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 POST-HEARING MEMORIAL

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25 July 2016

TABLE OF CONTENTS

Introduction

1. The parties essentially agree on the questions the Tribunal should answer to resolve this case. Lilly has organized its post-hearing brief around these questions:

- *First*, whether Lilly's claim is time barred under Article 1116/1117 of NAFTA. As set out in **Part I**, Canada's jurisdictional objection fails because it is both untimely and unfounded.

- *Second*, whether Canada's promise utility doctrine is a radically new, additional requirement for patentability. As discussed in **Part II**, the radical change in Canadian law worked by the promise utility doctrine is evident from multiple sources, including the revisions to Canada's Manual of Patent Office Practice ("MOPOP"), the contemporaneous reactions of Canada's patent examiners to those revisions, Canadian case law, the dramatic increase in Canadian inutility findings, and a comparison with the utility requirements of Canada's NAFTA partners.

- *Third*, whether denial of justice is the sole basis of liability for judicial measures under Articles 1110 and 1105 of NAFTA. As set out in **Part III**, Canada lacks any support for its categorical assertion that denial of justice is the exclusive theory of liability for judicial measures. To the contrary, multiple authorities recognize that judicial measures may constitute an expropriation or violation of the Minimum Standard irrespective of whether they constitute a denial of justice.

- *Fourth*, whether Canada's application of the promise utility doctrine to Lilly's patents for Zyprexa and Strattera is inconsistent with Articles 1110 and Article 1105. As discussed in **Part IV**, the testimony and argument presented at the Hearing further substantiate Lilly's claims under both articles that Canada has breached its NAFTA obligations.

2. A summary of the witness testimony at the Hearing is provided immediately following this introduction. This brief also contains an **Appendix** reflecting Lilly's responses to the questions posed by the Tribunal over the course of the proceeding, which are also addressed in the relevant portions of the discussion below.

3. While the Tribunal will weigh the evidence presented during the Hearing, it should also consider what was *not* said. Lilly has repeatedly cited the contemporaneous observations of Canada's own patent examiners, for example, to show that the promise utility doctrine represented a radical change in Canadian law. Lilly discussed these observations in its Reply brief, during its Opening, and again at

Closing. Canada has not responded to this evidence. Nor has Canada offered any explanation for the significant revisions to Canada's MOPOP demonstrating the advent of the promise utility doctrine. Canada's silence on these points speaks volumes.

4. Just as Canada's silence underscores the merit of Lilly's factual evidence, Canada's alarmist rhetoric underscores the merit of Lilly's legal claims. Canada's theme throughout this case has been a parade of horribles — that a ruling for Lilly would "open the floodgates"; that it would transform NAFTA tribunals into "supranational courts of appeal"; and that it would "usurp the sovereignty of states."

5. But this rhetoric masks the reality that it is *Canada*, not Lilly, that — in an effort to avoid liability — has taken a series of extreme and unsupported positions that would lead the Tribunal into uncharted waters. It is Canada that is seeking an interpretation of NAFTA's time bar that would require foreign investors to bring NAFTA arbitrations before their patents have been invalidated — or even challenged. It is Canada that is seeking an unprecedented ruling that would immunize national judiciaries for measures that violate substantive rules of international law. And it is Canada that would relegate intellectual property rights to second-class status under NAFTA by affording them lesser protection than other types of investments.

6. This last point bears emphasis. Though Canada pays lip service to the fact that patents are protected investments under NAFTA, Canada would strip those investments of meaningful Chapter 11 protection. Unless confronted with facially defective procedure, claimants could not seek relief for judicial revocations of intellectual property rights (no matter how unfair or arbitrary) because, according to Canada, such revocations mean the intellectual property never existed in the first place. Canada would also require tribunals to dismiss Article 1110 claims whenever the challenged measures were *consistent* with Canada's intellectual property obligations under NAFTA Chapter 17, but, should a tribunal conclude that the challenged measures were *inconsistent* with Chapter 17, the tribunal would be barred from considering this (highly relevant) fact.

7. Lilly, by contrast, seeks nothing more than a straightforward application of the fact-intensive, totality-of-the-circumstances standards that Articles 1110 and 1105

contain. That Canada revoked the Zyprexa and Strattera patents under a doctrine that violates Chapter 17 is one relevant circumstance the Tribunal should consider — indeed, under Article 1110(7), it is a circumstance this Tribunal *must* consider in assessing whether Canada's measures are expropriatory. Yet Canada's violations of Chapter 17 are not the only indicia of the wrongfulness of Canada's measures. So too are the arbitrariness of the promise utility doctrine, Canada's violation of Lilly's legitimate expectations, and Canada's discrimination against pharmaceutical patents held by foreign firms.

8. Regardless of the analytical framework to be applied, the essential fact is that Canada dramatically changed the rules after Lilly invested in Canada, and it did so in a way that singles out pharmaceutical patents and subjects them to Kafkaesque scrutiny unknown anywhere else in the world. Only in Canada were Zyprexa and Strattera invalidated for lacking utility, and only in Canada has there been a dramatic spike in inutility findings for pharmaceutical inventions.

9. Canada has the sovereign right to change its patent law, but when it does so in a way that violates its Chapter 11 obligations, there are consequences. Here, the overwhelming evidence demonstrates that Canada has violated its obligations under Article 1110 and Article 1105, and Lilly is accordingly entitled to relief.

Summary of Witness Testimony

10. ***Lilly's fact witnesses (Robert Armitage, Peter Stringer, Robert Postlethwait, and Anne Nobles)***. In their written testimony, Lilly's fact witnesses presented a consistent account of Lilly's decision to launch Zyprexa and Strattera in Canada. In both instances, patent protection was critical to the decision to invest. Accordingly, Lilly carefully monitored its patent applications in Canada, sensitive to any possible risk to its investments. At no time during the process were any concerns raised that Lilly might be denied patent protection — and certainly not on the basis that Lilly's patents lacked utility. *See* Part IV.C.2. The reason was simple: Canada's utility requirement at the time was longstanding and well-understood, and Lilly's patent applications easily met it.

11. During the Hearing, Canada did not meaningfully challenge this consistent account. Instead, Canada sought to impeach Lilly's witnesses by asking if they were briefed on specific Canadian court cases. This approach, however, bore Canada no fruit. The fact that senior Lilly executives and lawyers were not briefed on individual Canadian decisions does not rebut the fact that Lilly maintained a robust process for identifying patent-related risk in foreign jurisdictions, or that the process worked as designed when Lilly decided to launch Zyprexa and Strattera in Canada. *See* Part IV.C.2. Insofar as Canada's questioning was aimed at suggesting that Lilly should have factored in the risk that its patents would be invalidated under the promise utility doctrine, Canada's argument fails for an additional reason: at the time Lilly received patents on Zyprexa (July 1998) and Strattera (October 2002), the promise utility doctrine did not exist, and the dramatic increase in inutility findings in Canadian courts had not yet begun. *See* Part II.

12. ***Lilly's statistics expert (Professor Bruce Levin) and Canada's fact witness (Dr. Marcel Brisebois)***. Confirming his written expert opinion on the discriminatory effects of Canada's promise utility doctrine, Professor Bruce Levin testified that: "post-2005, there [has been] a statistically significant difference in [patent] invalidation rates based on lack of utility between pharmaceutical and non-pharmaceutical sectors in Canada." Professor Levin's evidence was the only statistical evidence presented by a

qualified statistical expert, and Canada did not contest Professor Levin's statistical method. Professor Levin's results were also robust. They were confirmed by patent litigation outcomes in the months following Professor Levin's September 2015 expert report, and they stood up to *every* amendment that Canada proposed to his data set — save one, which Professor Levin opined was statistically unsound. *See* Parts II.D, IV.B.4(b), IV.C.2(c).

13. Canada's witness, Dr. Marcel Brisebois, provided several other theories for why Canada invalidates only pharmaceutical patents on grounds of inutility at such a significant rate; none of those other theories withstood scrutiny. *See* Parts II.D, IV.B.4(b). Dr. Brisebois's testimony was not confined to statistical matters. He also provided the only witness testimony in support of Canada's argument that the promise utility doctrine is connected to a legitimate policy objective: deterring speculation. Dr. Brisebois's evidence on this point amounted to nothing more than an attack on Lilly's patent practices. Yet, on cross-examination, Dr. Brisebois ultimately agreed that he had "no insight" into the research and business decisions that caused Lilly to file for patents. As a result, Canada's speculative patenting theory fell apart. *See* Part IV.C.2(b)(2).

14. ***Expert witnesses on Canadian law (Professor Norman Siebrasse, Mr. Andrew Reddon, and Mr. Murray Wilson for Lilly; Mr. Ronald Dimock and Dr. Michael Gillen for Canada)***. Professor Norman Siebrasse was the *only* scholar of Canadian law that gave evidence in this arbitration. He described Canada's traditional mere scintilla utility test and explained, in detail, why the promise utility doctrine had no antecedent in Canadian law and only emerged after Lilly's patents for Strattera and Zyprexa were granted. *See* Part II.C. Canada sought to impugn Professor Siebrasse's expertise in its Closing by noting that he teaches and publishes not only in the area of patent law, but also in other areas of law. The breadth of Professor Siebrasse's expertise does not detract from its depth. His expertise in Canadian patent law has been acknowledged by the very courts that developed the promise utility doctrine he criticizes: his patent law writings have been cited by Canadian courts at every level, up to and including the Supreme Court of Canada.

15. Two other witnesses on Canadian law, Mr. Andrew Reddon and Mr. Ronald Dimock, provided practitioners' perspectives on Canadian patent law. Mr. Reddon provided his firsthand experience of the radical changes in Canada's utility requirement since the mid-2000s. *See* Parts II.C.2, IV.B.1. The basis of Mr. Reddon's testimony is his extensive experience at the front lines of Canadian pharmaceutical patent litigation: he has handled scores of pharmaceutical patent cases and damages actions in the Canadian courts. Mr. Dimock, by contrast, conceded that he has not litigated a single pharmaceutical patent case since 2005 involving a utility challenge. *See* Part II.C.2(a).

16. Seeking to turn Mr. Dimock's lack of relevant experience into a strength, Canada claimed at Closing that Mr. Reddon's credibility was compromised by his exposure to pharmaceutical patent litigation and his representation of innovative pharmaceutical firms. But Mr. Reddon has no previous association with Lilly and, while Mr. Reddon is a prolific litigator with substantial expertise in pharmaceutical patent cases, he also regularly handles significant patent matters in other fields of technology.

17. Rather than Mr. Reddon, it was Mr. Dimock who strained credulity through his attempts to find some precursor for the promise utility doctrine in prior Canadian law. Finding no direct support for many of his arguments, Mr. Dimock instead pointed to what he called "implied" holdings and offered readings of decisions for which he admitted there was no express textual basis. Mr. Dimock even argued that Canadian law incorporated points that courts had expressly rejected, at times in cases Mr. Dimock himself argued unsuccessfully. *See* Parts II.C.2, IV.C.2.

18. The remaining pair of Canadian witnesses, Mr. Murray Wilson and Dr. Michael Gillen, provided a summary of Patent Office practice regarding utility. Mr. Wilson worked at the Canadian Intellectual Property Office ("CIPO") for 37 years – starting as a Patent Office examiner and retiring as the Acting Chair of the Patent Appeal Board. Canada did not challenge Mr. Wilson's qualifications, experience, or credibility in its Closing, likely because Mr. Wilson and Dr. Gillen largely agreed on office practices and the fact that the MOPOP reflects Canadian law. Tellingly, Dr. Gillen

never once referred to the word "promise" in his direct or cross-examination — that is not surprising, since when he worked as an examiner (from 1988-2002), patents were not held to have promises but, rather, merely needed to have industrial value to satisfy the utility requirement. *See* Part II.A.

19. ***Expert witnesses on United States law (Professor Robert Merges and Mr. Stephen Kunin for Lilly; Professor Timothy Holbrook for Canada)***. Professor Robert Merges and Professor Timothy Holbrook provided an analysis of the utility requirement in the United States, and how it compares to the promise utility doctrine. Both experts agreed that the U.S. utility requirement is a low bar that is not comparable to Canada's elevated utility test. Professor Merges, one of the foremost patent law scholars in the United States and an author of the most-used teaching text in the field, also explained that there is no analogue to the promise utility doctrine in any U.S. patentability requirement. *See* Part II.E.

20. At Closing, Canada criticized Professor Merges for not having canvassed the full range of Canadian cases and commentaries, on utility and other grounds. But study at that level of granularity was hardly required for the comparative questions asked of him. It was, instead, Professor Holbrook who revealed a surprising lack of familiarity with basic aspects of the Canadian utility requirement. For example, Professor Holbrook did not know that Canadian courts find promises of utility in the disclosure part of the patent, without reference to the claims; that multiple promises of utility may be found in a single patent; or that evidence of soundly predicted utility, under Canada's additional disclosure rule, must be included in the patent. Further, it became clear during cross-examination that Professor Holbrook's analysis of other U.S. patentability requirements did not reflect an objective assessment of those patentability requirements as applied by the courts. *See* Part II.E.

21. Finally, Mr. Stephen Kunin provided testimony regarding the application of the utility requirement within the U.S. Patent and Trademark Office ("USPTO"), where he served in senior roles for more than three decades, including as Deputy Commissioner for Patent Examination Policy. Mr. Kunin summarized the low bar of the U.S. utility requirement, as applied by examiners and as described in office

guidelines. It is notable that, in its Closing, Canada merely contested the relevance of Mr. Kunin's testimony regarding utility. Canada did not challenge the veracity or reliability of Mr. Kunin's patent office practice evidence, which corroborated the testimony of Professor Merges. *See* Part II.E.

22. ***Expert witnesses on Mexican law (Professor Gilda Gonzalez and Mr. Fabian Salazar for Lilly; Ms. Hedwig Lindner for Canada).*** With regard to Mexico, two experts — Professor Gilda Gonzalez and Ms. Hedwig Lindner — provided testimony regarding the industrial applicability requirement in Mexican law. From 2002 until 2011, Professor Gonzalez served in senior roles, including as Deputy Director General, at the Mexican Institute of Industrial Property ("IMPI"), the agency that grants patents and resolves first instance patent litigation. Ms. Lindner, by contrast, is a private practitioner who has never worked in government, and whose clients are predominantly generic drug companies. Indeed, on behalf of a large generic industry association, Ms. Lindner lobbied for statutory amendments to elevate Mexico's industrial applicability requirement — amendments that the Mexican government rejected. A third expert, Mr. Fabian Salazar, testified about the practice of examiners at IMPI and the application of the industrial applicability requirement. Mr. Salazar worked at IMPI for more than two decades, including as Director of Patents.

23. Professor Gonzalez and Mr. Salazar were emphatic during their examinations that Mexico's industrial applicability requirement is a low bar, and that the requirement has not changed for over two decades. Professor Gonzalez explained that the Mexican standard of industrial applicability requires no more than the possibility of a practical use. Professor Gonzalez and Mr. Salazar further explained that minor amendments to the definition of industrial applicability in 2010 did not involve any substantive change — and that a legislative proposal to raise the bar was rejected in part due to Mexico's international treaty commitments, as Ms. Lindner conceded. All three experts agreed that there is no record of patents being denied or nullified in Mexico for lack of industrial applicability. In Closing, Canada sought to impugn Professor Gonzalez's credibility on the basis of a transcription error on a single demonstrative slide — an innocent mistake of no consequence, given her consistent reports and oral testimony. *See* Part II.E.1.

24. ***Expert witnesses on international intellectual property law (Professor Jay Erstling and Mr. Philip Thomas for Lilly; Mr. David Reed and Professor Daniel Gervais for Canada)***. The first pair of international experts (Professor Jay Erstling and Mr. David Reed) addressed the Patent Cooperation Treaty ("PCT"), an international agreement that incorporates a definition of industrial applicability that reflects the traditional low bar of the utility requirement. The witnesses addressed the requirements of the PCT with respect to the form and contents of international applications. Professor Erstling relied on his 15 years of experience as a senior World Intellectual Property Organization ("WIPO") official, including as Director of its Office of the PCT, and his scholarly work as a leading expert on PCT issues. Mr. Reed, by contrast, drew on his career at Proctor & Gamble, along with his recent consulting work at WIPO as an instructor and PCT Help Desk staffer.

25. Professor Erstling testified that Canada's requirement that evidence of sound prediction be included in the patent application is inconsistent with core principles of the PCT system, and puts applicants such as Lilly in a difficult bind. Canada attempted to question the independence of his views, but was unable to point to anything in Professor Erstling's prior work even remotely inconsistent with his opinion in this proceeding. Mr. Reed, meanwhile, acknowledged during cross-examination that he had no relevant experience in the pharmaceutical industry. Mr. Reed further acknowledged that he had no understanding of the utility requirement for selection patents — even though he stated in his expert report that they were subject to a heightened requirement as compared to other inventions. *See* Part II.F.1.

26. The second pair of international intellectual property law experts (Mr. Philip Thomas and Professor Daniel Gervais) joined issue on a straightforward question: whether the proceedings of WIPO underscore or rebut the uniqueness of Canada's promise utility doctrine. The two witnesses approached this question from different backgrounds and with different stores of knowledge. Mr. Thomas participated in the relevant WIPO proceedings as a senior member of the WIPO secretariat responsible for drafting the proposed Substantive Patent Law Treaty; Professor Gervais, who did not participate in the Substantive Patent Law Treaty

negotiations, based his analysis solely on public WIPO documents (including the drafts that Mr. Thomas oversaw).

27. Mr. Thomas testified that although countries used different nomenclature to define their utility or industrial applicability requirements, the standards did not vary substantially in practice and were easily met across jurisdictions. Given that utility was not an issue in practice, there was little need to harmonize its definitional language. By contrast, Professor Gervais's cross-examination revealed that he over-read the WIPO documents on which he relied. Rather than establish differences in practice, the WIPO record — in particular, the listed examples of those inventions found to lack utility (e.g., perpetual motion machines, ghost catchers) — revealed a remarkable consistency of practice across jurisdictions. As Professor Gervais was forced to admit, WIPO documents reveal that not a single WIPO member state was invalidating pharmaceutical patents as Canada is now doing. Further, the WIPO record establishes that utility was not considered a controversial issue or a point of divergence by WIPO member states. *See* Part II.F.2.

I. Canada's Jurisdictional Objection Is Both Untimely and Unfounded.

28. At the Hearing, Canada again insisted that Lilly's claims are time barred, making this one of the four principal themes of its presentation.[1] But Canada had no viable explanation for the fact that it filed its jurisdictional objection too late. *See* Part I.A. Instead, Canada repeatedly adopted new arguments to justify its belated objection, as flaws in its old arguments became clear. *See* Part I.B. Even if reached on the merits, however, Canada's time bar argument should not be accepted by the Tribunal. Canada's interpretation of NAFTA Articles 1116 and 1117 finds support neither in the text of NAFTA nor in arbitral practice. Canada's view, moreover, is at odds with common sense, as it would require investors to initiate NAFTA claims for purely hypothetical harms. *See* Part I.C.

A. UNCITRAL Rule 21(3) Precludes Canada's Belated Jurisdictional Objection.

29. UNCITRAL Rule 21(3) states unambiguously: "A plea that the arbitral tribunal does not have jurisdiction shall be raised not later than in the statement of defence."

30. As Lilly noted in its Opposition to Respondent's Jurisdictional Objection of 8 December 2015 and at the Hearing, Canada raised no jurisdictional objection in its Statement of Defense.[2] To the contrary, in its Counter-Memorial, Canada affirmatively

[1] This Section responds to the Tribunal's ***Questions 1***, **2, 3,** and ***41***. The Tribunal's ***Question 1*** invited the parties to address "the significance, if any, of the patent for raloxifene in these proceedings?" ***Question 2*** asked whether the "Respondent's objection to jurisdiction *ratione temporis* untimely," and if so "what are the implications." The Tribunal's ***Question 41*** asked whether "the time-bar issue in Article 1116(2) / 1117(2) NAFTA [can] be waived by a respondent," and if not whether "Article 1116(2) / 1117(2) NAFTA prevail over Article 21(3) of the UNITRAL Rules" and what is the "relevance, if any, of provision Article 1120(2) NAFTA."

[2] Cl. Opp. to Resp. Jur. Objection at ¶ 1; Cl. Closing Statement, Tr. at 2008:13-20; *see* Resp. Statement of Defence at ¶ 83 (accepting the Tribunal's jurisdiction regarding alleged NAFTA Chapter Eleven breaches).

represented that it was "not seeking dismissal of the claim on the basis of lack of jurisdiction."[3]

31. Under the plain terms of Rule 21(3), Canada's jurisdictional objection — raised for the first time in its Rejoinder — is simply too late.[4]

B. Canada Has No Answer to the Plain Language of Rule 21(3).

32. Canada has sought to overcome the plain language of Rule 21(3) by relying on three successive arguments — each less credible than the last.

33. *First*, Canada argued in its Rejoinder and at the Hearing that Lilly changed its arguments between its opening Memorial and its Reply.[5] However, Lilly's claims have not changed.[6] Instead, from the very outset of this arbitration, Lilly has argued that: (i) the "three [core] features of the promise utility doctrine" operated together to (ii) "deprive Lilly of its investments in the Zyprexa and Strattera patents in contravention of Canada's obligations to protect investments under NAFTA Chapter 11."[7] In other words, Lilly has consistently sought redress under NAFTA Chapter 11 for the revocation of two specific investments in Canada: its patents on Zyprexa and Strattera. And, consistently, Lilly has maintained that it is entitled to a remedy under NAFTA Chapter 11 because its patents were invalidated through the application of Canada's arbitrary and discriminatory promise utility doctrine.

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[3] Resp. CM at ¶ 209; *see also* Recording of First Procedural Hearing (10 May 2014), at 3:14:38-3:14:59 ("We are not, as I said, challenging the basic competence of this Tribunal to hear this matter inasmuch as we are within the four corners of having a U.S. plaintiff-claimant with investments in Canada alleging damages flowing from a measure attributable to the Government of Canada.").

[4] Cl. Opp. to Resp. Jur. Obj. at ¶¶ 7-8; Cl. Closing Statement, Tr. at 2008:13-2009:2.

[5] Resp. Rejoinder at ¶¶ 63, 91; Resp. Opening Statement, Tr. at 252:17-253:7. As evidence of this change, Canada relies prominently on a quote from Canada's *Redfern* schedule submitted during the document production phase of the case. *See* Resp. Rejoinder at ¶ 85 (quoting Lilly's objection to Canada's Document Request No. 1 without clarifying that the substance of Lilly's objection to the request was expressly that the request did not adequately "relate to Claimant's expectation that the [Strattera] Patent satisfied the utility requirement under Canadian law").

[6] Cl. Opp. to Resp. Jur. Objection at Section I.B; Cl. Opening Statement, Tr. at 19:11-15; Cl. Closing Statement, Tr. at 2010:21-2011:2.

[7] Cl. Mem. at ¶ 10; *see also* Cl. Reply at ¶¶ 70-115.

34. *Second*, in its Opening, Canada asserted that Rule 21(3) does not actually mean what it says. It asserted that Rule 21(3) is intended to apply exclusively where "the Statement of Defense will be the only written submission from the Respondent prior to the oral submissions at the hearing."[8] This argument was made — without any support or explanation — for the first time at the Hearing.

35. There is no basis for Canada's assertion. Rule 21(3) does not refer to the "statement of defense or other further written statements." It refers exclusively and specifically to the "statement of defence."[9] Further, tribunals enforce Rule 21(3) — as written — even in complex cases that require multiple rounds of briefing.[10] This is for good reason. As shown in this very case, a late-filed objection disrupts the proceeding, triggering costly additional briefing on the basis of a rushed and limited record.[11] The parties spent over a year of their time and expense briefing the merits — only to find that Canada, suddenly, had come to the view that Lilly's claims were time-barred.[12]

36. *Third*, Canada asserted during its Closing that Rule 21(3) is somehow preempted by NAFTA.[13] Again, this argument was made — without any support — for the first time at the Hearing.

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[8] Resp. Opening Statement, Tr. at 254:11-15.

[9] Cl. Closing Statement, Tr. at 2009:3-15. The omission is particularly notable because Rule 22 contemplates that further statements are possible. *See* UNCITRAL Rule 22 ("The arbitral tribunal shall decide which further written statements, in addition to the statement of claim and the statement of defence, shall be required from the parties or may be presented by them and shall fix the periods of time for communicating such statements."). Rule 21(3) should not be read in isolation from the Rule that immediately follows.

[10] In *Canfor v. United States*, for example, the respondent attempted to reserve its right to raise jurisdictional objections on particular issues until after the filing of its Statement of Defense. *Canfor Corporation v. United States*, UNCITRAL, Decision on the Place of Arbitration, Filing a Statement of Defence and Bifurcation of the Proceedings (23 Jan. 2004), at ¶ 48 (CL-175). This request was promptly denied. *Id*. *Canfor* was not a simple case with only one round of written submissions. It was a multi-stage NAFTA dispute, just like this one.

[11] Cl. Opp. to Resp. Jur. Objection at ¶ 9.

[12] *Id*.

[13] Resp. Closing Statement, Tr. at 2238:2-13 ("MR. SPELLISCY: . . . This is an issue that goes to the very heart of the consent of the NAFTA parties to jurisdiction. And so you have to assure yourself that you have jurisdiction to hear this claim. But your jurisdiction is limited to hearing claims that have been (continued…)

37. This argument is nonsensical. NAFTA itself identifies the UNCITRAL Rules (among others) to govern Chapter 11 proceedings.[14] While the Treaty may "modif[y]" the Rules,[15] there is nothing in Articles 1116 and 1117 that indicates an intent to modify Rule 21(3).[16] Instead, without any conflict between them, Rule 21(3) and Articles 1116 and 1117 operate together in a coherent fashion. On this issue, NAFTA does not trump or displace the UNCITRAL Rules.

38. It is precisely for this reason that Canada's own courts have held that a NAFTA State Party can waive its jurisdictional arguments by failing to timely raise them.[17] After a Chapter 11 NAFTA tribunal rendered a partial award on liability against Canada in *S.D. Myers v. Canada*, Canada sought judicial review before the Federal Court of Canada, arguing that the tribunal lacked jurisdiction to decide that the

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brought within three years of the measures of knowledge of the measures and knowledge of[ ]loss. And so that is a treaty provision in our view. THE PRESIDENT: So that overrides that provision in your submission Article 21(3) of the UNCITRAL rules? MR. SPELLISCY: Absolutely. . . .").

[14] *See* NAFTA Art. 1120(1).

[15] NAFTA Article 1126(1) ("A Tribunal established under this Article shall be established under the UNCITRAL Arbitration Rules and shall conduct its proceedings in accordance with those Rules, except as modified by this Section.").

[16] *Compare* NAFTA Articles 1116, 1117 *with* NAFTA Article 1128 ("On written notice to the disputing parties, a Party may make submissions to a Tribunal on a question of interpretation of this Agreement.") *and* NAFTA Article 1129 ("1. A Party shall be entitled to receive from the disputing Party, at the cost of the requesting Party a copy of: (a) the evidence that has been tendered to the Tribunal; and (b) the written argument of the disputing parties. 2. A Party receiving information pursuant to paragraph 1 shall treat the information as if it were a disputing Party."). NAFTA has modified the UNCITRAL Rules in certain respects. For example, UNCITRAL Rule 6(2) states that "either party may request the Secretary-General of the Permanent Court of Arbitration at The Hague to designate an appointing authority." NAFTA overrides this Rule, however, by designating ICSID as the appointing authority. *See* NAFTA Article 1124.

[17] *See Attorney Gen. of Can. v. S.D. Myers, Inc.*, 2004 FC 38, at ¶¶ 46-53 (holding that Canada waived its jurisdictional objection under UNCITRAL Rule 21(3)) [hereinafter *S.D. Myers*] (CL-1). To the extent Canada contends that the defenses under Articles 1116 and 1117 cannot be waived, that simply is not the case. Jurisdictional defenses under Chapter 11 *can* be waived through host State consent — whether implicit or explicit. *See Marvin Feldman v. Mexico*, NAFTA/ICSID No. ARB(AF)/99/1, Award (16 Dec. 2002), at ¶ 63 (noting that tolling or estoppel of the three-year time bar in Articles 1116(2) and 1117(2) is permitted when a State acknowledges a claim) (CL-109).

claimant met the definition of an "investor" under NAFTA.[18] The Federal Court held Canada had waived its jurisdictional objections:

> Jurisdiction is a term of art and a legal objection must be raised clearly at the outset of the arbitration. Canada failed to do so in this case, and cannot now argue that the Tribunal did not have jurisdiction to render the three decisions which are the subject of these applications for judicial review. To find otherwise would undermine the clear and express procedures incorporated in NAFTA for the resolution of disputes.[19]

C. Canada's Jurisdictional Objection Fails as a Matter of Law.

39. Even if the Tribunal were to reach Canada's jurisdictional objection, it would be bound to reject it. Lilly's claims are not defeated by the mere fact that Lilly has provided the Tribunal with the factual background and context necessary to understand its claims for the expropriation of the Zyprexa and Strattera patents.[20]

40. Canada cited no legal support in its Rejoinder for the argument that the treatment of one of Lilly's investments, the raloxifene patent, somehow started the time limitation clock on claims regarding the future expropriation and mistreatment of the two legally and factually distinct investments at issue in this arbitration, the Zyprexa and Strattera patents.[21] And despite Lilly pointing this out in its Opposition brief, Canada again offered no legal support for its argument at the Hearing.[22]

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[18] *S.D. Myers*, at ¶¶ 2-3, 46 (CL-1).

[19] *Id*. at ¶ 53.

[20] Cl. Opp. to Resp. Jur. Objection at Section II.B; Cl. Closing Statement, Tr. at 2013:1-8. Many arbitral decisions – including *Grand River Enterprises v. United States*, *Mondev v. United States*, *Glamis Gold v. United States*, *Apotex v. United States*, *Feldman v. Mexico*, *UPS v. Canada*, and *Bilcon v. Canada* – have noted that a factual predicate to a claim is distinct from the incurrence of a loss related to specific investments. *See* Cl. Opp. to Resp. Jur. Objection at ¶¶ 40-41 & nn.60-69. For example, in *Bilcon v. Canada*, the tribunal noted, "While Article 1116(2) bars breaches in respect of events that took place more than three years before the claim was made, events prior to the three-year bar . . . are by no means irrelevant. They can provide necessary background or context for determining whether breaches occurred during the time-eligible period." *Bilcon of Delaware Inc. v. Canada*, PCA/UNCITRAL, Award on Jurisdiction and Liability (17 March 2015), at ¶ 282 (CL-166).

[21] *See* Cl. Opp. to Resp. Jur. Objection at ¶¶ 44-47.

[22] Cl. Closing Statement, Tr. at 2011:3-2012:25.

41. Instead, Canada offered an analogy between the promise utility doctrine and a hypothetical statute that "said certain patents were going to be taken away."[23] According to Canada, an investor knowing that its patent is subject to revocation under the statute "can't wait until that legislation is applied against [it] in order to bring a challenge under NAFTA."[24]

42. The unpredictable and inconsistent application of the promise utility doctrine makes Canada's analogy inapt — pharmaceutical investors had no advance way of knowing that their patents "were going to be taken away." In particular, it is simply not the case that Lilly had knowledge of a loss associated with the Zyprexa and Strattera patents as the result of the prior invalidation of the raloxifene patent.[25] As Mr. Robert Armitage explained, 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: Lilly believed that the utility of its patents had been demonstrated by its pre-filing clinical trials and that it would not need to rely on a sound prediction of utility.[26]

43. More fundamentally, it cannot be the case that NAFTA requires investors to bring claims for conjectural future losses to their investments. All pharmaceutical patents face a somewhat higher theoretical risk of invalidation under the promise utility

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[23] Resp. Opening Statement, Tr. at 270:7-9.

[24] *Id*. at 270:9-11.

[25] Resp. Opening Statement, Tr. at 261:6-265:20; 269:4-13; 271:4-16.

[26] Testimony of Robert Armitage, Tr. at 370:14-371:4 ("My understanding, when I was briefed on this opinion, is that there was no doubt that olanzapine had utility under the law of utility as well understood in any patent jurisdiction of which I'm aware, but that the court was actually doing, as is suggested in what you had read here, attempting to read in the patent a set of promises such that unless Lilly had actually been able to demonstrate what the court viewed as a promise, the compound that had utility would nonetheless be determined not to have utility, irrespective of how useful the compound actually was at that point as a medicine in Canada. So what I was incredulous about, in sum, was that a utility requirement that would invalidate a patent where it was clear the patent was useful."); *id*. at 385:13-22 ("[W]ith respect to atomoxetine [Strattera], we would not have needed an enhanced disclosure of any kind because if we had conducted a clinical trial — which we did in this case — that we believe showed statistical significance, it should have been accepted without being disclosed in the Canadian patent application . . . as a matter of a demonstration that, in fact, Strattera had been shown to be effective to treat ADHD.").

doctrine than they did under Canada's traditional mere scintilla requirement. Thus, under Canada's theory, Lilly should have brought claims with respect to *all* its patents in Canada the moment that its raloxifene patent was found to lack utility in 2008. Indeed, *every* foreign investor with constructive knowledge of breach and loss would have had to do the same.[27] But that is simply not how the investment arbitration system works. An investor who loses one investment is not required to also bring claims for every other investment that might hypothetically be subjected to the same government measures.[28]

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44. For these reasons, the Tribunal should reject Canada's jurisdictional argument. UNCITRAL Rule 21(3) is unequivocal and precludes Canada's belated objection. And Canada's successive arguments in support of its position — two of

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[27] Resp. Opening Statement, Tr. at 265:10-20, 267:1-5. Canada's unprecedented approach prompted several questions from the Tribunal. *See id*. at 265:21-266:1 (question by Mr. Gary Born) ("Would I be right in thinking that the consequence of that analysis is that the Claimant, and I guess also other companies, should bring NAFTA arbitrations before any invalidation litigation has been started, or I guess even threatened?"); *id*. at 267:18-24 (question by Sir Daniel Bethlehem) ("Can I follow up on that and the proposition from your colleagues that the courts are neutral and the revocation of a patent is not certain until it happens? How, then, do you address the issue of 1116(2) and knowledge of the loss if the revocation of a patent is entirely speculative until it happens?"); *id*. at 271:1-3 (question by the President) ("How do you know that you will win or lose the case, now in the case of invalidation of a patent?").

[28] Cl. Closing Statement, Tr. at 2012:13-25; *see* Resp. Opening Statement, Tr. at 269:18-270:3 (question by the President) ("Is it one thing to be aware of the doctrine and another thing to be confronted with the application of the doctrine, and especially in the context of what you mentioned, the loss. Until you have an invalidation of your patent, you don't know whether it will be first invalidated with finality, and the second thing is you also don't know whether you will have a loss, even quantified or not. So is it not more that you have to look at the application rather than the awareness of the doctrine itself?"); *id*. at 273:9-16 (question by Mr. Gary Born); Resp. Closing Statement, Tr. at 2233:25-2234:10 (question by the President) ("Put yourself in the shoes of an investor and you see a doctrine developing. You have here two patents. Are you sure that the patent will be invalidated because of this change of doctrine or say, well, we have to see what happens in the courts? Especially when the doctrine is, as we heard from the investor, it can go this way, can go the other way, we don't know. So is it not better, then, to wait until you have actually an invalidation decision so you can show, you see, this doctrine affects my investment?").

which were made for the first time at the Hearing — are unsupported and unconvincing. In any case, Canada's argument fails as a matter of law. It has been unable to demonstrate that the treatment of the raloxifene patent somehow started the time limitation clock on claims regarding the Zyprexa and Strattera patents.

II. Canada's Promise Utility Doctrine Is a Radically New, Additional Requirement for Patentability.

45. Testimony at the Hearing confirmed that Canada's promise utility doctrine did not exist when Lilly applied for and received its patents for Zyprexa and Strattera.[29] At that time, the test for utility in Canada was a low bar consistent with international practices regarding patentability. Under the traditional test, inventions were required to have some industrial value, and only inventions that were inoperable or "totally useless" were found to lack utility.[30] Lilly's applications for the Zyprexa and Strattera patents easily cleared that bar.

46. By contrast, when Lilly's patents were revoked, the Canadian courts had radically departed from their traditional "mere scintilla" test and imposed an additional, elevated utility requirement. As explained in Lilly's briefs and confirmed at the Hearing, the promise utility doctrine applied to invalidate the Zyprexa and Strattera patents encompasses three components:[31]

- *First*, patentees are held to additional "promises" of utility above and beyond the claimed use of the invention, including promises derived from statements made in the patent disclosure and even implied promises.

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[29] This Section responds to ***Tribunal Questions 4, 5, 11, 27,*** *and* ***29***. The Tribunal's ***Question 4*** asked whether the "promise utility" is a doctrine. ***Question 5*** asked what are "the implications, if any, of the contents of Canada's Manual of Patent Office Practice for the determination of Claimant's claims." ***Question 11*** asked what the implications would be if one accepted Respondent's claim that the promise utility doctrine is "several distinct patent law rules, all of which were part of Canadian law when Claimant filed its patents." ***Question 27*** asks whether Claimaint is alleging a violation of Articles 1110 and 1105 "as a consequence of the cumulative effect of the judicial development of the alleged Canadian 'promise utility' doctrine" or "whether the alleged breach of NAFTA can be traced back to any one of these decisions individually." ***Question 29*** asked the parties to identify the extent to which each of the three elements of the promise utility doctrine "was or was not a new development in Canadian law."

[30] Cl. Opening Statement, Tr. at 20:22-21:4, 23:8-15; Testimony by Murray Wilson, Tr. at 771:10-14.

[31] Cl. Closing Statement, Tr. at 2038:2-8; Cl. Closing Slides at 43.

- *Second*, patentees are subject to a heightened evidentiary burden, where reliance on post-filing evidence of utility (such as commercial success or infringement) is no longer permitted.

- *Third*, where the patentee relies on a sound prediction of utility, an additional disclosure rule applies and requires all evidence of utility to have been included in the patent application as filed.

47. At the Hearing, Canada insisted that each aspect of the promise utility doctrine has "deep roots" in Canadian law, purportedly consistent with longstanding principles of patent law.[32] The record before the Tribunal, however, contradicted Canada's position at every turn.

48. A wide range of sources revealed the unprecedented nature of the promise utility doctrine. As summarized below, evidence of the radical change included: extensive revisions to the MOPOP (*see* Part II.A); the contemporaneous reactions of Patent Office examiners to these revisions (*see* Part II.B); the transformation of Canada's utility jurisprudence in the 2000s (*see* Part II.C); the dramatic, disproportionate spike in revocations of patents on safe and effective pharmaceutical products since 2005 for lack of utility (*see* Part II.D); the striking divergence between Canada's utility test and those of its NAFTA partners (*see* Part II.E); and the shared understanding of utility/industrial applicability in international patent law negotiations, which included nothing remotely similar to Canada's promise utility doctrine (*see* Part II.F).

49. In all of these respects, the evidence presented to the Tribunal at the Hearing established that Canada's promise utility doctrine is both new and radically distinct from the traditional test for utility, not only in Canada but also around the world. Solely on the basis of this sea change in Canadian law,[33] the Canadian courts invalidated Lilly's patents for Zyprexa and Strattera.

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[32] Resp. Closing Statement, Tr. at 2244:22-25, 2276:2-6.

[33] *See e.g.*, Testimony of Norman Siebrasse, Tr. at 525:7; *see also* Cl. Closing Statement, Tr. at 2004:13-14.

A. The MOPOP Revisions Demonstrate the Radical Change in Canada's Utility Requirement.

50. As demonstrated in Lilly's Reply and at the Hearing, the radical shift in Canada's utility law was reflected in changes to the MOPOP between the 1990s and 2000s. Canada has not disputed that the MOPOP's utility sections changed dramatically between the 1990s and 2000s. Nor has Canada shown that these dramatic revisions were prompted by anything other than changes in Canadian utility law by the courts.

51. That the MOPOP is a reliable restatement of Canadian patent law is common ground. As both Mr. Murray Wilson and Dr. Michael Gillen explained, MOPOP represents the Canadian Patent Office's interpretation of the Patent Act, the Patent Rules, and jurisprudence as of the date each chapter came into effect.[34] During his testimony, Dr. Gillen acknowledged that the MOPOP is the *only* comprehensive summary of Canadian patent law available to patent examiners and practitioners[35] and that the MOPOP should be treated with deference as an interpretative tool.[36]

52. Therefore, the uncontroverted evidence before the Tribunal is that when Lilly's patents were filed, examined, and granted, the 1990s MOPOPs reflected Canada's utility requirement.[37] Those MOPOPs reflect that the utility requirement was

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[34] Testimony of Murray Wilson, Tr. at 769:21-770:7 (noting that MOPOP is "a very important reference tool" that was "created by the Patent Office, taking the requirements of the Patent Act, the requirements of the Patent Rules and relative jurisprudence, and explaining all of this material in practical terms to tell examiners how to do their work, how to examine patent applications"); Testimony of Michael Gillen, Tr. at 982:24-983:3 (agreeing that "[p]ractices expressed in the MOPOP arise from the Office's interpretation of the Patent Act, Patent Rules and jurisprudence as of the date each chapter came into effect").

[35] Testimony of Michael Gillen, Tr. at 1014:3-13; 1016:3-16 ("[T]here's no other manual that the examiners would use.").

[36] *Id*. at 984:20-985:8 (agreeing that MOPOP should be treated "with a reasonable degree of deference as an interpretive tool").

[37] During the Hearing, Canada questioned why the 1990 version of MOPOP, in addition to the 1996 version, was relevant to the Zyprexa patent. *See* Testimony of Murrary Wilson, Tr. 784:23-785:2. Lilly filed its patent application for Zyprexa in April 1991 and requested examination in October 1995. *See* Wilson First Report at ¶ 31. At that time, the 1990 MOPOP was in force. *Id*. A revised MOPOP issued in October 1996, with no change in the utility requirement ("industrial value"). Testimony of Murray Wilson, Tr. at 771:17-22. Similarly, there was no change to the utility requirement as set out in the 1998 (continued…)

a simple test: the invention must not be "totally useless" and must have an application in industry.[38]

53. Canada's characterization of the MOPOP as merely a "high-level summary"[39] does not rebut the fact that the traditional test was a low bar. Nor does Canada's characterization of the MOPOP as "high-level" explain the *changes* in MOPOP regarding the utility requirement over time. As Mr. Wilson testified, the 1990s MOPOP section on utility was short because the utility requirement itself was simple: "Utility was so basic, it didn't need pages to describe it. Utility was 'not totally useless.' You can describe it in three or four words, not five pages."[40] Canada did not present any evidence that the Patent Office during the 1990s applied a different utility requirement than the one set forth in the MOPOP.

54. Canada's only response at the Hearing was to note, through its questioning of Mr. Wilson, that the *Consolboard* case was cited in the 1990s MOPOPs.[41] These citations, however, in no way reflect the promise utility doctrine. First, the only case expressly cited for utility in the 1990s MOPOPs was *Northern Electric*, which simply required that an invention not be "totally useless," be operable, and have industrial value.[42] At no point in the 1990s did the MOPOP cite directly to or quote from

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MOPOP, which was in force when the patent application for Strattera was filed, examined, and granted. *See* Wilson First Report at ¶¶ 39-40; Testimony of Murray Wilson, Tr. at 771:17-22; *see also* Cl. Opening Statement, Tr. 20:22-25:19.

[38] Cl. Closing Statement, Tr. at 2039:16-21; Cl. Closing Slides at 47; Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, §§ 12.02.01; 12.03 (January 1990) (C-54); Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 16.02.01 (Oct. 1996) (C-55); Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 16.02.01 (March 1998) (C-57).

[39] Resp. Opening Statement, Tr. at 193:20-194:8.

[40] Testimony of Murray Wilson, Tr. at 794:5-13.

[41] Tr. at 800:8-802:21.

[42] *See* Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 12.03 (January 1990) ("To be acceptable in the patentable sense, [an invention] must be something that will impart industrial value to what is sought to be patented (Northern Electric v. Browns Theatres supra).") (C-54); *see* Closing Statement, Tr. at 2039:22-2040:2; Cl. Closing Slides at 47.

Consolboard regarding utility.[43] Second, Canada's suggestion that *Consolboard*'s "promise" language is somehow reflected in the 1990s MOPOPs is demonstrably inaccurate. That language did not appear in the MOPOP until the 2000s.[44] As Mr. Wilson noted, the phrase highlighted by Canada from the 1996 and 1998 MOPOPs — "if an invention lacks utility for its described purpose, it will result in an invalid patent" — is not the same as the "promise" language in *Consolboard*.[45] Finally, as Mr. Wilson testified, *Consolboard* was never interpreted by the Patent Office in the 1990s to require applicants to meet "promises" of utility.[46] The language in Consolboard did not take on that meaning until it was repurposed by the Canadian courts starting in 2005, and nothing in the 1990s MOPOPs suggests otherwise.

55. As demonstrated at the Hearing, the 2009 and 2010 MOPOP amendments reflected the changes in Canadian law incorporated all three elements of the promise utility doctrine.[47] Mr. Wilson testified about these MOPOP changes in detail, including: (i) a new section on "promises," requiring that an inventor must meet each "promise" of particular advantages mentioned in a patent application;[48] (ii) a new bar on post-

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[43] In the 1990 utility chapter, there is no mention of *Consolboard*. In the 1996 and 1998 utility chapters, it was simply listed at the end as one of no fewer than 20 relevant cases. Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 16.10 (Oct. 1996) (C-55); Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 16.10 (March 1998) (C-57).

[44] Testimony of Murray Wilson, Tr. at 772:18-24; Cl. Closing Statement, Tr. at 2041:6-9.

[45] Testimony of Murray Wilson, Tr. at 801:12-13 ("Those two sentences are not synonymous.").

[46] Testimony of Murray Wilson, Tr. at 808:2-14 ("MR. BORN: So far as you can recall, was the promise of the patent rule or doctrine something that was taken into account in agency practice prior to 2002? MR. WILSON: I don't believe so, no, not to establish utility. Utility was very simple. Couldn't be completely useless."); *id.* at 810:1-8 ("MR. BORN: [D]id in agency practice the examiners give effect to the language or portion of the Consolboard decision suggesting that a patent that made a promise needed to fulfill that promise to satisfy the utility standard? MR. WILSON: I think the short answer is no."); *see also id*. at 809:10-20 (describing the changing interpretation of *Consolboard* by the Patent Office over the years).

[47] *See* Cl. Opening Slides at 18-21; Cl. Closing Slides at 47, 49. The fact that MOPOP included all three elements together in the new revision confirms that these elements work together as a unitary standard, *see* Cl. Opening Statement, Tr. at 15:12-17, and rebuts Canada's argument that this is not a unitary doctrine, *see* Resp. Opening Statement, Tr. at 182:13-17; Resp. Closing Statement, Tr. at 2245:7-9; *see also infra* Part II.C.1.

[48] Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 12.08.01 (Dec. 2009) (C-59); Cl. Opening Statement, Tr. at 25:1-9; Cl. Opening Slides at 19; Cl. Closing Statement, Tr. at (continued…)

filing evidence of utility;[49] and (iii) a new requirement that all evidence of soundly predicted utility must be in the patent application as filed.[50]

56. All three elements were new to the 2000s MOPOPs and to Canadian Patent Office practice. As Mr. Wilson explained, "the amendments to MOPOP in the 2000s reflected a substantial change in the utility requirements that did not exist when Lilly's olanzapine [Zyprexa] and atomoxetine [Strattera] patent applications were filed and examined."[51] Canada has not argued that these elements previously existed together in the MOPOP or in Patent Office practice prior to 2009 or 2010 — nor can it.

57. It is undisputed that the changes to the MOPOP were driven by changes in the law. The revised MOPOP sections on utility and sound prediction cite to new cases for everything but operability, the traditional requirement.[52] Dr. Gillen agreed that the MOPOP's utility section was amended to reflect recent court cases, including *AZT* and *Raloxifene*.[53]

2040:15-17; Cl. Closing Slides at 49; Testimony of Murray Wilson, Tr. at 772:18-773:2, 773:12-22; Wilson Slide Presentation at 13.

[49] Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 12.08.05 (Dec. 2009) (C-59); Cl. Opening Statement, Tr. at 25:10-14; Cl. Opening Slides at 20; Cl. Closing Statement, Tr. at 2040:14-21; Cl. Closing Slides at 49; Testimony of Murray Wilson, Tr. at 773:3-6, 773:23-774:3; Wilson Slide Presentation at 14.

[50] Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 9.04.01a (Dec. 2010) (C-60); Cl. Opening Statement, Tr. at 25:10-17; Cl. Opening Slides at 21; Cl. Closing Statement, Tr. at 2040:17-19; Cl. Closing Slides at 49; Testimony of Murray Wilson, Tr. at 773:7-10, 774:4-9; Wilson Slide Presentation at 15.

[51] *See* Testimony of Murray Wilson, Tr. at 773:11-774:14.

[52] As Dr. Gillen noted, the recent jurisprudence prompting the 2010 MOPOP amendments are found in footnotes 38 to 47. *See* Testimony of Michael Gillen, Tr. at 963:7-964:7. Those footnotes contain only new cases — the 2002 AZT decision and decisions dating from 2005. *See* Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, Chapter 9, at 29 (Dec. 2010) (C-60). Similarly, the revised Chapter 17 published in 2009 cites only to recent decisions on sound prediction, including *Pfizer v. Apotex* 2007 FC 25, *Eli Lilly Canada Inc. v. Apotex Inc* 2008 FC 142 (Raloxifene), and *Aventis Pharma Inc v. Apotex*, 2005 FC 1283, aff'd 2006 FCA 64. Canadian Intellectual Property Office — Patent Office, Manual of Patent Office Practice, § 17.03.01-03 & nn.18-22 (January 2009) (C-351).

[53] Testimony of Michael Gillen, Tr. at 935:20-9:36:4 (noting that *AZT* was a "new development in the law" that prompted the amendments to MOPOP); *id*. at 969:8-970:8 (remarking that *AZT* must have been one of the "recent decisions" referenced in the MOPOP Update Priority document produced by Canada); (continued…)

58. Canada's expert, Dr. Gillen, who served at CIPO from 1988 to 2014 (as an examiner from 1988 to 2002), never once used the term "promise" in his testimony before the Tribunal. It is not surprising that Dr. Gillen never used the term "promise," because the "promise" concept was never relevant to the traditional utility test applied when he was an examiner at the Patent Office.[54]

59. The dramatic changes to the MOPOP were accompanied by parallel changes in Patent Office practice. Canada and its experts failed to identify a single example of a patent application rejected on the basis of the promise utility doctrine prior to the 2000s. Dr. Gillen agreed that there was nothing in earlier MOPOPs that would have instructed examiners to reject applications that did not meet the new utility requirement reflected in the 2009 and 2010 MOPOPs.[55] As Dr. Gillen explained, the "section on utility in those [1990s] versions of MOPOP simply referred to the invention being useful and for its desired purpose."[56] Dr. Gillen also testified that prior to 2002, he could not recall any Office Actions or Commissioner's Decisions that denied a patent application for failure to include evidence to support a sound prediction of utility.[57]

60. In sum, the uncontroverted evidence remains that the MOPOP was dramatically revised in 2009 and 2010 to incorporate the radical changes in Canada's

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"MOPOP Update Priority List" (9 Sept. 2005), [Canada Doc. No. 1119, at 067254] (C-355); *see* Testimony of Michael Gillen, Tr. at 963:7-964:7 (noting *Eli Lilly v. Apotex* (Raloxifene) was a recent case that was used to update MOPOP in 2010).

[54] Cl. Closing Statement, Tr. at 2004:2-8 ("Also of note, Mr. Gillen never used the word 'promise' in his presentation, and he never used the word 'promise,' I don't believe, in any of his testimony. And I would submit that that's because Mr. Gillen, during his 14 years as a patent examiner, from 1988 to 2002 did not examine patent applications looking for promises of utility.").

[55] Testimony of Michael Gillen, Tr. at 994:6-17 ("MR. DEARDEN: Nowhere written in those editions of MOPOP will I find an instruction to examiners to reject applications that didn't include the factual basis and line of reasoning for the prediction in the patent. DR. GILLEN: You won't find those instructions in the MOPOP, no. MR. DEARDEN: In those '90, '96 and '98 MOPOPs. I won't find it in those MOPOPs, correct? DR. GILLEN: That's correct.").

[56] Testimony of Michael Gillen, Tr. at 991:20-24.

[57] *Id*. at 960:12-962:1 (agreeing that he was not "aware of any" final actions or Patent Appeal Board decisions that "dealt with the issue of whether a rejected patent application failed to disclose the factual basis and line of reasoning in the patent" prior to 2002).

utility law. Moreover, there is simply no evidence in the record that, prior to 2005, the Canadian Patent Office applied any aspect of the promise utility doctrine.

B. CIPO Examiner Reactions to the 2009 and 2010 MOPOP Revisions Demonstrate the Radical Change in Canada's Utility Requirement.

61. As discussed in Lilly's Opening, numerous CIPO examiners expressed confusion and concern about the new utility sections in early drafts of what became the 2009 and 2010 MOPOPs.[58]

62. One examiner, Ms. Black, noted with respect to *Pfizer v. Apotex*, a case decided in 2007: "This case is really new. Has the office even completed a study of this case?"[59]

63. Another examiner, Mr. Rymerson, noted that the new draft of Chapter 12 on utility "contains information that's not in our current examination practice."[60]

64. A third examiner, Ms. Trus, expressed substantial concern that the proposed changes might be unethical and urged that the wording be modified:

> 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

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[58] Cl. Opening Statement, Tr. at 16:19-17:4 ("The rules changed so dramatically that in the contemporaneous internal communications of the Canadian Intellectual Property Office that were provided as part of the document production phase of this case, Respondent's own patent examiners at CIPO, the Canadian IP Office, were asked to comment on the changes to their patent examination manual, the MOPOP, in 2009 and 2010, the changes that incorporated this new utility test. They were confused at these new requirements."); *see* Cl. Reply at ¶¶ 129-137.

[59] Opening Statement, Tr. at 17:8-10; Cl. Opening Slides at 9; *see also* "Chapter 17 Working draft (July 2007) comments from C9," Comments of Daniel Begin and Marsha Black [Canada Doc. No. 1065, at 066681] (C-357).

[60] Cl. Opening Statement, Tr. at 17:5-8; Cl. Opening Slides at 8; *see also* "Comments on MOPOP Chapter 12 Compiled from Section C5 Biotech," Comments from Rob Rymerson (25 January 2008) [Canada Doc. No. 910, at 065383] (C-358).

> 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*.[61]

65. Lilly provided additional examples of CIPO examiner confusion in its Reply submission.[62] One illustrative email noted that examiners had "a number of questions" about how the new utility requirement in the revisions to Chapter 17 should be implemented.[63] That document also noted that the "majority" of patent examiners thought the Chapter 17 amendments related to utility were inconsistent with current practice and felt that they "were being forced to change their office practices."[64] Another examiner noted that the new ban on post-filing evidence appeared "to directly contradict a [1999] Commissioner's decision (albeit not a widely known one yet) #1238 in the biotech field," which allowed post-filing proof of utility.[65]

66. Similar confusion persisted even when the Patent Office provided internal guidance to examiners. An internal CIPO case study produced by Canada, entitled "Let's Talk About Literal Assertions and Promised Utility," published on 18 March 2010, underscores the confusion regarding the radical new changes to the utility requirement in Canada.[66] The document recounts a training session involving nine patent examiners who were presented with a case study and guidance regarding the utility of an invention. The examiners were polled at the beginning and end of the discussion on how they would have handled the application. The results were split not

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[61] Cl. Opening Statement, Tr. at 17:11-24; Cl. Opening Slides at 10; *see also* "MOPOP Chapter 12 feedback C14 - part 2," Comments of Nancy Trus (Examiner) (17 March 2008) [Canada Doc. No. 921, at 065459] (emphases added) (C-361).

[62] *See* Cl. Reply at ¶¶ 130-137.

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

[64] *Id*.

[65] *See* Cl. Reply at ¶ 137 (quoting "Comments on Chapter 12," (13 May 2008) [Canada Doc. No. 891, at 065268] (C-360)). This also corroborates Mr. Wilson's testimony on post-filing evidence. *See* Testimony of Murray Wilson, Tr. at 773:23-774:3 (explaining that the MOPOP requirement barring post-filing evidence of utility "is new" and that "[u]nder the traditional requirement the applicant could use any evidence to confirm that the invention was useful, including post-filing evidence, if the utility had been questioned by the examiner").

[66] Cl. Closing Slides at 50; *Let's Talk About Literal Assertion*s, Canada Doc. No. 39 (C-491)

only in the first poll, but also in the second: both times, three of the nine examiners would have found the invention useful; three would have found the invention not useful; and three confessed to being unsure. A well-established doctrine would not have resulted in such confusion.[67]

67. The reactions of multiple CIPO examiners to the 2009 and 2010 MOPOP amendments confirm the radical change in Canada's utility test and, consequently, in Canadian Patent Office practice. At the Hearing, Canada offered no response at all to this compelling evidence identifying the promise utility doctrine as a distinctly new and confounding rule for examiners to follow.[68]

68. In sum, the reactions of CIPO examiners provide extensive contemporaneous evidence of the dramatic changes to the utility requirement — evidence that Canada has not even addressed, let alone rebutted.

C. Canadian Case Law Demonstrates the Radical Change in Canada's Utility Requirement.

69. Despite the clear indicia from its own Patent Office that its law had changed, at the Hearing Canada continued to insist that its elevated utility requirement had long been applied by its courts.[69] However, as testimony revealed, and as Canada's own witnesses conceded, the promise utility doctrine that invalidated Lilly's patents for Zyprexa and Strattera did not exist in Canadian case law when those patents were granted by CIPO.

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[67] At the beginning of the session, 3 of the 9 examiners would not have objected to the application, 3 would have objected, and 3 were on the fence. *Let's Talk About Literal Assertion*s, Canada Doc. No. 39 (C-491). Even "[a]t the conclusion of the session the examiners were re-polled and the results were the same!" *Id*. As Lilly explained at the Hearing, this also demonstrates the arbitrariness of the promise utility doctrine. Cl. Closing Statement, Tr. 2041:17-2042:12.

[68] Indeed, Canada's silence on this point continued even after Lilly called attention to it at the Hearing. *Id*. at 2003:7-12 ("The contemporaneous evidence in the record of the CIPO examiners questioning the new utility requirement being incorporated into the MOPOP is significant. It's significant because it's contemporaneous. It's significant because it's not addressed at all by Canada.").

[69] *See, e.g.*, Resp. Opening Statement, Tr. at 184:11-12.

70. Canada has sought to disaggregate the doctrine into what it calls "three distinct rules," but the evidence shows that these elements are applied as a unitary, elevated, and additional utility requirement. *See* Part II.C.1. Moreover, while Canada asserted that each element has "deep roots" in Canadian law, at the Hearing Canada's witnesses failed to identify a single case in which any element standing alone — much less the doctrine in its entirety — was applied to invalidate a patent until after the *AZT* ruling in 2002. *See* Part II.C.2.

1. The Promise Utility Doctrine Is A New, Unitary Utility Requirement.

71. As Lilly's witnesses explained, the radical change in Canada's utility requirement is manifest in the case law, through which the new promise utility doctrine was adopted and applied to invalidate pharmaceutical patents.

72. When Lilly's patents were granted, inventions were found to lack utility by courts only if the inventions were inoperable.[70] As Professor Siebrasse explained, "the bar was low, post-filing evidence was admissible to establish utility, sound prediction could be established on the basis of all the evidence."[71] As a result, according to Mr. Reddon, "utility challenges were very rare . . . . It was not the winning basis to attack a patent that was in the market curing people and that you wanted to copy, to stand up in court and say 'But it's useless.'"[72]

73. By contrast, when Lilly's patents were invalidated, Canadian courts were invalidating patents for commercially successful pharmaceutical inventions for lack of utility, based on elevated "promises" of utility — promises construed from the

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[70] Testimony of Norman Siebrasse, Tr. at 518:6-15 ("So when were inventions held to lack utility? Not very often. And it was primarily in the case or only in the case of inoperable inventions.").

[71] *Id*.

[72] Testimony of Andrew Reddon, Tr. at 821:22-822:19; *see id.* at 821:19-22 ("The question historically has been does the invention do something, and the tests for what that something had to be was a mere scintilla.")

disclosure of the patent — that could not be demonstrated or soundly predicted as of the filing date given a heightened evidentiary standard.[73]

74. This new, additional utility requirement operates as a single test. That the three elements of Canada's promise utility doctrine constitute an integrated, single utility requirement is apparent from the table of contents of numerous decisions.[74] Different aspects of the doctrine may play a more prominent role in some cases than in others, but all three aspects form part of a single utility test.

75. Canada does not dispute that the three elements all relate to utility and form part of the test for utility in Canadian law.[75] Still, Canada contends that the promise utility doctrine is not a "unitary doctrine," in that it reflects "three distinct rules."[76] Canada apparently takes this position because not every case raises all three elements of the promise utility doctrine. For example, Canada emphasized that "the disclosure requirement for sound prediction, one of the three branches that Claimant challenges, was not applied to invalidate the olanzapine [Zyprexa] patent."[77]

76. But Canada's argument engages a straw man — Lilly has never argued that every case raises all three elements of the promise utility doctrine.[78] Of course, application of the new utility requirement in Canada is based on the specific facts of

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[73] Testimony of Norman Siebrasse, Tr. at 519:3-524:1 (summarizing Canada's new doctrine); Testimony of Andrew Reddon, Tr. at 830:13-831:2 ("[T]hose three changes together were fatal to the validity on the basis that they were useless of many Canadian patents that are, in fact, useful, and those changes were surprising, dramatic and unforeseen by practitioners and, in my view, unknown to the court until they were proclaimed.").

[74] *See, e.g.*, Cl. Closing Slide 44 (showing table of contents from *AstrazenecaCanada Inc. v. ApotexInc.*, 2014 FC 638, at 2-3 (C-48)).

[75] *See* Resp. Opening Statement, Tr. at 183:15-20 (conceding that the promise element sets the standard for utility and that the other two aspects relate "to how that threshold is implemented").

[76] Resp. Closing Statement, Tr. at 2245:9-17.

[77] *Id*. at 2246:5-7.

[78] From the beginning, Lilly made clear that the Zyprexa invalidation did not involve Canada's new disclosure rule for sound prediction. *See, e.g.*, Cl. Mem. at ¶ 111 (quoting Professor Siebrasse's conclusion that the Zyprexa invalidation reflected "the exclusion of post-filing evidence and the heightened utility requirement established by the promise of the patent," with no reference to the disclosure rule for sound prediction).

each case. With respect to the Zyprexa patent, for example, all pre-filing evidence relied on by Lilly was in the patent application itself, such that the third element — the additional disclosure rule for sound prediction — was not relevant. The Zyprexa patent was nonetheless invalidated based on the court's construction of an additional, elevated promise of utility, combined with the bar on post-filing evidence to show that this heightened standard had been met.

77. The reason Canada has sought to present the doctrine as a series of independent rules is to facilitate its search for isolated, purported antecedents in prior law. But this is not how the promise utility doctrine operates in practice. Testimony confirmed that the three elements of this new, additional utility requirement interact with one another, such that their combined effects are dramatic — especially in the pharmaceutical sector.[79] As Mr. Reddon noted, the result is clear "in the statistics about the dramatic emergence of revocation of factually useful patents in Canada upon judicial findings that they're not useful."[80] Professor Siebrasse explained the dynamic through which the different elements of the doctrine have combined to produce such dramatic changes in pharmaceutical patent litigation:

> [I]f we have . . . a requirement to establish clinical efficacy in the longer term, you really need longer term clinical trials to establish this, but those very trials that are needed to establish the higher elevated standard are excluded by this rule against after-the-fact evidence. This means utility of [a] commercially successful product cannot always be demonstrated.
>
> This means that the ability to establish utility based on sound prediction is much more important, even for commercially successful pharmaceuticals. It was never used previously for commercially successful pharmaceuticals because utility would be demonstrated. That sound prediction is now important but we now have this more onerous evidentiary standard for

[79] Testimony of Andrew Reddon, Tr. at 828:22-829:17 ("The combined effect of those two changes [promise and no post-filing evidence] has been dramatic. Courts now find or imply promises from disclosures instead of claims. Those promises are held up as the 'promised utility' of the patent, instead of the claimed invention. . . . Then AZT is applied to require that the promised utility has to be proven or soundly predicted at the filing date . . . . All of that was difficult but step 3 came along in Raloxifene.").

[80] *Id*. at 829:6-9.

> sound prediction, excluding potentially probative pre-filing tests that are not in the patent itself.
>
> In the patents at issue, post-filing evidence, in particular commercial success/regulatory approval, would have established validity under old law but the elevated standard to which they were held could not be proven at the time of filing.[81]

78. In sum, the different aspects of the promise utility doctrine — the elevated "promise" and restrictions on the range of evidence that patentees can rely upon to deonstrate or soundly predict that the elevated promise has been met — work together as a unitary utility requirement, making it far more difficult for innovators to show the utility of patents on products that are, in fact, useful in the commercial sphere.

2. No Element of the Promise Utility Doctrine Existed When Lilly Applied for and Was Granted Its Patents for Zyprexa and Strattera.

79. Canada and its witnesses at the Hearing did not dispute that Canadian courts today derive promises of utility from the disclosure of the patent, disregard post-filing evidence of utility, and require that evidence of sound prediction of utility be disclosed in the patent. Moreover, Canada conceded that its utility requirement as applied by the courts has changed over time.[82]

80. The issue before the Tribunal is thus whether the emergence of the promise utility doctrine constituted a "sea change" in Canadian patent law compared to the traditional "mere scintilla" test.[83] In the face of overwhelming testimony of such a sea change, Canada continued to insist at the Hearing that all three aspects of the promise utility doctrine have "deep roots" in Canadian law.[84]

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[81] Testimony of Norman Siebrasse, Tr. at 523:16-525:5.

[82] Resp. Opening Statement, Tr. at 184:16-18 ("To be clear, Canada's position is not that there has been absolutely no change or evolution in Canadian law.")

[83] *Id*. at 184:20 ("[T]he notion that there has been a sea change in Canadian law is baseless."); Testimony of Norman Siebrasse, Tr. at 525:6-11 ("[M]y conclusion is that there has been a sea change in the Canadian law of utility . . . .").

[84] Resp. Closing Statement, Tr. at 2244:22-25, 2276:2-6.

81. In fact, not one of the core elements of the promise utility doctrine was ever applied to invalidate a patent for lack of utility until *after* the *AZT* ruling in 2002. Moreover, no witness for either Lilly or Canada suggested that elements of the promise utility doctrine were ever applied *in combination* to invalidate a patent before 2005, as has occurred repeatedly since 2005. Indeed, Canada's own witness, Mr. Dimock, expressly conceded that there was no case before 2005 in which a patent was invalidated for failure to demonstrate or soundly predict a "promise" of utility construed from the disclosure based on evidence available at filing.[85]

82. Unable to avoid this simple fact, Canada at Closing relied on the following evidence in an attempt to show that the promise utility doctrine predated 2005: the arguments of litigants (without any showing they were adopted by the courts);[86] unrelated *obiter* language;[87] and what it described as an "implied" holding.[88] Canada even resorted to speculation about universal compliance with an unacknowledged rule, suggesting that the absence of decisions applying the promise utility doctrine reflected the fact that "[w]hen a rule is being complied with, there won't be court decisions finding violations of that rule."[89] Canada's reliance on strained assertions of this sort would hardly be necessary if the promise utility doctrine had "deep roots." Canada's

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[85] Testimony of Ronald Dimock, Tr. at 1065:12-1066:5 ("So the question I posed to you was, prior to 2005, how many patents were invalidated for lack of utility for failure to soundly predict or demonstrate a promise construed from the disclosure of the patent, and you've given me three cases, New Process Screw, Consolboard and Amfac, and in none of those cases, Mr. Dimock, was there an analysis of a demonstration or sound prediction, correct? MR. DIMOCK: In none of those three cases was there an issue of sound prediction, that's right. MR. DEARDEN: And was there an issue that the demonstration had to be as of the date of filing in those three cases? MR. DIMOCK: Not that I recall in the Amfac case, and not what I could discern from reading the reasons for judgment in either New Process, nor Consolboard trial division. And, based on also my recollection, having worked on Consolboard.").

[86] Resp. Closing Statement, Tr. at 2260:6-8 ("Counsel advanced the argument based on promises in the disclosure . . . .")

[87] *Id*. at 2260:10-12 ("[L]anguage in the court decisions makes very clear that the court would have considered a promise in the disclosure sufficient to invalidate the patent . . . .").

[88] *Id*. at 2272:18-23 ("Monsanto does not expressly state that you cannot use evidence beyond what is in the patent and the common general knowledge, but that does not mean that the rule wasn't there. As Mr. Dimock testified, this was the implied holding of the case given its facts.").

[89] *Id*. at 2274:9-11.

various attempts at the Hearing to identify in the case law any precursor for the promise utility doctrine as it exists today were all in vain.

83. While the promise utility doctrine is a unitary utility test, even if one disaggregates the doctrine as Canada suggests, there is no antecedent in Canadian law for the various elements of the doctrine, as explained below.

a) Finding Elevated "Promises" Beyond the Claimed Invention's Use Is New.

84. Traditionally in Canada, a "mere scintilla" of utility sufficed; "very little" would do.[90] But since 2005, as Lilly's witnesses explained, the Canadian courts have identified or inferred additional promises of utility from the disclosure that go beyond the utility of the claimed invention, imposing an elevated requirement for utility.[91] Canada's own expert witness, Mr. Dimock, admitted that the now routine practice in pharmaceutical cases of finding elevated "promises" in the disclosure part of the patent arose around 2005, once the argument was successfully advanced in litigation.[92]

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[90] Testimony of Norman Siebrasse, Tr. at 516:4-10 ("At the time the standard for utility was very low. It was normal to say 'a slight amount' or 'very little will do.' Since 2005 it's become normal for the courts to say a 'mere scintilla' of utility is required. No one has ever suggested this is any different; it all reflects the same standard.").

[91] *Id*. at 520:10-15 ("So this promise of the patent, promise doctrine, I call it here, or promise of the patent, may result, as the courts have said, in an elevated standard for utility that's an exception to the Act. So it represents a standard above the scintilla that would otherwise be required."); Testimony of Andrew Reddon, Tr. at 827:9-16 ("Courts now derive, and sometimes using considerable lengths and expert evidence imply, promises into the disclosure of patents, . . . but it's now done without reference to the utility of the claimed invention.").

[92] Mr. Dimock acknowledged it was only after some successful promise cases "as of 2005" that other counsel begin to routinely "run that same argument" in their cases. Testimony of Ronald Dimock, Tr. at 1060:21-1062:25. Mr. Dimock himself, however, has no experience with the doctrine in pharmaceutical patent litigation. Although asked by Canada to opine on the promise utility doctrine as applied by the courts, Mr. Dimock admitted that, since 2005, he has not litigated a single pharmaceutical patent case involving the sound prediction of utility or whether a promise derived from the disclosure was demonstrated as of the filing date. *Id*. at 1173:13-25 ("[F]rom 2005 to date, have you done any pharmaceutical patent litigation that involved the issue of sound prediction of utility? MR. DIMOCK: No. MR. DEARDEN: And from, again, 2005 to now, how many pharmaceutical patent cases have you litigated that involve the issue of whether the promise of utility derived from the disclosure was demonstrated or soundly predicted at the date of filing? MR. DIMOCK: None."). Mr. Reddon, by (continued…)

85. Canada argued that it had identified "an abundance of authority" for the bifurcated utility requirement that Canadian courts apply today — under which (i) a "mere scintilla" of utility is enough, unless (ii) a patent is found to have made promises of utility, in which case every promise must be demonstrated or soundly predicted.[93] But as Lilly's witnesses explained, the cases and commentaries on which Canada purports to rely do not support its assertion that it is a longstanding principle of Canadian law that statements derived from the patent disclosure are construed as elevated promises of utility.

(1) *Consolboard* Was Not Cited as Establishing a Bifurcated Test until 2005.

86. Canada has relied heavily on a line from *Consolboard* describing the traditional low bar for utility in Canada, under which "not useful" means "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 that it will do."[94] But the simple fact that *Consolboard* quoted a passage using the word "promise" does not mean that it embodied today's promise doctrine or represented a bifurcated requirement.[95] *Consolboard* neither established nor reflected today's practice of finding elevated "promises" of utility in the disclosure, beyond the utility of the claimed invention. As Professor Siebrasse explained at the Hearing, the *Consolboard* passage, understood in context, merely

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contrast, has litigated a wide range of pharmaceutical patent cases involving the issue of utility since 2005. *See* Reddon Report at ¶¶ 1, 13.

[93] Resp. Closing Statement, Tr. at 2259:23-24.

[94] Resp. Opening Statement, Tr. at 186:21-187:8; Resp. Closing Statement, Tr. at 2294:14-2295:8, 2308:2-10; *see Consolboard Inc. v MacMillan Bloedel (Sask) Ltd.*, (1981) 1 SCR 504, 525 (C-118).

[95] Remarkably, Canada argued at closing that Professor Siebrasse had acknowledged that the *Consolboard* standard is bifurcated. *See* Resp. Closing Statement, Tr. at 2251:11-14 (asserting that Prof. Siebrasse "in his testimony recognized . . . that the standard from Halsbury's approved in Consolboard has two parts"); Resp. Closing Slides at 98 (quoting Testimony of Norman Siebrasse, Tr. at 587, stating "I agree the word 'or' appears in the sentence, yes"). In reality, however, Professor Siebrasse consistently and expressly rejected that view. *See* Testimony of Norman Siebrasse, Tr. at 588:2-8 ("[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."); *id*. at 597:8-10 ("I did not agree that the language is bifurcated. I agreed that there is an 'or' in the sentence. I could happily elaborate."); *id*. at 598:22-599:4 (explaining why *Consolboard* "does not represent a bifurcated standard").

rejected comparative utility in favor of simple operability, the traditional low bar for utility in Canada:

> [T]hat's not a bifurcated standard. It's a lower standard. It's not saying that you have to meet any purpose; it's saying it's enough that it works. . . . So that's why that sentence, particularly in the context of Consolboard as a whole, does not represent a bifurcated standard. It represents a rejection of comparative utility in favor of operability.[96]

87. This reading of *Consolboard* is consistent with how the Canadian courts themselves previously understood that case. Professor Siebrasse emphasized that before 2005, the Canadian courts never cited or relied upon *Consolboard* as supporting a bifurcated or elevated test for utility.[97] Rather, the very same language on which Canada purports to rely was presented by the courts as merely requiring that the claimed invention work for its intended purpose.

88. In its Closing, Canada argued that "courts prior to 2005, in cases like Feherguard, Almecon and Goldfarb affirmed this two-part Consolboard standard."[98] But none of these references identifies the *Consolboard* language as setting a high bar or presenting a bifurcated standard. To the contrary, as Professor Siebrasse emphasized during cross-examination, these cases reveal that *Consolboard* was understood to present a unitary test focused on basic operability:

> If you look at Paragraph 47 [of *Almecon*], they quote this passage, and then they say counsel . . . urged it simply "did not work." 48. "It was a commercial success." "On the evidence before me 'it worked'." A, taking commercial success, post-filing evidence is proof of utility and, B, citing that very passage as simply standing for a unitary operability standard.

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[96] *See id*. at 598:22-599:6; *id*. at 724:5-728:21 (explaining that the U.K. false promise doctrine referenced in the Halsbury's excerpt in *Consolboard* is distinct from the promise utility doctrine and was never incorporated into Canadian law).

[97] *Id*. at 522:8-15, 526:3-527:7. While *Consolboard* is cited today for its promise language, Professor Siebrasse noted that the Canadian courts have not analyzed or considered in any detail whether this reading of the case is appropriate. *Id*. at 546:23-548:18.

[98] Resp. Closing Statement, Tr. at 2252:1-3.

> Feherguard is to the same effect. Goldfarb is to the same effect. I mean yes, they say these words [*i.e.*, promise of the patent], but these cases show that, prior to 2005, the courts did not interpret these words as adopting a bifurcated standard. It worked.[99]

89. It is common ground that under Canada's traditional test, the invention *as claimed* must work and be operable, such that specific assertions of utility in the claims (which is part of the specification) must be fulfilled.[100] That basic principle is hardly controversial, in Canada or elsewhere.[101] Indeed, as Mr. Reddon emphasized, Canadian courts previously rejected arguments in the *Mobil Oil* case that a "promise" of utility could be derived from the disclosure if not expressly stated in the claims.[102]

90. During its Closing, Canada contended that Mr. Reddon "recognize[d] the bifurcated nature of the Consolboard standard."[103] To the contrary, Mr. Reddon did not indicate that the *Consolboard* language was traditionally understood, before 2005, to present a bifurcated requirement. Rather, Mr. Reddon simply acknowledged that the language in *Consolboard* was susceptible to being utilized as a *post hoc* rationalization of

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[99] Testimony of Norman Siebrasse, Tr. at 591:20-592:7. During its Closing Statement, Canada also pointed to its 2001 and 2003 submissions to WIPO, which quote the same phrases from *Consolboard*. Resp. Closing Statement, Tr. at 2252:5-11. But like the three cases, the WIPO submissions in no way indicate that Canada has a bifurcated or elevated test.

[100] *See* Testimony of Andrew Reddon, Tr. at 826:2-25, 910:5-11:21; Testimony of Ronald Dimock, Tr. at 1079:1-1082:1; Resp. Closing Statement, Tr. at 2259:3-20. Canada argued in its Closing that Professor Siebrasse and Mr. Reddon disagreed on how to read the *Consolboard* language, with Professor Siebrasse saying that the invention must work for its intended purpose, and with Mr. Reddon saying that a promise of utility in the claims must be met. Resp. Closing Statement, Tr. at 2252:12-2254:1. In fact, however, their substantive views of the traditional utility standard are consistent: both Prof. Siebrasse and Mr. Reddon made clear that the invention as claimed must work, *and* that it must be operable for its basic or intended purpose. *See, e.g.*, Testimony of Norman Siebrasse, Tr. at 526:18-527:5 (claimed invention must work); *id*. at 734:25-735:1 ("It was enough that invention worked for the identified purposes."); Testimony of Andrew Reddon, Tr. at 824:16-18 ("[T]he practice was to decide what is the claimed invention . . . . and does it have utility."); *id*. at 878:6-8 ("[T]hat which you invented . . . has to work.").

[101] Testimony of Timothy Holbrook, Tr. at 1476:4-14; Cl. Closing Slides at 54 (WIPO Guidelines).

[102] Testimony of Andrew Reddon, Tr. at 837:7-839:1 (discussing *Mobil Oil*); *see* Testimony of Ronald Dimock, Tr. at 1189:5-1190:18 (acknowledging that the court in *Mobil Oil* assessed utility based on language in the claims and rejected argument that a promise of utility was made in the disclosure).

[103] Resp. Closing Statement, Tr. at 2252:24-25.

the promise utility doctrine, as in fact occurred after 2005.[104] Acknowledgement of that possibility is by no means an admission that the utility test was in fact previously bifurcated.

91. As witness testimony at the Hearing and the case law confirm, the *Consolboard* language did not establish an elevated, bifurcated utility test in 1981 — and was never cited for that purpose until 2005, *almost 25 years later*. The distinctly new reading of *Consolboard* seen in cases since 2005 did not dust off an old concept that had fallen out of favor. There was no bifurcated utility test lying dormant in prior law. The practice of identifying elevated "promises" of utility in the disclosure came into being only once the Canadian courts entirely re-purposed a non-controversial statement from *Consolboard* that previously stood for the straightforward proposition that an invention must work.

(2) Other Pre-2005 Cases and Commentaries Do Not Include Decisions Applying a Bifurcated Test.

92. At the Hearing, Canada's witness, Mr. Dimock, put forward a "Selected History" listing specific cases and commentaries from 1944 to 2001 that, in his view, indicate the promise element has long been part of Canadian law.[105] However, not one of the cases listed by Mr. Dimock, nor any case cited in the listed commentaries, construes an elevated promise of utility from statements found in or inferred from the patent disclosure.

93. Mr. Dimock identified only three cases before 2005 that, in his view, invalidated a patent for failure to soundly predict or demonstrate an elevated "promise" of utility.[106] His reading of these three cases, however, is not credible:

- In two cases, the *Consolboard* trial decision[107] and *New Process Screw*,[108] the purported "promise" of utility was specifically stated in the patent's claims and did not

[104] Testimony of Andrew Reddon, Tr. at 910:2-18.

[105] *See* Dimock Slide Presentation at 15 ("Promise of Utility: Selected History of Case Law and Legal Commentary"); *see also* Cl. Closing Slides at 56 (reproducing the Dimock timeline).

[106] Testimony of Ronald Dimock, Tr. at 1063:3-12, 1065:12-1066:5.

constitute an additional "promise" derived from the disclosure above and beyond the basic utility of the claimed invention.[109]

- In the third case, *Amfac*,[110] Mr. Dimock conceded that the invention worked and thus did not lack utility. A single claim fell on the distinct ground of overbreadth.[111]

Moreover, even with respect to these three cases, Mr. Dimock conceded that the issue of whether utility was demonstrated or predicted based only on pre-filing evidence was not at issue.[112]

94. Several cases listed by Mr. Dimock, like the *Consolboard* trial decision and *New Process Screw*, simply held that the invention, as claimed, was inoperable. Those cases include the following:

- In *Wandscheer*,[113] the invention — a snow blower — would not blow snow.[114]
- In *Hoechst*,[115] the patent was held invalid because the claim included wholly inoperable species.[116]

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[107] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* (1978), 39 CPR (2d) 191 (R-359).

[108] *New Process Screw Corp. v. PL Robertson Mfg Co. Ltd.*, (1961), 39 CPR 31 (Ex Ct) (R-162).

[109] Testimony of Ronald Dimock, Tr. at 1080:21-1082:2 (admitting that the requirement of uniformity in the patent at issue in the *Consolboard* trial decision was specifically set out in the claims); Testimony of Norman Siebrasse, Tr. at 530:11-23 (*Consolboard* trial decision); *id*. at 556:13-561:9 (*New Process Screw*); *see* Cl. Closing Slides at Slide 58.

[110] *Amfac Foods Inc. v. Irving Pulp & Paper, Ltd.*, (1986), 12 CPR (3d) 193 (FCA) (R-168).

[111] Testimony of Donald Dimock, Tr. at 1064:17-19 ("MR. DEARDEN: And the decision was an overbreadth decision? MR. DIMOCK: That's correct."); *id*. at 1064:24-25 (MR. DEARDEN: "It worked? MR. DIMOCK: It worked."); *see* Cl. Closing Slides at 59.

[112] Testimony of Ronald Dimock, Tr. at 1065:12-1066:5 (conceding that the three pre-2005 invalidations he identified did not analyze sound prediction or require that demonstration of utility must be as of the filing date).

[113] *Wandscheer et al. v. Sicard Ltd.* (1948) SCR 1 (C-42).

[114] Testimony of Norman Siebrasse, Tr. at 529:21-530:10, 662:4-21; *see* Cl. Closing Presentation, Slide 58.

[115] *Hoechst Pharmaceuticals of Canada Limited et al. v. Gilbert & Company et al.*, (1964), Fox Pat C 28 (Ex Ct) (R-195).

[116] Testimony of Norman Siebrasse, Tr. at 721:22-722-5 ("Hoechst v Gilbert was a case of inoperable species, so the patentee had claimed a large genus, some of the species in that genus were wholly inoperable, and for that reason the patent was held invalid, but that was not a case in which the patent (continued…)

- In *Feherguard*,[117] the claimed invention — a telescoping roller for retracting swimming pool covers — did not work, and the patent was held invalid, because the patent did not specify the nuts and bolts required to make it operable.[118]

- In *TRW*,[119] the claimed invention was inoperable to produce compressor blades, so the patent was held invalid.[120]

95. As Professor Siebrasse explained at the Hearing, a number of cases listed by Mr. Dimock held that the invention had utility because it worked — which is all that the traditional utility test in Canada required:

- In *Metalliflex*,[121] the "promise" language referred to the intended purpose of the invention, an expandable watch band. The patent was held valid even though the claim did not specify how the parts were to be held together because the disclosure made that clear.[122]

- In *Corning Glass*,[123] the patent for a waveguide, or fiber optic cable, with specified levels of impurities was held to be valid because it was useful for some purposes,

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was held to a higher standard of utility, because the inoperable species were wholly inoperable. They had no utility at all. So that patent failed on a scintilla standard.").

[117] *Feherguard Products Ltd. v. Rocky's of B.C. Leisure Ltd.* (1994), 53 PCR (3d) 417 (FCTD) (R-360).

[118] Testimony of Norman Siebrasse, Tr. at 526:10-527:7, 589:20-592:19; *see* Cl. Closing Slides at 58. As Professor Siebrasse explained, the statement by the Federal Court of Appeal that "[t]he patent as a whole, and not only the claims, must be considered when assessing the utility of an invention," simply indicated that a claim will not be held to lack utility if the disclosure provides the information needed to make the invention work, as in *Metalliflex* (*see infra* ¶ 95 & nn.121-122). The statement had nothing to do with deriving elevated promises of utility from the disclosure of the patent. *See* Testimony of Norman Siebrasse, Tr. at 731:3-732:22.

[119] *TRW Inc. v. Walbar of Canada Inc.*(1991), 39 CPR (3d) 176 (FCA) (R-376).

[120] Testimony of Norman Siebrasse, Tr. at 528:12-19 ("The only other case is TRW, and in that case it was a patent for claim to a product article, and the product article included compressor blades and turbine blades, and the claimed method worked to produce turbine blades but was inoperable and useless, I believe were the words the court used, to produce compressor blades.").

[121] *Rodi & Wienenberger Aktiengesellschaft v. Metalliflex Ltd*. (1959), 32 CPR 102 (Que CA) (R-8).

[122] Testimony of Norman Siebrasse, Tr. at 731:22-732:2 ("Metalliflex, where the invention was an expandable watch band, and the claim had not specified that the little pieces had to be held together. The Supreme Court of Canada said well, you can look to the disclosure to understand the obvious, that it has to be held together."); *see* Cl. Closing Presentation at 59.

[123] *Corning Glass Works v. Canada Wire & Cable Ltd.* (1984), 81 CPR (2d) 39 (FCTD) (R-375).

even though there was evidence that it might not be commercially viable for long-distance transmission.[124]

- In *Wellcome Foundation*,[125] a claimed process to make pharmaceutical intermediates was held valid. The court looked to the disclosure to identify the intended use of the end products, but did not hold the patentee to — or even consider — statements in the disclosure about the level of utility possessed by the end products.[126]

- In *Almecon*,[127] the court quoted the "promise" language from *Consolboard*, then held that the patent was valid and the invention useful because "it worked."[128]

- In *Goldfarb*,[129] the court quoted the *Consolboard* language and held the invention to be useful, characterizing the test as follows: "As I see it the test of utility or usefulness reflects the notion that what is patented will work."[130]

96. Utility challenges in two cases were rejected because the disputed assertion of utility was found in the disclosure, not in the claims, and the court refused to hold the patentee to statements found in the disclosure:

- In *Mobil Oil*,[131] the court rejected the argument that utility should be assessed by reference to statements made in the disclosure, and instead — as Mr. Dimock conceded — assessed utility solely by reference to statements in the claims.[132]

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[124] Testimony of Norman Siebrasse, Tr. at 570:22-573:9, 730:3-731:2; *see* Cl. Closing Presentation, Slide 57.

[125] *Wellcome Foundation Ltd. v. Apotex Inc.*, [1995] FCJ No 226, 60 CPR (3d) 135 (FCA) (R-401).

[126] Testimony of Norman Siebrasse, Tr. at 569-70; *see also* Cl. Closing Presentation, Slide 57.

[127] *Almecon Industries Ltd. v. Anchortek Ltd.* (2001), 17 CPR(4th) 74 (FCTD) (C-230).

[128] Testimony of Norman Siebrasse, Tr. at 591:15-592:7 ("If you look at Paragraph 47, they quote this passage, and then they say counsel for the invention urged it simply 'did not work.' 48. 'It was a commercial success.' 'On the evidence before me 'it worked.'"); *see id*. at 526:10-527:7; Cl. Closing Slides at 57.

[129] *Goldfarb v. W.L. Gore & Associates Inc.* (2001), 11 CPR (4th) 129 (R-187).

[130] Testimony of Norman Siebrasse, Tr. at 602:23-603:2 ("I'm looking at Goldfarb right now . . . where the court quotes that passage and immediately it says 'As I see it the test of utility or usefulness reflects the notion that what is patented will work.'"); *see* Cl. Closing Slides at 57.

[131] *Mobil Oil Corp v Hercules Canada Inc.*, (1994), 57 CPR (3d) 488 (FC) (C-347).

[132] Testimony of Andrew Reddon, Tr. at 836:23-838:20 ("In Mobil Oil there was an allegation that the patent lacked utility because it promised an adhesion between two layers of film of 250 grams per square meter. Not only did the defendant's product not have the 250 but they were able to show that the plaintiff's product within the claims of the patent didn't deliver the 250 which the defendant said was the (continued…)

- In *Unilever v. Proctor & Gamble*,[133] the court rejected a challenge to a patent on grounds of failure to meet a "promise" of reduced staining because the alleged promise was from the disclosure, not the claims.[134]

97. As for the two remaining cases on Mr. Dimock's list, one did not involve a utility determination at all: the *Consolboard* Supreme Court decision[135] held simply that an invention's utility need not be stated or disclosed in the patent.[136] Another, *American Cyanamid*,[137] was an English ruling applying that country's subsequently abandoned "false promise" doctrine, which is entirely distinct from the promise utility doctrine.[138]

98. Presumably since no case decided prior to 2005 held a patentee to an elevated utility requirement based on statements in the disclosure, Mr. Dimock also

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promise. . . . And the court rejected it because, the court said, it's not in the claims."); Testimony of Ronald Dimock, Tr. at 1190:9-18 ("MR. DIMOCK: They were suggesting that not only was there a promise of enhanced adhesion but a promise of enhanced adhesion at a particular level. MR. BORN: Right, and that particular level promise came from the disclosure, not the claims. MR. DIMOCK: That's correct. MR. BORN: And the court said we don't find that promise. MR. DIMOCK: That's correct."); Testimony of Norman Siebrasse, Tr. at 576:25-577:2 (noting that in set of cases including *Mobil Oil*, "[n]one of them actually applied an elevated standard"); *see* Cl. Closing Slides at 61.

[133] *Unilever PLC. v. Procter & Gamble Inc.*, (1995), 61 CPR (3d) 499 (FCA) (R-172).

[134] Testimony of Andrew Reddon, Tr. at 839:2-21 ("And a similar result in Proctor & Gamble in a case in which Mr. Dimock was counsel. In Proctor & Gamble the claims said 'a distributing agent' for putting sheets in a dryer to soften fabrics. In the specification it said 'reduces staining of the clothes.' Mr. Dimock argued, and there was evidence that again embodiments within the claims didn't reduce staining, so Mr. Dimock argued that look, the promise of the patent is reduction of staining, it's right there in the description, there's proof that embodiments don't reduce staining; therefore, the patent fails to deliver on the promise and it's invalid. Rejected. Rejected, because it wasn't in the claims. The court construed the claims and said the function of the SMS is as a distributing agent. There's no promise, even though it was in the specification, to reduce staining. So the challenge to the validity of the patent on the basis of breach of the promise was rejected because it wasn't in the claims."); *see also* Cl. Closing Slides at 61.

[135] *See Consolboard Inc. v MacMillan Bloedel (Sask) Ltd.*, (1981) 1 SCR 504 (C-118).

[136] Testimony of Norman Siebrasse, Tr. at 609:4-5 ("That was the issue in Consolboard. Do you have to explain why your invention works."); *see* Cl. Closing Slides at 57.

[137] *American Cyanamid Company v. Ethicon Limited*, [1979] RPC 215 (R-173).

[138] Cl. Closing Slides at 60 ("United Kingdom decision that applied the UK Patent Act 1949 and the old English false promise doctrine codified therein."); *see* Testimony of Norman Siebrasse, Tr. at 725:14-728:21 (distinguishing England's former false promise doctrine from Canada's promise utility doctrine). The analogue to the U.K. false promise doctrine in Canada is Section 53 of the Patent Act, which requires, *inter alia*, that the representation in fact be false at the time of challenge. *See* Cl. Reply at ¶ 88.

listed a handful of commentators on Canadian law: Gordon Henderson, Harold Fox, Donald MacOdrum, William Hayhurst, and Donald Hill. [139] Yet, as Lilly explained at Closing, these commentators primarily discussed the very same cases separately listed by Mr. Dimock.[140] As the survey of cases above demonstrates and as Professor Siebrasse explained, none of these commentators cited a single Canadian case in which the court found an additional or elevated "promise" beyond the utility of the invention as claimed.[141] None of these commentors provide support to Canada's argument that the promise utility doctrine existed in Canadian law prior to 2005.

- The case note written by Gordon Henderson pertained to the *New Process Screw* decision, in which the court held that there was a "failure to meet the promise of the patent" because the invention failed to produce double-threaded screws, which were specifically claimed.[142] The claimed invention was inoperable.

- The commentary by Harold Fox cited only U.K. cases in the section entitled "Promised Results," and, as noted by Professor Siebrasse, the question was whether the "promised results" were "true in fact."[143] Fox noted that, under this old English "false promise" case law, it was enough that the promises were true in fact and that commercial success could be evidence of utility.[144]

- In the section relating to "promised utility," the text by Donald MacOdrum cites three Canadian cases (*New Process Screw*, *TRW*, and *Feherguard*) in which the claimed invention was inoperable.[145]

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[139] *See* Dimock Slide Presentation at 15 ("Promise of Utility: Selected History of Case Law and Legal Commentary") (listing commentator publications).

[140] Cl. Closing Statement, Tr. at 2047:23-2048:1; Cl. Closing Slides at 62.

[141] Cl. Closing Slides at 62; Testimony of Norman Siebrasse, Tr. at 584:4-18 (discussing Fox); *id*. at 720:15-723:6 (discussing Hayhurst); Testimony of Norman Siebrasse, Tr. at 527:16-528:22 (discussing MacOdrum); Siebrasse Second Report at ¶ 40 (discussing that Fox, Henderson, and Hill only cited old English "false promise" cases that did not form part of Canadian law).

[142] Testimony of Norman Siebrasse, Tr. at 557:6-558:2; *see New Process Screw Corp. v. PL Robertson Mfg Co. Ltd.*, (1961) 39 CPR 31 (Ex Ct) (R-162).

[143] Testimony of Norman Siebrasse, Tr. at 717:7-21.

[144] *Id*. at 716:15-720:14; *see* Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969) (R-163).

[145] Testimony of Norman Siebrasse, Tr. at 527:16-528:22; *see* Donald H. MacOdrum, *Patent Law in Canada: Cases and Materials* (Lang Michener LLP, 1995) (R-361).

- The William Hayhurst article cited only one Canadian case, *Hoechst*, a case in which the patent was held invalid because the claims included species that were wholly inoperable.[146]

- The article by Donald Hill, entitled "Claim Inutility," also cited only to Canadian inoperability cases, *Metalliflex* and *Minerals Separation*, and focused on the claimed utility as opposed to the disclosure.[147]

99. Given the absence of any prior case law, Mr. Dimock tried to explain the new practice of deriving "promises" of utility from the disclosure by suggesting, in his Second Report, that patentees make "promises" today in order to meet other patentability requirements.[148] But that theory is not borne out in fact. As Mr. Reddon explained, Lilly's Zyprexa and Strattera patents had no such aim: the "promises" found in Lilly's patents were entirely irrelevant to other patentability requirements.[149]

100. In sum, Canada and its witnesses provided no support at the Hearing for their claim that Canadian courts have long required patentees to meet elevated promises of utility based on statements found in or inferred from the patent disclosure. Indeed, the record is so bare that at Closing, when asked about the historical basis for finding promises of utility in the disclosure, Canada was left merely to invoke the ambiguous language from *Consolboard* and to contend that courts had on occasion entertained arguments from counsel about promises of utility, even if they had not in fact found or held patentees to any such promises.[150]

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[146] Testimony of Norman Siebrasse, Tr. at 721:3-723:6; *see* W.L. Hayhurst, "Disclosure Drafting" (1971), 28 PTIC Bull (7th) 64 (R-164).

[147] Siebrasse Second Report, at ¶¶ 28, 40; *see Rodi & Wienenberger Aktiengesellschaft v. Metalliflex Ltd.* (1959), 32 CPR 102 (Que CA) (R-8) (holding the patent valid even though the claim did not specify how the parts of a watchband were to be held together on the basis that it was permissible to look to the disclosure to learn that how the parts should be held together); *see also* Donald Hill, "Claim Inutility" (1960), 35 CPR 185, at 190 (R-160).

[148] *See* Dimock Second Report, at ¶¶ 12-25.

[149] Testimony of Andrew Reddon, Tr. at 832:23-834:6 ("The promises for which these patents were invalidated did not advance Lilly's patent position, did not establish patentability of either of the inventions.").

[150] Resp. Closing Statement, Tr. at 2260:1-12 ("I would say that the sources of that authority are the Supreme Court of Canada's articulation of the meaning of not useful in Canadian patent law in 1981, as (continued…)

b) Declining to Consider Post-Filing Evidence of Utility Is New.

101. The record presented at the Hearing is unambiguous: in Canada, prior to 2002, the Canadian courts routinely relied upon post-filing evidence in resolving utility challenges. As Professor Siebrasse explained:

> Post-filing evidence was always admissible to establish utility, and in particular two kinds of post-filing evidence were commonly used. One is commercial success so the fact that the product was sold in the marketplace was considered evidence of utility. And also use by the defendant. If the defendant was actually infringing, this would be considered also proof that the invention was useful on the view the infringer would not infringe something useless, or couldn't really infringe something useless.
>
> The rationale for this under prior law was that proof today that the invention works is proof that it would have worked yesterday.[151]

Mr. Reddon confirmed that "[a]s a practical matter the commercial success of the invention was often relied upon to establish that it had a mere scintilla of utility, and, frankly, the defendant's desire to copy the invention effectively established that it was something useful and worthy of being copied."[152]

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well as the many court decisions in which the courts — first of all, Counsel advanced the argument based on promises in the disclosure, courts entertained those arguments based on promises in the disclosure. Court decisions such as New Process Screw or Corning Glass Works, where language in the court decision makes very clear that the court would have considered a promise in the disclosure sufficient to invalidate the patent . . . . ").

[151] Testimony of Norman Siebrasse, Tr. at 516:11-24.

[152] Testimony of Andrew Reddon, Tr. at 822:4-10; *see id*. at 822:3-4 ("The prior practice is clear. Post-filing evidence was commonly used to establish usefulness."). This is clear not only from the case law, but also from commentaries — including the Fox treatise on which Canada otherwise sought to rely at the Hearing. Testimony of Norman Siebrasse, Tr. 716:23-719:11 (discussing inconsistencies between the Fox treatise and the *AZT* rule barring post-filing evidence); Testimony of Andrew Reddon, Tr. at 822:10-11 ("The Fox article . . . explicitly says so. These two pieces of evidence [commercial success and the defendant's desire to copy the invention] are admissible to establish utility before the law changed in Canada.").

102. Canada's witness, Mr. Dimock, agreed that post-filing evidence was commonly used to establish operability.[153] Moreover, Mr. Dimock further conceded that in prior case law, such as the *Ciba-Geigy* and *AZT* rulings of the Federal Court of Appeal, post-filing evidence was accepted to establish a sound prediction of utility as of the date of filing. Mr. Dimock did not dispute that the court in *Ciba-Geigy* relied upon post-filing evidence to confirm the invention's utility; he could only disagree with the court's reasoning.[154] Similarly, with regard to the ruling of the Federal Court of Appeal in *AZT* that was later reversed by the Supreme Court, Mr. Dimock agreed that the appeals court confirmed that post-filing evidence could be relied upon to establish utility at the filing date.[155] Again, Mr. Dimock was left simply to express his disagreement with the court's reasoning.[156]

103. Indeed, because the law on post-filing evidence changed so dramatically, the generic drug manufacturer Apotex submitted to the Federal Court that it should be entitled to amend its pleadings post-2002 in order to allege that an innovative drug manufacturer had failed to soundly predict the utility of a drug *as of the date of filing*. Specifically, Apotex argued that the 2002 *AZT* decision had changed the law by barring post-filing evidence.[157]

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[153] Testimony of Ronald Dimock, Tr. at 1042:17-21 ("Post-filing evidence cited by the Claimant's experts deals with operability, and yes, evidence is adduced about commercial success of an invention. That's to show that it does work or doesn't work.").

[154] *Id*. at 1148:4-12 ("Then they deal with the fact that five new examples, as you see at the bottom, were provided by the applicants of post-filing evidence, not in the patent itself, that illustrated that they worked and that was accepted. The Board got overturned, correct? MR. DIMOCK: That's what it says, that's right. It's the logic of it, Mr. Dearden, that I quarrel with . . . . ").

[155] *See id*. at 1153:16-1154:7.

[156] *Id*. at 1154:13-1155:6 (arguing that the appeals court ruling in *AZT* was based on "logic that I thought was not sound").

[157] The motion judge agreed that *AZT* had changed the law, and therefore allowed the amendment. While Mr. Dimock testified that the motion judge's decision was overturned on appeal, he conceded that the appellate court had rejected Apotex's motion only because "[Apotex] waited very long afterwards to say that there was a change in the law." Testimony of Ronald Dimock, Tr. at 1185:25-1186:8; *see id*. at 1173:10-1178:17; *Bristol-Myers Squibb Company v. Apotex Inc*., 2010 FC 1304, at ¶ 31 (C-532); *Apotex Inc. v. Bristol-Myers Squibb Company*, 2011 FCA 34 , at ¶ 23 (C-545).

104. Professor Siebrasse confirmed that the rule barring reliance on post-filing evidence of utility came into being only with the Supreme Court's 2002 ruling in *AZT*, which reversed a contrary Federal Court of Appeal ruling below and overturned the prior ruling of the Federal Court of Appeal in *Ciba-Geigy*.[158]

105. Confronted with this inescapable fact, Canada sought refuge in various arguments, none of which withstands scrutiny:

106. *First*, Canada argued at Closing that the voluminous case law allowing post-filing evidence of utility was not about utility at all, but rather about what Canada termed "a distinct issue of operability."[159] Yet operability is by no means a distinct issue; testimony throughout the Hearing established that operability is the core of the utility requirement, both in Canada and elsewhere.[160] Moreover, Canada's attempt to distinguish all of these cases is tautological. It is only since the 2002 *AZT* decision that patentees must show not only that an invention works today (*i.e.*, is operable), but also that the invention's "promised" utility was demonstrated or soundly predicted at filing based solely on pre-filing evidence.

107. *Second,* given the clear holding by the Federal Court of Appeal in *Ciba-Geigy* that post-filing evidence can be relied upon to establish utility at the time of filing, Canada was left to argue at Closing that the rule recognized in *Ciba-Geigy* was "*obiter dicta*" that "cannot be taken as an unequivocal statement of the law."[161] Yet the court's language in *Ciba-Geigy* was in fact unequivocal, and at the time uncontroversial: "[I]f

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[158] Testimony of Norman Siebrasse, Tr. 518:16-519:2 (noting that in *AZT* "the Supreme Court of Canada said that fact that [the patented drug] is actually being used cannot be considered"); *id*. at 519:3-520:3 (detailing evidence showing that the rule announced in *AZT* was new).

[159] Resp. Closing Statement, Tr. at 2269:4-16 (arguing that whether the invention works is distinct from whether the invention established utility at the time of filing).

[160] *See, e.g.*, Testimony of Norman Siebrasse, Tr. at 518:9-12 (noting that under Canada's traditional utility test, only "inoperable inventions" failed); Testimony of Robert Merges, Tr. at 1285:11-13 (noting that in U.S. law "the basic standard is just operability"); Testimony of Jay Erstling, Tr. at 1574:1-3 (noting that the PCT definition of industrial applicability excludes inventions "that defy laws of nature, that are simply not operable, or workable").

[161] Resp. Closing Statement, Tr. at 2267:21-2268:25.

indeed what is in the patent specification was mere speculation or prediction, the speculation or prediction having turned out to be true, ought to be considered to have been well founded at the time it was made."[162] Canada's reading of *Ciba-Geigy*, which rests on conjecture about what the court would have decided on the basis of pre-filing evidence alone, is at odds not only with this express language, but also with the Court of Appeal's reliance on this precedent in the Court of Appeal's subsequent *AZT* decision.[163]

108. *Third*, in an attempt to find support for its position outside of the distinctly unhelpful realm of utility cases, Canada pointed at Closing to cases addressing inventorship disputes.[164] But inventorship cases do not require that an invention's utility be "tested" to establish that the invention was made.[165] As Canada's own witness conceded, inventorship cases focus on which inventor was the first to file, and the mere act of filing an allowable patent application is sufficient. Mr. Dimock agreed that the act of filing was "the crowning step" for demonstration of inventorship.[166]

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[162] *Ciba-Geigy AG v. Canada (Commissioner of Patents)*, (1982) 65 CPR (2d) 73, 77 (FCA) (C-44).

[163] *Apotex Inc. v. Wellcome Found. Ltd.*, (2000) 10 CPR (4th) (FCA), at ¶ 50 ("In my view, this Court's decision in *Ciba-Geigy* stands for the proposition that even where an invention constitutes a speculation as of the priority date claimed in the patent, the patent will not be invalid if it turns out that the speculation is valid at the time the patent is attacked.") (C-117).

[164] Resp. Closing Statement, Tr. at 2264:23-2266:11 (discussing inventorship cases regarding "reduction to a definite and practical shape").

[165] Testimony of Norman Siebrasse, Tr. at 534:15-536:6 ("Mr. Dimock says, and I agree, that the test for whether the invention was made, as he puts it, under these inventorship disputes was whether or not it was reduced to a definite and practical form. That says nothing about testing. . . . In his Second Report Mr. Dimock has made it clear that he views that part of this reducing to definite and practical form is that not only must it exist but it must have been tested, in effect, and this is incorrect as a matter of law. In fact, the very case cited by Mr. Dimock in his First Report, Christiani v Rice, a leading Supreme Court of Canada decision on this case from the 1930s, I believe, in the very paragraph cited by Mr. Dimock, there's a contrast drawn between when the invention was reduced to a definite and practical shape at this date, only tested at a later date, and the Privy Council in that case, accepted by the Supreme Court, held that the date of being reduced to definite and practical form is when it's written down in a manner that allows some third party to implement it, and not when it was tested. So definite and practical shape, on the one hand, means more than an idea floating through someone's brain, but less than testing.").

[166] Testimony of Ronald Dimock, Tr. at 1136:16-1137:22 ("So the crowning step [to show inventorship] is the act of filing an allowable application, correct? MR. DIMOCK: That is the crowning step.").

109. The simple fact, reinforced at the Hearing, is that there is not a single case before *AZT* in 2002 in which a Canadian court declined to consider post-filing evidence of utility:

- Professor Siebrasse testified that prior to *AZT*, no commercially successful product was ever held to lack patentable utility.[167]
- Canada's witness, Mr. Dimock, could not think of a single case before 2002 in which a commercially useful invention was found to lack utility.[168]
- Nor could Mr. Dimock identify a single case before 2002 in which a court did not allow a patentee to rely on post-filing evidence to prove utility.[169]
- That *AZT* changed the law also is evident because, as Professor Siebrasse explained, subsequent decisions had to clarify whether the relevant cut-off date was the priority date or the Canadian filing date.[170] Mr. Dimock conceded that clarification was required in later rulings.[171] If the rule had been long established, as Canada contends, no such clarification would have been required.

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[167] Testimony of Norman Siebrasse, Tr. at 519:24-520:3 ("[P]atents for commercially successful products are now often held to lack patentable utility. Prior to AZT no commercially successful product was ever held to lack patentable utility.").

[168] Testimony of Ronald Dimock, Tr. at 1169:25-1170:6 ("Can you cite a case decided prior to 2002 that invalidated a patent for a commercially useful invention because the patentee could not demonstrate or soundly predict the utility at the date of filing? MR. DIMOCK: As I said, there are so few sound prediction cases, and so right now at this time in this chair, I can't think of any.").

[169] *Id*. at 1170:10-23 ("Can you cite a decision prior to 2002 in which the court did not allow the patentee to rely on post-filing evidence to prove utility? . . . MR. DIMOCK: . . . [N]o, I can't think of any right now.").

[170] Testimony of Norman Siebrasse, Tr. at 519:13-23 ("Also there was subsequent clarification required as to the scope of this rule. I believe you heard that a patent filed in Canada can claim priority to a prior, subsequent or foreign application, and the question was well, does after-the-fact mean after the priority date or after the filing date. Subsequent to AZT the Court of Appeal clarified, interpreting AZT, that this meant post filing. If this had been a long-established rule; that clarification shouldn't have been necessary.").

[171] Testimony of Ronald Dimock, Tr. at 1121:22-25 ("So there were issues left unresolved by AZT and Justice Mactavish [in *Aventis Pharma Inc v. Apotex Inc*, 2005 FC 1283] has decided that it's going to be the filing date, Canadian filing date, correct? MR. DIMOCK: Yes. She does that."); *id*. at 1126:2-5 ("So that's the first Court of Appeal decision [*Aventis Pharma Inc v. Apotex Inc*, 2006 FCA 64 (C-214)] to decide that the relevant date is the Canadian filing date? MR. DIMOCK: That's right."); *id*. at 1128:5-8 ("So the cut-off date [in *Pfizer Canada Inc v. Apotex Inc*, 2007 FCA 209 (C-215)], Canadian filing date, right? MR. DIMOCK: That's what this Court of Appeal said, yes.").

110. Confronted with this clear shift in the case law, Canada in its Closing presented a litany of responses, none persuasive, in an attempt to rescue its argument. For example, Canada identified one 2003 article on *AZT*, but the author, a practitioner, acknowledged that prior rulings were contrary to *AZT*.[172] Canada also argued that there were no dissents on the Supreme Court in *AZT*, but a judicial rule can be new even if not accompanied by a separate opinion.[173] None of Canada's responses call into question the unambiguous case law record: post-filing evidence of utility, including commercial success, was admissible in Canada until the *AZT* ruling in 2002.

c) Requiring Evidence of Sound Prediction To Be in the Patent Is New.

111. As Lilly's witnesses explained at the Hearing, evidence from outside the patent was traditionally admissible and relied upon to establish a sound prediction of utility.[174] Even Canada's witness, Mr. Dimock, conceded that in *Olin Mathieson*, a U.K.

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[172] Resp. Closing Statement, Tr. at 2261:13-15; Resp. Closing Slides at 119 (quoting 2003 article stating that the Supreme Court in *AZT* "rejected the suggestion, *arising from earlier Canadian Federal Court of Appeal decisions*, that mere speculation which later turned out to be true would be considered a sound prediction" (emphasis added)). The author of the article, John Bochnavic, was not known to Mr. Reddon. Testimony of Andrew Reddon, Tr. at 868:24-869:6 ("I've never come across him in any of the litigation cases that I've done, ever, that I can recall.").

[173] Resp. Closing Statement, Tr. at 2263:16-25 ("[T]here was not a single dissent or a word of concurring opinion expressing any concern that the judgment would . . . disrupt settled patent law . . . . There were no such doubts expressed by any of the nine judges of the Supreme Court of Canada because this was not a major change in the law.").

[174] Testimony of Norman Siebrasse, Tr. at 517:24-518:5 ("Evidence from outside the patent was admissible to establish sound prediction, so this is a quote from Olin Matheson, a UK case, but it is one that was accepted into Canadian law by Monsanto in '78. It's clear from that case the works relied on to establish the sound prediction were outside the patent."); *id*. at 523:11-13 ("[P]rior sound prediction cases like Olin Matheson and Ciba-Geigy admitted evidence from outside the patent."); Testimony of Andrew Reddon, Tr. at 829:19-830:5 ("[I]n Monsanto the Supreme Court itself relied on affidavit evidence extrinsic to the patent to justify a prediction of utility, and all of that based upon their affirmation in Monsanto of the Olin Mathieson case from England . . . . In Olin Mathieson, the data for the prediction was not in the patent. It was from test results that were extrinsic to the patent and put into evidence in the case, and in Monsanto the Supreme Court said that's okay. It affirmed Olin Mathieson as the law of Canada.").

case incorporated into Canadian law by the Supreme Court of Canada, the court relied on evidence of sound prediction that was not included in the patent.[175]

112. Canada's principal response to *Olin Mathieson* at Closing was a suggestion that only its sound prediction principle — but not "the factual context" — was accepted into Canadian law in the *Monsanto* decision of the Supreme Court.[176] Canada identified no basis, in *Monsanto* or elsewhere, for this risible reading of *Monsanto*.

113. As Professor Siebrasse and Mr. Reddon explained at the Hearing, the longstanding practice of allowing patentees to rely on evidence of sound prediction from outside the patent was reversed only in the 2008 *Raloxifene* ruling, which interpreted *AZT*.[177] In that *Raloxifene* decision, a Canadian court for the first time declined to consider pre-filing evidence of utility that was not disclosed in the patent. Even Canada's witness, Dr. Gillen, conceded that it was only after the *Raloxifene* decisions in 2008 and 2009 that Patent Office examiners were instructed to require the factual basis and line of reasoning for a sound prediction to be in the patent itself.[178]

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[175] Testimony of Ronald Dimock, Tr. at 1098:4-18 ("[T]here's no doubt as a fact that Justice Graham [in *Olin Mathieson*] relied on post-filing evidence and evidence also that was not in the patent, right? MR. DIMOCK: For the reasons I gave, yes. MR. DEARDEN: . . . We have reference, sir, without a doubt to post-filing evidence and evidence that's not in the disclosure, correct? MR. DIMOCK: Yes, I've agreed with you on that.").

[176] Resp. Closing Statement, Tr. at 2273:13-17 ("And it is true that the Supreme Court in Monsanto received the principle of sound prediction from Olin Mathieson, but this doesn't mean that it received into Canadian law the factual context of Olin Mathieson as well.").

[177] Testimony of Norman Siebrasse, Tr. at 522:16-523:3 ("The third aspect of the law that we're considering is that the additional disclosure requirement for sound prediction — so now it's clear law that only evidence in the patent itself can be used in support of sound prediction, this was established by the Raloxifene decision in interpreting the AZT decision. But, on the other hand, it's equally clear law that evidence outside the patent can be used to demonstrate utility, and so the courts say that the disclosure requirements for sound prediction are more onerous than to demonstrate utility."); Testimony of Andrew Reddon, Tr. at 829:10-13 ("All of that was difficult but step 3 came along in Raloxifene. Prior to AZT no Canadian court had ever articulated any disclosure requirement related to predicting utility.").

[178] Testmony of Michael Gillen, Tr. at 992:12-25 ("[I]t's only after the Raloxifene decisions in 2008 and 2009 that examiners get instructed by the 2009 MOPOP to require the factual basis and line of reasoning for the prediction to be in the patent? DR. GILLEN: I think that's correct. . . . Certainly, after the AZT decision came out, there was a question as to whether the third part of that test, the disclosure requirement, was in the application or whether it could be provided at some later date.").

114. At the Hearing, Canada and its witnesses attempted in vain to find applications of this new, additional disclosure rule prior to 2008. For example, in his Second Report, Dr. Gillen argued that a 1995 Commissioner's Decision had applied the disclosure rule.[179] At the Hearing, by contrast, he admitted that the decision did not contain "that exact finding," but insisted "that's my interpretation of that decision."[180] Mr. Dimock admitted that *Monsanto*, a leading sound prediction case, did not expressly require the factual basis for a sound prediction of utility to be in the patent.[181] Nonetheless, Mr. Dimock attempted to argue that it *impliedly* required disclosure of the factual basis and line of reasoning to support a sound prediction.[182] At Closing, Canada tried a similar argument, by invoking unstated rules like Dr. Gillen and Mr. Dimock did: "Monsanto does not expressly state that you cannot use evidence beyond what is in the patent and the common general knowledge, *but that does not mean that the rule wasn't there*."[183] Unfortunately for Canada, the rule was not there prior to *Raloxifene.*

115. Canada also argued that the new disclosure rule was reflected in the 2002 *AZT* ruling of the Supreme Court.[184] There is no dispute that the court in *Raloxifene* interpreted and applied language from *AZT* regarding disclosure. But as Lilly's witnesses explained, the *AZT* ruling itself expressly declined to decide what would be

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[179] Dr. Gillen wrote that "the examiner, the Patent Appeal Board, and the Commissioner all found the patent invalid because of the failure to disclose in the patent a factual basis for the sound prediction as well as a sound line of reasoning." Second Witness Statement of Michael Gillen, at ¶¶ 15-16 (discussing Commissioner's Decision 1206, relating to Application No. 529,362, 11 Dec. 1995 (R-381)).

[180] Testimony of Michael Gillen, Tr. at 980:19-981:23 ("You can't show me anywhere in this tab, R-381, this decision 1206, where that specific finding is made that you have in paragraph 16 of your statement? DR. GILLEN: I can't find that exact finding, no, but that's my interpretation of that decision.").

[181] Testimony of Ronald Dimock, Tr. at 1086:6-10 ("Agree or disagree. Monsanto made no finding that the factual basis had to be disclosed? MR. DIMOCK: It didn't make that explicit finding. Yes, it did not.").

[182] *Id*. at 1083:2-17 ("You'll agree that the Monsanto decision of the Supreme Court of Canada does not make a finding that the factual basis and line of reasoning for sound prediction of utility must be disclosed in the patent? MR. DIMOCK: Impliedly, it did. . . .[I]t didn't use the very words that are found in Justice Binnie's decision in the AZT. However, that's the inference you draw from reading the case and knowing the facts of it.").

[183] Resp. Closing Statement, Tr. at 2272:18-22 (emphasis added).

[184] *Id*. at 2269:20-2270:25.

considered "proper disclosure" where utility is based on a sound prediction.[185] Moreover, as Lilly's witnesses emphasized, the court in *AZT* considered evidence from outside the patent as supportive of a sound prediction of utility.[186]

116. Canada's own witness, Mr. Dimock, admitted that the case law provides no support for Canada's claim that this additional disclosure rule was longstanding:

- Mr. Dimock conceded that there were no cases between the *AZT* ruling in 2002 and the *Raloxifene* decision in 2008 that imposed a heightened or additional disclosure requirement where utility was based on sound prediction.[187]

- Mr. Dimock further conceded that the Federal Court of Appeal, in a decision after *AZT* but before *Raloxifene*, considered evidence from outside the patent in determining whether there was a factual basis for sound prediction.[188]

- And Mr. Dimock agreed that the scope of this disclosure rule remains in dispute, with some judges expressing views that it should apply only to new use patents.[189]

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[185] Testimony of Norman Siebrasse, Tr. at 683:21-684:3 ("[Y]ou're saying that the rule was established by Raloxifene but that it had its origin in AZT? PROFESSOR SIEBRASSE: Well, if we actually look at the — I don't know if we need to look at the paragraph in AZT but the paragraph says — expressly says it's obiter. It says it wasn't raised by the parties."); Testimony of Andrew Reddon, Tr. at 871:13-872:21 ("This is not a holding that everything in the AZT patent necessarily has to be disclosed. This is a holding that the AZT patent hits any standard we might later articulate because it has everything, and we'll get back to you in a case where it matters about what you have to disclose.").

[186] Testimony of Norman Siebrasse, Tr. at 689:10-21 ("Wellcome in that case was explicitly relying on facts that were not in the patent. . . . The disclosure requirement was never an issue between the parties. And the factual basis itemized by the trial judge and summarized by the Supreme Court was not all in the patent. Some elements were, some were not. In fact, one of the items that wasn't in the patent was some testing done by Martha Sinclair, who is actually named as an inventor the testing was so important, and that testing was not in the patent."); Testimony of Andrew Reddon, Tr. at 873:21-874:3 ("Justice Binnie says in AZT that you need to lead evidence about what was known. . . . That's inconsistent with the determination that you can only consider that which is in the application for the patent.").

[187] Testimony of Ronald Dimock, Tr. at 1112:21-1113:3 ("Mr. Dimock, I don't recollect seeing any case prior to this decision of Justice Hughes in 2008 [*Raloxifene*] that required a patentee to disclose the factual basis and line of reasoning for sound prediction of utility in the patent. Do you recall any between AZT in 2002 and this decision in 2008? MR. DIMOCK: Oh, between 2002 and 2008, as far as I know, there were no cases on point.").

[188] *Id*. at 1127:9-1129:17 (admitting that in *Pfizer Canada Inc v. Apotex Inc*, 2007 FCA 209 (C-215), the court relied upon rat tests that Mr. Dimock conceded "were likely not in the Canadian patent as filed").

[189] *Id*. at 1117:14-20 ("There's an unresolved issue whether the proper disclosure requirement only applies to new use patents, and that issue is definitely unresolved today, isn't it? MR. DIMOCK: Justice Rennie (continued…)

117. In sum, there was no case, prior to *Raloxifene*, in which a Canadian court declined to consider evidence of soundly predicted utility because that evidence was not included in the patent.

118. At Closing, Canada conceded this point by asking a rhetorical question: "So if the disclosure requirement for sound prediction has been there since Monsanto, why do we not see a case striking down a patent for failing to disclose the basis of the prediction until Raloxifene?"[190] Canada's proposed answer was tellingly implausible — that all challenged patents other than Lilly's, across all fields of technology and for decades, *all* included appropriate disclosures of soundly predicted utility: "[P]atentees were providing, as a matter of course, ample disclosure in the patent to support their sound predictions of utility," and "[w]hen a rule is being complied with, there won't be court decisions finding violations of that rule."[191]

119. This argument, for which Canada provided absolutely no evidentiary support, should be treated as an implicit concession that the additional disclosure rule first applied to invalidate a patent in *Raloxifene* had no roots whatsoever in prior Canadian law.

D. The Dramatic Increase in Canadian Inutility Findings Demonstrates the Radical Change in Canada's Utility Requirement.

120. In addition to evidence regarding the qualitative transformation of Canada's utility law, discussed above, the Hearing included new quantitative data — updated to 22 April 2016 — demonstrating the unmistakable effects of the doctrinal change on patent litigation outcomes.

121. In particular, as Lilly reiterated at the Hearing, since 2005 there has been a sudden and unprecedented spike in the number of patent revocations by Canadian

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did refer to that, and there's some other judges who thought that that may not be, indeed, the case."); *see* Testimony of Norman Siebrasse, Tr. at 523:14-18 (identifying the divergent judicial opinions as evidence that the requirement is new). Strattera was a new use patent.

[190] Resp. Closing Statement, Tr. at 2273:22-2274:1.

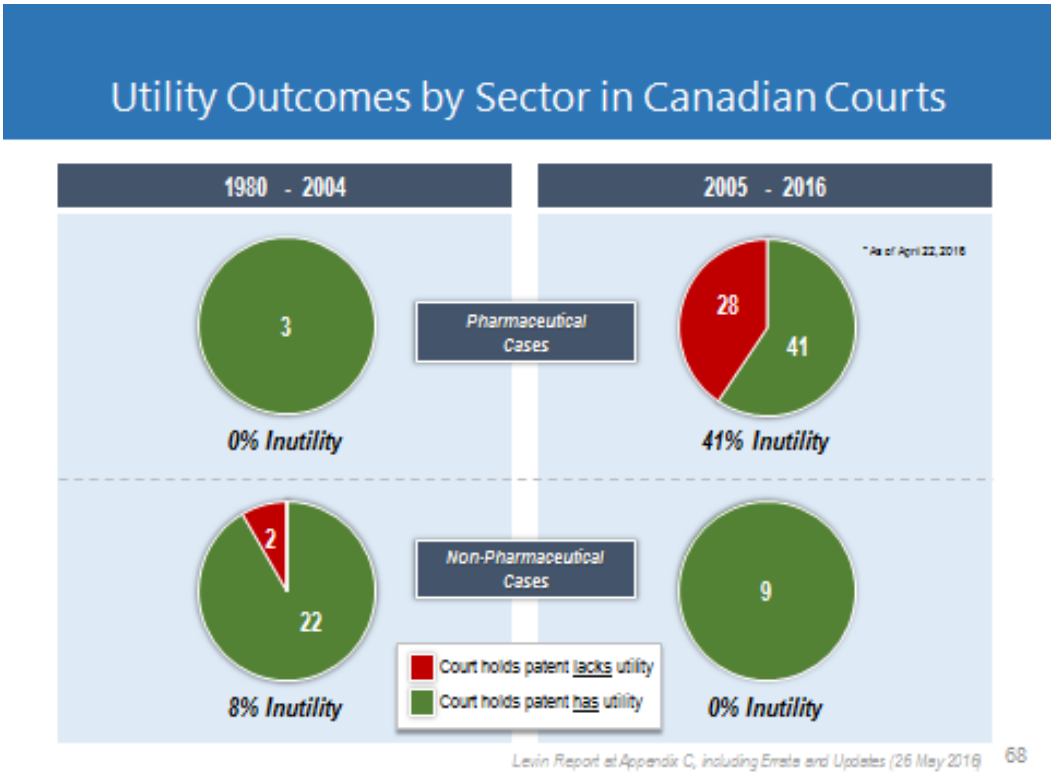
[191] *Id*. at 2274:5-11.

courts for lack of utility, and that dramatic increase has been concentrated exclusively in the pharmaceutical sector. As Lilly emphasized in its Opening:

> Since we filed the Memorial in September 2014 there have been 14 additional utility rulings, and the picture remains the same. There's been a dramatic shift in the pharmaceutical sector. In the early period utility was rarely challenged in that sector and never successfully but, since 2005, given the change in Canada's test, utility challenges have spiked and 28 cases (41 percent) have been successful.
>
> Second, there's been no change across all other sectors. Both before and after 2005 there were relatively few challenges, and over more than three decades there have been only two judicial rulings in any other sector invalidating a patent for lack of utility, and none since 2005 after the advent of Canada's new test.[192]

With the updated case counts, the pattern of outcomes remains striking.

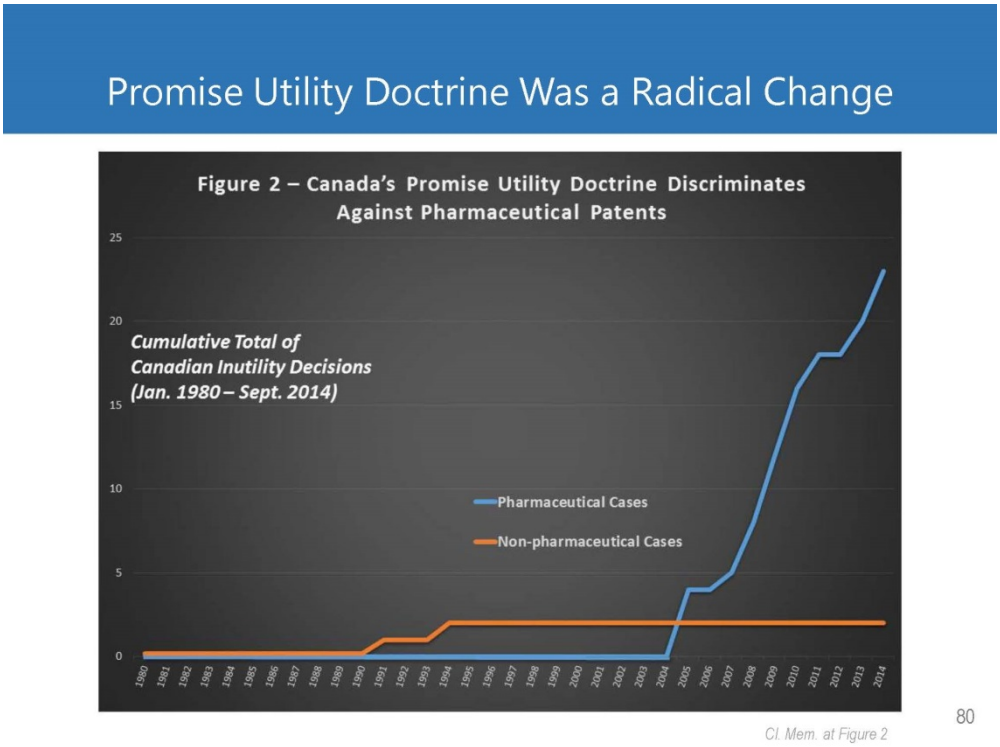
Lilly's Opening Presentation, Slide 68



[192] Cl. Opening Statement, Tr. at 95:8-23.

122. The discontinuity in litigation outcomes, before and after 2005, is compelling evidence of the underlying changes in Canada's utility requirement. As Lilly explained, the dramatic shift in the number and success rate of utility challenges since 2005 reflected parallel and equally dramatic shifts in Canadian utility law.[193]

Lilly's Closing Presentation, Slide 80



123. At the Hearing, Canada provided no plausible alternative explanation for this conspicuous contrast in litigation outcomes over time. And the two alternative causes it did identify were untested and unavailing.[194]

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[193] Cl. Opening Statement, Tr. 95:6-96:12 (noting that a "dramatic change . . . has taken place only in Canada . . . and only in the pharmaceutical sector").

[194] Canada, notably, did not run a similar statistical test, or any test at all, for any alternative causal explanation. Given the nature of his statistical method, which evaluates the likelihood that a pattern of outcomes is the result of random chance, Professor Levin explained that he was "not opining on causality." Testimony of Bruce Levin, Tr. at 1266:23-24. Rather, as a statistician, Professor Levin opined that the pattern of litigation outcomes in Canada since 2005 "is consistent with" Lilly's assertion that the promise utility doctrine has had a disparate impact on the pharmaceutical sector. *Id*. at 1266:2-1267:6.

124. *First*, Canada argued at Closing that "the end of compulsory licensing in 1993 and the introduction of the PM(NOC) regulations led to a significant increase in pharmaceutical litigation."[195] Those changes, however, took place 12 years before the application of Canada's new promise utility doctrine, and thus are not linked in time to the changes in utility litigation since 2005. Moreover, even if proximate in time, increases in litigation *volume* cannot account for changes or differences in the success *rate* of utility challenges specifically, as Professor Bruce Levin explained.[196]

125. *Second*, Canada argued that "other crucial developments have influenced and affected trends and outcomes in litigation," such as "variables at play when deciding to litigate a patent."[197] Among the variables Canada identified were "the skill of counsel on either side, the particular experiences of the fact finder, the quantum and quality of evidence presented, including the credibility of witnesses, and the quality of the patents themselves all influence litigation outcomes."[198] Yet Canada provided no plausible case — indeed, Canada made no argument at all — to explain how such highly case-specific factors varied systematically over time in a way that could possibly account for the overall spike in inutility rulings after 2005.

126. With no plausible alternative explanation for this dramatic change, Canada tried to suggest that the change was not so dramatic. Specifically, Canada argued that if the cutoff date between the pre- and post-2005 periods is moved from 1 January 2005 to 2 September 2005, two findings of inutility in the pharmaceutical sector shift to the earlier period, increasing the inutility rate in the pre-2005 period from 0% (0 of 3 cases) to 40% (2 of 5 cases).[199] Even if Canada were right that the "correct date" for

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[195] Resp. Closing Statement, Tr. at 2249:22-24.

[196] Testimony of Bruce Levin, Tr. at 1268:7-11 ("[J]ust because there were more pharmaceutical challenges post-2005 than pre-2005 does not mean that the difference between pharmaceutical and non-pharmaceutical would necessarily be anything but zero."); *see* Cl. Opening Statement, Tr. at 96:6-8 ("[T]he overall volume of patent litigation can't explain the dramatic change in the rate of successful utility challenges.").

[197] Resp. Closing Statement, Tr. at 2249:14-20.

[198] *Id*. at 2281:12-18.

[199] Resp. Closing Slide 86 ("Claimant's Opening Slide 70 — If Measured from the Correct Date").

the conceded change in its law was September 2005, the dramatic effects of that change would remain apparent. The spike in inutility findings in the pharmaceutical sector is no less dramatic if the start date for the post-2005 period is September (from 2 to 26 cases) rather than January (from 0 to 28 cases). While the inutility rate in the pharmaceutical sector pre-2005 would increase, that is simply due to the extremely small number of cases in that period. As Professor Levin emphasized, it is inappropriate to draw conclusions from the pre-2005 period, given the small case counts.[200] Further, Canada is wrong to assusme that both cases it proposes to shift do not reflect applications of its new utility requirement. In *Merck v. Apotex*, decided on 26 May 2005, the patent was for an approved and commercially successful osteoporosis drug, Fosomax (alendronate), whose utility could not have been successfully challenged until *AZT* barred reliance on post-filing evidence in 2002.[201]

127. As demonstrated at the Hearing, these data not only show that the promise utility doctrine is new, they also show that this new utility requirement has had a disproportionate, disadvantageous effect on the pharmaceutical sector.[202] As Professor Levin explained, the difference in invalidation rates across sectors since 2005 is statistically significant and consistent with the view that Canada's promise utility doctrine has had uniquely adverse effects on the pharmaceutical sector:

> I concluded that post-2005, there is a statistically significant difference in invalidation rates based on lack of utility between pharmaceutical and

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[200] For example, Professor Levin emphasized that given the small number of cases before 2005, he drew no conclusion from the lack of a statistically significant difference across sectors in that earlier era. Testimony of Bruce Levin, Tr. at 1277:2-12 ("The point you're raising is exactly the point I drew as an important caveat when I testified about table 2. . . . I said I draw no conclusion from the lack of significance between pre and post, and the reason is precisely that. The number of cases pre-2005 challenged on utility was too small. . . . [P]ushing to a logical extreme, suppose there were no challenges prior to 2005, obviously we could not draw any conclusion. So we don't draw any conclusion.").

[201] *See Merck v. Apotex*, 2005 FC 755, at 73-74 (applying *AZT* bar on post-filing evidence and holding that dog studies in patent application were insufficient to demonstrate or soundly predict utility at the date of filing) (C-354). The other case, *Abbott v. Ratiopharm,* involved a claim that included inoperable species, such that the claimed invention failed the traditional mere scintilla test. 2005 FC 1095, at 35-38 (finding *Markush* claim invalid for lack of utility because three of the claimed solvents were inoperable) (C-441).

[202] This discriminatory impact on the pharmaceutical sector is discussed in greater detail in the context of NAFTA Article 1709(7). *See infra* Part IV.B.4(b).

> non-pharmaceutical sectors in Canada. Prior, pre-2005, there is no significant difference across sectors. On grounds other than utility, there is no significant difference between the invalidation rates. And the above findings are consistent with the view that Canada's utility requirement has had a disproportionate impact on the pharmaceutical sector since 2005.[203]

Professor Levin's statistical analysis, in other words, demonstrated that the large difference across sectors on utility since 2005 is not mere happenstance.[204]

128. Canada also sought in various ways to challenge Professor Levin's findings of statistical significance and disparate impact on the pharmaceutical sector, but those efforts likewise were to no avail. Most of Canada's criticisms related to the coding of cases in the data set, for which Canada relied on the testimony of Dr. Marcel Brisebois, a fact witness and current employee of Industry Canada who helps devise strategic policies to assist Canadian industry.[205]

129. For example, Canada suggested that the data set should exclude all PM(NOC) proceedings — even though Dr. Brisebois conceded that such cases apply the same law as infringement actions, are cited as precedent, and are relied upon by the Patent Office, and even though he knew of no patent found to lack utility in a PM(NOC) case but later found useful in an infringement action.[206] The proposed change thus

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[203] Testimony of Bruce Levin, Tr. at 1199:10-22; *see id.* at 1210:5-10 (confirming that his conclusions "did not change at all" after adding newly decided cases to his analysis).

[204] To be specific, with regard to the updated data through 22 April 2016, Professor Levin calculated that there is only a 1.37% probability that the lopsided pattern of results disfavoring the pharmaceutical sector was the result of random chance. *See* Updated Table 1A, Levin Demonstrative Slide 3 (reporting that $P = 0.0137$). At the request of the Tribunal, Professor Levin provided his formula and specific calculations to the parties and the Tribunal in handwritten form. *See* Levin Demonstrative Slides 9 and 10; Testimony of Bruce Levin, Tr. at 1270:9-1273:20 (explaining the steps in his original calculation).

[205] Testimony of Marcel Brisebois, Tr. at 482:12-18. Dr. Brisebois indicated that a notable part of his job is to advise the Canadian government on matters specific to this arbitration. *Id.* at 482:19-22.

[206] *Id*. at 483:20-484:8 ("Now, Mr. Brisebois, are you aware that PM(NOC) proceedings apply the same utility law as infringement cases? MR. BRISEBOIS: Yes. MS. CHEEK: And are you aware that PM(NOC) decisions are cited as precedent in subsequent patent case, both pharma cases and in other sectors? MR. BRISEBOIS: Yes . . . MS. CHEEK: And PM(NOC) cases are relied upon by the Canadian patent office as well, as reflected in the MOPOP. Is that right? MR. BRISEBOIS: I'm not sure about that, but could be right, yes."); *id.* at 488:5-25 ("[A]re you aware of a single case where a patent that was found (continued…)

made little sense, but also made no difference. While the exclusion substantially reduced the universe of cases, the difference in inutility rates across sectors actually increased — and also remained statistically significant, as Professor Levin emphasized in his testimony at the Hearing.[207]

130. In its Closing — for the first time — Canada also suggested that instead of counting cases, Professor Levin should have counted patents and made a handful of case-specific corrections. Such changes, though inappropriate,[208] again had no impact on the difference in inutility rates across sectors, which remained large and statistically significant, as Professor Levin explained at the Hearing.[209]

131. Canada also took issue with the time frame of the data set, contending that the start date for the analysis should have been 2 September 2005, rather than 1

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to lack usefulness, a patent that was found not useful in a PM(NOC) proceeding, was later found to be useful in a subsequent infringement proceeding? MR. BRISEBOIS: I would have to review all the cases, but from my head I cannot think of one.").

[207] Testimony of Bruce Levin, Tr. at 1212:13-1213:8 ("[T]he proportion of invalid cases in the pharmaceutical sector held invalid on utility grounds — has, if anything, continued to increase. There's now almost 43 percent of the cases among the 14 held invalid still versus 0 percent among the non-pharmaceutical cases. . . . [W]hen we have markedly reduced marginal totals such as we have here and, yet, we still have statistically significant difference, it arises because of the large substantive difference in the proportions of invalidity."); Cl. Closing Statement, Tr. at 2116:24-2117:10 ("Canada next says that we should not count the PM(NOC) litigation and we should remove those cases from the calculus, even though, as you've heard, those cases are heard by the same Federal judges. They're considered precedential when it comes to an application of the law, et cetera, and actually the majority of pharmaceutical litigation in Canada. . . . But still even applying . . . that tweak, you're still looking at a significant disproportionate, disadvantageous effect.").

[208] Professor Levin explained that if one were to change the unit of analysis to patents, rather than cases, it would be essential to control for the "clustering" of related patents within a single case, which Canada failed to do. Testimony of Bruce Levin, Tr. at 1214:3-7 ("[O]wing to the fact that you can have several patents under consideration in a single case, one has to deal with the issue of the clustering of the unit of analysis within the case. So there are methods of addressing that.").

[209] *Id*. at 1215:6-11 ("[Y]et again, what we see is the difference persists. It's a large proportional percentage point difference, 36.4 versus 0. The P-value is still below 5 percent, so those two modifications did not alter the conclusion of statistical significance."); Cl. Closing Statement, Tr. at 2116:15-23 ("[W]e accounted for both counting patents instead of cases, and we also made the case-specific corrections that they thought were critical, although we dispute that, but in any case, even if you accept their changes, these numbers barely budge. We're still looking at a significant disproportionate impact of the pharmaceutical sector, 35 percent of inutility finding for patents versus zero percent in other non-pharmaceutical industries.").

January 2005.[210] But as Professor Levin explained, this change would have no impact on the results of his disparate impact analysis, which still would find a statistically significant difference across sectors after 2 September 2005.[211]

132. Next, Canada suggested in its Closing that the data improperly included inutility findings that may not reflect "applications of the promise standard."[212] The data set, however, was comprehensive. As Professor Levin noted, the data set is a "census" of all relevant cases, not a sample.[213] And notably, while Canada has had the list of utility cases since Lilly filed its Memorial, Canada has never identified a subset of cases that it thought should be removed from the data set as not reflecting application of the promise utility doctrine.

133. Canada and Dr. Brisebois proposed only one change of potential consequence to Professor Levin's analysis — that two non-pharmaceutical cases, *Eurocopter* and *Uponor*, should be counted twice, both as wins *and* as losses. But such a change would defy basic statistical principles, legal realities, and common sense. In particular, Professor Levin "strongly objected" to doing the calculation at all because Dr. Brisebois's approach is "entirely statistically invalid . . . and inconsistent":

> It's invalid because it violates a fundamental statistical rule, which is that when you're classifying units such as we are here as either valid or invalid, the classification system must be mutually exclusive and

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[210] Resp. Closing Statement, Tr. at 2247:11-2248:10.

[211] Testimony of Bruce Levin, Tr. at 1261:7-8 ("I don't see the relevance of that for my primary findings [post-2005]."); *see* Cl. Closing Statement, Tr. at 2336:6-2337:2 ("Respondent referred to the fact that they changed a date on this chart to September 2005 and that as a result, two of the 23 inutility findings from 2005 to 2014 shifted, and those two inutility findings would be in the pre-2005 period . . . . Professor Levin's testimony is if you happen to shift two pharmaceutical inutility findings to the earlier period in time, it does not change his view that there is still a statistically significant difference between pharma and non-pharma cases post-2005.").

[212] Resp. Closing Statement, Tr. at 2248:12-25 ("Claimant's statistics conflate inutility findings with applications of the promise standard.").

[213] Testimony of Bruce Levin, Tr. at 1200:1-3. Moreover, if Professor Levin had focused his analysis on only a subset of cases, Canada would no doubt have argued that selection of the sample was biased to achieve a desired result.

> exhaustive. That means that every patent, if that is your unit, must be classifiable as one or the other, not both.
>
> I understand the rationale Dr. Brisebois took, which was to somehow reflect the different claims clustered within given patents in Eurocopter, but that's an inconsistent approach. Inconsistent because he could have, but did not, enumerate all the individual claims, shifting the unit of analysis down to the level of claims clustered within patents. He could have asked what was the proportion of all claims held invalid, but he did not do that. Nor did I.
>
> You have to decide on your unit of analysis. If you're talking about claims, well, go do that analysis. If you're talking about patents, however, you can't all of a sudden clone a patent and call it both valid and invalid. Obviously, for example, if you look at the total number in the margin of the table, you'd get the wrong number of patents. So this is not a statistically valid approach.[214]

134. This invalid approach is also flatly inconsistent with the practical and legal realities of the *Eurocopter* and *Uponor* decisions, both of which were victories for the patentee. Dr. Brisebois acknowledged that patents on the commercial embodiments of the invention (*i.e.*, the actual marketed product protected by the patent) remained valid.[215] Dr. Brisebois acknowledged that, in *Eurocopter*, the court awarded the patentee punitive damages given its finding that the valid patent was infringed with respect to the only commercialized embodiment of the invention.[216] And Dr. Brisebois acknowledged that in *Uponor*, the court issued an injunction against infringement of the valid patent and awarded damages to the patentee, including pre-judgment interest.[217]

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[214] Testimony of Bruce Levin, Tr. at 1216:12-1217:17.

[215] Testimony of Marcel Brisebois, Tr. at 498:22-499:20; *id.* at 501:22-502:16.

[216] *Id*. at 496:25-497:3 ("So the court found infringement and awarded punitive damages in this case. Is that right? MR. BRISEBOIS: Yes."); *id*. at 498:5-9 ("Mr. Brisebois, are you aware that the embodiment that was found to be infringed was the only commercialized embodiment of this invention? MR. BRISEBOIS: Yes . . . .").

[217] *Id*. at 500:18-501:9 ("So in paragraph 4, you see, Mr. Brisebois, it says 'Pexcor and Heatlink... are enjoined from manufacturing, using, offering for sale and/or selling to others for their use the apparatus of the heating polymer material that infringes the '376 patent.' You see that? MR. BRISEBOIS: Yes. MS. CHEEK: And then at Paragraph 5, it says here that the plaintiff is entitled to damages as a result of Pexcor and Heatlink's infringement? MR. BRISEBOIS: Yes. MS. CHEEK: And in paragraphs 7 and 8 it (continued…)

135. In sum, with the sole exception of Dr. Brisebois's invalid and inconsistent proposal to double-count two cases, Canada was unable to challenge Professor Levin's robust statistical finding of the promise utility doctrine's disparate impact on the pharmaceutical sector since 2005. Nor did Canada identify any plausible alternative causal theory for the dramatic change in litigation outcomes identified in Professor Levin's data set. Accordingly, the spike in inutility findings since 2005 stands as powerful evidence of the underlying change in Canada's utility requirement and the disproportionate effects of that new requirement on the pharmaceutical sector.

E. The Utility Requirements of Canada's NAFTA Partners Demonstrate the Radical Change in Canada's Utility Requirement.

136. Testimony at the Hearing confirmed that Canada's promise utility doctrine diverges sharply not only from Canada's traditional "mere scintilla" test, but also from the utility requirements of its NAFTA partners, the United States and Mexico. The difference is clear in terms of both doctrine and outcomes. *See* Part II.E.1. Canada's responses to its outlier status at the Hearing — *e.g.*, that its NAFTA partners achieve the same results through other patentability requirements, that the policy objective purportedly behind its doctrine is shared by the United States and Mexico, or that U.S. and Mexican patent laws have changed in similar respects — did nothing to obscure the clear contrast between Canada and its neighbors. *See* Part II.E.2.

137. This recent divergence on utility, which Canada does not dispute, is additional evidence of the radical change in Canadian law from when NAFTA entered into force to when Lilly's patents were invalidated solely for lack of utility.

1. Neither the United States Nor Mexico Has a Utility Requirement Remotely Similar to Canada's New Promise Utility Doctrine.

138. Lilly's witnesses on U.S. and Mexican law confirmed at the Hearing that the utility requirement is a low bar in both jurisdictions. Canada's witnesses, meanwhile, acknowledged significant differences, in both doctrine and outcomes,

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says the plaintiff is entitled to pre-judgment interest on that damages award, correct? MR. BRISEBOIS: 7 and 8? MS. CHEEK: Yes. MR. BRISEBOIS: Yes.").

between U.S. and Mexican law, on the one hand, and current Canadian law, on the other.

139. In the United States, according to Professor Robert Merges, the traditional utility test "presents a very low bar to patentability" for which "the basic standard is just operability."[218] Mr. Stephen Kunin, a former senior official at the U.S. Patent and Trademark Office, similarly described the U.S. utility test — which requires "a single asserted or well-established utility [that] is specific, substantial and credible" — as "a low and easy standard to meet."[219]

140. Core aspects of the U.S. test are common ground between the parties. Canada's U.S. expert, Professor Timothy Holbrook, expressly endorsed a series of points regarding the U.S. utility requirement, including:

- that the utility requirement is a low bar in the United States;[220]
- that assessing utility with respect to the claims is a bedrock principle of U.S. patent law;[221]
- that so long as an invention works for a single claimed use, it will be found to have utility even if the disclosure includes statements about other uses that are not credible;[222]

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[218] Testimony of Robert Merges, Tr. at 1282:13-17, 1285:12-19 ("The invention just has to work. . . . . So when we ask does this invention have utility, we simply say does the claimed invention work for its basic purpose. That's really the question, and it's very straightforward.").

[219] Testimony of Stephen Kunin, Tr. at 1419:25-1420: 4.

[220] Testimony of Timothy Holbrook, Tr. at 1475:4-12 ("[Y]ou, Professor Merges and Mr. Kunin notably agree . . . [t]hat the utility requirement is a low bar in the United States . . . . PROFESSOR HOLBROOK: That's correct.").

[221] *Id*. at 1476:11-14 ("You'd agree with me that assessing utility with respect to the claims is a bedrock principle of U.S. patent law. PROFESSOR HOLBROOK: Yes."). Professor Holbrook further agreed that importing limitations into the claims based on statements in the disclosure is improper. *Id*. at 1497:3-9 (But that rule, as you note, is well established in U.S. law, the impropriety of importing claim limitations from the specification? PROFESSOR HOLBROOK: The impropriety of importing claims from the specification is a strong rule.").

[222] *Id*. at 1480:13-20 ("MR. SMITH: So if you claim a cold treatment but you also assert in the disclosure unrelated uses regarding baldness and any number of other conditions as long as you are able to establish utility of that claimed treatment for the cold, other statements in the disclosure regarding other (continued…)

- that post-filing evidence can be relied upon to substantiate the accuracy of assertions of utility made in the specification;[223]

- that there is no obligation in U.S. law to include all evidence of utility in the patent application as filed;[224] and

- that examiners will consider and allow applicants to rely upon evidence not disclosed in the application to support a prediction of utility.[225]

141. In these respects and others, the U.S. utility requirement stands in stark contrast to Canada's promise utility doctrine.[226] At the Hearing, Professor Holbrook, whose mandate was to assess whether U.S. law had any rules equivalent to the promise utility doctrine,[227] was unfamiliar with basic aspects of the Canadian requirement, including the fact that Canadian courts (i) find promises of utility in the disclosure, without regard to the claims;[228] (ii) may identify and require patentees to meet multiple

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uses are irrelevant under U.S. law? PROFESSOR HOLBROOK: Yes."); *id.* at 1483:13-17 ("Additional statements of utility that are not credible would not be a basis for denial or invalidation if they were not read into the claim. PROFESSOR HOLBROOK: Correct.").

[223] *Id*. at 1491:8-17 ("You wrote — and you're referring to a Federal Circuit case . . . , In re Brana? PROFESSOR HOLBROOK: Yes. MR. SMITH: That post-filing evidence was used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification. Is that correct? PROFESSOR HOLBROOK: That's correct."); *id.* at 1494:25-1495:2 ("[Y]ou do not dispute the existence of the [*In re Brana*] rule, right? PROFESSOR HOLBROOK: Correct.").

[224] *Id*. at 1487:18-21 ("And that's because there's no obligation to include all evidence of utility in the patent application, right? PROFESSOR HOLBROOK: Correct.").

[225] *Id*. at 1489:8-12 ("So if there's a prediction of utility about which the examiner has some doubt, the examiner will consider evidence that was not disclosed or included in the application, correct? PROFESSOR HOLBROOK: Correct.").

[226] *See* Testimony of Robert Merges, Tr. at 1292:18-1298:13 (explaining how "there's nothing in U.S. utility law that's at all like the promise utility doctrine").

[227] Testimony of Timothy Holbrook, Tr. at 1458:16-1459:20 (acknowledging mandate).

[228] *Id*. at 1466:1-9 ("Is it also your understanding that this promised utility might be different from the claimed utility? PROFESSOR HOLBROOK: My understanding is that that question doesn't make sense, that the claimed utility is in part determined by construing the claim, and once you've actually looked at the claim that's when you determine what the promised utility is."); *id.* at 1468:22-1469:7 ("Is it also your understanding that in Canada statements about the invention's performance made in the disclosure may be construed by a court as promises of utility? PROFESSOR HOLBROOK: At this point we're going into such specificity about Canadian law that I'm not comfortable answering that definitively. My understanding is that they look generally to the specification, assess what is required by the claim, and if that is the promise then it's incorporated back in."); *id.* at 1483:18-24 ("Under Canadian law, as you (continued…)

promises of utility;[229] and (iii) require that evidence of sound prediction must be disclosed in the patent.[230] Over the course of his examination, Professor Holbrook recognized that the promise utility doctrine is "not comparable" to the U.S. utility test.[231]

142. In Mexico, according to Professor Gilda Gonzalez, former Deputy Director General of IMPI, the statutory standard for industrial applicability is a similarly low bar. The Industrial Property Law ("IPL") requires that inventions be "susceptible of industrial application," which is defined as the simple "possibility that an invention has a practical utility or can be produced or used in any field of economic activity for the purposes described in the application."[232] This requirement is a low bar, Professor Gonzalez explained, because "it is clear . . . that evidence or proof of industrial application is not required."[233] That evidence or proof of utility is not required during examination was confirmed by Mr. Fabian Salazar, former director of the patent division at IMPI.[234]

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understand it, a failure to demonstrate or soundly predict a single promise of utility is a basis for invalidation. Is that correct? PROFESSOR HOLBROOK: If that promise is required by the claim and the claim requires only that promise or other promises, yes.").

[229] *Id*. at 1472:1-6 ("Is it your understanding, Professor Holbrook, that in Canada a court may find multiple promises of utility in a single patent? PROFESSOR HOLBROOK: I don't have enough knowledge to know whether that can actually arise or not.").

[230] *Id*. at 1489:13-21 ("By contrast, in Canadian law, as you understand it, evidence of a sound prediction of utility must be included in the application? PROFESSOR HOLBROOK: Again, my understanding is the main concern is that evidence of sound prediction that is generated after the filing date is not admissible. I'm not entirely certain about the rules, what happened beforehand.").

[231] *Id*. at 1495:13-20 ("[I]s it fair to say that the U.S. utility standard is by no means equivalent to the Canadian utility requirement? PROFESSOR HOLBROOK: If you're doing a strict utility, . . . substantial, credible, specific utility, that doctrine versus what Canada does, they're not comparable . . . .").

[232] Testimony of Gilda Gonzalez, Tr. at 1853:1-4 (quoting IPL Article 12-IV).

[233] *Id*. at 1859:14-23 (emphasizing statutory language such as "susceptible," "possibility," "exemplify," and "illustrated").

[234] Testimony of Fabian Salazar, Tr. at 1900:25-1901:5 ("The analysis is based on indications, references within the description which illustrate that the invention can be produced or used in any branch of economic activity. The examiner does not demand evidence or proof because that is not contemplated under the law.").

143. The definition of industrial applicability in Mexico was amended in 2010, but as Professor Gonzalez and Mr. Salazar confirmed, the statutory revisions merely clarified existing law and did not involve any substantive change in the requirement.[235] At the outset of the legislative process, there was an attempt to modify the standard substantively, for example by replacing the word "possibility" with "fact," a change supported by generic drug companies in Mexico.[236] This proposal, however, was rejected by the Mexican Senate. Canada's witness, Ms. Hedwig Lindner, an attorney who represents generic pharmaceutical companies and who participated in this legislative process as counsel to a major generic drug association advocating for the amendment,[237] acknowledged that the proposal was rejected in part because of concerns that it would be inconsistent with Mexico's treaty commitments, under which inventions that are merely capable of industrial application must be patentable.[238] Simply put, the Mexican requirement, before or after the 2010 amendments, does not in any way resemble Canada's promise utility doctrine: the mere possibility of a practical use suffices for industrial applicability in Mexico.

144. These unambiguous differences in doctrine in the United States and Mexico on the one hand, and in Canada on the other, are matched by a stark divergence in outcomes. While utility is routinely and often successfully challenged in Canada (at

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[235] Testimony of Gilda Gonzalez, Tr. at 1878:21 -23 ("The standard for industrial property has not changed with the 2010 amendment."); *id.* at 1881:4-8 ("It was to clarify the definition of the article, correct, because if the idea had been to change the standard for industrial application, they would have done so directly in Article 16."); Testimony of Fabian Salazar, Tr. at 1906:13-15 ("The practice of IMPI examiners regarding the analysis of industrial application did not change with the reform of the IPL in 2010.").

[236] Testimony of Gilda Gonzalez, Tr. at 1855:10-20 ("[I]n 2008 a number of legislators presented an initiative in order to amend this statute. There was an original proposal that was supported by, indeed, a national association of medicine manufacturers. They produce generic medicines. . . . What were they seeking? They were seeking to change the word 'possibility' and replace it with the word 'fact.'").

[237] Testimony of Hedwig Lindner, Tr. at 1941:22-1942:2 (acknowledging that her patent litigation work is for generic drug companies); *id.* at 1944:18-1948:5 (acknowledging her roles as counsel to major generic trade association and as supporter of the rejected reforms).

[238] *Id*. at 1955:20-1956:4 ("MR. SMITH: So the senators noted that there are many reasons not to change the word 'possibility' to 'fact,' including the ones you just discussed, right? MS. LINDNER: That is correct, yes. MR. SMITH: But an additional reason, and the first reason they mention in this report, was the international law obligation of Mexico not to make this change, correct? MS. LINDNER: That is correct, yes.").

least in the pharmaceutical sector since 2005), it is a non-issue in the rest of North America.[239]

145. In the United States, as Mr. Kunin testified, utility rejections during patent examination are exceedingly rare.[240] With respect to U.S. litigation, Professor Merges emphasized a multi-year survey in which only one patent, across 239 cases, was found to lack utility.[241] Professor Holbrook offered no contrary empirical evidence, either in general or with respect to pharmaceutical patents specifically,[242] and conceded that the scarcity of utility challenges suggests patentees are readily clearing the low U.S. bar.[243]

146. In Mexico, meanwhile, Canada's witness, Ms. Lindner, confirmed that no Mexican patent has ever been invalidated for lack of industrial application, before or

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[239] Cl. Opening Statement, Tr. at 92:16-93:8 ("According to one study only five challenges on utility were decided in U.S. courts over an 8-year period when NAFTA entered into force. . . . . In Mexico there's no evidence of even a single patent application being denied for lack of industrial applicability, nor is there evidence of even a single patent being declared invalid on that ground in a nullity proceeding. In Canada, by contrast, utility is routinely challenged. A majority of all patent validity rulings since 2005 include a decision on utility, some 53 percent, and in the pharmaceutical sector at least no fewer than 28 such challenges have been successful.").

[240] Testimony of Stephen Kunin, Tr. at 1424:2-13 ("With respect to utility rejections the USPTO has a Tribunal called the Patent Trial and Appeal Board ["PTAB"]. It reviews patent examiners' decisions in refusing to allow applicants' claims. I . . . looked at the decisions over a ten-year period . . . , and from these decisions and my review of the PTO's annual reports I determined that fewer than 1 percent of all final ex parte PTAB decisions involved a lack of utility rejection.").

[241] Testimony of Robert Merges, Tr. at 1299:2-6 ("[I]n that Allison/Lemley study from the American Intellectual Property Law Association quarterly journal, again, one patent in that study out of 239 cases was invalidated for lack of utility.").

[242] Testimony of Timothy Holbrook, Tr. at 1529:19-1530:2 ("You did not testify about or offer into evidence any other empirical study of U.S. case law and litigation outcomes, did you? PROFESSOR HOLBROOK: I did not. MR. SMITH: You did not provide any other statistical evidence that utility is a significant barrier for the pharmaceutical sector, did you? PROFESSOR HOLBROOK: I did not."); *id.* at 1531:5-9 ("And you don't dispute the accuracy of Mr. Kunin's statistics on the rarity of utility rejections of the — PROFESSOR HOLBROOK: No. MR. SMITH: — PTO?"); *id.* at 1531:10-16 ("You have not provided any empirical data or statistics to support your claim that pharmaceutical inventions in the U.S. have more difficulty than inventions in other fields clearing the high jump bar, right? PROFESSOR HOLBROOK: I have not relied on any empirical evidence.").

[243] Testimony of Timothy Holbrook, Tr. at 1528:13-19 ("So it's fair to say that, in the absence of litigation, results finding invalidity on the basis of lack of utility, applicants in the United States must be complying with the utility requirement? PROFESSOR HOLBROOK: I'd say there's a good chance that that's happening. It's a low bar.").

after the 2010 amendments.[244] Nor has any Mexican patent application ever been denied on that basis, as Professor Gonzalez and Mr. Salazar both attested.[245]

2. While Broadening the Lens to Other Patentability Requirements Is Inappropriate, Canada's New Promise Utility Doctrine Remains an Outlier Even when Compared to U.S. and Mexican Patent Law as a Whole.

147. About a decade after NAFTA entered into force, a sharp divergence in North America began to emerge on utility, in terms of both doctrine and practice. Canada did not, and cannot, dispute that the promise utility doctrine is categorically unlike utility in the United States and industrial applicability in Mexico. Instead, Canada attempted to broaden the lens and find connections to distinct patentability requirements and unrelated developments in U.S. and Mexican patent law more generally. These arguments are irrelevant, and the Tribunal need not reach them; but in any event, Canada's attempts to depict itself as in step with the other NAFTA parties fail.

148. *First*, Canada argued that utility is connected to distinct patentability requirements, such as enablement and written description in the United States, and that a "proper comparative analysis" requires consideration of all.[246] However, the fact that there is some relationship does not mean that these distinct legal requirements can be conflated, either in the United States or in Canada. Indeed, Canada has a separate requirement for sufficient description (also known as "sufficiency") that Professor

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[244] Testimony of Hedwig Lindner, Tr. at 1970:17-21 ("Yet, not a single patent in any field of technology has been invalidated based on the industrial application requirement, right? MS. LINDNER: I haven't found any case of nullity as such."); *see also* Testimony of Gilda Gonzalez, Tr. at 1861:4-10 ("No patent was ever invalidated for lack of industrial application, and I know of no instance in which an application for a nullity trial was based on a lack of industrial application.").

[245] Testimony of Gilda Gonzalez, Tr. at 1861:9-11 ("IMPI never refused to grant any application for lack of industrial application."); Testimony of Fabian Salazar, Tr. at 1906:15-20 ("[D]uring my almost 20 years at IMPI, I recall almost no refusal of an application for lack of industrial application, nor do I remember being asked for a technical opinion in a patent nullity proceeding based on a lack of industrial application.").

[246] Resp. Closing Statement, Tr. at 2312:23-2313:9.

Holbrook acknowledged is comparable to enablement in the United States.[247] As Lilly noted in its Closing, the Canadian courts held that the Zyprexa was sufficiently described because the patent taught how to make and use the invention.[248] The sufficiency of the Strattera patent was not even challenged.[249] Similarly, with regard to non-obviousness, the Canadian courts found the Zyprexa and Strattera patents to be inventive. Notably, with respect to the Zyprexa selection patent, this required an endorsement of olanzapine's advantages.[250] Both patents were invalidated solely on the basis of Canada's unique promise utility doctrine.

149. In the United States, as both Professor Merges and Professor Holbrook noted, the link between utility and enablement is a simple matter of logic: to teach how to make and use an invention, the invention must have a use, so an invention with no qualifying use, by definition, also has not been enabled.[251] The reverse, however, is not

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[247] Professor Holbrook said he was not familiar with the exact contours of the Canadian requirement for sufficiency of disclosure, but understood it to be "comparable to part of the enablement requirement of the United States" and assumed that it would serve similar policy concerns. Testimony of Timothy Holbrook, Tr. at 1473:19-1474:16. Yet the sufficiency requirement in Canada was omitted from his expert reports.

[248] Cl. Closing Statement, Tr. at 2065:10-20 ("Sufficiency of disclosure was advanced as a separate challenge and rejected because, as the court stated, the '113 patent describes the compound of the invention, its advantages and how to make it and the range within which it can be dosed."); *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, at ¶ 272 ("I must conclude, therefore, that Novopharm's attack on the sufficiency of the '113 patent fails.") (C-146).

[249] Cl. Mem. ¶ 127 (noting that the trial court rejected challenges to the Strattera patent based on obviousness, anticipation, and incomplete disclosure of the compound's selection).

[250] The same result was reached in a prior PM(NOC) proceeding regarding Zyprexa. The Federal Court found the patent valid after rejecting challenges on obviousness, anticipation, double patenting, and Section 53 misrepresentation. The trial court expressly considered, and accepted, the patent's advantages over the genus. *Eli Lilly Canada Inc. v. Apotex Inc.*, 2007 FC 455, at ¶¶ 350-51 ("The Court concludes that the discovery of the special advantages of olanzapine required empirical research and was inventive. Also, having considered the evidence as a whole, the Court has no doubt that the overall side effect profile described in the '113 Patent constitutes a substantial advantage of the selected compound over the other members of the '687 Patent as well as other known antipsychotic agents.") (R-207).

[251] Testimony of Robert Merges, Tr. at 1371:1-12 ("So section 112 as a matter of law incorporates section 101. PROFESSOR MERGES: Not quite. The utility requirement is necessary but not sufficient to satisfy the how to use prong of section 112. So in the sense of it being logically inclusive or prior, that's the relationship. 'Incorporates' is a little bit too loose, I think. If you have no use for your invention how can you possibly satisfy a requirement that says you have to teach people how to use it if there's no use. As a logical matter it's prior to the larger consideration."); Testimony of Timothy Holbrook, Tr. at 1511:12-20 (continued…)

true; inventions routinely pass the U.S. utility test but are found invalid for lack of enablement.[252] Indeed, Professor Holbrook conceded there could be no case in which an enabled invention was found to lack utility.[253] In light of these and other differences, Professor Holbrook testified that the requirements of enablement and written description are distinct from, and not co-extensive with, the utility requirement.[254]

150. Despite this concession, Professor Holbrook at other times continued to erroneously conflate references to "enablement," on the one hand, and to "utility," on the other. For example, when asked to identify the basis for his claim that Professor Merges said "post-filing evidence is routinely used to support enablement," Professor Holbrook pointed to passages in which the word "enablement" does not actually appear. He then sought to justify his error by alleging that Professor Merges "falsely believes that enablement and utility are different" and "ignor[es] the fact that [utility] also includes enablement."[255] Similarly, when asked about his claim that the "U.S.

("So section 101, which . . . requires a use, . . . is part of the section 112 enablement requirement on how to use, right? PROFESSOR HOLBROOK: Correct. MR. SMITH: And that's only because one cannot teach how to use without there being a use. PROFESSOR HOLBROOK: Correct.").

[252] Testimony of Timothy Holbrook, Tr. at 1512:14-1513:1 ("But the inverse logic is not correct, right? PROFESSOR HOLBROOK: Correct. There are occasions when there may not be a 101 rejection but there is a 112 rejection, that's true. MR. SMITH: So an invention can have a qualifying use but the description may fail to teach how to use the invention? PROFESSOR HOLBROOK: Correct. MR. SMITH: In that case the application would pass the utility test but fail the enablement test? PROFESSOR HOLBROOK: Yes.").

[253] *Id*. at 1514:3-12 ("Are you aware of a case in which a court found an invention to be enabled but not useful? PROFESSOR HOLBROOK: That would be nonsensical because to be enabled it has to be both useful and how to make. You have to teach how to make and use. If it doesn't have a use then you can't use it so no, it's not possible. MR. SMITH: There is no such case? PROFESSOR HOLBROOK: Correct.").

[254] *Id*. at 1502:3-11 ("You would agree that utility, enablement and written description are distinct requirements in U.S. patent law? PROFESSOR HOLBROOK: They are distinct doctrines."); *id.* at 1514:13-18 ("On that basis you agree as well that the requirements of enablement and written description are not co-extensive with the requirement for utility? PROFESSOR HOLBROOK: Absolutely, they're not co-extensive.").

[255] *Id*. at 1500:18-1501:24 ("[W]hat you have not noted is that he also does not use the word 'enablement.' Isn't that correct? PROFESSOR HOLBROOK: Because he falsely believes that enablement and utility are different . . . MR. SMITH: So when Professor Merges used the word 'utility' you believe he used the word incorrectly? PROFESSOR HOLBROOK: I believe he used it in a very narrow sense in that he was ignoring the fact that it also includes enablement. MR. SMITH: But he never, in either of his reports, asserted that post-filing evidence is routinely used to support enablement, correct? PROFESSOR (continued…)

doctrines of utility, enablement, and written description 'often rise or fall together,'" Professor Holbrook responded: "That's not my assertion. *That's the statement of the Federal Circuit.*"[256] When asked for his source, Professor Holbrook pointed to a Federal Circuit ruling that makes no reference to utility, and then to a distinct trial court ruling that makes no reference to enablement.[257] In the end, Professor Holbrook conceded that he had "extrapolated" from multiple cases in different courts, *none* of which states that utility, enablement, and written description "often rise or fall together."[258] The purpose behind this erroneous conflation was, presumably, to justify his opinion that utility in Canada is the same as enablement in the United States. But the evidentiary record simply does not support Professor Holbrook's academic thesis in this regard.

151. The distinct roles of the utility and enablement requirements, and the differences between U.S. enablement and Canada's promise utility doctrine, are well illustrated by the U.S. enablement cases on which Professor Holbrook and Canada relied at the Hearing. As Professor Merges explained, utility is a binary question of basic operability — does it work, yes or no — while enablement and written description involve questions of breadth, where broader claims require more teaching.[259] This is

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HOLBROOK: He did not use the word 'routinely.' That was my characterization of his testimony. MR. SMITH: And he did not use the word 'enablement,' correct? PROFESSOR HOLBROOK: He did not use the word 'enablement.'").

[256] *Id*. at 1505:25-1506:6 (emphasis added).

[257] *Id.* at 1508:16-20 ("There's no reference to 'utility' in that [Federal Circuit] quotation, is there? PROFESSOR HOLBROOK: Not in that quotation. The reference for utility comes from a different court.").

[258] *Id.* at 1509:1-18 ("Does that [different court] assert that utility, enablement, and written description often rise and fall together? PROFESSOR HOLBROOK: Well, I basically took what the Federal Circuit said, it said enablement and written description usually rise and fall together. Another court said written description and utility usually rise and fall together. If you realize that enablement incorporates utility as stated by the courts, typically enablement and utility rise and fall together. So if you're wanting to say that that extrapolation is my assertion, I'm comfortable with that . . . . "). Professor Holbrook then attempted to revise his original assertion — that the Federal Circuit had said all three doctrines often rise and fall together — by claiming that his testimony was "specific to" enablement and written description only. *Id*. at 1509:23-24 ("PROFESSOR HOLBROOK: I didn't attribute them to the Federal Circuit."); 1510:3-8.

[259] Testimony of Robert Merges, Tr. at 1291:19-1292:14 ("Enablement and written description are keyed to how broad your claim is, right? You've heard a lot about genus and species because that's a concept we use in patent law a lot, and you have to think about a patent claim as covering a technological space, right? It's a set of words that defines a verbal boundary and inside that boundary are many different (continued…)

exemplified by *In re Wright*,[260] a case presented by Professor Holbrook. The patent in that case claimed a wide range of vaccines against viruses, but provided only a single working example, and thus was found by the USPTO and the court to lack enablement with respect to the wider range.[261] This case, as Professor Holbrook noted, shows how enablement acts to police claim scope, the breadth of the claimed invention.[262] The inventor had discovered a vaccine for a specific virus, but claimed a far wider range of vaccines and viruses. There is nothing controversial in that result — nor is there anything in the decision comparable to Canada's promise utility doctrine. In particular, the analysis in *In re Wright* focused on enablement of the *claimed invention*, and whether the claims were adequately supported by the description. There was no "promise" analysis. Indeed, the holding in *In re Wright* is the *inverse* of the Zyprexa decision in Canada, where Lilly claimed a specific compound and claimed use of that compound for treatment of a specific disease (schizophrenia), but was held to a far wider range of "promised" utilities, including an implied promise of long-term effectiveness, based on statements in the disclosure, not the claims.

152. Other U.S. enablement cases presented by Canada at Closing are likewise distinguishable.[263] As Professor Merges emphasized, *Rasmusson* is an interference case

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embodiments which are things that are covered by that verbal formula. Enablement and written description have to do with have you taught enough to merit or deserve the breadth of your claims. Narrow claims, less teaching. Broad claims, more teaching. There's a sense of commensurateness that's built into enablement and written description. Utility is very different. We ask is the claimed invention workable, is it operable, does it basically work. We look at the nature of the invention from the claims and then we simply ask has it been shown or is it self-evident that it works, and, if so, you clear that first hurdle very, very easily.").

[260] *In re Wright*, 999 F.3d 1557 (Fed. Cir. 1993) (R-80).

[261] The court held that Dr. Wright had failed to teach how to make the claimed range of vaccines. *Id.* at 1562 ("The general description and the single example in Wright's specification . . . did nothing more in February of 1983 than invite experimentation to determine whether other vaccines having in vivo immunoprotective activity could be constructed for other RNA viruses.").

[262] Testimony of Timothy Holbrook, Tr. at 1452:14-1453:24 ("Enablement does act to police claim scope, breadth."); Holbrook Slide Presentation at 10.

[263] *See* Resp. Closing Statement, Tr. at 2314:16-2315:18 (discussing *Rasmusson* and *In re '318*).

in which the issue was which inventor had priority over the patent.[264] As is common in such cases, the court awarded the patent to the inventor who had done more work. It did not invalidate the patent for the benefit of a challenger who had done no work, as happened in the Zyprexa and Strattera cases in Canada. And, as Professor Merges emphasized, the *In re '318* case involved a patent with a written description no longer than one page, granted in 1987, at an extremely early stage of research in the Alzheimer's field.[265] The evidence of operability and the state of the art at the time of filing in the *In re '318* case in no way compare to the extensive evidence supporting Lilly's Zyprexa and Strattera patents.[266] Indeed, in the U.S. Strattera litigation, the Federal Circuit explicitly contrasted the very thin record of evidence in the *In re '318* case with the broad range of evidence supporting the Strattera patent.[267]

153. *Second*, Canada tries to justify its outlier utility doctrine by suggesting that if, as it asserts, enablement in the United States, the statutory reforms in Mexico, and the promise utility doctrine in Canada all reflect similar policy goals, it must be the case

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[264] Testimony of Robert Merges, Tr. at 1368:4-13 (describing summary of *Rasmusson* in Merges casebook); *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005) (R-63).

[265] Testimony of Robert Merges, Tr. at 1377:9-1380:23; *In re '318 Patent Infringement Litigation*, 583 F.3d 1317 (Fed. Cir. 2009) (C-279).

[266] Lilly extensively and successfully tested the Zyprexa and Strattera compounds before filing, including in humans. Cl. Mem. at ¶¶ 84-87, 119-122, 128-129. The patent in *In re '318*, by contrast, was summarized by the Federal Circuit as follows: "The specification for the '318 patent was only just over one page in length, and it provided almost no basis for its stated conclusion that it was possible to administer 'an effective Alzheimer's disease cognitively-enhancing amount of galanthamine.'' *See In re '318 Patent Infringement Litigation*, 583 F.3d 1317, 1321 (Fed. Cir. 2009) (C-279); *see also* Testimony of Robert Merges, Tr. at 1379:10-23 ("[G]alantamine is a compound — it's interesting. It appears in a natural product, . . . the Eurasian snowdrop, and it was one of these things where chemists had an interest in the compound, but because the mechanism for Alzheimer's is not particularly well known even to cite animal studies for related compounds in that setting, this court said, was not enough to show that it would work because it was just too early in the history of that field, but in many cases, once you have the characteristics of the compound well understood, citing animal or even in vitro studies of related compounds could be enough to support workability for the claimed invention.").

[267] *See Eli Lilly & Co. v. Actavis Elizabeth LLC*, No. 2010-1500, at 8 (Fed. Cir. July 29, 2011) ("In the case of atomoxetine, however, the norepinephrine relationship was known, safety for antidepressant activity had been established, the specification contained a full description of the utility, experimental verification had been obtained before the patent was granted, and the examiner had not requested additional information.") (C-83).

that the doctrines are substantively similar as well.[268] But the mere fact that countries might share similar, broad policy goals does not imply that the legal rules themselves are similar or that the promise utility doctrine is legitimate. For example, in the name of promoting personal safety in public transit, the government may mandate the installation of bright lights in transit stations, or alternatively may allow transit users to carry semiautomatic weapons. The simple fact that both legal rules may be traceable in some way to the same, general policy objective of promoting public safety does not mean that these measures are similar in design or scope, or that they would have similar effects.

154. *Third*, Canada attempted to identify changes in U.S. law to support its position that changes in the Canadian utility requirement reflect normal common law development. In particular, Canada asserted that patentability requirements in the United States have undergone similar revisions at the hands of the courts.[269] This argument, notably, concedes that the utility requirement in Canada has changed; moreover, it is erroneous as to purported changes in U.S. law. With regard to Canada's assertion that the U.S. utility requirement tightened over time, Professor Merges and Mr. Kunin explained that this is not the case. Both experts testified that the U.S. case cited by Canada in support of its argument, *In re Fisher*, merely applied traditional U.S. utility doctrine to an area of new technology.[270] As for changes to other requirements,

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[268] Resp. Closing Statement, Tr. at 2315:19-21 (arguing that for U.S. enablement and the promise utility doctrine "there really is a similarity in terms of goals, in terms of trying to police speculative patenting"); *id.* at 2148:9-11 (arguing that "the drafters of the 2010 legislation were directly concerned with the same sort of speculative patenting in Mexico").

[269] Resp. Closing Statement, Tr. at 2313-14 (arguing that the U.S. utility standard was "tightened" over time "as new issues have come before the U.S. courts"); *id.* at 2216-17, 2282 (discussing the potential impact of the *Alice* ruling by the U.S. Supreme Court on the patentability of software).

[270] Testimony of Robert Merges, Tr. at 1360:4-13 ("Fisher was a case that involved patent applications on these little gene snippets which required an application of utility doctrine to this new kind of technological ideas. It's typical of cases sort of at the forefront where you get a little bit of ferment or wavering. Or you might say at the cutting edge of the law opinions can differ, but you're talking about arguments about whether the line is here or here. . . . These are small arguments."); Testimony of Stephen Kunin, Tr. at 1423:7-16 ("The 2001 utility guidelines did not change the utility standard applied by the USPTO. If you look at the In re Fisher case, you'll see that in the Fisher case what the Federal Circuit does is it looks at the utility guidelines and essentially says that the utility guidelines are consistent with the (continued…)

Professor Merges explained that none of the other developments in U.S. patent law identified by Canada or Professor Holbrook resemble the radical transformation of outcomes produced by the promise utility doctrine in Canada.[271] Of course, even if there were some comparably dramatic change in some aspect of U.S. or Mexican patent law, it would not justify or inoculate Canada from responsibility for the striking change in Canada's utility requirement since 2005.

155. In sum, despite Canada's arguments to the contrary, nothing in U.S. or Mexican patent law resembles Canada's new promise utility doctrine, which is an outlier in terms of both legal principles and validity outcomes. If Canada were correct that the U.S. and Mexican patent law systems, considered as a whole, have rules that resemble the promise utility doctrine, one would expect to see some evidence of similar invalidations in all three jurisdictions with respect to the very same patents. Yet, among the more than 20 patents found to lack utility by Canadian courts, Canada has not identified a single case in the United States or Mexico where a patent revoked in Canada on the basis of the promise utility doctrine was invalidated on enablement or written description grounds in the United States, or on any ground in Mexico. There is no credible evidence of similarity, either with regard to utility or more generally. The promise utility doctrine is *sui generis*. This is presumably why U.S. Government "Special 301" reports on the adequacy of intellectual property protections among U.S. trading partners have, since 2013, expressed "serious concerns" relating to "the heightened utility requirements for patents that Canadian courts have applied recently" to invalidate pharmaceutical patents.[272] These reports also discuss the intellectual property laws of Mexico (and dozens of other states), yet express no concerns whatsoever about the utility requirements of any country other than Canada.

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standard applied by that court, and also makes reference to the fact that the basic standards for utility again come from the Brenner v Manson 1966 case.").

[271] Testimony of Robert Merges, Tr. at 1302:16-1305:2 (discussing *Ariad* and *Alice* decisions and concluding that neither thus far has produced a dramatic shift in U.S. law, measured in terms of litigation outcomes).

[272] Office of the United States Trade Representative, 2014 SPECIAL 301 REPORT 49-50 (Apr. 2014) (C-331); *see* Cl. Reply at ¶ 52; Office of the United States Trade Representative, 2015 SPECIAL 301 REPORT 66-67 (Apr. 2015) (same language) (C-332).

156. Canada's recent status as an outlier within NAFTA, as demonstrated by the expert testimony at the Hearing and confirmed by views of other NAFTA states, provides further evidence that Canada's law on utility has undergone a radical change.

F. International Discussions Regarding Utility/Industrial Applicability Demonstrate the Radical Change in Canada's Utility Requirement.

157. The testimony of Mr. Philip Thomas and Mr. Jay Erstling confirmed that the traditional utility requirement, a low bar for patentability, was uncontroversial not only in Canada prior to 2005, but across a range of other countries. *See* Part II.F.1. Canada's experts did little to rebut this showing. Rather, the Hearing revealed that Professor Daniel Gervais's testimony was grounded in selective readings of the documents upon which he relied — none of which provided any support for the proposition that an approved and marketed pharmaceutical product could be invalidated for lack of utility. Meanwhile, Mr. David Reed, who is not a lawyer, confirmed that the PCT definition of industrial applicability is widely accepted by PCT member countries. *See* Part II.F.2.[273]

158. The shared international understanding of utility reflected in WIPO negotiating documents confirms that Canada's promise utility doctrine constitutes a new and radical departure from the traditional patent law concept of utility, as reflected in the laws of many countries. Moreover, this shared understanding sheds light on the proper interpretation of the terms "useful" and "capable of industrial application" in international agreements, including NAFTA.

1. Negotiations at the World Intellectual Property Organization Demonstrate that the Traditional Utility Requirement Was Uncontroversial Not Only in Canada, but Across a Range of Member States.

159. Much of the expert testimony on the international norm for utility has focused on international negotiations at WIPO. Canada raised these WIPO negotiations for the first time in its Counter-Memorial in support of its argument that the utility

[273] This Section responds in part to the Tribunal's ***Question 12*** asking what is the "relevance, if any, of the Patent Cooperation Treaty, for the purposes of determining Claimant's claims."

requirement was the subject of international controversy, and that it was applied differently across jurisdictions both before and after the conclusion of NAFTA.[274]

160. However, as shown through the testimony of Professor Gervais and Mr. Thomas, the record of WIPO discussions demonstrated no such thing. At the WIPO negotiations on a Substantive Patent Law Treaty ("SPLT"), the central tenet of the utility requirement — that "an invention must have some practical use" — was not the focus of discussions.[275] Mr. Philip Thomas, the former director of the Patent Policy Department at WIPO, a role in which he supervised the staff preparing draft texts of the SPLT, testified that the central tenet of utility was not a point of controversy at all during the negotiations.[276]

161. Drawing on his experience as a participant in all meetings of the Standing Committee on the Law of Patents concerning drafts of the SPLT,[277] Mr. Thomas noted that countries wanted to see that "the practical outcome of filing applications and of obtaining patents [was] substantially the same in other countries, and the fact that different language may be used in legislation [was] — well, a subsidiary matter."[278] Although WIPO member states used different language to describe the utility requirement, "[i]t was a low bar to patentability," and "there was consistent practice in the practical outcomes in the sense that very few applications at this stage were rejected

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[274] Resp. CM at ¶ 192.

[275] Testimony of Philip Thomas, Tr. at 1695:16-22 ("The fundamental point I'd like to make at the outset is that the central tenet or the core principle of the utility requirement was not the subject of controversy during any negotiations which I took part in in my career, so I mention the central tenet or core principle which I describe as being that an invention must have some practical use.").

[276] *Id*. at 1696:4-11 ("It is a very low bar to patentability. Different legislation uses different language in order to implement or elaborate this requirement, but the fact that there are those differences was not controversial. In particular, that central tenet of the requirement was not a point of controversy in either of the two sets of negotiations which my report deals with."); *id*. at 1698:1-7; *see* Thomas Report at ¶ 4.

[277] Testimony of Philip Thomas, Tr. at 1698:1-13 ("I say this as someone who worked in WIPO for nearly 20 years. . . . I took part in all meetings of the WIPO body which considered those drafts, the Standing Committee on the law of patents, or SCP. Prior to that, I'd been in the Australian Patent Office, which I left as an assistant commissioner responsible for policy and legislation matters.").

[278] *Id*. at 1708:2-6.

on the basis of the utility requirement."[279] Indeed, it was precisely because of the consistency in practical outcomes that "there was simply no need for an agreed wording" in nomenclature.[280]

162. Professor Jay Erstling, another former senior official at WIPO, corroborated these points. As he explained at the Hearing, the PCT, which is administered by WIPO, also shows that the traditional utility requirement was uncontroversial across a range of WIPO member states.

163. While the PCT "is not a substantive law treaty and . . . does not harmonize law," Professor Erstling emphasized that "it's a treaty that is informed by and reflects understandings and norms about patent law and particularly about the substantive conditions of patent law."[281]

164. In particular, Article 33 of the PCT provides a definition of industrial applicability — one that, according to Professor Erstling and consistent with Mr. Thomas's testimony about WIPO negotiations, constitutes a low bar to patentability:

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[279] *Id*. at 1713:4-8. Canada sought in its Closing to portray Mr. Thomas's testimony on this point as inconsistent with a "contemporaneous documentary record that was prepared by his own organization when he was there." Resp. Closing Statement, Tr. at 2147:21-22. This obscure document, the informal 2001 WIPO study on utility that was "not noted or discussed" by delegates to WIPO's Standing Committee on Patents, *see* Testimony of Philip Thomas, at 1705:3-4, states that "there is a wide range of differences among SCP members concerning the interpretation and practice relating to the 'industrial applicability/utility' requirement," WIPO, "The Practical Application Of Industrial Applicability/Utility Requirements Under National And Regional Laws" (April 2001) (R-407); *see* Testimony of Philip Thomas, at 1712:5-11. As Mr. Thomas testified, the word "practice" in this sentence referred simply to regulations, guidance and other legal implementing texts — not to the practical focus and results of the utility analysis. Testimony of Philip Thomas, Tr. at 1712:12-19. Later drafts of the document confirm Mr. Thomas's reading, noting that "*practices* in the countries which require utility (or usefulness) vary," but going on to clarify that the "practices" of these countries lead to common outcomes, such as the rejection of "absurd or non-realistic" uses. WIPO, "Industrial Applicability" and "Utility" Requirements: Commonalities and Difference, document SCP/9/5 (17 March 2003), at ¶¶ 49-51 (R-230) (emphasis added). As the document explains, "[u]nder the *practice* of the United States of America, this concept seems to be covered *by the expression* 'specific and substantial utility.'" *Id*. at ¶ 51 (emphasis added). Under the practice of Australia and Canada, different words ("manner of manufacture") were used to achieve the same effect. *Id*.

[280] Testimony of Philip Thomas, Tr. at 1697:20-25.

[281] Testimony of Jay Erstling, Tr. at 1603:4-9.

> Article 33 defines industrial applicability by saying that an invention is industrially applicable if it can be made or used in a technological sense in any kind of industry with industry having the broadest definition. This is a longstanding, non-controversial and generally accepted definition of industrial applicability. It's actually a very low bar and, among the substantive conditions of patentability, it's the lowest bar.
>
> Its purpose is to root out inventions that defy laws of nature, that are simply not operable, or workable, or inventions the use of which has not yet been determined.[282]

Canada's expert on the PCT — Mr. Reed — likewise acknowledged that PCT Article 33 guides international patent examinations with regard to the widely-accepted meaning of the industrial applicability requirement.[283]

165. The PCT's definition of industrial applicability thus reflects a shared understanding among WIPO member states of the traditional requirement's low bar. That definition, moreover, as Professor Erstling noted, is widely deemed to be synonymous with utility, according to the PCT, NAFTA, TRIPS, and other international instruments.[284]

2. Canada Has Failed to Show There Was Any Controversy about Utility During the WIPO Negotiations.

166. In support of Canada's argument that utility was controversial during WIPO negotiations, Canada and its expert witness, Professor Gervais, rely heavily on studies from 2001 and 2003 conducted by the WIPO Secretariat. According to Canada, these studies indicate that the notions of industrial applicability and utility apply

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[282] *Id*. at 1573:16-1574:4.

[283] Testimony of David Reed, Tr. at 1641:13-1642:2 ("In the search of prior art and also of the written opinion, the examiners will follow the guidelines that are provided under the WIPO . . . . [A]s to whether the invention appears to be novel or appears to be inventive or have industrial application or utility, these are judged against the guidelines in the PCT in Article 33. . . . Article 33 does give the standards that you can go in and see what the examiner is using to make the judgments on that.").

[284] Testimony of Jay Erstling, Tr. at 1573:9-15 ("Article 33 of the PCT, for the purposes of international preliminary examination, provides definitions of the substantive conditions of patentability, of novelty, of inventive step and of industrial applicability which, according to the PCT, as well as NAFTA and TRIPS and other international instruments, is synonymous with utility.").

differently across jurisdictions.[285] But Canada's argument rests on a misreading of these reports. As witness testimony made clear, the 2001 and 2003 WIPO studies not only reveal no controversy at all regarding the central tenet of utility, they also indicate the complete absence of any discussion, let alone disagreement, regarding the utility of patents for pharmaceutical inventions relating to approved drugs.

167. As an initial matter, these reports — Canada's key pieces of evidence — were not "acknowledged," "mentioned," or "discussed" at any WIPO negotiating session.[286] As Mr. Thomas explained at the Hearing with respect to the 2003 study: "It was just there, but it attracted no interest. There's certainly no basis for saying there was any controversial discussion on the basis of it. Indeed, there was no discussion of that study."[287] Mr. Salazar also attended the negotiations and confirmed, in his Second Report, that "industrial applicability was not one of the contested issues."[288]

168. In any event, the studies reflect the traditional, low bar of the utility requirement. At the Hearing, Professor Gervais conceded that the reports list only wholly inoperable inventions as ones that would fail to meet the utility/industrial

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[285] Resp. Closing Statement, Tr. at 2147:18-23, 2317:24-2319:10 ("[T]here is significant variance amongst jurisdictions in the industrial application and utility standards. I'll just bring you to a couple of documents as an example."); *see* Testimony of Daniel Gervais, Tr. at 1744:7-11 ("The 2001 study that is referred to in my report, that was highlighted in a previous expert's testimony, makes very clear that this is not just a matter of nomenclature but a matter of practice. The word 'practice' is there; it's quite clear."); *id*. at 1745:25-1746:2, 1781:21-1782:11; *see also* WIPO, "Industrial Applicability" and "Utility" Requirements: Commonalities and Difference, document SCP/9/5 (17 March 2003), online: http://www.wipo.int/edocs/mdocs/scp/en/scp_9/scp_9_5 (R-230); WIPO, "The Practical Application Of Industrial Applicability/Utility Requirements Under National And Regional Laws" (April 2001) (R-407).

[286] Testimony of Philip Thomas, Tr. at 1704:19-1705:4 ("The other point to make is that, in referring to the matter of promise being acknowledged by the Committee, well, the 2001 study was on the table. It was an informal document, but it was made available to members of the committee. The 2003 study was submitted as a formal document. But on neither occasion did the committee acknowledge the report. It was not mentioned by any delegation in the reported minutes — in the minutes reporting the results of the Committee's deliberations. It was not noted or discussed by the Committee.").

[287] *Id*. at 1701:16-20; *see id*. at 1728:21-25 ("When one looks at the minutes of the meeting which considered the document, the only reference to it is the fact that it was on the table. There was no noting, no acknowledging, no approval — nothing.").

[288] Second Report of Fabian Salazar, at ¶¶ 59-60.

applicability requirement. The examples, he acknowledged, include a perpetual motion machine (which Professor Gervais described as "the classroom textbook example"[289]), "a ghost catcher," and "a method for preventing the increase in ultraviolet rays associated with the destruction of the ozone layer by covering the whole surface of the earth with an ultraviolet ray absorbing plastic film."[290]

169. Although the reports refer to the word "promise,"[291] Mr. Thomas explained that there is "no elaboration of what the approach was on promise, and certainly there's nothing there which would suggest that anything was taking place such as is currently the subject of some contention in these proceedings."[292] Rather, as explained above and as Professor Gervais acknowledged, the only examples about how this requirement operates in practice relate to wholly inoperable devices.[293] As Canada acknowledged, the language it submitted in 2001 and 2003 for the WIPO survey merely

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[289] Testimony of Daniel Gervais, Tr. at 1783:12-13.

[290] *Id*. at 1783:5-1784:6; *id*. at 1795:24-1796:15 ("Let's start with paragraph 40, which is 'Under the law of Canada, the term 'invention' means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter. Utility means having industrial or commercial value in a manner that benefits the public. For example, a perpetual motion machine that serves no useful purpose does not comply with the utility requirement.' Do you see that? PROFESSOR GERVAIS: I do. MR. BERENGAUT: The perpetual motion machine is back. PROFESSOR GERVAIS: Again.").

[291] Testimony of Philip Thomas, Tr. at 1704:2-7 ("In looking particularly at the 2001 study, since Professor Gervais mentions that expressly in his Second Report, the word 'promise' is most certainly used, but to suggest that a promise approach is discussed in that study would exaggerate the position.").

[292] *Id*. at 1704:11-15.

[293] *Id*. at 1788:11-1789:19 ("MR. BERENGAUT: Paragraph 19 does have two examples. . . . The first one is 'An invention related to control circuits for gas discharge lamps. The specification indicated that the invention would reduce heat generation in the ballast. However, the evidence was that some circuits falling within the scope of the claims failed to work and caused lamp failure because of excessive heat generation. Consequently, the promise of the invention was not fulfilled.' Do you see that? PROFESSOR GERVAIS: I do. MR. BERENGAUT: In this example, the lamp did not work, correct? PROFESSOR GERVAIS: Well, it did not work as claimed, I suppose. It doesn't say didn't work at all; it said there was eventually failure causing excessive heat generation, so it may have worked for a while. I don't know. The example isn't precise enough. MR. BERENGAUT: So, despite the reference to the fact that excessive heat generation caused lamp failure, you're unsure whether the lamp worked in that example? PROFESSOR GERVAIS: It eventually failed. It doesn't mean that it didn't work at the beginning, is what I'm saying. MR. BERENGAUT: Okay. In the next example is the promise of a cheese for permanent keeping. Are you aware of an invention that is operable that keeps cheese permanently? PROFESSOR GERVAIS: No, I am not.").

quoted *Consolboard*.[294] For the reasons given at Part II.C.2(a)(1), above, that language in *Consolboard* was never interpreted as reflecting an elevated, bifurcated requirement until later, in 2005.

170. Tellingly, Professor Gervais could point to nothing in the studies suggesting that an approved pharmaceutical invention claiming to treat a specific medical condition could lack industrial applicability or utility.[295]

171. The Hearing also revealed that Professor Gervais — who did not attend the WIPO negotiations[296] — substantially over-read documents in order to make his points. For example, he discussed several documents cited in his reports related to patent law harmonization: the Joint Proposal (a priority list of issues circulated by the United States, Japan, and the European Patent Office to try to focus the talks and spur progress during the SPLT negotiations),[297] the Tegernsee Group Report,[298] and the

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[294] Resp. Closing Statement, Tr. at 2252:7-9 ("[I]n 2001 and 2003, Canada submitted information on its utility standard to WIPO quoting the same wording that is found in Consolboard.").

[295] Testimony of Daniel Gervais, Tr. at 1784:4-1787:7 ("MR. BERENGAUT: Again, no indication in these examples of a pharmaceutical invention that claimed to treat a medical condition and actually treated that condition being found to lack industrial applicability, is there? PROFESSOR GERVAIS: In those examples, no."); *id*. at 1796:16-1798:15 ("MR. BERENGAUT: Again, no references in this paragraph to a pharmaceutical invention that claims to treat a condition and actually treats that condition being invalidated because it does not comply with the utility requirement, correct? PROFESSOR GERVAIS: In this paragraph, no.").

[296] *Id*. at 1764:1-5 ("MR. BERENGAUT: Just to be clear, Professor, the WIPO sessions to which Mr. Thomas refers that you're discussing in this paragraph, you did not attend those sessions, correct? PROFESSOR GERVAIS: Correct."); *id*. at 1801:14-16 ("I do not know what, again, they were thinking. I wasn't there. I'm just reading the documents and drawing conclusions from what it says."). In addition to having no personal knowledge of the relevant negotiations, Professor Gervais seemed unfamiliar with basic principles of treaty interpretation under the Vienna Convention. *See* Testimony of Daniel Gervais, Tr. at 1832:16-1833:10 ("THE PRESIDENT: Are you allowed to look outside this treaty under 31(1)? PROFESSOR GERVAIS: Well, that's the whole question of other relevant norms. There's some jurisprudence on what other relevant norms are that I'm sure you're well aware of. Are you allowed to? Yes. . . . THE PRESIDENT: Under 31(1), I have not seen that one. . . . PROFESSOR GERVAIS: I was talking about 31 globally. Sorry. THE PRESIDENT: Let's take it paragraph by paragraph, because the holistic view of 31 is already a dangerous exercise in my view.").

[297] *Id*. at 1798:23-1799:5 ("MR. BERENGAUT: Next topic. In your report you talk about the joint proposal. This is paragraph 44. You testified that 'After several rounds of negotiations on the basis of those WIPO documents, the United States, the European Union and Japan presented in 2004 a proposal (the 'Joint Proposal') to try to move the debate forward. PROFESSOR GERVAIS: Yes."); *see also* Gervais First Report at ¶¶ 44-47.

United States Patent and Trademark Office notice of a roundtable on the Tegernsee Group Report.[299] Professor Gervais made much of the fact that the utility/industrial applicability requirement is not discussed in these documents.[300] He testified that the omissions indicate utility had not been "an easy target for negotiators and an easy 'win' for WIPO."[301] That is, Professor Gervais assumed that WIPO member states declined to address utility because it was a topic of sharp disagreement.

172. But Professor Gervais created this explanation out of thin air. At the Hearing, Professor Gervais could not point to any language in the documents explaining why the utility/industrial applicability requirement was omitted.[302] On

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[298] Testimony of Daniel Gervais, Tr. at 1802:21-1803:6 ("MR. BERENGAUT: You make a similar point about the Tegernsee Group. Let's go back to your First Report, paragraph 53. This was, as you quote, 'a new dialogue on the state of affairs concerning international harmonization of substantive patent law.' And you note that this Tegernsee Report does not discuss the harmonization of utility or industrial applicability. That's a quote from the middle of paragraph 53. PROFESSOR GERVAIS: I see it.").

[299] *Id*. at 1805:7-13 ("MR. BERENGAUT: Going back to paragraph 53 of your First Report, you cite the USPTO notice of a Roundtable on the Tegernsee Group report, and you note about it that, again, utility and industrial applicability are left out. Do you see that? PROFESSOR GERVAIS: I do.").

[300] *Id*. at 1799:13-1801:16 ("PROFESSOR GERVAIS: . . . So the first paragraph [of the Joint Proposal] actually says there's a list of issues, and it does mention industrial applicability, and then basically leaves it out."); *id*. at 1803:2-6 ("MR. BERENGAUT: . . . And you note that this Tegernsee Report does not discuss the harmonization of utility or industrial applicability. That's a quote from the middle of paragraph 53. PROFESSOR GERVAIS: I see it."); *id*. at 1805:7-13 ("MR. BERENGAUT: Going back to paragraph 53 of your First Report, you cite the USPTO notice of a Roundtable on the Tegernsee Group report, and you note about it that, again, utility and industrial applicability are left out. Do you see that? PROFESSOR GERVAIS: I do.").

[301] *Id*. at 1800:1-8; *id*. at 1803:7-15 ("MR. BERENGAUT: Now, your opinion is that the reason utility/industrial applicability was not included in the Tegernsee Report was because it was the subject of disagreement, right? PROFESSOR GERVAIS: I don't know for a fact that that's what happened but I do not draw inference from the fact that it's not on the list, that there was agreement, because every document I see points me in the other direction."); *id*. at 1806:5-11 ("MR. BERENGAUT: No indication why utility or industrial applicability were left off the agenda for the session? PROFESSOR GERVAIS: Well, the words mean what they mean. It says 'issues most suitable for further progress.' This one is not most suitable for further progress. It doesn't tell us why.").

[302] *Id*. at 1800:13-1801:2 ("MR. BERENGAUT: And nothing in the document, R-235 [the Joint Proposal], which is behind tab 14, says why utility was left off the agenda, does it? . . . . PROFESSOR GERVAIS: . . . It doesn't, I believe, say why it leaves it out directly . . . ."); *id*. at 1803:24-1804:7 ("MR. BERENGAUT: . . . You have not cited to any language in this report explaining why utility or industrial applicability was left out, do you? PROFESSOR GERVAIS: Correct, I don't recall seeing that language in there. I'm not saying it's not, but I do not recall seeing it when I read it."); *id*. at 1805:14-1806:11 ("MR. BERENGAUT: (continued…)

cross-examination, he conceded it was possible that the utility/industrial applicability requirement was omitted from the reports because it was not causing any problems in practice.[303]

173. Other evidence directly contradicts Professor Gervais's explanation for the omissions. With respect to the Joint Proposal, Mr. Thomas proffered that 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.[304] And there is no evidence that any stakeholder, in response to requests for feedback from the Tegernsee Group,[305] identified utility or industrial applicability as, in Professor Gervais's words, "caus[ing] problems due to differences in laws practiced in each country."[306] Indeed, Professor Gervais ultimately conceded it was a "reasonable inference" that industrial applicability/utility was not an important topic to put on the table for harmonization.[307]

174. Moreover, as Professor Gervais further admitted, his First Report omitted obviously relevant and highly significant language from a joint World Trade

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No indication why utility or industrial applicability were left off the agenda for the session? PROFESSOR GERVAIS: . . . It doesn't tell us why.").

[303] *Id*. at 1801:23-1802:3 ("MR. BERENGAUT: Well, isn't it possible, then, Professor, that the reason utility was left off the agenda was because negotiators did not think it was a priority to harmonize those definitions? PROFESSOR GERVAIS: It's possible. MR. BERENGAUT: And isn't it possible that the reason they did not think it was a priority to harmonize those definitions was because at the time there was little variation in practical outcomes among countries regarding utility? PROFESSOR GERVAIS: It's possible . . . ."); *id*. at 1804:8-16 ("MR. BERENGAUT: So, Professor, isn't it possible that here again, the reason that utility and industrial applicability were not included was because it was not important for parties to harmonize their utility/industrial applicability requirements because they were not causing any problems in practice? PROFESSOR GERVAIS: Theoretically, yes . . . .").

[304] *See* Testimony of Philip Thomas, Tr. at 1725:20-1726:2 ("MR. THOMAS: This suggestion by the International Bureau is that the SCP 'may' wish to consider — I wouldn't use the word 'must' — but it may wish to consider the possibility of doing these things, but in practice the SCP did not so proceed, and I think that is borne out in the statement made in paragraph 12 of my report. Priority was not given to this matter."); *see also* Thomas Report at ¶ 37.

[305] Testimony of Daniel Gervais, Tr. at 1806:12-16 ("MR. BERENGAUT: Were you aware, Professor, that other countries also responded to the requests for feedback from the Tegernsee Group? PROFESSOR GERVAIS: I haven't read those submissions.").

[306] *Id*. at 1807:1-1809:10.

[307] *Id*. at 1809:5-10.

Organization ("WTO"), WIPO, and WHO study, language that reflects the traditional definition of industrial applicability/utility and expressly states that the application of this requirement by member states, in fact, poses no problems:

> Industrial applicability (or utility) means that the invention can be made or used in any industry, including agriculture, or that it has a specific, credible and substantial utility. *In general, the application of this requirement does not pose practical problems.*[308]

Professor Gervais, in his testimony about this joint study, also asserted that WIPO member states had particular concerns over pharmaceutical patents — but he conceded that those concerns do not appear in the text.[309] In other words, at the Hearing as in his written reports, Professor Gervais sought to conjure support for his creative interpretation of the negotiations by selectively citing WIPO studies that did not at all support the proposition that utility was a controversial issue or that Canada had anything other than a traditional utility test pre-2005.

175. In sum, while there are differences in nomenclature across jurisdictions (*e.g.*, with the use of "industrial applicability," "useful," or "utility"), these variations do not detract from the substantive common core of the utility requirement. No WIPO documents referenced by Canada or by Professor Gervais suggest otherwise.

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[308] WTO, WIPO and WHO, Promoting Access to Medical Technologies and Innovation, Intersections between public health, intellectual property and trade (2013), at 59 (emphasis added) (R-220); Testimony of Daniel Gervais, Tr. at 1811:7-23 ("PROFESSOR GERVAIS: Yeah, I agree with that. For most types of inventions, it doesn't. That paragraph is quoted in my Second Report, by the way. MR. BERENGAUT: . . . . You do not quote it in your First Report, correct? PROFESSOR GERVAIS: No.").

[309] Testimony of Daniel Gervais, Tr. at 1813:3-1815:6 ("[P]aragraph 59 does not give a unique definition. There is one definition followed by 'or' in the second. And, second, what I said was in general, it is true — however you define utility and industrial applicability, and it doesn't mean there's consensus on what it means, what it means is, in general, most inventions, certainly outside of biotech and pharma, will easily surpass whatever definition a country adopts, or meet the test. . . . MR: BERENGAUT: Professor, in your answer just now, you said what it means is in general, most inventions, certainly outside of biotech and pharma, will easily surpass whatever definition a country adopts. . . . Now, in this paragraph, there is no discussion of difficulties faced by the pharmaceutical industry, is there? PROFESSOR GERVAIS: Well, it says — it mentions biotech, which I believe is not that far from pharma . . . . MR. BERENGAUT: There's no indication in this paragraph that, apart from this one area of biotechnology, in the broader context of pharmaceutical inventions, utility 'needs some consideration,' is there? PROFESSOR GERVAIS: Not in this paragraph."

III. No Treaty or Customary Principle Exempts Judicial Measures from Articles 1110 and 1105 of NAFTA.

176. Canada insists that the only claim Lilly can assert before this Tribunal is a claim for denial of justice.[310] As became clear at the Hearing, moreover, Canada agrees that denial of justice is a purely procedural doctrine that does not apply where a court has breached a substantive rule of international law.[311] Thus, on Canada's view, there can be no remedy under NAFTA where a court takes or mistreats an investment by applying a doctrine that is substantively arbitrary, that is discriminatory, that violates legitimate investment-backed expectations or that conflicts with relevant international obligations of the host state. *See* Part III.A.

177. Canada's categorical position must be rejected. Canada has no answer to the substantial body of arbitral authorities — in the context both of expropriation and the Minimum Standard of Treatment — analyzing judicial measures and finding violations without any allegation (let alone proof) of a denial of justice. If Canada were correct that denial of justice is the *only* theory of liability for judicial measures, these awards would not exist. *See* Part III.B.

178. By the same token, if Canada's categorical position were correct, there would be at least some authority supporting it. Yet, no treaties, no tribunals, and only one scholar (even arguably) support Canada's position. *See* Part III.C.[312]

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[310] *See* Resp. Closing Statement, Tr. at 2149:13-24; Resp. Rejoinder at Parts IV.B, V.B.

[311] Resp. Closing Statement, Tr. at 2208:4-23; *see infra* Part III.A.

[312] This Part III responds to the Tribunal's ***Questions 13, 23(a), 28, 38,*** and ***40***. ***Question 13*** invited the parties to address whether "denial of justice [is] the only basis of liability in international law for the judgments of domestic courts interpreting domestic law." ***Question 23(a)*** asked: "is a denial of justice a prerequisite for a finding of expropriation based on a judicial measure?" ***Question 38*** sought the parties' views on "whether an alleged expropriation as a consequence of a judicial decision is or is not limited to a denial of justice and what, for purposes of this answer, they mean by denial of justice." ***Question 40*** asked, "what relevance, if any, does practice under the U.S. takings clause have for these proceedings?"

A. Both Parties Agree that Denial of Justice is a Purely Procedural Doctrine That Does Not Apply in Situations Where a Court Has Breached a Substantive Rule of International Law.

179. As Canada argued in its Opening, courts often act as "expositors of what the law is, and neutral adjudicators of how it applies."[313] But as Canada acknowledged at Closing, courts also make new law: "In the common law world some of the most important legal developments have occurred when a country's Supreme Court overrules its own previously longstanding judicial precedent."[314]

180. The doctrine of denial of justice is capable of addressing only the first (adjudicatory) role of the courts, not their second (lawmaking) role.[315] This is because, as both parties agree, the doctrine addresses only procedural wrongs.[316] As Canada put it: "denial of justice focuses upon the procedural aspects of the adjudication rather than the substantive reasons for the decision."[317]

181. The limited, procedural focus of the denial of justice doctrine is well-established, and is supported by a well-known rationale. As explained by Professor Jan Paulsson, whom both parties have relied on as an authority on the denial of justice

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[313] Resp. Opening Statement, Tr. at 240:14-16.

[314] Resp. Closing Statement, Tr. 2216:14-18; *id*. at 2217:5-8 ("*Changes in the law*, corrections, consolidations, rationalizations . . . these are all normal aspects of a functioning judicial system." (emphasis added)); *id*. at 2214:6-7 ("It's what courts do. They interpret. They evolve. Sometimes they overrule."). Canada correctly points out that judicial lawmaking "by itself, cannot possibly amount to a violation of international law." *Id*. at 2216:10-11. That is correct — there is nothing intrinsically improper about judge-made law. Rather, judicial lawmaking is subject to the same international standards as parliamentary statutes or executive regulations. *See* Cl. Reply Mem. at ¶ 330 ("no *special immunity* [is] considered or applied with respect to judicial measures" (emphasis added)).

[315] While denial of justice is most frequently applied to address the adjudicatory functions of courts, it does not apply exclusively to the judicial branch of government. Rather, it has been applied also to the exercise of adjudicative functions by other branches of government. *See, e.g.*, *Genin v. Estonia*, ICSID Case No. ARB/99/2, Award (25 June 2001), at ¶¶ 357-365 (considering whether the procedure followed by a bank regulatory agency constituted a denial of justice) (RL-32).

[316] *See* Cl. Closing Statement, Tr. at 2016:24 ("[D]enial of justice is always procedural."); Resp. Closing Statement, Tr. at 2210:14-16 ("Does this mean that there's such a thing as a substantive denial of justice? No."); *see also* Cl. Reply at ¶¶ 242-244.

[317] Resp. Closing Statement, Tr. at 2209:8-10.

doctrine:[318] "denial of justice is *always* procedural."[319] This is because the doctrine of denial of justice is simply not needed to deal with violations of substantive international rules. Writing about the fair and equitable treatment provision in the US-Bahrain Bilateral Investment Treaty, for example, Professor Paulsson observed:

> [D]enial of justice is not the only rule of international law. If other rules are disregarded by national courts to the detriment of an alien entitled to rely on this provision, the judgment is not compliant with international law and should properly be disregarded by an international tribunal competent to apply the treaty.[320]

182. In his work on *Denial of Justice in International Law*, Professor Paulsson both explains what he characterizes as the procedural "*raison d'être*" of the denial of justice doctrine,[321] and sets out the two corollaries that follow from the limited focus of the doctrine. These are the same two corollaries that were discussed by Lilly in its Closing:

- *first*, "the only theory for misapplication of domestic law is denial of justice";[322]
- *second*, as implied by the passage above, "if a claimant alleges a violation of a rule of international law, that is not a denial of justice at all,"[323] but is instead a freestanding violation of the relevant rule of international law.

In other words, as Professor Paulsson explains, "to 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."[324]

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[318] *See, e.g.*, Cl. Closing Statement, Tr. at 2016:21-24 ("[W]e have associated ourselves with Professor Paulsson's definition of denial of justice . . . . "); Resp. Closing Statement, Tr. at 2208:20-23 ("Let me start with a simple statement of proposition, and I will quote Jan Paulsson here. 'Denial of justice is always procedural.'").

[319] Jan Paulsson, DENIAL OF JUSTICE IN INTERNATIONAL LAW 7 (2010) (emphasis added) (CL-147).

[320] *Id*. at 71.

[321] *Id* at 7.

[322] Cl. Closing Statement, Tr. at 2016:21-2017:17.

[323] *Id*. at 2017:18-2018:1; *see* Cl. Reply at ¶¶ 242-246.

183. There is nothing novel or controversial in Professor Paulsson's second corollary, or in an investor's right to rest a claim on an inconsistency between a domestic court judgment and a substantive rule of international investment law.[325] To the contrary, Professor Paulsson's corollary has been recognized in the NAFTA context, with the tribunal in *Feldman v. Mexico* observing that: "this Tribunal is not bound by a decision of a local court if that decision violates international law."[326]

184. Canada has been hesitant to confront this second corollary head-on. When pressed, for example, Canada refused to exclude the possibility that a state's courts may be liable for breaches of NAFTA Article 1102, NAFTA Article 1103, and, potentially, other rules of international law — even absent a denial of justice.[327] But

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[324] Paulsson, at 4; *id*. at 72 & n.39 ("State responsibility for acts of the judiciary does not exhaust itself in the concept of denial of justice") (quoting Jiménez de Aréchaga, "International Responsibility" in M Sorensen (ed.), MANUAL OF PUBLIC INTERNATIONAL LAW (London 1968)).

[325] In 1849, a U.S. Mexico Claims Commission explained: "It is well settled that the decisions of a court, condemning the property of citizens of another country, are not conclusive evidence of the justice or legality of such condemnation." *Id*. at 4 & n.6 (quoting *The Orient (U.S. v. Mexico*), 3 Moore Int'l Arbitrations 3229, 3229-30, and explaining that it is representative of "abundant arbitral jurisprudence of the nineteenth century"). A century and a half later, the tribunal in *Feldman v. Mexico* came to the same conclusion. *See infra* n.326.

[326] *Feldman v. Mexico*, NAFTA/ICSID Case No. ARB(AF)/99/1, Award (16 Dec. 2002), at ¶ 140 (CL-109); *see Robert Azinian et al. v. The United Mexican States*, NAFTA/ICSID Case No. ARB(AF)/97/2, Award (1 Nov. 1999) (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)) (noting international liability may rest on "a decision of a municipal court *clearly incompatible with a rule of international law*") [hereinafter *Azinian v. Mexico*] (CL-61).

[327] *See* Resp. Closing Statement, Tr. 2225:10-2226:1 ("We've very carefully limited our comments here to 1110 and 1105, the only two claims that are actually at issue here. There's been no allegation of a violation of 1102 or 1103. It's not before you. . . . I think we wouldn't take a position in this arbitration."); *id*. at 2207:25-2208:9 ("Let's assume that there was a specific provision in Chapter 11, within your competence, that said no court shall, under any circumstances, invalidate a patent once it has been issued by the Patent Office. If one of the courts of the NAFTA parties then invalidated a patent, even if it did so consistently with the domestic law, there would be no question that the act of the court breached an international law obligation in NAFTA. There would be no need to prove a denial of justice.").

Canada has failed to explain why, if Professor Paulsson's corollary applies in those circumstances, it does not also apply here.[328]

B. Investment Tribunals Regularly Consider Whether Judicial Measures Conform with Substantive Rules of International Law.

185. The parties agree that the law to be applied in this case includes the general international law of expropriation (under Lilly's Article 1110 claim)[329] and the customary Minimum Standard of Treatment (under Lilly's Article 1105 claim).[330] These bodies of law do not differentiate between measures taken by the legislature, by the executive, or by the courts. To the contrary, in both the expropriation and Minimum Standard contexts, there is substantial authority for the proposition that liability is not limited to denial of justice. Canada has offered no convincing response to these authorities. It has failed to challenge their reasoning and its attempts to distinguish them are unconvincing.

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[328] Professor Paulsson's second corollary is also rooted in the basic principle of state responsibility that a state is responsible equally for the conduct of all of its organs. This principle is discussed in Cl. Reply at ¶ 333 & n.673.

[329] *See, e.g.*, Cl. Closing Statement, Tr. at 2084:21-24 ("Article 1110 is certainly no narrower than what the customary international law standard, and it may even be broader because of the language tantamount to expropriation"); Resp. Closing Statement, Tr. at 2194:20-2195 (referencing the Tribunal's ***Question 39*** on "the relationship between Article 1110 of NAFTA and expropriation in general international law," and going on to rely on asserted principles "under international law"); *see* Resp. Rejoinder at ¶ 214 ("As Canada explained in its Counter Memorial, Article 1110 reflects the customary international law of expropriation."). *Accord S.D. Myers, Inc. v. Government of Canada*, NAFTA/UNCITRAL, Partial Award (13 Nov. 2000), at ¶ 280 ("The term 'expropriation' in Article 1110 must be interpreted in light of the whole body of state practice, treaties and judicial interpretations of that term in international law cases.") (CL-6); *Fireman's Fund Insurance Company v. Mexico*, ICSID Case No. ARB(AF)/02/01, Award (17 July 2006), at ¶ 173 ("It is true that the Algiers Accords give a notion of expropriation different from Article 1110 of the NAFTA and also partially depart from customary international law . . . . However, keeping these caveats in mind, it is justified to rely on certain awards, or at least portions thereof, in determining the customary international law meaning of expropriation in the present case.") [hereinafter *Fireman's Fund v. Mexico*] (CL-45).

[330] *See* Resp. Rejoinder at ¶ 243 (describing the applicable standard as "the customary international law minimum standard of treatment); Cl. Mem. at ¶ 254 ("The FTC Notes thus link the 'fair and equitable treatment' standard under Article 1105(1) to the Minimum Standard of Treatment.").

186. With respect to expropriation, as explained in Lilly's written briefing[331] and at the Hearing,[332] multiple investment awards have applied the international law of expropriation to judicial measures irrespective of whether they constitute a denial of justice. Such awards include: *Saipem v. Bangladesh* (finding a judicial expropriation based on a violation of the New York Convention);[333] *ATA v. Jordan* (finding an expropriation as a result of the decision of the Jordanian Court of Appeal and Court of Cassation to "apply retroactively [a] new rule introduced in the . . . Jordanian Arbitration Law");[334] *Rumeli Telkom v. Kazakhstan* (finding that a judicial taking constituted an unlawful expropriation where the court awarded insufficient compensation);[335] and *Oil Field of Texas v. Iran* (which held, two decades ago, 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 attributable to the state of that court").[336]

187. Similarly, in the context of the Minimum Standard, multiple tribunals (applying a variety of Fair and Equitable Treatment clauses, including some — like NAFTA — expressly tethered to the Minimum Standard) have scrutinized judicial measures not just for denial of justice, but also for arbitrariness, discrimination, and violations of legitimate investment-backed expectations — *i.e.*, precisely the protections that Lilly is invoking here. These decisions often apply the Article 1105 standard articulated in NAFTA cases and include the tribunals in: *Liman Caspian Oil v. Kazakhstan* (considering not only whether the Kazakh courts effected a denial of justice,

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[331] *See* Cl. Reply at ¶¶ 246-251 (discussing authorities in the context of expropriation); *id* at ¶¶ 325-327, 330-333 (discussing authorities in the context of the Minimum Standard of Treatment).

[332] *See* Cl. Closing Statement, Tr. at 2015:23-2030:3.

[333] *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).

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

[335] *Rumeli Telekom A.S. v. Republic of Kazakhstan*, ICSID Case No. ARB/05/16, Award (29 July 2008), at ¶¶ 705-706 ("the final act of 'taking' . . . was the decision of the Presidium of the Supreme Court") [hereinafter *Rumeli Telekom v. Kazakhstan*] (CL-58).

[336] *Oil Field of Texas v. Iran*, 12 Iran-U.S. C.T.R. 308, 318 (1986) (CL-59).

but also whether they violated other aspects of the Minimum Standard of Treatment as articulated in *Waste Management v. Mexico*);[337] *White Industries v. India* (considering not only whether the Indian courts effected a denial of justice, but also whether they frustrated the investor's legitimate expectations);[338] and *Frontier Petroleum v. Czech Republic* (considering not only whether the Czech courts effected a denial of justice, but also whether their actions "otherwise amount[ed] to a breach of the fair and equitable treatment standard" as defined in *Metalclad v. Mexico*, *Waste Management v. Mexico*, and *International Thunderbird v. Mexico*).[339]

188. In its written briefing and in its Opening, Canada's answer to these authorities was that they resulted from "conduct that shocked a sense of judicial propriety."[340] In other words, Canada suggested that — as a factual matter, if not as a matter of legal analysis and pleading — these were really cases about denials of justice. Lilly refuted this argument in its Opening and Closing.[341] Far from constituting a denial of justice, for example, the final action of the Kazakh courts in *Rumeli Telekom* was characterized by the *Rumeli* tribunal as a decision "made 'for a public purpose,' namely the administration of justice and the execution of the laws of the host State . . . in 'accordance with due process of law.'"[342] Similarly, the *Saipem* tribunal made clear that: "While the Tribunal concurs with the parties that expropriation by the courts

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[337] *Liman Caspian Oil BV v. Republic of Kazakhstan*, ICSID Case No. ARB/07/14, Award (22 June 2010), at ¶¶ 268, 285 (RL-27).

[338] *White Industries Australia Ltd. v. India*, UNCITRAL, Award (3 Nov. 2011), at ¶¶ 10.1.1, 10.3.1-10.3.13 (CL-157).

[339] *Frontier Petroleum Services Ltd. v. the Czech Republic*, UNCITRAL, Award (12 Nov. 2010), at ¶¶ 284, 286, 290, 292, 525 (RL-67). Like NAFTA, the fair and equitable treatment clause of the investment treaty at issue in *Frontier Petroleum Services* prescribed fair and equitable treatment "in accordance with principles of international law." *Id*. at ¶ 268.

[340] Resp. Rejoinder at ¶ 252; Resp. Opening Statement, Tr. at 241:22-243:7.

[341] Cl. Opening Statement, Tr. at 105:6-23; Cl. Closing Statement, Tr. at 2026:1-2027:10.

[342] *Rumeli Telekom v. Kazakhstan*, at ¶ 705 (CL-58). Canada sought to distinguish *Rumeli* on the grounds that it involved "collusion between the state and the competitor that was manifested in a court decision." Resp. Opening Statement, Tr. at 242:7-243:7. But as Lilly has repeatedly pointed out, *see* Cl. Reply at ¶ 249 & n.501, the collusion discussed by the tribunal was limited to Kazakhstan's "Investment Committee" and Rumeli's competitor — *i.e.,* it did *no*t involve the Kazakh court proceedings through which the investment was ultimately expropriated. *Rumeli Telekom v. Kazakhstan*, at ¶ 715 (CL-58).

presupposes that the courts' intervention was illegal, *this does not mean that expropriation by a court necessarily presupposes a denial of justice*."[343]

189. Lacking a response to this plain and unmistakable language, Canada changed its argument in its Closing. In its Closing, Canada argued: "the cases the Claimant relied upon, *Saipem*, *ATA*, *Rumeli*, not a single case involved a dispute under Article 1105 or 1110."[344] It is true that *Saipem*, *ATA*, and *Rumeli* are not NAFTA cases. But insofar as Canada is suggesting that NAFTA caselaw articulates a different rule, Canada is not correct. While there are only a handful of NAFTA arbitrations that deal with judicial measures, NAFTA tribunals have in fact recognized that judicial measures may breach Articles 1105 and 1110 even absent a denial of justice.

190. For example, in *Mondev*, a case involving a challenge to a judicial decision of the Supreme Judicial Court of Massachusetts, the tribunal did not confine itself to reviewing the procedure accorded the claimant in Massachusetts courts. Rather, it considered whether the underlying court decision was based on the retroactive application of new law,[345] and it considered also whether the Massachusetts decision rested on a rule that was "inconsistent with the principles embodied in Article 1105 and with contemporary standards of national and international law concerning governmental liability for contractual performance."[346] The tribunal suggested that, if it had answered either question in the affirmative, the claimant would not have been confined to arguing a denial of justice under Article 1105.[347]

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[343] *Saipem v. Bangladesh*, at ¶ 181 (emphasis added) (CL-62).

[344] Resp. Closing Statement, Tr. at 2205:24-2206:1.

[345] *Mondev International Ltd. v. United States of America*, NAFTA/ICSID Case No. ARB(AF)/99/2, Award (11 Oct. 2002), at ¶¶ 133-134 (concluding that it was "doubtful whether the SJC made new law") [hereinafter *Mondev v. United States*] (CL-7).

[346] *Id*. ("[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 . . . [i]n its context the remark was merely supplementary and was not itself the basis for the decision.").

[347] *Id*. While the *Mondev* analysis related to Article 1105, tribunals considering Article 1110 claims have also recognized that judicial measures may breach international law absent a denial of justice. In particular, the tribunal in *Azinian v. Mexico* quoted from Judge Aréchaga's explanation of the different (continued…)

191. Canada has failed entirely to address the relevant passages in *Mondev*. It did not respond to these passages in its Rejoinder, and it maintained its silence even after being invited to respond in Lilly's Opening *and* its Closing.[348]

192. But even if Canada were correct about the absence of NAFTA-specific authority, it would not matter. As noted, both parties agree that Article 1110 incorporates the general international law of expropriation and that Article 1105 incorporates the Minimum Standard of Treatment at customary international law. Thus, it is not just NAFTA awards that are relevant here, but rather the broader set of awards interpreting treaties that incorporate the same standards as those in NAFTA. Indeed, this is presumably the reason Canada itself routinely relies on awards from outside the NAFTA context in support of its Article 1110 and Article 1105 arguments.[349]

193. Despite its own reliance on arbitral awards, Canada raised at the Hearing and in its written briefing the same reflexive argument it raises in every NAFTA case:

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situations in which a judicial decision may result in international liability. Before going on to discuss the doctrine of denial of justice, the passage quoted in *Azinian* noted that "[t]he first [such situation] is a decision of a municipal court *clearly incompatible with a rule of international law*." *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 in original) (CL-61).

[348] Cl. Opening Statement, Tr. at 134:9-22 ("*Mondev* . . . implicitly recognized that a judicial measure could violate Article 1105 irrespective of its procedural fairness. In Paragraph 134 the Tribunal discussed a rule articulated by the judiciary which could be interpreted as 'affording [a] governmental prerogative to violate investment contracts.' The Tribunal held that this substantive rule would appear to be inconsistent with the principles embodied in Article 1105 but ultimately held that it need not reach this question because the relevant rule had not clearly been adopted by the Massachusetts court and was not the basis for the Massachusetts court's decision."); Cl. Closing Statement, Tr. at 2024:19-25 ("Canada has not once — not in its rejoinder, not in its Opening Statement — addressed paragraph 134 of *Mondev* where the Tribunal pointed out that a judicially articulated prerogative to violate investment contracts would appear to be inconsistent with the principles embodied in Article 1105.").

[349] For example, in a single footnote of its Counter Memorial (¶ 244 n.441), Canada relied on the following awards as authority: *GEA Group Aktiengesellschaft v. Ukraine*, ICSID Case No. ARB/08/16, Award, 31 March 2011 (RL-26); *Liman Caspian Oil and NCL Dutch Investment BV v. Republic of Kazakhstan*, ICSID Case No. ARB/07/14, Excerpts of Award dated 22 June 2010 (RL-27); and *Jan de Nul N.V. Dredging International NV v. Egypt*, ICSID Case No. ARB/04/13, Award, 6 Nov. 2008 (RL-28). Two footnotes later (¶ 249 n.443), Canada cited to: *Joseph Charles Lemire v. Ukraine*, ICSID Case No. ARB/06/18, Decision on Jurisdiction and Liability, 14 January 2010 [hereinafter *Lemire v. Ukraine*] (RL-29) and *LG&E Energy Corp. v. The Argentine Republic*, Decision on Liability, ICSID ARB/02/1, 3 Oct. 2006 (RL-30).

that the claimant must "adduce evidence [of] state practice" beyond awards and scholarship — including, in this case, a country-by-country analysis of domestic law on judicial takings.[350] As explained in Part IV.C.1, this argument is without merit. It merely serves to highlight the absence of support in arbitral practice for Canada's position on judicial measures. If, in the face of multiple awards that analyze judicial conduct under the same rules as legislative and executive conduct, Canada continues to insist that customary international law establishes a special immunity for expropriations or Minimum Standard of Treatment violations founded on judicial measures,[351] then it is Canada (not Lilly) that must establish the existence of this immunity. Canada has not done so.[352]

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[350] Resp. Opening Statement, Tr. at 243:8-21 ("[T]hey made no effort to show that judicial expropriation is recognized in Canada, Mexico, United States, United Kingdom, Russia, South Africa . . . . "). The Tribunal's ***Question 40*** asks, "What relevance, if any, does practice under the U.S. takings clause have for these proceedings?" As an initial matter, there is no necessary parallel between domestic rights to compensation for takings and the international law of expropriation, and thus the interpretation of the Fifth and Fourteenth Amendments to the U.S. Constitution is not relevant to the interpretation of Article 1110 (or Article 1105). In its Article 1128 submission, the U.S. Government asserted that "the United States has not recognized the concept of 'judicial takings' as a matter of domestic law." *See* U.S. Article 1128 Submission at ¶ 29. But, as Lilly pointed out in its Comments on NAFTA Article 1128 and Non-Disputing Party *(Amicus)* Submissions, at ¶ 22, the U.S. Government's position in this arbitration is directly contrary to the plurality view of the U.S. Supreme Court that judicial measures *can* qualify as takings (*i.e.*, expropriations) of property. This discrepancy between the U.S. Government's litigation position in this arbitration and U.S. law as articulated by the U.S. Supreme Court underscores the fact that Article 1128 submissions often reflect defensive concerns and do not articulate an objective view on questions of treaty interpretation under NAFTA. *See* Cl. Comments on NAFTA Article 1128 and Non-Disputing Party *(Amicus)* Submissions at ¶¶ 4-5, 22.

[351] *See* Resp. Closing Statement, Tr. at 2220:7-11 ("[I]n our view, the content of the substantive obligations as applied to the judiciary are limited in recognition of the judicial function so that it is only in the context of a denial of justice.").

[352] In a colloquy related to its proposed customary rule that judicial measures can be analyzed solely under the doctrine of denial of justice, Canada noted that it did not seek to ground its rule in the *Neer* case, Resp. Opening Statement, Tr. at 218:23-25 ("[I]t's not really necessarily something that was dealt with directly in the *Neer* case, from what I recall."), but suggested that its rule somehow found support in "Mondev, for example, Loewen, for example. Azinian." Resp. Opening Statement, Tr. at 219:23-24. But none of those three awards support Canada's position, as discussed below, and in fact, as explained above, *Mondev* and *Azinian* affirmatively refute Canada's position that judicial measures enjoy a special immunity except where they amount to a denial of justice.

C. None of Canada's Authorities Support the Proposition that Denial of Justice is the Exclusive Theory of Liability for Judicial Measures.

194. At the Hearing, Canada repeatedly and expressly recognized that "Claimant has not alleged a denial of justice."[353] In other words, as Canada stated in its Closing, this is not a case where a claimant is questioning whether it was "afforded due process."[354] And, as Canada has also noted, this is not a case where a claimant is "alleging . . . a misapplication of [domestic] law."[355] That much is common ground.

195. But despite recognizing that this arbitration does not involve an alleged denial of justice, Canada relies almost exclusively on awards issued in cases where such an allegation *was* made. Put differently, Canada has not identified a single award where a claimant (i) alleged an inconsistency with substantive international law (*i.e.*, an international rule other than denial of justice) and (ii) was told it was limited to alleging a denial of justice. Rather, each of the awards Canada relies on focuses solely on procedural irregularities or misapplications of domestic law.[356]

196. In its Closing Argument, for example, Canada again discussed the *Loewen v. United States* and *Waste Management v. Mexico (II)* decisions. But these are both cases involving express allegations of denial of justice — *i.e.*, *procedural* unfairness. In *Loewen*, the claimant argued that a U.S. court had committed an international wrong because of "the way in which it conducted [a] trial, in particular by its conduct of the *voir dire* and its irregular reformation of the initial jury verdict . . . [and] by permitting extensive

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[353] Resp. Closing Statement, Tr. at 2150:16-17; *see*, *e.g.*, Resp. Opening Statement, Tr. at 166:4-5 ("[T]he Claimant has never alleged a denial of justice.").

[354] Resp. Closing Statement, Tr. at 2152:7.

[355] *Id*. at 2152:13-15.

[356] *See* Cl. Reply at ¶¶ 250-253 (discussing Canada's authorities in the Article 1110 context); *id*. at ¶¶ 325-334 (discussing Canada's authorities in the Article 1105 context). Canada also suggests that the United States and Mexico agree with its position on the special treatment accorded to judicial measures. Lilly has addressed the relevant portions of the United States and Mexican Article 1128 submissions in its Comments on NAFTA Article 1128 Submissions and Non-Disputing Party (*Amicus*) Submissions at ¶¶ 17-20, 49 & n.118.

nationality-based, racial and class-based testimony and counsel comments."[357] And in *Waste Management*, the claimant's complaint against Mexico's courts was that they had been misused as part of a scheme to "obstruct its access to judicial and arbitral forums to resolve claims under the concession."[358] These awards, which analyze challenges to the *procedural* adequacy of domestic adjudication, are inapposite here, where Lilly has — it bears repeating — alleged that Canada's judicial measures violate *substantive* rules of international law.[359]

197. Canada has also repeatedly invoked another category of inapposite cases: those involving an allegation of misapplication of *domestic* law. In its Opening, for example, Canada discussed *Grand River v. United States*.[360] But as demonstrated by the very paragraph of *Grand River* displayed in Canada's Opening Slides, the claimant's allegation in that case related to the misapplication of "delicate and complex questions" relating to the interaction between "U.S. constitutional and Indian [U.S. tribal] law."[361] In particular, the claimant argued that it was subjected to the regulation of U.S. states in connection with activity that should have been regulated by U.S. tribal law. But the competing jurisdiction of various U.S. authorities presented no international issue. In

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[357] *Loewen Group, Inc. v. United States*, NAFTA/ICSID No. ARB(AF)/98/3, Decision on Hearing of Respondent's Objection to Competence and Jurisdiction (5 January 2001), at ¶ 39 (CL-8).

[358] *Waste Management, Inc. v. Mexico (II)*, NAFTA/UNCITRAL, ICSID Case No. ARB(AF)/00/3, Award (30 April 2004), at ¶ 87 [hereinafter *Waste Management (II)*] (CL-65).

[359] Canada has also previously relied on *Liman Caspian Oil v. Kazakhstan* and *Azinian v. Mexico.* As noted above, the analysis in *Liman Caspian* was not limited to the doctrine of denial of justice, but also considered other aspects of the Minimum Standard of Treatment. *See Liman Caspian Oil BV v. Republic of Kazakhstan*, ICSID Case No. ARB/07/14, Award (22 June 2010), at ¶ 431 (court decision that "might have been incorrect as a matter of Kazakh law" did not violate the Minimum Standard of Treatment where it was "not arbitrary, grossly unfair, unjust, idiosyncratic, discriminatory *or* lacking due process") (emphasis added) (RL-27). As for *Azinian*, Lilly pointed out in its Closing that this arbitration involved no allegation against a judicial measure at all. Cl. Closing Statement, Tr. at 2023:5-22; *Azinian v. Mexico*, at ¶ 87 (CL-61).

[360] Resp. Opening Statement, at 228:13-229:22.

[361] *See* Resp. Opening Slides at 78 (quoting *Grand River Enterprises. v. United States*, NAFTA/UNCITRAL, Award (12 January 2011), at ¶ 234 [hereinafter *Grand River v. United States*] (RL-10)) (noting claimant's allegation that the domestic court had been incorrect about "the permissible reach of state regulation over Indian [*i.e.*, Native American] peoples and lands under U.S. law").

other words, the claimant had alleged nothing more than a misapplication of domestic law — a classic denial of justice under Professor Paulsson's first corollary.[362]

198. Canada is thus left with just one source of support for its argument: an article by Professor Zachary Douglas.[363] Or, more specifically, the three-and-a-half pages of a 34-page article by Professor Zachary Douglas, which address the question: "Can the Transgression of an International Legal Norm within the Context of a Domestic Adjudicative Procedure Supply the Predicate Conduct for Delictual Responsibility Towards Foreign Nationals?"[364] Professor Douglas does answer this question in the negative. But, as Lilly has repeatedly observed, he offers no authority to support his view[365] and he expressly recognizes that his position runs counter to the only arbitral award discussed in the relevant section of his article — *Frontier Petroleum Services v. the Czech Republic* — where Professor Douglas served as counsel for the Czech Republic.[366]

199. Even setting aside the lack of support for Canada's position in case law or commentary, Canada has never explained why, even as a matter of logic, the articulation of a new legal rule through the judiciary should be treated differently than

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[362] The same observation holds for *Arif v. Republic of Moldova*, ICSID Case No. ARB/11/23, Award (8 April 2013), at ¶ 187 ("Claimant submits that his investment was taken not on the basis of any alleged wrongdoing attributable to him, but on the basis of the alleged misapplication of Moldovan laws by the organs of the State that granted him these rights.") (RL-63).

[363] Zachary Douglas, "International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed," INT'L & COMP. L.Q. (Sept. 2014) (R-323).

[364] *Id*. at 30-34.

[365] It is no answer to argue, as Canada did in its Opening, that Professor Douglas included a large number of footnotes in the article as a whole. *See* Resp. Opening Statement, Tr. at 208:13-209:10 (encouraging the Tribunal to "read the 118 footnotes" in Professor Douglas's article and beginning to read the authorities in those footnotes into the record). As Lilly pointed out in its Closing, the article as a whole is largely irrelevant to this dispute and focuses on a taxonomy of procedural denial of justice and the rule of finality. *See* Cl. Closing Statement, Tr. at 2019:14-21. Canada did not attempt to rehabilitate its reliance on Professor Douglas's article in its Closing.

[366] *See* Douglas, at 33 (stating that the *Frontier Petroleum v. Czech Republic* award was not "directed to the proper issues arising in the adjudication of international delictual responsibility for the results of domestic adjudication") (R-323).

the articulation of the very same legal rule by a different branch of government.[367] This is a point Lilly has repeatedly raised but that Canada has simply ignored.[368] Canada's insistence that this Tribunal provide special immunities to judicial lawmaking over parliamentary legislation and executive rulemaking (or risk being branded a "supranational court of appeal"[369]) is thus built neither on sound authority nor on sound reasoning. It relies solely on rhetoric. Canada's position must, therefore, be rejected.

IV. Canada's Application of the Promise Utility Doctrine to Lilly's Patents for the Zyprexa and Strattera Patents Is Inconsistent with NAFTA Articles 1110 and 1105.

200. In revoking Lilly's investments — its patents for Zyprexa and Strattera — under the radically new promise utility doctrine, Canada breached its obligations under Articles 1110 and 1105 of NAFTA.

201. The complete destruction of Lilly's patent rights by Canada's courts amounts to a direct expropriation of those rights under Article 1110. The treatment accorded Lilly's patents also qualifies as an indirect expropriation of its investments. Lilly lost its ability to enforce the rights of exclusivity conveyed by the Zyprexa and Strattera patents, and so was substantially (in fact, *completely*) deprived of the value of the patents. Moreover, under both the general international law of expropriation and the specific language of Article 1110(7), Canada's measures cannot be excused as a non-

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[367] Such treatment introduces an impermissible distinction between the acts of courts and the acts of other State entities, which is inconsistent with the principle that a State is internationally responsible for the conduct of all of its organs, equally. *See* Cl. Reply at ¶ 333 & n.673.

[368] *See id*. at ¶¶ 332-334 ("Canada's position is inconsistent with the principle that a State's internal political system cannot alter its obligations under customary international law."); Cl. Closing Statement, Tr. at 2029:2-2030:3 ("Let's consider, for example, the measure that Professor Gervais provided that would arguably violate Article 1709(1), a utility standard requiring that a medicine work 100 percent of the time. Now, if Canada passed this law through its legislature and under the law revoked patents for drugs that don't work 100 percent of the time, then that would likely be an expropriation, even under Canada's interpretation. Yet, under Canada's view, if it articulated the very same rule through the judiciary, then that could not be an expropriation because it is not a denial of justice. There is no basis for treating these two measures differently.").

[369] Resp. Opening Statement, Tr. at 162:23.

compensable exercise of state authority. Canada has thus breached Article 1110, as it has expropriated Lilly's patents without compensation. *See* Part IV.A.

202. Canada has also breached NAFTA Article 1105. It is common ground between the parties that Article 1105 protects against measures that violate the Minimum Standard of Treatment under customary international law — a standard that has frequently been interpreted by tribunals applying NAFTA, as well as other investment treaties. As explained in Lilly's written submissions and at the Hearing, this process has elucidated the Minimum Standard and, as a result, tribunals (both inside and outside of the NAFTA context) routinely rely on arbitral awards to understand and apply the Minimum Standard. *See* Part IV.B.1.

203. In this case, Canada has violated three separate aspects of the Minimum Standard:

- Article 1105 protects against violations of investors' legitimate, investment-backed expectations; yet, Canada revoked Lilly's patents by retroactively applying a radically new test, one that found no parallel in prior Canadian law, among Canada's NAFTA partners, or beyond.

- Article 1105 protects against arbitrariness; yet, Canada developed an additional, arbitrary utility requirement and applied it to invalidate Lilly's patents.

- Article 1105 protects against discrimination; yet, Canada developed a patent test that plainly discriminates against the pharmaceutical sector, a sector that consists almost entirely of foreign investors.

These three violations each provide an independent basis for liability under Article 1105. However, they also compound one another, and thus need not be considered in isolation. *See* Part IV.B.2.

A. Canada's Measures Are Cognizable as Both Direct and Indirect Expropriations.

204. As Lilly showed in its Memorial, its Reply, and at the Hearing, Canada's courts applied the promise utility doctrine to invalidate Lilly's Zyprexa and Strattera

patents on the sole ground of inutility.[370] Lilly lost all rights under its patents (and all ability to enforce those rights) as a result of these invalidations.[371] Its investments were completely destroyed.[372]

205. The destruction of Lilly's investments satisfied "the central element" of a direct expropriation: "that the property must be 'taken' by State authorities *or the investor must be deprived of it by State authorities*."[373] Echoing an argument made in its written submissions,[374] Canada argued at the Hearing that the destruction of property does not suffice to show a direct expropriation. Rather, Canada maintains, a direct expropriation "require[s] the state to seize the property for its own or someone else's possession."[375] Canada identified no support for its position; nor did it address the authorities cited in Lilly's Reply that contradict Canada's interpretation.[376] Canada also failed to respond to Lilly's showing that the invalidation of the Zyprexa and Strattera

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[370] Cl. Mem. at ¶¶ 110, 140; Cl. Reply at ¶¶ 211-217; Cl. Opening Slides at 16-38; Cl. Closing Statement, Tr. at 1998:3-1999:7; Cl. Closing Slides at 2-8.

[371] Lilly's patents are distinct investments as a matter of law. *See* Cl. Mem. at ¶ 163; Cl. Reply at ¶ 314. Moreover, Lilly treated its patents as distinct and valuable assets as a matter of practice. *See* Testimony of Robert Armitage, Tr. at 360:23-361:7 ("[P]erhaps other arenas work differently where you're maybe buying a thousand patents and you just want a probabilization of whether there are 500 or so that might survive, that typically isn't how our business works and it typically isn't how these decisions actually get made. That's why, at least in the pharmaceutical business, patents are really the bedrock asset on which you make the investment to develop pharmaceutical products.").

[372] This section responds to the Tribunal's ***Question 22***, which asked for the parties' views on the "criteria to establish the alleged direct expropriation in this case."

[373] Campbell McLachlan et al., INT'L INV. ARBITRATION, § 8.69 (2008) (emphasis added) (CL-46); *see* Cl. Mem. at ¶¶ 170-171, 239; Cl. Reply at ¶¶ 309-312.

[374] Resp. CM at ¶ 405.

[375] Resp. Closing Statement, Tr. at 2193-2194.

[376] Cl. Reply at ¶¶ 310-311 & n.622 ("The 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.") (quoting McLachlan, at § 8.69); *see id*. at ¶ 311 & n.623 (noting "total destruction of an investment due to measures by a government authority without transfer of rights" may qualify as a direct or an indirect expropriation) (quoting *Fireman's Fund v. Mexico*, at ¶ 176(e) (CL-45)).

patents *did* result in the *de facto* transfer of the value of Lilly's property rights to those firms that manufactured and distributed generic versions of Lilly's inventions.[377]

206. Canada's measures qualify not only as direct expropriations but also as indirect expropriations. By revoking Lilly's Zyprexa and Strattera patents and leaving Lilly without any means of enforcing the rights of exclusivity they conveyed, Canada substantially deprived Lilly of the value of those patents.[378] These substantial deprivations constitute compensable takings, as opposed to non-compensable exercises of governmental authority, for multiple reasons: they resulted from a breach of Chapter 17; they violated Lilly's legitimate, investment-backed expectations; and they applied an arbitrary doctrine of law that is not supported by any legitimate policy purpose.[379]

B. Canada Has Failed to Rebut Lilly's Showing That The Invalidations of the Zyprexa and Strattera Patents Were Expropriatory.

207. In its written submissions and at the Hearing, Canada raised four basic arguments for why its measures are not expropriatory:

- *First*, it argued that Lilly's patent rights were declared *void ab initio* under domestic law, and thus were incapable of being expropriated absent a denial of justice. As became clear during the Hearing, however, this argument finds no support in Canadian law. As Mr. Reddon testified, invalidation "*ab initio*" does not change the fact that the patent holder possessed a valid domestic property right through the date of invalidation. And Canada's argument fares no better at international law: it is flatly inconsistent with the principle that a host state cannot rely on a challenged measure to justify that very measure. *See* Part IV.B.1.

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[377] The situation can be analogized to *Marguerite de Joly de Sabla (United States) v. Panama*, (1934) 28 AJIL 602 (CL-156), where a claims tribunal found that the claimant's land had been expropriated because, *inter alia*, the host state had granted cultivation licenses to others on land owned by the claimant. *See* Cl. Reply at ¶ 312.

[378] *See infra* Part IV.B.2.

[379] Cl. Mem. at ¶¶ 239-243; Cl. Reply at ¶¶ 313-318. Whether analyzed as a direct or an indirect expropriation, Canada's measures were clearly wrongful under Article 1110(1). Canada has never contested that Lilly's patents were invalidated without compensation. And, in any case, the taking was discriminatory, lacking in public purpose, and in breach of Article 1105. *See infra* Part IV.C; *see also* Cl. Mem. at ¶¶ 244-250; Cl. Reply at ¶¶ 319-321.

- *Second*, Canada argues that Lilly was not substantially deprived of the value of its patents. But by Canada's own account, Lilly's patents were declared "void." From the date of invalidation, Lilly lost its exclusive rights and all ability to enforce its patents. Put differently, Lilly was not just substantially deprived of the value of its patents, it was completely deprived of that value. *See* Part IV.B.2.

- *Third*, Canada argues that this Tribunal is prohibited from considering, as part of its expropriation analysis, the inconsistency between Canada's invalidation of the Zyprexa and Strattera patents and Canada's Chapter 17 obligations. Lilly has shown that Canada's argument is incompatible with the general international law of expropriation and with NAFTA Article 1110(7). Canada's argument also cannot be squared with its express acknowledgement that this Tribunal has competence to consider the consistency of the promise utility doctrine with NAFTA Chapter 17. *See* Part IV.B.3.

- *Fourth*, Canada argues its measures are consistent with Chapter 17. In fact, Canada's measures violate multiple provisions of Chapter 17, including the requirements to make patents available for inventions that are new, non-obvious *and useful* (Article 1709(1)); not to discriminate between patents based on field of technology (Articles 1709(1) and 1709(7)); and not to invalidate patents by retroactively applying new rules of patent validity that did not exist at the time a patent was granted (Article 1709(8)).[380] *See* Part IV.B.4.

1. Patent Rights Are Protected Under NAFTA to the Same Extent as Other Property Rights.

208. During the Hearing, Canada reiterated its argument that when a court invalidates a patent, its ruling "is not a taking of a property right, it is a declaration that the property right did not exist."[381] The invalidation of the Zyprexa and Strattera patents were, according to Canada, "decision[s] that [the patents] did not constitute

[380] The promise utility doctrine is also inconsistent with NAFTA Article 1701(1). *See infra* Part IV.B.4.

[381] Resp. Closing Statement, Tr. at 2300:18-20.

property that could be expropriated."[382] This argument has no merit under domestic Canadian law, and it finds no support at international law.[383]

209. As to domestic law, Lilly held patents that were validly issued under then-existing Canadian law.[384] Canada maintains that, because Lilly's patents were subsequently declared "void *ab initio*," they effectively "never existed" under Canadian law.[385] But the phrase "void *ab initio*" does not have the significance Canada assigns it. As Mr. Reddon testified: "The real effect and intent of the judicial statement that a patent is void *ab initio* is really only this: You can't sue for damages on it anymore."[386] In other words, the purpose of an invalidation "*ab initio*" is simply to prevent the patent holder from claiming that the patent was infringed during the period before it was invalidated.

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[382] *Id*. at 2163:9-11; *see* Resp. Opening Statement, Tr. at 300:1-6 ("[W]hen a domestic court makes a determination that the property did not exist, as the Federal courts did with respect to Claimant's atomoxetine and olanzapine patents, it is not an expropriation or taking that can give rise to a claim under Article 1110.").

[383] This section responds to the Tribunal's ***Question 19*** on whether patents constitute 'property' capable of expropriation.

[384] Lilly's patents were invalidated solely under the new promise utility doctrine. *See* Cl. Mem. at ¶¶ 110, 140; Cl. Reply at ¶¶ 211-217.

[385] Resp. Rejoinder at ¶ 117 (emphasis in original). At various times, Canada has also suggested that Lilly's patents were somehow conditional when issued because they were subject to potential invalidation in later court proceedings. *See* Resp. Closing Statement, Tr. at 2299:1-17 (noting validity "will be determined by a court if it is later challenged in litigation. And patentees know this."). The legal significance of this suggestion has never been clear, as Canada's own authorities recognize that "virtually all" property rights are subject to some level of litigation risk. *See* Testimony of Robert Merges, Tr. at 1324:13-1325:22 (quoting Mark A. Lemley and Carl Shapiro, Probabilistic Patents, 19 J. Econ. Perspectives 75, 76 (2005) (R-437)); *see also* Cl. Reply at ¶¶ 231-232. At any rate, Mr. Reddon's undisputed testimony established that Lilly's patent rights were legally enforceable immediately upon issuance. *See* Testimony of Andrew Reddon, Tr. at 820:2-17. That is presumably why Canada agrees that Lilly's Zyprexa and Strattera patents are investments in Canada that suffice to vest this Tribunal with jurisdiction. In its Closing Statement, Canada insisted that, in arguing that Lilly lacked property rights under Canadian law, it was not questioning the Tribunal's jurisdiction. More specifically, Canada insisted that it accepted that "the patents [at issue in this arbitration], even if revoked, were investments" entitled to protection under NAFTA. Resp. Closing Statement, Tr. 2163:5-23.

[386] Testimony of Andrew Reddon, Tr. at 820:12-15.

210. The revocation of Lilly's patents "*ab initio*" does not airbrush those patents from the factual record. As Mr. Reddon explained:

> [T]he fact that the patent has been declared void ab initio doesn't mean the people who took and used the disclosure have to give back what benefit they took from it. It doesn't mean a party who stayed out of the market because of the existence of the patent can come forward and sue and say look, your patent was invalid and I stayed out of the market and now I want to claim damages. It doesn't mean the price regulator in Canada, who would have regulated Lilly's price below what otherwise the market might bear because of the existence of the patent — and that's what triggers their jurisdiction — it doesn't mean that Lilly can come back and say okay, now that the patent has gone we want the price differential. There are a lot of things the revocation of a patent does not do.[387]

Mr. Reddon's testimony on this point stands unrebutted.[388]

211. Even if Canada were correct as to the implications of an invalidation "*ab initio*" under domestic law, however, it would not matter. As a matter of international law, where an investment is extinguished by a measure that is challenged as inconsistent with international law, the challenged measure cannot be relied on to argue that no valid investment exists.[389]

212. Were it otherwise, the judicial expropriation awards discussed in Part III, such as *Saipem v. Bangladesh* and *ATA v. Jordan*, would not exist. While Canada has sought to distinguish these cases by arguing that they involved property rights

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[387] *Id*. at 819:15-820:6.

[388] *See* Resp. Closing Statement, Tr. at 2299:18-20 ("So again, as Mr. Reddon testified, the patentee is not forced to give back the benefits enjoyed during the time the patent was extant.").

[389] *See* Cl. Reply at ¶ 235. It is not clear that Canada contests this principle. It agrees that, if Lilly had alleged that the judicial declaration that its patents were "void *ab initio*" constituted a denial of justice, Lilly would be entitled to "bring a claim under [Article] 1110." Resp. Opening Statement, Tr. at 300:21-301:6. The unspoken premise of Canada's statement is that because denial of justice is a theory of liability directed at judicial measures, Canada would not be able to invoke the challenged judicial measure (including any finding that a property right was void *ab initio*) in defense of the claim. Here, Lilly has not alleged a denial of justice, but it *has* alleged that the judicial measures revoking its patents were otherwise wrongful under international law. If Canada is willing to acknowledge that it could not rely on its own challenged judicial measure in defense of a denial of justice claim, it must also agree that it could not invoke its judicial measure when it is challenged in other respects.

"acknowledged to be valid at domestic law,"[390] Lilly demonstrated in its Opening that this characterization is false.[391] In *Saipem*, for example, the Bangladeshi courts determined that the claimant's ICC arbitration award *did not exist* under Bangladeshi law, and ruled that "[a] non-existent award can neither be set aside nor can it be enforced."[392] Nevertheless, the tribunal determined that Bangladesh had expropriated "Saipem's residual contractual rights under the investment *as crystallised in the ICC Award*."[393] Canada did not address these aspects of *Saipem* in its closing argument.

213. *Saipem* illustrates a basic principle that was also recognized by the tribunal in *Azinian v. Mexico*: an international tribunal called to rule on a Government's compliance with an international treaty cannot be "paralysed by the fact that the national courts have approved the relevant conduct."[394] When faced with "the asserted original invalidity" of a domestic property right, a claimant may "prove[] that the [domestic] legal standards for the annulment [of the right] . . . violate […] Chapter Eleven obligations" or that the "law governing such annulments is expropriatory."[395] This is the only sensible position. Under Canada's preferred rule, states could avoid liability for blatant expropriations simply by providing that their nationalization decrees take effect "*ab initio*."[396]

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[390] Resp. Rejoinder at ¶ 125.

[391] Cl. Opening Statement, Tr. at 104:3-105:5.

[392] *Saipem v. Bangladesh*, at ¶ 50 (quoting from the underlying court decision) (CL-62); *see also ATA v. Jordan*, at ¶ 47 (CL-63) (noting that the Jordanian courts had called claimant's arbitration award a "nullity").

[393] *Saipem v. Bangladesh*, at ¶ 128 (emphasis added) (CL-62).

[394] *Azinian v. Mexico*, at ¶ 98 (RL-2).

[395] *Id*. at ¶¶ 95-96 (RL-2).

[396] Canada's position would also deny effect to language in NAFTA Article 1110(7). *See* Cl. Reply at ¶ 237. Article 1110(7) deals with the "*revocation*, limitation or creation" of intellectual property rights, and Canada has never contested that "revocations" principally take place in the courts. Accordingly, if judicial invalidations of patents could not constitute expropriations, the reference to "revocation" in Article 1110(7) would be surplasage. At the Hearing, Canada argued that Article 1110(7) was intended to apply only to: "compulsory license[s]" ("arguably") and hypothetical laws such as a law "that revoked all automobile patents." Resp. Opening Statement, Tr. at 245:4-246:10. But this is no response. Compulsory licenses are covered by the word "limitation" in Article 1110, and Canada's hypotheticals (continued…)

2. The Invalidation of the Zyprexa and Strattera Patents Substantially Deprived Lilly of the Value of its Investments.

214. Lilly's investments — its Zyprexa and Strattera patents — were revoked by the Canadian courts. They ceased to exist under Canadian law. Lilly's legal rights, including its rights of exclusivity, were extinguished, and its competitors immediately began making and selling generic versions of Lilly's medicines. Nevertheless, at various times in this arbitration, Canada has proposed theories for why the invalidation of Lilly's patents did not substantially deprive Lilly of the value of those patents.[397]

215. Canada first argued that there was no substantial deprivation because Lilly's Canadian enterprise, Eli Lilly Canada Inc., remains in business.[398] After Lilly showed that its enterprise is a legally distinct investment from the Zyprexa and Strattera patents at issue in this arbitration,[399] Canada dropped this argument in its Rejoinder and at the Hearing.

216. Canada next argued that Lilly "had years of monopoly sales" before its patents were invalidated.[400] This is beside the point — an investor always enjoys the benefits of its property *before* that property is expropriated. Similarly, Canada argued in its Rejoinder that "the invalidation of [Lilly's] patents did not prevent [Lilly] from continuing to produce and sell its atomoxetine- and olanzapine-based drugs."[401] Again, this argument has nothing to do with whether Lilly was substantially deprived of the value of its patents. As Lilly pointed out in its Opening Argument, the Zyprexa and

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are just that: hypotheticals unlikely to occur in the real world. It is simply not credible to believe that what Canada itself describes as the "very broad terms in Article 1110(7)," *see* Resp. Rejoinder at ¶ 127, were intended to apply only in the narrow circumstances Canada has identified.

[397] This section responds to the Tribunal's ***Question 21*** on the implications of Respondent's argument that Lilly has not been substantially deprived of its investment.

[398] Resp. CM at ¶¶ 409-411 ("In assessing whether there has been a substantial deprivation, the investor's enterprise must be considered as a whole . . . . Claimant's atomoxetine and olanzapine products form just one part of Claimant's overall enterprise in Canada, which continues to grow and enjoys substantial profits in numerous lines of business.").

[399] *See* Cl. Reply at ¶ 314.

[400] Resp. Rejoinder at ¶ 227.

[401] *Id*.

Strattera patents conveyed "a bundle of exclusive rights to make, sell and use" Lilly's inventions and those exclusive rights were revoked in their entirety.[402] Canada did not respond to this argument.

217. Rather, in its Closing, Canada developed a fourth theory of why no substantial deprivation has taken place. Citing to Mr. Reddon's testimony that the invalidation of a patent "*ab initio*" may not erase, from inception, all consequences of the grant of a patent, Canada argued that unspecified patent-related rights "continue to exist" in respect of Zyprexa and Strattera such that Lilly was not substantially deprived of the value of those patents as of the date of their revocation.[403] This position finds no support in Mr. Reddon's testimony (or elsewhere in the record).[404]

218. In short, despite Canada's ever-changing arguments to the contrary, it cannot seriously be contested that the invalidation of Lilly's Zyprexa and Strattera patents substantially deprived Lilly of the value of those investments.

3. Canada's Revocation of Lilly's Patents Rights Is a Compensable Expropriation.

219. If the Tribunal concludes, as it should, that Lilly experienced a substantial deprivation in the value of the Zyprexa and Strattera patents, it must still determine whether Canada's measures qualify as compensable takings, as opposed to non-

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[402] Cl. Opening Statement, Tr. at 102; *see* Cl. Reply at ¶ 232 ("[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.*'") (emphasis in original) (quoting Patent Act (Canada), R.S.C., 1985, c. P-4, at § 42 (C-50)).

[403] Resp. Closing Statement, Tr. at 2303:1-17 ("[T]here are other aspects of a patent right that may continue to exist. . . . [T]here are many rights that continue to exist, in order to establish an expropriation, there has to be substantial deprivation. So we would say that the Claimant hasn't established that all of those — all of the value of its patent right has been substantially deprived.").

[404] Mr. Reddon testified that the invalidation of a patent "*ab initio*" does not mean that independent rights contingent on the patent (such as licenses and other contractual rights) are suddenly unwound. *See supra* Part IV.B.1. On the basis of this testimony, Canada asserted in its Closing Statement that similar rights exist in the case of Zyprexa and Strattera, effectively challenging Lilly to prove a negative (that they do not). Resp. Closing Statement, Tr. at 2301:11-2303:17. There is, however, no evidence that such rights exist. And even if they did, Canada has offered no reason why the continuing existence of such separate and independent rights outside the patent would preclude a finding of expropriation as to the patent itself. *See generally* Testimony of Andrew Reddon, Tr. at 819:9-820:17.

compensable exercises of state authority.[405] This additional step follows from *Saipem*'s observation,[406] which Lilly freely accepts, that not every judicial invalidation of a property right is an expropriation. Here, Lilly has established that the revocation of the Zyprexa and Strattera patents cannot be defended as legitimate exercises of state authority but are instead compensable takings. This conclusion is compelled by the general international law of expropriation,[407] which requires this Tribunal to consider the internationally unlawful character of the promise utility doctrine; its arbitrariness; and the fact that the application of the promise utility doctrine to invalidate the Zyprexa and Strattera patents violated Lilly's legitimate, investment-backed expectations. It is compelled also by NAFTA Article 1110(7), which instructs the Tribunal to consider — as part of its expropriation analysis — the consistency of Canada's measures with NAFTA Chapter 17.[408]

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[405] Lilly has repeatedly affirmed that it is necessary in this case to distinguish between a valid annulment of a domestic right and an improper taking. Cl. Mem. at ¶ 179; Cl. Reply at ¶ 253. Accordingly, Canada's suggestion that, under Lilly's theory, every patent invalidation could result in an expropriation claim cannot be taken seriously. *See* Resp. Closing Statement, Tr. at 2300:4-20.

[406] *Saipem v. Bangladesh*, at ¶¶ 133-134 (CL-62).

[407] The Tribunal's ***Question 25*** asked the parties what NAFTA Arts. 102(2) and 1131(1) mean by their reference to "applicable rules of international law." In addition, the Tribunal's ***Question 39*** asked, "what is the relationship between Article 1110 of NAFTA and expropriation in general international law, if any?" At a minimum, Articles 102(2) and 1131(1) permit this Tribunal to consider customary international law and the general international law of expropriation as incorporated into Article 1110. Because the facts here suffice to show an expropriation under the general international law of expropriation — which compels the Tribunal to consider the consistency of Canada's measures with its other international obligations — this Tribunal need not determine whether Article 102(2) and Article 1131(1) should be read any more broadly.

[408] This section responds to the Tribunal's ***Questions 20, 24, 25, 30, 31, 37, 39,*** and ***42***. ***Questions 25*** and ***39*** seek the parties' views on the law applicable under NAFTA Articles 102(2) and 1131(1), and the related question of the "relationship between Article 1110 of NAFTA and expropriation in general international law." ***Questions 30*** and ***31*** invite the parties to address the Tribunal's competence to consider Chapter 17, and to address the consequences of a finding of consistency with or a breach of Chapter 17 for Lilly's expropriation claims. Relatedly, ***Questions 20*** and ***37*** invite the parties "to elaborate their positions regarding NAFTA Article 1110(7)" and ***Question 42*** asks the parties to elaborate on whether awards such as *Saipem v. Bangladesh* provide an alternative basis for the Tribunal to consider Chapter 17. ***Question 24*** asks whether it is "significant that the alleged violation of international law in this case is NAFTA Chapter 17[.]"

a) The International Law of Expropriation Establishes That a Judicial Measure Is Expropriatory When it Substantially Deprives an Investment of Value While Violating a Rule of International Law.

220. Awards like *Saipem v. Bangladesh* and *ATA v. Jordan* illustrate that one method tribunals have applied to distinguish between a compensable expropriation and a non-compensable exercise of state authority is to consider whether the taking violates another substantive rule of international law (here, Chapter 17). Canada has argued that these awards, each of which based findings of expropriation on the acts of host state judiciaries, resulted from procedural deficiencies in the domestic courts. But, as explained in Part III.B, that argument is incorrect.

221. Rather, the analysis in *Saipem* began from the proposition that "the most significant criterion to determine whether the disputed actions amount to indirect expropriation or are tantamount to expropriation is the impact of the measure" (*i.e.*, whether the measure results in a substantial deprivation).[409] Because the judicial revocation of a property right always results in a substantial deprivation, however, the *Saipem* tribunal required the claimant also to demonstrate the internationally "unlawful character of the [government's] actions."[410] The claimant satisfied this burden by, among other things, demonstrating that the measures violated the host state's obligations under the New York Convention.[411] The logic of *Saipem* is clear: a judicial measure that effects a substantial deprivation of an investment, and that is unlawful under a sufficiently related rule of international law, constitutes an expropriation.[412]

222. *Saipem*'s analysis is grounded in the general international law of expropriation. It reflects an application of the broader rule — described in *Fireman's Fund v. Mexico* and other awards as a rule applicable in NAFTA arbitrations and under "customary international law in general" — that a tribunal should consider, among

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

[410] *Id*. at ¶¶ 133-134.

[411] *Id*. at ¶ 170.

[412] Cl. Mem. at ¶¶ 180-181; Cl. Reply at ¶ 247.

other factors, "the (public) purpose and effect of the measure" and "the bona fide nature of the measure."[413] A measure that, in *Saipem*'s words, is "illegal" under international law cannot be justified as having a proper public purpose or as a "bona fide . . . measure."[414]

223. As Lilly pointed out in its Closing, the general international law of expropriation calls for analysis tailored to the facts of specific cases.[415] Such an approach is consistent with *Saipem*, with *Fireman's Fund v. Mexicio*, and with another NAFTA case: *Feldman v. Mexico.* Applying the "internationally accepted scope of the term expropriation," the *Feldman* tribunal determined that the expropriation analysis must be adapted to fit "the facts of specific cases."[416] It then went on to consider, among other factors, whether the challenged Mexican actions in the case before it (relating to the taxation of cigarette re-exports) were consistent with Mexico's other international obligations. Observing that "neither NAFTA nor rules of customary international law require a state to permit gray market cigarette exports,"[417] the tribunal went on to conclude that "the actions of Mexico . . . do not constitute an expropriation under Article 1110 of NAFTA."[418] Like *Saipem*, *Feldman* thus stands for the proposition that one way to discern a compensable taking from a non-compensable exercise of state authority is whether the measure otherwise violates a State's international obligations.

224. Given *Saipem*'s basis in the general international law of expropriation, it is unsurprising that multiple tribunals have come to consistent conclusions — not just the tribunals in *ATA v. Jordan* and *Rumeli Telecom v. Kazakhstan*, discussed in Part IV, but

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[413] *Fireman's v. Mexico*, at ¶ 176 (CL-45).

[414] *See Saipem v. Bangladesh*, at ¶ 134 (noting that both parties were "in agreement that the unlawful character of the actions was a necessary condition") (CL-62).

[415] Cl. Closing Statement, Tr. at 2334:6-2335:11.

[416] *Feldman v. Mexico*, at ¶¶ 101-103 & n.7 (CL-109).

[417] *Id*. at ¶¶ 115-116.

[418] *Id*. at ¶ 153.

also tribunals that have adopted *Saipem*'s analysis while declining to find expropriations on the facts of the particular cases before them.[419]

225. The international law analysis conducted by the *Feldman*, *Saipem*, *ATA* and *Rumeli* tribunals is compelled by logic. In the circumstances of this case, it is also compelled by the plain text of NAFTA Article 1110(7), as discussed below. It makes no sense to insist, as Canada does, that the consistency of a measure with a state's applicable international obligations does not affect its character.[420] Canada has identified no authority that supports this proposition.

b) Other Factors in the Expropriation Analysis Also Demonstrate That Canada's Measures Constitute an Expropriation.

226. The internationally unlawful character of Canada's measures is not the only basis on which those measures qualify as expropriatory under the international law of expropriation. In its Closing, Canada expressly agreed that "the extent to which [a] measure interferes with distinct, reasonable, investment-backed expectations" is relevant to the expropriation analysis (at least where the expectation is grounded in a host state representation).[421] And, as Lilly pointed out in its Reply, "Canada has not disputed that arbitrariness . . . [is] relevant . . . [to] determining whether a measure engages Article 1110."[422]

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[419] *See* Cl. Reply at ¶¶ 248-249 (citing, *inter alia*, *Swisslion DOO Skopje v. Former Yugoslav Republic of Macedonia*, ICSID Case No. ARB/09/16, Award (6 July 2012), at ¶¶ 313-314 (RL-65) and *GEA Grp. Aktiengesellschaft v. Ukraine*, ICSID Case No. ARB/08/16, Award (31 March 2011), at ¶¶ 232-237 (RL-26)).

[420] *See* Resp. Closing Statement, Tr. at 2194:20-2195:21 (accepting that tribunals should "consider . . . the character of the measure" but arguing that considering whether there has been "a violation of a substantive rule of international law . . . is just wrong").

[421] *Id*. at 2194:1-19 ("If we are talking about indirect expropriation, there are generally several more questions to consider . . . . The second factor is the extent to which the measure interferes with distinct, reasonable, investment-backed expectations. I want to be clear here, interference with such expectations does not mean that there has been an indirect expropriation. Whether the investor had a legitimate expectation arising from a written and specific commitment of the host state that the state would not act in the way that it did is simply one of the relevant considerations.").

[422] Cl. Reply at ¶¶ 317-318.

227. The promise utility doctrine effected a dramatic change in Canadian patent law, and it resulted in the adoption of a utility requirement that Canadian generic pharmaceutical firms, Canadian patent examiners and the governments of other NAFTA states have described as: a "free-for-all,"[423] "potentially unethical,"[424] and the cause of "serious concerns."[425] In other words, the promise utility doctrine is an arbitrary doctrine that could not have been anticipated by Lilly when it obtained its Zyprexa and Strattera patents.[426] The arbitrariness of the doctrine used to invalidate Lilly's patents, and the fact that the invalidations violated Lilly's legitimate expectations (grounded not only in Canadian law but also in the patents themselves), provide independent bases for the Tribunal to find an expropriation.[427]

c) Article 1110(7) Provides a NAFTA-Specific Basis To Conclude that Canada Expropriated Lilly's Zyprexa and Strattera Patents.

228. The text of NAFTA provides a separate basis, in addition to the general international law of expropriation, to conclude that Canada's measures were expropriatory in nature: Article 1110(7).

229. Article 1110(7) provides, "This Article [1110] does not apply 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)." The plain language of Article 1110(7) leads to three inescapable conclusions: First, this Tribunal has authority to determine the consistency of Canada's measures with Chapter 17. Second, if the Tribunal finds Canada's measures consistent with Chapter 17, then Canada's measures cannot qualify as an expropriatory measures

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[423] 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 (30 Sept. 2013) (C-375).

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

[425] 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).

[426] *See supra* Part II.

[427] *See infra* Part IV.C.2.

under Article 1110. Third, if the Tribunal finds Canada's measures inconsistent with Chapter 17, then Canada's measures may qualify as expropriatory measures under Article 1110 as long as there is also a substantial deprivation. In other words, consistency with Chapter 17 is a factor relevant to differentiating between an expropriation under Article 1110 and a non-compensable taking that does not engage Article 1110.

230. Canada agrees with the first two points above: it agrees the Tribunal may rule on whether its "measures are consistent with Chapter Seventeen." It agrees also that, if the Tribunal finds its measures consistent with Chapter 17, then those measures are not expropriations under Article 1110. Canada insists, however, that a finding of inconsistency has no legal effect: it may not be considered as part of the Tribunal's expropriation analysis. But there is no basis in NAFTA for this incongruous result.[428]

231. First, Article 1110(7) expressly establishes Chapter 17 as relevant to whether an intellectual property right has been expropriated: it instructs tribunals to consider "the extent" to which an "issuance, revocation, limitation or creation [of an intellectual property right] is consistent with Chapter 17." This does not mean that a Chapter 17 inconsistency, by itself, is sufficient to establish an expropriation — a measure must still substantially deprive an investor of an intellectual property right to qualify as expropriatory. But it does mean that Chapter 17 may be used by a tribunal to differentiate between an indirect expropriation and a non-compensable exercise of governmental authority.[429]

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[428] Describing Lilly's argument as "a logical fallacy," Canada likens Article 1110(7) to a statement that: "'If it is raining, then the streets are wet.'" Resp. Rejoinder at ¶ 220. From this, Canada argues, one cannot infer that if it is not raining, then the streets are not wet. *Id*. Lilly, however, has not argued that a violation of Chapter 17 alone suffices to demonstrate an expropriation. Rather, Lilly has shown that a "violation of Chapter 17 is highly *relevant* to [the Tribunal's] determination as to whether or not there's been an expropriation of intellectual property rights." Cl. Opening Statement, Tr. at 112:3-22. To use Canada's analogy, Lilly is arguing that the fact that the streets are wet is highly relevant to figuring out whether it has been raining.

[429] Cl. Mem. at ¶¶ 183-184 (emphasis in original).

232. This point is confirmed by reference to the context of Article 1110(7).[430] Chapter 11 contains two sets of reservations and exceptions clauses, which do in fact operate as safe harbors for NAFTA states: Article 1110(8) (Reservations and Exceptions) as well as Article 1101(3) (Scope and Coverage: Financial Services). The language of these provisions is unambiguous. They establish categorical exceptions from the provisions of Chapter 11.[431] They do not articulate "consistency" tests of the sort introduced by Article 1110(7).[432]

233. Canada argued in its Closing that Lilly's interpretation of Article 1110(7) would "open the floodgates," exposing all Chapter 17 violations to challenge under Chapter 11.[433] In a similar vein, it argued that looking to Chapter 17 under the general international law of expropriation would expose "to challenge[] . . . [violations] of all of the other substantive laws, international law, that is out there."[434] This is alarmist rhetoric, nothing more. The floodgates were not opened by *Saipem*, by *ATA*, or by any of the other awards that looked to related international obligations to determine whether a challenged measure was expropriatory. And they would not be opened here.

234. This is for two reasons. First, in agreeing to NAFTA's Chapter 17, Canada agreed to abide by specific rules for the grant *and revocation* of patents held by investors

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[430] *See* Cl. Reply at ¶¶ 256-258. Citing to NAFTA Articles 1503(2) and 1502(3)(a), Canada argues that "when the NAFTA parties wanted to make the breach of the obligations in another chapter of NAFTA the possible source of a finding of a breach of Chapter 11 by a Chapter 11 Tribunal, they did so." Resp. Closing Statement, Tr. at 2198:7-11. But this argument mistakes the purpose of Articles 1503(2) and 1502(3)(a). These provisions do not "make the breach of the obligations in another chapter of NAFTA the possible source of a finding of a breach." Rather, they make clear that state monopolies and enterprises are, like arms and agencies of host states, bound to respect Chapter 11. In other words, they are mere rules of attribution. *See* Cl. Comments on NAFTA Article 1128 and Non-Disputing Party *(Amicus)* Submissions at ¶ 46.

[431] For example, Article 1101(3) (emphasis added) provides that Chapter 11 "does not apply to measures . . . to the extent they are *covered* by Chapter Fourteen" (not "consistent with" Chapter Fourteen).

[432] Moreover, as Lilly has shown, Article 1110(8) (which provides that non-discriminatory measures shall not be considered measures tantamount to an expropriation of a debt security or loan in certain circumstances) is not applied merely as a safe harbor, and has been used to interpret Article 1110 to the benefit of a claimant. Cl. Reply at ¶¶ 257-258.

[433] Resp. Closing Statement, Tr. at 2196:1-4.

[434] *Id*. at 2195:11-2195:18.

of other NAFTA states. These rules are contained in the very same treaty as Chapter 11, and are expressly referred to by the article of Chapter 11 that governs the expropriation analysis the Tribunal is bound to apply. And, as in *Saipem*, Canada does not contest that it is bound by the rules in Chapter 17.[435] Not every violation of a substantive rule of international law will have a similarly direct nexus with an alleged expropriation of an established domestic property right.

235. Second, as demonstrated by multiple real world examples, just as not every substantial deprivation of an intellectual property right violates Chapter 17, not every violation of Chapter 17 results in a substantial deprivation.[436] As discussed above, the touchstone of the indirect expropriation analysis is a showing of substantial deprivation.[437] In many cases, such a showing is, without more, "dispositive" of the fact of an expropriation.[438] Nothing in Lilly's argument undermines the need for an investor to prove a substantial deprivation. In basing its claim of expropriation on (i) a substantial deprivation and (ii) a violation of an applicable international rule, Lilly simply asks this Tribunal to apply well-established law.

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[435] *See Saipem v. Bangladesh*, at ¶ 165 (CL-62). In *Saipem*, as here, the host state did not deny it was bound by the relevant rule of international law (the New York Convention), but insisted that the rule applied only "between States" and could not, for example, be invoked by a litigant in domestic court. *Id*. at ¶ 164. As the tribunal observed, these points were "irrelevant . . . . [A] breach of the Convention would still engage Bangladesh's international responsibility," and would thus remain an internationally unlawful act capable of differentiating an expropriation from a non-compensable exercise of state authority. *Id*. at ¶ 165.

[436] In its Comments on NAFTA Article 1128 and Non-Disputing Party *(Amicus)* Submissions, at ¶ 32, Lilly provided three examples of such violations, each arising from an actual WTO Dispute: (i) the stockpiling of patent-infringing goods before patent expiry for sale after patent expiry; (ii) the re-sale of trademark infringing goods seized by authorities; and (iii) a domestic law permitting amplification of music broadcasts by food service and retail establishments without payment of a royalty to persons holding copyrights on the broadcast music.

[437] Cl. Mem. at ¶¶ 172-175.

[438] *Fireman's Fund v. Mexico*, at ¶ 176(f) ("The effects of [a] host State's measure are dispositive . . . . ") (CL-45); *Biwater Gauff (Tanzania) Ltd. v. United Republic of Tanzania*, ICSID Case No. ARB/05/22 (18 July 2008), at ¶ 463 (concluding that expropriation is generally measured "by reference to the effect of the relevant acts, rather than the intention behind them") (emphasis in original) (CL-52).

4. Canada's Promise Utility Doctrine Is Inconsistent with Multiple Provisions of NAFTA Chapter 17.

236. At the Hearing, testimony confirmed the various ways in which Canada's new utility requirement breaches the intellectual property obligations undertaken by Canada in NAFTA Chapter 17.[439] Specifically, the promise utility doctrine is inconsistent with requirements:

- In Article 1709(1) to make patents available for inventions that are new, non-obvious, and useful, under which Canada cannot deny or invalidate patents for lack of utility under a new, additional utility test where the patented inventions meet the treaty standard.

- In Article 1709(7) to make patents available without discrimination as to field of technology, under which a record of overwhelmingly disproportionate effects on the pharmaceutical sector constitutes impermissible *de facto* discrimination.

- In Article 1709(8) not to revoke a patent retroactively on the basis of a new patentability requirement that did not exist when the patent was granted.[440]

237. Confronted with clear evidence of these breaches at the Hearing, Canada sought to defend its measures by interpreting the relevant Chapter 17 provisions in a manner that minimizes, or altogether eliminates, any affirmative obligations:

- With regard to Article 1709(1), Canada argued that it has unfettered discretion to interpret "useful,"[441] and that Article 1709(1) is not a mandatory obligation.[442] But

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[439] This Section responds to the Tribunal's ***Questions 8, 9, 10, 32,*** and ***33***. ***Question 8*** asks what is the meaning of "shall make patents available" in Article 1709(1) of NAFTA. ***Question 9*** asks "as of what date was Respondent in breach of its obligations under NAFTA Chapter Seventeen" and what is the relevance, if any, of the Canadian Supreme Court's decision in *AZT*. ***Question 10*** asks what is "the relevance, if any, of the utility standards in the other NAFTA jurisdictions with respect to Claimant's claims." ***Question 32*** asks "[d]oes Article 1709(8)(a) of NAFTA apply to an actual refusal to grant a patent or does it apply to the situation in which the grant could have been refused." ***Question 33*** invites the parties to "comment on the meaning of Article 1709(1) of NAFTA and the extent to which it imposes substantive obligations."

[440] The promise utility doctrine is also inconsistent with NAFTA Article 1701(1), which requires Canada to provide U.S. nationals with adequate and effective protection and enforcement of intellectual property rights. Canada's only Article 1701(1) argument contrasted the number of pharmaceutical patents granted since 2005 with the smaller number found to lack utility. *See* Resp. Opening Statement, Tr. at 314:19-315:16. But the denial of effective protection and enforcement with respect to certain patents is not offset by inaction with respect to other patents. Lilly rests on its prior submissions regarding Canada's breach of Article 1701(1). *See* Cl. Mem. at ¶¶ 232-234; Cl. Reply at ¶¶ 306-308.

witnesses at the Hearing, including Canada's own witnesses, uniformly acknowledged that Article 1709(1) limits Canada's discretion.

- With regard to Article 1709(7), presented with overwhelming evidence of the promise utility doctrine's effects on the pharmaceutical sector, Canada argued that evidence of disproportionate impact is "legally irrelevant" to field of technology discrimination.[443] Canada provided no support for this argument.

- And with regard to Article 1709(8), Canada argued that the provision has nothing to do with retroactivity and instead merely requires Canada to maintain symmetrical criteria for denying patent applications and revoking granted patents.[444] Again, Canada provided no support for this argument.

238. In all three instances, Canada's strained interpretations are at odds with the treaty text, properly understood under the Vienna Convention on the Law of Treaties.[445]

a) Canada has Denied Patent Protection to Inventions That Meet the "Useful" Criterion Under Article 1709(1) on the Sole Ground That They Lack Utility.

239. NAFTA Article 1709(1) requires that Canada "shall make patents available for any inventions" that are new, non-obvious, and capable of industrial application (or useful). At the Hearing, as in its written submissions, Lilly analyzed the text of Article 1709(1) consistent with the Vienna Convention and demonstrated that the treaty terms "capable of industrial application" and "useful," which are deemed synonymous under the treaty, simply require that an invention be capable of some practical use.[446]

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[441] Resp. Closing Statement, Tr. at 2305:8-11.

[442] Resp. Opening Statement, Tr. at 316:23-24.

[443] Resp. Closing Statement, Tr. at 2282:3-11.

[444] Resp. Opening Statement, Tr. at 295:7-16.

[445] In response to ***Question 25*** from the Tribunal, the references to "applicable rules of international law" in NAFTA Article 102(2) and Article 1131(1) permit the Tribunal to consider other relevant rules of international law, including the Vienna Convention on the Law of Treaties, in connection with its interpretation of NAFTA.

[446] Cl. Closing Statement, Tr. at 2099:20-2112:6; *see* Cl. Mem. at ¶¶ 185-206; Cl. Reply at ¶¶ 259-290.

240. As Lilly explained in Closing, "if the patent satisfies the capable of industrial application standard that's embodied in 1709(1), a patent cannot be withheld or, in our case later revoked, for a want of utility."[447] In other words, by invalidating patents on the sole ground of inutility based on an additional, heightened utility requirement, when those patented inventions in fact met the "useful" requirement set forth in NAFTA, Canada acted inconsistently with Article 1709(1).[448]

241. Canada at the Hearing advanced two principal defenses. Neither withstands scrutiny, as both would have the effect of eliminating any affirmative obligation under Article 1709(1).

242. Canada's first argument was that the NAFTA parties have infinite discretion to define and apply the patentability requirements of Article 1709(1) as they wish, unconstrained by the treaty text. Specifically, Canada argued that because the NAFTA parties did not define "capable of industrial application" or "useful," they must have "wanted to have flexibility on the meaning and the implementation of those obligations."[449] In making this argument, however, Canada utterly failed to offer a good faith interpretation under the Vienna Convention. The absence of a specific definition does not mean that treaty terms are devoid of meaning; it simply means that it is necessary to utilize the tools provided in the Vienna Convention to give the terms effect.

243. As Lilly has argued, and as witness testimony at the Hearing confirmed, the ordinary meaning of "capable of industrial application" and "useful," understood in

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[447] Cl. Closing Statement, Tr. at 2114:3-6.

[448] Zyprexa and Strattera are examples of this phenomenon. With respect to Zyprexa, the court held that it would have demonstrated utility under the mere scintilla test, but it could not "accept that the '113's promise was *so small*." *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, at ¶ 209 (emphasis added) (C-146). Similarly, on Strattera, the court held that Lilly would have met the mere scintilla test but that patent promised more. *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, at ¶ 93 (C-160). Zyprexa and Strattera were capable of a practical use and met the mere scintilla standard embodied in NAFTA Article 1709(1). Nonetheless, both were later invalidated solely on the ground of inutility under an additional, heightened utility requirement.

[449] Resp. Closing Statement, Tr. at 2305:4-2307:15.

context and in light of their object and purpose under Vienna Convention Article 31(1), is a capacity or ability to be put to a specific or practical use in industry. This is apparent from traditional dictionary definitions; from the context of how those terms of art are understood within the field of patent law; and from the stated object and purpose of NAFTA, which is to promote innovation and provide effective protection and enforcement of intellectual property rights.[450]

244. This interpretation is further confirmed by the subsequent practice of the NAFTA parties and by relevant rules of international law, which are additional considerations under Vienna Convention Articles 31(3)(b) and 31(3)(c). Lilly's experts on U.S. and Mexican law and patent office practice all emphasized that the utility requirement in the United States and Mexico has consistently been understood as a low bar since NAFTA entered into force, and that no other patentability requirement resembles the promise utility doctrine (*supra* Part II.E). For a full decade after NAFTA came into effect, until the mid-2000s, Canada also applied a low bar under its traditional "mere scintilla" test, as Professor Siebrasse and Mr. Wilson attested (*supra* Part II.C). Meanwhile, as Professor Erstling testified, the shared understanding of "industrial applicability" as a low bar is reflected also in Article 33(4) of the PCT, an agreement that is in force among the NAFTA parties and is a relevant rule of international law in this context (*supra* Part II.F).

245. Given that all of these sources and interpretive tools point in the same direction, toward a definition that tracks Canada's "mere scintilla" test but bears no resemblance to the promise utility doctrine, Canada largely declined to engage in a traditional Vienna Convention analysis at the Hearing. Instead Canada merely emphasized — supposedly as part of its ordinary meaning inquiry — that no definition of "useful" or "capable of industrial application" appears in NAFTA.[451]

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[450] *See* Cl. Reply at ¶¶ 266-273.

[451] Resp. Closing Statement, Tr. at 2305:3-8 ("So let's start off with the ordinary meaning in its context under Article 31(1). The first thing to note is that the NAFTA parties did not include a definition of useful, and it did not include a definition of capable of industrial application.").

246. Canada's analysis of ordinary meaning at the Hearing remained noticeably thin, capped by its assertion in Closing that the exercise "is not very useful."[452] As for context, Canada pointed again to the fact that the terms were undefined, and argued again this was because the NAFTA parties left interpretation to domestic legal systems — as if the mere fact that domestic law addresses these concepts somehow implies that the treaty terms lack any identifiable meaning and can be freely interpreted without limitation so long as the Patent Act includes the word "useful."[453] Such a view deprives the treaty terms of any meaning or effect.[454] Further, the text of Article 1709(1) already acknowledges the degree of variability permitted in domestic legal regimes with respect to the utility requirement, noting that "capable of industrial application" is deemed synonymous with "useful" for purposes of Article 1709(1). But the question still remains: what is the meaning of "capable of industrial application" and "useful" in this context? International principles of treaty interpretation provide the interpretive tools to answer this question.

247. Regarding subsequent state practice by the NAFTA parties, a topic on which Lilly presented extensive evidence at the Hearing, Canada at Closing responded by pointing only to the Article 1128 submission of the United States and arguing that it represents the "one true piece of subsequent practice" that clearly falls within Vienna Convention Article 31(3)(b).[455] That Canada attempted to place such weight on a

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[452] *Id*. at 2308:11-13.

[453] Resp. Closing Statement, Tr. at 2308:13-23 (arguing the parties "have left them undefined precisely because they will evolve and emerge in the context of legal systems"); *id.* at 2323:17-2324:2 (arguing that evolution of the utility requirement makes it "necessary to allow states to have the discretion" to implement, and that Canada and the United States "have Patent Acts that use the word 'useful'").

[454] Canada also argued that the NAFTA parties did not assign a special meaning to the terms, as permitted by Vienna Convention Article 31(4), and that Lilly attempted unsuccessfully to ascribe a special meaning based on U.S. law and relating to evidentiary rules, timing, and disclosure. *Id*. at 2305:20-2306:2; *id*. at 2307:16-25. That is incorrect. At the Hearing, as in its written submissions, Lilly called for the terms to be understood consistent with their straightforward, traditional meaning, under which an invention must be capable of a practical use. Lilly also argued that because Article 1709(1) uses patent terminology, it is reasonable to assume that the special meaning of those terms of art in a patent context was agreed by the treaty parties. *See* Cl. Reply at ¶¶ 279-282.

[455] Resp. Closing Statement, Tr. at 2309:17-25.

document that reflects the litigation position of a single government[456] is emblematic of how far Canada had to stretch in its attempts to find support for its infinitely flexible reading of Article 1709(1). And, in any event, the U.S. Article 1128 submission does not actually support Canada's position. Rather, the view of the United States is that Canada's discretion to change its law is, and must be, limited:

> The Parties retain discretion to change or refine their domestic law, but that discretion is not without limits. Were it otherwise, the obligation stated in 1709(1) would be without meaning or effect. A NAFTA Party may not apply requirements or conditions that would vitiate the obligation to make patents available for inventions that meet the requirements, including the "utility" requirement, of Article 1709(1).[457]

248. Further, the United States has repeatedly expressed its concern with "the lack of clarity and the impact of the heightened utility requirements for patents" under which Canadian courts have "recently . . . invalidated several valuable patents held by U.S. pharmaceutical companies on utility grounds."[458]

249. Canada has identified no subsequent state practice — in the United States, Mexico, or elsewhere — that remotely resembles the promise utility doctrine. To the contrary, the "concordant, common, and consistent" subsequent practice in the United States, Canada, and Mexico for a full decade after NAFTA's enactment was a utility test that focused on operability and was a low bar.[459]

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[456] *See* Cl. Comments on NAFTA Article 1128 and Non-Disputing Party (*Amicus*) Submissions, at ¶¶ 2-5 (explaining why Article 1128 submissions do not constitute subsequent agreement or subsequent practice under Vienna Convention Article 31(3)).

[457] U.S. Art. 1128 Submission at ¶ 41.

[458] Office of the United States Trade Representative, 2015 SPECIAL 301 REPORT 66-67 (Apr. 2015) (C-332); *see* Cl. Reply at ¶ 52; Office of the United States Trade Representative, 2014 SPECIAL 301 REPORT 49-50 (Apr. 2014) (C-331).

[459] As the tribunal in *Canadian Cattlemen for Fair Trade v. United States* observed, in applying Article 31(3)(b) of the Vienna Convention, "'[t]he value and significance of subsequent practice will naturally depend on the extent to which it is concordant, common, and consistent." UNCITRAL, Award on Jurisdiction (28 Jan. 2008), ¶ 182 (quoting Ian Sinclair, THE VIENNA CONVENTION ON THE LAW OF TREATIES 137 (2d ed. 1984)) (RL-147).

250. Finally, without analysis, Canada asserted that the way "not useful" was defined in *Consolboard* qualifies as a "perfectly reasonable" assessment of ordinary meaning in context.[460] As an initial matter, Canada's assertion is at odds with how the Vienna Convention works; under a proper approach, the analysis must start with the treaty text, not the definition provided by Canada's courts prior to the treaty's enactment. As a factual matter, Lilly would agree that the definition of "not useful" in *Consolboard*, as understood and applied for decades by the Canadian courts prior to 2005, was reasonable. As Professor Siebrasse and Mr. Wilson explained, *Consolboard* was long understood to require no more than simple operability under the mere scintilla requirement — *i.e.*, does the claimed invention work for its intended purpose (*see supra* Part II.C). As re-interpreted by the Canadian courts since 2005, however, the *Consolboard* language is decidedly unreasonable. And Canada's attempt to conflate these sharply divergent readings of *Consolboard*, before versus after 2005, does not withstand scrutiny.

251. Canada's argument that its courts have unfettered discretion to interpret "useful" is not only contrary to a proper Vienna Convention analysis, it was contradicted by the testimony of multiple witnesses at the Hearing. Every witness who opined on the issue affirmed Lilly's position that NAFTA Article 1709(1) establishes a minimum baseline of protection for patentees, imposing a limit on state discretion.[461] Even Canada's witnesses, Professors Holbrook and Gervais, agreed that Article 1709(1) imposes a substantive constraint. Professor Holbrook testified that "there is no obligation that the laws be exactly the same," but they do "have to be similar" under "the NAFTA requirement that patents be useful," and in his view Article 1709(1)

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[460] Resp. Closing Statement, Tr. at 2308:2-10 (arguing that "certainly the ordinary meaning of useful can be read exactly as the Supreme Court of Canada said in Consolboard"); *id.* at 2309:10-16 (arguing that the way useful has been interpreted by the Canadian courts "is perfectly reasonable in the application of an ordinary meaning in context").

[461] Professor Merges, for example, testified that Article 1709(1) constrains U.S. substantive law developments, such that Congress could not "define one of those [three core patentability] standards in a way that's completely radically different from the historical standard and still be in compliance." Testimony of Robert Merges, Tr. at 1416:6-18.

represents high-level harmonization.[462] Professor Gervais likewise conceded that there could be interpretations of "useful" that are inconsistent with Article 1709(1), for example if a court held that "a pharmaceutical product is only useful if it cures 100 percent of the patients entirely."[463] In Professor Gervais's view, "there are limits to the leeway, otherwise, the Treaty means nothing, but the question is where is that limit."[464]

252. In terms of how to identify the limit, Professor Gervais confirmed that "state practice is obviously relevant."[465] For guidance, Professor Gervais looked to WIPO documents wherein states reported their practice.[466] As Mr. Thomas explained, those documents reflect substantial consistency in outcomes and a shared understanding of the central tenet of the utility/industrial applicability requirement: that an invention have a practical use (*supra* Part II.F). And while different statutes may use different language to implement that requirement, Mr. Thomas confirmed that it is consistently a low bar across jurisdictions.[467]

253. At the Hearing, Canada continued to emphasize that the utility requirement is not harmonized in NAFTA or internationally,[468] but Lilly has not argued otherwise: Lilly's argument is that Article 1709(1) establishes a minimum baseline of protection, reflected in the widely-shared understanding of the utility/industrial

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[462] Testimony of Timothy Holbrook, Tr. at 1546:15-16; *id.* at 1558:14-1559:7 ("SIR DANIEL BETHLEHEM: You said, 'Moreover, there is no obligation that the laws be exactly the same. They just have to be similar.' I'd like to know what you mean by obligation, where you find this obligation. PROFESSOR HOLBROOK: So the obligation would be in the NAFTA requirement that patents be useful. . . . SIR DANIEL BETHLEHEM: So you are addressing Article 1709(1) as a high-level harmonization but not requiring exact similarity or not requiring equivalence? PROFESSOR HOLBROOK: Correct.").

[463] Testimony of Daniel Gervais, Tr. at 1827:6-1828:6. Canada's required showing of long-term clinical effectiveness under Canada's promise utility doctrine is strikingly close to Gervais's "cures 100 percent of the patients entirely" hypothetical.

[464] *Id*. at 1759:10-12.

[465] *Id*. at 1831:5-10.

[466] *Id*. at 1831:10-14 (arguing there is "no better source of state practice" than the WIPO reports).

[467] Testimony of Philip Thomas, Tr. at 1696:1-11 ("In practice, very few inventions are denied patentability on the basis of the utility requirement. Very rarely is an application rejected or a patent invalidated for want of utility. It is a very low bar to patentability"); *id.* at 1700:9-1702:2.

[468] Resp. Closing Statement, Tr. at 2305:16-18.

applicability requirement. The Hearing offered a powerful example of a NAFTA party acknowledging the constraint imposed by this baseline obligation. As Professor Gonzalez explained, the Mexican Congress in 2010 rejected a proposal to amend the definition of "industrial application" by replacing the word "possibility" with the word "fact."[469] According to the legislative history, and as conceded by Canada's Mexican law witness Ms. Lindner, this proposal was rejected by the Mexican Congress because such a change would have been inconsistent with Mexico's international treaty commitments to make patents available to inventions that are merely "capable of industrial application," not proven (*supra* Part II.E).

254. Canada also offered a second argument: that "Article 1709(1) is not a mandate or an obligation" at all, regardless of how one defines "useful."[470] Specifically, Canada argued that the phrase "shall make patents available" — despite its mandatory phrasing — does not obligate Canada to grant a patent for an invention that is new, non-obvious, and useful, because those are merely necessary, but not sufficient, conditions for patentability, as there are additional conditions that must also be satisfied and that are left to domestic law.[471]

255. This reading is contrary to the plain text of Article 1709(1). The treaty text, "shall make patents available," read in context of 1709(2) and 1709(3), defines the scope of inventions for which patent rights must be provided. As Lilly explained in Closing, if an invention meets the treaty requirement for useful/capable of industrial application, an invalidation for lack of utility under an additional, elevated requirement is a breach of Article 1709(1).[472]

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[469] Testimony of Gilda Gonzalez, Tr. at 1855:10-20.

[470] Resp. Opening Statement, Tr. at 316:23-24.

[471] *Id*. at 315:17-318:25.

[472] Cl. Closing Statement, Tr. at 2113:11-2114:9 ("What that means is that if the utility test was met, . . . the utility test in 1709(1)[,] when the patents were challenged, you don't get to move the goal posts 100 meters farther down the field or withhold or deny a patent based on a new, unilaterally redefined heightened utility requirement."). Similarly, although not at issue here, inventions that meet the treaty standard for useful/capable of industrial application cannot be denied a patent in the first instance because the invention lacks utility under an additional, elevated standard.

256. Furthermore, in the context of this case, Lilly's patents for Zyprexa and Strattera, along with various other pharmaceutical patents reviewed by Canada's courts, were invalidated under the promise utility doctrine on the *sole ground of inutility*. The other core patentability requirements of novelty and non-obviousness, as well as the entire range of other conditions of patentabiltiy such as sufficiency of disclosure, were fully satisfied.[473] The hypothetical that Canada *might* have revoked these patents on some other basis is beside the point. By denying patent rights to inventions that meet the treaty requirement for utility, Canada failed to comply with the mandatory terms of Article 1709(1).

b) Canada's Utility Test Discriminates Against Pharmaceutical Inventions in Violation of Article 1709(7).

257. NAFTA Article 1709(7) requires that patents shall be available, and patent rights enjoyable, without discrimination as to the field of technology.[474] In its submissions and at the Hearing, Canada has not disputed that this provision prohibits not only *de jure* discrimination, but also *de facto* discrimination, in the form of facially neutral measures that in practice produce differentially disadvantageous effects on a particular field of technology.

258. At the Hearing, Lilly presented compelling evidence of the promise utility doctrine's overwhelmingly disproportionate effects on the pharmaceutical sector (*supra* Part II.D). Since 2005, more than two dozen pharmaceutical patents (for drugs approved as safe and effective by Health Canada) have been found not to be useful, whereas not a single patent in any other technological field has been ruled to lack utility. As a proportion, 41 percent of utility decisions in the pharmaceutical sector since 2005 have found a lack of utility, versus zero percent in all other sectors

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[473] *Id*. at 1991:5-9 ("[I]t's undisputed that the Zyprexa patent was revoked on a single ground — . . . lack of utility."); *id.* at 1998:23-1999:4 ("Canada acknowledged . . . that the court had found that the '735 [Strattera] patent cleared the hurdles of obviousness and anticipation. . . . The '735 patent is invalidated solely for lacking utility.").

[474] This Section responds to the Tribunal's ***Question 18*** asking the parties to elaborate upon the alleged discriminatory intent.

combined.[475] Given its magnitude, this disproportionate impact across sectors is sufficient to establish a breach of Article 1709(7). Notably, as Professor Levin explained at the Hearing, the difference is not merely large, it is also statistically significant, removing any doubt that the pattern of outcomes might be due to chance or to a small number of decided cases.[476]

259. At the Hearing, as in its prior written submissions, Canada's principal arguments in response to this claim focused on the facts, not the law. In particular, Canada called into question the construction and coding of the database of cases analyzed by Professor Levin. But, as Professor Levin explained, and as summarized above at Part II.D, none of Canada's proposed changes to Professor Levin's data set had a material effect on his findings — with the exception of a proposed counting methodology that Professor Levin regarded as statistically invalid and inconsistent. Even accepting Canada's changes, the gap between the pharmaceutical and non-pharmaceutical sectors, in terms of the number and rate of inutility findings, remains substantial. For example, after excluding all PM(NOC) decisions, which constitute the lion's share of the data set, the inutility rate in the pharmaceutical sector *increases* to 43% (6 of 14), and there remain zero inutility findings in all other sectors combined.[477]

260. Unable to rebut the substantial evidence of discriminatory effects since the advent of the promise utility doctrine, Canada argued that Professor Levin's statistical analysis does not itself establish causation. Professor Levin acknowledged that his statistical methodology does not lead to an explicit finding of causation, but he also emphasized that his findings of significance "are consistent with the Claimant's view that Canadian utility law has had a disproportionate impact on the pharmaceutical sector since 2005."[478] Canada, meanwhile, offered no plausible alternative causal

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[475] Cl. Opening Statement, Tr. at 2114:19-24.

[476] *See supra* Part II.D.

[477] *See supra* n.207; Levin Demonstrative Slide at 6.

[478] Testimony of Bruce Levin, Tr. at 1207:14-17; *id.* at 1266:8-11 ("The statement was 'it is consistent with.' I'm not opining about causality as a statistician in this case. But it is consistent.").

account.[479] Simply put, Professor Levin's statistical analysis powerfully corroborates Lilly's claim of *de facto* discrimination.

261. Finally, Canada made a passing reference in its Opening to a legal argument not put forward in its Counter-Memorial or Rejoinder, but first noted in its 22 April 2016 comments on the U.S. Article 1128 submission — which is that "differential effects of a measure on a particular sector, even if shown, do not necessarily prove discrimination as to field of technology within the meaning of Article 1709(7)."[480] Canada did not develop or defend this position at the Hearing , and with good reason — such a position contradicts its past positions on the same issue in WTO litigation.[481] In any event, the argument is misplaced. As Lilly explained at the Hearing, the only case cited in support, a WTO dispute involving Canada's protection of pharmaceutical patents, included no evidence of discriminatory effects at all.[482] Even if objective indicia of intent were required, which they are not, the promise utility doctrine would be understood and expected to have a disparate impact on pharmaceutical innovators given the timing nature of the drug development process.[483]

262. Canada simply cannot explain away the dramatic, disproportionate impact the promise utility doctrine has had on the pharmaceutical sector. For the first time at Closing, Canada suggested that somehow the factual evidence of disproportionate impact is "legally irrelevant."[484] Canada identified no legal authority

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[479] *See supra* Part II.D.

[480] Resp. Opening Statement, Tr. at 326:21-24. In addition to discriminatory effects, Canada argued in its comments on the U.S. submission, evidence of discriminatory objectives is also required. Resp. Observations on Issues Raised in 1128 Submissions of the United States and Mexico at ¶ 43.

[481] *See* Cl. Comments on NAFTA Article 1128 and Non-Disputing Party (*Amicus*) Submissions at ¶¶ 36-37.

[482] Cl. Opening Statement, Tr. at 123-26; *see* Cl. Comments on NAFTA Article 1128 and Non-Disputing Party (*Amicus*) Submissions at ¶¶ 36-37.

[483] *Id*. at 123-26; *see* Cl. Reply at ¶¶ 223-225.

[484] Resp. Closing Statement, Tr. at 2282:8-11 (arguing that evidence of a disproportionate impact on a particular industry does not show discrimination and "is a legally irrelevant point").

for this assertion, which is contrary not only to the traditional test for *de facto* discrimination,[485] but also to common sense.[486]

263. In sum, confronted with robust evidence of the promise utility doctrine's disparate effects, Canada's defense was to assert — without support — that this overwhelming evidence of *de facto* discrimination is somehow legally irrelevant. To the contrary, this unrebutted evidence of disparate impact is legally dispositive regarding Canada's breach of Article 1709(7).

c) Canada Revoked Lilly's Patents based on the Promise Utility Doctrine, a Ground for Revocation That Did Not Exist When the Patents Were Granted, in Violation of Article 1709(8).

264. NAFTA Article 1709(8) states that a party may invalidate a patent only when "grounds exist that would have justified a refusal to grant the patent." As Lilly explained at the Hearing, the explicit text of this provision — given its past tense, "*would have justified*" — makes clear that it operates as a bar on retroactivity.[487] The provision requires that Canada may revoke a patent only on the basis of grounds that existed and would have justified a refusal to grant the patent in the first instance, at the time of review.[488]

265. As evidence presented at the Hearing confirmed, when Lilly's patents for Zyprexa and Strattera were granted, Canada had only the traditional, "mere scintilla" utility requirement. By the time those patents were challenged, however, Canada had

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[485] Cl. Mem. ¶¶ 216-218; Cl. Reply ¶¶ 291-300.

[486] The argument is of a pair with Canada's equally baseless assertion that the promise utility doctrine has affected the pharmaceutical sector because only innovators in that sector "are the ones patenting upstream." Resp. Closing Statement, Tr. at 2281:21-24. Again, Canada provided no support for its suggestion that competitive pressures to patent early are unique to the pharmaceutical field — a claim that makes no sense. Second Witness Statement of Robert Armitage, at ¶¶ 10-11 (emphasizing that Lilly and other pharmaceutical firms "patent significantly less frequently than companies in other research-based industries, despite spending a great deal more on R&D").

[487] Cl. Opening Statement, Tr. at 126:7-127:3.

[488] In response to Tribunal ***Question 32,*** it is common ground that this rule applies only to actions at the moment of revocation, not the time of grant. *See* Cl. Closing Statement, Tr. at 2122:23-2123:20; Resp. Closing Statement, Tr. at 2324:12-2325:17.

added an additional and elevated test for utility in the form of the promise utility doctrine (*see supra* Part II.A-C). That new utility test — which did not exist when Lilly's patents were granted — was then applied retroactively to revoke Lilly's patent rights. Canada's retroactive application of this new patentability requirement, one that did not exist at the time of grant and thus could not have been the basis for denial, is squarely inconsistent with Article 1709(8).

266. Contrary to Canada's claims at the Hearing, Lilly does not advocate that Article 1709(8) operates to "freeze . . . intellectual property laws from the date of review."[489] Rather, as Lilly explained, the provision prohibits the retroactive application of an entirely new ground for revoking a patent (as occurred to Lilly's patents).[490]

267. At the Hearing, Canada revised the text of this provision, converting it to the present tense. Specifically, Canada argued that Article 1709(8) should be interpreted to mean that "if the grounds [of revocation] exist at the time when the validity is questioned," then revocation on that ground would be consistent with the provision.[491] Under this narrow interpretation, Article 1709(8) merely indicates that a patent may be revoked on any ground that exists in domestic law on the date of challenge. The law as it existed on the date of grant, in Canada's view, is entirely irrelevant. Canada's interpretation not only is contrary to the text, it also drains the provision of any significance.

268. Canada's proposed reading also ignores the verb tense in the provision, as Lilly explained at the Hearing.[492] Canada's interpretation would be plausible only if the

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[489] Resp. Opening Statement, Tr. at 292:23-293:2.

[490] Cl. Closing Statement, Tr. at 2122:4-2123:20.

[491] Resp. Opening Statement, Tr. at 293:16-19.

[492] Cl. Closing Statement, Tr. at 2122:10-2123:6 ("Article 1709(8) provides a clear and objective standard defining when it's appropriate and when it's not appropriate to revoke a patent. And the words 'would have justified' are past tense and, thus, expressly refer back to the time of grant, not to the time of challenge or revocation, which I believe Canada contends. If Canada's view were correct that it simply means what was the state of the law at the time of revocation, then 1709(8) would be written differently. (continued…)

provision were written in the present tense — *i.e.*, only if Article 1709(8) were drafted to state that a party may invalidate a patent only when "grounds exist that *would justify* a refusal to grant the patent."

269. Once again, Canada's argument is at odds with the treaty text. Rules against retroactivity are common in many legal realms, and well justified. The straightforward purpose of Article 1709(8) is to protect existing patent rights from being retroactively revoked pursuant to a patentability requirement that did not exist at the time of grant.

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270. There can be no reasonable debate about the fact that Canada revoked two of Lilly's protected investments in Canada — its patents on Zyprexa and Strattera — thereby depriving Lilly of those investments not just substantially, but completely.

271. Rather than rely on the many awards that have articulated and applied a "sole effects" test,[493] Lilly has recognized that in the context of a judicial expropriation, a tribunal must consider not just whether an investor has been substantially deprived of its investment, but also something more.

272. Looking to the general international law of expropriation and to the text of NAFTA's Article 1110(7), Lilly has identified several independent bases upon which the Tribunal may conclude that Canada's taking of Lilly's patents constituted an expropriation under Article 1110: the international wrongfulness of the measure under Chapter 17; the arbitrariness of the measure; and the fact that the measure is

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It would talk about a party may revoke a patent only when grounds exist that would justify refusal to grant a patent rather than would have justified.").

[493] *See, e.g.*, *Tecnicas Medioambientales Tecmed S.A. v. Mexico*, ICSID Case No. Arb(AF)/00/2, Award (29 May 2003), at ¶ 116 ("The government's intention is less important than the effects of the measures . . . . ") (CL-47); *Phelps Dodge Corp. et al v. Iran*, 10 Iran-US CTR 121, 130 (1986-1) ("[T]he Tribunal understands the financial, economic and social concerns that inspired the law pursuant to which it acted, but those reasons and concerns cannot relieve the Respondent of the obligation to compensate Phelps Dodge for its loss.") (CL-55).

inconsistent with legitimate investment-backed expectations.[494] Here, all of those factors support a finding of expropriation.

C. Canada's Measures Are Inconsistent with NAFTA Article 1105.

1. Arbitral Practice Under BITs Has Elucidated the Minimum Standard of Treatment.

273. Both parties agree that the governing standard under Article 1105(1) is the Minimum Standard of Treatment under customary international law.[495] The parties disagree, however, on what the Minimum Standard of Treatment actually protects in the context of this case. For Canada, this analysis has a simple answer: nothing. Canada argues that the standard does not protect legitimate investment-backed expectations — even where those expectations are supported by specific, written representations.[496] It argues that the standard does not protect against discrimination.[497] And, after first agreeing that the standard protects at least against arbitrary governmental conduct,[498] it now contests that protection as well.[499] Perhaps

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[494] This observation responds to the Tribunal's ***Question 23***, which asks, "On what basis does Claimant argue that its alleged investment has been indirectly expropriated?"

[495] This section responds to the Tribunal's ***Questions 6, 34, 35***, and ***36***. The Tribunal's ***Question 6*** asks in what way the identification of the "promise" is subjective. ***Question 34*** invited the parties to "address the sources and current content of the" Minimum Standard of Treatment, and ***Question 35*** asked whether the Minimum Standard has "been evolved and shaped by the 3000 BITs." The Tribunal's ***Question 36*** invited Lilly to summarize its allegations of a breach of Article 1105 and in particular "the extent to which its legitimate expectations, arbitrariness and discrimination allegations constitute separate heads of alleged breach."

[496] Resp. Closing Statement, Tr. at 2191:1-14 ("THE PRESIDENT: . . . You say there's no general obligation, but what about a state undertaking a specific obligation vis-à-vis a specific foreign investor? . . . . MR. SPELLISCY: Again, in our view certainly there have been tribunals that have talked about there needing to be a specific written representation, but in our view there is no obligation to respect an investor's legitimate expectations under customary international law.").

[497] *Id*. at 2188:6-2189:8 (stating "there is no principle of customary international law preventing host states from providing different treatment to foreign investors" and "there is no prohibition at customary international law on discrimination in the granting of patents based on the industrial sector of operations").

[498] *See* Resp. CM at ¶¶ 249-251 ("Arbitrariness in international law means that 'prejudice, preference or bias is substituted for the rule of law.' In order to be arbitrary, a measure must have no legitimate purpose, not be based on legal standards or must have intentionally ignored due process and proper procedure.").

unsurprisingly, the *only* form of misconduct which Canada freely admits *is* covered by the Minimum Standard of Treatment also happens to be the one form of misconduct that is *not* at issue here: procedural denial of justice.[500]

274. But the Minimum Standard is not as narrow as Canada suggests. The Minimum Standard is frequently interpreted and has repeatedly been applied both in the NAFTA context and in the context of many other treaties. The awards that interpret and apply the Minimum Standard consistently recognize that the standard incorporates each of the protections at issue here.[501] And despite advocating for a restrictive interpretation of the Minimum Standard by criticizing the relevance of arbitral awards, Canada simultaneously cites such awards to articulate the rules on which it relies.[502]

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[499] Resp. Closing Statement, Tr. at 2189:9-20 ("I note that a number of NAFTA tribunals have suggested that a certain level of arbitrariness violates the minimum standard of treatment. In my view, none of these tribunals have undertaken an analysis of state practice and *opinio juris* to identify the content of the rule.").

[500] Resp. Closing Statement, Tr. at 2186:21-23 ("As I said just a few seconds ago, there is no dispute that customary international law protects against a denial of justice."). Canada purports to agree that customary international law has evolved beyond the *Neer* standard of the 1920s. Resp. Closing Statement, Tr. at 2183:9-24. Asked repeatedly *how* the *Neer* standard has evolved, however, Canada declined to provide an answer pertinent to this arbitration. It ignored any evolution that may have occurred in the standard's protections of legitimate expectations, against arbitrariness, and against discrimination. Instead, it asserted that "*denial of justice*, it hasn't evolved in a way that the Claimant has suggested, that it has evolved to a point where actions of a judiciary and the absence of a denial of justice can violate the minimum standard of treatment." Resp. Opening Statement, Tr. at 218:25-219:6 (emphasis added). But of course, Lilly's case is *not* that the denial of justice standard has evolved so as to somehow encompass Lilly's claims. Rather, Lilly has proven violations of aspects of the minimum standard *other than* denial of justice.

[501] *See*, *e.g.*, *Bilcon v. Canada*, at ¶ 442 (CL-166) ("Taken together, the *S.D. Myers*, *Mondev*, *ADF* and *Loewen* cases suggest that the minimum standard of treatment of fair and equitable treatment is infringed by conduct attributable to the State and harmful to the claimant if the conduct is arbitrary, grossly unfair, unjust or idiosyncratic, is discriminatory and exposes the claimant to sectional or racial prejudice, or involves a lack of due process leading to an outcome which offends judicial propriety - as might be the case with a manifest failure of natural justice in judicial proceedings or a complete lack of transparency and candour in an administrative process. In applying this standard it is relevant that the treatment is in breach of representations made by the host State which were reasonably relied on by the claimant.") (quoting *Waste Management (II)*, at ¶ 98).

[502] Among other examples, Canada relies on *Mondev v. United States* as the authority that "set[s] out the basis upon which a NAFTA Chapter Eleven tribunal may review judgments of domestic courts pursuant to Article 1105." Resp. CM at ¶ 236; *see id.* at ¶ 271 (noting "arbitral awards may contain valuable (continued…)

275. Indeed, the Tribunal now has over three hundred distinct legal authorities before it, submitted by both parties. Many of those are awards and orders made in other investment arbitrations. Many more interpret or opine on such awards and orders. It would not be appropriate, as Canada now suggests, for the Tribunal to simply set aside the standards articulated in these authorities and adopt Canada's argument that, when it comes to legitimate expectations, arbitrariness, or discrimination, the Minimum Standard has no proven content at all.[503] NAFTA tribunals have consistently relied on arbitral awards in identifying and analyzing customary norms of international law,[504] and this Tribunal should do the same.[505]

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analysis of State practice and *opinio juris* in relation to a particular rule of custom, and can be considered accordingly").

[503] In its Closing Statement, Canada discussed the International Court of Justice's *Case Concerning A.S. Diallo (Guinea v. DRC)*, which noted that the particular investment arbitration authorities relied on by Guinea in that case were not representative of the Minimum Standard of Treatment. Resp. Closing Statement, Tr. at 2182:3-18. As described by the Court, those authorities comprised cases involving "special international agreements" that did not incorporate the customary Minimum Standard of Treatment, as well as concession contracts "concluded directly between a company and the State allegedly responsible for the prejudice to it." *Case Concerning A.S. Diallo (Guinea v. DRC)*, I.C.J. Judgment of 24 May 2007, at ¶ 90 (RL-41). Canada's reliance on this case is misplaced because the Court went on to suggest that if Guinea had relied on authorities interpreting the Minimum Standard of Treatment itself (as opposed to an inapposite standard), the Court likely would have accepted them. As the Court observed: "in contemporary international law, the protection of the rights of companies and the rights of their shareholders, and the settlement of the associated disputes, are essentially governed by bilateral or multilateral agreements for the protection of foreign investments, such as the treaties for the promotion and protection of foreign investments. . . . In that context, the role of diplomatic protection is somewhat faded, as in practice recourse is only made to it in rare cases where treaty régimes do not exist or have proved inoperative." *Id*. at ¶ 88. In other words, the only significant source of state practice on investor protection that exists in the modern world is practice under investment treaties. This is a point Lilly made in its Reply, s*ee* Cl. Reply at ¶ 352, and a point to which Canada has never responded — even though Canada nominally agrees that the Minimum Standard of Treatment "evolves," Resp. Closing Statement, Tr. at 2183:19-21.

[504] Cl. Reply at ¶ 353 & n.714 (collecting awards); s*ee 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 . . . . It is an efficient manner for a party in a judicial process to show what it believes to be the law.") (CL-100).

[505] Given the many authorities interpreting the Minimum Standard — and the fact that Lilly is entitled to relief under those authorities — this Tribunal need not determine whether the Minimum Standard has converged with the autonomous Fair and Equitable Treatment Standard (and whether the Tribunal may, therefore, also rely on authorities interpreting the latter standard). *See* Cl. Reply at ¶ 353. Nonetheless, it is clear that the autonomous treaty standard has heavily influenced the Minimum Standard, such that (continued…)

2. Canada Has Breached Three Distinct Protections Under Article 1105.

276. Lilly's evidence shows that Canada's revocation of the Zyprexa and Strattera patents under the new promise utility doctrine breached the Minimum Standard in three distinct ways: violating the Standard's protection of legitimate investment-backed expectations; its protection against arbitrary government measures; and its protection against discrimination "based on unreasonable distinctions."[506] These are independent bases for liability, and each alone constitutes a violation of the Minimum Standard.[507]

277. But that does not mean that Canada's violations of the Minimum Standard have to be considered in isolation from one another. The Minimum Standard is a

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there is no practical difference between them. Judge Schwebel recognized this point, writing that "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." Hon. Stephen Schwebel, *The Influence of Bilateral Investment Treaties on Customary International Law*, 2004 ASIL Proceedings 27, 29-30 (CL-98). It has been recognized also by the multiple NAFTA tribunals which have concluded that, where a diversity of states with divergent interests sign up to a single standard, that is evidence of a developing norm. *Chemtura Corp. v. Government of Canada*, NAFTA/UNCITRAL Award (2 Aug. 2010), at ¶ 121 (quoting *Mondev v. United States*, at ¶ 125 (CL-7)) ("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); *see* Cl. Mem. at ¶¶ 254-255; Cl. Reply at ¶¶ 350-354.

[506] *Tenaris S.A. v. Venezuela*, ICSID Case No. ARB/11/26, Award (29 January 2016), at ¶¶ 385-388 (quoting *Saluka Investments BV (The Netherlands) v. The Czech Republic,* UNCITRAL, Partial Award, 17 March 2006, ¶ 307 (CL-85)) (CL-187); *see* Cl. Reply at § V.B.

[507] This section responds to the Tribunal's ***Questions 14*** and ***43***. ***Question 14*** asks, "What are the implications, if any, of paragraph B.3 of the FTC Notes of Interpretation regarding Article 1105 for Claimant's claims?" Relatedly, ***Question 43*** asks, "[T]o what extent are alleged violations of Chapter 17 relevant to an application of Article 1105(1) NAFTA?" Canada's breach of Chapter 17 is relevant to (i) the reasonableness of Lilly's investment-backed expectations and (ii) the arbitrariness of Canada's measures. *See* Cl. Reply at ¶¶ 348 n.703, 364 n.740. As Lilly explained in its Comments on NAFTA Article 1128 and Non-Disputing Party *(Amicus)* Submissions, at ¶ 25, the FTC Statement does not suggest that an investor "may not invoke," or raise, another NAFTA chapter in the context of an Article 1105(1) claim. Rather, the FTC Statement provides only that a breach of another international obligation does not itself "establish" a violation of Article 1105(1).

"flexible [standard] which must be adapted to the circumstances of each case."[508] In the circumstances of this case, the Tribunal should consider the cumulative impact of the arbitrary, discriminatory and retroactive effects of the promise utility doctrine.[509]

a) Legitimate Expectations

278. As multiple NAFTA tribunals have determined, the Minimum Standard protects legitimate investment-backed expectations, including those grounded in the established legal frameworks of host states.[510] As the tribunals in *Grand River* and *Thunderbird* recognized, the legitimate expectations protected by the Minimum Standard should be analyzed by reference to the "Contracting Party's *conduct*" — *i.e.*, not just its express commitments.[511] Canada has never distinguished, or even addressed, this aspect of the two tribunals' analyses.

279. At the Hearing and in its written briefing, Canada suggested that the protection of expectations grounded in a host state's legal framework amounts to a

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[508] *Bilcon v. Canada*, at ¶ 442 (quoting *Waste Management (II)*, at ¶ 99) (CL-166). Since the close of the record in this case, the same language has also been quoted and relied on by the tribunal in *Mesa Power v. Canada*.

[509] *See* Cl. Reply at ¶¶ 369-370.

[510] *See id*. at ¶¶ 356-360. This section responds to the Tribunal's ***Questions 15***, ***16***, and ***17***. Tribunal ***Question 15*** asks whether Article 1105(1) protects an investor's legitimate expectations, and ***Question 16*** asks whether such protection is limited to expectations "based on specific representations." Relatedly, ***Question 17*** asks whether Lilly's patents "constitute specific representations."

[511] *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 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.") (CL-107). Prominent commentators have reached the same conclusion. *See Int'l Thunderbird Gaming v. Mexico*, NAFTA/UNCITRAL, Separate Opinion of Walde (1 December 2005), at ¶¶ 36-37 ("The most relevant NAFTA (and ICSID) awards have translated these authoritative objectives and instruments provided by the NAFTA and similar investment treaties into an emphasis on 'transparency' and a concept of 'legitimate expectation' that takes up, but further develops the meaning of this concept . . . .") (CL-113); Rudolf Dolzer and Christoph Schreuer, PRINCIPLES OF INTERNATIONAL INVESTMENT LAW § VII(1)(d) (2d ed. 2012) (relying on NAFTA and non-NAFTA awards to conclude that "[a]n 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).

freeze on regulatory development and evolution.[512] But, as Lilly has previously noted, the doctrine of legitimate expectations expressly allows for a "margin of change" in municipal law after an investment is made.[513] Inherent in this concept is a distinction between measured change in the law or clarification of previously unsettled law, on the one hand, and the adoption of a completely new doctrine in a well-settled area, on the other.[514]

280. Here, however, it is not just the extent of the change that is striking. It is also the inconsistency between Canada's new promise utility doctrine and relevant international treaties and practices. In particular, Lilly's legitimate expectations were reinforced by NAFTA Chapter 17, under which Canada was obligated not to develop and retroactively apply a doctrine like the promise utility doctrine.[515] And, with respect to the Strattera patent, Lilly's expectations were reinforced by the form and contents requirements of the PCT.[516]

281. In any event, Lilly did not ground its expectations in Canada's legal framework alone, but also in the Canadian government's grant of its Zyprexa and Strattera patents. As Lilly has explained in its written briefing,[517] and at the Hearing,[518] a patent constitutes a representation that the patent holder will enjoy the exclusive right

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[512] *See, e.g.*, Resp. Closing Statement, Tr. at 2190:19-24 ("Article 1105 is not, and was never intended to amount to, a guarantee against regulatory change or to reflect a requirement that an investor is entitled to expect no material changes to the regulatory framework within which an investment is made.").

[513] Cl. Mem. at ¶ 279; Cl. Reply at ¶ 330 n.663.

[514] *See* Cl. Mem. at ¶ 279 (citing Rudolf Dolzer and Christoph Schreuer, PRINCIPLES OF INTERNATIONAL INVESTMENT LAW 148 (2d ed. 2012) (CL-50)).

[515] *Id.*; *see* Cl. Opening Statement, Tr. at 156:3-8 ("[I]f the Tribunal concludes, as it should, that Canada's measures violate Chapter 17 for purposes of Lilly's Article 1110 claim, then that is an additional reason for concluding that they are arbitrary, in violation of Lilly's legitimate expectations, and discriminatory.").

[516] *See* Cl. Reply at ¶¶ 188-189; Cl. Mem. at ¶¶ 280-283.

[517] Cl. Mem. at ¶ 286 (noting "the Zyprexa and Strattera patents were *more* than a mere representation to Lilly from the government of Canada; they were a bundle of legally enforceable rights"); Cl. Reply at ¶ 360.

[518] Cl. Closing Statement, Tr. at 2134:5-2135:19.

to make, use, and sell the covered invention until expiration of the patent. Canada's own patent law expert agreed that patents are "akin to a contract" between the patent holder and the Government.[519]

282. Like the validity of a contract, a license or a deed to real property, the validity of a patent is subject to judicial challenge. As Lilly has demonstrated,[520] however, there is a categorical difference between a challenge based on the law as it stood at the time of grant and a challenge based on entirely new law. This risk of a challenge based on existing law can be assessed and accounted for before the fact; the risk of a dramatic and retroactive change in law cannot be predicted. This difference was critical to Lilly, as it would have been to any investor.

283. In particular, Mr. Armitage testified on cross-examination that Lilly relied on established law so as to make reasoned and informed investment decisions. In deciding whether to "build a business" on a patent, Lilly had to be able to "look at [the] patent based on [Lilly's] best understanding of the . . . domestic patent law of whatever country in which [the] patent was issued [and] make a determination that [the] patent should be able to survive [an] invalidity challenge."[521] This is precisely what Lilly did in the case of Zyprexa and Strattera.

284. Mr. Armitage and his colleagues, who led the global launches of Zyprexa and Strattera, explained in their written testimony that (i) Lilly expected its Zyprexa and Strattera patents were useful; (ii) Lilly relied on those expectations; and (iii) those expectations were reasonable.[522] At the Hearing (and in its prior written briefing),

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[519] Testimony of Ronald Dimock, Tr. at 1046:15-17. While Canada argues that courts cannot make representations "on the outcome of a litigation," Resp. Opening Statement, Tr. at 235:6-7, this is beside the point. As Lilly pointed out in its Closing Statement, Canada's representations were made through its Patent Office, not its courts. Cl. Closing Statement, Tr. at 2135:1-3.

[520] Cl. Reply at ¶ 361.

[521] Testimony of Robert Armitage, Tr. at 359:1-360:16.

[522] Lilly's witnesses affirmed in their written witness statements that they "fully expected that the utility requirement could not possibly pose an issue for the Strattera and Zyprexa patents." First Witness Statement of Robert Armitage at ¶ 8; *see* Witness Statement of Robert Postlethwait at ¶ 25 ("I do not recall any concerns that we would be unable to protect Zyprexa with a patent in Canada."); Witness Statement of Anne Nobles at ¶ 23 ("I do not recall any concerns at all about our Canadian patent application. Given (continued…)

Canada did not challenge that Lilly in fact held the expectations it asserts, and that it relied on them: It did not cross-examine Lilly's witnesses on whether they believed the Zyprexa and Strattera patents to be valid under Canadian law at the time of grant. It also did not challenge the proposition that "patent protection [is] an extremely important consideration in determining whether and how to launch" a pharmaceutical product — a point on which the testimony is clear and consistent.[523] Canada argued only that Lilly's expectations were not reasonable.

285. *First*, Canada argues that its law did not change, so Lilly's confidence in its patents must have resulted from a misunderstanding of Canadian law when those patents were filed and granted. As shown in Part II, this argument cannot stand. It is contradicted by the testimony of Professor Siebrasse, Mr. Reddon, and Mr. Wilson; belied by the surprise and confusion of Canadian patent examiners asked to implement the new promise utility doctrine; and undermined by Mr. Dimock's concession that, prior to 2005, pharmaceutical patents were not invalidated on utility grounds.[524]

286. *Second*, Canada argues that Lilly's expectations were not sufficiently informed to be reasonable. But Canada's position is not borne out by the evidence. Mr. Postlethwait, Ms. Nobles, and Mr. Armitage each confirmed that Lilly relied on qualified local counsel and patent agents to ensure the compliance of Lilly's Canadian patents with Canadian patent law.[525] As Mr. Armitage explained:

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the lack of concerns that had been raised, we were confident that the Strattera patent would be granted by the Canadian Intellectual Property Office.").

[523] Testimony of Anne Nobles, Tr. at 443:10-14 ("MS. ZEMAN: So patent protection was an extremely important consideration in determining whether and how to launch Strattera specifically in a particular market. Is that right? MS. NOBLES: That's correct.); Testimony of Robert Postlethwait, Tr. at 425:6-9 ("MS. ZEMAN: And strong patent protection was an important part of deciding where to launch your products. Is that right? MR. POSTLETHWAIT: Yes.").

[524] Testimony of Ronald Dimock, Tr. at 1073:12-18 ("MR. DEARDEN: So, from 1993 to 2004, there isn't a single Patented Medicines (Notice of Compliance) case that decided that a pharmaceutical patent lacked utility, right? Not one. Zero. MR. DIMOCK: I believe you are right. As I said — well, I've answered your question. That's all I have to do."); Tr. at 1169:17-1171:13 (containing additional questions and concessions on related points).

[525] *See* Testimony of Robert Postlethwait, Tr. at 426:6-9 ("MS. ZEMAN: And you expected your legal team to raise with you any issues they identified that might affect the products in your portfolio? MR. (continued…)

> Lilly maintained a network of patent agents whose responsibility it was to provide advice on matters of patent law and practice to keep Lilly abreast of those developments. That global network included patent agents in each of the countries in which Lilly sought patents around the world, and in the case of Canada included highly competent Canadian patent agents located in Canada who routinely provided that kind of advice to Lilly.[526]

Mr. Stringer corroborated this point on cross-examination, noting Lilly's "expectation" that its local patent attorneys in Canada and elsewhere "would advise us as to an important change in the law."[527]

287. Canada responded to this evidence by placing individual Canadian judicial opinions before Mr. Peter Stringer, Mr. Robert Postlethwait and Ms. Anne Nobles, and asking them whether they were made aware of those decisions by Canadian counsel. This line of questioning served only to distract. Mr. Stringer was responsible for maintaining a high-level understanding of worldwide patent law, and retaining qualified counsel in each of them. He did not purport to be an expert in Canadian law.[528] Mr. Postlethwait and Ms. Nobles were employed as business executives, not lawyers, and their jobs thus required a general familiarity with patent law in Canada, but not a detailed knowledge of specific judicial decisions.[529] Moreover,

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POSTLETHWAIT: Yes."); Testimony of Anne Nobles, Tr. at 443:15-20 ("MS. ZEMAN: So you expected the patent attorney to be familiar with the patent law framework in each country in which you were launching? MS. NOBLES: That would be correct. That would be the expert we would be relying on.").

[526] Testimony of Robert Armitage, Tr. at 343:18-344:1.

[527] Testimony of Peter Stringer, Tr. at 410:4-7 ("Yes. I mean, the expectation would be that our local patent attorney would advise us as to an important change in the law.").

[528] Witness Statement of Peter Stringer at ¶ 27 ("A routine part of my job at Lilly (and part of my role on the Foreign Patent Committee) was to advise research and development groups, and senior management, as to the prospects of obtaining valid international . . . patent protection. I was familiar with patent laws around the world, including Canada."); *see* Testimony of Peter Stringer, Tr. at 405:12-406:1 ("MR. SPELLISCY: You are not and have never been a Canadian patent attorney? MR. STRINGER: Correct. MR. SPELLISCY: We just went to paragraph 27 of your witness statement and we saw you said that 'I was familiar with patent laws around the world including Canada,' so I take it, then, that you were familiar with Canadian law because you would receive briefings and advice from qualified Canadian lawyers, correct? A: That's correct.").

[529] *See* Testimony of Robert Postlethwait, Tr. at 425:15-24 ("MS. ZEMAN: As the person with ultimate oversight of the product launch, you were familiar with the patent law systems of all the countries where you would launch? MR. POSTLETHWAIT: I was familiar with them, yes. Not being a patent lawyer, of (continued…)

many of the decisions Canada put before Mr. Stringer, Mr. Postlethwait, and Ms. Nobles post-dated the grant of Lilly's patents in July 1998 and October 2002, and thus have no bearing on the reasonableness of Lilly's initial investment decision.[530]

288. Furthermore, as Mr. Armitage made clear in the course of his cross-examination, Lilly's network of Canadian patent agents and attorneys was *not* tasked with advising Lilly every time a Canadian patent case was published. Rather, they were tasked with drawing conclusions from the case law; briefing Lilly on those conclusions; and conforming specific patent applications to the law as it stood at the time those applications were filed.[531]

289. It is notable that not a single lawyer in Lilly's network of counsel, patent agents, and internal subject-matter experts provided Lilly with specific advice on Canadian utility law during the period leading up to the filing of the Zyprexa and Strattera patents — *i.e.*, in the period through October 2002.[532] This is to be expected.

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course, I was not in-depth aware of those. MS. ZEMAN: You had some general familiarity? MR. POSTLETHWAIT: Familiarity, yes.").

[530] Relatedly, the witnesses had in many cases retired or moved on to other roles before the publication of several of these decisions. For example, Mr. Stringer testified that he "no longer had direct responsibility for the filing of foreign patent applications" after 1999, and that while he retained the title of Executive Director of International Patents, he moved to a litigation-focused role. Testimony of Peter Stringer, Tr. at 401:3-402:24. Yet, Canada sought to question him on the 2002 *AZT* decision and the development of the promise doctrine through cases decided in 2005. *Id*. at 411:3-412:19. Mr. Postlethwait, a non-lawyer, retired from Lilly in 1999. Witness Statement of Robert Postlethwait at ¶ 5. He was first asked whether he was personally familiar with a particular Canadian patent law treatise, and was then asked whether he would have expected his "patent attorneys to be familiar with [a particular legal] decision" (he was provided no context on the decision or its importance). Testimony of Robert Postlethwait, Tr. at 433:21-435:4, 437:3-438:1. Ms. Nobles, who like Mr. Postlethwait was employed by Lilly as a business executive, not a lawyer, moved into a risk-management and compliance job in 2007. Testimony of Anne Nobles, Tr. at 441:1-20. She was asked whether she had discussed the 2002 *AZT* decision with Lilly patent attorneys, but also whether she had been "advised about" cases decided in 2008 and 2010. *Id*. at 449:3-451:25.

[531] Testimony of Robert Armitage, Tr. at 344:1-25, 372:13-376:2 ("I was aware that there were decisions in Canadian patent law by 2011 that had set out the promise doctrine, that's correct, and I was aware that the promise doctrine was applied factually in each patent that came before the Canadian courts"; "I don't have a specific recollection of whether that briefing would have gone into the details of individual decisions and holdings"; "I'm unaware of any more reliable way in which to secure that advice than from the individuals who then actually filed and prosecuted Lilly's Canadian patent applications.").

[532] As Canada noted at paragraphs 154-155 of its Rejoinder, Canada asked Lilly to produce documents that "provided views or contained discussion on the compliance or expected compliance of Claimant's (continued…)

As Mr. Armitage explained, he would have been "shocked if there were evidence that advice on Canadian utility law had been given during that time frame, since it was so well understood that the threshold for meeting the Canadian utility requirement for pharmaceutical inventions was so low."[533] Mr. Armitage's testimony is corroborated by the lack of utility-based invalidations of pharmaceutical patents prior to 2005 — *i.e.*, under Canada's traditional "mere scintilla" standard for utility.[534] It is corroborated also by the testimony of Mr. Erstling and Mr. Thomas, both of whom confirmed that utility had never been a significant issue at WIPO.[535]

290. Even Canada's expert, Professor Gervais, was unable to discern in any of the WIPO documents he relied on that a pharmaceutical invention actually used to treat a medical condition could be found to lack utility.[536] To the contrary, in the two WIPO studies on utility prepared in connection with the negotiation of the draft Substantive

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patent applications for olanzapine and atomoxetine" with Canadian patent law. Resp. Rejoinder at ¶¶ 154-155 (emphasis added); *see* Procedural Order No. 2, Annex B, Requests 4 and 5. Lilly objected to these requests in part, but offered to produce "documents responsive to this request . . . insofar as they . . . contain discussion of the compliance or expected compliance of *the patent application[s]* resulting in the" Zyprexa and Strattera patents "with the utility standard under Canadian law." Procedural Order No. 2, Annex B, Requests 4 and 5. Lilly also make clear that it understood the request as extending only to "documents contemporaneous with, or pre-dating, the prosecution" of its patents. *Id*. The requests were granted "as offered." *Id*. Lilly was unable to locate any documents responsive to these document requests — *i.e.*, it was unable to locate any documents discussing the compliance of its Zyprexa and Strattera patent applications with Canadian utility law. The absence of such discussion and advice confirms Lilly's evidence that Canada's traditional utility requirement — the requirement in force during the pendency of Lilly's patent applications and at the time of their grant on 14 July 1998 and 1 October 2002, respectively —was well-understood and did not require analysis. Under the traditional standard, working pharmaceutical inventions were always useful. *See supra* Part II.A-C. The *AZT* decision did not issue until December 2002, two months after the grant of the Strattera patent. The advice Lilly received on its patent applications could not have included advice on the development and functioning of the new promise utility doctrine.

[533] Testimony of Robert Armitage, Tr. at 344:18-25.

[534] *See supra* Part II.D.

[535] Testimony of Philip Thomas, Tr. at 1702:22-1703:1 ("[T]he central tenet of that requirement, the core principle involved, has not attracted controversy in international negotiations at WIPO concerning a patent law . . . . "); Testimony of Jay Erstling, Tr. at 1573:23-1574:4 ("It's actually a very low bar and, among the substantive conditions of patentability, it's the lowest bar. Its purpose is to root out inventions that defy laws of nature, that are simply not operable, or workable, or inventions the use of which has not yet been determined.").

[536] *See* Testimony of Daniel Gervais, Tr. at 1781:12-1798:15.

Patent Law Treaty,[537] the examples of claimed inventions lacking in utility included: a "ghost catcher"; "a method for preventing the increase in ultraviolet rays associated with the destruction of the ozone layer by covering the whole surface of the earth with an ultraviolet ray absorbing plastic film"; "an invention asserted to change the taste of food using a magnetic field"; and a perpetual motion machine that defied the laws of physics (which Professor Gervais described as "the classroom textbook example" of an invention lacking utility).[538]

291. Given this evidence reflecting a well-settled, low bar for utility (not just in Canada, but internationally), Canada's invalidation of the Zyprexa and Strattera patents was shocking. As Mr. Armitage testified with respect to the invalidation of Zyprexa:

> Q: I'm trying to understand what you were incredulous about. Maybe let's look at that decision, and you can help me here.
>
> * * *
>
> A: [T]here was no doubt that olanzapine had utility under the law of utility as well understood in any patent jurisdiction of which I'm aware . . . . [W]hat I was incredulous about, in sum, was . . . a utility requirement that would invalidate a patent where it was clear the patent was useful.[539]

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[537] WIPO Document SCP/9/5 (17 March 2003) (R-230); WIPO, Informal Paper Concerning the Practical Application of Industrial Applicability/Utility Requirements Under National And Regional Laws (April 2001) (R-407).

[538] Testimony of Daniel Gervais, Tr. at 1783:5-1786:3. Asked whether there was any indication — in the two WIPO studies, in the other negotiating material relating to the draft Substantive Patent Law Treaty, or in certain other international materials he cited to — that a patent on a medicine actually used to treat patients could fail for lack of utility, Professor Gervais could not answer affirmatively. *Id*. at 1784:7-13 (discussing the 2001 WIPO Survey, R-405), 1786:18-1787:7 (discussing the 2001 WIPO study, R-407), 1797:21-1798:22 (discussing the 2003 WIPO Survey, R-230), 1813:1-1815:11 (discussing a 2013 WTO, WIPO and WHO joint study, R-220).

[539] Testimony of Robert Armitage, Tr. at 366:2-371:4. Mr. Armitage was asked how he could have been surprised by the invalidation of the Zyprexa and Strattera patents given the prior revocation of the raloxifene patent. *Id*. at 380:17-386:18. As Mr. Armitage explained, the doctrine was insufficiently certain to predict the invalidation of the Zyprexa and Strattera patents, and there were pertinent factual distinctions between the cases (such as the existence of pre-filing clinical data supporting the Zyprexa and Strattera patents). *Id*. at 384:24-386:18. More to the point, the invalidation of raloxifine took place in 2009, years after Lilly made its investment decision. See *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97 (C-119).

And as Mr. Armitage testified with respect to the invalidation of Strattera:

> Canada didn't consider the dispositive facts on the issue of whether or not Strattera was useful to treat ADHD . . . . So again, it goes to my earlier statement of ignoring the fact that a compound is useful in an attempt to determine whether the compound meets the requirement to be useful. . . . I didn't believe that this could be part of a rational patent law.[540]

292. Mr. Armitage's testimony, and that of his colleagues,[541] makes clear that Lilly's reasonable expectations — expectations that Canada accepts were central to Lilly's investment decision[542] — were upended when the Zyprexa and Strattera patents were invalidated as a result of Canada's retroactive application of its radically new promise utility doctrine.

b) Arbitrariness

293. In its Closing, Canada acknowledged that "a number of NAFTA tribunals have suggested that a certain level of arbitrariness violates the Minimum Standard of Treatment."[543] Yet, in the next sentence, it asserted that "*none of these* tribunals have undertaken an analysis of state practice and *opinio juris*," implying that the Tribunal should place no reliance on their decisions.[544]

294. This argument is puzzling, given that in its Counter-Memorial Canada accepted that a measure having "no legitimate purpose" is arbitrary under the Minimum Standard of Treatment.[545] It cited for this position the decision in *Lemire v. Ukraine*, which defined an "arbitrary" measure as one that, among other things, either: (i) "is not based on legal standards but on discretion" or (ii) "inflicts damage on the

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[540] Testimony of Robert Armitage, Tr. at 366:2-11, 377:15-378:9.

[541] *See*, *e.g.*, Testimony of Anne Nobles, Tr. at 450:8-14 (reaffirming her "surprise" at the invalidation of the Strattera patent); Witness Statement of Robert Postlethwait at ¶ 25 ("I do not recall any concerns that we would be unable to protect Zyprexa with a patent in Canada.").

[542] *See supra* nn.523, 525.

[543] Cl. Closing Statement, Tr. at 2189:9-13.

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

[545] Resp. CM at ¶ 249.

investor without serving any apparent legitimate purpose."[546] Despite Canada's apparent change of the heart, the law remains clear. As Lilly showed in its written briefing and at the Hearing, and consistent with the standard articulated in *Lemire*, a measure is arbitrary: (i) "when it is unpredictable and incoherent, even if it is not motivated by bad faith" and also (ii) "when it has no legitimate purpose."[547] The application of the promise utility doctrine to invalidate the Zyprexa and Strattera patents qualifies as arbitrary under both prongs of this standard.

(1) The Promise Utility Doctrine Is Unpredictable and Incoherent.

295. As explained in detailed testimony at the Hearing, the promise utility doctrine imposes an additional and elevated utility requirement on pharmaceutical patents that is unpredictable and incoherent in its application.[548] First, the Canadian courts subjectively construe the "promises" contained in a patent.[549] Second, Canadian courts apply a heightened evidentiary burden and also bar use of post-filing evidence to meet the elevated "promise."[550] Third, the Canadian courts impose a heightened disclosure requirement as a result of which pre-filing evidence considered by the court to determine whether utility had been "demonstrated" will then be ignored when determining whether utility was "soundly predicted" (unless the evidence was disclosed in the patent itself).[551] All of these elements contribute to the promise utility doctrine's arbitrariness, as was illustrated in the application of the doctrine to invalidate Lilly's Zyprexa and Strattera patents.

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[546] *Lemire v. Ukraine*, at ¶ 262 (RL-29); *see* Resp. CM at ¶ 249 ("In order to be arbitrary, a measure must have no legitimate purpose, not be based on legal standards or must have intentionally ignored due process and proper procedure.") (citing *Lemire v. Ukraine*, at ¶¶ 262-263).

[547] *See* Cl. Reply at ¶¶ 335-338 (collecting authorities); Cl. Opening Statement, Tr. at 150:15-151:21.

[548] *See* Cl. Reply at ¶ 339.

[549] *See supra* Part II.C.2(a).

[550] *See supra* Part II.C.2(b).

[551] *See supra* Part II.C.2(c).

296. The subjective construction of the promise is "inherently arbitrary," as Professor Siebrasse testified, because it leads courts to ignore the distinction between the carefully drafted claims in a patent and the disclosure portion of the patent.[552] The purpose of the claims is to define the scope of the invention; in contrast, the purpose of the disclosure is to explain the invention in fulsome terms to the public: patentees are "supposed to say everything they know about the invention" in the disclosure.[553] Yet, as Mr. Reddon testified, under the promise utility doctrine, the language of the disclosure is scrutinized for "promises," including "implied" promises that do not appear on the face of the patent.[554]

297. The result of this exercise is incoherence. Apotex — Canada's largest generic drug manufacturer and a prolific patent litigant[555] — obtained leave to appeal to the Supreme Court of Canada by aptly describing the promise doctrine as follows: "The situation is now a free-for-all in which the outcome of cases depends upon the particular judge or panel hearing the dispute, rather than legal authority. The outcome of cases (particularly cases like the present case, where the stakes to the parties are counted in the hundreds of millions of dollars) must not be determined so arbitrarily. The proposed appeal raises this intolerable confusion for resolution."[556]

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[552] Testimony of Norman Siebrasse, Tr. at 633:3-634:25.

[553] *Id*. at 708:24-709:5 ("[I]t's inherently arbitrary because the disclosure is being put to purposes for which it was not intended and, in fact, disclosure must serve the function of disclosure, it's now being used to define the invention, that tension is inherent, and so it's fundamentally arbitrary."). Mr. Reddon corroborated this point, explaining: "The disclosure part of a patent is the teaching part. It's the part where the patentee who's come up with something new and useful and important tells the public what their work was, what they've done, and in my experience patentees take the disclosure seriously. It would not be right for the discoverer of a new compound who discovers, let's say, latanoprost to treat glaucoma, to leave out the observation that in our study there were no side effects." Testimony of Andrew Reddon, Tr. at 831:22-832:6.

[554] Testimony of Andrew Reddon, Tr. at 827:8-18; *see supra* Part II.C.2(a).

[555] *See* Testimony of Ronald Dimock, Tr. at 1171:17-22.

[556] 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 (30 September 2013) (C-375); *see* Testimony of Ronald Dimock, Tr. at 1181:5-18 (acknowledging that Apotex obtained leave to appeal on the basis of that submission).

298. As Professor Siebrasse established, cases finding implied promises often cannot be reconciled with one another. This is best exemplified by the *Latanoprost* cases, in which two panels of the Federal Court of Appeal found different promises in construing the same patent on a drug for the treatment of glaucoma.[557] In one decision (*Latanoprost I*), the Federal Court of Appeal found that the latanoprost patent did not contain a promise of chronic treatment and held the patent useful.[558] In the other decision (*Latanoprost II*), the Federal Court of Appeal found that, because glaucoma was a chronic condition, the latanoprost patent *did* implicitly promise chronic treatment of glaucoma and held the patent *not* useful.[559]

299. The *Latanoprost* cases are not the only example of such inconsistency. As Professor Siebrasse noted, *Latanoprost II* stands in contrast not just with the earlier *Latanoprost I* decision, but also with "the subsequent *Plavix* decision" where the Federal Court of Appeal — the very same court — "said there must be an *explicit* promise" and rejected the *Latanoprost II* approach of finding promises by implication.[560]

300. It bears emphasis: these three decisions (*Latanoprost I*, *Latanoprost II*, and *Plavix*) were all decisions of the Federal Court of Appeal. And the judges on the three panels overlapped.[561] These inconsistent results — as well as the other examples of incoherence discussed at pages 80 to 92 of Lilly's Reply — bear out Professor Siebrasse's testimony that there is simply no consistency in Canada's new utility test.[562] Or, in Professor Siebrasse's own words: "this is the point: […] it's hard to know [what the

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[557] Cl. Mem. at ¶ 64.

[558] *Pharmascience Inc. v. Pfizer Canada Inc.*, 2011 FCA 102, at ¶ 9 (C-98).

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

[560] Testimony of Norman Siebrasse, Tr. at 627:15-23 (discussing *Sanofi-aventis et al. v. Apotex Inc.*, 2013 FCA 186).

[561] Specifically, Justice Trudel sat on both *Latanoprost I* and *Latanoprost II*, and Justice Noel sat on both *Latanoprost II* and *Plavix*. There were no dissents in any of the three cases.

[562] Testimony of Norman Siebrasse, Tr. at 633:2-20 (describing the application of the promise utility doctrine as "unprincipled").

promise of a patent will be] until you get a judge to sit down and actually go through it."[563]

301. While the subjective construction of the promise provides some of the clearest examples of the promise utility doctrine's inconsistency and arbitrariness, the Hearing reinforced that this is not the only arbitrary aspect of the doctrine. The doctrine's heightened evidentiary burden is arbitrary because even though it is uncontested that the early tests showing a drug's likely effectiveness were ultimately proved correct, post-filing evidence of the drug's efficacy and commercial success is barred from consideration.[564] Moreover, Canadian courts are remarkably inconsistent regarding the amount of evidence required to establish the utility of a pharmaceutical product, leaving patentees in the dark as to what evidence a particular judge may require.[565]

302. The bar on post-filing evidence has had apparently unintended consequences, particularly when combined with the extensive evidence that may be required to meet the elevated promise construed by the courts. In *AZT* the Federal Court of Appeal observed that a bar on post-filing evidence could have led to the rejection of a hypothetical Wright Brothers' airplane patent on the basis of "expert testimony . . . that by December 10, 1903, [the state of the art was that] machines heavier than air could not fly."[566] The Federal Court of Appeal viewed such a result as absurd.[567] Dr. Gillen, responding to a Tribunal question, also regarded such a result as illogical.[568] On appeal, the Supreme Court of Canada in its 2002 *AZT* decision explicitly

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[563] *Id*. at 631:19-22; *see* Cl. Reply at ¶¶ 340-344.

[564] *See* Cl. Reply at ¶¶ 181-182; Cl. Opening Statement, Tr. at 41:8-44:18, 153:12-23.

[565] *See* Cl. Reply at ¶ 183. In the Zyprexa case, for example, the trial court noted Lilly's catalogue of cases "where courts found that the utility of an invention could be inferred from a weaker factual basis than existed for olanzapine," but it rejected the comparison because those cases "involved different factual bases and different levels of promise." *Eli Lilly Inc. v. Novopharm Ltd.*, 2011 FC 1288, at ¶¶ 221-229 (C-146).

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

[567] *Id*.

[568] Testimony of Michael Gillen, Tr. at 1019:8-17 ("If you've described your airplane and you've described how to make it and you've described why you think it will fly, then that, to me, sounds like a sound (continued…)

considered and dismissed that scenario as improbable, and thus not a concern, because "it is hard to accept the 'hypothetical' that experts would continue to insist, after [the airplane] had flown, that the prediction was unsound."[569] Yet, as Mr. Dimock conceded, equivalent results are routinely reached in Canada today: "drugs that have flown," *i.e.*, safe and effective, approved drugs, are routinely invalidated by Canadian courts based on testimony from the generic industry's experts.[570] The bar on post-filing evidence is also arbitrary because post-filing evidence remains admissible to satisfy other patentability criteria, such as non-obviousness, but not to confirm that the claimed invention fulfills its intended use.[571] Canada also permits generic drug companies challenging a patent to rely on post-filing evidence to attack the utility of a patent, but does not allow patent holders to use the same evidence to support utility.[572]

303. As Lilly's evidence established even before the Hearing, the interaction between the heightened evidentiary burden (including its bar on post-filing evidence) and the subjective construction of promises often creates a Catch-22 for pharmaceutical patent holders.[573] Pharmaceutical patent holders cannot know whether they will be

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prediction because you haven't actually flown the airplane yet, but if you can soundly predict that it will fly because you understand something about wings and air flow around wings and the whole concept of lift and so forth, then your application might be complete depending on what you've given the public.").

[569] *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, at ¶ 82 ("If the essentials of the heavier-than-air flying machine were set out with sufficient precision to allow the reader actually to make a flying machine that flies, it is hard to accept the 'hypothetical' that experts would continue to insist, after it had flown, that the prediction was unsound.") (C-213).

[570] Testimony of Ronald Dimock, Tr. at 1158:13-1160:19 (MR. DEARDEN: . . . That passage about Justice Binnie finding it hard to accept a hypothetical that experts would continue to insist, after it had flown, that the prediction was unsound turned out to be pretty wrong, didn't it, because generics have experts all the time saying that, you know, drugs that have flown, safe and effectively approved drugs, so they've flown — that any expert would actually question. And they do that all the time, right? MR. DIMOCK: Sorry, maybe it's the lateness of the day. I don't understand your question. . . . MR. DEARDEN: Mr. Dimock, in sound prediction cases post AZT, safe and effective drugs — so they actually work, they're being consumed by thousands of patients, they're being sold and the generics want to sell a generic version of that very same drug, those drugs actually work, the generics are putting on experts, questioning or saying that the prediction was unsound. Agreed? MR. DIMOCK: Yes, that's happening . . . .").

[571] Cl. Mem. at ¶ 72.

[572] *Id*. at ¶ 268.

[573] *Id*. at ¶¶ 32, 266; Cl. Reply at ¶¶ 192-194.

required by the Canadian courts to show that they had clinical proof of a drug's safety and effectiveness at the time of patent filing; yet, they cannot invest in the clinical trials necessary to demonstrate safety and effectiveness without first filing a patent application (and thereby securing a fixed priority date for purposes of the obviousness and novelty conditions of patentability). This point was reinforced by *amici* the Seven IP Scholars.[574] And it was driven home at the Hearing. As Professor Siebrasse testified:

> [A]s a practical matter, pharmaceuticals have to be patented before any large scale clinical trials, otherwise there's a risk of anticipating your own patent by having clinical trials and the nature of the invention becomes public, in which case you can't get a patent . . . .[575]

304. Finally, the heightened disclosure rule of the promise utility doctrine is both unprincipled and unfair. It is unprincipled because it introduces an unjustified distinction between the evidence Canadian courts consider to determine whether utility is demonstrated and the evidence Canadian courts consider to determine whether utility is soundly predicted. The unfairness is manifest because patents are invalidated based on a disclosure rule that did not exist when the patents were filed (and that could not have been anticipated by patentees given that the disclosure requirement is inconsistent with the form and contents requirements of the PCT).[576] Compounding the situation, as Canada's expert Mr. Dimock acknowledged on cross-examination, the circumstances under which the heightened disclosure obligation applies remain unclear

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[574] *See* Cl. Comments on NAFTA Article 1128 and Non-Disputing Party *(Amicus)* Submissions at ¶ 50-51.

[575] Testimony of Norman Siebrasse, Tr. at 523:20-524:1.

[576] *See supra* Part II; Cl. Mem. at ¶ 75; Cl. Reply at ¶ 184; Cl. Opening Statement, Tr. at 76:5-25 (explaining that PCT applicants "would never have expected that [disclosure rule] and don't have any way to deal with it"). As Professor Erstling testified, the PCT limits member countries' ability to require applicants to make disclosure in the PCT (international) application that is not contemplated by the PCT rules, and constrains member countries' ability to penalize applicants for not making such disclosure in the PCT application, for reason that the very purpose and objective of the PCT is to allow applicants to rely on the single PCT application in the national phase. Testimony of Jay Erstling, Tr. at 1576:3-9, 1593:11-1594:10, 1616:1-1617:25.

even today — leaving patent holders and applicants unable to predict whether they must comply with it.[577]

305. The arbitrariness of the promise utility doctrine is also reflected in its application,[578] driving one Canadian patent examiner to declare in confusion, after reading a draft MOPOP chapter on the promise utility doctrine: "[t]he inconsistency may lie with me . . . either I or the chapter may need some clarification."[579] This examiner was not alone in his reaction. As Lilly noted in its Closing, a CIPO training document produced by Canada reveals that, at the beginning of a March 2010 training session on the promise utility doctrine involving nine patent examiners: three "would not have objected" to the application in the case study; three "would have absolutely objected"; and three "were on the fence."[580] As the document explains: "At the conclusion of the session the examiners were re-polled and the results were the same!"[581]

306. It was not just patent examiners who struggled to predict outcomes flowing from the application of the promise utility doctrine. The incoherence of the doctrine was reinforced by the expert testimony of Professor Siebrasse and Mr. Reddon,[582] and also by the comments of generic pharmaceutical firms and the U.S. Government.[583]

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[577] Testimony of Ronald Dimock, Tr. at 1117:20-1118:2. Some Canadian courts have observed that there is no statutory basis for the heightened disclosure requirement for sound prediction of utility. Cl. Closing Slides at 91 (citing *Astrazeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638, at ¶ 144 (C-48)).

[578] *See* Cl. Reply at ¶¶ 192-194.

[579] Comments from Tony Candeliere, (17 March 2008) [Canada Doc. No. 910, at 065397] (C-358). Additional patent examiner comments are excerpted in Claimant's Closing Slides at 9-13.

[580] *See* Canada Doc. No. 39, at 000157 (emphasis in original) (discussed in Cl. Closing Statement, Tr. at 2041-2042 and Cl. Closing Slides at 50) (C-491).

[581] *See id*.

[582] *See supra* ¶¶ 296-305.

[583] *See supra* ¶ 227.

307. The application of the promise utility doctrine, and the arbitrary results it creates, are also illustrated by the invalidation of the Zyprexa and Strattera patents.[584] It is undisputed that both the Zyprexa and the Strattera patents were construed to a promise of clinical effectiveness in chronic patients — *i.e.*, over a long-term treatment horizon.[585] As in other cases, the Canadian courts implied this promise even though, as Professor Siebrasse testified, "the word 'chronic' or similar words did not appear in the disclosure . . . [or] in the claims."[586] A promised utility of long-term effectiveness also was construed for Straterra even though the drug was approved and prescribed for short-term (acute) use in patients.

308. The subjective construction of this elevated promise caused the Canadian courts, in both the Zyprexa and the Strattera proceedings, to discount pre-filing scientific studies demonstrating the claimed utility of the drugs to treat schizophrenia and ADHD, respectively. Applying the promise utility doctrine's heightened evidentiary burden, the Zyprexa trial court expressly stated that it would be satisfied by nothing less than "placebo controlled clinical trials . . . in large groups of patients."[587] In Strattera, the court held that a peer-reviewed, published study conducted by one of the world's premiere medical research institutions, the Massachusetts General Hospital (MGH), failed to demonstrate the promised utility.[588] Finally, while the promise utility doctrine's heightened disclosure obligation was not applied in the Zyprexa case, it was

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[584] *See generally* Cl. Mem. at ¶¶ 99-112 (describing the invalidation of the Zyprexa patent under the promise utility doctrine) and ¶¶ 130-140 (describing the invalidation of the Strattera patent under the promise utility doctrine).

[585] Cl. Opening Statement, Tr. at 288:21-289:6 (noting the Strattera court found a "promise of long-term effectiveness"); Cl. Closing Statement, Tr. at 1992:4-12 ("We also noted that the [Zyprexa] court found an additional promise, implied promise of long-term clinical effectiveness, and Canada doesn't deny that nor did they highlight it.").

[586] Testimony of Professor Siebrasse, Tr. at 624:17-23. Pharmaceutical patentees, including Lilly, do not intend to promise long-term clinical effectiveness at the time of patenting. As Mr. Armitage noted in his written testimony, it is well understood in the field that long-term clinical effectiveness can only be demonstrated through clinical trials that can only take place after a patent application is filed, and a priority date established. Second Witness Statement of Robert Armitage at ¶¶ 26-27.

[587] Cl. Reply at ¶ 213 (quoting *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, at ¶ 212 (C-146)).

[588] *Id*. at ¶ 215.

relied on in the Strattera case to preclude Lilly from arguing that the long-term safety and efficacy of Strattera was soundly predicted through the MGH study.[589]

309. The arbitrariness of the promise utility doctrine's application to the Zyprexa and Strattera patents is further confirmed by the outcomes of those cases. The Canadian courts were confronted with the question of whether medicines viewed in the field as revolutionary,[590] approved as safe and effective by Health Canada and other health authorities around the world,[591] and prescribed to millions of patients,[592] were "useful." The Canadian courts' answer was "no."[593] Canada was the only jurisdiction in the world to reach that result. Indeed, Canada was the only jurisdiction (among the 26 jurisdictions in which corresponding Zyprexa or Strattera patents were challenged) where the utility of these successful drugs was even challenged.[594]

(2) The Promise Utility Doctrine is Not Supported by Any Legitimate Policy Purpose.

310. The incoherence and unpredictability of the promise utility doctrine, set out above, demonstrate that the doctrine is not supported by any legitimate policy purpose.[595] As the *Occidental v. Ecuador* tribunal recognized, a rule of law that is confusing and unclear cannot serve a legitimate policy objective because it does not

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[589] *Id*. at ¶ 216.

[590] *See* Cl. Opening Statement, Tr. at 11:14-14:17; Cl. Opening Presentation, Slides 3-5; *see also* Cl. Mem. at ¶¶ 31, 83, 117; Witness Statement of Robert Postlethwait at ¶ 31-32; Witness Statement of Anne Nobles at ¶¶ 24-25.

[591] *See* Cl. Mem. at ¶¶ 92, 125.

[592] *See* Witness Statement of Robert Postlethwait at ¶ 31; Witness Statement of Anne Nobles at ¶ 25.

[593] *See* Cl. Reply at ¶ 221 n.443. Lilly's Zyprexa patent was upheld in every jurisdiction except Slovenia and Saudi Arabia. As Mr. Armitage noted in his written testimony, "In Slovenia, a single claim was invalidated on novelty grounds. In Saudi Arabia, where Zyprexa was protected by both a Saudi patent and a Gulf Cooperation Council patent, the Saudi patent was struck down on an issue related to the calculation of priority dates. The Gulf Cooperation Council patent, however, remained valid and enforceable in Saudi Arabia." First Witness Statement of Robert Armitage at ¶ 17. The Strattera patent was successfully challenged only in Canada. *Id*. at ¶ 21.

[594] Second Witness Statement of Robert Armitage at ¶ 48.

[595] The inconsistency and unpredictability inherent in the promise utility doctrine is set out in detail at pages 80-95 of Lilly's Reply, and pages 37-40 and 125-129 of Lilly's Memorial.

produce consistent results and cannot promote *ex ante* compliance.[596] The same principle applies here.

311. To the extent Canada claims that the promise utility doctrine reflects enforcement of the patent bargain specifically for new use and selection patents,[597] that claim has no logical basis in law or fact. First, Canada has presented no evidence to suggest that new use and selection patents are unique and therefore require special rules.[598] Second, as the report of Dr. Brisebois makes clear, the promise utility doctrine as a matter of fact has been applied to invalidate *all* types of pharmaceutical patents, not just new use and selection patents, including those relating to new compounds.[599] Canada does not contest that Lilly disclosed, through its patents, revolutionary and previously unknown treatments for schizophrenia and ADHD, respectively — it is this disclosure that satisfied Lilly's end of the "patent bargain."

312. Canada also argues that the promise utility doctrine serves to deter speculative patenting.[600] There is no dispute between the parties that one objective of the traditional patent utility requirement is to deter speculation — not just in Canada, but also in the United States and Mexico.[601] Yet the United States and Mexico do not invalidate patents on approved and marketed pharmaceutical products for lack of utility.[602]

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[596] *See* Cl. Reply at ¶¶ 335-338 & n.679.

[597] *See* Resp. Closing Statement, Tr. at 2165:5-8 ("I would suggest that [Lilly's] approach would fundamentally unbalance the patent bargain, eliminating the quid that the public gets for the offered quo.").

[598] That Canada has presented no such evidence is hardly surprising, given that the Supreme Court of Canada has expressly held that "selection patents are to be subject to the same considerations as other patents." *See Apotex v. Sanofi-Synthelabo Canada*, 2008 SCC 61, at ¶ 108 (C-196).

[599] Brisebois First Report at Annex B; Cl. Closing Slides at 85.

[600] *See, e.g.*, Resp. Closing Statement, Tr. at 2315:9-22.

[601] Testimony of Robert Merges, Tr. at 1357:5-1358:13; Testimony of Gilda Gonzalez, Tr. at 1892:7-16.

[602] Testimony of Robert Merges, Tr. at 1293:24-25 ("Utility in the U.S. rarely invalidates a patent."); Testimony of Holbrook, Tr. at 1528:19-1530:25 ("It's a low bar. That's not rejected much."); Testimony of Gilda Gonzalez, Tr. at 1861:9-15 ("IMPI never refused to grant any application for lack of industrial application. No patent was ever invalidated for lack of industrial application, and I know of no instance (continued…)

313. This is because the traditional utility requirement, as applied in all three NAFTA states, targets a specific concern, illustrated in a joint WTO, WHO, and WIPO study by attempts to patent gene snippets.[603] Professor Merges explained this concern as follows:

> It was an idea where if we got a bunch of sequence tags, then when other people later figured out what these genes do, we would take our sequence tags down off the shelf and say, oh, well, your long gene sequence which now codes for a valuable protein because it's a human therapy, we own a piece of it. So for you to use your gene you have to infringe our patents. So the whole trick was we're going to randomly characterize gene snippets, put them in the closet and wait until somebody else did the work that created the real value. And that's a classic case, sometimes [we] call it nominal utility, where you're just trying to free ride on other people's work.[604]

314. Canada has not asserted that the promise utility doctrine is needed to deter this type of speculation, where the real-world use of an invention is entirely unknown. Instead, Canada has focused on alleged speculative patenting practices in the pharmaceutical sector. Canada supported its argument with the witness statement of Dr. Marcel Brisebois, whose testimony focused on attacking Lilly's patenting practices as speculative. Relying on Dr. Brisebois's evidence, Canada concluded that "Claimant's own patent filing behaviour . . . suggests the importance of Canada's

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in which an application for a nullity trial was based on a lack of industrial application."). It is also uncontested that the Zyprexa and Strattera patents were almost uniformly upheld in the face of challenges on a range of grounds, undermining Canada's argument that the promise utility doctrine addresses policy concerns that other states address through other doctrines of patent law. *See* First Witness Statement of Robert Armitage at Attachments A and B.

[603] WTO, WIPO, and WHO, Promoting Access to Medical Technologies and Innovation, Intersections between public health, intellectual property and trade (2013), at 59 ("In general, the application of this requirement [utility] does not pose practical problems. However, in the area of biotechnology, it needs some consideration, given concerns that patent applications claiming gene-related inventions would block the use of the claimed gene sequence for uses that were not yet known by the applicant and, therefore, would not justify the grant of a patent in respect of the function which the applicant was not even aware of.") (R-220).

[604] Testimony of Robert Merges, Tr. at 1357:5-1358:13.

rules."[605] Specifically, Canada relied on Dr. Brisebois's conclusions in his written testimony that Lilly:

- *First*, filed for "secondary patents" on new uses of existing compounds.[606]
- *Second*, filed for such patents without extensively discussing the scientific support for its claimed uses in its patent applications themselves (which, Dr. Brisebois alleged, showed that Lilly's filings were made "at a time when relevant research was either very preliminary, or simply non-existent").[607]
- *Third*, often did not bring patented uses of pharmaceutical products to market.[608]

315. As Lilly explained in its written briefing, however, Dr. Brisebois's statement did not address fundamental and well-known facts about the innovative pharmaceutical industry and drug development.[609] Even if Dr. Brisebois had been right about Lilly's patenting practices, the patenting practices of a single company are not capable of justifying a patent doctrine of general applicability.[610]

316. Whatever weight Canada's policy argument might have had prior to the Hearing, Dr. Brisebois made a series of concessions on cross-examination that destroyed the very foundation of Canada's argument.

- *First*, Dr. Brisebois admitted that the concept of "secondary patents" does not exist at Canadian law, but rather is a term Dr. Brisebois adopted for use in these

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[605] Resp. CM at ¶ 150.

[606] First Witness Statement of Marcel Brisebois at ¶¶ 16-17. In this witness statement, Dr. Brisebois defines a secondary patent as "a patent directed to modified forms of that base compound, or to a new medical use of a known drug, to new combinations of known drugs, to particular formulations, dosage regiments and processes, or other secondary modifications to an already well-known drug." *Id*. at ¶¶ 41. Drawing on Dr. Brisebois's statement, Canada has characterized the Zyprexa and Strattera patents as "secondary patents." Resp. Rejoinder at ¶¶ 51-52. It argues that Lilly "enjoyed monopolies relating to [the Zyprexa, Strattera and raloxifene compounds] for years before it filed applications for the patents at issue in these proceedings" and sought to extend these "monopolies" by obtaining its "secondary patents" through "a 'scattershot' approach to patent filings." *Id*. at ¶¶ 51-54.

[607] First Witness Statement of Marcel Brisebois at ¶¶ 18-20, 68.

[608] *Id*. at ¶¶ 21-22.

[609] Cl. Reply at ¶¶ 199-208.

[610] *Id*. at ¶ 200.

proceedings.[611] Dr. Brisebois also agreed that the definition he proposed in his written statements was incorrect. While Dr. Brisebois defined "secondary patents" as patents on "already well-known drugs," he testified on cross-examination that this was not what he had meant: he had merely meant a patent on a "known *molecule*, or patented *molecule*."[612] But even this definition is wrong. Dr. Brisebois characterized the Zyprexa patent as a secondary patent, but as Dr. Brisebois agreed, the Zyprexa compound (olanzapine) was not a "known molecule" — to the contrary, it "was never even synthesized until two years after the genus patent was issued."[613]

- *Second*, Dr. Brisebois agreed he had "no insight into the research and development taking place . . . inside Lilly laboratories."[614] In other words, Dr. Brisebois had no foundation for suggesting that Lilly's patent filings were made on the basis of "very preliminary or simply non-existent" research: he did not actually know the amount of testing Lilly performed prior to filing its patent applications, and his statement did not account for the fact that Lilly's scientists studied individual molecules over a period of years or decades, becoming closely familiar with those molecules and their expected functioning.[615]

- *Third*, Dr. Brisebois confirmed that he had no knowledge of why Lilly might decline to commercialize a product.[616] In other words, he had no basis to conclude that the failure to commercialize a claimed use made the patent claiming that use speculative.[617]

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[611] *See* Testimony of Marcel Brisebois, Tr. at 502:20-504:23 (emphasis added). These observations respond to the Tribunal's ***Question 7***, which asked whether the classification of Lilly's patents as "secondary patents is relevant to Claimant's claims."

[612] *See* Testimony of Marcel Brisebois, Tr. at 502:20-504:23 (emphasis added).

[613] *Id*. at 504:24-505:4 ("MS. CHEEK: So are you aware that the olanzapine compound itself was never even synthesized until two years after the genus patent was issued? MR. BRISEBOIS: I think I read about this, yeah."). In response to a question from President van den Berg, Mr. Armitage explained that "synthesized" in this context refers to the first time a chemist idenitifies the structure of the molecule and discovers how to make it. *See* Testimony of Robert Armitage, Tr. at 393:10-24. Until that discovery and synthesis, the compound is unknown.

[614] Testimony of Marcel Brisebois, Tr. at 506:1-510:25.

[615] *Id*. at 507:1-509:21.

[616] *Id*. at 510:4-511:25.

[617] As Mr. Armitage explained in his Second Witness Statement, at ¶¶ 28-30, 90% of pharmaceutical compounds found to be active in laboratory testing are not commercialized. The decision to commercialize a drug is not, he emphasized, a purely scientific decision but "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 (continued…)

317. Simply put, Canada's evidence of a policy rationale for the promise utility doctrine did not stand up to scrutiny. Dr. Brisebois readily admitted the limitations in his testimony. In light of his admissions, there is no basis on the record to suggest that the promise utility doctrine, a law that uniquely invalidates patents on innovative, commercially successful pharmaceutical products at the behest of generic competitors, could possibly serve a legitimate policy objective.[618]

c) Discrimination

318. Except where a court engages in a denial of justice through "unjustifiable discriminatory treatment in court proceedings founded on the investor's foreign nationality,"[619] Canada's position is that Article 1105 does not afford protection against discrimination. Rather, Canada argues, Article 1105 *permits* nationality-based discrimination, and it *permits* discrimination based on field of technology.[620]

319. Canada's vanishingly narrow conception of the protection against discrimination under Article 1105 finds support neither in arbitral awards, nor even in the litigation positions taken by other host states. Canada has never once discussed the recent *Tenaris v. Venezuela* award — noted by Lilly in its Comments on Article 1128 and Amicus submissions,[621] in its Opening,[622] and in its Closing[623] — which determined that

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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."

[618] As explained in Lilly's Reply at ¶¶ 206-209 and 345, even if Dr. Brisebois's written statement is credited, it does not support Canada's argument that the promise utility doctrine serves to deter speculation.

[619] Resp. CM at ¶ 262; *see* Resp. Closing Statement, Tr. at 2225 ("[I]f there's truly a nationality-based discrimination in court that would violate 1102 and 1103, it might be difficult as seeing that not rise to a denial of justice.").

[620] Resp. Closing Statement, Tr. at 2188:10-2189:8 ("[T]here is no principle of customary international law preventing host states from providing different treatment to foreign investors"; "[T]here is no prohibition at customary international law on discrimination in the granting of patents based on the industrial sector of operations.").

[621] Cl. Comments on NAFTA Article 1128 and Non-Disputing Party *(Amicus)* Submissions at ¶ 15.

[622] Cl. Opening Statement, Tr. at 153:24-154:7.

[623] Cl. Closing Statement, Tr. 2133:3-15.

the Minimum Standard protects against "any differential treatment of a foreign investor . . . based on unreasonable distinctions and demands," and which explained that the Government of Venezuela agreed with this standard as "the applicable test" at customary international law.[624] The same standard has been articulated in other awards, including *Saluka v. Czech Republic*.[625]

320. Once *Tenaris* is recognized as the appropriate standard, Canada's liability is inescapable. As Professor Levin testified — and as the raw numbers standing alone demonstrate — Canada discriminates against pharmaceutical patents as a field of technology.[626] Because field of technology discrimination is impermissible under NAFTA (a point Canada has never contested),[627] it is necessarily an "unreasonable" or "unjustifiable" ground of distinction.[628]

321. Canada has also failed to contest that: (i) the principal beneficiaries of the promise utility doctrine are generic drug makers (many of which are based in Canada) and (ii) those harmed are innovative foreign firms.[629] In other words, it has failed to contest that the promise utility doctrine discriminates in favor of a prominent domestic industry at the expense of foreign patent holders. This is itself a violation of Article

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[624] *Tenaris S.A. v. Venezuela*, at ¶¶ 385-388 (CL-187) (quoting *Saluka v. Czech Republic,* at ¶ 307 (CL-85)).

[625] *Saluka v. The Czech Republic*, at ¶ 309 (Fair and Equitable Treatment standard protects against discrimination on any ground of "unjustifiable distinction[]") (CL-85); *see Lemire v. Ukraine*, at ¶¶ 335, 356 (recognizing as improper under the minimum standard political discrimination in favor of a "political ally and supporter of [a previous] President of the Ukraine") (RL-29).

[626] *See supra* Part IV.B.4.

[627] *See supra* Part IV.B.4.

[628] Canada argues that "there is no prohibition at customary international law on discrimination in the granting of patents based on the industrial sector of operations." Resp. Closing Statement, Tr. at 2188:6-2189:8. But rules of customary international law do not (and need not) form at such a specific level of granularity. There may well be no specific prohibition at customary international law on discrimination in the granting of patents based on the age of the inventor, whether the inventor is a member of a particular political party, whether the inventor speaks a particular language, or any number of other objectionable bases. As recognized in *Tenaris*, *Saluka*, and *Lemire*, what an investment tribunal is charged to do is to identify the ground of distinction, and make a determination whether it is reasonable in the circumstances of the case before it.

[629] *See* Cl. Reply at ¶ 368.

1105,[630] and it also suggests that Canada's promise utility doctrine is driven *not* by legitimate policy considerations, but by the interests of domestic manufacturers.

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322. The promise utility doctrine is a new rule of law that was applied retroactively to invalidate Lilly's Zyprexa and Strattera patents — patents that met the requirements for patentability in force at the time they were granted. It is an arbitrary and subjective rule of law, which was applied to Lilly's Zyprexa and Strattera patents based on an idiosyncratic process of construing "promises" from isolated sentences in the patents. And it is a discriminatory rule of law that has been applied to invalidate only one type of patent: pharmaceutical patents held by foreign investors. The promise utility doctrine's application to the Zyprexa and Strattera patents is precisely the sort of measure that Article 1105 is intended to address. Canada has failed to meet its obligations to provide a minimum standard of treatment to Lilly's investments.

[630] *See id*. at ¶¶ 365-368.

V. Conclusion

323. For the foregoing reasons, Lilly reiterates its request for relief, as set forth in its Statement of Claim.

Respectfully submitted,

[signed]

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Appendix: Summary of Responses to Tribunal Questions

For ease of reference, this table summarizes Lilly's responses to the Tribunal's questions, which are set out in greater detail in Lilly's Opening and Closing, and in the body of the Post-Hearing Memorial.

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
1. What is the significance, if any, of the patent for raloxifene in these proceedings?	Canada's finding of inutility with respect to Lilly's patent for raloxifene is not a challenged measure in this case. The raloxifene patent is not an investment before this Tribunal. The raloxifene ruling is relevant as background, as it was the first time that a Canadian court rejected evidence of a soundly predicted utility because the evidence was not disclosed in the patent application itself (the third element of the promise utility doctrine). Raloxifene is a widely prescribed osteoporosis medication, and the raloxifene ruling is also relevant as one of the 28 inutility decisions in the pharmaceutical sector since 2005.	19:18-20:7	Cl. Post-Hearing Mem. at Part I.C Cl. Mem. at ¶¶ 74-75 Cl. Reply at ¶¶ 113-14, 191, 203, 342 Cl. Jx Opp. at ¶¶ 30, 32-48
2. Is Respondent's objection to jurisdiction *ratione temporis* untimely, as Claimant submits? If so, what are the implications?	The applicable UNCITRAL Rule 21(3) is unambiguous. By not including a core jurisdictional objection in its Statement of Defense, Canada failed to comply with the rule. Lilly's claims have remained consistent throughout this proceeding, and Canada had no excuse for its delay. The Tribunal should, therefore, reject Canada's jurisdictional objection as inadmissible.	19:7-19:15 2008:20-2010:23	Cl. Post-Hearing Mem. at Part I.A, I.B Cl. Jx Opp. at Part I

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3. According to Respondent, what is the meaning of the United States' statement that the "time limitations period in Articles 1116(2) and 1117(2) … relate to the particular investment for which the investor seeks a remedy for the breach and loss"? (see U.S. Article 1128 Submission ¶ 3 and Claimant's Observations on Article 1128 Submissions ¶ 9)	While this question is directed to the Respondent, Lilly's view is that there is no legal support for the argument that the treatment of one of Lilly's investments, the raloxifene patent, somehow started the time limitation clock on claims regarding the future expropriation and mistreatment of the two legally and factually distinct investments at issue in this arbitration, the Zyprexa and Strattera patents.	2011:2-2012:11	Cl. Post-Hearing Mem. at Part I.C Cl. Jx Opp. at Part II
4. Is "promise utility" a doctrine, as submitted by Claimant? Why or why not?	Canada's courts, in multiple decisions, have used "promise doctrine"' as a shorthand for this additional utility requirement in Canada. *Eli Lilly v. Hospira Healthcare*, 2016 FC 47, at ¶ 40 (C-535), is one example of a recent case. Lilly has used "promise utility doctrine" rather than "promise doctrine" in its submissions for the sake of clarity, since it is undisputed that it is Canada's utility requirement that is at issue in this case.	15:5-15:12	Cl. Post-Hearing Mem. at Part II.C.1 Cl. Reply at ¶ 73 n.121
5. What are the implications, if any, of the contents of Canada's Manual of Patent Office Practice for the determination of	The MOPOP, the patent examination manual of the Canadian Patent Office, is the authoritative and comprehensive reference guide used by patent office examiners. MOPOP is also made available to the public as a compendium of existing patentability requirements. MOPOP does not have the force of law, but both Lilly's expert witness (Mr. Murray	22:17-23:3 2004:9-11	Cl. Post-Hearing Mem. at Parts II.A, II.B

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Claimant's claims?	Wilson) and Canada's expert witness (Dr. Michael Gillen) agree that it accurately reflects Canadian law. Extensive revisions to the MOPOP in 2009 and 2010 are also compelling evidence of the dramatic change in Canada's utility requirement.		Cl. Mem. at ¶¶ 47, 76-78 Cl. Reply at ¶¶ 116-146, 318
6. In what way, if any, is the identification of the "promise" of a patent by a judge "subjective", as submitted by Claimant? (see Memorial ¶ 60)	The process of construing the promise of the patent is subjective in the sense that it reflects an unpredictable parsing of isolated statements in the disclosure that are not intended to relate to utility. The subjectivity is also reflected where courts find multiple promises, despite the fact that a single utility should suffice under the "mere scintilla" standard, and where courts find implied promises, as t in the Zyprexa and Strattera cases underlying this arbitration. Unable to rely on the explicit claimed use of the invention, patentees are left to guess how promises of utility will be construed from the disclosure by courts in the future. Construal of the promise is also subjective because having construed a heightened promise, the Canadian courts then consider the evidence in view of it and, as Lilly has explained, the promise and the heightened evidentiary burden become linked. As the promise grows, so does the evidentiary burden to demonstrate or soundly predict the promise.	29:14-30:8	Cl. Post-Hearing Mem. at Part IV.C.2(a) Cl. Mem. at ¶¶ 59-65 Cl. Reply at ¶¶ 174-180
7. Is the classification of Claimant's patents as secondary patents relevant	No. There is no Canadian case which uses the term "secondary patent." Dr. Brisebois admitted that the concept of "secondary patents" does not exist at Canadian law, but, rather, is a term he adopted for use in these	64:13-24 502:20-505:17	Cl. Post-Hearing Mem. at Part

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to Claimant's claims? If so, how?	proceedings. Canada's expert, Mr. Dimock, does not use the term "secondary patent." Mr. Dimock instead appears to maintain that the elevated promise standard is particularly relevant to certain types of patents, specifically new use and selection patents. But the promise utility doctrine has been used to invalidate all types of patents, including new compound patents. Canadian court practice does not support Canada's suggestion in this proceeding that the promise utility doctrine is applied only, or even primarily, to new use and selection patents.		IV.C.2(b)(2) Cl. Reply at ¶ 89 & n.154 Cl. Cmts. on 1128 and Amicus Submissions at ¶ 64
8. What is the meaning of "shall make patents available" in Article 1709(1) of NAFTA?	The treaty text, "shall make patents available," read in context of 1709(2) and 1709(3), defines the scope of inventions for which patent rights must be provided. If an invention meets the treaty standard for useful/capable of industrial application, an invalidation or denial for lack of utility under an additional, elevated standard is a breach of Article 1709(1). In other words, if a patent satisfies the capable of industrial application standard embodied in Article 1709(1), a patent cannot be withheld, or later revoked, for want of utility.	2113:10-2114:6	Cl. Post-Hearing Mem. at Part IV.B.4(a) Cl. Mem. at ¶¶ 37, 188-189, 204 n.398 Cl. Reply at ¶¶ 259-262
9. According to Claimant, as of what date was Respondent in breach of	Canada has been in breach of its obligations under Chapter 17 since 2005, and those violations continue to this day. The post-filing evidence rule in the 2002 *AZT* decision is critically important, but it was not until	121:14-121:22	Cl. Post-Hearing Mem. at Part

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its obligations under NAFTA Chapter Seventeen, and what was the basis of such breach? In this context, what is the relevance, if any, of the 2002 decision of the Canadian Supreme Court in the case of *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77 (Exh. C-213, also referred to as "*AZT*")?	that rule was married with the promise of the patent that Canada began denying patents to otherwise useful pharmaceutical inventions.		IV.B.4 Cl. Mem. at ¶¶ 81, 207-209 Cl. Reply at ¶¶ 275, 291-292, 298-300
10. What is the relevance, if any, of the utility standards in the other NAFTA jurisdictions with respect to Claimant's claims?	The utility standards in the United States and Mexico are relevant to Lilly's claims in two respects. Factually, they demonstrate that the change in the utility requirement is unique to Canada. Legally, they inform the interpretation of "capable of industrial application" consistent with Article 31 of the Vienna Convention, which provides for interpretation based on subsequent practice in the application of the treaty which establishes the agreement of the parties. In both the United States and Mexico, the bar for utility was low when NAFTA entered into force. The bar in Canada was similarly low under its traditional mere scintilla utility requirement. Unlike in Canada, however, utility in the United States and Mexico has remained a low bar consistent with widely shared international practice. Canada's new promise utility doctrine is a clear outlier.	89:3-89:20 2101:1-7; 2105:4-2106:3	Cl. Post-Hearing Mem. at Parts II.E, IV.B.4(a) Cl. Mem. at ¶¶ 7-8, 36, 55 Cl. Reply at ¶¶ 147-172

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11. If one were to accept Respondent's factual submission that the promise utility doctrine is "several distinct patent law rules, all of which were part of Canadian law when Claimant filed its patents," what implication would this have on Claimant's claims? (see, e.g., Counter-Memorial ¶ 86)	Lilly strongly disagrees that Canada has shown that any of the three aspects of the promise utility doctrine were part of Canadian law prior to 2002. But even if all three aspects had existed in prior law, it was only in 2005 that multiple aspects were married together in a way that resulted in the invalidation of pharmaceutical patents, including Lilly's patents. Neither Canada nor its experts have suggested that multiple aspects of the doctrine were applied in combination before the 2000s. Additionally, these elements cannot be considered in isolation because they are all part of Canada's utility requirement. Given the particular facts of each case, not every element is relevant to every utility decision. But courts cannot refuse to apply a particular element. The promise utility doctrine operates as a unitary utility requirement. Even if the promise utility doctrine were "several distinct patent law rules, all of which were part of Canadian law" when Lilly filed its patents (which Lilly contests), the unified utility test applied to Lilly's patents in 2010 and 2011 was fundamentally different from the utility requirement in prior law, and it is this unitary test that is relevant for determining whether Canada is in violation of its NAFTA obligations.	122:4-122:19 2014:10-18; 2033:12 *et seq.*; 2036:13-2037:9	Cl. Post-Hearing Mem. at Parts II, II.C.1 Cl. Reply at ¶¶ 6, 70-71
12. What is the relevance, if any, of the Patent Cooperation Treaty, for the purposes of determining Claimant's claims?	The PCT should be considered a relevant rule of international law that is applicable to the relations between the parties, since the PCT has applied to the NAFTA parties since 1995 and includes a definition of "industrial applicability." The PCT is also relevant to Lilly's expectations, particularly with regard to the international application it filed under the PCT for Strattera, which it then pursued during the	122:24-123:11 2081:10-20; 2110:15-2111:9	Cl. Post-Hearing Mem. at Parts II.F.1, IV.B.4(a)

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
	national examination phase in Canada.		Cl. Mem. at ¶¶ 121, 192, 202-206, 280-283 Cl. Reply at ¶ 276-278
13. Is denial of justice the only basis of liability in international law for the judgments of domestic courts interpreting domestic law, as argued by Respondent (see Counter-Memorial ¶ 213)?	No. Neither Article 1110 or Article 1105 creates any special rules for judicial measures, nor does customary international law. Canada has no answer to the substantial body of arbitral practice — in both the expropriation context and the Minimum Standard context — analyzing judicial measures and finding violations without any allegation (let alone proof) of a denial of justice. If Canada were correct that denial of justice is the only theory of liability in international law for judicial measures, these awards would not exist. By the same token, if Canada's categorical position were correct, there would be at least some authority articulating it. Yet, no treaty, no tribunal, and only one scholar (even arguably) supports Canada's position. A ruling in support of Canada's position would create a broad immunity for national courts that does not exist under international law.	105:6-106:2; 132:8-135:22 2015:22-2033:11	Cl. Post-Hearing Mem. at Part III Cl. Mem. at ¶ 179-184 Cl. Reply at ¶¶ 242-253
14. What are the implications, if any, of paragraph B.3 of the FTC Notes of Interpretation regarding	The Tribunal may, consistent with the FTC statement, consider Canada's breach of Chapter 17 as relevant to (i) the reasonableness of Lilly's investment-backed expectations and (ii) the arbitrariness of Canada's measures.	155:9-156:12	Cl. Post-Hearing Mem. at Part IV.C.2

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
Article 1105 for Claimant's claims? ("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).")	The FTC Statement provides only that a breach of another international obligation does not itself "establish" a violation of Article 1105(1). The FTC Statement does not state (or imply) that such a breach cannot be considered as a relevant factor in an Article 1105(1) analysis.		Cl. Mem. at ¶ 271 n.499 Cl. Reply at ¶ 348 n.703 Cl. Cmts. on 1128 and Amicus Submissions at ¶ 25
15. Does Article 1105(1) of NAFTA protect an investor's legitimate expectations?	Narrowing the focus of the scrutiny to only those awards interpreting Article 1105 after the FTC statement, many awards, including *Bilcon*, *Waste Management*, *Grand River*, and *Thunderbird*, recognize that legitimate expectations play a role in the Article 1105 analysis. These awards make clear that the expectations protected by the Minimum Standard include those grounded in the established legal frameworks of host states.	142:24-144:20 2134:4-19	Cl. Post-Hearing Mem. at Part IV.C.2(a) Cl. Mem. at ¶¶ 259 & n.471, 272, 284 & n.527 Cl. Reply at ¶¶ 354-362
16. Should the Tribunal find that Article 1105(1) does	No. As recognized by *Thunderbird v. Mexico* and *Grand River v. United States* (among other authorities), reliance may be based in a state's	144:3-8	Cl. Post-Hearing

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
protect an investor's legitimate expectations, is it required that such expectations are based on specific representations to the investor, as argued by Respondent (Counter-Memorial ¶ 279)?	overall conduct. Here, the relevant state conduct includes Canada's longstanding and well understood utility requirement at the time Lilly sought and received its Zyprexa and Strattera patents.	2134:4-11	Mem. at IV.C.2(a) Cl. Mem. at ¶ 284 & n.527 Cl. Reply at ¶ 359 & nn.731-732
17. Do Respondent's grants of Claimant's patents constitute specific representations to Claimant in the context of determining Claimant's legitimate expectations?	Yes. A patent constitutes a representation that the patent holder will enjoy the exclusive rights to make, use, and sell the invention until expiration of the patent. Canada's own patent law expert agreed that patents are "akin to a contract" between the patent holder and the Government.	144:9-19 1046:15-18 2134:21-2135:11	Cl. Post-Hearing Mem. IV.C.2(a) Cl. Mem. at ¶ 285-289 Cl. Reply at ¶¶ 360-362
18. Please elaborate upon the alleged discriminatory intent, which according to Claimant "can be inferred from the objective characteristics of the promise utility doctrine"	This Tribunal need not evaluate Canada's discriminatory intent under NAFTA Article 1709(7). International law does not require it, and the magnitude of the disproportionate impact across sectors by itself is sufficient to establish a breach of Article 1709(7) in this case. Nevertheless, in light of the structure of the promise utility doctrine and the way it is applied by the Canadian courts — with findings of	125:15-126:6	Cl. Post-Hearing Mem. at Part IV.B.4(b) Cl. Mem. at ¶¶ 223-226

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(Memorial ¶ 223).	elevated promises, such as long-term clinical effectiveness, that must be met as of the date of filing — Canada's utility requirement would be understood and expected to have a disparate impact on pharmaceutical innovators. This is due to the nature of the drug development process, where innovative companies develop patentable inventions long before they conduct the human clinical trials necessary to demonstrate long-term clinical effectiveness. Discriminatory intent can thus be inferred from the structure and operation of the promise utility doctrine.		
19. Do Claimant's patents constitute "property" capable of expropriation within the meaning of Article 1110(1) of NAFTA? Is Respondent's argument that "the property interests alleged to have been taken were not valid property interests under domestic law" an "untimely jurisdictional objection" as submitted by Claimant? (Counter-Memorial ¶ 326; Reply ¶ 230). What, if any, are the implications of the invalidation of Claimant's	As Mr. Andrew Reddon explained, the revocation of Lilly's patents "*ab initio*" does not airbrush those patents from existence as a matter of domestic law. As a factual matter, Lilly held valuable exclusive rights to its inventions up until the moment that the Canadian courts revoked those patents. But even if Canada were correct as to the implications of an invalidation "*ab initio*" under domestic law, it would not matter. As a matter of international law, where an investment is extinguished by a measure that is challenged as inconsistent with international law, the challenged measure cannot be relied upon to argue that no valid investment exists.	99:7-100:23; 818:7-820:17 2069:6-2073:11	Cl. Post-Hearing Mem. at Part IV.B.1 Cl. Reply at ¶¶ 230-238

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
patents ab initio for the purposes of determining whether an expropriation has taken place under Article 1110(1)?			
20. What are the implications of Article 1110(7) of NAFTA for Claimant's claims? ("[t]his Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property)"). In this context, according to Respondent, if one were to accept Claimant's allegation that	If the Tribunal finds that Canada is acting consistently with Chapter 17, that its revocations of the Zyprexa and Strattera patents are consistent with Chapter 17, then by the plain terms of Article 1110(7), Article 1110 would not apply. The provision is thus a defense for Canada. But, by the same token, if the Tribunal finds an inconsistency with Chapter 17 and that a substantial deprivation has occurred, that finding leads to the conclusion that the challenged measures are expropriatory.	114:2-14 2086:8-2091:24	Cl. Post-Hearing Mem. at Part IV.B.3(c) Cl. Mem. at ¶¶ 16-17, 183-184, 235-238, 241 Cl. Reply at ¶ 254-258

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
Respondent's actions were inconsistent with Chapter 17, what effect would this have on Claimant's claim under Article 1110? According to Claimant, if one were to accept Respondent's submission that that its actions were consistent with Chapter 17, what effect would this have on Claimant's claim under Article 1110?			
21. What are the implications, if any, of Respondent's argument that Claimant has not been substantially deprived of its investment because Respondent's measures did not prevent Claimant from continuing to produce and sell its atomoxetine and olanzapine based products, and Claimant still holds a valid Notice of	Lilly's investments — its Zyprexa and Strattera patents — were revoked by the Canadian courts. They ceased to exist under Canadian law. When Canada invalidated Lilly's patents it deprived Lilly of its exclusive rights and its ability to enforce those exclusive rights against others. The fact that Lilly's Canadian enterprise continues to sell olanzapine and atomoxetine products does not change the fact that Lilly was substantially (in fact, completely) deprived of the value of its patents.	101:22-102:21 2082:21-2083:1	Cl. Post-Hearing Mem. at Part IV.B.2 Cl. Mem. at ¶ 163 Cl. Reply at ¶¶ 313-314 & nn.629-631

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
Compliance permitting it to sell these products (Counter-Memorial ¶ 411).			
22. What are the criteria to establish the alleged direct expropriation in this case? In particular, is it necessary for Claimant to prove that its property rights were transferred to the State or to a third party, as argued by Respondent (Counter-Memorial ¶ 405)? Can destruction of an investment also constitute expropriation, as argued by Claimant (Reply ¶ 311)?	There is no requirement that Lilly demonstrate that its investments were transferred to the state or transferred by the state to a third party. Multiple cases have recognized that an expropriation, whether direct or indirect, may occur if an investment is destroyed, which is what happened here.	127:20-128:4	Cl. Post-Hearing Mem. at Part IV.A Cl. Mem. at ¶ 171 & nn.329-330 Cl. Reply at ¶ 311
23. On what basis does Claimant argue that its alleged investment has been indirectly expropriated? In particular, is denial of justice a prerequisite for a	Denial of justice is not the exclusive basis upon which a judicial measure may be found expropriatory. *See* Question 13, above. Canada's measures qualify as an indirect expropriation. As relevant here, an indirect expropriation is established where an investment is substantially deprived of value as a result of: (i) a breach of Chapter 17 as examined under *Saipem* and other, similar authorities; (ii) a breach of	102:21-106:25; 156:15-157:4 2082:2-2083:18.	Cl. Post-Hearing Mem. at Parts III, IV.A Cl. Mem. at ¶¶ 179 - 184

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
finding of expropriation based on a judicial measure?	Chapter 17 as examined under Article 1110(7); (iii) the application of an arbitrary doctrine of law; or (iv) the application of a legal doctrine that violates an investor's legitimate investment-backed expectations.		Cl. Reply ¶¶ 239-253
24. In relation to Claimant's position that Article 1110 prohibits "measures that substantially deprive investments of value while violating a rule of international law", is it significant that the alleged violation of international law in this case is NAFTA Chapter 17? Would a breach of an international obligation found outside of NAFTA have the same result? (see, e.g., Memorial Section VII.A.1)	As reflected in *Saipem* and the other cases discussed in Lilly's submissions, it is not necessary that the substantive rule be contained in the same treaty as the investment agreement. However, there must be a nexus between the breach and the protected investment. In agreeing to NAFTA Chapter 17, Canada agreed to abide by specific rules for the grant and revocation of patents held by investors of other NAFTA states, establishing a close nexus between a breach of Chapter 17 and Lilly's protected investments (its patent rights).	106:15-108:22 2083:24-2084:14	Cl. Post-Hearing Mem. at Part IV.B.3 Cl. Mem. at ¶ 180-181 Cl. Reply at ¶¶ 246-249
25. What are the "applicable rules of international law" referred to in Articles 102(2) and 1131(1) of NAFTA that are applicable in this case?	The references to "applicable rules of international law" in Article 102(2) and Article 1131(1) permit the Tribunal to consider other relevant rules of international law, including the Vienna Convention on the Law of Treaties, in connection with its interpretation of NAFTA. As applied to Lilly's Article 1105 and Article 1110 claims, these provisions permit the Tribunal to consider the customary Minimum	2076:16-2079:14	Cl. Post-Hearing Mem. at Part IV.B.3 Cl. Mem. at ¶¶ 190-192,

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
	Standard of Treatment and the general international law of expropriation in applying the standard of investment protection offered by NAFTA.		202-203
26. Are there circumstances in the present case where the burden of proof may shift and, if so, what are they?	To the extent Chapter 17 operates solely as a safe harbor, or an affirmative defense for Canada as Canada advocates (an interpretation that Lilly vigorously contests), then Canada bears the burden of proving that its measures are consistent with Chapter 17.	N/A	N/A
27. The Claimant is invited to clarify whether, having regard to the invalidity decisions concerning Zyprexa and Strattera, it is alleging a violation Articles 1105 and/or 1110 of NAFTA as a consequence of the cumulative effect of the judicial development of the alleged Canadian "promise utility" doctrine by the AZT decision in 2002, the Aventis, Pfizer and Bristol-Myers decisions of 2005, and the Raloxofine decision of 2008, or whether the	The NAFTA violations Lilly has alleged stem from the promise utility doctrine as a whole, not from any individual case through which aspects of the doctrine developed. The promise utility doctrine is the utility requirement that was applied to invalidate the '113 patent and the '735 patent, solely for lack of utility, in 2010 and 2011.	1993:15-1994:25	Cl. Post-Hearing Mem. at Parts II.C.1, IV.C.2(b)(1) Cl. Mem. at ¶ 57, 262 Cl. Reply at ¶¶ 6, 70-71

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
alleged breach of NAFTA can be traced back to any one of these decisions individually?			
28. In response to a question from the Tribunal, counsel for Respondent, referring to Jan Paulsson's views, appeared to accept that "a decision by a court that is so fundamentally baffling and no reasonable judge could ever come to that conclusion" could amount to a denial of justice. Respondent is invited to clarify whether it accepts that a court decision of this character could amount to a denial of justice.	While this question is directed to the Respondent, the way Lilly would analyze this question is first to ask why is it baffling. If the decision is irrational because it is a misapplication of national law, then Lilly would agree that it fits within Professor Paulsson's first category, and the only theory of liability there would be a denial of justice. Setting aside whether national law has been applied properly or improperly, if the decision is unpredictable, incoherent, and totally irrational, then liability does attach. Liability attaches under that circumstance because the measure is arbitrary and in violation of Article 1105 as a substantive matter.	2032:5-2032:20	Cl. Reply at ¶¶ 244-245 & n.483
29. With respect to each of the three claimed elements of the alleged Canadian "promise utility" doctrine (namely, the AZT decision	Each element of the promise utility doctrine is a new development in Canadian law that came into existence in the 2000s, after Lilly's patents for Zyprexa and Strattera were applied for and granted. Each element is not only new, but a complete and surprising reversal from prior law. Applied together, these elements result in an incoherent utility	2036:22-2037:10	Cl. Post-Hearing Mem. at Part II.C

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in 2002, the *Aventis*, *Pfizer* and *Bristol-Myers* decisions of 2005, and the *Raloxofine* decision of 2008), please identify the extent to which each such element was or was not a new development in Canadian law.	requirement that sets the bar for utility much higher than before in Canada and much higher than in other jurisdictions. In Lilly's view, each element of the promise utility doctrine cannot properly be considered in isolation because the Canadian courts apply the promise utility doctrine as a unitary utility requirement. Neither Canada nor its experts have suggested that multiple elements of the promise utility doctrine were ever applied together before the 2000s.		Cl. Mem. at ¶¶ 70-71
30. The Parties are invited to address to what extent the Tribunal's competence under Chapter 11 allows it, or requires it, to address Chapter 17, in particular in relation to Articles 1110 and 1105 of NAFTA.	As Canada has acknowledged, Article 1110(7) vests this Tribunal with competence to rule on whether Canada's measures are consistent with Chapter 17. The same plain language in Article 1110(7) requires the Tribunal to consider whether Canada's measures are inconsistent with Chapter 17 for purposes of the expropriation analysis. In addition, the customary Minimum Standard of Treatment and the general international law of expropriation permit the Tribunal to consider Canada's breach of Chapter 17 as one factor contributing to a breach of Article 1105 and Article 1110, respectively.	2086:24-2090:22	Cl. Post-Hearing Mem. at Part IV.B.3(c) Cl. Mem. at ¶¶ 16, 235-238 Cl. Reply at ¶¶ 18, 226, 237, 254-258
31. The Parties are invited to address the consequences of a finding of either consistency with or breach of Chapter 17 for purposes	With respect to Article 1110, *see* Question 20. With respect to Article 1105, a finding of inconsistency with Chapter 17 could contribute to a finding that Canada's measures were arbitrary and/or violated Lilly's legitimate expectations.	156:3-8 2091:18-2091:24	Cl. Post-Hearing Mem. at Parts IV.B.3(c), IV.C.2(a)

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
of an assessment of whether Respondent is in breach of Article 1110 and/or Article 1105 of NAFTA.			Cl. Mem. at ¶¶ 16-17, 183-184, 235-242 Cl. Reply at ¶¶ 227, 254-258 & n.512, 292, 316, n.749
32. Does Article 1709(8)(a) of NAFTA apply to an actual refusal to grant a patent or does it apply to the situation in which the grant could have been refused?	Article 1709(8) applies to decisions to revoke previously granted patents. It does not apply to a decision to grant or deny a patent in the first instance. The text of the provision — given its past tense, "would have justified" — makes clear that it operates as a bar on retroactivity at the time of revocation.	126:7-127:3 2122:9-2123:6	Cl. Post-Hearing Mem. at Part IV.B.4(c) Cl. Mem. at ¶¶ 227-231 Cl. Reply at ¶¶ 301-305
33. The Parties are invited to comment on the meaning of Article 1709(1) of NAFTA and the extent to which it imposes	As discussed in response to Question 8, Article 1709(1) is a substantive obligation that defines the scope of inventions for which patent rights must be provided. If an invention meets the treaty standard for useful/capable of industrial application, an invalidation or denial for lack of utility under an additional, elevated standard is a breach of	2099:20-2100:5 2113:11-2114:9	Cl. Post-Hearing Mem. at Part IV.B.4(a)

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substantive obligations (in terms of harmonization, baseline or otherwise).	Article 1709(1). In other words, if a patent satisfies the capable of industrial application standard embodied in Article 1709(1), a patent cannot be withheld, or later revoked, for want of utility. In this way, Article 1709(1) establishes a baseline of patent protection. The ordinary meaning of "capable of industrial application" and "useful" in Article 1709(1), in context and in light of the treaty's object and purpose, is that an invention must be capable of a practical use. This is a low bar. This interpretation is corroborated by a concordant subsequent practice by the NAFTA parties; by the common understanding of these patent law terms of art internationally; and by the definition of industrial applicability in the PCT, a relevant rule of international law applicable to the NAFTA parties.		Cl. Mem. at ¶ 185-206 Cl. Reply at ¶ 259-90
34. The Parties are invited to address the sources and current content of the customary international law principle of "minimum standard of treatment of aliens" and "denial of justice", with particular reference to the FTC Note of 2001.	The Minimum Standard of Treatment is a frequently interpreted standard that has repeatedly been applied in the NAFTA context and in the context of the many other treaties that adopt it. As awards applying the standard make clear, it encompasses protections of legitimate investment-backed expectations, against arbitrariness and against discrimination. In light of the many authorities interpreting the Minimum Standard of Treatment — and the fact that Lilly is entitled to relief under those authorities — this Tribunal need not determine whether the Minimum Standard of Treatment has converged with the autonomous Fair and Equitable Treatment Standard (and whether the Tribunal may, therefore, also rely on authorities interpreting the latter standard).	2124:3-2126:14 *et seq.*	Cl. Post-Hearing Mem. at Part IV.C.1 Cl. Mem. at ¶¶ 253- 255

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
	Nonetheless, it is clear that the autonomous treaty standard has heavily influenced the Minimum Standard of Treatment, such that there is no practical difference between them.		
35. Has the minimum standard of treatment of aliens been evolved and shaped by the 3000 BITs, as contended by Claimant, and, if so, what is the content of the minimum standard?	*See* Question 34.		
36. The Claimant is invited to summarise / clarify its allegations of a breach of NAFTA Article 1105 and in particular the extent to which its legitimate expectations, arbitrariness and discrimination allegations constitute separate heads of alleged breach or whether these elements constitute strands of a single allegation of breach.	Canada's violations of the Minimum Standard of Treatment's protection of legitimate investment-backed expectations, its protection against arbitrary government measures, and its protection against discrimination "based on unreasonable distinctions" are independent bases for liability. Each alone constitutes a violation of the Minimum Standard. But that does not mean that Canada's violations of the Minimum Standard have to be considered in isolation from one another. As recognized in *Waste Management (II)* and the multiple NAFTA and non-NAFTA awards that have adopted the *Waste Management (II)* standard, the Minimum Standard of Treatment is a "flexible [standard] which much be adapted to the circumstances of each case." In the circumstances of this case, the Tribunal should consider the cumulative impact of the arbitrary, discriminatory, and retroactive effects of the	2130:3-2131:2	Cl. Post-Hearing Mem. at Part IV.C.2

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	promise utility doctrine.		
37. The Parties are invited to elaborate their positions regarding NAFTA Article 1110(7).	Lilly elaborates its position on NAFTA Article 1110(7) at Part IV.B.3(c) of its Post-Hearing Brief.	2088:8-2089:8	Cl. Post-Hearing Mem. at Part IV.B.3(c) Cl. Mem. at ¶¶ 16, 183-184, 238, 241-242 Cl. Reply at ¶¶ 18, 227, 237, 254-256 & n.513, 258 & n.515
38. The Parties are invited to address whether an alleged expropriation as a consequence of a judicial decision is or is not limited to a denial of justice and what, for purposes of this answer, they mean by denial of justice.	*See* Question 13. Like Canada, Lilly agrees with Professor Jan Paulsson's definition of denial of justice as a purely procedural doctrine.	2016:20-23; 2208:18-23	Cl. Post-Hearing Mem. at Part III

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
39. What is the relationship between Article 1110 of NAFTA and expropriation in general international law, if any?	Article 1110 provides protection that is at least commensurate with the general international law of expropriation.	2084:20-2084:24	Cl. Post-Hearing Mem. at Part IV.B.3
40. What relevance, if any, does practice under the U.S. takings clause have for these proceedings?	There is no necessary parallel between domestic rights to compensation for takings and the international law of expropriation, and thus the interpretation of the Fifth and Fourteenth Amendments to the U.S. Constitution is not relevant to these proceedings. However, the discrepancy between the U.S. Government's position in this arbitration (that domestic law does not recognize the concept of judicial takings) and U.S. law on judicial takings as articulated by the U.S. Supreme Court (which recognizes that judicial measures can qualify as takings under U.S. law) illustrates that Article 1128 submissions reflect current litigation positions of the non-disputing NAFTA parties rather than an objective view on questions of treaty interpretation under NAFTA. The reasoning of the U.S. Supreme Court is also compelling: "It would be absurd to allow a State to do by judicial decree what [it may not] do by legislative fiat." *Stop the Beach Renourishment v. Florida Dept. of Envt'l Protection*, 560 U.S. 702 (2010) (RL-46).	2338:25-2239:7	Cl. Post-Hearing Mem. at Part III.B Cl. Cmts. on Art. 1128 and Amicus Submissions at ¶ 22
41. Can the time-bar issue in Article 1116(2) / 1117(2) NAFTA be waived by a	The time-bar issue in Article 1116(2)/1117(2) can be waived, and it was waived once the deadline for raising jurisdictional objections under Article 21(3) of the UNCITRAL Rules had passed.	2010:8-15	Cl. Post-Hearing Mem. at Part

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respondent? If not, does Article 1116(2) / 1117(2) NAFTA prevail over Article 21(3) of the UNITRAL Rules? In light of this, what is the relevance, if any, of provision Article 1120(2) NAFTA ("The applicable arbitration rules shall govern the arbitration except to the extent modified by this Section")?	NAFTA identifies the UNCITRAL Rules (among others) to govern Chapter 11 proceedings, and the parties agreed to the UNCITRAL Rules to govern this proceeding. While NAFTA may "modif[y]" the UNCITRAL Rules, there is nothing in Articles 1116 and 1117 that indicates an intent to modify Rule 21(3). Even Canada's own courts have held that a NAFTA Party can waive jurisdictional arguments by failing to timely raise them.		I.B
42. With respect to the cases of *Saipem v. Bangladesh* and similar authorities invoked by the Claimant, the Tribunal notes the discussion between the Parties as to whether or not this case stands for the proposition that a judicial expropriation may occur. The Tribunal further notes that in para. 242 of the	The Tribunal's understanding is correct. Lilly elaborates on its view in Part IV.B.3(a) of its Post-Hearing Brief.	103:9-108:22 2083:2-18; 2086:8-15	Cl. Post-Hearing Mem. at Part IV.B.3(a)

Question	Summary of Responses from the Hearing and Post-Hearing Memorial	Transcript References	Memorial References
Memorial, the Claimant argues, "Second, even if Article 1110(7) NAFTA did not exist, cases such as *Saipem* stand for the proposition that Canada's breach of its patent obligations under Chapter 17 means that its measures are not 'non-compensable regulation[s].'" The Tribunal understands that the Claimant argues that the Tribunal is entitled to consider alleged violations of Chapter 17 in the alternative to Article 1110(7) NAFTA, on the basis of the *Saipem v. Bangladesh* case. The Parties are requested to elaborate on this alternative argument.			
43. With reference to Question 42, to what extent are alleged violations of	*See* Questions 30 and 31.		

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Chapter 17 relevant to an application of Article 1105(1) NAFTA?			