

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

ELI LILLY AND COMPANY

Claimant

v.

GOVERNMENT OF CANADA

Respondent

CLAIMANT'S REPLY POST-HEARING MEMORIAL

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1. Despite Canada’s continuing efforts to redefine Lilly’s claim, this is – and has consistently been – a case about substance, not process. Lilly’s Zyprexa and Strattera patents were revoked under an arbitrary and discriminatory doctrine of law that breached Canada’s international obligations and violated Lilly’s legitimate expectations. No amount of process can justify these revocations; nor can the fact that they reflect the application of domestic law by the Canadian courts. The taking of Lilly’s property rights violates the substantive protections of NAFTA Articles 1110 and 1105.

2. This Reply Post-Hearing Memorial addresses material omissions and misstatements in Canada’s Post-Hearing Memorial. These gaps in Canada’s arguments underscore Canada’s inability to meet Lilly’s claim on the merits.

I. Canada has identified no authority for the view that injury to one investment can trigger the limitations period for a legally distinct investment.

3. Canada’s jurisdictional objection rests on two dubious propositions. First, Canada argues that UNCITRAL Rule 21(3) is intended to apply only “in . . . commercial arbitration” and not “in the context of treaty-based investment arbitration” – even where the treaty selects the UNCITRAL Rules to govern procedure.¹ Second, Canada argues that harm to one investment can trigger the limitations period with respect to a second, legally distinct investment.² Canada cannot find, and has not found, any authority whatsoever to support either proposition.³ Its untimely jurisdictional

¹ See Resp. Post-Hearing Mem. at ¶¶ 84-88. Canada’s argument ignores the fact that the UNCITRAL Rules are incorporated in Chapter 11, except as expressly modified. Cl. Post-Hearing Mem. at ¶¶ 37-38. Canada has also argued that Lilly changed its argument such that Canada’s jurisdictional objection did not arise until after Canada filed its Counter-Memorial. But there has been no such change in Lilly’s argument, see Cl. Opp. to Resp. Jur. Objection at Part I.B, a fact that is perhaps best illustrated by Canada’s Post-Hearing Memorial, which strains to find what it describes as Lilly’s “first” argument in a fact witness statement submitted with Lilly’s Memorial (Resp. Post-Hearing Mem. at ¶ 80) and the “second” argument in a *Redfern* schedule (*id.* at ¶ 81). Even these stray comments do not support Canada’s claims. See generally Cl. Opp. to Resp. Jur. Objection at Part I.B.

² Resp. Post-Hearing Mem. at ¶ 96.

³ Remarkably, the only source cited in support of Canada’s argument that treaty-based jurisdictional objections cannot be waived is Canada’s own Closing Statement in this arbitration. See Resp. Post-Hearing Mem. at ¶¶ 84-88 & nn.159-160. There is no support for the notion that harm to one investment can start the limitations period for a legally distinct investment. To the contrary, *Grand River, Mondev, Feldman, UPS, Glamis Gold, Apotex, and Bilcon* each confirm the Tribunal’s ability to rely on the (continued...)

objection must be dismissed.⁴

II. MOPOP revisions, CIPO examiner reactions, Canadian case law, patent invalidation statistics, the practice of other NAFTA states, and discussions in international fora all confirm that the promise utility doctrine reflects a radical change in Canadian law.

4. Canada's Post-Hearing Memorial continues to misrepresent Lilly's position in this arbitration.⁵ Two examples are particularly flagrant. First, Canada asserts that Lilly "clarified" that none of the elements of the current utility test are sufficient in and of themselves to "breach Canada's obligations under NAFTA."⁶ Second, Canada asserts that Lilly admits it must prove that each element of the promise utility doctrine reflects a dramatic change in Canadian law.⁷ These statements are false. As Lilly made clear in responding to the Tribunal's Question 9, Canada has been in breach of its Chapter 17 obligations since at least 2005 (prior to the development of the heightened disclosure rule), which is the point at which Canada began revoking patents on pharmaceutical inventions used by Canadian patients on a daily basis.⁸ While the evidence proves that each element of the promise utility doctrine is new,⁹ Lilly's claim

development of the promise utility doctrine, including through the *Raloxifene* case, as a factual predicate to Canada's invalidation of the Strattera and Zyprexa patents. See Cl. Opp. to Resp. Jur. Objection at Part II.B.

⁴ See *id.* at ¶ 50. Even if Canada's legal position were correct, its objection would still fail on the facts. There were fact-specific reasons that Lilly did not know – and could not reasonably have known – that the new rule articulated in the *Raloxifene* case would also be applied to invalidate the Zyprexa and Strattera patents. Cl. Post-Hearing Mem. at ¶ 42; see *id.* at ¶¶ 28-38.

⁵ Canada also misrepresents Lilly's position in other proceedings. At ¶ 115 of its Post-Hearing Memorial, Canada asserts that "Claimant acknowledged the longstanding place of the promise standard in submissions to the Supreme Court of Canada." Lilly responded to this misstatement when it was made in the *amicus* submission of the Canadian generic pharmaceutical lobby. Cl. Comments on Art. 1128 and *Amicus* Submissions at ¶ 61 (explaining that the cited Lilly statement was not in response to the invalidation of its patent under the promise utility doctrine, but, rather, in response to a Federal Court of Appeal determination that Lilly's Zyprexa patent was not an "invalid selection patent" since there is no basis for treating selection patents differently from other patents under Canadian law).

⁶ Resp. Post-Hearing Mem. at ¶ 11.

⁷ *Id.* at ¶ 109.

⁸ See Cl. Post-Hearing Mem. at Appendix, Question 9; see also *id.* at Part IV.B.4; Cl. Opening Statement, Tr. at 121:14-22; Cl. Reply at ¶¶ 275, 291-292, 298-300; Cl. Mem. at ¶¶ 81, 207-209.

⁹ Cl. Post-Hearing Mem. at Part II; see *id.* at Part II.C.2.

is well-founded even if some element of the doctrine is found to have an antecedent in prior law. Such an antecedent would not alter the fact that, taken as a whole, the utility requirement Canada applied to revoke Lilly's patents is a radical departure from the utility requirement in force when Lilly's patents were filed and granted.¹⁰

5. Canada also asserts that Lilly has "conced[ed] that patentees have always been held to promises of utility . . . in the claims."¹¹ Lilly has never questioned that the invention, as claimed, must work and be operable.¹² This requirement remains part of Canada's mere scintilla standard and has no relationship with the promise utility doctrine.¹³ Whereas prior law simply required operability of the claimed invention, under the promise utility doctrine, the courts have for the first time derived elevated "promises" of utility from the patent disclosure¹⁴ and, even more egregiously, have found "implied" promises with no basis in either the claims or the disclosure.¹⁵ In these and other respects, Canada's Post-Hearing Memorial responds to a straw man rather

¹⁰ See *id.* at Parts II.A-B, II.D-F.

¹¹ Resp. Post-Hearing Mem. at ¶¶ 113-114.

¹² Cl. Post-Hearing Mem. at ¶ 89.

¹³ See *id.* at ¶ 93 (discussing the *Consolboard* and *New Process Screw* cases, where the purported "promise" of utility was specifically claimed). As Professor Siebrasse explained prior to these proceedings, finding that an invention is inoperable as claimed does "not imply a heightened utility." Norman V. Siebrasse, "The False Doctrine of False Promise," (2013) 29 CAN. INTELL. PROP. REV. 3, at 6-7 (published online in 2012, at <http://ssrn.com/abstract=2171762>) (C-205).

¹⁴ Canada asserts, at ¶ 125 of its Post-Hearing Memorial, that "[n]othing in any of the early promise authorities identified above supports Claimant's and Mr. Reddon's view that patentees would only be held to promises found in the claims." Canada's statement is directly contradicted by the *Mobil Oil* and *Unilever v. P&G* decisions, which rejected the challengers' arguments that the patentee should be held to so-called "promises" of utility made in the disclosure of the patent. Cl. Post-Hearing Mem. at ¶ 96.

¹⁵ *Id.* at ¶¶ 296-298, 307. The *Strattera* case provides an example of such "implied" promises, with the trial court holding: "What is *implicit* in this promise is that atomoxetine will work in the longer term" as a treatment for "chronic" ADHD. *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, ¶ 112 (C-160). The trial court came to this decision even though neither the phrase "longer term" nor the word "chronic" appeared in the claims or the disclosure, and even though *Strattera* is also approved to treat acute (*i.e.*, short-term) ADHD. Cl. Reply at ¶¶ 175, 214. The *latanoprost* case provides another example of the practice of finding implied promises. Cl. Post-Hearing Mem. at ¶ 298 (citing *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, at ¶ 29). In *Zyprexa*, too, after first construing the promise from the disclosure rather than the claims, the court went on to find an implied promise of long-term clinical effectiveness since "[c]learly, schizophrenia is a chronic condition." See *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, ¶ 210 (C-146); see also Cl. Reply at ¶ 105.

than the facts before it.¹⁶

6. In addition, Canada's continued attempt to present the bar on post-filing evidence and the sound prediction disclosure rule as something other than part of its utility requirement is inconsistent not only with Canadian law, which treats the promise utility doctrine as a unified whole,¹⁷ but also with Canada's own submissions in this case.¹⁸ Canada's effort to subdivide the promise utility doctrine is motivated by a single fact: Canada's inability to identify even one decision as an antecedent for the doctrine as a whole, and as applied by today's courts.¹⁹

A. The Canadian MOPOP confirms Canada's radical change in law.

7. Canada's own witness, Dr. Michael Gillen, testified that the MOPOP is an authoritative guide to Canadian patent law, used both by patentees and by examiners,

¹⁶ By way of a further example Canada argues that the Zyprexa patent hypothetically could have been invalidated for obviousness, as well as lack of utility. Resp. Post-Hearing Mem. at ¶ 257. This argument is not only speculative, it is demonstrably false. Every Canadian court to examine the Zyprexa patent on grounds of non-obviousness held that it was in fact non-obvious. See *Eli Lilly Canada Inc. v. Apotex Inc.*, 2007 FC 455, at ¶¶ 350-351 (“[T]he discovery of the special advantages of olanzapine required empirical research and was inventive [non-obvious]. . . . [T]he Court has no doubt that the overall side effect profile described in the [Zyprexa] Patent constitutes a substantial advantage of the selected compound over the other members of the [genus] Patent as well as other known antipsychotic agents.”) (R-207); *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197, at ¶¶ 57, 62-64 (also relying on “the special properties of the compound, along with its alleged advantages”) (C-46). Moreover, the Zyprexa trial court expressly rejected the generic challenger's argument that the patent should be invalidated under section 53 of the Patent Act (for false statements in the disclosure), stating: “Novopharm has not persuaded me that Lilly made any false statements.” *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 1018, at ¶ 151 (C-145). Not only is Canada's fiction that these patents could have been invalidated for lack of obviousness incorrect, it is also irrelevant. The investments at issue were invalidated solely based on the promise utility doctrine. Cl. Closing Statement, Tr. at 1991:1-17, 1998:12-1999:8; Cl. Reply at ¶¶ 210-211; Cl. Mem. at ¶¶ 111, 140.

¹⁷ See Cl. Post-Hearing Mem. at Part II.C.1.

¹⁸ Canada and its experts have repeatedly presented these rules as integrated with its substantive utility requirement. See, e.g., Resp. Post-Hearing Mem. at ¶ 264 & n.662 (stating that sound prediction is “a more flexible” test for utility “whereby utility will be presumed where the patentee makes a sufficient disclosure”) (quoting Dimock First Report, at ¶¶ 99-100); *id.* at ¶¶ 138-139 (post-filing evidence rule results from the fact that “the utility requirement is a precondition to an invention”) (internal quotations omitted). Canada further suggests that, “over the course of th[is] arbitration,” Lilly characterized the AZT bar on post-filing evidence as separate from the promise utility doctrine. *Id.* at ¶ 239 & n.585. But the only support for this position is an isolated quote from a November 2012 Notice of Intent. *Id.*

¹⁹ See Cl. Closing Statement, Tr. at 2035:19-2039:6.

and that there is no other manual used by patent examiners as part of their work.²⁰ Dr. Gillen testified also that revisions to the MOPOP are driven by changes in the law.²¹ Against these admissions, Canada's continued attempts to dismiss the relevance of the MOPOP are unconvincing,²² and merely underscore that Canada has no explanation for the significant changes in Canada's utility requirement that successive MOPOP drafts reveal.

B. Canadian patent examiners confirm Canada's radical change in law.

8. Having failed to present evidence at the Hearing to explain patent examiners' concern at the rapid change in Canada's utility requirement (and the resulting changes in Patent Office practice), Canada now suggests that Lilly misrepresented selected examiners' comments.²³ This new and belated response is false; the exhibits, read as a whole, speak for themselves.²⁴ Moreover, Canada has still offered no answer to multiple examiner comments that it does not discuss in its Post-Hearing Memorial, which clearly indicate that Canada's own subject matter experts viewed the promise utility doctrine as new and problematic.²⁵

²⁰ Testimony of Michael Gillen, Tr. at 959:13-18, 1016:3-16. Canada's other Canadian patent law expert, Mr. Ronald Dimock, also cited to MOPOP to support his expert opinions in this proceeding. Compare Dimock Second Report, at ¶ 97 ("This line of jurisprudence is also reflected in the January 1990 version of the Patent Office's *Manual of Patent Office Procedure* ('MOPOP'), which made clear that an inventor could not claim to have made an invention until the utility of the invention was established.") with Resp. Post-Hearing Mem. at ¶ 133 & n.272 (quoting Mr. Dimock as stating that he does not use MOPOP as a source of authority in cases he argues).

²¹ Testimony of Michael Gillen, Tr. at 970:18-971:11, 982:24-983:16.

²² See Resp. Post-Hearing Mem. at ¶¶ 133-134.

²³ *Id.* at ¶ 136.

²⁴ See Canada Doc. No. 910, at 065383, 65387, 065397 (C-358); Canada Doc. No. 794, at 063529 (C-356).

²⁵ See Cl. Post-Hearing Mem. at Part II.B; Cl. Closing Slides, at 11-13; Cl. Reply at ¶¶ 130-137. Examples of examiner comments and other internal CIPO documents left unanswered by Canada include: Canada Doc. No. 39 (discussed in Closing Slides) (C-491); Canada Doc. No. 1119, at 067254 (discussed in Reply) (C-355); Canada Doc. No. 921, at 065459-60 (noting that the new bar on post-filing evidence of utility "directly contradict[s] a Commissioner's decision") (discussed in Closing Slides) (C-362); Canada Doc. No. 1065, at 066681 (discussed in Cl. Post-Hearing Mem.) (C-357).

C. Canadian cases confirm Canada's radical change in law.

9. Canada seeks to undermine Professor Norman Siebrasse's expert evidence regarding the change in Canadian jurisprudence by accusing Professor Siebrasse of holding inconsistent views.²⁶ But in his academic writings, written reports, and oral testimony, Professor Siebrasse has consistently stated that the promise utility doctrine is new.²⁷ He has consistently stated that, prior to 2005, *Consolboard* was not understood as a bifurcated utility requirement allowing for the subjective construction of heightened promises, as it is today.²⁸ And he has made clear that *Welcome v. Apotex* also did not establish a bifurcated utility requirement.²⁹ The articles Canada cites in an effort to make its case are articles that Professor Siebrasse wrote about the emergence of the new

²⁶ Resp. Post-Hearing Mem. at ¶¶ 115, 119.

²⁷ For example, in an article published prior to these proceedings, "The False Doctrine of the False Promise" (published online in 2012, at <http://ssrn.com/abstract=2171762>) (C-205), Professor Siebrasse explained that: "The emergence of the 'promise of the patent' doctrine is an important recent development in Canadian patent law, which primarily impacts pharmaceutical patents." See also Siebrasse Second Report, at ¶ 27; Testimony of Norman Siebrasse, Tr. at 522:8-15.

²⁸ See Cl. Post-Hearing Mem. at ¶ 88 (discussing the *Feherguard*, *Almecon*, and *Goldfarb* cases, and related testimony). Canada's assertion, at ¶ 121 of its Post-Hearing Memorial, that "[e]ven Professor Siebrasse" cited *Consolboard* for the utility requirement (in a 2004 paper on another topic) is irrelevant. The question is not whether *Consolboard* was previously cited, but rather, what test it was understood to impose. Prior to 2005, *Consolboard* was understood to reflect the traditional mere scintilla test. See Siebrasse First Report, at ¶¶ 72-80; Testimony of Norman Siebrasse, Tr. at 522:11-15; *id.* at 587:2-588:4 ("MR. JOHNSON: . . . [Y]ou would agree that on the plain reading of these words on their face, there is a bifurcated statement here about what 'not useful' means in Canadian patent law. PROFESSOR SIEBRASSE: No, I disagree."). Professor Siebrasse's testimony that the Canadian courts' current reading of *Consolboard* is "plausible," see Resp. Post-Hearing Mem. at ¶ 120, also does not change the fact that it is a new and radically different reading of that case. Moreover, there is no conflict between Professor Siebrasse's position regarding *Consolboard* and that expressed by Mr. Reddon. Both consider it uncontroversial that utility, like other patentability requirements, must be assessed by reference to the claimed invention, and both presented as unremarkable the fact that, under prior law, the courts always required that the claimed invention be operable. See Cl. Post-Hearing Mem. at ¶ 89 & n.100. Finally, the text of *Consolboard* itself does not support the idea that it establishes a bifurcated standard: the words "or, more broadly" appearing at paragraph page 525 of *Consolboard* (C-118) typically connect two phrases denoting the same thing, not distinct alternatives. See Testimony of Norman Siebrasse, Tr. at 597:14-599:6.

²⁹ See Resp. Post-Hearing Mem. at ¶ 123, n.256; Testimony of Norman Siebrasse, Tr. at 733:12-735:1 ("[T]he court didn't apply any elevated standard. . . . It was enough that the invention worked for the identified purposes.").

doctrine – their very existence undermines Canada’s point.³⁰

10. Canada also falsely asserts that Professor Siebrasse agreed that various commentators expressly considered the promise utility doctrine to be part of the Canadian utility requirement decades ago.³¹ Professor Siebrasse did not say this. Rather, he testified that these authors were referring to the “promise” requirement under old English law, which finds its parallel not in Canada’s utility requirement but rather in section 53 of the Patent Act (addressing material false statements).³²

11. Regarding the bar on post-filing evidence, it is common ground that an invention must have a utility as of the filing date of the patent. But, contrary to Canada’s view, that rule does not speak to whether post-filing evidence can be relied on to confirm that utility.³³ As Professor Siebrasse explained at the Hearing, under prior law, proof today that an invention works was considered proof that it also worked yesterday – such that if the Wright brothers built an airplane on Day 1 and filed a patent application on Day 2 that perfectly described the plane, the fact that the airplane actually flew on Day 3 would be considered good evidence of its utility at the filing date.³⁴ In Canada, since 2002, that is no longer the case.³⁵

³⁰ As Professor Siebrasse testified at the Hearing, his academic research did not reveal any prior case law in which the current bifurcated promise requirement was applied by the Canadian courts. Testimony of Norman Siebrasse, Tr. at 576:3-577:24; see “The False Doctrine of the False Promise” at 2-3 (“The emergence of the promise of the patent doctrine is an important recent development in Canadian patent law.”) (C-205); *id.* at 22 (“The promise of the patent doctrine played no significant role in Canadian patent law until 2005.”); Norman Siebrasse, “Form and Function in the Law of Utility: A Reply to Gold & Shortt,” 30 CAN. INTELL. PROP. REV., at 2, 69 (2014) (concluding that while the “scintilla” branch is longstanding in Canadian law, the promise doctrine is not) (R-497).

³¹ Resp. Post-Hearing Mem. at ¶¶ 124-126.

³² Testimony of Norman Siebrasse, Tr. at 725:20-728:22. As Professor Siebrasse testified, to the extent these commentators cited Canadian cases at all, they did so for the simple proposition that an invention must be useful, as claimed. See Donald Hill, “Claim Inutility” (1960), 35 CPR 185, at 190 (“[A] *claim*, as opposed to a *disclosure*, is invalid on the ground of inutility.”) (emphasis in original) (R-160).

³³ Resp. Post-Hearing Mem. at ¶¶ 138-140. Canada continues to assert that the requirement to have “established” utility in order to have “made an invention” is somehow equivalent to the current bar on post-filing evidence. *Id.* at ¶¶ 141-143. The cases Canada cites are not utility challenges (but rather inventorship cases), and in any event – as Professor Dimock admitted – they do not support Canada’s position. Testimony of Ronald Dimock, Tr. at 1135:9-1137:22; see also Testimony of Norman Siebrasse, Tr. at 534:19-536:4.

³⁴ Testimony of Norman Siebrasse, Tr. at 516:22-517:13.

12. Canada's Post-Hearing Memorial also suggests that the Supreme Court's adoption of the doctrine of sound prediction in the 1979 *Monsanto* decision confirms that the bar on post-filing evidence existed as of that date, since "[t]here would have been no need for [sound prediction] . . . if applicants could simply patent based on speculation and then justify their claims with testing done after-the-fact."³⁶ But this new argument, which is supported by no expert evidence, is illogical. In *Monsanto*, sound prediction was used to establish the utility of molecules that had never been tested at all, neither before nor after the filing date.³⁷ *Monsanto's* analysis of sound prediction, moreover, accepted and relied upon post-filing evidence of utility.³⁸ Canada's assertion that post-filing evidence was barred prior to 2002 is also contradicted by the testimony of its own experts.³⁹

13. Regarding the heightened disclosure rule for evidence of sound

³⁵ Cl. Opening Statement, Tr. at 47:10-48:22, 68:10-16.

³⁶ Resp. Post-Hearing Mem. at ¶ 139.

³⁷ Siebrasse First Report, at ¶¶ 26-27.

³⁸ *Monsanto Co. v. Canada (Commissioner of Patents)* (1979) 2 SCR 1108, ¶¶ 1121-1123 (C-61). Prior to the 2002 *AZT* case, sound prediction allowed the patentee to claim broadly, based on a prediction rather than the testing of every claimed molecule. Genus patents covering millions of compounds are a good example of claims whose utility could be established through sound prediction because testing has not been done on every compound in the genus as of the date of challenge. See Testimony of Robert Armitage, Tr. at 388:15-389:6; Testimony of Norman Siebrasse, Tr. at 517:14-518:5.

Sound prediction has fundamentally changed post-*AZT*. Patentees can no longer rely on post-filing evidence to demonstrate the utility of the claimed invention (whether for a genus patent or otherwise), even if the compounds at issue have actually been prepared and tested by the date of challenge. As Professor Siebrasse explained: "With post-filing evidence excluded from the analysis, utility of even those compounds which are in fact routinely used as a treatment for a disorder must often be established on the basis of sound prediction, which . . . was originally relied upon to establish the utility of untested members of a genus claim to a large number of compounds." Siebrasse First Report, at ¶¶ 25-28, 58. Far from supporting Canada's position, this dramatic conversion of sound prediction – from sustaining patents that claim untested embodiments to invalidating patents under the promise utility doctrine – exemplifies Canada's radical change in law.

³⁹ Though he disagreed with its "logic," Mr. Dimock conceded that *Ciba-Geigy* accepted post-filing evidence and that the holding in *Ciba-Geigy* was relied upon by the Federal Court of Appeal in *AZT*. Testimony of Ronald Dimock, Tr. at 1147:14-1148:12; 1152:4-1154:7. Dr. Gillen conceded that *Monsanto* accepted post-filing evidence in the form of affidavits about testing, and that for sound prediction the burden was then on the Commissioner to show a lack of utility. Testimony of Michael Gillen, Tr. at 1002:2-1003:6; 1007:1-22.

prediction, Canada reiterates its position that *AZT* recognized a heightened disclosure obligation, and in doing so simply “affirmed” the *Monsanto* decision.⁴⁰ Again, Canada contradicts its own witnesses: Dr. Gillen conceded that *Monsanto* did *not* require disclosure in the patent of evidence supporting the soundness of a predicted utility.⁴¹

D. Patent invalidation statistics confirm Canada’s radical change in law.

14. Professor Bruce Levin conducted a comprehensive statistical analysis of all patent validity cases litigated in the Canadian courts over a period of more than 35 years.⁴² In the 25 years prior to 2005 (and, indeed, prior to 2002) not a single pharmaceutical patent was invalidated for lack of utility and only two non-pharmaceutical patents faced invalidation on that ground.⁴³ In the 11 years since Canada’s courts combined the *AZT* bar on post-filing evidence with the subjective construction of elevated promises, pharmaceutical patents have been found to lack utility 28 times (23 times since 2008).⁴⁴ These data reveal a fundamental shift in outcomes in the Canadian courts.⁴⁵ This shift is consistent with the change in law

⁴⁰ Resp. Post-Hearing Mem. at ¶ 156.

⁴¹ Testimony of Michael Gillen, Tr. at 998:14-22. It also remains clear that *AZT* did not apply a heightened disclosure rule (and in fact referred to evidence from outside the patent when considering sound prediction). Testimony of Norman Siebrasse, Tr. at 680:4-10, 683:24-689:21; Testimony of Andrew Reddon, Tr. at 872:9-874:10. Canada’s evidence – including the law firm marketing materials it cites at ¶ 157 of its Post-Hearing Memorial, which simply quote from the *AZT* case – does nothing to change that fact. But even if the additional disclosure rule can be traced to the 2002 *AZT* decision, it makes no difference to Lilly’s claim. *AZT* was rendered after Lilly had filed and was granted its Zyprexa and Strattera patents.

⁴² See Levin Report, at Appendix C (and errata of 26 May 2016). Canada suggests, in passing and without identifying any specific cases, that some subset of cases should have been excluded as not reflecting application of the promise utility doctrine. Resp. Post-Hearing Mem. at ¶ 165. But Professor Levin’s data set included all cases challenged on every major ground of validity in order to identify comparative trends. See Levin Report, at ¶ 24 (“[T]he question is a comparative one, and identifying 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”). Canada does not contest that all 28 post-2005 inutility findings identified in Lilly’s data set were in fact cases in which a patent was held to lack utility.

⁴³ *Id.* at Appendix C (and errata of 26 May 2016); Cl. Closing Slides, at 81.

⁴⁴ Levin Report at Appendix C (and errata of 26 May 2016); Cl. Closing Slides, at 81.

⁴⁵ As Professor Levin explained, the small case counts in the pre-2005 period (when utility was not a frequent ground of challenge) result in low statistical power that precludes a time-based statistical (continued...)

revealed by Canadian cases and Canadian Patent Office materials, including the MOPOP, and Canada has proposed no other plausible explanation for it.⁴⁶

15. The data also reveal a striking and statistically significant disproportion in the impact of the shift – all 28 findings of inutility involve pharmaceutical patents; none involve patents in other fields of technology.⁴⁷ Canada quibbles with this result. It has proposed a range of changes to Lilly’s data set of Canadian patent validity cases, criticizing everything from Lilly’s unit of analysis to its individual coding decisions.⁴⁸ Not only are these criticisms misplaced, they do nothing to alter the conclusion that the promise utility doctrine has had a disproportionate impact on pharmaceutical inventions. Only by improperly double-counting cases like *Eurocopter* and *Uponor* – or by proposing that they be treated as outright victories for the infringer, despite the fact that one infringer was sanctioned with punitive damages and the other made subject to an injunction⁴⁹ – can Canada produce a data set that lacks statistical significance.⁵⁰ And even accepting Canada’s nonsensical approach, the raw numbers still show a disproportionate impact on the pharmaceutical sector (28 decisions to 2 decisions).

E. Canada’s NAFTA partners confirm Canada’s radical change in law.

16. Lacking any credible argument that the promise utility doctrine is reflected in the utility laws of the other NAFTA states,⁵¹ Canada insists instead that the “same bargain is enforced through different mechanisms” in the United States and

analysis. Testimony of Professor Bruce Levin, Tr. at 1264:17-24 (“[T]hat is a very treacherous, shall we say, comparison because of the small numbers involved. If we’re going to rely, as I believe Respondent might, on the lack of statistical significance between those two proportions and draw from that conclusion, therefore, that they were identical in truth, that’s problematic because of low [statistical] power.”). The fact that utility was not frequently raised as a ground of challenge prior to 2005 does not detract from, but rather supports, the view that utility was a low and easily-met bar until the advent of the promise utility doctrine.

⁴⁶ Cl. Post-Hearing Mem. at ¶¶ 123-125.

⁴⁷ Levin Report, at Appendix C (and errata of 26 May 2016); Cl. Closing Slides, at 81.

⁴⁸ Resp. Post-Hearing Mem. at ¶ 167; Resp. Rejoinder at ¶¶ 195-201.

⁴⁹ See Resp. Post-Hearing Mem. at ¶ 224; Cl. Post-Hearing Mem. at ¶ 134.

⁵⁰ Cl. Post-Hearing Mem. at ¶¶ 128-135. This evidence establishes that Canada discriminates against pharmaceuticals as a field of technology in breach of NAFTA Article 1709(7). *Id.* at ¶¶ 257-263.

⁵¹ See *id.* at ¶¶ 140-143.

Mexico.⁵² Presumably, then, on at least one of the 28 occasions on which Canada found a pharmaceutical patent to lack utility, either the United States or Mexico would have found the same patent invalid under one of the “different mechanisms” to which Canada refers. Yet, Canada has identified not one case in which a patent found to lack utility in Canada was invalidated on *any* ground in the United States or Mexico – the best it can do is point to the U.S. Stratterra trial court decision involving enablement, which was summarily reversed by the Federal Circuit.⁵³

17. Canada also suggests that the U.S. utility requirement and Mexico’s industrial applicability requirement have “tightened” over time.⁵⁴ But Canada’s argument found no support at the Hearing, where its own witnesses conceded that the U.S. and Mexican requirements remain low bars that could not be used to invalidate operable inventions.⁵⁵ Even broadening the lens to look at other patentability requirements, Canada has not identified any change in U.S. or Mexican patent law that has had a comparable effect to Canada’s dramatic shift in its utility requirement.⁵⁶

F. International discussions confirm Canada’s radical change in law.

18. Canada has no answer to the testimony establishing that, with the recent and notable exception of Canada, WIPO member states treat utility as a low bar that is

⁵² Resp. Post-Hearing Mem. at ¶¶ 200, 218-220.

⁵³ 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). Canada suggests that differing experts, parties, counsel, judges, and arguments might explain divergent outcomes, and argues that a comparison of outcomes across NAFTA jurisdictions is “dangerous.” Resp. Post-Hearing Mem. at ¶ 207. To the contrary, given Canada’s arguments, such a comparison is essential, for it confirms that Canada is an outlier even taking other patentability requirements into account.

⁵⁴ *Id.* at ¶¶ 205-206.

⁵⁵ Cl. Post-Hearing Mem. at ¶¶ 140-146. Canada’s Post-Hearing Memorial simply ignores key aspects of this evidence. For example, Canada emphasizes that, “[i]n the United States, utility has to be established at the time that a patent application was filed,” without mentioning the testimony of its own expert that post-filing evidence may be used to establish utility. Compare Resp. Post-Hearing Mem. at ¶ 218 *with* Testimony of Timothy Holbrook, Tr. at 1491:8-17 (agreeing that post-filing evidence was used to substantiate utility in the *In re Brana* Federal Circuit case).

⁵⁶ Cl. Post-Hearing Mem. at ¶ 154.

rarely used to invalidate patents. Instead, Canada ignores that evidence⁵⁷ and seizes on isolated comments in documents that – according to unrebutted testimony – may never have been read by any WIPO delegate.⁵⁸ As Dr. Daniel Gervais ultimately agreed, nothing in the WIPO documents cited by Canada suggests that any country had a utility requirement that routinely invalidated patents on pharmaceutical products.⁵⁹

19. Canada also seeks support from discussions at the WTO, stating that “Canada is not aware of any complaints regarding its utility requirement from any State or international organization” prior to the launch of this arbitration in 2013⁶⁰ and asserting (without support or qualification) that “no State raised any concerns with Canada’s approach to utility in the WTO context.”⁶¹ Such statements are disingenuous. As Canada well knows, in its 2015 WTO Trade Policy Review,⁶² WTO members with significant innovative pharmaceutical sectors – the United States, the European Union, Switzerland, and Japan – all raised questions about the promise utility doctrine, and Taiwan raised questions as well. In other words, contrary to Canada’s bald assertions, WTO Members did in fact raise concerns over Canada’s change in law.

⁵⁷ For the proposition that there are differences “in the manner in which the industrial applicability and utility standards are applied,” Canada takes out of context a quote from Mr. Philip Thomas. *See* Resp. Post-Hearing Mem. at ¶ 213 & n.499 (quoting Mr. Thomas as agreeing that there is “significant variance in the standard”). In the lines immediately before Canada’s quote, Tr. at 1732:10-13, Mr. Thomas makes clear he is referring to the language used in “regulations and guidelines” rather than practical outcomes.

⁵⁸ *See* Resp. Post-Hearing Mem. at ¶ 121 & n.229, ¶¶ 213-214 (discussing a study on utility (WIPO Document SCP/9/5 (17 March 2003) (R-230)) and a draft of that study (Informal Paper Concerning the Practical Application of Industrial Applicability/Utility Requirements Under National And Regional Laws (April 2001) (R-407))). As Mr. Thomas testified, the study Canada relies on was not discussed at any meeting of the Standing Committee on Patents. Cl. Post-Hearing Mem. at ¶ 167.

⁵⁹ *Id.* at ¶ 290.

⁶⁰ Resp. Post-Hearing Mem. at ¶¶ 172-174.

⁶¹ *Id.* at ¶ 214. Canada cites to the testimony of Mr. Thomas as support for its assertion. *Id.* at ¶ 214 & n.502. But Mr. Thomas has not testified to WTO discussions at any point in this arbitration. Moreover, while Mr. Thomas testified that no concerns were raised about Canada’s utility requirement during the course of WIPO negotiations, *see* Tr. at 1719:19:21, 1735:14-1736:2, the relevant negotiations ended in 2004 and each question Mr. Thomas was responding to dealt specifically with the 2003 WIPO utility study).

⁶² The World Trade Organization conducts trade policy reviews of Canada once every four years, and as part of that process trading partners ask questions about measures that are of concern.

III. Canada has identified no authority for the view that judicial measures are exempt from the protections of Articles 1110 and 1105.

20. Canada accepts Professor Paulsson's definition of denial of justice as a purely "procedural" doctrine.⁶³ It also accepts the first corollary of this definition (that denial of justice is the exclusive theory for addressing misapplications of national law).⁶⁴ Canada, however, refuses even to acknowledge Professor Paulsson's second corollary (that violations of substantive rules by national courts are not denials of justice but rather freestanding violations of international law "like [those of] any other organ of a state"⁶⁵). And, aside from one unsupported article excerpt,⁶⁶ Canada has still not found a single authority for the rule it proposes: that judicial measures cannot qualify as expropriations or violations of the Minimum Standard absent a denial of justice.⁶⁷

21. On Article 1110, Canada argues that "the customary international law of expropriation has, for centuries, concerned only executive, legislative, military, and police actions."⁶⁸ This is untrue. There are multiple cases recognizing that judicial measures can be expropriatory.⁶⁹ And Canada's cases do not support the notion that expropriation is recognized *only* for executive, legislative, military, and police actions; they are simply examples of expropriations arising in those contexts.⁷⁰

22. On Article 1105, Canada again maintains that *Mondev* holds "that proof of

⁶³ Resp. Post-Hearing Mem. at ¶ 67.

⁶⁴ *Id.* at ¶ 70.

⁶⁵ Cl. Post-Hearing Mem. at ¶ 182 (citing Jan Paulsson, DENIAL OF JUSTICE IN INTERNATIONAL LAW 7 (2010)).

⁶⁶ *See id.* at ¶ 198 (discussing Zachary Douglas, "International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed," INT'L & COMP. L.Q. (Sept. 2014)).

⁶⁷ *See* Resp. Post-Hearing Mem. at ¶ 67 & n.122. The remainder of Canada's citations, *id.* at ¶¶ 68-70, simply elucidate the denial of justice standard or state in general terms the uncontroversial proposition that NAFTA tribunals do not sit as courts of appeal concerning matters of domestic law and procedure.

⁶⁸ *Id.* at ¶ 27.

⁶⁹ Cl. Post-Hearing Mem. at Part IV.B.3(a) (discussing *Saipem v. Bangladesh*, *ATA v. Jordan*, *Feldman v. Mexico*, and *Rumeli v. Kazakhstan*).

⁷⁰ *See* Resp. Post-Hearing Mem. at ¶¶ 27-28 & n.28 (citing, for example, the *Norwegian Shipowners'* and *German Interests in Polish Upper Silesia* cases). Canada also argues that the cases Lilly relies on as examples of judicial expropriations are in fact *sub silentio* denial of justice awards. This argument is refuted in Lilly's Post-Hearing Memorial at ¶¶ 188-189.

a breach of Article 1105” as a result of judicial measures “requires proof of a denial of justice.”⁷¹ As Lilly has repeatedly emphasized,⁷² however, paragraph 134 of *Mondev* directly contradicts Canada’s position: it explains that judicially developed rules are capable of violating “the principles embodied in Article 1105” irrespective of the procedural fairness of the proceedings in which they are applied.⁷³ Rather than address this language, Canada cites its own Article 1128 Submission in that case, implying that its briefing articulates the rationale of the award better than the tribunal’s own words.⁷⁴

IV. Canada’s legal position relies on rhetoric, not legal authorities.

A. Canada has no basis for distinguishing between takings of intangible and tangible property.

23. Pivotal to Canada’s case is its argument that intangible property should be treated differently than tangible property. Canada claims, for example, that disputes over tangible property are different from disputes over intangible property because, in the former case, there is no question about the existence of the property.⁷⁵ This

⁷¹ Resp. Post-Hearing Mem. at ¶ 63.

⁷² Cl. Post-Hearing Mem. at ¶ 191 (noting Canada “did not respond to these passages [from *Mondev*] in its Rejoinder, and it maintained its silence even after being invited to respond in Lilly’s Opening and its Closing”).

⁷³ *Mondev International Ltd. v. United States of America*, NAFTA/ICSID Case No. ARB(AF)/99/2, Award (11 Oct. 2002), at ¶ 134 (“To the extent that it might suggest the contrary, the [rule] might raise a delicate judicial eyebrow. Indeed a governmental prerogative to violate investment contracts 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 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.”) (footnote omitted) (CL-7).

⁷⁴ See Resp. Post-Hearing Mem. at ¶ 63 & n.113 (citing *not* the *Mondev* award but only the Second Submission of Canada in *Mondev* for the proposition that the *Mondev* tribunal “agreed with the well-established principle of international law that proof of a breach of Article 1105 in these circumstances requires proof of a denial of justice”).

⁷⁵ *Id.* at ¶ 178. Canada’s related argument that Lilly’s patents “should not have issued,” *id.*, also ignores the fact that Lilly’s patents were properly granted under the law as it stood in July 1998 and October 2002 (the time of grant); see Cl. Post-Hearing Mem. at Part II.C.2.

distinction is ill-conceived as a factual matter,⁷⁶ and it also runs squarely counter to NAFTA, which equally protects *all* covered investments, including all property “*tangible or intangible*, acquired in the expectation or used for the purpose of economic benefit.”⁷⁷

24. Canada’s attempt to create different rules for intangible property is also undercut by how tribunals have actually analyzed judicial expropriations. Canada argues that where awards have found judicial takings of intangible property, they have first determined that the existence of the property right is not in question.⁷⁸ But none of the judicial expropriation cases in the record involve such an analysis; to the contrary, some involve rights declared “non-existent” or a “nullity.”⁷⁹ As these decisions (and others, such as *Azinian*) make clear, a host state cannot cite its own challenged judicial measure as a *fait accompli*.⁸⁰

B. Canada has no basis for arguing that the international legality of a measure is irrelevant to its expropriatory character.

25. Canada accepts that this Tribunal must consider “the character of the measure or series of measures” that revoked Lilly’s investments.⁸¹ It insists, however, that the international illegality of its measures may not be considered as part of the Tribunal’s inquiry into the character of those measures.⁸² Lacking authorities to support this position,⁸³ which is contradicted by multiple awards,⁸⁴ Canada turns

⁷⁶ Canada’s distinction between property rights that are a “legal construct” and property rights that cover “physical thing[s]” is illusory. Resp. Post-Hearing Mem. at ¶ 178. All property rights are a legal construct. Canada could just as easily describe a freehold estate or a car title – both forms of property rights that pertain to “physical things” – as a “legal construct” that, without the relevant governing statutes and regulations, “would not exist.” Cf. *id.* (“Without the *Patent Act* . . . [patents] would not exist.”)

⁷⁷ See NAFTA art. 1139 (emphasis added).

⁷⁸ Resp. Post-Hearing Mem. at ¶ 38.

⁷⁹ Cl. Post-Hearing Mem. at ¶ 212.

⁸⁰ *Id.* at ¶¶ 211-213.

⁸¹ Resp. Post-Hearing Mem. at ¶ 26.

⁸² *Id.* at ¶¶ 35-39.

⁸³ Canada principally supports this argument by citing to the litigation positions taken by other NAFTA states in this arbitration. See *id.* Canada also relies on Article 1128 submissions, including the Second Article 1128 Submission of the United States (which largely restates aspects of the first U.S. submission), as its principal source of support for its reading of Article 1110(7) as “only a shield, safe-harbor and defence.” See *id.* at ¶¶ 34-36. Notwithstanding Canada’s extensive reliance on Article 1128 submissions (continued...)

instead to scaremongering. It intones that, under Lilly’s rule, “NAFTA tribunals would have potentially unlimited jurisdiction to consider any breach of any international law obligation of the NAFTA Part[ies].”⁸⁵

26. But Canada’s warnings ring hollow. Tribunals do not have freestanding jurisdiction to consider breaches of obligations outside Chapter 11. Rather, having first found a substantial deprivation (the touchstone of the expropriation analysis⁸⁶), tribunals may then consider, among other things (*e.g.*, the arbitrariness of the measure and the legitimate expectations of the investor), the international lawfulness of the measure in examining whether the measure is expropriatory or a legitimate exercise of state power. This analysis applies the general international law of expropriation⁸⁷ and the text of Article 1110(7)⁸⁸; it does not extend the Tribunal’s jurisdiction. Nor is it unbounded.

27. Canada seeks to dismiss as “untenable” the factors Lilly has identified that place limits on a tribunal’s authority to examine a NAFTA party’s compliance with its international obligations. But, in fact, the limiting principles Lilly has articulated, focused on the nexus between the international obligation and the challenged measure, are driven by the language of Chapters 11 and 17, and by the specific facts of this case.⁸⁹ Chapter 17 provides specific rules that govern not just the grant, but also the “revocation” of patents.⁹⁰ Chapter 17 is referenced specifically in Article 1110(7), which makes clear that consistency with Chapter 17 must be considered in differentiating

for these (and several other) points, they are not sources of law and are entitled to no special deference. *See* Cl. Comments on Art. 1128 *Amicus* Submissions at Part I.A.

⁸⁴ Cl. Post-Hearing Mem. at Part IV.B.3(a).

⁸⁵ Resp. Post-Hearing Mem. at ¶ 40.

⁸⁶ Cl. Post-Hearing Mem. at ¶¶ 235, 271.

⁸⁷ *Id.* at Part IV.B.3(a).

⁸⁸ *Id.* at Part IV.B.3(c).

⁸⁹ *See Saipem S.p.A. v. People’s Republic of Bangladesh*, ICSID Case No. ARB/05/7, Award (30 June 2009), at ¶¶ 165-168 (finding the New York Convention relevant to the expropriation analysis where (i) it directly applied to protect the right at issue and (ii) was acknowledged to bind the host state) (CL-62).

⁹⁰ Cl. Post-Hearing Mem. at ¶ 234.

between legitimate and compensable takings of intellectual property.⁹¹ These facts cannot simply be ignored as part of what even Canada acknowledges is the “case-by-case, fact-based” expropriation analysis mandated by the general international law of expropriation.⁹²

C. Canada has no basis for arguing that NAFTA Article 1709(1) provides it with unfettered discretion to impose a heightened utility requirement above and beyond the mere scintilla test.

28. Canada continues to suggest that Article 1709(1) provides it limitless flexibility to adopt any utility requirement it wishes.⁹³ Canada also insists that because “each NAFTA Party’s system includes other conditions that must be met for a patent to issue,”⁹⁴ Article 1709(1) does not discipline Canada’s revocation of patents under the promise utility doctrine. But the plain text of Article 1709(1) provides a baseline of patent protection: it defines the scope of inventions for which patent rights must be provided. Canada cannot revoke patents that otherwise satisfy the “capable of industrial application” standard articulated in Article 1709(1) on the basis that those patents fail to meet an additional, heightened utility requirement.⁹⁵ Canada also argues that other states accomplish the same ends through different doctrines. That is not only

⁹¹ Canada suggests that Lilly’s position could convert any invalidation of an intellectual property right into a Chapter 11 violation. But not every patent revocation is a violation of Chapter 17. Whether a patent revocation violates Chapter 17 is a fact-specific inquiry that examines the legal framework of the host state. And not every Chapter 17 violation will qualify as an expropriation. A violation of Chapter 17 may not, for example, amount to a substantial deprivation of property. *Id.* at ¶ 235.

⁹² In its Post-Hearing Memorial, at ¶ 26 & n.22, Canada cites to the Annexes of the Free Trade Agreement between Canada and the Republic of Panama, 14 May 2010 (R-349), and the Agreement Between Canada and the Hashemite Kingdom of Jordan for the Promotion and Protection of Investments, 28 June 2009 (R-350). Both cited Annexes state that “[t]he Parties confirm their shared understanding that . . . the determination of whether a measure or series of measures of a Party constitute an indirect expropriation requires a case-by-case, fact-based inquiry that considers, among other factors . . . iii. the character of the measure or the series of measures.”

⁹³ Resp. Post-Hearing Mem. at ¶ 194 (“Article 1709(1) leaves to each NAFTA Party the flexibility to define and implement the specific legal standard under each of the enumerated criteria of novelty, non-obviousness or inventiveness, and utility or industrial applicability.”).

⁹⁴ Resp. Post-Hearing Mem. at ¶ 191.

⁹⁵ See Cl. Post-Hearing Mem. at Part IV.B.4(a). Elements of the promise utility doctrine may violate Chapter 17 alone or in combination. See *id.* at ¶ 76 (“Lilly has never argued that every case raises all three elements of the promise utility doctrine.”).

false,⁹⁶ it is no answer to the fact that adding an additional, elevated utility requirement for pharmaceutical patents is a breach of Article 1709(1). Treating all patent law as an undifferentiated mass would permit evasion of the express terms of Article 1709(1).⁹⁷

29. Canada's argument that Article 1709(1) has nothing to say about "evidentiary or disclosure requirements," and thus cannot apply to the heightened evidentiary and disclosure elements of the promise utility doctrine,⁹⁸ again ignores the practice of Canada's own courts in treating these considerations as part of their unified *utility* analysis.⁹⁹ Canada has a separate requirement for sufficiency of disclosure. That requirement is not at issue here and was, in any case, found to have been met by the Zyprexa and Strattera patents.¹⁰⁰

D. Canada has no basis for the argument that an incoherent and unpredictable doctrine can serve a legitimate policy objective.

30. As a matter of both law and logic, an unpredictable and incoherent doctrine cannot be connected to a legitimate policy objective and is therefore arbitrary.¹⁰¹ Canada has identified no authority to the contrary.

31. In any event, Canada has abandoned the substance of its policy argument. Canada previously argued that the promise utility doctrine combatted speculative patenting and pointed to Lilly's patenting practices as illustrative of such

⁹⁶ Cl. Post-Hearing Mem. at ¶¶ 149-153; Cl. Reply at ¶¶ 89, 156-159, 171-172.

⁹⁷ Cl. Post-Hearing Mem. at ¶¶ 254-256 ("The treaty text, 'shall make patents available,' . . . defines the scope of inventions for which patent rights must be provided."); Cl. Comments on Art. 1128 and *Amicus* Submissions at ¶ 83; Cl. Reply at ¶¶ 89, 156-159, 171-172.

⁹⁸ Resp. Post-Hearing Mem. at ¶ 186.

⁹⁹ See Cl. Post-Hearing Mem. at Part II.C.1. As explained in Lilly's Reply, at ¶ 96, "evidentiary burdens are intrinsically tied to substantive law doctrines." The application of the heightened evidentiary burden and the heightened disclosure requirement is driven by the construction of a heightened promise; even as a practical matter, therefore, the three elements of the doctrine cannot be disentangled. See Cl. Post-Hearing Mem. at ¶ 74; Cl. Reply at ¶ 192; Cl. Mem. at ¶ 80. As Lilly explained in response to the Tribunal's Question 9, for example, "[t]he post-filing evidence rule in the 2002 AZT decision is critically important, but it was not until that rule was married with the promise of the patent that Canada began denying patents to otherwise useful pharmaceutical inventions." Cl. Post-Hearing Mem. at Appendix, Question 9.

¹⁰⁰ Cl. Post-Hearing Mem. at ¶ 256.

¹⁰¹ *Id.* at ¶ 310; Cl. Reply at ¶¶ 335-338, n.679.

“speculation.”¹⁰² In its Post-Hearing Memorial, however, Canada dropped its claim that Lilly patents speculatively – an argument that fell apart at the Hearing.¹⁰³ Instead, to explain the fact that the promise utility doctrine uniquely targets foreign pharmaceutical firms to the benefit of Canada’s large domestic generic industry, Canada now asserts that patentees in the innovative pharmaceutical industry are more likely to “patent[] upstream” and file “secondary patents” than patentees in other industries, implying that this explains the disparate outcomes in the pharmaceutical sector.¹⁰⁴ But Canada has developed no evidence at all on this point (in fact, the limited comparative evidence on patenting practices across industries that is in the record comes from Mr. Armitage and contradicts Canada’s view).¹⁰⁵

32. Perhaps recognizing the hole in its argument, Canada created, out of whole cloth and for the first time in its Post-Hearing Memorial, a new policy objective for the promise utility doctrine: ensuring the accuracy of patent disclosures.¹⁰⁶ There is no support on the record for this asserted policy objective.¹⁰⁷

33. As for Canada’s other arguments on Article 1105, they simply repeat points raised prior to the Hearing and need not be addressed here. It does bear emphasis, however, that Canada has entirely failed to rebut Lilly’s evidence that it

¹⁰² Cl. Post-Hearing Mem. at ¶ 314 (discussing Rep. Rejoinder at ¶¶ 51-62 and Resp. CM at ¶¶ 150-164).

¹⁰³ *Id.* at ¶¶ 314-317 (setting out a series of concessions by Dr. Brisebois, related to his analysis of Lilly’s patenting practices, which destroyed the foundation of Canada’s argument).

¹⁰⁴ Resp. Post-Hearing Mem. at ¶ 229. It has been established that Canada provides patent protection to new use and selection patents (which Canada has dubbed “secondary patents”) under the same patentability criteria as other types of patents. Testimony of Marcel Brisebois, Tr. at 503:6-10.

¹⁰⁵ As noted in Lilly’s Reply at ¶ 202, and in the Second Witness Statement of Robert Armitage at ¶¶ 8-11, pharmaceutical firms patent less frequently than firms in other industries, and spend many times more on research and development for each patent they receive than firms in other industries. If pharmaceutical firms patented in a speculative manner, the statistics would show the opposite (more patents, supported by less research).

¹⁰⁶ Resp. Post-Hearing Mem. at ¶ 244.

¹⁰⁷ While disclosures should be accurate, that goal is accomplished by section 53 of the Patent Act. *See* Cl. Reply at ¶ 88. There is no evidence that the promise utility doctrine is intended to (or does) contribute to that goal. To the contrary, the doctrine is not capable of contributing to the accuracy of disclosures, given that promises are construed based *not* on the plain meaning of the disclosure, but instead on an “inherently arbitrary” process of subjective construction, which frequently includes the identification of “implied” promises that do not appear in the patent. *See* Cl. Post-Hearing Mem. at ¶¶ 295-300.

believed its patents were valid at the time it made its investment, and that it relied on that expectation, which was supported by the grant of its patents and Canadian law at the time.¹⁰⁸ Thus, if the Tribunal concludes Canada’s law changed (such that Lilly’s expectations were reasonable at the time of investment), it is bound to find a violation of Article 1105.

V. Conclusion

34. Lilly’s investments in Canada, its Zyprexa and Strattera patents, were revoked in full by an organ of the Canadian government based on the retroactive application of a doctrine that is arbitrary, discriminatory, and could not have been predicted by Lilly at the time it made its investment decisions. Those facts establish Lilly’s entitlement to compensation under NAFTA Articles 1110 and 1105. Canada’s resort to ever more strident and categorical defenses serves only to highlight that, under any traditional understanding of those provisions, Lilly must prevail.

Respectfully submitted,

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¹⁰⁸ *Id.* at ¶¶ 10-11, 283-284. Canada’s argument, at Part IV.E of its Post-Hearing Memorial, that Lilly’s document production in this arbitration “show[s] that there was no dramatic change in the law” is addressed in Lilly’s Post-Hearing Memorial, at ¶ 289 & n.532.