphasis added) (C-358).

[231] "Comments on MOPOP Chapter 12 Compiled from Section C5 Biotech," Comments of Linda Brewer, (17 March 2008) [Canada Doc. No. 910, at 065407] (C-358).

[232] "Comments on Chapter 12" (13 May 2008) [Canada Doc. No. 891, at 065258] (C-360).

> is useful in the therapy of one disease (or more) he or she cannot assume that the composition can be used as a drug, thus in the treatment of *any* disease. The claim must be restricted to the diseases for which factual support (or proper sound prediction) is provided in the application.[233]

The lack of clarity expressed by the examiner over whether the "promised" utility must be specifically in the claim or merely in the application shows that this utility test was a new concept for patent examiners at CIPO.

135. Examiners also recognized the adverse impact that the proposed changes would have on innovators in the pharmaceutical and biotechnology fields. For example, in response to language in Chapter 12 that would require applicants to establish a drug's utility in treating diseases, an examiner objected that requiring actual proof would be not only "unrealistic" but "potentially unethical":

> In biotechnology drugs are rarely tested before a patent application is applied for. That aspect is usually left for other regulatory departments. In biotech the practice has always been that the applicant must be able to show some result indicating that the potential drug will be useful (ie. effects on cell cultures or animal models or comparison to other similar molecules) but actual proof of the ultimate utility is an unrealistic request, and potentially unethical. As written it would appear that most biotech applications direct to potential drugs, vaccines, etc., would have to be rejected as lacking utility based on the statements in these paragraphs. This wording should be modified or avoided.[234]

136. The prohibition against post filing evidence of utility was also new to examiners. One examiner questioned a statement in the draft section 12.08.04c regarding this aspect of the promise utility doctrine stating: "is this statement completely accurate? *Can they provide evidence after the fact of data obtained before the*

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[233] *Id*. at 065261 (emphasis in original).

[234] "MOPOP Chapter 12 feedback C14 - part 2," Comments of Nancy Trus, (17 March 2008) [Canada Doc. No. 921 at 065459] (C-361).

*filing date (supported by affidavit) in support of their claims?"*[235] Another examiner noted the apparent contradiction between the requirement that an applicant must provide evidence of utility as of the filing date and the statement in MOPOP that evidence of inutility can be provided at any time.[236] Finally, an examiner observed that the inclusion of "at the time of the filing date" for the disclosure requirement should be included "in order to reflect the latest ruling in *Apotex* the [sic] judgment."[237] Together, these statements confirm that the prohibition on post-filing evidence was a fundamental change from past practice and was a response to recent court decisions issued after 2002.

137. In an even more explicit example, one examiner noted that the MOPOP requirement providing that "the applicant must be in a position to establish the utility of the invention no later than their filing date" appeared "to directly contradict a [1999] Commissioner's decision (albeit not a widely known one yet) #1238 in the biotech field."[238] As the examiner explained, in that case, an applicant showed that a product had improved utility in affidavits filed "many years post filing."[239] The examiner rejected the patent based on the application as filed, but the Board held that the Applicant's submissions at later dates should not be disregarded. The Patent Appeal Board explained: "The Applicant is after all attempting to respond to the Examiner's rejection of the claims as being directed

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[235] "Chapter 12 Comments of N. Ohan," (14 August 2009), [Canada Doc. No. 717, at 062931] (emphasis added) (C-362).

[236] "MOPOP Chapter 12 feedback C14 - part 2," Comments of Nancy Trus (17 March 2008) [Canada Doc. No. 921, at 065460] (describing the bar on post-filing evidence as "a matter of the rules applying to only one side. The applicant cannot prove utility post filing but the office can prove inutility post filing. While this may in fact be office practice, *I'm not sure putting it down in writing is wise*.") (emphasis added) (C-361); "Comments on MOPOP Chapter 12 Compiled from Section C5 Biotech," Comments of Mimi Yurack, [Canada Doc. No. 910, at 065387] (noting that the rule against post-filing evidence and the rule permitting evidence of inutility to be provided at any time "seem contradictory") (C-358).

[237] "Comments on Chapter 12," (13 May 2008) [Canada Doc. No. 891, at 065264] (C-360).

[238] *Id*. at 065268 (citing Commissioner's Decisions 1238 (5 May 1999)).

[239] *Id*.

to old and known products."[240] The Board therefore allowed the patent. The examiner concluded: "It would therefore seem that post filing proof of utility is in fact acceptable."[241]

138. Contemporaneous comments on the MOPOP amendments from external stakeholders also highlight the dramatic shift in the law and Patent Office practice. As part of the amendment process, CIPO circulated its proposed amendments to certain intellectual property organizations for review. In its submission on January, 22, 2008, Intellectual Property Institute of Canada (IPIC) expressed "substantial concern" over the amendment to Chapter 17 that read: "If, however, it is promised to be useful as a drug for treating many diseases, its utility in treating all the diseases must be established." Accepting that CIPO must draft the MOPOP in a manner consistent with decisions promulgated by the Federal Courts, IPIC wrote:

> IPIC believes that it is a well-established if not trite principle of patent law that a novel and inventive composition of matter need only have one utility in order to be patentable as a composition of matter *per se*. If it is CIPO's position that if a patent application describes a novel and inventive compound, fully establishes one utility (e.g. by working examples), and identifies additional utilities, these utilities must also be established in order to patent the compound, then IPIC disagrees.
>
> IPIC further believes that a claim to the compound itself is patentable if even one utility is established or soundly predicted.
>
> If CIPO takes a different view, IPIC requests that specific controlling legal authority for this proposition be cited. Alternatively, if the above passage is intended to relate to claims to uses, rather than products, this should be clarified.[242]

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[240] *Id*.

[241] *Id*.

[242] IPIC, "Proposed Amendments to Chapter 17 of the Manual of Patent Office Practice" (22 January 2008) (C-366).

These 2008 comments from IPIC demonstrate that requiring an inventor to establish multiple utilities was a significant shift from the "well-established" requirements of patent law.

139. Finally, if Canada were correct that the promise utility doctrine were a longstanding practice within the Patent Office, one would expect that CIPO, like the Canadian courts, would have been rejecting patent applications for failure to meet promises prior to 2010. But the evidence does not bear this out. Mr. Wilson notes that there were no rejections for failure to demonstrate or soundly predict a particular "promise" during his time at CIPO, and the first Commissioner's Decision dealing with the issue of promised utility and sound prediction was not handed down until 2010.[243]

140. Several of the recent Commissioner's Decisions illustrate the shift in the law. In Commissioner's Decisions 1303 and 1310, for example, utility was not raised as a concern in the late 1980s and early 1990s when the applications were filed and the initial Office Actions were issued. But utility objections were raised for the first time in Office Actions in the mid-2000s, after the courts developed the promise utility doctrine.[244] As Mr. Wilson explains, because patent examiners are instructed to raise all grounds of objection in the first (and all) Office Actions to avoid piecemeal prosecution, the absence of utility objections in the early 1990s followed by the sudden appearance of utility objections in the mid-2000s demonstrates that there was an intervening change in the law with respect to utility.[245]

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[243] Wilson Second Report at ¶¶ 32-34. As acting Chair of the Patent Appeals Board, part of Mr. Wilson's duties was to review all of the rejected applications on appeal and assign them to Board Members. Mr. Wilson was therefore aware of all the different issues causing examiners to reject applications, but he did not see any rejections on the basis of the promise utility doctrine during his tenure at the Patent Office. *See id.* at ¶ 17.

[244] *Id.* at ¶¶ 34-36; *see also* Application No. 592,567 (Patent No. 1,341,621), Decision of the Commissioner of Patents no. 1303 (June 4, 2010) (C-412); Application No. 551,406 (Patent No. 1,341,624), Decision of the Commissioner of Patents no. 1310 (January 20, 2011) (C-413).

[245] Wilson Second Report at ¶ 36.

141. For example, the Final Action in application 2,248,228 issued to Bayer on February 1, 2011 demonstrates this change in the MOPOP and Patent Office practice. In the Final Action, the patent examiner explained a shift in how the rejection should be treated:

> The claims were previously considered defective from non-compliance with section 84 of the *Patent Rules*, on the basis that the lack of proper disclosure of a sound prediction implied a lack of proper support for the claims.
>
> *Following current Office practice, this objection is now presented as non-compliance with section 2 of the Patent Act (lack of utility).* Reference in this regard is made to section 17.03.04 of the Manual of Patent Office Practice, which came into force in January 2009.[246]

This Final Action also demonstrates that patent examiners rely on the MOPOP in rejecting applications and that changes in the MOPOP affect Patent Office practice.[247] The Final Action was upheld by the Patent Appeals Board in Commissioner's Decision 1340 on March 28, 2013.[248]

142. In light of the changes to the text of MOPOP and Patent Office practice, it is clear that the Canadian patent law on utility underwent a fundamental transformation after Lilly's patents were filed and granted.

### 3. MOPOP Is a Reliable Restatement of Canadian Law.

143. Ultimately, Canada does not have an answer to the plain and unequivocal changes in the language of the MOPOP. Canada thus tries to minimize the MOPOP by arguing that it is "not binding and does not have the force of law."[249] But simply because MOPOP does not have the *force of law* does

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[246] CIPO, Final Action for Application 2,248,228, at 3 (1 February 2011) (C-414).

[247] *See* Wilson Second Report at ¶ 37.

[248] Application No. 2,248,228, Decision of the Commissioner of Patents no. 1340 (28 March 2013) (C-415).

[249] Resp. CM at ¶ 74.

not mean it is not a *reliable statement of the law* governing CIPO's examination of patent applications.

144. Contrary to Canada's assertions, MOPOP is the *primary* reference tool for examiners: a comprehensive, day-to-day guide that is updated in light of new legal developments.[250] The purpose of MOPOP was to combine and digest the various sources of law — the *Patent Act*, the *Patent Rules*, and relevant patent jurisprudence — into a clear and easy-to-apply manual.[251] It is absurd to assume (as Canada apparently does) that the over 400 examiners at the Patent Office would independently consult the case law and come up with their own individual interpretations of the jurisprudence governing the utility requirement.

145. MOPOP is also an important resource for patent agents — the non-lawyer Canadian practitioners who prepare and file patent applications. Patent agent trainees review MOPOP while studying for patent agent examinations and MOPOP is used in patent agent training courses (including in examination questions).[252] Patent agents and patent examiners also consult and refer to MOPOP during the prosecution of patent applications.[253] Patent agents accordingly expect MOPOP to be an accurate reflection of the law and Patent Office practice.

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[250] Wilson Second Report at ¶¶ 13-15. The CIPO website states that "The Manual of Patent Office Practice (MOPOP) is maintained to ensure that it reflects the latest developments in the Canadian patent laws and practices." CIPO, "Manual of Patent Office Practice - MOPOP Updates," https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00758.html (C-410).

[251] Wilson Second Report at ¶ 14.

[252] *See* CIPO, "How to become a registered patent agent," http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr02066.html?Open&wt_src=cipo-agent-main (describing the "Manual of Patent Office Practice" as a "reference" to be considered when studying for the patent agent exam) (C-409).

[253] *See, e.g.*, CIPO, Final Action for application 2,248,228 (February 1, 2011) (In this Final Action against Bayer, the examiner explicitly relied on the amended section of MOPOP for the new utility rejection, stating: "Reference in this regard is made to section 17.03.04 of the Manual of Patent Office Practice, which came into force in January 2009") (C-414).

146. Finally, Canada argues that the MOPOP was unreliable as a statement of Canadian patent law because updates required significant time and resources and thus were infrequent. First, the fact that substantial effort is taken to ensure that the MOPOP accurately incorporates changes in the law undermines Canada's argument that the MOPOP is not an authoritative statement of the law.[254] Second, even if amendments took some time, they plainly would not have taken *over 10 years* — which is what would be necessary for Canada's argument to work.[255] If, as Canada suggests, the promise utility doctrine existed before Lilly filed its patent applications by the mid-1990s, one would expect the MOPOP to have incorporated the concept of "promised utility" prior to 2009.

### C. No Analogue for Canada's Promise Utility Doctrine Can Be Found in U.S. or Mexican Law.

147. These fundamental changes in Canada's utility standard over the past decade have made Canada an outlier within North America. Canada does not dispute that the utility and industrial applicability requirements of the United States and Mexico are strikingly different from its promise utility doctrine.[256] As detailed in Lilly's Memorial, the United States and Mexico require nothing more than the capacity for the invention to be put to a single use, such that patents are very rarely denied or revoked on that basis.[257] Rather than dispute this clear contrast, Canada attempts to distract attention from utility, for example by contending that the United States and Mexico pursue similar policy objectives as Canada, but do so through patentability requirements other than utility.[258] Yet

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[254] Canada produced over 7,000 pages of documents in this arbitration related to Patent Office discussion of MOPOP updates. It is difficult to imagine the Patent Office spending so much time deliberating on MOPOP changes if MOPOP was not meant to be a reference guide on Canadian patent law.

[255] Resp. CM at ¶ 76.

[256] Canada does not assert that the U.S. utility standard or Mexican industrial applicability requirement resembles the promise utility doctrine. Rather, Canada asserts that the U.S. patent law system must "be analysed as a whole," not with respect to utility alone, and that the "Mexican patent law system addresses utility in its own distinct manner." Resp. CM at ¶¶ 172, 176.

[257] *See* Cl. Mem. at ¶¶ 145-160.

[258] *See* Resp. CM at ¶¶ 172, 178.

there is no analogue, in theory or in practice, to Canada's promise utility doctrine within the patent law systems of Canada's NAFTA partners.

### 1. United States

148. The standard for utility in the United States diverges sharply from the promise utility doctrine in Canada in multiple, fundamental respects. As Professor Robert P. Merges explains, these include the following core features of U.S. law:

> (1) the operability aspect of utility deals with the basic question of whether the invention works and whether the asserted utility is credible; (2) the articulated utility is presumed to be true; (3) U.S. law requires that an invention have only one or "a" utility; and (4) that in the United States utility is tested according to the *claimed* invention, and that a wide range of evidence is permissible to establish utility.[259]

These features of U.S. utility law, all of which Professor Holbrook concedes in his report,[260] are common ground between Lilly and Canada, and yet are plainly inconsistent with Canada's promise utility doctrine.

149. Canada and Professor Holbrook misstate other aspects of the U.S. standard, for example by contending that utility in the United States "presents a substantial hurdle for patentees in the chemical and biological arts . . . given the inherent unpredictability of chemical compounds."[261] In fact, the utility hurdle for pharmaceutical inventions is no different from other technical fields — and is low. The U.S. Patent Office's Manual of Patent Examining Procedure ("MPEP") explicitly instructs examiners to apply the *same* utility standard to pharmaceutical inventions as other inventions: "Inventions asserted to have utility in the

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[259] Second Expert Report of Robert P. Merges ("Merges Second Report") at ¶ 2 (emphasis in original) (citations and quotation marks omitted).

[260] *Id.* at nn. 1-5 (listing citations to Holbrook).

[261] Resp. CM at ¶ 171; *see also* Holbrook Report at ¶ 18 (arguing that utility "remains a significant barrier to patentability in the pharmaceutical context").

treatment of human or animal disorders are subject to the same legal requirements of utility as inventions in any other field of technology."[262] The use of a chemical structure may be less apparent than that of a mechanical invention, but a compound still needs only a single use. As Professor Merges explains:

> Utility presents the same bar for machines, electronic circuits, software inventions, and chemical/pharmaceutical inventions. And it is a low bar: the inventor must show a use, period. The fact that a use is in inherent in many inventions (such as machines) does not mean that the use requirement is higher for other inventions (such as pharmaceuticals). In the pharmaceutical field, utility is more apparent as a requirement because it is not met inherently in assembling a chemical structure. But visibility is not the same thing as severity. A more noticeable bar may be no higher than a less noticeable one.[263]

150. As another example, Professor Holbrook misstates the evidentiary standard in the United States by asserting that U.S. law requires that the applicant "has demonstrated the efficacy of the drug."[264] This assertion, as Professor Merges explains, "is fundamentally in opposition to a basic precept of U.S. patent law":

> [U]tility is presumed under U.S. law upon mere *initiation* of a clinical trial. "Safety and efficacy" are the classic requirements for drug approval by the FDA, and it is extremely settled law in the United States that patentable utility does *not* equal FDA approval. Even more generally, efficacy suggests effectiveness or a degree of success beyond a mere aim or purpose, which is the core of the utility test in the United States.[265]

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[262] United States Patent and Trademark Office, Manual of Patent Examination Procedure, § 2107.01 (March 2014) (C-72); *see also* Second Expert Report of Stephen G. Kunin ("Kunin Second Report") at ¶ 3.

[263] Merges Second Report at ¶ 13.

[264] Holbrook Report at ¶ 17.

[265] Merges Second Report at ¶ 10.

151. U.S. law does not require a patent applicant to demonstrate safety or efficacy in satisfying the utility requirement. As explained in Lilly's Memorial and by Mr. Steve Kunin, former Deputy Commissioner of the U.S. Patent and Trademark Office, the MPEP instructs examiners *not* to require applicants to provide human clinical trials and states that the mere *initiation* of a clinical study creates a strong presumption of utility for a pharmaceutical invention.[266]

152. Professor Holbrook also asserts that "[t]he operability aspect of utility deals with the basic question of whether the invention has been proven to work."[267] But to satisfy the utility standard, inventions in the United States need not be "proven to work." As Professor Merges explains, "[u]nder U.S. utility doctrine, credible evidence of operability is required. In many cases the mere assertion of a utility that is plausible will be enough to satisfy this standard. This is obviously a far cry from a requirement that an invention be 'proven to work.' Assertions and presumptions are not the same as proof."[268]

153. As explained in the MPEP, the utility standard only requires "one credible *assertion* of specific and substantial utility," and "additional statements of utility, even if not 'credible,' do not render the claimed invention lacking in utility."[269] In the context of pharmaceuticals, the MPEP only requires a "reasonable correlation" between pharmacological or biological activity of a compound and the asserted utility, which does not have to be proved "as a matter

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[266] Cl. Mem. at ¶ 153; First Expert Report of Stephen G. Kunin ("Kunin First Report") at ¶ 39; Kunin Second Report at ¶ 12; United States Patent and Trademark Office, Manual of Patent Examination Procedure, § 2107.03; 2107.03(IV) (March 2014) ("Office personnel should not impose on applicants the unnecessary burden of providing evidence from human clinical trials. There is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders.") (C-72).

[267] Holbrook Report at ¶ 21; *see also id.* at ¶ 22 (asserting that an "inventor cannot obtain a patent until she knows the invention will actually work").

[268] Merges Second Report at ¶ 15.

[269] United States Patent and Trademark Office, Manual of Patent Examination Procedure, § 2107.01(II) (March 2014) (emphasis added) (C-72).

of statistical certainty," nor does an inventor "have to provide actual evidence of success in treating humans where such a utility is asserted."[270]

154. With regard to post-filing evidence, Professor Holbrook contends that "evidence of an invention's utility that is created after the filing date generally should not be considered."[271] Yet Professor Holbrook also affirmatively concedes that U.S. courts *allow* post-filing evidence "'to substantiate any doubts as to the asserted utility [when] this pertains to the accuracy of a statement already in the specification.'"[272] As a result, according to Professor Merges, "post-filing evidence of utility is quite routine in U.S. patent law," accepted to establish utility as of the filing date.[273]

155. U.S. courts have specifically and repeatedly *rejected* standards that resemble the promise utility doctrine.[274] A hallmark of the promise utility doctrine is that Canadian courts require convincing evidence in support of statements made in, or implied from, the patent specification regarding the performance characteristics of an invention. As Professor Merges explains, "[t]his exact approach has consistently been rejected by U.S. courts."[275] For example, in *Raytheon Co. v. Roper Corp.*, the U.S. Court of Appeals for the Federal Circuit made clear that it is legal error to find a patent invalid for lack of utility merely because

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[270] United States Patent and Trademark Office, Manual of Patent Examination Procedure, § 2107.03(I) (March 2014) (C-72); *see also* Kunin Second Report at ¶¶ 11-12 (explaining that many U.S. patent applications do not contain human clinical data and that an invention need only show a reasonable correlation between the pharmaceutical activity and the asserted utility).

[271] Holbrook Report at ¶ 34.

[272] Holbrook Report at ¶ 34 (quoting *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995)).

[273] Merges Second Report at ¶ 24; *see also* Kunin Second Report at ¶¶ 8-9 (explaining that patent applicants before the USPTO are permitted to supplement applications with post-filing evidence of utility to confirm the fact that an invention had utility at the time the patent application was filed). *See also* United States Patent and Trademark Office, Manual of Patent Examination Procedure, § 2107.02 (March 2014) (C-72).

[274] *See* Merges Second Report at ¶¶ 34-39 (summarizing multiple U.S. cases that reject approaches resembling the promise utility doctrine).

[275] Merges Second Report at ¶ 33.

the invention "failed to accomplish all objectives stated in the patent."[276] According to the Federal Circuit, "[w]hen a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown."[277] Professor Merges thus concludes: "Contrary to Professor Holbrook's statements, the U.S. equivalent of the promise utility doctrine not only does not exist; it has been explicitly rejected."[278]

156. In the face of indisputable contrasts between the two countries regarding utility, Canada seeks to blur the line between utility and other patentability requirements. In particular, Canada argues that there is "overlap" between utility and the distinct U.S. doctrines of enablement and written description, and that these distinct doctrines play a "similar role [in the United States] . . . to the law of utility in Canada."[279] Professor Holbrook even asserts that "the enablement doctrine in the United States operates in a manner comparable to the 'utility' requirements in Canadian patent law."[280] This claim of comparability is incorrect, in terms of both doctrine and outcomes.

157. With regard to doctrine, utility is a distinct requirement from enablement and written description under U.S. law. As Professor Merges explains, these U.S. doctrines use different tools in different ways:

> Both [utility and enablement in U.S. law] can serve to prevent an inventor from staking speculative claims – that is, from claiming subject matter that has not been effectively explored at the time of patent filing. In this regard, both utility and enablement can push an inventor to do more, and therefore teach more, prior to gaining the legal right to a broad claim over an invention. But the *way* the doctrines implement this common policy is quite distinct. Utility requires that the claimed invention be useful for some real-world

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[276] *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958-59 (Fed. Cir. 1983) (C-367).

[277] *Id.*

[278] Merges Second Report at ¶ 33.

[279] Resp. CM at ¶ 172.

[280] Holbrook Report at ¶ 155.

> purpose. Enablement and written description require that the inventor teach sufficient information to justify the full scope of the claims sought. Utility prevents claiming a structure before it has a credible use. Enablement and written description prevent claiming beyond what the inventor has actually achieved to date. The two sets of rules are aimed at curbing different types of speculation. Utility prevents claiming an invention before its use it established; it prevents inventors from stockpiling structures whose end purpose is as yet unknown. Enablement and written description prevent an inventor from overclaiming the bounds of an invention; they prevent inventors from in effect stockpiling variants and extensions of a given invention.
>
> So while the U.S. doctrines regarding utility, enablement, and written description serve somewhat similar goals, they do so very differently. Thus the overlap between them is far from complete, and they are not at all interchangeable. Nor do *any* of these U.S. requirements resemble Canada's promise utility doctrine.[281]

158. The divergence between these U.S. requirements and the promise utility doctrine in Canada is striking. In the United States, for example, the evaluation of patentability requirements focuses on the invention as *claimed*.[282] There is nothing in U.S. utility or enablement law that bears any likeness to Canada's far-ranging inquiries into the degree of "promised" utility, its imposing evidentiary burdens with respect to proof of utility, or its requirement that the factual basis for predicted utility be included in the patent application itself.

159. This difference is clear not only in terms of doctrine, but also in terms of litigation outcomes. The Zyprexa patent is a telling example: it was not invalidated on enablement, written description, or sufficient disclosure grounds in

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[281] Merges Second Report at ¶¶ 42-43 (emphases in original).

[282] *See* Kunin Second Report at ¶ 7 (noting that the focus of the utility requirement is on the claimed invention, not on unclaimed assertions of utility that may appear in the written description). *See also* United States Patent and Trademark Office, Manual of Patent Examination Procedure, § 2107.02(I) (March 2014) (title of the section is "The Claimed Invention is the Focus of the Utility Requirement"); *id* ("Statements made by the applicant in the specification . . . cannot, standing alone, be the basis for a lack of utility rejection.") (C-72). The MPEP further directs patent examiners "not [to] require an applicant to strike nonessential statements relating to utility from a patent disclosure, regardless of the technical accuracy of the statement or assertion it presents." *Id.*

either the United States or Canada, and it satisfied the traditional U.S. utility requirement. It failed *only* the elevated standard set by promise utility doctrine in Canada. As a result, Professor Merges concludes, "it seems clear that Canada's doctrine does not implement a policy concern that is coextensive with accepted enablement / written description / sufficient disclosure rules; nor does it embody the policy behind the traditional utility doctrine as still employed in the United States."[283]

160. Since Canada cannot credibly maintain that its utility standard did not change over the past decade, Canada asserts that the U.S. patent system has also evolved since NAFTA entered into force. In particular, Canada claims that the U.S. patentability requirements for utility, enablement, written description, and non-obviousness have all been raised at different points in time.[284] As Professor Merges explains, however, this development in U.S. law simply "represents normal variation around the core content of traditional patentability requirements," with only modest effects on patent validity.[285] This slight variation in U.S. law is nothing like the radical shift in Canada, where inutility rates for challenged pharmaceutical patents increased from 0 percent to 40 percent after the promise utility doctrine came into effect.[286] Professor Merges thus concludes:

> Through the mechanism of the promise utility doctrine, Canadian law has evolved what amounts to an additional, and very rigorous, test of patentability that invalidates a large portion of pharmaceutical patents. This is not normal legal variation. It is a striking legal innovation. It renders Canadian law highly divergent from the worldwide norm. The fact that Eli Lilly's patents survived utility analysis in every jurisdiction *except* Canada illustrates the extent to which Canadian law has become an extreme outlier.[287]

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[283] Merges Second Report at ¶ 47.

[284] Resp. CM at ¶ 173; *see also* Holbrook Report at Section IV.

[285] Merges Second Report at ¶ 51.

[286] *See* Cl. Mem. at ¶ 222.

[287] Merges Second Report at ¶ 52 (emphasis in original).

### 2. Mexico

161. As for Mexico, Canada does not attempt to argue that the industrial applicability standard or other patentability requirements in Mexican law resemble the promise utility doctrine in Canada, or have comparable effects.[288] It is thus undisputed that Mexico's industrial applicability standard, both as enacted in the 1990s and as amended in 2010, is distinct from the promise utility doctrine in all relevant respects. As explained in Lilly's Memorial, Mexican law requires only that inventions be "susceptible of industrial application," a term that 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."[289]

162. Finding nothing like the promise doctrine in Mexico, Canada mischaracterizes Lilly's arguments in order to attack two straw men. First, Canada argues that as Mexico joined NAFTA, "Mexican patent law did not undergo substantive harmonization with patent laws of Canada or the United States," and that its industrial applicability standard is distinct from utility.[290] But as discussed above (in Part I.D), Lilly does not contend that NAFTA "harmonized" patent law in North America, or that the traditional Mexican, Canadian, and U.S. standards for utility or industrial applicability are identical in all respects. Second, Canada argues that Mexican patent law has not remained fixed in its approach to industrial applicability,[291] but Lilly has not contended that NAFTA froze substantive patent law in Mexico or elsewhere.

163. What Lilly does contend is (i) that Mexico's industrial applicability standard, by design, is consistent with the floor of substantive protection established by NAFTA Chapter 17, and (ii) that while the definition of "industrial

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[288] *See* Resp. CM at ¶¶ 175-180.

[289] *See* Cl. Mem. at ¶¶ 155–156 (quoting Mexico's Industrial Property Law, Arts. 16 & 12(IV) (emphasis added)).

[290] Resp. CM at ¶ 177.

[291] Resp. CM at ¶¶ 175, 179.

application" in Mexico was slightly altered through legislative amendments in 2010, the revisions generated no substantive change in the practice of the Mexican agency that grants patents and adjudicates patent validity disputes in Mexico. Canada and Ms. Lindner have not offered any persuasive evidence to the contrary.

164. Ms. Lindner asserts that the establishment of Mexico's modern patent law through legislative reforms in 1991 and 1994, including its adoption of an industrial applicability requirement, had no connection to Mexico's international obligations under NAFTA Chapter 17.[292] But as Gilda Gonzalez, former Deputy Director General of the Mexican Institute of Industrial Property ("IMPI"), explains, and as the historical record makes abundantly clear, "Mexico implemented these reforms so it would be in compliance with the international standards subsequently mandated by NAFTA, and the legislature has since rejected further amendments to the industrial application standard that would violate those international obligations."[293]

165. With regard to the amendments in 2010, Canada flatly asserts that "[t]here is *no suggestion in any of the relevant discussions* that Mexican legislators were prevented from strengthening the Mexican application of 'industrial applicability' as a result of NAFTA Chapter Seventeen."[294] But the legislative history refutes this contention. It makes clear that Mexico's international obligations not only informed the debate; they were identified in the record as a reason not to elevate the industrial applicability standard.

166. Leading up to the 2010 amendment, a proposal was introduced in 2008 that would have changed Mexico's definition of "industrial application" from "the possibility" to "the fact" of an invention having a practical utility.[295] As Ms.

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[292] *See* Lindner Report at ¶ 15.

[293] Second Expert Report of Gilda Gonzalez ("Gonzalez Second Report") at ¶ 5.

[294] Resp. CM at ¶ 179 (emphasis added).

[295] Gonzalez Second Report at ¶ 26.

Gonzalez explains, the legislature rejected the 2008 proposal. The chief reason (among many) to reject the change, in the view of the legislature, was "because it would violate Mexico's obligations under international treaties."[296] The relevant treaties are the TRIPS Agreement and NAFTA Chapter 17; in identical language, both require Mexico to grant patents to inventions that are "*capable* of industrial application."[297] The legislative history conclusively establishes that this international obligation was understood to foreclose enactment of the proposed change:

> [M]odifying in the definition the concept of "possibility" to that of "fact" is unsuitable and contrary to what was established in the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter TRIPS), an international agreement to which Mexico is a party and that was published in the Diario Oficial de la Federación on December 30, 1994. This Agreement establishes that industrial application is a "possibility," not a "fact."
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> . . .We warn that including the term "fact" would necessarily make [industrial application] subject to proof, requiring the authority, moreover, to reproduce the invention in order to demonstrate the existence (the fact) of the mentioned industrial application.[298]

167. Ms. Lindner suggests the Mexican law requires pharmaceutical innovators to *prove* that they have satisfied the industrial applicability standard. For example, to support a claimed therapeutic use, Ms. Lindner says the inventor must provide "sufficient experimental *evidence* to support that the use of the compound has a beneficial effect on a determined condition or illness."[299] But this view is inconsistent with the governing Mexican statute, which, as noted, requires the mere possibility of practical utility, and that an invention be susceptible of

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[296] *Id.*

[297] *Id.* at ¶ 3.

[298] *See* Dictamen de las Comisiones de Comercio y Fomento Industrial, de Salud y de Estudios Legislativos, Segunda, a la Iniciativa con Proyecto de Decreto que Reforma y Adiciona Diversos Artículos de la Ley de Propiedad Industrial, at 5 (R-276).

[299] Lindner Report at ¶ 47 (emphasis added); *see also id.* at ¶¶ 45–46 (references to "evidence" of utility).

industrial application.[300] As Ms. Gonzalez emphasizes, "Mexican law has never required 'proof' or 'evidence' of industrial application, ever since the term was adopted."[301]

168. At most, as explained by Mr. Fabian Salazar, former Director of the Patent Division at IMPI, additional information may be requested during examination by IMPI, but only if industrial applicability is not self-evident from the description or nature of the invention contained in the application.[302] Requests for such information by IMPI are exceedingly rare, both before and after the 2010 amendments, which have not led to any change in IMPI's practice with respect to industrial applicability.[303] Moreover, IMPI examiners have no authority to require *proof* of industrial applicability in the application.[304] As Canada does not dispute, Mexican patent examiners can request post-filing information or documentation regarding industrial applicability,[305] and post-filing information can also be used in subsequent litigation.

169. While conceding that the Zyprexa and Strattera patents were never challenged in Mexico, Canada argues that this fact deserves little weight because "[t]he structure of the Mexican judicial system makes it difficult to challenge a patent," and "many patents that are intrinsically flawed go unchallenged."[306] But as Ms. Gonzalez explains, "[p]atent validity is routinely challenged before IMPI."[307] Indeed, when Ms. Gonzalez was head of litigation at IMPI, she saw

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[300] Gonzalez Second Report at ¶ 12; *see also* Industrial Property Law (Mexico) Art. 16, 12(IV) (C-424).

[301] Gonzalez Second Report at ¶ 30.

[302] *See* Second Expert Report of Fabian Salazar ("Salazar Second Report") at ¶¶ 20–23; *see also* Gonzalez Second Report at ¶¶ 45–47.

[303] *See* Gonzalez Second Report at ¶¶ 20–22; Salazar Second Report at ¶¶ 11–19, 22.

[304] *See* Salazar Second Report at ¶¶ 20–22; Gonzalez Second Report at ¶ 48.

[305] *See* Gonzalez Second Report at ¶ 47.

[306] Resp. CM at ¶ 180.

[307] Gonzalez Second Report at ¶ 51.

"approximately 200 contested cases involving new filings, half of which pertained to patents," and the vast majority of those involved pharmaceutical inventions.[308] Mr. Salazar also explains that Mexico's patent examination proceedings are rigorous, of high quality, and internationally recognized,[309] giving Canada no basis to assert that Mexican patents are "intrinsically flawed."[310]

170. Across this range of cases, industrial applicability is simply not a disputed issue in Mexico. As noted in her initial report, Ms. Gonzalez is still "aware of no instance in which a patent was declared invalid in a nullity proceeding, or was not granted during examination, on the basis of industrial applicability."[311] Likewise, Mr. Salazar recalls "no instance when IMPI ultimately refused to grant a patent because of the industrial applicability requirement."[312] In response, Ms. Lindner cites only two instances in which a patent examiner even raised the question of industrial application.[313] In both cases, as Ms. Gonzalez and Mr. Salazar emphasize, IMPI granted the patent.[314]

171. In an attempt to draw attention away from Mexico's industrial applicability standard, Canada suggests that "it is misleading to analyse 'industrial applicability' in isolation," because of its alleged connections to other patentability requirements, such as disclosure.[315] But as Ms. Gonzalez makes clear:

> Under Mexican law, the disclosure requirement is distinct from the industrial applicability requirement. An invention is either

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[308] *Id.* at ¶ 52.

[309] *See* Salazar Second Report at ¶¶ 7–10.

[310] Resp. CM at ¶ 180.

[311] Gonzalez Second Report at ¶ 56; *see also* Second Expert Report of Gilda Gonzalez-Carmona ("Gonzalez First Report") at ¶ 31.

[312] Salazar Second Report at ¶ 36.

[313] Lindner Report at ¶ 61.

[314] Gonzalez Second Report at ¶ 56; Salazar Second Report at ¶ 29.

[315] Resp. CM at ¶ 178.

> susceptible to industrial applicability, or it is not. Apart from that, the possible industrial applicability must be sufficiently disclosed. This can be accomplished either through a self-evident description or nature of the claimed invention, or with illustrative information.[316]

172. Relatedly, as Mr. Salazar explains, Mexican patent examiners treat each patentability requirement separately, and "never view the satisfaction of one requirement as automatically satisfying another."[317] Moreover, Mexico's straightforward industrial applicability requirement applies equally across all technical fields — and, within the pharmaceutical sector, to all patent types, irrespective of whether the invention is a "selection" or "new use" patent.[318]

### D. The Promise Utility Doctrine Is Arbitrary and Discriminatory.

#### 1. Canada Is Unable to Refute that the Promise Utility Doctrine Is Arbitrary.

173. Canada fails to refute the multiple respects in which the promise utility doctrine is arbitrary. As Lilly has shown,[319] the three core features of the promise utility doctrine — (1) the subjective promise of the patent, (2) the heightened evidentiary burdens, and (3) the additional disclosure requirement for sound prediction — do not merely add a second, elevated utility requirement, but also render that test fundamentally subjective, inconsistent, and unpredictable.

##### a) The Construction of a Patent's Promise is Driven Not by the Applicant's Pen, But by a Subjective and Unpredictable Process of Interpretation.

174. Canada suggests that the construction of a patent's promise is straightforward, and that "if the patent asserts that it will have a particular utility, the patent will be held to that assertion."[320] In Canada's view, "it is the pen of the

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[316] Gonzalez Second Report at ¶ 44; *see also* Salazar Second Report at ¶¶ 37–39.

[317] Salazar Second Report at ¶ 39.

[318] *See* Gonzalez Second Report at ¶ 49; Salazar Second Report at ¶¶ 19, 25.

[319] Cl. Mem. at ¶ 79 *et seq.*

[320] Resp. CM at ¶ 255.

patent applicant that makes the promise," and the Canadian courts "simply adjudicate whether that promise is supported by evidence at the time the patent was filed."[321] But Canada ignores that innovators made *no promises* and had *no expectation* that their application would be scrutinized for promises of utility. Nonetheless, the Canadian courts scour the entire application and find promises in the patent's disclosure, including "implied" promises.

175. Lilly's Strattera patent is a case in point. The patent claimed the use of atomoxetine to treat ADHD, but the trial court found that "[w]hat is *implicit* in the promise is that atomoxetine will work in the longer term."[322] On the basis of that implied promise of long-term effectiveness, the Canadian courts invalidated the Strattera patent — notwithstanding the fact that Strattera had been approved in Canada not only for long-term use, but also for short-term treatment of acute ADHD.[323] Having stated nothing in the patent regarding long-term effectiveness, Lilly could never have reasonably expected that it would be held to such a promise.

176. As the Strattera case exemplifies, the results of this tortuous interpretive process are arbitrary, unpredictable, and often inconsistent. Consider the following examples:

- In the Memorial, Lilly pointed to the contrast between two cases involving the glaucoma drug latanoprost.[324] Mr. Reddon explains that in parallel cases decided just five months apart, two panels of the Federal Court of Appeal, looking at the very same patent, found different promises, and their divergent interpretations of the patent led to contradictory results on the merits.[325] As in the Strattera case, one of the panels relied upon the fact that "glaucoma is a

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[321] *Id.* at ¶ 107.

[322] *See* Cl. Mem. at ¶¶ 131-133 (quoting *Novopharm v. Eli Lilly & Co.*, 2010 FC 915, ¶ 112) (emphasis added).

[323] *Id.* at ¶ 133.

[324] *Id.* at ¶ 64.

[325] *See* Reddon Report at ¶¶ 15-18. *Compare Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, at ¶¶ 5, 38, 54 (C-99) *with Pharmascience Inc. v. Pfizer Canada*, 2011 FCA 102, at ¶¶ 9, 32-36 (C-98).

chronic disease" to find an implied promise of clinical suitability for long-term or chronic use.[326]

- In yet another case, a firm that invented a treatment for Alzheimer's disease by combining two known compounds described the interaction between the compounds as "synergistic."[327] This word triggered paragraph after paragraph of judicial interpretation querying whether "additive" was instead the better term. In the end, despite a record that included positive clinical trial results, the patent was found to lack utility because the compounds were merely "additive," not "synergistic."[328]

- In a case involving the compound esamaprozole, the court considered that the description of the patent stated the "desirab[ility]" of "obtain[ing] compounds which *will* give . . . a lower degree of interindividual variation" and indicated that "[t]he present invention provides such compounds."[329] The court determined that because the patent used the word "will" (in place of "may" or "could"), the statement was a promise, not a mere goal.[330] Yet in a case involving a breast cancer drug, an almost indistinguishable statement ("it is a particular object of the present invention to provide . . . fewer side effects") was determined *not* to be a promise, only a goal.[331] Canadian courts have admitted that "[d]ifferentiating goals and promises is a question of characterization"[332] – a question, in practice, for which there are no predictable answers.

177. These are not isolated examples; they form part of a long string of cases in which the Federal Courts scour the text of a patent, at times reading between the lines, and find a fatal promise. Canada has offered no plausible explanation for this pattern of arbitrary and inconsistent results.

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[326] *See Apotex Inc. v. Pfizer Canada Inc.*, 201 FCA 236, at ¶ 7 (C-99).

[327] *Lundbeck v. Ratiopharm*, 2009 FC 1102, at ¶ 224 (C-371).

[328] *Id.* at ¶¶ 291-292 ("I do not, however, understand *ratiopharm* to dispute that treating moderate to severe Alzheimer's disease with memantine and donepezil can have an additive benefit, and thereby produce a better outcome than treatment with either memantine or donepezil on its own.").

[329] *Astrazeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638, at ¶ 113 (emphasis added) (C-48).

[330] *Id.* at ¶ 120 ("Had the patent stated that such compounds 'may' or 'could' give an improved therapeutic profile, then the argument that such statements referred merely to a goal would be more compelling.")

[331] *AstraZenena Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023, at ¶¶ 119, 139 (C-237).

[332] *AstraZeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638, at ¶ 116 (C-48).

178. Canada insists that the process of construing the promise (or promises) of a patent requires judges to apply nothing more than "settled rules of construction."[333] But, as the inconsistent pattern of rulings makes plain, there are no settled rules for construing promises of utility. Moreover, the rules to which Canada refers are principles of *claim construction*.[334] Given the fact that Canadian judges scouring an application to identify promises of utility in no way restrict or even focus their attention on the claims, Canada's attempt to invoke rules of claim construction is a striking conceptual stretch.[335] The courts' willingness to imply promises based on vague language is exacerbated further by the fact that courts look to language outside of — and not necessary for — the claimed invention.[336]

179. The inherent arbitrariness of this process is only compounded by the willingness of Canada's courts to read multiple promises into a single patent. As noted in Lilly's Memorial, the decision involving esomeprazole addressed as many as *five discrete promises* in a single patent.[337] Once multiple promises are found, it is not sufficient to satisfy just one (or even a majority). Rather, each and

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[333] Resp. CM at ¶ 255.

[334] *See* Siebrasse Second Report at ¶ 41; Reddon Report at ¶ 4.

[335] Canadian practitioners Bernstein and Bienenstock explain that the absence of any "real test, nor any standard approach that courts follow to ensure that promise is determined in a consistent and predictable manner[,] . . . stands in stark contrast to the law of claims construction, which is well-developed based on the principles set out by the Supreme Court . . . . The analysis is further complicated because, as opposed to claims construction, which focuses on the language of the claim, the analysis of promise seems — at least some of the time — to require an analysis of the entire specification (disclosure and claims) as a whole." Andrew Bernstein & Yael Bienenstock, *Unpacking the "Promise of the Patent,"* 28 CAN. I.P. REV. 245, 249 (July 2012) (C-372).

[336] *See, e.g.*, *Alcon Canada Inc. v. Cobalt Pharm. Co.*, 2014 FC 149, at ¶¶ 57-66 (finding implied promise from inventive concept and expert testimony) (C-353); *Pfizer Canada Inc. v. Pharmascience Inc.*, 2013 FC 120, at ¶¶ 164-178 (finding implied promise to treat *all* types of pain, including those mentioned in the written description and pains that "would have been reasonably have been associated" with such pains) (C-180); *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, at ¶¶ 24-29, *rev'g* 2010 FC 447 (finding implied promise for chronic treatment not based on any language in the patent application) (C-99); *AstraZeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638, ¶¶ 113-26 (finding implied promise based on ambiguous language in the written description) (C-48).

[337] *See* Cl. Mem. at ¶ 63 (discussing *Astrazeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638, at ¶¶ 214-218).

every promise of utility must be separately supported by demonstration or sound prediction, or else the entire patent is subject to a finding of invalidity.[338]

180. There are many more examples of inconsistency, subjectivity, and outright confusion.[339] As two Canadian patent law practitioners explained in a 2012 article, the "'promise of the patent' remains an esoteric concept," and "the case law lacks a coherent set of principles explaining how a court (or for that matter, the patent office during the examination process) should discern the promise. There is no real test, nor any standard approach that courts follow to ensure that promise is determined in a consistent and predictable manner."[340]

### b) The Heightened Evidentiary Burden Makes It Impossible to Predict the Quantum and Quality of Scientific Data Necessary to Support a Patent's Promises.

181. Canada makes much of the fact that scientific evidence in a promise utility case is "often" weighed and analyzed "with the assistance of expert

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[338] *Astrazeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638, at ¶¶ 214-218 (noting that the court found three promises of utility to be satisfied, but invalidated the entire patent for lack of utility with respect to two other promises) (C-48); *Sanofi-Aventis Canada Inc. v. Apotex Inc.(& Novopharm)*, 2009 FC 676, *aff'd* 2011 FCA 300, at ¶¶ 132-33, 212, 230 (finding patent invalid for failure to meet "dual promise" that all compounds would have utility as both ACE inhibitors and antihypertensives) (C-248); *Alcon Canada Inc. v. Cobalt Pharmaceuticals Co.*, 2014 FC 149, at ¶¶ 185-216 (finding patent invalid because it did not soundly predict additional promise regarding the solution's enhanced physical stability) (C-353).

[339] *Compare Ratiopharm Inc. v. Pfizer Limited*, 2009 FC 711, at ¶¶ 112, 183 (Justice Hughes invalidating amlodipine besylate patent for failing to meet the disclosure's promise of providing a "unique," "unexpected," and "outstandingly suitable" formulation) (C-374), *with Pfizer Canada v. Pharmascience,* 2008 FC 500, at ¶¶ 98-116 (Justice Hughes, one year earlier, upholding the very same patent with no emphasis on adjectives in the disclosure and concluding that the generic "failed to show on the data presented in the patent, or even beyond the patent, that the invention disclosed in the patent lacks utility") (C-373); *see also, e.g.*, *Pfizer Canada Inc. v. Ratiopharm Inc.*, 2010 FC 612, at ¶¶ 69, 112-113 (invalidating Pfizer's sildenafil compound, which claimed a use "for treating or preventing pulmonary hypertension," for failing to soundly predict such treatment in patients with *all* types of pulmonary hypertension, including COPD and CHF) (C-345).

[340] Andrew Bernstein & Yael Bienenstock, *Unpacking the "Promise of the Patent,"* 28 CAN. I.P. REV. 245, 249 (July 2012) (C-372); *see* Notice of Application for Leave to Appeal of Apotex Inc. et al, *Apotex Inc. v. Sanofi-Aventis*, S.C.C. File No. 35562, at ¶ 14 (September 30, 2013) (noting "contradictory approaches" taken by courts) (C-375).

testimony."[341] But at the end of the day, Canada cannot and does not contest that the evidentiary threshold to be cleared in any given case is a function of the construed promise. In other words, a broadly construed promise (or promises) can raise the evidentiary bar and result in invalidation despite strong scientific support for the invention.[342]

182. To make matters worse, the requirements concerning the quantum and type of evidence required to support a promise vary widely, even where promises are comparable. For example, in two cases concerning the same Sanofi-Aventis patent on ramipril, two judges arrived at similar conclusions about the patent's promise but reached inconsistent utility rulings, applying disparate evidentiary standards. In the first case, the court read the patent to promise "that the compounds claimed by the patent would have utility as both ACE inhibitors and anti-hypertensive agents," and determined that "as long as there would be any ACE inhibition or activity, then the promise of the patent is fulfilled."[343] Relying on expert evidence about the state of knowledge in the field of medical chemistry at the time, the court concluded that there was a sound basis for predicting ACE inhibition by the patent's compounds.[344] In the next ramipril case, the court similarly construed the patent as promising that "the compounds will

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[341] Resp. CM at ¶ 258.

[342] *See, e.g.*, *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, at ¶¶ 39-40, 50, 53 (where the court construed a heightened promise of chronic treatment, the patent's disclosed positive studies on animals and humans were deemed insufficient evidence for both demonstrated utility and sound prediction) (C-99); *Lundbeck Canada Inc. v. Ratiopharm Inc.*, 2009 FC 1102 (acknowledging that the inventor established some utility through positive clinical trials, but holding the patent invalid because the data did not support the promised utility ascribed to it by the court) (C-371); *Eli Lilly Canada Inc. v. Novopharm Limited,* 2011 FC 1288, *aff'd* 2012 FCA 232, at ¶¶ 209, 259 (acknowledging that olanzapine had established utility with some antispychotic properties, but invalidated the patent because it had not demonstrated that the drug was "markedly superior") (C-146); *Eli Lilly v. Mylan*, 2015 FC 125, at ¶¶ 90, 144, 148, 172 (acknowledging in separate obviousness analysis that the claimed dosage form had a reduced side effect profile, but invalidating patent for failing to meet particular promised utility) (C-376).

[343] *Sanofi-Aventis Inc. et al. v. Laboratoire Riva Inc. et al.*, 2007 FC 532, at ¶¶ 44-45 (C-377).

[344] *Id.* at ¶ 59.

have utility as both ACE inhibitors and hypertensives."[345] But this time around, the trial judge found that the patent failed to soundly predict its utility since, in his view, the evidence did not show that *all* of the compounds in the class possessed the promised characteristics.[346]

183. Judges have even applied divergent evidentiary standards within individual cases. For instance, in the *Nexium* decision, the court applied a different evidentiary standard to the numerous promises it found in the patent. With respect to one promise — the compound's use as a proton pump inhibitor and antiulcer agent — the court was satisfied that the promise was met despite the absence of any studies demonstrating this use.[347] With respect to the second promise, however, the court was not persuaded that evidence from two key studies — a human liver microsomal study and human blood plasma re-analyses — as well as numerous rat studies was sufficient to soundly predict the promise of an improved therapeutic profile.[348] As this case illustrates, Canadian courts exercise broad discretion to raise and lower the evidentiary bar for any given promise, leaving patentees in the dark as to what evidence a particular judge may require.

### c) Canadian Courts Apply Two Irreconcilable Disclosure Requirements Under the Promise Doctrine.

184. As Lilly explained in its Memorial,[349] Canadian courts consider evidence outside the patent application to determine whether utility is demonstrated. But they refuse to consider such evidence in determining whether

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[345] *Sanofi-Aventis Canada Inc. v. Apotex Inc.; Sanofi-Aventis Canada Inc. v. Novopharm*, 2009 FC 676, at ¶ 132 (C-248).

[346] *Id.* at ¶ 212.

[347] *AstraZeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638, at ¶ 165 (C-48).

[348] *Id.* at ¶¶ 193-195.

[349] Cl. Mem. at ¶ 75.

utility is soundly predicted.[350] There is no principled basis for this distinction.[351] Canada's *Patent Act* has a single utility requirement, and the concept of sound prediction merely recognizes that an invention's utility need not be demonstrated at the time of filing.

185. Canada suggests that the disclosure requirement associated with sound prediction is intended to ensure that "enough information [is] disclosed so that the skilled reader can recognize that prediction as sound."[352] Canada suggests that this allows the skilled reader to separate a justified claim from mere speculation.[353]

186. But in fact, the disclosure requirement does nothing of the sort.[354] As noted, there is no requirement to disclose demonstrated utility on the face of a

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[350] *Id*; *see also Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, ¶ 70 ("[I]t is beyond debate in Canada that where a patentee asserts that the utility of its invention has been demonstrated, it need not assert its supporting evidence in the patent. In a case involving a claimed sound prediction of utility, it is equally beyond debate that an additional disclosure obligation arises [which] 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.") (emphasis in original) (C-160).

[351] In addition to being unprincipled, Canada's heightened disclosure rule for sound prediction is unfair. Evidence not disclosed in the patent may be used by generic companies to attack inventiveness, but the same evidence may not be relied upon by innovative companies in support of soundly predicted utility. In this respect, the rule resembles Canada's selective bar on post-filing evidence. *See* Cl. Mem. at ¶ 268.

[352] Resp. CM at ¶ 259.

[353] *Id.*

[354] Canada's rationale for the heightened disclosure requirement also fundamentally mischaracterizes the purpose of disclosure in a patent, which simply obligates the patentee to "describe the invention and its operation or use as contemplated by the inventor." *Patent Act* (Canada), R.S.C., 1985, c. P-4, at § 27(3)(a) (C-50). As Professor Siebrasse has written, "the *quid pro quo* for the patent monopoly is the disclosure of an invention which is in fact beneficial in the sense of being new, useful and non-obvious, and which is sufficiently disclosed that the public may have its full benefit at the end of the term. So long as it is in fact useful, and the public may put it to that use, the public will have the benefit of the invention, even if the patentee does not explain exactly why it is useful. Suppose, for example, that an inventor discloses in the patent the new and nonobvious fact that compound X is a cure for cancer. That disclosure itself is the information that is valuable to the public and which provides the *quid pro quo* for the monopoly." Norman Siebrasse, *Must the Factual Basis for Sound Prediction be Disclosed in the Patent?*, 28(1) CAN. I.P. REV. 39, 69 (2012) (C-206); *see* Siebrasse Second Report at ¶¶ 45, 78-79. This view is also supported by the Supreme Court's analysis in *AZT*, in which the Court stated that "[t]he patent monopoly (continued…)

patent. Accordingly, a patent that does not disclose a factual basis for sound prediction is open to two equally plausible interpretations: (i) that no basis for sound prediction is disclosed because the claims reflect mere speculation, or (ii) that no basis for sound prediction is disclosed because the promise has been conclusively demonstrated through evidence that the inventor need not disclose. There is no reliable way for a "skilled reader" to determine which scenario applies.[355] Plainly, Canada's justification is mere pretext.

187. Canada next appears to suggest that the different disclosure requirements for demonstration and sound prediction are justified by the simple fact that demonstrated and soundly-predicted utility are different.[356] This reasoning is plainly circular.

188. Canada's purported justification obscures that when many patent holders (including Lilly) drafted their applications, they had absolutely no expectation that they would ever be limited to evidence of utility in the patent application. Indeed, the Supreme Court of Canada in *Consolboard* had expressly rejected burdensome disclosure rules for utility.[357] With regard to Strattera, moreover, Lilly's expectations regarding disclosure of evidence of utility were legitimate for an additional reason: the contents of the Strattera application met the requirements of the Patent Cooperation Treaty, which Canada ratified in 1989.[358]

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should be purchased with the hard coinage of new, ingenious, useful and unobvious disclosures." *AZT*, at 37 (C-213).

[355] This choice, moreover, assumes that the reader can accurately predict which promises a judge will find in the patent, and the level of evidence the judge will require to support each promise.

[356] Resp. CM at ¶ 259.

[357] *Consolboard Inc. v MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 SCR 504, 526 ("I do not read the concluding words of [Patent Act] s. 36(1) as obligating the inventor in his disclosure or claims to describe in what respect the invention is new or in what way it is useful. He must say what it is he claims to have invented. He is not obliged to extol the effect or advantage of his discovery, if he describes his invention so as to produce it.") (C-118).

[358] *See* Cl. Mem. at ¶¶ 280-283.

189. Canada contests that the PCT's "form and contents" requirements restrict Canada's ability to require specific disclosure in nationally filed patent applications.[359] It argues that the form and contents requirements, which cannot be varied under national law,[360] only "provide [for] certain elements or categories of information (*i.e.*, a request, description, claim or claims, drawing(s), and an abstract)" to be included in the international application.[361] But as explained by Professor Jay Erstling, former Director of the Office of the PCT at WIPO, these "categories" constitute the "form" of the application; the PCT's "contents" requirements also set out the type of information to be included in the international application.[362] The PCT specifies the information to be included in the international application, and there is no requirement to include evidence of utility. National examining authorities, consistent with domestic law, are free to request more evidence in the course of their examination.[363] Requiring that such evidence be disclosed in the PCT application, however, conflicts with the object and purpose of the PCT system — and also with Lilly's expectations.[364]

190. The arbitrariness of Canada's disclosure rule, in particular regarding the distinction between demonstration and sound prediction, is illustrated by the Federal Court decision in *GSK/rosiglitazone*.[365] This case concerned a patent for the use of the drug rosiglitazone in the treatment of hypoglycemia. The court held

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[359] Resp. CM at ¶ 200.

[360] PCT Art. 27(1) ("No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.") (CL-73).

[361] Resp. CM at ¶ 203.

[362] Second Expert Report of Jay Erstling ("Erstling Second Report") at ¶¶ 3, 6-8, 16-17. Indeed, the PCT's Post-Conference Documents explain that "form and contents mean not only the physical requirements and the identification data, but also the "*form and manner of describing* and claiming." *See* Post-Conference Documents: Records of the Washington Diplomatic Conference, at 751, ¶ 58, WIPO (1970) (C-109).

[363] PCT Art. 27(2)(ii) & (6) (CL-73).

[364] Erstling Second Report at ¶¶ 11-13.

[365] *GlaxoSmithKline Inc. v Pharmascience Inc.*, 2011 FC 239 (C-249).

that the patent promised only "potential use" in the treatment of this disease,[366] such that utility would be *demonstrated* if the patentee could show that, as of the filing date, rosiglitazone had *potential* for use in the treatment. Even though no data supporting utility was provided in the patent, the patent's utility was upheld based on tests that were not disclosed in the patent itself because the court characterized the question as one of demonstrated utility of *potential* use. Had the court, by contrast, characterized the question as one of the predicted utility of *actual* use of the drug, these same test results would have been inadmissible to show that utility was soundly predicted.[367]

191. Canada's bifurcated disclosure requirement substantially increases the uncertainty a patent applicant faces, making it difficult for an inventor to know what must be disclosed. For example, in *Lilly/raloxifene*, the court identified six different studies that were all relevant to the asserted utility of raloxifene, only one of which was disclosed in the patent itself.[368] Among several studies not disclosed in the patent, the court viewed two of them as "very good predictors" of the drug's efficacy and deemed a third "sufficient to turn that prediction into a sound prediction," but ultimately the allegation of invalidity was upheld based on this new disclosure rule for sound prediction.[369] Even with the benefit of this guidance in hindsight, however, it remains unclear whether the first two studies would have been sufficient to soundly predict the utility, or whether the third study would have been sufficient in the absence of the first two.[370] As Professor Norman V. Siebrasse has observed: "If that much uncertainty remains in hindsight, consider the uncertainty facing a patent drafter at the time of filing."[371]

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[366] *Id.* at ¶ 98.

[367] *See* Siebrasse First Report at ¶ 69.

[368] *Eli Lilly Canada Inc v Apotex Inc.*, 2008 FC 142, at ¶ 124 (C-115).

[369] *Id.* at ¶¶ 155-156, 164.

[370] Norman Siebrasse, *Must the Factual Basis for Sound Prediction be Disclosed in the Patent?*, 28(1) CAN. I.P. REV. 39, 75 (2012) (C-206).

[371] *Id.*

### d) The Elements of the Promise Utility Doctrine Work Together in Ways that Magnify the Doctrine's Effects and Make It Unreasonably Difficult for Pharmaceutical Innovators to Draft a Reliably Enforceable Patent Application.

192. Canada does not meaningfully respond to Lilly's showing that the promise utility doctrine places pharmaceutical inventors in a Catch-22 in Canada.[372] On the one hand, the doctrine's heightened evidentiary burdens and additional disclosure obligation require pharmaceutical patentees to develop and disclose substantial clinical evidence to guard against the risk of invalidation for inutility. On the other hand, generating that very same clinical evidence creates an ongoing risk that the invention will be disclosed, rendering it un-patentable for lack of novelty.[373] Given that patent applications must generally be filed at the same time around the world,[374] the risk of a novelty-destroying anticipatory disclosure arises not just in Canada but in all jurisdictions where a patent is sought. Simply put, pharmaceutical innovators are left between the proverbial rock and a hard place. In recognition of this dilemma, a Canadian examiner reviewing MOPOP amendments argued that requiring innovative drug companies to provide "actual proof of the ultimate utility is an unrealistic request, and potentially unethical."[375]

193. Canada disputes that clinical evidence is often necessary to satisfy the utility requirement, and Mr. Dimock points to two cases in which he says

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[372] Cl. Mem. at ¶¶ 32, 266; Stringer Statement at ¶¶ 16-17.

[373] Siebrasse First Report at ¶¶ 107-108 ("But it is effectively impossible to carry out long-term studies prior to filing, because it is very difficult to maintain confidentiality in large or long term clinical trials on human patients. This means that the trials necessary to show utility would render the patent invalid for lack of novelty, since the trials themselves would be prior art."). *See also* Armitage Second Statement at ¶ 37 (explaining that "[l]arge scale clinical testing significantly increases the risk of . . . an anticipatory disclosure").

[374] *See* First Expert Report of Jay Erstling ("Erstling First Report") at ¶ 12 (explaining that maintaining a PCT priority date requires filing "within . . . twelve months" of the first-filed application).

[375] MOPOP Chapter 12 feedback C14 - part 2," Comments of Nancy Trus, (17 March 2008) [Canada Doc. No. 921 at 065459] (C-361).

patents were upheld in the absence of human clinical trials.[376] Statements in those cases do indicate that an "inventor does not need to meet a high standard of clinical testing to show utility."[377] But this is mere dictum. Mr. Dimock fails to acknowledge that in both cited cases, the courts *explicitly relied on human clinical trial results* to justify their finding that the patent was useful.[378] Thus, both of Mr. Dimock's examples serve only to highlight that when Canadian courts construe a promise of treatment in humans, they routinely require human clinical trials.[379]

194. Even if some patents have been found useful without clinical evidence, moreover, Canada does not dispute that there is a substantial *risk* of invalidation without support from substantial and significant clinical evidence. Yet as noted, compiling such evidence while waiting to file a patent application creates its own risk, because if clinical trials are disclosed by trial participants, families of participants, or the innovator (pursuant to disclosure obligations that attach in certain jurisdictions),[380] then the patent may be lost for lack of novelty.

### 2. Canada Is Unable to Refute that the Promise Utility Doctrine Is Discriminatory.

195. In the Memorial, Lilly showed that the promise utility doctrine has had a disparate impact on pharmaceutical patents (now accounting for 25 findings of invalidity) as compared to non-pharmaceutical patents (accounting for zero

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[376] Dimock Report at ¶ 100; *see also* Resp. CM at ¶ 124 (citing *id.*).

[377] *Pfizer Canada Inc. v. Novopharm Ltd.*, 2009 FC 638, at ¶ 87 (R-188); *see also Allergan Inc. v. Canada (Minister of Health)*, 2011 FC 1316, at ¶ 21 (R-189).

[378] In the first case, the court's demonstrated utility holding rested entirely on the results of "Study 350," a human clinical trial "wherein a group of 16 impotent men were administered an oral dose of either 25 mg of sildenafil or a placebo three times a day for a period of six days." *Pfizer Canada Inc. v. Novopharm Ltd.*, 2009 FC 638, at ¶¶ 20, 86 (C-245). In the second case, the court found that the patent's utility was demonstrated by reference to an article that extensively discussed the drug's performance in human clinical trials, and to another article that reported the "results of a four-year double-masked, randomized, multicenter clinical trial." *Allergan Inc. v. Canada (Minister of Health)*, 2011 FC 1316, at ¶¶ 179, 208 (R-189).

[379] *See* Siebrasse First Report at ¶ 59.

[380] *See* Armitage Second Statement at ¶¶ 36-39.

invalidations).[381] While Canada cannot change these stark figures, it nevertheless argues that there is no "systemic discrimination" against pharmaceutical patents.[382] Yet as explained by Bruce Levin, professor of statistics and former Chair of the Biostatistics Department at the Mailman School of Public Health at Columbia University, the resulting difference between post-2005 utility-based invalidations in the pharmaceutical and non-pharmaceutical sector is statistically significant and supports the statistical inference of a disproportionate impact on pharmaceutical patents in the post-2005 period.[383] As Professor Levin explains:

> My analysis reveals that the proportion of cases held invalid on utility grounds increased from 0% pre-2005 to 39.7% post-2005 for pharmaceutical patents, while it decreased from 8.3% pre-2005 to 0% post-2005 for other sectors. In other words, a *higher* proportion of pharmaceutical patents were being found non-useful even as a somewhat *lower* proportion of non-pharmaceutical patents were being found non-useful.[384]

196. Faced with compelling evidence of discrimination, Canada offers a grab bag of unconvincing retorts. First, Canada argues that the pharmaceutical sector has been uniquely litigious since 1993, when compulsory licenses were abolished and *PM(NOC)* proceedings were created.[385] But as Professor Levin explains, this is a non sequitur. The *PM(NOC)* process was in place for more than a decade prior to the advent of the promise utility doctrine in 2005. Yet it is only after 2005 that a disproportionate impact on pharmaceutical patents is observed.[386] Moreover, there is a fundamental flaw in Canada's reasoning: the mere fact that

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[381] Cl. Mem. at ¶¶ 81; 219-222. In only one non-pharmaceutical case have any *claims* been found to lack utility, but the patent in that case, *Eurocopter v. Bell Helicopter Textron Canada Ltd.*, remained valid and enforceable. *See* Cl. Mem. at n.423.

[382] Resp. CM at ¶¶ 140-149.

[383] First Expert Report of Bruce Levin ("Levin Report") at ¶ 9.

[384] Levin Report at ¶ 24.

[385] Resp. CM at ¶ 142.

[386] *See* Levin Report at ¶ 25 (explaining that "it is reasonable to conclude that the finding of significance is not a numerical artifact of the increase in pharmaceutical patent litigation following the introduction of PM(NOC) proceedings").

there was a higher *absolute incidence* of pharmaceutical patent litigation after 1993 cannot explain the higher *rate (or proportion) of invalidity findings* under the utility doctrine. Nor can Canada explain why a similar rate or percentage increase is not observed outside of the pharmaceutical sector or with respect to other patentability requirements.[387]

197. Next, Canada argues that (i) overall invalidation rates have remained constant, and (ii) utility was not the most frequent basis for challenge in the 2005-2014 period.[388] In fact, while invalidation rates on *other* grounds of patentability have remained relatively stable before and after 2005; only utility challenges have seen a statistically significant increase in invalidations, and only in the pharmaceutical sector since 2005.[389] Given that no similar difference in outcomes can be seen on any other ground of invalidity, or in any other time period, Professor Levin concludes that the statistics point toward a "disproportionate impact attributable to the ground of utility alone."[390] Even if this were not the case, however, the fact would remain that with respect to the promise utility doctrine, pharmaceutical patents face a categorically different risk than inventions in any other field of technology.

198. Finally, Canada argues that patent revocations in *PM(NOC)* proceedings are not true "invalidations."[391] Accordingly, Canada submits, there have been only three invalidations on the ground of inutility, not 23 — or, now,

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[387] *See* Levin Report at ¶¶ 15, 19-21.

[388] Resp. CM at ¶¶ 143-144.

[389] Levin Report at ¶¶ 9, 15, 19-21; *see also* Levin Report at ¶ 24 ("[I]dentifying any disproportionate impact attributable to the utility requirement necessarily involves a comparison of the effect of the utility requirement as against the effect of other requirements within like time periods. . .[M]y analysis reveals that the proportion of cases held invalid on utility grounds increased from 0% pre-2005 to 39.7% post-2005 for pharmaceutical patents, while it decreased from 8.3% pre-2005 to 0% post-2005 for other sectors. In other words, a *higher* proportion of pharmaceutical patents were being found non-useful even as a somewhat *lower* proportion of non-pharmaceutical patents were being found non-useful.") (emphases in original).

[390] Levin Report at ¶ 27.

[391] Resp. CM at ¶ 148.

25. But Canada's distinction is artificial. *PM(NOC)* proceedings apply the exact same law as infringement or impeachment actions, follow the same analysis, involve the same judges, and result in statements of law that are equally precedential as to the substantive content of Canada's utility doctrine.[392] Moreover, the practical effects of a *PM(NOC)* finding of invalidity are real, immediate, and significant. These determinations allow generic competitors promptly to enter the market royalty-free, destroying the key economic benefit conferred by the patent — market exclusivity.[393] To ignore the results of these proceedings, as Canada urges, would be to turn a blind eye to a core component of Canada's pharmaceutical patent regime.

### 3. The Promise Utility Doctrine Has No Legitimate Public Policy Justification.

199. The ultimate red herring introduced by Canada in its defense is that the promise utility doctrine is necessary to address speculative patenting.[394] As

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[392] Reddon Report at ¶ 23 (noting that a subset of Federal Court judges hear most patent cases and apply the same jurisprudence, with the same precedential effect, in both PM(NOC) proceedings and actions pursuant to Section 60 of the *Patent Act*).

[393] Canada strains to frame the *PM(NOC)* process as one that has "strengthened the rights of pharmaceutical patent holders" in Canada. Resp. CM at ¶ 140. But in doing so, Canada ignores the numerous ways in which the *PM(NOC)* framework fundamentally disadvantages innovators. Most notably, only the innovator lacks the right of appeal if it suffers an adverse decision, and only the innovator can be held liable for damages. *See Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359, ¶¶ 3-4, 48 (holding that once an NOC has been issued, a patent holder's appeal from an application to prohibit the issuance of an NOC will be dismissed as moot) (C-208); *Patented Medicines (Notice of Compliance) Regulations,* SOR/93-133 at sec. 8 (allowing damages for generic companies but not patentees) (R-31). Moreover, successful generic *PM(NOC)* challenges typically attract a swarm of copycat suits from other generic manufacturers, further eroding the patent holder's market exclusivity. For example, in the year following the *PM(NOC)* decision on the drug Norvasc (*Ratiopharm Inc. v. Pfizer Limited*, 2009 FC 711 (C-374)), almost thirty notices of compliances were issued on generic versions of the drug. *See* "AMLODIPINE BESYLATE," Notice of Compliance Database (C-378). Within less than two weeks of the decision permitting Pharmascience to market the Valtrex drug (*GlaxoSmithKline Inc. v. Pharmascience*, 2008 FC 593 (C-348)), marketing authorization was issued to both Pharmascience Inc., the generic challenger, and to Apotex Inc. Later the same year, authorization was issued to two additional generic manufacturers, and the next year authorizations were granted to a further five companies. *See* "VALACYCLOVIR HYDROCHLORIDE," Notice of Compliance Database (C-379).

[394] Resp. CM at ¶¶ 150-164.

Professor Merges and Professor Siebrasse explain, the promise utility doctrine does not serve this goal.[395]

200. Canada does not introduce any evidence demonstrating that the promise utility doctrine deters speculation, or is otherwise rationally related to this asserted goal. In place of such evidence, Canada offers an attack on Lilly's individual patenting practices.[396] But there is nothing speculative in the Zyprexa and Strattera patents at issue in this proceeding, nor is there anything speculative about Lilly's patenting practices generally. Lilly files patent applications when it determines that its scientific discoveries meet the patentability criteria. Further, the patenting practices of a single company cannot justify a patent doctrine of general applicability.

201. As explained below, Canada has sidestepped fundamental and well-known facts about the innovative pharmaceutical industry and drug development, such as the following: that innovative pharmaceutical firms, including Lilly, obtain fewer patents than firms in almost any other industry; that medicinal compounds routinely treat more than one disease; that the full range of applications of a medicinal compound may take hundreds of millions of dollars and years of research to assess, and thus cannot economically be explored without patent protection; and, most fundamentally, that no firm in any industry is able to turn every one of its patents into a commercially successful product. In addition, while Canada asserts that Lilly's patents on alternate uses of olanzapine and atomoxetine are not supported by scientific data, this assertion is demonstrably false.

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[395] *See* Merges Second Report at ¶¶ 42-48; Siebrasse Second Report at ¶ 41-50. As Professor Siebrasse notes, in the absence of a "promise," a mere scintilla of utility is enough to fulfill the patent bargain and prevent speculative claiming where the invention's use is unknown. It is unclear what, if any, purpose is served by holding certain patents – those read to contain "promises" – to a higher standard. Likewise, while it is fair to say applicants should not be given a patent based on misrepresentations, this has no connection to utility; misrepresentation is prohibited by Section 53 of the *Patent Act*, under which a patent is invalid if a material assertion is untrue and willfully misleading. *See* Siebrasse Second Report at ¶¶ 43-44.

[396] Resp. CM at ¶ 150.

202. Canada accuses Lilly of "adopt[ing] a scattershot approach to patent filings," claiming "dozens of new uses . . . on the basis of little apparent evidence."[397] But Lilly, like other pharmaceutical companies, receives substantially fewer patents per dollar of research than companies in any other industry.[398] In 2014, it spent on average $107 million for each patent it obtained.[399] In terms of absolute numbers, Lilly's patent holdings (and those of its peer firms) are orders of magnitude smaller than the patent portfolios of leading industrial and electronics firms.[400] Even the makeup company L'Oreal files for more patents than Lilly.[401] If the promise utility doctrine truly addressed speculation, then it would not have effects solely in the pharmaceutical sector.

203. Canada also takes issue with the fact that Lilly filed multiple patent applications claiming new uses of atomoxetine and olanzapine. But there is nothing strange or unusual about these patent practices. Filing multiple new use patents on a particular compound, across the range of diseases that the compound is expected to treat, is standard practice across the industry.[402] Canada similarly cites the patents filed on raloxifene — even though that drug is not at issue in this case. In any event, as Mr. Armitage shows, Lilly's patents on raloxifene, like its patents on olanzapine and atomoxetine, reflect the fruits of extensive research and are well justified by science.[403]

204. Canada's observation that several of Lilly's patents did not result in marketed uses is unsurprising.[404] Pharmaceutical firms make products that must

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[397] *Id.* at ¶ 151.

[398] Armitage Second Statement at ¶ 11.

[399] *Id.* at ¶ 8.

[400] *See id.* at ¶ 8.

[401] *Id.* at ¶ 11.

[402] *Id.* at ¶ 17.

[403] *Id.* at ¶¶ 17-23 (explaining, among other things, that "many medical conditions that are classified separately for clinical purposes stem from overlapping biology and provide common 'targets' for drug action at a cellular and systems level").

[404] Resp. CM at ¶ 154.

be administered to patients — patients who are often already in poor overall health. Appropriately, therefore, pharmaceutical firms follow (and are required to follow) an extraordinarily rigorous product development process.[405] Across the industry, fully 90 percent of pharmaceutical compounds shown to be active in laboratory testing are lost in the development process for a complexity of scientific, ethical, and business reasons.[406] As Mr. Armitage explains:

> The decision to commercialize a drug is not simply a scientific one. It is also an ethical decision, requiring a complex balancing of the drug's benefits and its side effects, both on a standalone basis and in the context of other available treatment alternatives. And, like product development choices in any industry, it is a business decision, requiring at every stage an analysis of whether, for example, a new and better competitor has entered the market. In other words, the viability of a drug as a commercialized treatment is completely distinct from whether a drug is patentable.[407]

205. While Canada makes much of the fact that Lilly "abandons" patents on uses that it does not bring to market, it is unclear why this practice warrants criticism. Abandonment is a technical term that refers to a patent holder's decision to cease paying maintenance fees on a patent and thus relinquish the exclusive rights granted by the patent.[408] It cannot be the case that Canada would prefer that Lilly maintain exclusive rights over a use that Lilly determines it cannot develop. Notably, major public research institutions in Canada routinely abandon patents that cannot be commercialized.[409]

206. Canada's last attempt to establish that Lilly engages in "speculative" patenting relies on Marcel Brisebois, a Canadian government employee who has

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[405] Armitage Second Statement at ¶¶ 26-29.

[406] *Id.* at ¶¶ 28-30.

[407] *Id.* at ¶ 30

[408] *See id.* at ¶ 31.

[409] *See* "Search Results for Patents Owned by McGill" (C-380) (showing that McGill University has abandoned 250 Canadian patents and applications, whereas only 6 McGill patents have made it to expiry).

disclosed no professional experience in pharmaceutical drug development. Mr. Brisebois states that Lilly's patents are speculative because they often "included no reference to any relevant supporting experimental data in their disclosure," or "no data pertinent to the therapeutic use."[410] These conclusions, however, are based on misreadings of Lilly's patent applications.

207. For example, Mr. Brisebois faults Lilly's Canadian patent application number 2304472A1, which claims a use for olanzapine in treating sexual dysfunction, for containing only "prophetic examples" and "no relevant data."[411] Mr. Brisebois defines a prophetic example as one that "describes how a given test or assay *could be conducted* and/or how expected results should be interpreted *rather than working examples that describes* [sic] *work actually conducted* or results actually achieved."[412] But Mr. Brisebois fails to recognize that the application does, in fact, disclose the results of studies that were actually conducted before the patent filing, and which supported the claimed therapeutic use.[413] Under his own definition, Mr. Brisebois is incorrect that the application contains only "prophetic examples" with "no relevant data." Mr. Brisebois's assertion that numerous atomoxetine new use patents lacked any "data pertinent to the therapeutic use" is also erroneous.[414]

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[410] Brisebois Statement at ¶ 54 and Annex E.

[411] *Id*. at Annex E, at Row 5.

[412] *Id*. at ¶ 54 & n.17 (emphasis added).

[413] Specifically, Lilly disclosed pharmacological studies, as well as *in vivo* animal and clinical observations, that "support that [olanzapine] has a complex muscarinic receptor profile." Canadian Patent Application No. CA2304472A1 (published 25 September 1998) (Eli Lilly & Co., Applicant) (C-381). The application makes clear that "rats exposed to an overdose of the [olanzapine] compound surprisingly *exhibited* significant salivation. Further, clinical subjects *experienced* pupillary constriction rather than the expected pupillary dilation." *Id*. (emphases added). As the application explains, these results shed light on the compound's pharmacological profile and, together with the cited literature, support the claimed utility.

[414] *See* Brisebois Statement, Annex E, at Rows 3, 4, 10, 11 (citing applications for use of atomoxetine to treat Oppositional Defiant Disorder, Conduct Disorder, Stuttering, and Pervasive Development Disorder). In fact, these disclosures each incorporate by reference the preclinical profile of atomoxetine, and they establish the nexus between atomoxetine's preclinical profile and each therapeutic use by disclosing treatment of the disorders by another approved therapy, Ritalin, (continued…)

208. But even if Canada were right that Lilly generally did not include references to experimental data in its patent applications, the point is irrelevant. As of the dates Lilly applied for and was granted its patents, there was no legal requirement to include experimental data in a patent application to satisfy Canada's utility requirement.[415]

209. Finally, the existence of a legitimate policy rationale — which Canada plainly lacks — would not in any event excuse Canada's failure to comply with NAFTA Chapter 17. As explained in Lilly's Memorial, NAFTA Articles 1709(1) and (7) set forth a binding obligation to make patents available to inventions in all fields of technology so long as they are useful, novel, and non-obvious. Canada's additional promise utility doctrine requirement and the discriminatory impact of that doctrine on pharmaceutical inventions are inconsistent with these commitments.

## III. LILLY'S PATENTS FOR ZYPREXA AND STRATTERA WERE REVOKED ON THE SOLE GROUND OF INUTILITY PURSUANT TO THE PROMISE UTILITY DOCTRINE, WHICH DID NOT EXIST WHEN LILLY'S PATENTS WERE GRANTED.

210. In its Memorial, Lilly established that its Zyprexa and Strattera patents were revoked under Canada's novel promise utility doctrine, and that if

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which possesses an overlapping preclinical profile. *See, e.g.*, Canadian Patent Application No. 2304115A1 (published 1 April 1999) (Eli Lilly & Co., Applicant) (C-383); Canadian Patent Application No. 2304657C (published 1 April 1999) (Eli Lilly and Co., Applicant) (C-384). As is well known in the field, comparisons to other compounds with overlapping preclinical profiles and known therapeutic uses serve as reliable indicators of a compound's likely therapeutic use. *See, e.g.*, PRECLINICAL DEVELOPMENT HANDBOOK: TOXICOLOGY 599 (2008) (explaining that "[s]tandard statistical methods can be used to identify which marketed drugs have . . . profiles similar to that of a test compound of interest. The well understood clinical . . . properties of these known compounds can be used to help predict the *in vivo* . . . properties of the clinical candidate.") (C-382).

[415] Cl. Mem. at ¶ 73. As Mr. Wilson explains, "[a]pplicants would provide as many examples as they believed were necessary to help establish not only that the claimed invention has utility, but also that it satisfies the other criteria of patentability (*e.g.* novelty, non-obviousness)." Wilson Second Report at ¶ 23. *See also id.* ("Applicants might also provide additional working examples to satisfy the disclosure requirement, which is a separate requirement from utility.").

Canadian courts had applied the traditional mere scintilla utility test that existed at the time the patents were granted, the patents would have been upheld.[416]

211. Canada does not dispute that the Zyprexa and Strattera patents were invalidated on the sole ground of inutility. Its argument, rather, is that the Canadian courts invalidated Lilly's patents using the same utility requirement that Canada has always applied.[417] Canada argues that what Lilly refers to as the promise utility doctrine is in fact several distinct rules, each a longstanding part of Canadian patent law.[418] This argument finds no support in the case law and fails for the reasons discussed above.[419] But whatever label Canada might prefer to apply, it is clear that the three core aspects of the promise utility doctrine — (1) the subjective promise of the patent, (2) the heightened evidentiary burdens, and (3) an additional disclosure requirement for soundly predicted utility — were relied upon to invalidate Lilly's Zyprexa and Strattera patents.

212. ***Canada's invalidation of Lilly's Zyprexa patent.*** The Canadian courts applied all three aspects of the promise utility doctrine in invalidating Lilly's patent for Zyprexa. First, after the Federal Court of Appeal reversed the Federal Court for incorrectly invalidating the '113 patent for Zyprexa because it was "not a valid selection patent,"[420] the Federal Court subjectively construed the

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[416] Cl. Mem. at ¶¶ 111, 140.

[417] *See, e.g.*, Resp. CM at ¶ 394.

[418] *Id.* at ¶¶ 86-87.

[419] *See supra* Part II.A-B.

[420] *See* Cl. Mem. at ¶¶ 94-95; *Eli Lilly Canada v. Novopharm Ltd.*, 2009 FC 1018, at ¶¶ 138-139 (C-145). Canada asserts that in opposing Novopharm's request for leave to appeal the FCA reversal to the Supreme Court of Canada, Lilly argued that the FCA "did nothing more than follow established principles of patent law and the jurisprudence of this court." Resp. CM at ¶ 53. Canada also argues that Lilly's position in this appeal was "diametrically opposed to what Claimant argues before this tribunal." *Id.* Read in context, however, it is clear that Lilly's statement was directed toward the core issue of Novopharm's proposed appeal: whether the FCA had rightly determined that selection patents could not be subject to different standards of patentability. The statement therefore sheds no light on Lilly's view of the FCA's discussion of utility; indeed, as Lilly's filing made clear, it objected to review of that secondary issue only on grounds of ripeness, since the utility determination remained subject to remand. Eli Lilly Response to Novopharm's Application (continued…)

promise of the patent. The Court recognized at the outset that the patent's utility as a relatively safe and effective anti-psychotic had already been demonstrated.[421] Yet the Federal Court refused to "accept that the '113's promise was so small" and proceeded to scrutinize the patent for more ambitious promises, ultimately concluding that the Zyprexa patent application "promised" "that olanzapine treats schizophrenia patients in the clinic in a markedly superior fashion with a better side-effects profile than other known antipsychotics."[422] The court found this promise not in the patent's claims, but in summary statements from the patent's disclosure, and also found an implied promise regarding the drug's long-term efficacy.[423]

213. Second, the Zyprexa trial court applied the promise utility doctrine's heightened evidentiary burdens, including the prohibition on post-filing evidence. Measuring the patent against the broad promises described above, the Federal Court dismissed Lilly's extensive evidence of olanzapine's efficacy, concluding

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for Leave to Appeal to the Supreme Court of Canada, *Novopharm Ltd. v. Eli Lilly and Co.* (26 October 2010) at ¶ 45 (R-34).

[421] Cl. Mem. at ¶ 102. Indeed, the Federal Court expressly acknowledged that olanzapine "showed promise," that "some of the early positive indications were borne out." *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, at ¶ 267 (C-146). *See also Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 1018 ("Scientists, whether at Lilly or elsewhere, may well regard olanzapine as an invention, perhaps even a remarkable one.") (C-145).

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

[423] *See* Cl. Mem. at ¶¶ 102-105; *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, at ¶ 210 (C-146). Canada argues that Lilly "attempt[s] to re-write the trial record" by stating that the '113 patent's claimed utility was only as "a relatively safe and effective anti-psychotic." Resp. CM at ¶ 59. In fact, this is the *exact* "promise" that Lilly defended before the trial court. *See Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, at ¶ 96 ("Lilly maintains that the promise of the '113 patent is simply that olanzapine is a relatively safe and effective antipsychotic.") (C-146). Further, Lilly does not disagree that, as it explained in a submission to the Patent Office, the "*patentability* of [a selection patent compound] depends on proving that the compound has exceptional properties that could not be predicted from the prior art." Resp. CM at ¶ 60 (emphasis added). But contrary to Canada's assertion, that submission had nothing to do with the *utility requirement* and was made in the entirely separate context of the non-obviousness requirement. Indeed, whether a selection compound demonstrates an advantage over other compounds in its genus has no bearing on the utility requirement, the sole ground for invalidation here.

that Lilly would have "need[ed] to conduct placebo controlled clinical trials in . . . large groups of patients" in order to fulfill its promises.[424]

214. ***Canada's invalidation of Lilly's Strattera patent.*** The promise utility doctrine was likewise at work in the Strattera litigation. First, as with Zyprexa, the trial court engaged in the subjective exercise of promise construction, determining that the Strattera patent *implicitly* promised long-term effectiveness.[425] Despite the patent's silence as to the drug's long-term efficacy, the court viewed ADHD as "a chronic disorder requiring sustained treatment" and therefore concluded that because the Strattera patent claimed to effectively treat humans with ADHD, "implicit in this promise is that atomoxetine will work in the longer term."[426]

215. Second, in measuring the patent's utility against this implied promise, the Court also applied heightened evidentiary standards. As evidence of the patent's demonstrated utility at the time of its filing, Lilly relied on the positive results of a human clinical trial conducted in 1995 at the Massachusetts General Hospital ("MGH"). But the court, focusing on an implied promise of long-term efficacy, emphasized "limitations" in the study's design, such as its three-week duration.[427] Given the study's design, which was never intended to establish long-term efficacy, the court believed that the "fact that some positive

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[424] *See Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, at ¶ 212 (brackets omitted) (C-146). In attempting to discredit Lilly's characterization of its MGH study as "successful," Canada conveniently omits the court's summary observation that the study "appeared to indicate the presence of antipsychotic activity of olanzapine in some patients." *Id.* at ¶ 153. *See* Resp. CM at ¶ 56. Canada also questions the diligence of Lilly's trial counsel and the preparedness of Lilly's expert witnesses in the Zyprexa trial, but in doing so relies solely on the argumentation of Lilly's adversary, Novopharm. *See* Resp. CM at ¶ 49.

[425] *See Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, at ¶ 112 (C-160).

[426] *Id.*

[427] *Id.* at ¶ 113.

experimental data emerged" from the MGH study was "not enough" to demonstrate utility.[428]

216. Third, applying the promise utility doctrine's "additional disclosure obligation," the court concluded that the MGH study, which was complete by the time of Lilly's patent filing, was inadmissible for the purpose of establishing a sound prediction of utility because it had not been referenced "*in the patent*."[429]

217. Canada does not dispute — nor can it — that these substantive components of the promise utility doctrine were critical to the courts' ultimate invalidations of the Zyprexa and Strattera patents. Instead, Canada emphasizes the procedural history of each case, insisting (without any support) that the proceedings "took place on the basis of an evidentiary record far more complete than that in any other jurisdiction."[430] For example, Canada recites the number of witnesses each trial included and the number of days each trial spanned,[431] while maintaining that the judges "carefully weigh[ed]" and "extensively analyzed" the evidence through months of deliberation.[432] Canada does this because it would prefer to litigate whether the proceedings in Canada were procedurally fair. But that is not Lilly's case,[433] and Canada's recitation of the procedural history is irrelevant.[434]

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[428] *Id.* at ¶ 112.

[429] *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, at ¶¶ 117, 120 (emphasis in original) (C-160).

[430] Resp. CM at ¶ 64.

[431] *Id.* at ¶¶ 26, 46-48, 54.

[432] *Id.* at ¶¶ 30, 50, 54, 55.

[433] As discussed *infra* Part V.A, Lilly's claims under Article 1110 and 1105 do not rest on the argument that Canada's measures constituted a procedural "denial of justice." Rather, Canada's measures violate Article 1110 and 1105 because they are *substantively* arbitrary, discriminatory, and in violation of Canada's obligations in NAFTA Chapter 17 and Lilly's legitimate expectations.

[434] Also irrelevant are Canada's arguments (and its testimony from Kimby Barton) regarding the consequences of Health Canada's approval of the Zyprexa and Strattera patents. *See* Resp. CM at Part II.F. Continuing in its pattern of mischaracterizing Lilly's arguments, Canada claims that Lilly has suggested (incorrectly) that Health Canada's approvals showed that "it had fulfilled the requirement of 'utility' under the *Patent Act*." *Id.* at ¶ 165. Yet Lilly never argued that Health (continued…)

218. The courts' decisions in the Zyprexa and Strattera cases also belie another argument that Canada makes throughout its Counter-Memorial: namely, that the promise utility doctrine is a conflation of other, pre-existing patentability rules. For example, Canada insists that the promise utility doctrine's disclosure rule for sound prediction "flows from settled principles of disclosure."[435] But it is clear from the decisions invalidating the Zyprexa and Strattera patents that Lilly's patents were invalidated on the basis of lack of *utility*, and *only* utility.[436] Other patentability requirements were dealt with elsewhere in the decisions. For example, on remand in the Zyprexa litigation, the Federal Court separately analyzed the question of sufficient disclosure and held that the '113 patent met this requirement.[437] Likewise, in its Strattera decision, the Federal Court separately evaluated challenges to the '735 patent on distinct obviousness, anticipation, and utility grounds, finding against Lilly only on utility.[438] In considering whether the Strattera patent soundly predicted its utility, the court indicated that the additional disclosure obligation arose from the 2002 *AZT* case

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Canada's approval of Zyprexa and Strattera — on its own — established that Lilly satisfied Canada's utility standard. Rather, Lilly demonstrated that those approvals (and the subsequent commercial success of the two medicines) were relevant post-filing evidence that were permitted under Canada's traditional utility requirement but forbidden under the promise utility doctrine. Canada also argues that Lilly "aggrandizes" the value of the studies it disclosed in its patent applications "by suggesting that they were important to this subsequent Health Canada approval." Resp. CM at ¶ 165. This is simply not true, and none of the Lilly witness statements Canada cites for this proposition actually say what Canada claims. *See id.* at 165 & n.302.

[435] Resp. CM at ¶ 127.

[436] *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, at ¶ 122 (C-160) ("Because I have found the '735 Patent to be invalid on the basis of inutility, Novopharm is entitled to judgment against Lilly"); *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, at ¶ 273 (C-146) ("The patent's promise had not been demonstrated and could not have been soundly predicted on the basis of the evidence available to the inventors in 1991.").

[437] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, at ¶ 272 (C-146). In so holding, Justice O'Reilly noted that the Federal Court of Appeal had explicitly rejected his earlier interpretation conflating the utility and sufficiency requirements, under which he had imposed a sufficiency duty, in the case of an invention based on an alleged sound prediction of utility, "to set out the factual basis and line of reasoning supporting that prediction." *Id.* at ¶ 272.

[438] *See Novopharm Ltd. v. Eli Lilly & Co.*,., 2010 FC 915, at ¶¶ 77, 79-80, 83-87 (C-160).

and its recent progeny, not from any longstanding or settled principles of sufficiency, as Canada insists.[439]

219. In short, in both the Zyprexa and Strattera litigation, the Canadian courts invalidated Lilly's patents solely on the ground of utility, applying the additional promise utility doctrine requirement. Canada's invalidation of Lilly's Zyprexa and Strattera patents is directly attributable to the dramatic and fundamental changes in Canada's utility requirement discussed above.

220. It is equally clear that Lilly's patents would *not* have been invalidated under Canada's traditional mere scintilla requirement. Canada does not — and cannot — argue otherwise.[440] Indeed, the Strattera court "accept[ed] Lilly's point" that atomoxetine had been "shown to be somewhat useful to treat ADHD," but deemed this showing irrelevant because "utility is assessed against the inventive promises of the patent."[441] Likewise, the Federal Court in the Zyprexa case recognized that Lilly had demonstrated "early positive signals about olanzapine's efficacy and safety" and that one of the patent's supporting studies "appeared to indicate the presence of some antipsychotic activity."[442] These findings leave no question that Lilly's patents easily satisfied the low bar of the traditional utility standard.

221. Finally, the uniqueness of Canada's promise utility doctrine is confirmed by the fact that no other jurisdiction has invalidated the Zyprexa or Strattera patents on the ground of inutility.[443] Canada quibbles at the margins,

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[439] *Id.* at ¶ 117 *et seq.*

[440] In fact, with respect to the Zyprexa patent, Canada appears to concede that the patent possessed at least a scintilla of utility, arguing that this does not matter since "patents must meet their promised utility." Resp. CM at ¶ 97.

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

[442] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, at ¶¶ 153, 212 (C-146).

[443] As Mr. Armitage explains in section IV of his Second Report, Lilly held corresponding patents on Zyprexa and Strattera in 81 and 36 jurisdictions, respectively. Collectively, the patents were challenged in a total of 26 jurisdictions. Yet, Canada remains the only country in which either (continued…)

speculating as to *why* it was the only jurisdiction to invalidate these patents on utility grounds, but it cannot avoid the fact that the results in Canada are unique.

222. Canada asserts that the lack of *any* challenge in Mexico reflects the fact that "[t]he structure of the Mexican judicial system makes it difficult to challenge a patent."[444] But patent validity is routinely contested in Mexico, as Ms. Gonzalez explains.[445] Among hundreds of disputes, moreover, the vast majority of validity cases and nullity actions in Mexico involve pharmaceutical inventions.[446] Yet there was no challenge to the Strattera or Zyprexa patents in Mexico, much less a case alleging lack of industrial applicability.

223. Regarding Strattera, Canada's assertion that generic manufacturers lack the financial incentive to challenge this patent in other jurisdictions is simply wrong. Annual sales of Strattera have met or exceeded US$ 10 million in eight different markets.[447] Had the patent been vulnerable to invalidation on utility grounds, additional challenges would have been pursued.[448]

224. Canada likewise attempts to deflect the fact that, among the 81 jurisdictions to grant patent protection for Zyprexa, Canada was the only country

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patent faced a challenge on grounds of utility, and one of only three countries (the others being Saudi Arabia and Slovenia) where the patent on either drug was revoked on any ground.

[444] Resp. CM at ¶ 180.

[445] Gonzalez Reply at ¶ 51.

[446] *Id*. at ¶¶ 51–54.

[447] Armitage Second Statement at ¶ 49.

[448] Canada focuses on the ultimately overturned decision of the U.S. District Court for the District of New Jersey that invalidated Lilly's U.S. Strattera patent. Resp. CM at ¶ 37. As Lilly outlined in its Memorial, however, this lower court reasoned that the Strattera patent was invalid for failing to properly *enable* the invention. Cl. Mem. at ¶ 141. More importantly, this ruling was summarily reversed by the United States Court of Appeals for the Federal Circuit, which observed that even Lilly's generic challengers did "not dispute that the '590 patent describes the utility for tomoxetine for the treatment of ADHD, and that the utility is correctly described." *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). Moreover, the fact that the Federal Circuit overturned the district court in a non-precedential unpublished opinion only underscores how straightforward the reversal was.

to invalidate this patent for lack of utility. Canada offers numerous and varied theories to explain why it is an outlier in this regard: "some variation in the patents' claim drafting," "variations in national substantive laws," "the quality of litigation counsel," and the Canadian court being "more careful and thorough than courts in other jurisdictions."[449] It cites no evidence for any of these theories. Canada thus provides nothing more than speculation in an attempt to diminish the fact that no other jurisdiction has found the Zyprexa patent to lack utility.

## IV. CANADA'S REVOCATION OF THE ZYPREXA AND STRATTERA PATENTS CONSTITUTED A WRONGFUL EXPROPRIATION UNDER ARTICLE 1110.

225. When Canada signed NAFTA, it agreed to provide foreign investors with broad protection against uncompensated expropriation. Article 1110 of NAFTA expressly covers not just expropriation itself — direct *and* indirect — but also "measures tantamount" to expropriation. NAFTA tribunals have repeatedly recognized the breadth of these standards, and the case-specific and fact-intensive analysis necessary to determine whether a State measure qualifies as a taking under this Article.[450]

226. In its Memorial, Lilly established that Canada's measures engage Article 1110 because they (i) resulted in a substantial deprivation in the value of Lilly's investments; and (ii) they qualify as compensable takings as opposed to non-compensable exercises of state authority.[451] With respect to the latter

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[449] Resp. CM at ¶ 64.

[450] *Waste Mgmt., Inc. v. Mexico (II)*, NAFTA/UNCITRAL, ICSID Case No. ARB(AF)/00/3, Award (30 April 2004) [hereinafter "*Waste Management v. Mexico*"] (endorsing claimant's broad interpretation of the Article 1110 standard), at ¶¶ 144-145 (CL-65); *Metalclad Corp. v. United Mexican States,* NAFTA/UNCITRAL, ICSID Case No. ARB(AF)/97/1, Award (30 August 2000), at ¶¶ 103, 155 [hereinafter *Metalclad v. Mexico*] (embracing broad Article 1110 standard and noting that "[e]ach case has to be looked at in light of the factual situation and the basis for the measures in question.") (CL-49); *Robert Azinian et al. v. The United Mexican States*, NAFTA/UNCITRAL, ICSID Case No. ARB(AF)/97/2, Award (1 November 1999), at ¶ 90 [hereinafter *Azinian v. Mexico*] ("Labelling is . . . no substitute for [case-specific] analysis" for purposes of determining measures under Article 1110) (CL-61).

[451] Cl. Mem. at ¶ 179.

criterion, Lilly demonstrated that Canada's measures were cognizable expropriations because they violated Canada's obligations in Chapter 17 of NAFTA (a basis for liability that Article 1110(7) contemplates), because they were arbitrary, and because they were in conflict with Lilly's reasonable investment-backed expectations.[452]

227. In its Counter-Memorial, Canada responds to Lilly's showing with a series of formalistic objections that fail to refute the substance of Lilly's claim.

- *First*, Canada leads with the circular argument that Lilly's patents could not have been expropriated because patents are conditional property rights subject to judicial review, and here the Zyprexa and Strattera patents were declared void *ab initio*, which means that Lilly never had a property right to assert. This argument fails as a matter of logic, since it is based on the very measures (the revocation of Lilly's patents under the promise utility doctrine) that Lilly has proven are expropriatory. Setting that circularity aside, Canada's argument also fails under Canadian law, which makes clear that patents are legally enforceable immediately upon issuance, irrespective of whether they have been challenged in court. The fact that a patent may *later* be revoked by a court does not mean that, in the meantime, it does not qualify under NAFTA's expansive definition of "investment" as "real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes."[453] *Infra* Part IV.A.

- *Second*, Canada maintains that judicial measures — such as its revocations of the Zyprexa and Strattera patents — cannot be expropriatory unless they also constitute a procedural denial of justice. This is wrong as a matter of the customary international law on which Canada relies. *Infra* Parts IV.B.1 and V.A. Even if Canada were right, moreover, Article 1110(7) of NAFTA provides a fully independent basis for concluding — in the specific context of NAFTA — that revocations of patents in violation of Chapter 17 are expropriatory. *Infra* Part IV.B.2.

- *Third*, Canada fails to rebut Lilly's showing that the promise utility doctrine violates Canada's obligations in Chapter 17 of NAFTA, including its obligation to make patents available for "useful" inventions and its obligation not to discriminate based on field of technology. Canada continues to

[452] *Id.* at ¶¶ 239-243.

[453] NAFTA, Art. 1139.

disproportionately invalidate pharmaceutical patents under its unique utility doctrine in violation of Chapter 17's non-discrimination obligation. *Infra* Part IV.B.3.

- *Lastly*, Canada argues that (i) its measures cannot be a *direct* expropriation because the Zyprexa and Strattera patents were not transferred to another entity; and (ii) its measures cannot be an *indirect* expropriation because Lilly continues to maintain a business presence in Canada. But there is no requirement that direct expropriations involve a transfer to a third party (or the State), and even if there were such a requirement, it is readily met in this case because the value of Lilly's patents (*i.e.*, the right to preclude others from making and using its inventions) was transferred to the generic manufacturers that immediately entered the market after Lilly's patents were revoked. As for the fact that Lilly maintains *other* investments in Canada, it is irrelevant to whether the investments at issue here — the Zyprexa and Strattera patents — were expropriated. *Infra* Part IV.B.4.

228. As for the lawfulness of its actions under Article 1110, Canada does not even bother to defend the legality of its measures under the criteria set out in Article 1110(1). As Lilly demonstrated in its Memorial, Canada's measures are in breach of Article 1110 of NAFTA in at least four independent ways: (i) they lacked any compensation; (ii) they were discriminatory; (iii) they lacked a public purpose; and (iv) they violated Article 1105(1) of NAFTA. While Canada addresses several of these points in other areas of its submission, it completely ignores its obligation to tender NAFTA-compliant compensation for any expropriation. Accordingly, if the Tribunal concludes (as it should) that Canada's measures engage Article 1110, then the Tribunal must also conclude that Canada's expropriation is wrongful under NAFTA. *Infra* Part IV.C.

### A. Lilly's Patent Rights in Zyprexa and Strattera Were Valuable Property Rights that Were Capable of Being Expropriated.

229. Citing the non-controversial proposition that "[t]he property rights that are subject to protection under the international law of expropriation are created by host State law,"[454] Canada argues that the Zyprexa and Strattera

[454] Resp. CM at ¶ 312 (quoting Campbell McLachlan et al., INTERNATIONAL INVESTMENT ARBITRATION, § 8.65).

patents were not protected "investments" capable of being expropriated because, under Canadian law, patent validity may be litigated after grant and patents are subject to potential invalidation by the Canadian courts. Accordingly, Canada argues, Lilly's patent rights were "conditional" and thus not protected investments under NAFTA.[455]

230. As an initial matter, Canada's argument must be rejected because it is an untimely jurisdictional objection. The question whether an investor has a protected "investment" is a jurisdictional issue,[456] and under the UNCITRAL Rules, a "plea that the arbitral tribunal does not have jurisdiction shall be raised not later than in the statement of defence."[457] Canada's Statement of Defence did not challenge the Tribunal's jurisdiction, except to make the discrete argument that the "Tribunal lacks jurisdiction to rule on alleged violation of any of TRIPS, PCT, or NAFTA Chapter Seventeen."[458] Canada did not then contend that Lilly lacked a protected "investment," but instead waited until its Counter-Memorial to raise this issue, in plain violation of the Rules.

231. The Tribunal should accordingly not consider Canada's argument that Lilly lacks a protected "investment." Even if the Tribunal were to reach its merits, however, Canada's argument fails both on the law and on the facts. As a

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[455] *Id*. at ¶¶ 66, 329.

[456] The jurisdiction of Chapter 11 tribunals is set forth in Article 1101 of NAFTA, which makes clear that jurisdiction exists only with regard to "*investments* of investors of another Party in the territory of the Party." NAFTA, Art. 1101(1)(b); *see also Bayview Irrigation District v. United Mexican States*, ICSID Case No. ARB(AF)/05/1, Award on Jurisdiction (19 June 2007), at ¶ 85 ("The role of Article 1101 in determining the scope of the jurisdictions of tribunals established to hear Chapter Eleven claims is clear from the title of the Article.") (RL-12); *Grand River v. United States*, at ¶ 76 (Article 1101 "operates as 'gateway' to NAFTA arbitration") (CL-107). Accordingly, NAFTA tribunals have considered the question whether a protected "investment" exists to be jurisdictional. *See, e.g.*, *Grand River v. United States*, at ¶ 122 (dismissing claims for lack of jurisdiction where claimant could not show they had an "investment" for purposes of NAFTA Article 1139) (CL-197).

[457] *See* UNCITRAL Rules, Art. 21(3) ("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.").

[458] *See* Respondent's Statement of Defence, at ¶ 83.

legal matter, Canada wrongly assumes that simply because a patent may later be invalidated by a court, the patent is not a protected investment under NAFTA. NAFTA broadly defines "investment" to include "real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes."[459] Canada does not cite a single authority for the proposition that a property right is not a protected "investment" under NAFTA simply because it is subject to review (and potential invalidation) by a court, and with good reason: *all* property rights are "conditional" in the sense that they can be subject to a later court proceeding.[460] That does not mean that they are any less protected of an investment.

232. As discussed in Part I.C., there is nothing special about patents in this regard. CIPO's website makes clear that a granted patent is "*a valuable asset*" and "*like a deed to a physical property such a house*."[461] This statement is well-grounded in the Canadian Patent Act, which provides that a granted patent conveys "*the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used*."[462] As Mr. Reddon explains, this bundle of property rights are legally enforceable *immediately upon issuance* (and irrespective of whether the patent has been challenged in court) — a fact that has been recognized by multiple other provisions of Canadian law.[463] The entire

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[459] NAFTA, Art. 1139(g).

[460] *See supra* Part I.C; Reddon Report at ¶ 28.

[461] CIPO, *Protect your innovation*, http://www.ic.gc.ca/eic/site/ cipointernet-internetopic.nsf/eng/wr03586.html (emphasis added) (C-312); *see also* CIPO, *Stand out from your competitors,* http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00818.html#no1 ("Like physical assets, IP assets must be acquired and maintained, accounted for, valued, monitored closely, and properly managed in order to extract their full value.") (C-311).

[462] *Patent Act* (Canada), R.S.C., 1985, c. P-4, at § 42 (emphasis added) (C-50).

[463] Reddon Report at ¶ 27-28 & n.30 (emphasis added). Canada notes that "s. 42 of the *Patent Act* states that the right of exclusivity conferred by a patent it [sic] 'subject to this Act' and 'subject to adjudication' before any court of competent jurisdiction." Resp. CM at ¶ 329. As Mr. Reddon explains, however, this language does not imply that patent rights are any less legally enforceable than any other type of property rights. Reddon Report at ¶ 28. To the contrary, as already noted (and as Canada omits to mention), Section 42 provides: "to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, *the exclusive right,* (continued…)

PM(NOC) regulatory framework, for example, takes as its premise the fact that a patent is legally enforceable immediately upon issuance.[464]

233. As CIPO's website goes on to explain, the fact that a patent is a "valuable asset" immediately upon issuance is also recognized by the market-place, where a "granted patent . . . can become very valuable and can be sold, licensed or used to negotiate funding, venture capital or other forms of financing."[465] Thus, as Mr. Reddon notes, patent holders "can and often do exploit valuable rights in their patents following issuance, including by licensing to others the right to make, use and sell the subject-matter of the patent," and "[l]icensors and licensees do not wait until a patent has been adjudicated before a court (which may never occur) prior to entering a licensing agreement."[466] As Mr. Armitage makes clear, companies like Lilly also treat patents as valuable assets in other ways as well:

> Patents are often significant sources of revenue and are routinely valued and monetized in corporate and other commercial transactions. Patents are assets that are also routinely taken by lending institutions as collateral to secure loans. In other words, the marketplace treats a patent as a property right regardless of whether it has been the subject of litigation.[467]

234. Ignoring this commercial reality, Canada argues that the Zyprexa and Strattera patents are not property rights capable of expropriation because they were declared *void ab initio* by the Canadian courts. Canada contends that Lilly's

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*privilege and liberty of making, constructing and using the invention and selling it to others to be used*, subject to adjudication in respect thereof before any court of competent jurisdiction." (Emphasis added) (C-50). Section 42 says nothing about making this bundle of legal rights contingent on a granted patent being upheld in a later court proceeding.

[464] Reddon Report at n.30.

[465] *See* CIPO, *Protect your innovation*, http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr-03586.html (C-312).

[466] Reddon Report at ¶ 28.

[467] Armitage Second Statement at ¶ 43.

patents "were invalid under the statute that governs their creation (the *Patent Act*) and were therefore not property interests capable of being taken."[468]

235. This argument fails as a matter of logic. The promise utility doctrine — and the application of that doctrine by the Canadian courts to invalidate the Zyprexa and Strattera patents — *are the measures that Lilly is challenging*. Canada cannot establish that its measures comport with NAFTA Chapter 11 by pointing to the very same court decisions that invalidated Lilly's patents. To conclude otherwise would be completely tautological. Canada cites no authority to support this gambit, which would radically undercut the protections afforded by Chapter 11.[469]

236. Even setting aside this fundamental logical flaw, Canada overstates the significance of a patent being declared *void ab initio*. As Mr. Reddon explains, as a practical matter, the *ab initio* invalidation "simply means a patentee cannot obtain damages for infringement if the patent is declared invalid."[470] The fact that a patent can be voided *ab initio* does not mean, as a factual matter, "that it is treated as if it never existed in practice, or that, upon issuance, valuable property rights were not conferred."[471] For example, the fact that a patent is declared *void ab initio* does not mean that license agreements are necessarily void.[472]

237. Lastly, Canada's argument would render Article 1110(7) of NAFTA nonsensical. Article 1110(7) provides that "[t]his Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights,

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[468] Resp. CM at ¶ 327.

[469] Canada likens this case to *Azinian v. Mexico*, *Arif v. Moldova*, and *Liman Caspain v. Kazakhstan*, but as discussed in the following section, all three decisions are readily distinguishable. *See infra* Part IV.B.1. In *Azinian*, the claimant made no allegation at all against the actions of the Mexican courts, and in *Arif* and *Liman*, the claimant's complaint was that the municipal courts misapplied *national* law. *See infra* Part IV.B.1. Here, in contrast, Lilly has established that Canada's judicial measures are expropriatory because they violated *international* law.

[470] Reddon Report at ¶ 29.

[471] *See id.*

[472] *Id.*

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)."[473] Canada concedes that the reference to "revocations" in this Article embraces *judicial* revocations of patents — such as in the cases of Zyprexa and Strattera.[474] But if Canada's argument were correct — and a Canadian patent were no longer a protected "investment" after it was revoked *ab initio* — then a NAFTA party could avoid responsibility under Article 1110 when it revokes patent rights in their entirety, but would still be held responsible for compulsory licenses and other limitations placed on those rights that fall short of complete revocation. Similarly, the references to "revocation" in Article 1110(7) would be surplusage if once an IP right were revoked it could not constitute a protected investment under the treaty. It would be completely unnecessary to state that such revocations are not expropriatory when they comport with Chapter Seventeen.

238. The reality is that Lilly had two valuable "investments" — the Zyprexa and Strattera patents — and they remained fully enforceable property rights until the moment they were revoked by the Canadian courts under the promise utility doctrine. Whether those measures engage Canada's obligations under Chapter 11 is what this case is about. To permit Canada to cite the consequences of its own disputed measures to justify its conduct under Chapter 11 would short-circuit the dispute-resolution process to which Canada agreed when it signed NAFTA.

### B. The Revocation of Lilly's Patent Rights by the Canadian Courts Constituted an Expropriation Under Article 1110 of NAFTA.

[473] NAFTA Art. 1110(7) (emphasis added).

[474] Resp. CM ¶ 344 & n.592 ("Similarly, the 'revocation, limitation or creation' of intellectual property rights could be achieved through executive, legislative, or judicial action.").

### 1. A Judicial Measure Is Expropriatory Under NAFTA Chapter 11 When It Substantially Deprives an Investment of Value and Is Inconsistent with a Rule of International Law.

239. Article 1110 of NAFTA provides that "No Party may directly or indirectly nationalize or expropriate an investment of an investor" of another Party without fulfilling prescribed conditions.[475] On its face, Article 1110 applies to both direct and indirect expropriations and draws no distinctions among the various types of State measures that may constitute an expropriation. In particular, Article 1110 draws no distinctions between expropriations founded upon executive, legislative, and judicial measures. Indeed, Article 201 of NAFTA broadly defines "measure" to include "any law, regulation, procedure, requirement or practice." Noting the breadth of the terms "procedure" and "requirement," tribunals have held that judicial actions involving private parties are "measures" covered by NAFTA Chapter 11.[476]

240. In its Memorial, Lilly demonstrated that NAFTA's text is consistent with general principles of international law, which create no special rules for claims of expropriation based on judicial measures.[477] Rather, as noted in *Azinian v. Mexico,* judicial measures "emanat[e] 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."[478] Accordingly, a tribunal tasked with evaluating whether a judicial

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[475] NAFTA, Art. 1110(1).

[476] *See The Loewen Group, Inc. & Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Decision on Hearing on Respondent's Objection to Competence and Jurisdiction (January 5, 2001), at ¶ 60 ("We reject therefore the Respondent's objection that the Mississippi Court judgments are not 'measures adopted or maintained by a Party' because they resolved a dispute between private parties.") (CL-8).

[477] Cl. Mem. ¶¶ 177-178.

[478] *Robert Azinian 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).

measure constitutes an expropriation should apply the same analysis that is used to analyze exercises of executive or legislative power.[479]

241. As Lilly has explained, this analysis requires a claimant to make two basic showings: (i) that it suffered a "substantial deprivation" in the value of its investment; and (ii) that the measure at issue qualifies as a compensable taking as opposed to a non-compensable exercise of state authority. With respect to the latter criterion, tribunals have found that one way to distinguish a compensable expropriation from a non-compensable judicial measure is if the measure violates a substantive rule of international law.[480]

242. In its Counter-Memorial, Canada does not dispute "that a State is responsible in international law for the conduct of its organs, including the judiciary."[481] Yet Canada simultaneously maintains that "[t]he only rule of customary international law that relates to the acceptability of domestic court determinations of domestic rights is the rule against denial of justice."[482] According to Canada, in other words, a domestic court's violation of a *substantive* norm of international law cannot give rise to a cognizable expropriation under international law *unless* the domestic court also is *procedurally* unfair to the foreign investor.

243. Canada misstates the customary standard on which it relies. Contrary to Canada's assertions, a State is subject to liability for the acts of its

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[479] *See* Cl. Mem. at ¶ 179; *see also Sistem Muhendislik Insaat Sanayi Ve Ticaret A.S. v. Kyrgyz Republic*, ICSID Case No. ARB(AF)/06/1, Award (9 September 2009), at ¶ 118 ("That abrogation [of Claimant's contract rights] was effected by an organ of the Kyrgyz State [the decisions of the Kyrgyz courts, as affirmed by the Kyrgyz Supreme Court], for which the Kyrgyz Republic is responsible. It is well established that the abrogation of contractual rights by a State, in the circumstances which obtained in this case, is tantamount to an expropriation of property by that State. The Court decision deprived the Claimant of its property rights in the hotel just as surely as if the State had expropriated it by decree.") (CL-146).

[480] Cl. Mem. at ¶¶ 179-180.

[481] Resp. CM at ¶ 230 & n.416.

[482] *Id*. at ¶ 333.

judiciary under the primary rule regarding expropriation *both* when those acts violate a *substantive* norm of international law *and* when they violate a *procedural* norm of international law (*i.e.*, constitute a denial of justice). Put differently, denial of justice is *one basis* of liability under international law for expropriations based on judicial measures, but it is not the *only basis*.

244. As Professor Jan Paulsson explains in his treatise on the subject, "[d]enial of justice is *always* procedural."[483] Accordingly, when a domestic court violates a *substantive* rule of international law, that is not denial of justice at all, but rather a freestanding basis of liability. As Professor Paulsson explains: "A national court's breach of other rules of international law, or of treaties, is not a denial of justice, but a direct violation of the relevant obligation imputable to the state like any acts or omissions by its agents."[484]

245. Professor Paulsson elaborates on this fundamental principle elsewhere in his treatise: "To the extent that national courts disregard or misapply *national* law, their errors do not generate international responsibility unless they have misconducted themselves in some egregious manner which scholars have often referred to as *technical* or *procedural* denial of justice."[485] But "*[t]o the extent that the decisions of national courts disregard or misapply international law, they are subject to international censure like any other organ of a state*."[486] When a state disregards international law, "[r]esponsibility for such a delict could be invoked either by the disappointed applicant's state or by the applicant directly before any

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[483] Jan Paulsson, DENIAL OF JUSTICE IN INT'L LAW 7 (2010) ("At any rate, greater clarity may be achieved by observing that denial of justice is *always* procedural. The adjective is no longer needed.") (emphasis in original) (CL-147).

[484] *Id.* at 98.

[485] *Id.* at 5.

[486] *Id.* at 4 (emphasis added).

competent international tribunal."[487] As Professor Paulsson notes, other commentators have reached the same conclusions.[488]

246. Consistent with these basic principles, arbitral tribunals have found judicial measures to be expropriatory when they substantially deprive an investment of value and violate a substantive rule of international law. In *Saipem v. Bangladesh*, for example, the tribunal concluded that a judicial measure—the annulment of a commercial arbitration award — constituted an expropriation because, *inter alia*, it violated the New York Convention.[489] The tribunal reached this conclusion even though the claimant did not allege, and the tribunal did not find, a denial of justice.[490] Indeed, the tribunal expressly rejected the notion that "*expropriation by a court necessarily presupposes a denial of justice*."[491]

247. Canada argues that *Saipem* was a results-oriented decision that was really about procedural unfairness, but the claimant could not plead denial of justice in that case because the BIT did not confer jurisdiction for such a claim and the claimant had not exhausted local remedies.[492] Yet Canada does not address —

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[487] *Id.* at 86.

[488] *See id.* at 71-72 (quoting Jiménez de Aréchaga, *International Responsibility* in M. Sørensen (ed.), MANUAL OF PUBLIC INT'L LAW 555 (London: Macmillan, 1968) ("[T]he obvious objection is that denial of justice and State responsibility are not co-extensive expressions, and that State responsibility for acts of the Judiciary does not exhaust itself in the concept of denial of justice.").

[489] *Saipem S.p A. v. People's Republic of Bangladesh*, ICSID Case No. ARB/05/7, Award (30 June 2009), at ¶ 170 [hereinafter *Saipem v. Bangladesh*] (CL-62).

[490] *Id.* at ¶ 181.

[491] *Id.* (emphasis added).

[492] Resp. CM at ¶ 338. Canada makes a similar effort to distinguish *Oil Field of Texas v. Iran*, 12 Iran-U.S. C.T.R. 308, 318 (1986) [hereinafter *Oil Field v. Iran*] (CL-59), which held that judicial measure could qualify as an expropriation under international law. Canada maintains that *Oil Field of Texas* was "actually a denial of justice case, as the claimant could not access the Iranian courts to challenge the decision of the Iranian courts." Resp. CM at ¶ 343. But the *Oil Field* tribunal could have included a requirement of denial of justice in its articulation of the expropriation standard, and it did not. Rather, the tribunal invoked the ILC principle that "[t]he conduct of an organ of the State shall be considered as an act of that State under international law, whether that organ belongs to the constituent, legislative, executive, judicial or other power," and held categorically that "[i]t 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 (continued…)

let alone refute — the straight-forward logic of the *Saipem* decision, pursuant to which a substantive violation of international law is sufficient to render a judicial measure expropriatory.[493] Whether *Saipem* was "results-oriented" or not, its logic is well-grounded in international law and relevant to the case at hand. First, the *Saipem* tribunal explained, "the most significant criterion to determine whether the disputed actions amount to indirect expropriation . . . is the impact of the measure."[494] Second, the tribunal recognized that since the judicial revocation of property rights (in *Saipem*, an ICC award) *always* result in a "substantial deprivation" of those rights, it was necessary for the claimant to also demonstrate "the unlawful character of the actions."[495] Third, the tribunal found that one of the aspects in which the judicial measures at issue were unlawful was that they constituted a substantive violation of the New York Convention.[496]

248. Unable to identify any flaws in the *Saipem* tribunal's reasoning, Canada claims that insofar as the tribunal relied on violations of the New York Convention to find an expropriation, no other tribunal has adopted a similar approach. But Canada is wrong. First, other tribunals have discussed and applied *Saipem*'s analysis, including in particular its focus on the "the unlawful character"

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attributable to the state of that court." *Oil Field v. Iran*, at ¶ 42 & n.1 (citing Draft on State Responsibility by the International Law Commission, Art. 6) (CL-59).

[493] Canada quotes an article that criticizes *Saipem* for "an insufficiently rigorous distinction both between denial of justice and other mistreatments of investors, and between denial of justice and other obligations under international law." Resp. CM at ¶ 339 (quoting Martin Paparinskis, "The International Minimum Standard and Fair and Equitable Treatment" in OXFORD MONOGRAPHS IN INT'L LAW 208 (Oxford Univ. Press, 2013)). But the gravamen of Paparinskis' concern — the notion that *Saipem* could result in the "assumption of (unlimited) jurisdiction over all primary obligations addressed by the judicial organ" — is misplaced. *Id.* Far from resulting in "unlimited" jurisdiction, *Saipem* held that the judicial measures at issue in that case were cognizable expropriations because they (i) substantially deprived an investment of value; *and* (ii) had the requisite "unlawful character."

[494] *Saipem v. Bangladesh*, at ¶ 133 (CL-62).

[495] *Id.* at ¶ 134.

[496] *Id.* at ¶ 170.

of the relevant judicial measure.[497] Second, other tribunals have recognized that judicial measures that breach an international obligation — such as the New York Convention — can qualify as an expropriation irrespective of whether the measures qualify as a denial of justice.

249. In *ATA v. Jordan*, for instance, the tribunal found that the investor's contractual right to arbitrate was expropriated by the Jordanian courts.[498] The tribunal did not base its determination on a finding of denial of justice.[499] Rather, the tribunal concluded that Jordan violated the BIT because its judicial invalidation of the investor's right to arbitrate violated Article II of the New York Convention.[500] Other tribunals have similarly concluded that judicial measures

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[497] *See Swisslion DOO Skopje v. Former Yugoslav Republic of Macedonia*, ICSID Case No. ARB/09/16, Award (6 July 2012), at ¶¶ 313-314 [hereinafter *Swisslion v. Macedonia*] (applying *Saipem*'s requirement that "the courts' intervention was illegal" and concluding that "[s]ince there was no illegality on the parts of the courts, the first element of the Claimant's expropriation claim is not established.") (RL-65); *GEA Grp. Aktiengesellschaft v. Ukraine*, ICSID Case No. ARB/08/16, Award (31 March 2011), at ¶¶ 232-237 [hereinafter *GEA Group v. Ukraine*] (referring to *Saipem* and applying its illegality criterion) (RL-26). Canada argues that the tribunal in *GEA Group* did not focus on the part of *Saipem* that addressed Bangladesh's substantive violation of the New York Convention. Resp. CM at ¶¶ 340, 337 & n.576. But the *GEA Group* tribunal's emphasis was perfectly consistent with the GEA Group's claims, which focused on alleged procedural unfairness, rather than on a substantive violation of the New York Convention. *GEA Group v. Ukraine*, at ¶ 235 (characterizing claimant as "contending that Ukraine committed 'a travesty of justice in applying a discriminatory law to avoid enforcement of GEA's Award.") (RL-26).

[498] *ATA Construction, Indus. & Trading Co. v. Hashemite Kingdom of Jordan*, ICSID Case No. ARB/08/2, Award (18 May 2010), at ¶¶ 125-128 [hereinafter *ATA v. Jordan*] (CL-63).

[499] *Id.*

[500] *Id.* Canada tries to distinguish *ATA v. Jordan* by arguing that in that case "it was new legislation that extinguished a previously acknowledged right to arbitration under Jordanian law that was at issue." Resp. CM at ¶ 341. But the tribunal was clear that it was the Jordanian courts that were responsible for reconciling the relevant Jordanian statute with the New York Convention, and that they failed to do so. *See ATA v. Jordan*, at ¶ 128 ("In the Tribunal's view, the Jordanian Court of Appeal and Court of Cassation could have complied with their duty [under the New York Convention] in this case by refusing to apply retroactively the new rule introduced in the last sentence of Article 51 of the Jordanian Arbitration Law.") (CL-63).

may qualify as an expropriation under the governing treaty without requiring a denial of justice.[501]

250. The cases cited by Canada, meanwhile, are not to the contrary. Canada emphasizes *Azinian v. United States*, which involved a claim that the invalidation of a concession contract constituted an expropriation under Article 1110.[502] The claimants first sought relief from the Mexican courts, which upheld the invalidation, and then initiated the NAFTA arbitration. Once in arbitration, the claimants directed their complaints *only* at the administrative agency that granted the concession — *i.e.*, the claimants "raised no complaints against the Mexican courts" and did "not allege a denial of justice."[503] The tribunal concluded that the claimant's failure to challenge the actions of the Mexican courts was fatal to their claim.[504] But, the tribunal explained, even if the claimants *had* alleged a denial of justice, the claim would have failed because the Mexican judgments did not satisfy that standard.[505]

251. In other words, *Azinian* in no way detracts from the proposition that a judicial measure may constitute an expropriation by violating a substantive rule

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[501] *See 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 [hereinafter *Rumeli v. Kazakhstan*] (observing that "the final act of 'taking' … was the decision of the Presidium of the Supreme Court," and noting that "the decision was made 'for a public purpose'" and that "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). Canada seeks to distinguish *Rumeli* by arguing that "subsequent tribunals have observed that the *Rumeli* tribunal's finding was based on 'collusion between the State and claimants' competitor, which collusion was then effected through court proceedings.'" Resp. CM at n.587. But the improper collusion found by the *Rumeli* tribunal was limited to Kazakhstan's "Investment Committee" and Rumeli's competitor, "Telecom Invest" — *i.e.*, it did *not* involve the Kazakh court proceedings through which the investment was ultimately expropriated. *Rumeli v. Kazakhstan*, at ¶ 715 (CL-58). *Rumeli* accordingly belies Canada's argument that a finding of expropriation based on a judicial measure necessarily presupposes a denial of justice in the court proceedings themselves.

[502] *Azinian v. Mexico*, at ¶ 87 (CL-61).

[503] *Id.* at ¶ 100.

[504] *Id.*

[505] *Id.* at ¶¶ 101-120.

of international law. There was no reason for the tribunal to analyze this scenario in *Azinian* because there was no apparent international norm that the Mexican judgments could have breached and none was asserted by the claimants. The only theory of potential liability given the record before the tribunal was denial of justice, which was why the tribunal analyzed that theory. Here (unlike in *Azinian*), Lilly *is* challenging the decisions of the Canadian courts that applied the promise utility doctrine to invalidate Lilly's patents, and Lilly *has* identified a substantive international norm (NAFTA Chapter 17) that Canada's measures have violated.

252. The other cases cited by Canada are inapposite for the same reason. Canada quotes, for example, the tribunal's observation in *Loewen v. United States* that "[i]n the circumstances of this case, a claim alleging an appropriation in violation of Article 1110 can succeed only if *Loewen* establishes a denial of justice under Article 1105."[506] But that was only because the claimants' theory of expropriation was rooted in the same allegations of procedural unfairness as its claim for a denial of justice under Article 1105 — namely, a proceeding tainted by nationality-based, racial and class-based testimony that was insulated from appellate review by an arbitrary bonding requirement.[507] Like *Azinian*, *Loewen* simply did not address the theory of expropriation at issue here.[508]

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[506] Resp. CM at ¶ 320 (quoting *Loewen Grp., Inc. & Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Award (26 June 2003), at ¶ 141 [hereinafter *Loewen v. United States*]).

[507] *See id.*; *see also Loewen v. United States*, at ¶ 39 (summarizing the various aspects of claimants' claim) (RL-13). Canada's citation of Judge Greenwood's expert witness statement from *Loewen* is inapposite for the same reason. Resp. CM at ¶ 319. Canada quotes Judge Greenwood as observing that "*in the present case* the expropriation claim is another aspect of the denial of justice." *Loewen v. United States*, Opinion of Christopher Greenwood Q.C., 26 March 2001, at 10 (internal quotation marks omitted and emphasis added) (RL-25). Thus, Judge Greenwood's comments were closely tethered to the particular circumstances of that case.

[508] The same is true of *Arif v. Moldova* and *Liman Caspian v. Kazakhstan*, both cases on which Canada relies. *See* Resp. CM at ¶ 324 (quoting *Arif v. Republic of Moldova*, ICSID Case No. ARB/11/23, Award (8 April 2013), at ¶¶ 415-416 [hereinafter *Arif v. Moldova*]); Resp. CM at ¶ 325 (quoting *Liman Caspian Oil BV & NCL Dutch Invest. BC v. Republic of Kazakhstan*, ICSID Case No. ARB/07/14, Award (22 June 2010), at ¶ 431 [hereinafter *Liman Caspian v. Kazakhstan*]). In both *Arif* and *Liman* (continued…)

253. There is, in short, substantial support for the conclusion that denial of justice is not a prerequisite for a finding of expropriation based on a judicial measure. Tribunals have considered a wide range of considerations to "distinguish between a compensable expropriation and a non-compensable regulation by a host State," including whether the measure has violated a substantive norm of international law.[509] And while Canada has cited cases in which denial of justice was a relevant consideration to the expropriation analysis on the facts of the particular case, Canada can point to *no* arbitral award finding that denial of justice is *always* a requirement for a finding of expropriation, or that a substantive violation of international law is insufficient to establish that a judicial measure is expropriatory.

### 2. Article 1110(7) Establishes that Patent Revocations in Violation of NAFTA Chapter 17 are Expropriatory.

254. For the reasons discussed above, customary international law recognizes that judicial measures may be expropriatory even if they do not constitute a procedural denial of justice. But even if Canada's argument to the contrary had merit (it does not), Article 1110(7) of NAFTA provides a fully sufficient and treaty-specific basis for concluding that judicial revocations of patents in substantive violation of NAFTA Chapter 17 are expropriatory, irrespective of whether the revocation was procedurally fair to the patent holder.

255. Article 1110(7) 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)." Lilly has previously

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*Caspian*, the claimants' position was that the misapplication of municipal law by the host state courts amounted to an expropriation, and in both cases the tribunal rejected the claim in an absence of a denial of justice. *See Arif v. Moldova*, at ¶ 415 ("Claimant's position in essence is rather that the actual misapplication of Moldovan law by the courts amounts to expropriation.") (RL-63); *Liman Caspian v. Kazakhstan*, at ¶ 431 (RL-27). As discussed above, Lilly's expropriation claim is based, *inter alia*, on Canada's violation of *international law*. *Arif* and *Liman Caspian* are accordingly inapposite on this point.

[509] *Fireman's Fund Ins. Co. v. The United Mexican States*, ICSID Case No. ARB(AF)/02/01, Award (17 July 2006), at ¶ 176(j) [hereinafter *Fireman's Fund v. Mexico*] (CL-45).

shown that "[b]y its plain implication, Article 1110(7) provides that revocations of intellectual property rights that *violate* Chapter 17 qualify as expropriations."[510]

256. In its Counter-Memorial, Canada maintains that "Article 1110(7) clarifies that an expropriation claim cannot even be brought in the context of intellectual property rights barring inconsistency with Chapter Seventeen."[511] According to Canada, in other words, Article 1110(7) is an "additional hurdle" to a finding of liability and does not imply that judicial measures in violation of Chapter 17 are expropriatory.[512] Yet Canada cites no authority for this narrow interpretation, which is contradicted by the plain language of the provision and the decision of the one arbitral tribunal that has addressed a related provision of NAFTA: Article 1110(8).[513]

257. Similar to Article 1110(7), Article 1110(8) of NAFTA provides that "[f]or purposes of this Article and for greater certainty, a non-discriminatory measure of general application shall not be considered a measure tantamount to an expropriation of a debt security or loan covered by this Chapter solely on the

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[510] Cl. Mem. at ¶¶ 184, 241. *See also* 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).

[511] Resp. CM at ¶ 345.

[512] *Id.*

[513] Canada cites one treatise, but it offers no support to Canada's interpretation of Article 1110(7). Resp. CM at ¶ 345 & n.592 (citing M. Kinnear, A. Bjorklund & J. Hannaford, INVESTMENT DISPUTES UNDER NAFTA: AN ANNOTATED GUIDE TO NAFTA CHAPTER 11 1110-1157 (Kluwer: 2006)). This treatise merely concludes that without Article 1110(7), "one can imagine an investor claiming [that] the revocation . . . of intellectual property rights effectively expropriated its investment" and that "[p]resumably the drafters of NAFTA included Article 1110(7) to avoid any such argument." M. Kinnear, A. Bjorklund & J. Hannaford, INVESTMENT DISPUTES UNDER NAFTA: AN ANNOTATED GUIDE TO NAFTA CHAPTER 11 (Kluwer: 2006) (R-343). But Article 1110(7) does not carve out *all* revocations of intellectual property rights from the scope of Article 1110 — only revocations that are *consistent* with Chapter 17. By expressly conditioning Article 1110(7) on compliance with Chapter 17, the NAFTA Parties were distinguishing measures that engaged Article 1110 from those that did not.

ground that the measure imposes costs on the debtor that cause it to default on the debt." In *Waste Management v. Mexico*, the tribunal explained that

> Evidently the phrase "take a measure tantamount to nationalization or expropriation of such an investment" in Article 1110(1) was intended to add to the meaning of the prohibition, over and above the reference to indirect expropriation. *Indeed there is some indication that it 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 even 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".*[514]

258. *Waste Management* is flatly inconsistent with Canada's view of Article 1110(7) as an "additional hurdle" that does not imply anything about the circumstances in which the revocation of a patent can constitute an expropriation. As the tribunal in *Waste Management* recognized, when NAFTA's drafters carved out a category of measures from Article 1110 in only certain circumstances, they implied that such measures otherwise could fall within the scope of Article 1110. If anything, this implication is *stronger* with respect to Article 1110(7) than 1110(8), since Article 1110(7) lacks the "for greater certainty" clause that gave the *Waste Management* tribunal pause.[515]

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[514] *Waste Management v. Mexico*, at ¶ 144 (emphasis added) (CL-65).

[515] Canada's proposed interpretation of Article 1110(7) is also undermined by the position it has taken in the negotiation of the Comprehensive Trade and Economic Agreement (CETA) between Canada and the European Union. Canada originally sought the following provision: "For greater certainty, this Article does not apply to a decision by a court, administrative tribunal, or other governmental intellectual property authority, limiting or creating an intellectual property right, *except where the decision amounts to a denial of justice or an abuse of right*." *See* EU Canada FTA Negotiations: Investment Chapter, Trade B2/CBA/cg/Ares 1151153 (7 April 2014) (emphasis added) (C-386). It would appear that the European Union rejected this proposal, as it does not appear in the CETA final text. Rather, CETA incorporates a different formulation: "For greater certainty, the revocation, limitation or creation of intellectual property rights to the extent that these measures are consistent with TRIPS and Chapter X (Intellectual Property) of this Agreement, (continued…)

### 3. Canada's Measures Violate Chapter 17 of NAFTA.

#### a) Canada's Measures Violate NAFTA Article 1709(1) Because Canada Revoked Lilly's Patent Rights Even Though the Zyprexa and Strattera Patents Met the "Capable of Industrial Application" Criterion.

259. As explained in Lilly's Memorial, Chapter 17 of NAFTA sets forth the obligations of the NAFTA parties with respect to protecting intellectual property rights. Under Article 1709(1), 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."[516] NAFTA thereby establishes a mandatory obligation that Canada, the United States, and Mexico make patents available for inventions that meet these three requirements.[517]

260. Canada's measures violate Article 1709(1) because Canada revoked Lilly's patent rights even though the Zyprexa and Strattera patents met the "capable of industrial application" criterion set out in Article 1709(1).[518] As commonly understood at the time the treaty was concluded, "capable of industrial application" in the patent context is a low threshold requiring that an invention

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do not constitute expropriation. *Moreover, a determination that these actions are inconsistent with the TRIPS Agreement or Chapter X (Intellectual Property) of this Agreement does not establish that there has been an expropriation*." Canadian Department of Foreign Affairs, Trade, and Development, CETA Final Text, at Art. X.11(6) (emphasis added) (C-387). The NAFTA Parties could have included either of these formulations in NAFTA, but they opted for Article 1110(7) instead.

[516] NAFTA, Art. 1709(1) (emphasis added) (CL-44). Article 1709(1) also states that "a Party may deem the terms 'inventive step' and 'capable of industrial application' to be synonymous with the terms 'non-obvious' and 'useful', respectively." *Id.* Because "capable of industrial application" is synonymous with "useful," the terms can be used interchangeably to refer to Canada's obligation under Article 1709(1). Even if that were not the case, the meanings of both terms individually support Lilly's proposed interpretation of Canada's obligation, as explained below.

[517] NAFTA also allows Parties to exclude inventions from patentability under specific enumerated exceptions. *See* NAFTA, Art. 1709(2) & (3) (CL-44). Canada does not argue that Lilly's patents at issue fell within one of these permitted exceptions.

[518] Canada does not dispute that the Zyprexa and Strattera patents met the other patentability requirements in Article 1709(1) of being new and resulting from an inventive step.

have the capacity or ability to be put to a specific or practical use in industry.[519] While Canada retains a "mere scintilla" utility test that is consistent with this "capable of industrial application" criterion, Canada's promise utility doctrine places an *additional* requirement on inventors above and beyond the "capable of industrial application" standard set forth in NAFTA. This additional requirement has deprived Lilly and others of patent rights that Canada was obligated to award and maintain under NAFTA.

261. Canada has not put forward a satisfactory explanation as to how its promise utility doctrine complies with its NAFTA obligation to make patents available for inventions that are "capable of industrial application." Canada's primary defense is that the language of Chapter 17 "was never meant to impose on the NAFTA parties a unique and specific obligation to grant patents";[520] that "utility" and "industrial applicability" "bear a range of meanings, reflecting their diverse usages in various national patent law systems";[521] and that "the term 'utility' can therefore reasonably be informed by the various national definitions,"[522] including Canada's new promise utility doctrine. In essence, Canada argues that the terms in Chapter 17 have no meaning and that Canada is free to interpret its obligations as it sees fit.

262. Unfortunately for Canada, its interpretation is squarely incompatible with the Vienna Convention on the Law of Treaties ("Vienna Convention"), Article 31(1) of which provides that a "treaty shall be interpreted 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."[523] In this case, these straightforward interpretative principles are all the Tribunal needs to conclude that "capable of industrial application" is a simple, threshold inquiry that is

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[519] *See supra* Parts I.D, II.C.

[520] Resp. CM at ¶ 352.

[521] *Id.* at ¶ 358.

[522] *Id.* at ¶ 361.

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

irreconcilable with the additional patentability requirement imposed by the promise utility doctrine. *Infra* Part IV.B.3(1). This interpretation is strengthened by several additional considerations that Vienna Convention Article 31(3) instructs "shall be taken into account, together with the context" of the Treaty, namely: (a) "subsequent practice in the application of the treaty"; and (b) "relevant rules of international law applicable in the relations between the parties." *Infra* Part IV.B.3(2). It is also supported by an analysis under Article 31(4) of the Vienna Convention, which provides that a "special meaning shall be given to a term if it is established that the parties so intended." *Infra* Part IV.B.3(3). Lastly, Lilly's interpretation of Article 1709(1) is confirmed by consideration of "supplementary means of interpretation" under Vienna Convention Article 32. *Infra* Part IV.B.3(4).

**(1) Under the interpretive principles of Vienna Convention Article 31(1), the term "capable of industrial application" is a low threshold requirement that an invention be capable or susceptible of being put to a practical or specific use in industry.**

263. Canada does not offer an interpretation of Article 1709(1) that is informed by Article 31(1) of the Vienna Convention. Instead, Canada sweepingly asserts that it "is plainly in compliance with Article 1709(1) because, as required by that provision, Section 2 of the Canadian *Patent Act* states explicitly that patents are available for inventions in Canada provided they are 'useful.'"[524] According to Canada, the "bare listing of patentability criterion in Article 1709(1) was never meant to impose on the NAFTA Parties a unique and specific obligation."[525] Canada's claim, in other words, is that its only obligation under Article 1709(1) is to have the word "useful" in its domestic patent law.

264. This argument fails at the threshold. The very first clause of Article 31(1) provides that a "treaty shall be interpreted in good faith,"[526] which means

[524] Resp. CM at ¶ 350.

[525] *Id.* at ¶ 352.

[526] Vienna Convention on the Law of the Treaties, Art. 31(3) (CL-66).

that treaties must be interpreted to give their words meaning and effect.[527] NAFTA's choice of "capable of industrial application" and "useful" are not empty terms: they represent a substantive patentability criterion that the NAFTA parties agreed to respect. Article 1709(1) would be rendered superfluous if the patentability criteria listed did not impose *any* obligation on the NAFTA parties. Put differently, an interpretation that bends to whatever new legal regime Canada wishes to adopt cannot be a good faith interpretation of its obligations under Article 1709(1), because such an interpretation imposes no obligation at all.

265. Canada's infinitely flexible reading of Article 1709(1) not only violates the Vienna Convention's cardinal principle of good faith interpretation, it also fails under the remaining interpretative guidelines of Article 31(1).

266. ***Ordinary meaning.*** The starting point for interpreting the ordinary meaning of "capable of industrial application" and "useful" is the text itself: "Interpretation must be based above all upon the text of the treaty."[528] In considering the text of the treaty, dictionary definitions are a logical starting place. Canada claims that Lilly's "reli[ance] on dictionary definitions to support a bare

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[527] *Urbaser S.A. & Consorcio de Aguas Bilbao Biskaia, Bilbao Biskaia Ur Partzuergoa v. Argentine Republic*, ICSID Case No. ARB/07/26, Decision on Jurisdiction (19 December 2012), at ¶ 52 ("Any treaty rule is to be interpreted in respect of its purpose as a rule with an effective meaning rather than as a rule having no meaning and effect. This principle is one of the main features of the law of treaties and has been applied by many ICSID Tribunals. It is given effect within Article 31(1) of the Vienna Convention by virtue of the requirement to interpret in good faith.") (CL-148); *European Media Ventures SA v Czech Republic*, Judgment on Jurisdiction, [2007] EWHC 2851 (Comm), IIC 313 (5 December 2007), at ¶ 36 ("[T]he 'ordinary meaning' is the meaning attributed to those terms at the time the treaty is concluded.") (CL-149); Sir Gerald Fitzmaurice, "The Law and Practice of the International Court of Justice 1951–4: Treaty Interpretations and other Treaty Points," 33 BRITISH YEARBOOK OF INT'L L. 203, 212 (Oxford Univ. Press, 1958) ("The terms of the treaty must be interpreted according to the meaning which they possessed, or which would have been attributed to them, and in light of current linguistic usage, at the time when the treaty was originally concluded.") (CL-150).

[528] *Pope & Talbot Incorporated v Canada*, NAFTA/UNCITRAL, Interim Award (26 June 2000), ¶ 69 (CL-120); *see also Methanex Corp. v. United States of America*, NAFTA/UNCITRAL, Award (3 August 2005), at Part II, Chap. B, ¶ 22 ("'[T]he text of the treaty is deemed to be the authentic expression of the intentions of the parties; and its elucidation, rather than wide-ranging searches for the supposed intentions of the parties, is the proper object of interpretation.'") (quoting YEARBOOK OF THE INT'L L. COMM'N, 1966, Vol. II, p. 223, ¶ 18) (CL-48).

definition of the terms" is "not a 'good faith' interpretation in the context of Chapter 17."[529] Yet tribunals have often turned to dictionary definitions of words to cast light on their ordinary meaning.[530] In other arbitrations, Canada itself has proposed looking to dictionary definitions to help discern a term's ordinary meaning.[531] Lilly never argued that dictionary definitions are the *only* source that can be considered in interpreting "capable of industrial application," but they are clearly one relevant source and a reasonable starting point.

267. Canada does not challenge the dictionary definitions offered by Lilly beyond deeming them irrelevant because a term may have more than one meaning.[532] Nor does Canada identify *any* dictionary definitions that support an interpretation of Article 1709(1) that could encompass the additional patentability requirement of the promise utility doctrine. There is a reason that Canada eschews dictionary definitions: they uniformly support the proposition that "capable of industrial application" and "useful" mean that an invention has the capacity or ability to be put to a specific or practical use in industry. The definition of "useful" in the Oxford English Dictionary, for example, contains the

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[529] Resp. CM at ¶ 359.

[530] *See, e.g.*, *MTD Equity Sdn. Bhd. and MTD Chile S A. v. Republic of Chile*, ICSID Case No. ARB/01/7, Award (25 May 2004), at ¶ 113 (quoting the Concise Oxford Dictionary of Current English) (CL-151); *ADF Group Inc. v. United States*, ICSID Case No. ARB(AF)/00/1, Award (9 January 2003), at ¶ 161 (Webster's New Twentieth Century Dictionary of the English Language) (RL-5); *ADF Group Inc. v. United States*, ICSID Case No. ARB(AF)/00/1, Procedural Order No. 2 (1 July 2001), at ¶ 20 (Black's Law Dictionary) (CL-9); *Marvin Feldman v. Mexico*, NAFTA/ICSID Case No. ARB(AF)/99/1, Award (16 December 2002), at ¶ 96 (Webster's New Collegiate Dictionary) (CL-109); *S.D. Myers, Inc. v. Government of Canada*, NAFTA/UNCITRAL, Partial Award (13 November 2000), at ¶ 285 (The Oxford English Dictionary) (RL-76); *see also Mobil Investments Canada Inc. and Murphy Oil Corp. v. Canada*, ICSID Case No. ARB/07/4, Decision on Liability and on Principles of Quantum (22 May 2012) ("It is appropriate to begin with ordinary meaning. There is no disagreement between the Claimants and the Respondent that the ordinary meaning may be ascertained by reference to reputable dictionaries, which include the Oxford English Dictionary and Webster's New International Dictionary (as referred to by the United States).") (CL-112).

[531] *See, e.g.*, Panel Report, *Canada - Measures Affecting the Importation of Milk and Exportation of Dairy Products*, WTO Doc. No. WT/DS103/R (17 May 1999), ¶ 4.369 ("Canada argued that to establish ordinary meaning, some guidance could be obtained from authoritative dictionaries.") (CL-152).

[532] Resp. CM at ¶ 359 (citing *Agual del Tunari, S A. v. Republic of Bolivia* for the proposition that "[t]he meaning of a word or phrase is not *solely* a matter of dictionaries") (emphasis added).

concept of "capable of," defining "useful" as "*capable* of being put to good use" or "*suitable* for use."[533] The Merriam-Webster Dictionary similarly defines "useful" as "*capable* of being put to use" and "serviceable for *an* end or purpose."[534] Further, the term "useful arts" is defined by the Oxford English Dictionary as the "industrial arts."[535] These dictionary definitions confirm that the plain meaning of "capable of industrial application" and "useful" is that an invention is capable of being put to a use in industry.[536]

268. ***Context.*** Article 31(1) next provides that the terms of a treaty should be interpreted "in their context." Canada states, and Lilly agrees, that "[t]he terms 'capable of industrial application' and 'utility' included in Article 1709 of NAFTA must . . . be interpreted in the particular context of the subject matter of Chapter Seventeen, *i.e.* intellectual property law."[537] In this regard, the terms "capable of industrial application" and "useful" are legal terms of art in the intellectual property field. As such, the meanings of these terms should be informed by the definitions of these terms in an intellectual property context, which can be ascertained by looking to Black's Law Dictionary.[538] Under Black's Law dictionary, the legal definition of "useful" is "(of an invention) having *a practical application*."[539] This legal definition comports with the ordinary meanings of "useful" and "capable of industrial application" as requiring an invention to have

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[533] *Id.* (emphases added).

[534] "Useful," Merriam Webster Dictionary Online, http://www.merriam-webster.com/dictionary/useful (September 2015) (CL-153). "*Utility*" is defined in a similar manner as "fitness for *some* purpose or worth to *some* end." *See* "Utility," Merriam Webster Dictionary Online, http://www.merriam-webster.com/dictionary/utility (September 2015) (CL-164).

[535] "Useful Arts," OED Online, Oxford University Press (September 2015) (CL-154).

[536] While Article 1709(1) itself provides "a Party may deem the term[] . . . 'capable of industrial application' to be synonymous with the term[] … 'useful,' one reaches the same conclusion based on the ordinary meaning of the terms.

[537] Resp. CM at ¶ 360.

[538] Canada does not refute the relevance of Black's Law Dictionary for interpreting "useful" within its patent law context.

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

the capacity to attain *a* practical use in industry.[540] Thus, the intellectual property context of Article 1709(1) helps inform the ordinary meaning of the treaty text.[541]

269. Canada's contextual argument, in contrast, inappropriately leaves NAFTA behind and focuses on "the various national definitions recognized by WIPO, including Canada."[542] This is not "context" for purposes of interpreting NAFTA. When interpreting NAFTA Article 1709(1), WIPO documents and international harmonization efforts among WIPO member states are not relevant treaty "context" under Article 31(1) of the Vienna Convention, but, rather, if considered at all, are more appropriately viewed as supplementary means of interpretation under Vienna Convention Article 32. In any case, as discussed below, the WIPO documents to which Canada refers do not support Canada's suggestion that "capable of industrial application" and "useful" in NAFTA Article 1709(1) have no agreed meaning and are only to be defined by each NAFTA signatory in a domestic context.

270. Canada also argues that "[t]he absence of definitions of these terms again provides important context," demonstrating that the NAFTA parties intended to have "flexibility" in their interpretation.[543] Canada is mistaken. The absence of definitions of "capable of industrial application" and "useful" within NAFTA does not bestow upon NAFTA parties endless discretion in interpreting and implementing their Article 1709(1) obligations. To the contrary, the absence

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[540] Cl. Mem. at ¶ 195; *see* Black's Law Dictionary (9th ed. 2009) (CL-71). Other panels have also referred to specialized dictionaries to confirm the ordinary meaning of a term within a technical context. For example, a WTO panel confirmed the ordinary meaning of the term "interconnection" by looking at its specialized meaning within the telecommunications context, including by consulting a specialized dictionary. Panel Report, *Mexico – Measures Affecting Telecommunications Services*, WTO Doc. WT/DS204/R (2 April 2004), at ¶¶ 7.108-7.110 (CL-69).

[541] As discussed above, the context of Article 1709(1) also includes the limited exceptions to patentability in Articles 1709(2) and 1709(3). These articles serve as relevant "context" for interpreting Article 1709(1) and establish that the obligation in 1709(1) is a substantive baseline, subject to explicitly enumerated carve outs.

[542] Resp. CM at ¶ 361.

[543] *Id*. at ¶ 367.

of definitions for "useful" and "capable of industrial application" simply means that the Tribunal should look to the principles of treaty interpretation in Article 31 and 32 of the Vienna Convention to interpret these terms.[544]

271. More fundamentally, Canada confuses the latitude that Chapter 17 gives to parties in *implementing* obligations under NAFTA with the interpretation of the obligation itself.[545] That NAFTA parties have leeway in choosing how to implement a treaty obligation does not mean that parties may alter what the obligation is (or interpret an obligation out of existence). Article 1702 of NAFTA provides that a party "may implement in its domestic law *more* extensive protection of intellectual property rights than is required"[546] under Chapter 17, but *less* extensive protection is not permitted. This provision represents an essential component of the "context" of Article 1709(1). The promise utility doctrine, by adding an additional utility requirement to pharmaceutical patents, contravenes this contextual requirement by providing less protection than the baseline set forth in NAFTA Article 1709(1).[547]

272. ***Object and purpose.*** Lastly, Article 31(1) of the Vienna Convention requires that a term be interpreted in light of the object and purpose of the treaty. Canada offers no explanation for how its infinitely flexible interpretation of "capable of industrial application" is consistent with the object and purpose of

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[544] *See* Panel Report, *Canada – Measures Affecting the Importation of Milk and Exportation of Dairy Products*, WTO Doc. No. WT/DS103/R (17 May 1999), at ¶ 4.368 ("In the absence of a definition, recourse had to be made to the principles of treaty interpretation in customary international law, as expressed in Articles 31 and 32 of the Vienna Convention.") (CL-152).

[545] Resp. CM at ¶¶ 370-372.

[546] *See* NAFTA, Art. 1702 (emphasis added) (CL-44).

[547] The same is true of another relevant contextual provision, Article 1701(2), which states: "To provide adequate and effective protection and enforcement of intellectual property rights, each party shall, at a minimum, give effect to this Chapter and to the substantive provisions of" four core IP treaties. The plain implication of this provision is that each NAFTA Party is required to give effect to the "substantive provisions" of Article 1709(1) *in addition to* the substantive provisions of the enumerated IP treaties. In other words, Article 1701(2) is further confirmation that Article 1709(1) was intended to afford a substantive floor of patent protection.

NAFTA.[548] Instead, Canada states that it has a "world-class system of patent registration,"[549] as if this non sequitur should somehow demonstrate that Canada is living up to its obligations under Article 1709(1) in light of NAFTA's object and purpose.

273. Canada's failure to account for NAFTA's object and purpose reflects its inability to do so. The object and purpose of NAFTA (as stated in the Preamble and NAFTA Article 102(d)) is to promote innovation and investment and provide "adequate and effective protection and enforcement of intellectual property rights."[550] Contrary to these principles, Canada's proposed interpretation of Article 1709(1) is arbitrary and, as such, does not provide for a predictable commercial framework for innovation and investment. Canada's interpretive view, that Article 1709(1) "was never meant to impose on the NAFTA parties a unique and specific obligation to grant patents,"[551] runs counter to the object and purpose of NAFTA to *provide adequate and effective protection and enforcement of intellectual property rights*. Having a "world-class" system of registration is meaningless if Canada can revoke an inventor's intellectual property rights in an arbitrary manner on the basis of an additional utility requirement that goes beyond the "capable of industrial application" standard explicitly referenced in the treaty text.

**(2) Considering the criteria set forth in Article 31(3) lends additional support to the ordinary meaning analysis of "capable of industrial application."**

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[548] Under Article 31(1) of the Vienna Convention, the terms of a treaty must be interpreted in light of the treaty's object and purpose. *See* Vienna Convention on the Law of the Treaties, Art. 31(1) (CL-66).

[549] Resp. CM at ¶ 374. Canada's touting of its "world-class" system also is in tension with Canada's statements that the Patent Office lacks the resources to conduct meaningful substantive reviews and that Lilly should not have relied on the Patent Office's decision to grant its patents. Resp. CM at ¶¶ 70-72, 80.

[550] NAFTA Preamble (CL-44); NAFTA Art. 102(d) (CL-44); *see* Cl. Mem. at ¶ 190; *see also* Resp. CM at ¶ 374.

[551] Resp. CM at ¶ 352.

274. Article 31(3) of the Vienna Convention identifies additional considerations, which "shall be taken into account, together with the context," when interpreting a treaty, including "(b) Any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation"; and "(c) Any relevant rules of international law applicable in the relations between the parties."[552] These considerations lend further support to the conclusion — reached as a result of a good faith interpretation under Vienna Convention Article 31(1) — that the term "capable of industrial application" in Article 1709(1) NAFTA requires only that an invention have the capacity or ability to be put to a single specific or practical use in industry.

275. ***Subsequent practice***. Canada does not dispute that the subsequent practice of the NAFTA parties is relevant to the interpretation of Article 1709(1). Canada argues, however, that "the subsequent practice [of the three NAFTA parties] is fundamentally at odds with Claimant's implausible notion of a fixed standard 'enshrined' in the NAFTA text."[553] Canada's argument, however, disregards two key facts: first, that the United States, Mexico, and Canada all had a consistently low requirement for utility and industrial applicability after the conclusion of NAFTA;[554] and second, that, Canada's patent law at the time NAFTA was enacted did not include the promise utility doctrine.[555] As discussed *supra* in Part II and by Professor Siebrasse and Mr. Wilson in their expert reports, the promise utility doctrine is a new doctrine that fundamentally changed the Canadian law on utility from 2005 onwards.[556] As reflected in the 1998 Manual of Patent Office Practice, Canada's own subsequent practice until the introduction of the promise doctrine in 2005 required only that an invention have "*a practical*

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[552] Vienna Convention on the Law of the Treaties, Art. 31(3) (CL-66).

[553] Resp. CM at ¶ 376.

[554] *See* Cl. Mem. at ¶¶ 198-201; *see supra* Part II.C.

[555] *See supra* Part II.A-B.

[556] *See id.*; Siebrasse Second Report at ¶¶ 3-12; Wilson Second Report at ¶¶ 27-37.

*application*" and be "more than a mere scientific principle or abstract theorem."[557] Moreover, the fact that the United States and Mexico have maintained utility and industrial applicability requirements that are consistent with the ordinary meaning of "capable of industrial application" in Article 1709(1) undercuts Canada's assertion that the provision imposes no substantive baseline of protection.

276. ***Relevant rules of international law***. Lilly's Memorial demonstrated that the definition of "industrial applicability" in the Patent Cooperation Treaty (PCT) is a relevant rule of international law that should be taken into account when interpreting NAFTA Article 1709(1). Canada disagrees, arguing that the PCT definition of industrial applicability is not a relevant rule of international law because the PCT is a procedural and not substantive patent law treaty.[558] But this distinction misses the point: the PCT is a major patent-related treaty *that defines the concept at issue in this case* and was signed by the NAFTA parties.[559] It is accordingly highly relevant to how the basic concept of utility was understood by the NAFTA parties.

277. Canada also argues that the PCT definition of "industrial applicability"[560] is irrelevant because it is different from the phrases "capable of

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[557] Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, §§ 16.02.01, 16.03 (March 1998) (C-57). *See supra* Parts II.B.1-2 (tracking post-2005 changes in the MOPOP and demonstrating that they resulted from new jurisprudence).

[558] Resp. CM at ¶¶ 378-380.

[559] *See* Erstling Second Report at ¶ 18 (explaining that "[w]hile the PCT does not harmonize substantive patent law, the definition of industrial applicability in the PCT and Examination Guidelines is instructive as to the commonly held international understanding of the requirement"); *see also id.* at ¶ 22 ("In my experience, the PCT definition of industrial applicability . . . is non-controversial.").

[560] Article 33(4) of the PCT defines "industrial applicability" as "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." Patent Cooperation Treaty, 28 U.S.T. 7645, 7679 (1976-77), art. 33(4) (CL-73). This PCT definition is focused on plausible industrial applicability, not demonstrated usefulness.

industrial application" and "utility" in NAFTA 1709(1).[561] The fact that the PCT uses the shorter formulation of "capable of industrial application" does not diminish its relevance. Canada itself has acknowledged this. In a 2013 Examiners' Bulletin addressed to Canadian patent examiners, the Canadian Patent Office expressly recognized that "the term 'industrial applicability' may be viewed synonymously with the national practice term 'utility,'" and merely requires that the invention "have a practical 'real-world' context."[562] According to the Bulletin, an invention can be denied for lack of industrial applicability under the PCT only when it "is clearly non-operable in view of well-established laws of nature, and has no application in industry or is not useful for any purpose."[563]

278. In short, because NAFTA Article 1709(1) itself recognizes that "capable of industrial application" and "useful" are synonymous, the PCT definition of "industrial applicability" informs the interpretation of both terms.

**(3) Considering "capable of industrial application" as a concept with a "special meaning" under Vienna Convention Article**

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[561] Resp. CM at ¶ 381. The formalistic nature of Canada's argument is underscored by the nomenclature that Canada itself has used. Canada refers repeatedly to "utility" in its Counter-Memorial in discussing the content of Article 1709(1). *See, e.g.*, Resp. CM at ¶ 354 ("In reality, Claimant is advocating a highly specific and self-serving definition of the terms 'capable of industrial application' and 'utility.'"); *id.* at ¶ 355 ("But in any event, Claimant goes far beyond this, loading the term "utility" with an array of specific content."); *id.* ¶ 356 ("All of these specific rules are, according to Claimant, imposed upon Canada through the simple and undefined reference to 'utility' or in the alternative 'industrial applicability' in Chapter Seventeen of NAFTA."); *id.* at ¶ 360 ("Claimant itself acknowledges that 'capable of industrial application' and 'utility' are terms of art in the intellectual property context."); *id.* at ¶ 381 ("Claimant has no basis for arguing that the PCT's definition of 'industrial applicability' is relevant, let alone consistent with, the 'capable of industrial application' and 'utility' criteria in NAFTA Article 1709(1), which are in any event undefined."). NAFTA does not use the word "utility," but instead uses the word "useful." Canada does not object to the interchangeability of "useful" and "utility."

[562] CIPO, Examiners' Bulletin (October 2013), [Canada Doc. No. 561, at 061114] (C-388).

[563] *Id.* Canada's objection to the relevance of the PCT definition likely reflects the divergence between that definition and Canada's practice — a conflict that CIPO itself recognizes. The 2013 Bulletin emphasizes that "[e]xaminers should refrain from applying the national practice of 'sound prediction' or 'predicted utility' during international examination since these are concepts stemming from national jurisprudence and do not apply to the PCT." *Id.*

**31(4) is consistent with the analysis under Article 31(1).**

279. Lacking a substantial response to Lilly's analysis under Article 31(1), Canada argues that Lilly is advocating for a special meaning under Article 31(4) of the Vienna Convention. Canada begins its response on Chapter 17 by arguing that "[i]n reality, Claimant is advocating a highly specific and self-serving definition of the terms 'capable of industrial application' and 'utility,' contrary to the ordinary measures of the terms — that is, a 'special meaning' under Article 31(4) of the Vienna Convention."[564] The intended effect of this argument is unclear, since Article 31 does not create a hierarchy; Articles 31(1) and 31(4) are equally valid means of treaty interpretation. In any case, whether the term "capable of industrial application" is given its ordinary meaning within the patent law context or ascribed a "special meaning" as a term of art in patent law, the result is the same.

280. As mentioned above, Canada acknowledges that "capable of industrial application" and "useful" are "terms of art" in intellectual property law.[565] To the extent "capable of industrial application" and "useful" have a "special meaning" under Article 31(4), it is their technical meaning as patent law terms of art. As a WTO panel found in an analogous context, when a treaty term "is a technical one that is in common use in its field," the treaty "parties can be presumed to have been aware of" that technical meaning.[566] That is precisely the case here. The negotiators of the intellectual property provisions of NAFTA had knowledge pertaining to the subject matter of the treaty provisions they were negotiating. They chose the terms "capable of industrial application" and "useful" — both terms of art in the patent law context. Then, in recognition of the fact that some countries implement the utility criterion through a "capable of industrial

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[564] Resp. CM at ¶ 354.

[565] *Id.* at ¶ 360 ("Claimant itself acknowledges that 'capable of industrial application' and 'utility' are terms of art in the intellectual property context.").

[566] Panel Report, *Mexico – Measures Affecting Telecommunications Services*, WTO Doc. WT/DS204/R (2 April 2004), at ¶ 7.169 (CL-69).

application" requirement and others through a "useful" requirement, the NAFTA parties agreed that the two concepts may be deemed synonymous. This provision makes sense only if one starts from the premise that the NAFTA parties intended the terms "capable of industrial application" and "useful" to have their special technical meaning.

281. Canada nevertheless argues that Lilly seeks to ascribe a "special meaning" *beyond* the technical meaning by "loading the term 'utility' with an array of specific content," including that (1) "assertions of utility set out in the patent shall have no weight, even where such assertions go to the core of the invention;" (2) "normal principles of patent construction do not apply with regard to such assertions of utility;" (3) "evidence produced years after filing must be taken into account when considering whether an applicant had a valid basis to claim a particular utility at the time that it filed its patent;" (4) "such evidence must be taken at face value and not subject to court scrutiny on the basis of expert testimony;" and (5) "disclosure of the basis of a predicted utility cannot be required in patent specifications."[567] Canada claims that Lilly failed to prove that the Parties intended the term "utility" to contain all these "specific rules."[568] But Canada has incorrectly stated Lilly's position.

282. Lilly seeks to have the terms "capable of industrial application" and "useful" applied using their straightforward and simple meaning that an invention must have the capacity for a specific or practical use in industry. Nowhere in its Memorial or this Reply does Lilly seek to imbue the term "utility" with additional rules as Canada alleges. Notably, Canada does not provide any citations for its claim that Lilly "ascribe[s] a range of rules" to the terms in Article 1709(1).[569]

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[567] Resp. CM at ¶ 355.

[568] *Id.* at ¶ 356.

[569] *Id.* at ¶¶ 359, 355.

### (4) Considering supplementary materials of interpretation under Vienna Convention Article 32 further confirm the ordinary meaning of "capable of industrial application."

283. Under Vienna Convention Article 32, the Tribunal may consider supplementary materials of interpretation to confirm the ordinary meaning of "capable of industrial application" and "useful." While Article 1709(1) is sufficiently clear, Lilly nevertheless noted in its Memorial that certain supplementary materials related to the circumstances of NAFTA's conclusion confirmed the ordinary meaning analysis. Lilly identified the concurrent negotiation of the TRIPS Agreement as relevant in this regard.[570]

284. Canada does not rebut Lilly's showing that the TRIPS Agreement negotiating documents — which show that negotiators relied on the PCT Article 33(4) definition under which any invention "can be made or used . . . in any kind of industry" — confirm the ordinary meaning of "capable of industrial application" demonstrated above.[571]

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[570] Cl. Mem. at ¶¶ 204–206.

[571] As explained in Part I.D.2, Canada's insistence that TRIPS does not harmonize substantive patent law is a red herring. Lilly has not argued that patent law is internationally harmonized; rather, Lilly has argued that NAFTA establishes a *baseline* or minimum level of patent protection. *See also* Cl. Mem. at ¶ 205 (showing that "the TRIPS negotiators in Geneva were aware of and relied on the special meaning of industrial applicability set forth in PCT Article 33(4)").

On April 6, 2015, the Tribunal ordered Canada to produce "negotiating memoranda or negotiating drafts" of Chapter 17 of NAFTA and "other responsive documents which become identifiable as a result of such reasonable search." Procedural Order No. 2 - Annex A, p. 57–58. On June 22, 2015, when Canada provided responsive documents to Lilly as ordered by the Tribunal, it confirmed that it has responsive Chapter 17 documents but said: "Canada is currently reviewing these documents and consulting with the United States and Mexico to determine whether all of the Parties agree that the drafts in question are indeed authentic negotiating drafts of Chapter Seventeen . . . . If Canada identifies any additional potentially responsive documents, and if the United States and Mexico agree that such additional documents constitute authentic negotiating drafts that can be released, Canada will do so promptly." Canada Document Product Report Letter of 22 June 2015, at 6. The document request granted by the Tribunal was not limited to "authentic negotiated drafts," but included all "negotiating memoranda or negotiating drafts" and "other responsive documents." Given that nearly three months have passed and Canada has not produced any further documents — and given that Canada lacked any basis for withholding the documents under the Procedural Order or Confidentiality Order — Lilly reserves the right to ask (continued…)

285. Instead, Canada attempts to deflect attention from these supplementary materials by focusing on WIPO negotiations on substantive patent law harmonization.[572] As many of the WIPO discussions referenced by Canada took place well after NAFTA was negotiated, they are not appropriate supplementary means of interpretation to consider with regard to NAFTA Chapter 17. Even if they are considered, the WIPO negotiations referenced by Canada do not support Canada's view that there was no common understanding of "capable of industrial application" and "useful" among the NAFTA parties at the time NAFTA was enacted, and that Canada is therefore free to interpret Article 1709(1) however it wants.[573] What the WIPO negotiations do show is that there was consistent practice among WIPO members with regard to utility, and that because of this common practice, harmonizing the utility requirement across jurisdictions was simply viewed as a low priority among WIPO members.[574]

286. Canada seeks to support its WIPO arguments with the statement of Professor Daniel Gervais, although it is not clear that he was an active participant in any of the patent discussions in the WIPO Standing Committee on the Law of Patents. In any case, Professor Gervais's inferences that the utility requirement was a "hot topic" are unfounded. As Mr. Thomas, who served at WIPO for two decades including as Director of the Patent Policy Department and Senior Director-Advisor (PCT and Patents), explains:

> Industrial applicability (utility) and the other the core substantive patentability requirements are like the planks of a hardwood floor. Consistency in international practice creates a floor of secure rights

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that the Tribunal draw an adverse inference and conclude that these documents confirm the ordinary meaning of "capable of industrial application" put forward by Lilly.

[572] As noted above, Canada inappropriately invokes the WIPO discussions as "context" under Vienna Convention Article 31(1).

[573] Resp. CM at ¶ 362.

[574] *See supra* Part I.D.2; *see also* Thomas Report at ¶¶ 20, 24, 39 (noting the lack of controversy over the industrial applicability (utility) requirement in negotiations over the 1991 Basic Proposal and the SPLT and explaining that "the terms 'utility' and 'industrial applicability' are treated as equally acceptable terms that lead to the same practical outcomes"); Salazar Second Report at ¶ 60.

> that people and companies rely on every day to make decisions. Debates in WIPO focused on gaps between these planks. In other words, the substantive talks focused on issues where there were disparate approaches across jurisdictions, and where resolution of those differences would significantly advance the goal of harmonization and further strengthen the floor. In contrast, commonalities in practice, while relevant, were generally not a focal point of discussion.[575]

287. Canada maintains that during WIPO negotiations between 2000 and 2006 over a proposed substantive patent law treaty (the "SPLT") and certain recent "post-SPLT" negotiations, there was no single, fixed, harmonized definition of utility upon which the parties agreed.[576] Canada argues that there were a range of approaches and that the terms "utility or "industrial applicability" were "not meant to refer to any one specific national definition, or *a fortiori* to the highly specific definition Claimant seeks to impose."[577]

288. Once again, the timing of these negotiations arguably makes them irrelevant to interpreting NAFTA, which was signed in 1992 and entered into force in 1994. In any case, as Mr. Thomas makes clear, while some WIPO countries have an industrial applicability standard and others a "utility" standard, the core substantive requirement was consistently applied by WIPO members.[578] Moreover, as explained at length in Part I.D.2 *supra*, the WIPO documents upon which Canada relies do not support Canada's account of the WIPO negotiations.[579]

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[575] Thomas Report at ¶ 13.

[576] Resp. CM at ¶¶ 189–199, 362.

[577] *Id.* at ¶ 364.

[578] Thomas Report at ¶¶ 11–12. Canada also claims that Lilly seeks to import U.S. patent law into Canada. Resp. CM at ¶ 363. Canada is mistaken. Lilly does not seek to apply U.S. patent law extraterritorially. Rather, Lilly seeks to have the terms "capable of industrial application" and "useful" interpreted based on the *common*, *objective* understanding shared by the NAFTA parties at the time the treaty was enacted.

[579] *See also* Thomas Report at ¶¶ 20, 25, 31 (discussing various SCP documents and noting: "[T]he terms 'utility' and 'industrial applicability' are treated as equally acceptable terms that lead to the (continued…)

289. Quite simply, utility was never a significant issue at WIPO. Attempts by WIPO members to conclude a substantive patent law treaty failed for unrelated reasons, such as disagreement over the "first-to-invent" rule for attribution of inventorship.[580] As Mr. Thomas puts it, the account of WIPO negotiations offered by Canada "simply cannot be squared with the negotiations I observed or participated in during my two decades at WIPO."[581]

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290. Under Vienna Convention Article 31, the Tribunal should consider the text, context, object and purpose, subsequent practice, and relevant rules of international law to interpret the ordinary meaning of the terms "capable of industrial application" and "useful." These sources all show that that the terms in NAFTA Article 1709(1) should be interpreted to mean capable or susceptible of a practical or specific use in industry. If the Tribunal needs to reach supplemental material under Article 32 of the Vienna Convention, these sources confirm the same ordinary meaning of "capable of industrial application" and "useful." Nothing in the interpretive sources under Articles 31 and 32 of the Vienna Convention suggests that these terms were understood by the NAFTA parties to permit Canada to incorporate an additional, onerous utility requirement into the treaty's terms. Instead, "capable of industrial application" was understood to be a low bar, focused on the capacity for an industrial use. Given the proper interpretation of "capable of industrial application" and "useful" under NAFTA Chapter 17, and the fact that Canada has a "mere scintilla" test that meets that basic requirement, Canada's suggestion that Chapter 17 also permits it to require patentees to meet the additional, burdensome promise utility doctrine test must fail.

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same practical outcomes. As such, the linguistic choice between these two terms was not a negotiation priority.").

[580] *See supra* Part I.D.2.

[581] Thomas Report at ¶ 39.

b) **Canada's measures violate NAFTA Article 1709(7) because they discriminate against pharmaceuticals as a field of technology.**

291. As explained in Lilly's Memorial, Article 1709(7) requires that Canada make patent rights available and enjoyable "without discrimination as to the field of technology."[582] The promise utility doctrine, as applied by the Canadian courts, has led to the invalidation of patents for lack of utility *exclusively* in the pharmaceutical sector. Since the introduction of Canada's elevated test in 2005, the courts have not revoked a single patent for lack of utility in any other field of technology.[583]

292. Canada inaccurately characterizes this breach of NAFTA Chapter 17 as "tangential,"[584] relying upon the testimony of Mr. Brisebois, who claims that Lilly's "statistics on alleged utility-based invalidation are misleading in several respects."[585] To the contrary, Lilly's field of technology discrimination claim provides an independent, substantive basis for a finding of expropriation under NAFTA Article 1110. This *de facto* discrimination claim is supported by overwhelming evidence that the promise utility doctrine has had disproportionate effects on the pharmaceutical sector. While Canada has argued that there is no systemic discrimination against pharmaceutical patents under the promise utility doctrine, the analysis of Professor Bruce Levin, a well-respected statistician and former Chair of the Department of Biostatistics at the Columbia School of Public Health, refutes that claim. The disparate impact of Canada's utility standard across sectors since 2005 is not only substantial in magnitude, but as Professor Levin shows, it is also statistically significant and thus highly unlikely to be the

[582] *See* Cl. Mem. at ¶¶ 213-218.

[583] *See supra* Part II.D.2.

[584] Resp. CM at ¶ 305.

[585] Brisebois Report at ¶ 11.

result of mere chance.[586] Canada has offered no credible defense to Lilly's discrimination claim, legally or factually.

293. As to the applicable law, Canada does not dispute that the pharmaceutical sector is a distinct field of technology protected by Article 1709(7). Nor does Canada contest that this NAFTA provision bars *de facto* discrimination as well as *de jure* discrimination. And Canada raises no objection to the traditional legal standard for *de facto* discrimination claims, which requires evidence that a challenged measure has produced "differentially disadvantageous" effects against a specific technical field as compared with other fields of technology.

294. As to the facts, Canada does not, and cannot, dispute that only pharmaceutical patents have been found invalid for lack of utility under the promise utility doctrine. Not a single patent outside the pharmaceutical field has been invalidated under Canada's elevated standard — indeed, not a single patent in any other industrial sector has been ruled to lack utility in the last two decades.[587] Nor does Canada contest that the majority of inutility rulings against pharmaceutical patents were based on the sole ground of lack of utility, such that the promise utility doctrine was the only basis for invalidation.[588]

295. Canada's only response to this clear record of discrimination is a series of unsuccessful attempts to recast the facts. First, Canada suggests that the recent spike in utility litigation "simply reflects" a broader increase in pharmaceutical patent litigation across the board, a change associated with the implementation of PM(NOC) proceedings and other changes in Canadian patent law during the early 1990s.[589] As Figure 1 makes clear, however, the spike in

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[586] Levin Report at ¶ 9 (finding the difference in inutility rates across sectors of 39.7 percentage points to be statistically significant at the one-tailed 0.05 level).

[587] *See* Figure 1, "Annual Number of Canadian Inutility Decisions, 1980 – present" (C-342).

[588] *See* Brisebois Statement at Annex B (identifying 12 of 23 rulings as "[l]ack of utility only").

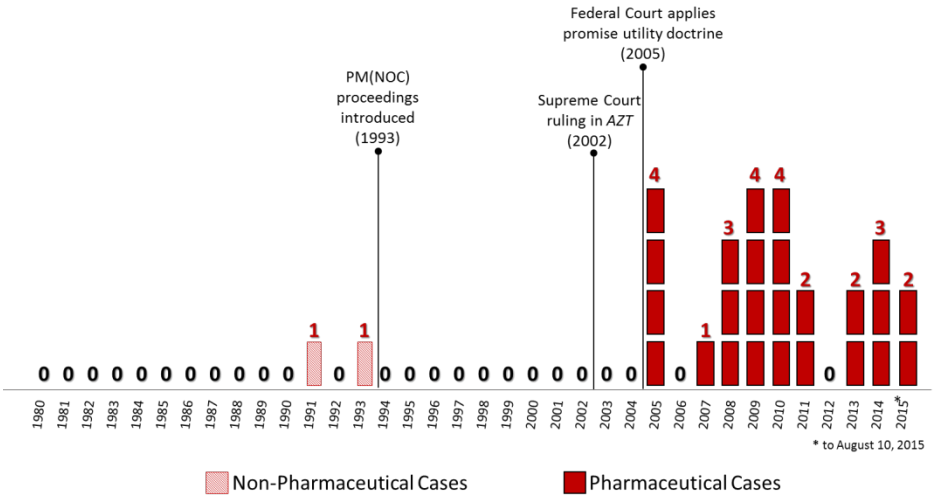
[589] *See* Resp. CM at ¶¶ 138-141.

inutility rulings began only in 2005, more than a decade after the legal reforms to which Canada draws attention.[590]

296. In any event, as Professor Levin explains, the relevant indicator is not the overall *frequency* of invalidity rulings, but rather the *proportion* of successful challenges across sectors:

> Raw frequencies cannot be used to meaningfully analyze the comparative impact of the utility doctrine as between pharmaceutical and non-pharmaceutical patents. To be relevant in statistical analysis, comparisons must be based on proportions rather than frequencies, because increases in the number of patent cases over time make comparisons of raw frequencies unreliable and misleading.[591]

**Figure 1: Canadian Inutility Decisions (1980 – Present)**




297. Testing Canada's alternative account, Professor Levin looked at the subset of cases decided between 1994 and 2004, the decade that followed the introduction of PM(NOC) proceedings and other patent law reforms in Canada. With respect to challenges based on utility and other grounds in that time period,

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[590] *See* Figure 1, "Annual Number of Canadian Inutility Decisions, 1980 – present" (C-342).

[591] *See* Levin Report at ¶ 23.

Professor Levin found no statistically significant differences in invalidity rates between the pharmaceutical sector and other sectors. As a result, Professor Levin explains that the pre-2005 increase in pharmaceutical litigation emphasized by Canada is of no consequence:

> [E]ven considering only those cases decided after the introduction of the PM(NOC) process, I found no statistically significant difference between invalidity rates for pharmaceutical and non-pharmaceutical patents on any ground (including utility) prior to 2005. Yet, such a significant difference does exist for the ground of utility post-2005. Accordingly, it is reasonable to conclude that the finding of significance is *not* a numerical artifact of the increase in pharmaceutical patent litigation following the introduction of PM(NOC) proceedings.[592]

Canada is simply incorrect to suggest that earlier changes in the Canadian patent law system somehow explain the disproportionate and discriminatory impact of the promise utility doctrine since 2005.

298. Canada makes a similar mistake when arguing that since a majority of pharmaceutical patents challenged on the basis of utility manage to clear the elevated bar set by the promise utility doctrine, there is no discrimination against the pharmaceutical sector.[593] The relevant metric is the *comparative rate* of invalidity rulings between sectors, not the rate for pharmaceutical cases in isolation. Since 2005, pharmaceutical patents have been invalidated for lack of utility far more often than patents in all other sectors — by a staggering difference of 40 percentage points.[594]

299. Finally, Canada emphasizes that the overall rate of invalidity findings in the pharmaceutical sector has been stable over time, and that Lilly's statistics include certain patents found invalid not only for lack of utility, but also

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[592] *Id.* at ¶ 25.

[593] *See* Resp. CM at ¶ 387; Brisebois Statement at ¶ 36.

[594] *See* Levin Report at ¶ 9.

on other grounds.[595] As noted, the majority of inutility rulings against pharmaceutical patents have been based on that sole ground alone. That said, invalidity rulings based on multiple grounds remain important because the question is whether the Canadian courts have applied the utility, novelty, or obviousness tests in a manner that discriminates against pharmaceutical patents. As Professor Levin explains, the task is to compare "the effect of the utility requirement as against the effect of other requirements within like time periods," and his analysis already "accounts for the correlations between holdings on different grounds within the same cases."[596] When utility is compared to other grounds, only utility — not non-obviousness or novelty — displays a statistically significant difference in invalidity rates between the pharmaceutical sector and other sectors.[597] Professor Levin concludes that the finding of disproportionate effect is *specific* to the utility requirement.[598]

300. In sum, a rigorous statistical analysis rebuts Canada's and Dr. Brisebois's claims that the discriminatory pattern of utility rulings since 2005 can be explained by something other than the dramatic change in Canada's utility standard. This analysis shows that the promise utility doctrine has had overwhelmingly disproportionate and statistically significant effects in the pharmaceutical sector. No comparable pattern of discrimination is apparent in utility cases before 2005, or in novelty or obviousness rulings at any time. Notwithstanding Canada's arguments to the contrary, the disparate impact of the promise utility doctrine cannot be explained by the general pattern of pharmaceutical patent litigation, or by reference to validity determinations on distinct or multiple grounds. And this clear evidence of disproportionate effects,

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[595] Resp. CM at ¶¶ 143, 388.

[596] *See* Levin Report at ¶¶ 24, 26.

[597] Canada also presents evidence regarding validity rulings on the ground of sufficiency, which is not a core requirement in NAFTA Article 1709. But even if one includes sufficiency rulings, the statistical results are no different. *See* Levin Report at ¶ 20 ("Adding sufficiency to my analysis does not meaningfully change the results.").

[598] *See* Levin Report at ¶¶ 16-21, 26-27.

by itself, provides a sufficient basis to conclude that Canada has breached Chapter 17, and thereby expropriated Lilly's investments in violation of NAFTA Article 1110.

**c) Canada has violated NAFTA Article 1709(8) by invalidating the Zyprexa and Strattera patents under a rule of law that did not exist when the patents were granted.**

301. Under NAFTA Article 1709(8), a patent may be revoked only when "grounds exist that would have justified a refusal to grant the patent." As explained in Lilly's Memorial,[599] the plain language of this article 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 the patents were granted.

302. In response, Canada repeats its refrain that the Strattera and Zyprexa patents were invalidated based on "longstanding rules" and that the Patent Office simply "assumed" Lilly's patents complied with the law when it granted the patents.[600] But this assertion is demonstrably wrong because the promise utility doctrine simply did not exist when Lilly applied for and was granted patent protection for Strattera and Zyprexa by Canada's Patent Office.[601]

303. Canada next argues that if the promise utility doctrine were to violate Article 1709(8), then so would all "patent law developments in the United States" (and, presumably, Mexico) that have restricted patent eligibility standards and been applied retroactively.[602] But this argument suggests a parallel between Canada's creation of an entirely new and additional patentability requirement (the

[599] Cl. Mem. at ¶¶ 227-231.

[600] Resp. CM at ¶¶ 392-394.

[601] *See supra* Parts II.A-B & III.

[602] Resp. CM at ¶ 398.

promise utility doctrine), on the one hand, and marginal evolution in existing U.S. and Mexican legal requirements, on the other. No such parallel exists.[603]

304. Lilly has recognized from the outset that the law governing its patents was subject to gradual evolution consistent with the core substantive commitments embodied in NAFTA.[604] Relatedly, Lilly has recognized from the outset that Chapter 17 does not harmonize international patent law, but rather requires a baseline or minimum level of protection.[605]

305. There is, however, a categorical difference between the "subtle changes in U.S. law"[606] that have taken place since NAFTA, and the "sea change in the Canadian law of utility"[607] effected by the promise utility doctrine in a manner inconsistent with Chapter 17. As Professor Merges states, the changes in U.S. law highlighted by Canada amount to nothing more than "normal variation around the core content of traditional patentability requirements" that served in part to "restore[] U.S. law to its traditional contours."[608] Canada did not simply modify the application of its traditional utility standard, in the way that the United States effected a "slight tightening in the non-obviousness test" that returned to historical norms.[609] Rather, Canada maintained its traditional "mere scintilla" utility test,[610] and then added to it a new utility requirement with discriminatory effects on pharmaceutical patents: the promise utility doctrine.[611] It is the creation of this fundamentally new patentability requirement, and its retroactive application, that violate NAFTA Article 1709(8).

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[603] *See* Merges Second Report at ¶¶ 50-52.

[604] Cl. Mem. at ¶¶ 196-201.

[605] *See supra* Part I.D.

[606] Merges Second Report at ¶ 51.

[607] Siebrasse First Report at ¶ 105.

[608] Merges Second Report at ¶ 51.

[609] *Id.*

[610] *See* Cl. Mem. at ¶ 60; Siebrasse First Report at ¶ 41.

[611] *See supra* Part II.

### d) **Canada has violated NAFTA Article 1701(1) by denying Lilly adequate and effective protection and enforcement of its intellectual property rights.**

306. As Lilly set out in its Memorial,[612] NAFTA Article 1701(1) requires Canada to "provide in its territory . . . adequate and effective protection and enforcement of intellectual property rights," including patent rights. As a matter of plain English, this obligation required Canada to maintain a "sufficient, suitable, or acceptable" level of protection for the Zyprexa and Strattera patents.[613] Instead, as discussed above, Canada's promise utility doctrine fundamentally and retroactively destroyed the level of protection accorded to those patents, and did so in a way that was unforeseeable, arbitrary, and discriminatory.[614] Further, through the judicial decisions revoking Lilly's Strattera and Zyprexa patents, the doctrine was applied to prevent Lilly from enforcing its patents, in contravention of Canada's obligation to provide for "effective . . . enforcement" of intellectual property rights.

307. Canada disputes these plain English conclusions, suggesting that its obligation under Article 1701(1) is principally procedural — to provide "full and fair procedure before domestic courts."[615] But this limited reading ignores the language that NAFTA's drafters chose to employ. Article 1701(1) mandates "adequate and effective" protection and enforcement of patent rights; in other words, it requires that the substantive protections stipulated under other provisions of Chapter 17 exist in reality, not simply in theory or as a matter of procedure.[616] Canada's transformation of its utility requirement in a manner that

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[612] Cl. Mem. at ¶¶ 232-234.

[613] *Id.* at ¶ 233 (quoting OED Online, Oxford University Press).

[614] *See supra* Part II.D.

[615] Resp. CM at ¶ 401.

[616] *See* "Adequate," OED Online (Oxford University Press) ("fully satisfying what is required") (CL-70); "Effective," OED Online (Oxford University Press) ("producing a notable effect) (CL-70); *see also* "Effective," Black's Law Dictionary (10th ed. 2014) ("performing within the range of normal and expected standards" or "achieving a result") (CL-155).

subverts the meaning of the term "useful" as incorporated in Article 1709(1) violates Article 1701(1).

308. By developing an impermissible and discriminatory utility test, and by applying it to invalidate the Strattera and Zyprexa patents, Canada failed to provide Lilly with adequate and effective protection and enforcement of its intellectual property rights, and thereby acted in contravention of Article 1701(1).

### 4. Canada's Measures Constitute an Expropriation Under Article 1110.

309. In its Memorial, Lilly demonstrated that Canada's measures qualify as both a direct and indirect expropriation under Article 1110. They constitute a direct expropriation because they involve an "open, deliberate, and acknowledged taking[] of property."[617] And they qualify as an indirect expropriation because, regardless of their purpose, they have result in "a substantial deprivation" in the value of Lilly's protected investments.[618]

310. Canada maintains that neither theory of expropriation is applicable to its revocation of the Zyprexa and Strattera patents. With respect to direct expropriation, Canada argues its measures cannot amount to a direct expropriation because they did not "result in the transfer of property rights to the State or to any other party."[619] Rather, Canada claims, "there was a determination that no valid property rights existed."[620]

311. Contrary to Canada's contention, however, there is no requirement that claimants establish that their property rights were transferred to the State or to a third-party in order to prove a direct expropriation. While some authorities

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[617] *See* Cl. Mem. at ¶ 170 (quoting *Metalclad v. Mexico*, at ¶ 103).

[618] *See id.* at ¶ 173 (quoting *Pope & Talbot v. Canada*, NAFTA/UNCITRAL, Interim Award (26 June 2000), at ¶ 102 [hereinafter *Pope & Talbot v. Canada*] (CL-120)).

[619] Resp. CM at ¶ 406.

[620] *Id.*

have described such transference as a hallmark of direct expropriation, that is only because direct expropriations of tangible property often result in the property being transferred to the State or a third-party.[621] As commentators and tribunals have recognized, however, "*the central element* [of direct expropriation] is that property must be 'taken' by State authorities *or the investor must be deprived of it by State authorities*."[622] This articulation of the core standard does not turn on whether the property has been transferred, and indeed tribunals have recognized that expropriation (both direct and indirect) can result in the destruction of an investment, not just its transferal to a third-party.[623]

312. Even if Canada were correct (it is not) that transference is a necessary precondition for direct expropriation, Canada's measures *did* result in a *de facto* transfer of Lilly's property rights to third parties — namely, the manufacturers that could sell generic versions of Zyprexa and Strattera without being required to compensate Lilly. As discussed above, a patent encompasses a bundle of property rights to exclude others.[624] Just as a deed to physical property includes the right to

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[621] *See, e.g.*, Campbell McLachlan et al., INT'L INV. ARBITRATION, § 8.69 (2008) ("Arbitral tribunals have considered direct expropriation as being relatively easy to recognize: for example, 'governmental authorities take over a mine or factory, depriving the investor of all meaningful benefits of ownership and control, or there has been a compulsory transfer of property rights.") (internal quotation marks and footnotes omitted) (CL-46).

[622] *Id.* (emphasis added). As Professor McLachlan notes, "[t]he Tribunal in *Tippetts, Abbett, McCarthy, Stratton v. TAMS-AFFA Consulting Engineers of Iran, the Government of the Islamic Republic of Iran* (1984) 6 Iran-USCTR 219, 225, stated that it 'prefers' the term "deprivation" to the term "taking", although they are largely synonymous, because the latter may be understood to imply that the government has acquired something of value, which is not required." *Id.*

[623] *See Fireman's Fund v. Mexico*, 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). Canada argues that this passage "did not define direct expropriation, but referred to expropriation generally (both direct and indirect)." Resp. CM at ¶ 405. Canada is correct that the tribunal was discussing "both direct and indirect" expropriation in this passage, but that is because the proposition at issue — *i.e.*, that transference is not necessary to prove an expropriation — is true for both direct and indirect expropriation.

[624] *See supra* Parts I.C and IV.A; *see also* Patent Act (Canada), R.S.C., 1985, C. P-4, at § 42 ("Every patent granted under this Act . . . subject to this Act, *grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used*, subject to (continued…)

exclude others from using or exploiting the property, a patent grants the right to prevent others from manufacturing, using, or selling the patented invention. CIPO itself has observed this congruence.[625] In the case of physical property, if a State authorizes a third party to exploit a landowner's property, the result is a direct expropriation.[626] Here, the court decisions invalidating the Zyprexa and Strattera patents led to a parallel outcome; namely, Lilly's exclusive rights were extinguished and third parties could appropriate the value of Lilly's innovation by making, using, and selling the medicines. The only difference here is that the property upon which the State is permitting a third party to intrude is an intangible patent, rather than tangible land. But since both types of property are equally protected "investments" under NAFTA, this is a distinction without a difference.

313. With respect to indirect expropriation, Canada's principal argument is that its revocation of the Zyprexa and Strattera patents did not amount to an expropriation because it did not substantially deprive Lilly's investments of value. Canada argues that "[i]n assessing whether there has been a substantial deprivation, the investor's enterprise must be considered as a whole."[627] And, Canada submits, since Lilly's "overall enterprise in Canada . . . continues to grow

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adjudication in respect thereof before any court of competent jurisdiction.") (emphasis added) (C-50).

[625] As CIPO's website has recognized, a "granted patent is an asset like a deed to physical property such as a house" that "give[s] you an effective means to stop others from making, using, selling, or importing your product or process." CIPO, *Protect your innovation, http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03586.html* (C-312).

[626] For example, Canada cites Andrew Newcombe's treatise for the proposition that "[d]irect expropriation requires that 'the government measures in question result in a state sanctioned compulsory transfer of property from the foreigner to either the government or a state-mandated third party." Resp. CM at ¶ 405 (quoting Andrew Newcombe, "Law and Practice of Investment Treaties, Standards of Treatment," February 2009, at ¶ 7.3). One of Newcombe's cited examples of direct expropriation was the *de Sabla* case, in which the tribunal found a direct expropriation when, *inter alia*, the government granted cultivation licenses on land owned by the claimant. *See id.*; *see also Marguerite de Joly de Sabla (United States) v. Panama*, (1934) 28 AJIL 602 (CL-156).

[627] Resp. CM at ¶ 410.

and enjoys substantial profits in numerous lines of business," there has not been a substantial deprivation in the value of that investment.[628]

314. But tribunals only consider "the investor's enterprise as a whole," when the investor's enterprise *is the investment at issue*, and here it is not.[629] Rather, as Canada well knows, Lilly's protected investments at issue in this arbitration are *the Zyprexa and Strattera patents*.[630] It is undisputable that Canada's measures substantially deprived *those* investments of value. The fact that Lilly maintains *other* investments in Canada is immaterial, and Canada's argument to the contrary rests on a mischaracterization of the investments at issue in this arbitration.[631]

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[628] *Id.* at ¶ 411.

[629] Canada cites four cases in support of this argument, but in each case, the expropriation claim was based on the investor's business, not a discrete intangible asset like the patents at issue here. *See Grand River Enters. Six Nations, Ltd. v. United States*, ICSID/UNCITRAL, Award (12 January 2011), at ¶ 146 [hereinafter *Grand River v. United States*] ("The Tribunal has jurisdiction over Arthur Montour's claim, including his claim that improper enforcement actions by various states other than New York affecting Native Wholesale Supply's sales have resulted in the expropriation of a substantial portion of the value of his investment.") (CL-107); *Merrill & Ring Forestry L.P. v. Canada*, NAFTA/UNCITRAL, Award (31 March 2010), at ¶ 143 [hereinafter *Merrill & Ring v. Canada*] (analyzing the claim that the investor's "log export business" was expropriated) (CL-51); *Marvin Feldman v. Mexico*, NAFTA/ICSID No. ARB(AF)/99/1, Award (16 December 2002), at ¶¶ 1, 152 (identifying the investment at issue to be the claimant's Mexican company, Corporación de Exportaciones Mexicanas, S.A. de C.V.) (CL-109); *Pope & Talbot v. Canada*, at ¶¶ 2, 101 (defining claimant's "Investment" to be "a British Columbia corporation, Pope & Talbot Ltd." and noting that "the sole 'taking' that the investor has identified is interference with the Investment's ability to carry on its business of exporting softwood lumber to the U.S.") (CL-120).

[630] Cl. Mem. at ¶ 163 ("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.").

[631] Even if the Zyprexa and Strattera patents were arbitrarily combined with Lilly's other Canadian investments, Canada's argument would still be unavailing. As the tribunal recognized in *Fireman's Fund v. Mexico*, an expropriation "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)." *Fireman's Fund v. Mexico*, at ¶ 176(c) (emphasis added) (CL-45). At a minimum, the Zyprexa and Strattera patents were "identifiable distinct parts" of Lilly's investments in Canada.

315. Setting aside the issue of whether Lilly's investments were substantially deprived of value, Canada maintains that the "character of [its] measures heavily weights against a finding of indirect expropriation."[632] Canada argues that because its measures are acts of the judiciary, they must be subject to a heightened standard under Article 1110. Otherwise, according to Canada, "[i]f every judicial decision with respect to property rights could amount to an expropriation, the judicial system would be paralyzed."[633]

316. Lilly has never argued that "every judicial decision with respect to property rights could amount to an expropriation," and Canada's alarmist rhetoric on this point is yet another example of its repeated mischaracterization of Lilly's arguments. As discussed in detail above, Lilly's argument is that judicial measures may be expropriatory when they substantially deprive an investment of value *and violate a substantive rule of international law*. This is both a general principle of international law and a rule embodied in the text of NAFTA, which recognizes that judicial patent revocations engage Article 1110 if they are inconsistent with Chapter 17. Since Canada's measures — in this case, the invalidations of Lilly's patents under the promise utility doctrine — *do* violate Chapter 17 for the reasons discussed above, the "character" of Canada's measures weighs in favor of a finding of expropriation, not against.

317. Lastly, Lilly demonstrated that Canada's breach of Chapter 17 was just one of several bases upon which the Tribunal could conclude that Canada's revocation of the Zyprexa and Strattera patents were expropriatory.[634] Canada's measures may also be recognized as expropriations because they are arbitrary and in conflict with Lilly's reasonable investment-backed expectations.[635] Canada does

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[632] Resp. CM at ¶ 413.

[633] *Id.* at ¶ 414.

[634] Cl. Mem. at ¶ 243.

[635] *Id.*

not dispute that arbitrariness and interference with legitimate expectations are relevant criteria for determining whether a measure engages Article 1110.[636]

318. Since arbitrariness and violation of legitimate expectations are both free-standing bases for determining that Canada's measures are expropriatory, Canada's defense to Lilly's claim under Article 1110 rises or falls based on Canada's ability to demonstrate that its measures were not arbitrary and that Lilly's expectations were not legitimate. But as discussed in Part II.D. below in greater detail, Canada fails on both counts.[637] In short:

- ***Arbitrariness***. Canada denies that the promise utility doctrine is arbitrary, but it has no answer to the reality — recognized by even those generic companies that have benefitted most from the doctrine — that it represents a "free for all" and a "hopeless tangle of contradictory approaches."[638] Nor does Canada rebut that the promise utility doctrine is utterly unpredictable and unreasonably difficult to satisfy.[639]

- ***Legitimate expectations***. Canada does not and cannot dispute that when Lilly made its investments in Canada in the 1990s, it did so in reliance on Canada's long-standing and well-understood traditional ("mere scintilla") utility requirement.[640] Accordingly, Canada's sole defense on this point is its argument Lilly's expectations were not reasonable because the promise utility doctrine pre-existed Lilly's investments. As discussed above, however, this argument is flatly contradicted by the stark shift in Canada's utility requirement, reflected in changes to Canada's MOPOP. The notion that the promise utility doctrine has always been part of Canadian law also finds no support in the cases on which Canada relies.[641]

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[636] Resp. CM at ¶¶ 412-416.

[637] For avoidance of doubt, Lilly's showings below that Canada's actions are arbitrary and in conflict with Lilly's legitimate expectations are equally relevant to Lilly's expropriation claim should the Tribunal choose to rest its finding of expropriation on the arbitrary and unreasonable nature of Canada's measures irrespective of whether they are consistent with Chapter 17.

[638] Notice of Application for Leave to Appeal of Apotex Inc. et al, *Apotex Inc. v. Sanofi-Aventis*, S.C.C. File No. 35562, at ¶ 14 (September 30, 2013) (C-375).

[639] *See supra* Part II.D.

[640] *See infra* Part V.B.2.

[641] *See supra* Part II.A.

### C. Canada Makes No Effort to Defend the Legality of Its Measures Under Article 1110(1).

319. Article 1110(1) of NAFTA requires, *inter alia*, that any expropriation: (i) be taken "on payment of compensation" in accordance with NAFTA; (ii) be "on a non-discriminatory basis"; (iii) be "for a public purpose"; *and* (iv) be taken in accordance with Article 1105(1) of NAFTA. Any expropriation that fails to meet any one of these conditions is unlawful under NAFTA.

320. In its Memorial, Lilly demonstrated that Canada's revocation of the Zyprexa and Strattera patents violated all four of these conditions. Canada has not tendered any compensation for the expropriation of Lilly's patents.[642] Canada's measures were not taken "on a non-discriminatory basis" because they subjected pharmaceutical patents to treatment less favorable than to patents in other fields of technology.[643] Canada's promise utility doctrine lacks a public purpose because it is arbitrary and serves no rational policy interest.[644] And Canada's measures violated Article 1105(1) for the reasons detailed in Lilly's Memorial.[645]

321. Canada does not address Article 1110(1) anywhere in its Counter-Memorial. And while Canada does maintain that its measures were non-discriminatory, in service of a valid public purpose, and in accordance with Article 1105(1),[646] it completely ignores its obligation to make "payment of compensation in accordance with" NAFTA's requirements. As the tribunal in *Burlington Resources v. Ecuador* has observed, "[m]any tribunals have held that lack of payment is sufficient for the expropriation to be deemed unlawful."[647] Here, it

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[642] Cl. Mem. at ¶¶ 245-246.

[643] *Id.* at ¶¶ 247-248.

[644] *Id.* at ¶ 249.

[645] *Id.* at Part VII.B.

[646] Resp. CM at Part IV.C.

[647] *See Burlington Reso. v. Republic of Ecuador*, ICSID Case No. ARB/08/5, Decision on Liability (14 December 2012) at ¶¶ 543-544 (CL-81); *see also 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), (continued…)

is undisputed that Canada has failed to tender any compensation for its measures, let alone the specific compensation required by NAFTA. Accordingly, if the Tribunal concludes (as it should) that Canada's measures engage Article 1110, then those expropriatory measures are necessarily unlawful under the criteria of Article 1110(1).

## V. CANADA'S CONDUCT IN REVOKING THE ZYPREXA AND STRATTERA PATENTS FAILED TO MEET THE STANDARD OF FAIR AND EQUITABLE TREATMENT GUARANTEED IN NAFTA ARTICLE 1105(1).

322. NAFTA Article 1105(1) 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." In its Memorial, Lilly showed that Article 1105(1) embraces protections against arbitrariness, violation of legitimate investment-backed expectations, and discrimination.[648] Lilly further demonstrated that Canada's use of the promise utility doctrine to invalidate the Zyprexa and Strattera patents violated each of these standards.[649]

323. In its Counter-Memorial, Canada seeks repeatedly to narrow the scope of protection afforded by Article 1105(1). Foremost among Canada's arguments is the assertion — parallel to Canada's similar argument in respect of Article 1110 — that in cases involving judicial measures, Article 1105(1) is engaged *only* by procedural denials of justice. This unduly narrow interpretation of Article

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at ¶ 7.5.21 (CL-82); *Bernardus Henricus Funnekotter & ors. v. Zimbabwe*, ICSID Case No. ARB/05/6, Award (22 April 2009), at ¶ 98 (CL-83); *Rumeli Telekom A.S. & 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).

[648] *See* Cl. Mem. at ¶¶ 258-60.

[649] *See* Cl. Mem. at Part VII.B.

1105(1) lacks any support in the text of NAFTA and in the cases on which Canada relies. Canada's attempt to shield the acts of its judiciary from international responsibility also is inconsistent with the fundamental principle that a state's international responsibility is independent of its internal political structure. *Infra* Part V.A and *supra* Part IV.B.1.

324. Canada's attempts to narrow the substantive protections embodied in Article 1105(1) also come up short. For each of the three relevant prohibitions embodied in Article 1105(1)'s fair and equitable treatment standard — arbitrariness, discrimination, and violation of legitimate expectations — Canada advances a restrictive interpretation that does not withstand scrutiny:

- ***Arbitrariness***. Canada does not dispute that Article 1105(1) encompasses an obligation to refrain from arbitrary treatment of investments. Canada argues, however, that its measures are not arbitrary because they serve a valid policy rationale. But Canada fails to meaningfully answer Lilly's extensive evidence that the promise utility doctrine is, in the words of one generic company, a "free-for-all" and "hopeless tangle of contradictory approaches,"[650] including because it (i) involves the inherently subjective process of construing the "promises" contained in a patent; (ii) imposes an unpredictable heightened evidentiary burden; and (iii) arbitrarily applies a disclosure rule for "sound prediction" cases but not "disclosure" ones, introducing two inconsistent disclosure rules for a unitary legal requirement. Canada also fails to articulate any rational policy objective that could possibly be served by this incoherent and unpredictable doctrine. *Infra* Part V.B.1.

- ***Legitimate expectations***. Canada insists that Lilly has not met its burden of demonstrating — through state practice and *opinio juris* — that the protection of legitimate expectations is part of Article 1105(1). Even if such expectations were protected, Canada argues, they must be grounded in express representations by the government. Both of these arguments are wrong as a matter of law, as detailed below, but even if they were correct, Lilly's evidence readily meets Canada's overly restrictive standard. Having relied on Canada's long-standing, well-understood and NAFTA-consistent utility requirement ("mere scintilla") — *and having been granted patents by Canada on that basis* — Lilly could not reasonably anticipate the dramatic and fundamental changes in

[650] Notice of Application for Leave to Appeal of Apotex Inc. et al., *Apotex Inc. v. Sanofi-Aventis*, S.C.C. File No. 35562, at ¶ 14 (September 30, 2013) (C-375).

Canada's utility standard occasioned by the advent of the promise utility doctrine in the mid-2000s. *Infra* Part V.B.2.

- ***Discrimination***. Canada does not contest the general proposition that Article 1105(1) protects against discriminatory treatment, but it argues that discrimination based on the foreign investor's nationality is the only form of discrimination that is cognizable for purposes of Article 1105(1). Here again, Canada can muster no support for its narrow interpretation, or any evidence to rebut Lilly's showing that the promise utility doctrine discriminates against pharmaceutical innovators as a field of technology. And, as discussed below, even if Canada's narrow focus on nationality was the relevant criterion, the promise utility doctrine would *still* be discriminatory because it favors generic manufacturers (many of which are based in Canada) over foreign patent holders. *Infra* Part V.B.3.

### A. Article 1105(1) Is Not Limited to Only Denial of Justice in Cases Involving Judicial Measures.

325. Echoing its argument in regard to Article 1110, Canada argues that Article 1105(1) binds only its legislative and executive branches and, subject to a single narrow exception, is irrelevant to the conduct of its judiciary.[651] There is only one way, in Canada's view, that judicial measures can breach Article 1105(1): through a procedural denial of justice.[652] Yet the text of Article 1105(1) draws no distinction among measures of the legislature, executive, or judiciary. Rather, Article 1105(1) provides that "Each *Party* shall accord to investments of investors treatment in accordance with international law, including fair and equitable treatment[.]" As already noted, judicial measures "emanat[e] 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."[653] If the NAFTA Parties wanted to hold national

[651] Resp. CM at ¶ 231 ("[J]udgments of national courts interpreting domestic law cannot be challenged as a violation of international law in the absence of a denial of justice – for example, refusal to entertain a suit or serious failure to adequately administer justice or if there has been a clear and malicious misapplication of the law") (internal quotations omitted).

[652] *Id.* ("There must be a very serious failure in the *administration* of justice before a State can be found in violation of international law for the domestic law decisions of its domestic courts.") (emphasis added).

[653] *Azinian v. Mexico*, at ¶ 98 (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) (CL-61).

judiciaries to a different standard than their executive or legislative branches, they easily could have done so, but such limitations are nowhere to be found in the language of Article 1105(1).

326. Canada maintains that its assertion about denial of justice is supported by general principles of international law, which are incorporated into Article 1105(1). As previously explained, the "fair and equitable treatment" standard under Article 1105(1) is linked to the minimum standard of treatment of aliens under customary international law (Minimum Standard of Treatment), and this Minimum Standard of Treatment, in turn, is shaped by the standard of Fair and Equitable Treatment that has been adopted by most international investment treaties in force today.[654] But analyzing Article 1105(1) in light of the Minimum Standard of Treatment serves only to undermine Canada's position. Contrary to Canada's contentions, multiple arbitral awards have confirmed that denial of justice is *just one part* of the protection afforded by the Minimum Standard of Treatment in respect of judicial measures, and that national courts (just like other national authorities) may violate the Minimum Standard in other ways as well.

327. Thus, in *Liman Caspian Oil v. Kazakhstan*, the tribunal expressly characterized denial of justice as just "*an example* of the standard of fair and equitable treatment" and agreed that "the two standards [denial of justice and fair and equitable treatment] are not synonymous with regard to acts of courts."[655] In *White Industries v. India*, the tribunal analyzed the acts of India's courts under three distinct aspects of the minimum standard: denial of justice, but also the protection of legitimate expectations and the requirement of transparency.[656] And again, in *Frontier Petroleum v. the Czech Republic*, the tribunal considered not only whether the conduct of the Czech courts may have breached the requirements of

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[654] Cl. Mem. at ¶¶ 253-254.

[655] *Liman Caspian Oil v. Kazakhstan*, at ¶ 268 (emphasis added) (RL-27).

[656] *White Industries Australia Ltd. v. India*, UNCITRAL, Award (3 November 2011), at ¶ 10.1.1 (CL-157).

"procedural propriety and due process," but also whether the Czech courts' decision was "made in an arbitrary or discriminatory manner."[657]

328. As for the cases cited by Canada, none supports its position. As discussed above with respect to Article 1110, Canada cites awards — including *Azinian v. Mexico*, *Waste Management v. Mexico*, and *Loewen v. United States* — where denial of justice was the only relevant theory of potential liability "*in the circumstances of the case*."[658] *Loewen*, for example, dealt with a challenge to the "conduct of [a Mississippi] trial"[659] related to a commercial dispute between the claimant and a local business, and with procedural impediments to the appeal of the outcome at trial. In contrast to the present case, the claimant did not argue that the substantive law at issue — the Mississippi law of contract, business tort and competition — was itself inconsistent with Art. 1105(1).[660] Rather, it was the

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[657] *Frontier Petroleum Services Ltd. v. the Czech Republic*, UNCITRAL, Award (12 November 2010), at ¶¶ 284, 525 [hereinafter *Frontier Petroleum v. Czech Republic*] (RL-67). Canada repeatedly cites an article by Professor Zachary Douglas, who asserts that "[d]enial of justice is the sole form of international delictual responsibility . . . for acts or omissions within an adjudicative procedure . . ." Resp. CM at ¶ 231 (quoting Zachary Douglas, "International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed," INT'L & COMP. L.Q. 34 (September 2014)). An examination of Professor Douglas's article reveals that his view is not supported by a single citation to any award, article or other authority. To the contrary, the sole decision discussed by Professor Douglas in the relevant section of his article is *Frontier Petroleum v. Czech Republic*, which he acknowledges is inconsistent with his position. Professor Douglas neglects to mention that he was counsel for the respondent in that case.

[658] *Loewen v. United States*, at ¶ 141 (emphasis added) (RL-13). *Jan de Nul v. Egypt*, which Canada discusses in a different part of its Counter-Memorial (at ¶ 287), is inapposite for the same reason: the claimant was focused on procedural defects. It alleged that the Egyptian courts "committed a 'gross miscarriage of justice' because of the 'inordinate duration and blatant defiance of the principles of fairness and due process' of the local proceedings, the behavior of the Egyptian judiciary amounting to an 'abuse of process and obstruction of justice.'" *Jan de Nul N.V. v. Arab Republic of Egypt*, ICSID Case No. ARB/04/13, Award (6 November 2009), at ¶ 112 (RL-28).

[659] *Loewen v. United States*, at ¶ 44 (emphasis added) (RL-13).

[660] The same is true of the underlying facts in *Liman Caspian Oil v. Kazakhstan* and *White Industries v. India*, discussed in the preceding paragraph. However, in *Frontier Petroleum v. Czech Republic*, the investor raised (and the tribunal considered at some length) a claim that Czech courts had implemented the "public policy" exception to the enforcement of an arbitral award in a substantively unreasonable manner. *See Frontier Petroleum v. the Czech Republic*, at ¶¶ 525-530 (RL-67).

procedural fairness of the trial and appeal process that was at issue. *Loewen*, in other words, in inapposite here.

329. Canada also places great emphasis on *Mondev v. United States,* a NAFTA case where the challenged measure was a decision of the Massachusetts Supreme Judicial Court (SJC). Canada suggests that the *Mondev* tribunal treated denial of justice as the sole basis for an Art. 1105(1) claim against a judicial measure despite the fact that the claimant had accused the SJC of effecting an unexpected and retroactive change in Massachusetts law.[661]

330. Canada mischaracterizes the *Mondev* case. In fact, the *Mondev* tribunal concluded that it was "*doubtful whether the SJC made new law*" in resolving the domestic case.[662] The tribunal emphasized that even if the SJC had effected a change in law, the change would have been minor and evolutionary ("within the limits of common law adjudication").[663] The tribunal then went on to note that a more significant change in law may have occurred with respect to a *different* principle of law (a heightened burden for government contracts) discussed in the SJC opinion.[664] However, the tribunal determined that this changed principle was "merely supplementary and *was not itself the basis for the decision*."[665] The award implies that, had the SJC decision rested on a changed legal principle, the claimant would not have been confined to arguing a denial of justice.[666] As in every other

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[661] Resp. CM at ¶¶ 235-238.

[662] *Mondev v. United States*, at ¶ 133 (emphasis added) (CL-7).

[663] *Id.* As Lilly explained in its Memorial, investors must reasonably anticipate an "acceptable margin of change" in municipal law after an investment is made. Cl. Mem. at ¶ 279 (quoting Rudolf Dolzer & Christoph Schreuer, PRINCIPLES OF INTERNATIONAL INVESTMENT LAW 148 (2d ed. 2012)). As discussed previously and again below, however, the dramatic departure in Canada's patent law represented by the promise utility doctrine was plainly outside any such "acceptable margin of change." *See supra* Parts II and IV.B.2.

[664] *Mondev v. United States*, at ¶ 134 (CL-7).

[665] *Id.* at ¶ 134 (emphasis added).

[666] *Id.* (The award explained that the changed legal principle may have been suggestive of "a governmental prerogative to violate investment contracts [that] would appear to be inconsistent with the principles embodied in Article 1105 and with contemporary standards of national and international law concerning governmental liability for contractual performance. But in the (continued…)

case cited by Canada, no special immunity was considered or applied with respect to judicial measures.

331. In contrast to *Loewen* and *Mondev*, the measures at issue here are not problematic merely for reasons of process or procedure. Rather, the issue in this case is that Canada's courts have developed and applied an arbitrary and discriminatory *substantive* doctrine of patent law and have retroactively applied this doctrine to revoke two Lilly patents.[667] The effect of Canada's position in this arbitration is to exempt all such judge-made law from the requirements of international law. Because denial of justice is a uniquely procedural concept,[668] on Canada's view, judicially-created rules and laws could not be challenged unless they were developed in a procedurally unfair manner. This result is incongruous, not least because it conflicts with two fundamental principles of international law.

332. First, Canada's position is inconsistent with the principle that a State's internal political system cannot alter its obligations under customary international law.[669] States differ in the extent to which their national judiciaries serve a law-making function. In civil law jurisdictions, for example, law-making may emanate more from the legislative and executive branches rather than the courts.[670] Whereas in common law jurisdictions, it may be more commonplace for judges to make law. Because Canada's position would impose a heightened

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Tribunal's view, the SJC's remark was at most a subsidiary reason for a decision founded on normal principles of the Massachusetts law of contracts, and the SJC expressly disclaimed any intention to absolve governments from performing their contractual obligations. In its context the remark was merely supplementary and was not itself the basis for the decision.").

[667] *See supra* Parts II-III.

[668] *See supra* Part V.A at ¶¶ 262-68. Canada does not contest — and, indeed, relies on — the procedural nature of the denial of justice standard. *See* Resp. CM at ¶ 231 (characterizing the denial of justice as dealing with failures "to adequately *administer* justice") (emphasis added).

[669] *See* THE OXFORD HANDBOOK OF INTERNATIONAL INVESTMENT LAW 555 (Oxford University Press 2008) ("[T]o allow a state to rely on its internal law to evade international responsibility would have a completely nullifying effect on the rules and principles of international law") (CL-158).

[670] John H. Merryman and Rogelio Perez-Perdomo, THE CIVIL LAW TRADITION 37 (3d ed. 2007) (noting that civil law judges traditionally play a "more modest role than [those] in the common law tradition") (CL-159).

standard for judicial measures — but not legislative or executive measures — it could advantage some countries more than others.[671]

333. Second, as recognized in *Liman Caspian*, to hold that judicial measures can be challenged only under the denial of justice framework (and are immune from all other requirements of international law) is to introduce an impermissible "distinction between acts of courts and acts of other State entities."[672] Such a distinction is inconsistent with the principle that a State is internationally responsible for the conduct of all its organs, equally.[673]

334. Rather than grapple with these inconsistencies, Canada relies on rhetoric. In particular, Canada repeatedly intones that this tribunal must not act as a "supranational court of appeal."[674] But it is uncontroversial that arbitral tribunals must be properly sensitive in their role of reviewing *all* State measures —

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[671] In Mexico, for example, the Patent Act is principally interpreted by an administrative agency (the Instituto Mexicano de la Propiedad Industrial or "IMPI") and not by its courts. *See* Gonzalez First Report at ¶ 15 ("decisions issued by the Federal Courts [of Mexico] are only binding in the specific case under review . . . [and] are not binding on IMPI in similar cases"). Under Canada's approach, a Canadian investor could use Art. 1105(1) to challenge the loss of its patent based on a discriminatory or arbitrary interpretation of the Mexican Patent Act by IMPI. A Mexican investor, in contrast, would be unable to challenge a patent revocation by a Canadian court — except on the ground of denial of justice.

[672] *Liman Caspian Oil v. Kazakhstan*, at ¶ 268 (RL-27).

[673] ILC Draft Articles on State Responsibility, Art. 4, United Nations General Assembly Resolution 56/83, Annex A (December 12, 2001) ("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") (CL-57). Art. 4 of the ILC Draft Articles is intended to "allow[] for the fact that the principle of separation of powers is not followed in any uniform way, and that many organs exercise some combination of public powers of a legislative, executive or judicial character." James Crawford, THE INTERNATIONAL LAW COMMISSION'S ARTICLES ON STATE RESPONSIBILITY 96 (Cambridge 2002) (CL-160). It would thus be inconsistent with Art. 4 to apply a different rule to a governmental organ simply because it is identified, under domestic law, as judicial. *See Salini Costruttori S.p A. v. the Federal Democratic Republic of Ethiopia*, ICC Case No. 10623/AER/ACS, Award (7 December 2001), at ¶¶ 168-170 (considering Art. 4 and finding that it is inconsistent with Art. 4 for a state to use judicial measures to preclude a party's access to arbitration, even when the judiciary is acting in good faith and in compliance with domestic law) (CL-161).

[674] *See* Resp. CM at Part II.D.

including those of a national judiciary.[675] At the same time, however, it is clear that this Tribunal is *not* being asked to perform anything resembling an appellate function. Lilly has *not* alleged that the Federal Court and Federal Court of Appeal misapplied Canadian law as it stood in 2010 and 2011. Rather, Lilly is alleging — and, indeed, has shown — that the dramatic change in Canada's domestic laws as reflected in the promise utility doctrine renders them fundamentally at odds with its international commitments.

### B. Canada's Measures Contravened the Standard of Fair and Equitable Treatment Guaranteed Under NAFTA Article 1105(1).

#### 1. Canada's Measures Violate Article 1105 Because They Are Arbitrary.

335. Canada does not dispute that Article 1105(1) encompasses a protection against arbitrary measures. Instead, Canada argues that the protection against arbitrariness is a high bar — one that requires "manifest arbitrariness," not just arbitrariness.[676] Adjectives aside, however, Canada does not dispute that a measure is arbitrary when it is unpredictable and incoherent, even if it is not motivated by bad faith.[677] Canada acknowledges that a measure is arbitrary when it "ha[s] no legitimate purpose."[678] When a law is incoherent and unpredictable, it plainly cannot serve any "legitimate purpose."[679]

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[675] Rudolf Dolzer and Christoph Schreuer, PRINCIPLES OF INTERNATIONAL INVESTMENT LAW 141 (2d ed. 2012) (CL-50).

[676] Resp. CM at ¶¶ 250-251. Canada also quotes from the definition of arbitrariness in the ICJ case of *Elettronica Sicula SpA* (ELSI). *See* Resp. CM at ¶ 250 (quoting *Elettronica Sicula SpA United States v. Italy*, ICJ, Judgment, 20 July 1989 ("[a]rbitrariness is not so much something opposed to a rule of law, as something opposed to the rule of law")). The *ELSI* case involved one form of arbitrariness — certain political and bureaucratic responses to the liquidation of a factory and a related event of labor unrest — but it did not exclude the possibility of other forms of arbitrariness. As Canada itself acknowledges, a government measure is also arbitrary if it has "no legitimate purpose" or is not "based on legal standards" (among other things). Resp. CM at ¶ 249.

[677] *See* Cl. Mem. at ¶ 261.

[678] Resp. CM. at ¶ 249.

[679] It is in part for this reason that tribunals have repeatedly emphasized the importance of transparency in the context of Article 1105(1). *See Metalclad v. Mexico*, at ¶ 99 (recognizing that (continued…)

336. The tribunal's decision in *Occidental v. Ecuador* provides further support for this interpretation of the protection against arbitrariness.[680] In *Occidental*, the tribunal held 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."[681] The tribunal concluded that it was the "*very confusion and lack of clarity that resulted in some form of arbitrariness,* even if not intended by" Ecuador's tax service.[682]

337. Canada strains to distinguish *Occidental* by arguing that it was decided under a treaty with a Fair and Equitable Treatment clause, rather than under the Minimum Standard of Treatment.[683] Canada asserts that "the *Occidental* Tribunal specifically distinguished the autonomous fair and equitable treaty standard it was bound to apply as distinct from the customary international law

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Article 1105(1) requires NAFTA states to provide "a transparent and predictable framework for … business planning and investment." ) (CL-49); *CMS Gas Transmission Co. v. Argentina*, ICSID Case No. ARB/01/8, Award (12 May 2005), at ¶ 276 ("the significant number of treaties . . . that have dealt with this standard also unequivocally shows that fair and equitable treatment is inseparable from stability and predictability") (CL-96); *MTD Equity Sdn. Bhd. v. Chile*, ICSID Case No. ARB/01/7, Award (25 May 2004), at ¶ 164 (host state "has an obligation to act coherently and apply its policies consistently") (CL-151); *Maffezini v. Spain*, ICSID Case No. ARB/97/7, Award (9 November 2000), at ¶ 83 ("the lack of transparency with which this loan transaction was conducted is incompatible with Spain's commitment to ensure the investor a fair and equitable treatment") (CL-163). While the *Metalclad* decision was set aside by Canada's courts because of its emphasis on the principle of transparency, commentators have criticized this decision. Rudolf Dolzer and Christoph Schreuer, PRINCIPLES OF INTERNATIONAL INVESTMENT LAW 150 & n.143 (2d ed. 2012) (observing that the set-aside "appears incorrect") (CL-50); David A.R. Williams, "Challenging Investment Treaty Awards," in Albert Jan van den Berg, INTERNATIONAL COMMERCIAL ARBITRATION: IMPORTANT CONTEMPORARY QUESTIONS 458 (2003) ("In *Metalclad* the court in effect took the view that it could set aside a decision which was inconsistent with its view of the applicable law.") (CL-162).

[680] *Occidental Exploration and Production Co. v. Republic of Ecuador*, UNCITRAL/LCIA Case No. UN 3467, Award (1 July 2004) [hereinafter *Occidental v. Ecuador*] (CL-97).

[681] *Id.* at ¶ 163.

[682] *Id.* (emphasis added).

[683] Resp. CM at ¶ 253 & n.475. Canada also notes that in *Occidental*, "the challenged actions were those of Ecuador's administrative tax authorities," not its courts. *Id.* But this attempt to distinguish *Occidental* is entirely reliant on Canada's position that its judiciary is immunized for violations of substantive norms of international law — a position already shown to be wrong. *See supra* Parts IV.B.1 and V.A.

minimum standard of treatment applicable in the NAFTA."[684] In fact, the tribunal found the *exact opposite*, concluding that "in the instant case *the Treaty standard is not different from that required under international law concerning both the stability and predictability of the legal and business framework of the investment*."[685]

338. Canada also attempts to distinguish *Occidental* by emphasizing that it involved decisions that were based on "wholly unsatisfactory and thoroughly vague" rationales that "failed to reconcile inconsistent and confusing practices and regulations."[686] Yet in these respects, the conduct of the Ecuadorian tax authorities is indistinguishable from the conduct of Canada's Federal Courts in developing the promise utility doctrine and applying it to the Zyprexa and Strattera patents.

339. As shown in Lilly's Memorial,[687] and again in Part II.D of this Reply Memorial, the promise utility doctrine is subjective, unpredictable and unreasonably difficult to satisfy for at least three reasons:

- *First*, the promise utility doctrine requires judges to undertake the inherently unpredictable task of identifying the "promises" contained in a patent and allows judges to "imply" such promises based on their reading of the patent.
- *Second*, the promise utility doctrine imposes a heightened evidentiary burden in respect of utility, and it results in judicial second-guessing of the scientific evidence submitted in support of a patent's utility.[688]

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[684] *Id.*

[685] *Occidental v. Ecuador*, at ¶ 190 (emphasis added) (CL-97). Canada points to paragraph 192 of the *Occidental* decision, in which the tribunal observed that since it was applying the Minimum Standard of Treatment, "[t]he question whether there *could* be a Treaty standard more demanding than a customary international law standard that has been painfully discussed in the context of NAFTA and other free trade agreements does not therefore arise in this case." *Id.* (emphasis added). In other words, the tribunal held that since Ecuador's measures violated the Minimum Standard of Treatment, it was not necessary to independently analyze whether there could be a Treaty-based Fair and Equitable standard that was more demanding. Nothing in this sentence supports Canada's assertion that the *Occidental* tribunal was "bound to apply" the autonomous Fair and Equitable Treatment Standard, as opposed to the Minimum Standard of Treatment.

[686] Resp. CM at ¶ 253 (quoting *Occidental v. Ecuador*, at ¶¶ 163, 184).

[687] Cl. Mem. at ¶¶ 263-271.

- *Third*, the disclosure requirement for "sound prediction" cases under the promise utility doctrine introduces an additional dimension of unpredictability, since evidence that is considered by the court to determine whether utility has been "demonstrated" is then ignored to determine whether utility is "soundly predicted."

340. Canada disputes each of these points. It argues that the construction of the promise is based on "long-standing" rules of construction.[689] It argues that the heightened evidentiary burden requires nothing more than an "ordinary balance of probabilities test" involving the standard adjudicative function of assessing "expert evidence put forward by the parties."[690] And it argues that the doctrine's disclosure requirement is merely a device to help skilled readers "recognize [a] prediction as sound."[691] As explained at length in Part II.B.3, Canada's arguments do not withstand scrutiny.

341. Canada's insistence that there is nothing incoherent or unpredictable about Canada's promise utility doctrine is also belied by actual litigation outcomes.[692] For example, in its Memorial, Lilly noted that the Canadian patent on latanoprost, a highly successful glaucoma drug, was construed completely differently by two Federal Court of Appeal panels, resulting in findings of two completely different promises.[693] As a result, one generic drug company was barred from selling a copy of the drug because the patent was deemed valid, even as another was permitted to enter the market because the patent was deemed invalid solely because it lacked utility.[694] Canada barely mentions this example in its Counter-Memorial, and offers no explanation for this patently absurd outcome.

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[688] Canada contends that no such burden exists. *See* Resp. CM at ¶ 257. This is simply not correct. *See supra* Part II.A.2.

[689] Resp. CM at ¶ 255.

[690] *Id.*

[691] *Id.* at ¶ 259.

[692] *See* Cl. Mem. at ¶¶ 64, 68.

[693] *Id.* at ¶¶ 64, 263.

[694] *Id.*

342. Canada's sole reference to the latanoprost litigation is its statement that "Claimant's reference to the outcome of two other patent cases involving the glaucoma drug latanoprost is irrelevant to this dispute. Those litigations did not involve the Claimant and the patents are completely unrelated to those at issue in this arbitration."[695] Given that Canada devotes a substantial portion of its submissions to raloxifene, a drug not at issue in this arbitration, it is ironic that Canada would seek to distinguish the latanoprost cases on this basis. In any event, Canada does not dispute that the courts in the latanoprost cases were applying precisely the same promise utility doctrine that resulted in the revocation of Lilly's Zyprexa and Strattera patents. Nor, as illustrated by the several similar cases discussed in Part V.B., can Canada meaningfully contend that the latanoprost litigation is merely an isolated or extreme case.

343. Canada's eagerness to gloss over the practical outcomes generated by the promise utility doctrine is unsurprising: even the doctrine's principal beneficiaries, Canadian generic drug companies, have acknowledged that the doctrine is in practice "a hopeless tangle of contradictory approaches" and a "'free-for-all' in which the outcome of cases depends upon the particular judge or panel hearing the dispute, rather than on legal authority."[696] Such incoherence cannot be squared with Canada's claims that the promise doctrine is objective and non-arbitrary.

344. Nor can the promise utility doctrine's inherent incoherence be reconciled with any of the purported policy objectives that Canada claims it serves. Canada maintains that the doctrine "ensures that the public receives its end of the patent bargain . . . where a particular promised utility [*i.e.*, an effective treatment for the claimed condition] is the only consideration that the public receives in exchange for the monopoly that it confers."[697] Yet Canada has not

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[695] Resp. CM at ¶ 256 & n.460 (citation omitted).

[696] Notice of Application for Leave to Appeal of Apotex Inc. et al, *Apotex Inc. v. Sanofi-Aventis*, S.C.C. File No. 35562, at ¶ 14 (September 30, 2013) (C-375).

[697] *See* Resp. CM at ¶¶ 7, 100.

alleged that Zyprexa, Strattera, or any of the other patented drugs affected by the promise utility doctrine actually failed as treatments. To the contrary, as Lilly has repeatedly made clear, the patents revoked under the promise utility doctrine cover pharmaceuticals that were approved by Canada's own health regulators as safe and effective and that are prescribed by doctors to Canadian patients every day.[698]

345. Canada next suggests that the promise doctrine addresses speculative patenting.[699] But as stated in Part II.D.3, Canada has submitted *no evidence at all* that the promise utility doctrine deters speculative patenting or that speculative patenting is somehow concentrated in the innovative pharmaceutical sector targeted by the promise utility doctrine. In place of such evidence, Canada relies on an attack on Lilly's patenting practices. But the patenting practices of one solitary company cannot support a rule of general applicability. And in any event, Canada's characterization of Lilly's patenting practices is pure fiction.[700]

346. As a last try, Canada suggests that the disclosure required under the doctrine of sound prediction helps skilled readers "recognize [a] prediction as sound" and thus assess the validity of the patent.[701] This last justification, even if it made sense, would not provide a rationale for the promise utility doctrine as a whole, since in some cases utility is "demonstrated" and the sound prediction analysis is never reached. There is also no way to tell from the face of a patent whether utility has been "demonstrated" or must be "soundly predicted." As explained in Part II.D, where a patentee is able to "demonstrate" utility, there is no obligation to include evidence of utility in the patent.

347. Canada has not explained why it is more important for skilled

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[698] *See* Cl. Mem. at ¶ 36; *supra* Part I.A.

[699] *See* Resp. CM at Part II.E; *see also id.* at ¶ 7.

[700] *See supra* Part II.D.3.

[701] Resp. CM at ¶ 259; *see also id.* at ¶ 100 ("The promise standard also promoted accuracy and discourages overstatement in patent disclosures, which is of paramount importance in a system aimed at securing public benefit from improvement in the state of knowledge.").

readers to be able to recognize "soundly predicted" utility than "demonstrated" utility. And the disconnect between the two disclosure rules is particularly perplexing because, as already mentioned, it is impossible to tell from the face of a patent which rule applies.[702] In other words, a skilled reader looking at a patent cannot know whether the patentee was required to include evidence of utility under the doctrine of sound prediction, let alone whether the patent satisfies that requirement. Thus, yet again, Canada's assertion is merely an attempt to manufacture a *post hoc* justification for the promise utility doctrine.

348. Canada has thus not only failed in its attempt to redefine the standard of arbitrariness under Article 1105(1), it has also failed in its attempt to re-cast the promise utility doctrine as rational or internally coherent. The doctrine's inherent subjectivity, vagueness and unpredictability, and its internal contradictions and inconsistencies, make clear that the doctrine cannot serve any legitimate policy objective. What is more, Canada has not credibly identified any policy objective that the doctrine was intended to serve. Instead, the doctrine has been applied to injure pharmaceutical innovators almost at random, sowing, as was found in *Occidental v. Ecuador*, "confusion and lack of clarity that resulted in some form of arbitrariness."[703]

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[702] In addition to this uncertainty regarding the promise utility doctrine's two disclosure rules, the promise utility doctrine's application depends on the subjective and unpredictable construction of the promise, as explained in Part II.D.1(a).

[703] Cl. Mem. at ¶ 271 (quoting *Occidental v. Ecuador*, at ¶ 163). The arbitrariness of Canada's measures is also underscored by the fact that they violate Canada's commitments in Chapter 17 of NAFTA. *See supra* Part IV.B.3. Canada observes that the FTC Notes provide that a "determination that there has been a breach of another provision of the NAFTA, or of a separate international agreement, does not establish that there has been a breach of Article 1105(1)." Resp. CM at ¶ 221 (quoting FTC Notes). But as Lilly has explained, "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 measures is arbitrary, and thus, in turn, a violation of Article 1105." Cl. Mem. at ¶ 271 & n.499.

### 2. The Revocation of Lilly's Patents Under the Promise Utility Doctrine Contravened Lilly's Legitimate Expectations.

349. Lilly's Memorial, and the evidence enclosed with it, showed that Lilly expected its patents would not be revoked under a radically new promise utility doctrine that was created after its patents were drafted, filed and granted.[704] Canada cannot and does not dispute that Lilly held this expectation.[705] Instead, Canada argues (i) that legitimate expectations are irrelevant to the Section 1105(1) analysis; and (ii) that such expectations must be grounded in a State's express representations, as opposed to its overall legal framework. These arguments are equally unavailing, leaving Canada in the position where its entire defense rests on the assertion that Lilly's expectations could not have been contravened, because Canada's utility requirement did not change. And as shown above in Parts II.A-B, this assertion is wrong as well.

#### a) Article 1105 protects against measures that violate legitimate, investment-backed expectations

350. Canada contends that Lilly's legitimate, investment-backed expectations are irrelevant to the minimum standard of treatment guaranteed under Article 1105(1).[706] According to Canada, Lilly has failed to independently produce "evidence of state practice or *opinio juris*" recognizing the relevance of an investor's legitimate expectations to the Minimum Standard of Treatment.[707]

351. Canada's argument — which it reflexively invokes in every NAFTA proceeding — is without merit. It ignores the fact that Lilly *has* produced ample

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[704] *See, e.g.*, Cl. Mem at ¶¶ 86-91, 123-24.

[705] *See infra* at ¶ 356 and accompanying note (describing Canada's failure to dispute the existence of Lilly's expectations, as reflected in the testimony of Robert Armitage, Peter Stringer, Robert Postlethwait and Anne Nobles).

[706] Resp. CM at ¶ 266.

[707] *Id.* at ¶ 269. The parties agree that under the 2001 Statement of the NAFTA Free Trade Commission, the Tribunal should apply "the customary international law minimum standard of treatment of aliens" as the standard of protection prescribed by Article 1105(1). *See* Cl. Mem. at ¶ 253 & n.453; Resp. CM at ¶ 221.

evidence of state practice and *opinio juris*. Specifically, Lilly's Memorial demonstrated that the treaty-based standard of fair and equitable treatment typically incorporated in bilateral or multilateral investment treaties (BITs) protects an investor's legitimate expectations, including those grounded in the host state's "legal and business framework."[708] Multiple tribunals and scholars have acknowledged that the practice of states in concluding more than 3,000 BITs constitutes relevant state practice and *opinio juris*.[709] As explained by Judge Schwebel, "when 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 . . . [concordant] BITs."[710]

352. In fact, because states have increasingly entrusted the resolution of significant investment disputes arising under international law to treaty-based tribunals, it is unclear how state practice and *opinio juris* could be demonstrated *without* considerable reliance on the "widespread and consistent practice" under investment treaties.[711] It is for this reason that tribunals and scholars have

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[708] *BG Group v. Argentina*, ICSID Case No. ARB/02/1, Award (24 December 2007), at ¶ 298 (CL-111). S*ee* Cl. Mem. at ¶¶ 254-55, 259, 272-73. *See also Tecnicas Medioambientales Tecmed S.A. v. Mexico*, ICSID Case No. Arb(AF)/00/2, Award (29 May 2003), at ¶ 154 (an investor may expect to "know beforehand any and all rules and regulations that will govern its investments, as well as the goals of the relevant policies") (CL-47); *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.") (CL-106); *LG&E Energy Corp. v. Argentina*, ICSID Case No. ARB/02/1, Decision on Liability (3 October 2006), at ¶ 130 (CL-110).

[709] *See* Cl. Mem. at ¶¶ 254-55; *Chemtura Corp. v. Government of Canada*, NAFTA/UNCITRAL Award (2 August 2010), at ¶ 121 (quoting *Mondev v. United States*, at ¶ 125) ("In holding that Article 1105(1) refers to customary international law, the 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.") (CL-92).

[710] Hon. Stephen Schwebel, *The Influence of Bilateral Investment Treaties on Customary International Law*, 2004 ASIL PROCEEDINGS 27, 29-30 (CL-98).

[711] Canada "does not disagree . . . that the content of the international minimum standard may evolve over time with the development of customary international law." Resp. CM at ¶ 227. But it proposes no forum or method for such evolution. There is an obvious one: the practice of states in entering into investment treaties, delegating authority to investment tribunals, participating in (continued…)

repeatedly recognized that the Minimum Standard of Treatment has evolved to provide protections coextensive with the treaty-based standard of Fair and Equitable Treatment[712] — including protections in respect of legitimate investment-backed expectations.[713]

353. This Tribunal, however, need not decide that the Minimum Standard of Treatment affords investors the same level of protection as the treaty-based Fair and Equitable Treatment Standard, or that BITs or arbitral awards constitute state practice or evidence of *opinio juris*, in order to accept that legitimate expectations are protected by NAFTA Art. 1105(1). Tribunals consistently rely on arbitral awards in identifying and analyzing customary norms of international law with regard to the Minimum Standard of Treatment, even without determining that such awards formally constitute state practice.[714] Thus, for example, the tribunal

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investment arbitrations, and complying with their results. Notably, Canada itself cites extensively to arbitral awards in an attempt to support its own narrow conception of Article 1105(1).

[712] *See Merrill & Ring v. Canada*, at ¶¶ 207, 210 (considering, *inter alia*, state practice in settling investment disputes as well as the practice of the Iran-U.S. Claims Tribunal as reflecting a "trend towards liberalization of the standard applicable to the treatment of business, trade and investments [that has] continued unabated over several decades and has yet not stopped") (CL-51); *Deutsche Bank v. Sri Lanka*, ICSID Case No. ARB/09/2, Award (31 October 2012), at ¶¶ 418-19 (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 Investments BV v. Czech Republic*, PCA/UNCITRAL Partial Award (17 March 2006), at ¶ 291 [hereinafter *Saluka v. Czech Republic*] (CL-85); *CMS Gas Transmission Company v. Argentina*, ICSID Case No. ARB/01/8, Award (12 May 2005), at ¶¶ 282-84 (CL-96). S*ee also Occidental v. Ecuador*, at ¶ 70 (CL-97).

[713] This position has been accepted by multiple NAFTA tribunals. *See, e.g.*, *Int'l Thunderbird Gaming Corp. v. Mexico*, at ¶ 147 (CL-104); *id.*, *Separate Opinion of Professor Thomas Walde*, at ¶ 34 (CL-104); *Grand River v. United States*, at ¶ 140 (CL-107); *see also Fireman's Fund v. Mexico*, at ¶ 176(k) n.163 ("Under a common view . . . 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-47).

[714] Notably, such awards include *Mobil & Murphy*, which is heavily relied upon by Canada. *See Mobil & Murphy v. Canada*, at ¶ 152 (summarizing the Art. 1105 standard "on the basis of the NAFTA case law and the parties' arguments") (CL-112). Other awards include: *Waste Management, Inc. v. Mexico*, at ¶ 98 (applying Article 1105 in light of "the *S.D. Myers*, *Mondev*, *ADF* and *Loewen* cases") (CL-64); *Loewen v. United States*, at ¶ 133 (relying on *Mondev v. United States*) (RL-13); *Bilcon of Delaware Inc. v. Government of Canada*, PCA/UNCITRAL, Award (17 March 2015), at ¶¶ 440-42 (continued…)

in *Railroad Development Corp. v. Guatemala* took the restrictive view that "arbitral awards do not constitute state practice," but nonetheless relied on NAFTA jurisprudence to interpret and apply the Minimum Standard of Treatment.[715] And Canada itself concedes that arbitral awards "may contain valuable analysis of State practice and *opinio juris* … and can be considered accordingly."[716]

354. As discussed in the following section, the analysis contained in these prior arbitral awards is clear: NAFTA tribunals applying Article 1105(1) have affirmed that it protects investment-backed expectations that are reasonable in light of a "Contracting Party's *conduct*," including in enacting and applying a legal and regulatory framework.[717]

**b) Lilly's expectations were legitimately grounded in Canada's patent law and the grant of the Zyprexa and Strattera patents.**

355. Lilly's evidence establishes that when it invested in Canada, it relied on Canada's long-standing and well-understood utility requirement.[718] Lilly closely tracked variations and risks in local patent law — particularly in significant markets like Canada — and no concerns were raised with respect to the

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[hereinafter *Bilcon v. Canada*] (relying on prior NAFTA cases including, in particular, *Waste Management v. Mexico*); *Int'l Thunderbird v. Mexico*, at ¶ 194 (citing multiple NAFTA and non-NAFTA awards to support its conception of the Art. 1105 standard) (CL-104). This practice, moreover, is not confined to NAFTA tribunals. *See TECO Guatemala Holdings LLC v. Guatemala*, ICSID Case No. ARB/10/23, Award (19 December 2013), at ¶¶ 455-56 (citing to NAFTA jurisprudence in a customary international law minimum standard claim under the CAFTA-DR) (RL-52).

[715] *Railroad Development Corp. v. Guatemala*, ICSID Case No. ARB/07/23, Award (29 June 2012), at ¶ 217 ("[P]arties in international proceedings use [awards] in their pleadings in support of their arguments of what the law is on a specific issue. There is ample evidence of such practice in these proceedings. It is an efficient manner for a party in a judicial process to show what it believes to be the law.") (CL-100).

[716] Resp. CM at ¶ 271.

[717] *Grand River v. United States*, at ¶ 140 (CL-107) (quoting *Int'l Thunderbird Gaming v. Mexico*, at ¶ 147).

[718] *See* Cl. Mem. at Part IV.A.1 and IV.B.1; *see also supra* Parts I.A-B and III.

usefulness of the Zyprexa and Strattera patents.[719] Further, in connection with the disclosure included in the Strattera patent, Lilly has demonstrated that it relied on Canada's ratification of the PCT, which does not permit Canada to require that proof of the utility of an invention be disclosed within the patent specification itself.[720]

356. As noted, Canada does not contest that Lilly, in fact, expected that its patents comported with Canada's utility requirement.[721] Canada argues, however, that Lilly's expectations are not protected under Article 1105(1) because they were grounded in Canada's legal regime, its treaty commitments, and its past practice under the *Patent Act* as opposed to express representations of Canadian officials.[722] Yet as the tribunal in *Grand River* explained, the Minimum Standard of Treatment protects investment-backed expectations that are reasonable in light of the "Contracting Party's *conduct*" — not just its express commitments.[723]

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[719] Cl Mem. at ¶¶ 275-79.

[720] *See supra* Part II.D.1(c); *see also* Cl. Mem. at ¶¶ 280-84.

[721] Instead, Canada argues that the senior Lilly attorneys and managers who have testified as to their expectations (Robert Armitage, Peter Stringer, Robert Postlethwait and Anne Nobles) have not "offere[d] evidence that they had any real understanding of Canadian patent law." Resp. CM at ¶ 293. Not only is this argument irrelevant to Lilly's actual expectations, it is also incorrect. Lilly's witnesses showed that (i) they expected Lilly's patents would meet Canada's utility and patentability standards and (ii) their expectations were based on Lilly's standard operating procedures, which kept senior Lilly employees abreast of patent validity risks across significant markets. *See, e.g.*, Armitage First Statement at ¶ 22 ("If our patent team had any concerns about our ability to protect Zyprexa in any of the countries where we had submitted an application — particularly a major market — those concerns would have been raised to me. We had frequent and periodic coordinating meetings . . . [and] I would specifically ask my team if there were any patent issues about which we should be concerned."); Postlethwait Statement at ¶ 23 ("the Canadian regulatory framework (both patent and health approval) was well-understood and did not pose any unique challenges"); Nobles Statement at ¶¶ 14, 17 ("I received regular updates about the prosecution of the Strattera patent in the jurisdictions where the patent had not already been granted, such as Canada . . . . If utility had been an issue, it certainly would have been flagged for my team by our patent attorney, and my team would have brought it to my attention.").

[722] *See* Resp. CM at ¶ 294 ("More to the point is that Canada made no promise or assurance to the Claimant with respect to its patents.").

[723] *Grand River v. United States*, at ¶ 140 (As the tribunal in *Int'l Thunderbird Gaming* explained, the "concept of 'legitimate expectations' relates . . . to a situation where a Contracting Party's conduct creates reasonable and justifiable expectations on the part of an investor (or investment) to act in (continued…)

357. Such "conduct" can include the conduct of a state as reflected in its legal and regulatory environment. As the tribunal in *Bilcon* recently recognized, while "state authorities with the power to change law or policy must have reasonable freedom to proceed without being tasked with having breached the minimum standard," this "freedom is not absolute; breaches of the international minimum standard might arise in some special circumstances—*such as changes in a legal or policy framework that … have retroactive effect*."[724]

358. Canada's restrictive interpretation, meanwhile, lacks persuasive support. Canada relies extensively on *Glamis Gold v. United States* and a second award, *Mobil and Murphy v. Canada*,[725] which itself draws heavily on *Glamis Gold*.[726] Central to both cases, however, is the 1927 decision of the Mexican Claims Commission in *Neer v. Mexico*.[727] It is by now well established that *Neer,* an almost century-old decision dealing with a state's response to a murder, no longer reflects the modern Minimum Standard of Treatment.[728] As the tribunal noted in *Bilcon*, "[t]he contemporary minimum international standard involves a more significant

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reliance on said conduct, such that a failure by the NAFTA Party to honour those expectations could cause the investor (or investment) to suffer damages.") (emphasis added) (CL-107).

[724] *Bilcon v. Canada*, at ¶ 572 (emphasis added) (CL-166); *see also* Cl. Mem. at ¶¶ 272-74 (quoting, *inter alia*, *BG Group v. Argentina*, at ¶ 298 ("The duties of the host state must be examined in light of the legal and business framework as represented to the investor at the time that it decides to invest.")).

[725] Resp. CM at ¶¶ 276-77.

[726] *See Mobil & Murphy v. Canada*, at ¶ 147 (describing the treatment of legitimate expectations in *Glamis Gold* as "of considerable relevance to the present case") (CL-112).

[727] *Glamis Gold, Ltd. v. United States of America*, NAFTA/UNCITRAL, Award (14 May 2009), at ¶ 627 (noting that claimant had failed to show a different standard applied) (CL-116).

[728] *See Bilcon v. Canada*, at ¶ 435 ("NAFTA tribunals have, however, tended to move away from the position more recently expressed in *Glamis*, and rather move towards the view that the international minimum standard has evolved over the years towards greater protection for investors.") (CL-166); *Merrill & Ring Forestry L.P. v. Canada*, at ¶ 201 ("The approach of the Neer Commission and of other tribunals which dealt with due process may best be described as the first track of the evolution of the so called minimum standard of treatment . . . . A second track . . . is also discernable in so far it concerns business, trade and investment.") (CL-51); *see also* Cl. Mem. at ¶ 254 & n.466.

measure of protection."[729]

359. Canada cites several other NAFTA cases, but none follow the restrictive approach of *Glamis Gold* and *Mobil and Murphy*. More importantly, none of these cases states — or even suggests — that Art. 1105(1) fails to protect legitimate expectations, or that such protection is limited to expectations grounded in specific representations of the host government.[730] In fact, many of the cases cited by Canada undercut its position.[731]

360. And even if Canada's restrictive interpretation were accepted, Canada's measures would still contravene Lilly's legitimate expectations because Canada *did* make specific representations to Lilly in the form of the grant of the Zyprexa and Strattera Patents.[732] Lilly relied on these representations in

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[729] *Bilcon v. Canada*, at ¶ 433 (CL-166).

[730] Canada cites *Waste Management v. Mexico*, but the dispute in that case did not involve any claims relating to the investor's legitimate expectations and the tribunal had no occasion to discuss whether the standard protects expectations grounded in conduct. *See Waste Management v. Mexico*, at ¶ 98 (noting in passing that it is relevant to the minimum standard whether "treatment is in breach of representations made by the host state") (CL-65).

[731] Canada cites to *Metalclad*, *Grand River* and *International Thunderbird* – three cases in which tribunals considered evidence that the host government had made specific representations to an investor. But none of these cases presents such evidence as *necessary* to a determination that a host state had violated an investor's legitimate expectations. Resp. CM at ¶ 280. To the contrary, *Metalclad* emphasized the importance of the "totality of the[] circumstances" surrounding an investment. *Metalclad v. Mexico*, at ¶ 99 ("Mexico failed to ensure a transparent and predictable framework for Metalclad's business planning and investment. *The totality of these circumstances* demonstrates a lack of orderly process and timely disposition in relation to an investor of a Party acting in the expectation that it would be treated fairly and justly in accordance with the NAFTA.") (emphasis added) (CL-49). And both the *Grand River* and *International Thunderbird* tribunals expressly recognized the relevance of a host state's "*conduct*" in engendering investor expectations. *Grand River v. United States*, at ¶ 140 (quoting *Int'l Thunderbird Gaming v. Mexico*, at ¶ 147) (emphasis added) (CL-107). In fact, while *Grand River* did note that legitimate expectations are frequently grounded in specific representations, it also specifically contemplated that the general legal and regulatory landscape might, in an appropriate case, serve as a "source[] of reasonable or legitimate expectations for the purposes of a NAFTA claim." *Grand River v. United States*, at ¶ 141 (CL-107).

[732] *See Frontier Petroleum v. Czech Republic*, at ¶ 285 (explaining that an investor may rely on the "legal framework as well as on representations and undertakings made [in] . . . decrees, licenses, and contracts" and that "an arbitrary reversal of such undertakings will constitute a violation of fair and equitable treatment") (RL-67); *Metalclad v. Mexico*, at ¶ 98 (relying, inter alia, on the (continued…)

continuing to invest in the value of its patents, including by investing in regulatory approvals and marketing.[733]

361. Canada seeks to evade the specific commitments inherent in the Zyprexa and Strattera Patents by arguing that patents are subject to judicial invalidation.[734] Accordingly, Canada reasons, any reliance Lilly placed on the validity of its granted patents was not legitimate.[735] But Canada's position conflates the everyday risk that a patent (like any right to property[736]) might be invalidated under preexisting law with the categorically different risk at issue here: that a patent will be tested against a radically new patentability requirement that could not have been foreseen at the time of patenting.

362. Canada also argues that Lilly's patents cannot represent a specific assurance on the part of Canada because "judges do not – and cannot – make promises or representations to a foreign investor."[737] But this, too, is a *non sequitur*. The specific representations here were made in the form of patents granted by Canada's Patent Office, which sits within the executive branch. The capacity of Canada's judges to make specific representations to investors is not at issue.

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"issuance of . . . federal permits" in holding that the claimant's legitimate expectations were breached) (CL-49).

[733] *See* Nobles Statement at ¶ 23 ("Once we received the Strattera patent, moreover, we had a legal entitlement to exclusivity, which provided us with additional confidence in planning for launch."); Postlethwait Statement at ¶ 30 ("As 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.").

[734] Resp. CM at ¶ 294.

[735] *Id.*

[736] *See supra* Parts I.C and IV.A.

[737] Resp. CM at ¶ 288.

### c) The Revocation of Lilly's Zyprexa and Strattera Patents under the Promise Utility Doctrine Contravened Lilly's Legitimate Expectations.

363. The previous sections establish that Lilly's expectations were legitimately grounded both in Canada's long-standing traditional utility requirement *and* in Canada's specific representations to Lilly in the form of the grant of the Zyprexa and Strattera patents. Canada's defense to Lilly's evidence regarding its legitimate expectations thus hinges on the argument that Lilly's expectations could not have been contravened because Canada's utility requirement has not changed.

364. As discussed in Parts II.A-B above, however, this argument completely misses the mark. The promise utility doctrine reflected a dramatic departure in the legal framework that Lilly relied upon in applying for patent protection and in continuing to invest in the value of the Zyprexa and Strattera patents by marketing the medicines in Canada.[738] The law of utility was transformed: from a consistent, low bar requiring a single, identifiable use, to a highly burdensome test that could vary dramatically in application based on the subjective interpretation of the promise of the patent. The meaning of usefulness was upended, as was the extent and type of evidence required to show usefulness. As demonstrated above, this transformation was in no way foreshadowed.[739] It bore no relationship to prior practice or to the policies traditionally motivating the utility doctrine, and it violated Canada's international obligations under Chapter 17 of NAFTA.[740]

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[738] *See supra* Parts I.D and III; *see also* Cl. Mem. at ¶ 275.

[739] *See supra* Part II.

[740] *See supra* IV.B.3. As noted above, the Tribunal should consider Canada's breach of Chapter 17 as a factor among others in determining whether Canada's measures are in breach of Article 1105(1).

### 3. Canada's Revocation of the Zyprexa and Strattera Patents Also Violates Article 1105(1) Because It Was Discriminatory.

365. In its Memorial and in Part II.D.2. above, Lilly has demonstrated that Canada's promise utility doctrine discriminates against pharmaceutical innovation as a field of technology.[741] While Canada does not contest that Article 1105(1) protects against discrimination, it seeks to minimize this protection by arguing that Article 1105(1) is only triggered in connection with "unjustifiable discriminatory treatment in court proceedings *founded on the investor's foreign nationality*, not mere differential treatment."[742]

366. Here again, Canada's efforts to narrow the scope of Article 1105(1) are unavailing. It may be true that the most *common* form of discrimination under international law is nationality-based discrimination or discrimination on the basis of some other racial or sectional prejudice, including as alleged in the cases on which Canada relies.[743] But Canada does not cite any authority for the proposition that such discrimination is the *exclusive* form of discrimination cognizable under Article 1105(1). To the contrary, tribunals have defined discrimination more broadly than Canada maintains.[744] As explained in

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[741] Cl. Mem. at ¶¶ 219-222.

[742] Resp. CM at ¶ 262 (emphasis added); *see also id.* at ¶ 262 & n.470 (arguing that "discrimination in international law means targeting an investor because of its foreign status," and that no other form of discrimination is cognizable under Article 1105(1)).

[743] *See* Resp. CM at ¶ 262 (citing *Loewen v. U.S.* and *Waste Management v. Mexico*).

[744] At least one of the cases relied on by Canada suggests that impermissible discrimination in the context of fair and equitable treatment covers broader ground than national, sectional or racial discrimination alone. In *Lemire v. Ukraine*, the tribunal determined that a "politically motivated preference" can represent a cognizable instance of "discrimination" in contravention of the standard of fair and equitable treatment. *Lemire v. Ukraine*, ICSID Case No. ARB/06/18, Decision on Jurisdiction and Liability (14 January 2010), at ¶¶ 335, 356 (recognizing political discrimination in favor of a "political ally and supporter of [a previous] President of the Ukraine") (RL-29). Further, the very paragraph of *Lemire* cited by Canada makes clear that discrimination in the context of a fair and equitable treatment claim can arise not only in connection with a measure that is "discriminatory and expose[s] the claimant to sectional or racial prejudice" or that "target[s] Claimant's investments specifically as foreign investments," but also in connection with a measure that treats a given case "differently from similar cases without justification." *See* Resp. CM at ¶ 262 & n.470 (citing *Lemire v. Ukraine*, ICSID Case No. ARB/06/18, Decision on Jurisdiction and Liability (14 January 2010), at ¶ 261). Far from supporting Canada's position, *Lemire* is in fact an (continued…)

*Saluka v. Czech Republic*, for example, discrimination encompasses differential treatment on the basis of *any* "unjustifiable distinction[]."[745]

367. As discussed above,[746] Lilly's statistical evidence demonstrates that the promise utility doctrine violates this standard. It has been used to revoke dozens of pharmaceutical patents but not a single non-pharmaceutical patent. As explained by Professor Levin, a statistical analysis of all Canadian patent validity cases decided between 1980 and the present reveals a statistically significant "disproportionate impact" on pharmaceutical patents — one that appears to be "attributable to the ground of utility alone."[747]

368. And even if Canada's limited, nationality-focused understanding of the scope of impermissible discrimination were correct, the promise utility doctrine would still be discriminatory. The principal beneficiaries of the promise utility doctrine are generic drug makers (many of which are based in Canada), and those harmed are innovative foreign firms.[748] Canada argues that the promise

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example of the principle that discrimination may extend to differential treatment based on a range of unjustifiable distinctions.

[745] *Saluka v. Czech Republic*, at ¶ 290 & n.536 (CL-85). This interpretation follows from the dictionary definition of "Discrimination," which covers any differential treatment that cannot be justified by a reasonable distinction.

[746] *See supra* Part II.D.2.

[747] Levin Report at ¶ 27. As noted above, that Canada's discriminatory conduct also violates Chapter 17 of NAFTA is further support for the conclusion that Canada's measures violate Article 1105(1).

[748] Cl. Mem. at ¶ 291 & n.539 ("The groups [adversely] affected [by the promise utility doctrine] 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, at 11 (2013) (C-307). Both Apotex and Pharmascience are generic drug companies. *Id.*

(continued…)

utility doctrine applies equally to "Canadian innovator companies, including biopharmaceutical companies," but that only tells part of the story.[749] While facially neutral, the promise utility doctrine has — in fact — only been used to invalidate patents held by foreign investors.[750] According to Canada's own data, nine of the top 18 generic drug companies operating in Canada are domestically owned, and even this figure understates the prominence that Canadians have in the generic drug industry globally.[751] The promise utility doctrine discriminates in favor of this prominent domestic industry at the expense of foreign patent holders.

* * *

369. Article 1105(1) is often analyzed through separate lenses, including those of arbitrariness, discrimination, and legitimate expectations. But as noted in Lilly's Memorial, these are each different "aspects" of a single rule.[752] Much of Canada's response consists of technical arguments as to why its measures do not fall within (or cannot be evaluated under) one or another of the three cited aspects

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Relatedly, Article 1709 of NAFTA forbids discrimination "as to . . . the territory of the Party where the invention was made." NAFTA Art. 1709(7) (CL-44). The promise utility doctrine runs afoul of this requirement, as well. In particular, every patent invalidated under the promise utility doctrine is derived from a non-Canadian patent, indicating that it covers a non-Canadian invention, and none were invented by a Canadian national. *See* Canadian Patents Invalidated on Grounds of Inutility Post-2005 (C-392); *see also* Cl. Mem. at ¶ 291 & n.539 (noting that all patents invalidated under the promise utility doctrine were owned by non-Canadian firms).

[749] Resp. CM at ¶ 264.

[750] Cl. Mem. at ¶ 291 & n.539.

[751] Resp. CM at ¶ 264. Canada's figures also understate the presence and influence of the generic pharmaceutical sector in its economy. One of the largest of the firms it classifies as foreign, Teva, traces its Canadian roots to Novopharm, a half-billion dollar generic drug behemoth founded by Leslie Dan, a celebrated Canadian citizen who, among other things, has been awarded the Order of Canada and the Order of Ontario and has been memorialized as a Canadian "nation builder" by the Canadian Museum of Immigration. *See* Nation Builder: Leslie L. Dan, C.M., O.ONT., http://www.pier21.ca/about/our-nation-builders/leslie-l-dan (C-390); Leslie Dan, The Royal Conservatory, https://www.rcmusic.ca/governance/leslie-dan (C-389).

[752] Cl. Mem. at ¶ 257. Or as others have put it, arbitrariness, discrimination, and legitimate expectations are merely part of "a list of factual situations covered by FET" that is "not exhaustive." *See* Ioana Tudor, THE FAIR AND EQUITABLE TREATMENT STANDARD IN THE INTERNATIONAL LAW OF FOREIGN INVESTMENT 155 (Oxford 2008) (C-391).

of the Minimum Standard of Treatment. These arguments are incorrect. But they also fail to account for the "totality of the circumstances" surrounding the promise utility doctrine and its use in the invalidation of the Zyprexa and Strattera patents.[753]

370. In determining whether Article 1105(1) has been breached, the Tribunal should consider the cumulative impact of the arbitrary, discriminatory and retroactive effects of the promise utility doctrine. In other words, as recognized in *Waste Management*, it should "adapt[] [its analysis] to the circumstances of [the] case."[754] A holistic examination of the promise utility doctrine and its application to Lilly's patents unmistakably reveals that Canada has failed to respect the values of "stability, transparency . . . [and] legitimate expectations" which sit at the core of the Minimum Standard of Treatment as it is applied in modern investment arbitration.[755]

[753] *Metalclad v. Mexico*, at ¶ 99 (emphasis added) (CL-49).

[754] *See Waste Management v. Mexico*, at ¶ 99 ("Evidently the [minimum] standard is to some extent a flexible one which must be adapted to the circumstances of each case.") (CL-65).

[755] *See* Rudolf Dolzer and Christoph Schreuer, PRINCIPLES OF INTERNATIONAL INVESTMENT LAW § VII(1) (2d ed. 2012) ("An examination of the practice of tribunals demonstrates that several principles can be identified which are embraced by the standard of fair and equitable treatment. The cases discussed below clearly speak to the central role of stability, transparency and the investor's legitimate expectations for the current understanding of the FET standard.") (CL-50); *see also Int'l Thunderbird Gaming v. Mexico*, Separate Opinion of Walde at ¶¶ 36-37 (explaining that an emphasis on transparency is also consistent with the objectives of NAFTA) (CL-113).

## VI. CONCLUSION

371. For the foregoing reasons, Lilly respectfully requests that the Tribunal dismiss the defenses raised in Canada's Counter-Memorial and render an award in favor of the Claimant granting the relief set forth in its Statement of Claim.

Respectfully submitted,

[signed]

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**Figure 1: Canadian Inutility Decisions (1980 – Present)**

(Based on Case List at Levin Report, Appendix C)