IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN OF THE NORTH AMERICAN FREE TRADE AGREEMENT AND THE UNCITRAL ARBITRATION RULES (1976)

BETWEEN:

ELI LILLY AND COMPANY

Claimant/Investor

AND:

GOVERNMENT OF CANADA

Respondent/Party

(Case No. UNCT/14/2)

GOVERNMENT OF CANADA

POST-HEARING SUBMISSION

July 25, 2016

Trade Law Bureau
Departments of Justice and of Foreign Affairs, Trade and Development
Lester B. Pearson Building
125 Sussex Drive
Ottawa, Ontario
K1A 0G2
CANADA

TABLE OF CONTENTS

I. PRELIMINARY STATEMENT

1. This is a claim that should never have been brought to Chapter Eleven arbitration. A NAFTA Chapter Eleven tribunal is not the appropriate body to consider whether the interpretation by a domestic court of domestic laws is appropriate or correct. Nor is it the appropriate body to consider whether a NAFTA Party has acted consistently with its obligations outside of Chapter Eleven of NAFTA. As the NAFTA Parties have made clear, a NAFTA Chapter Eleven tribunal is not a court of appeal or a tribunal of plenary jurisdiction.

2. Claimant has made significant efforts to try to convince the Tribunal that it is not appealing the specific court decisions invalidating its patents on the grounds of an error of Canadian law. Yet, acting as a supra-national court of appeal on a potentially unlimited array of domestic and international law questions is exactly what Claimant is asking this Tribunal to do. It is asking this Tribunal to declare that the Canadian courts, including the Supreme Court of Canada, erred as a matter of Canadian law when, in a series of decisions between 2002 and 2008, they interpreted the term "useful" in Canada's *Patent Act*. It is also asking this Tribunal to find a breach of Canada's obligations under Article 1110 and Article 1105 because of alleged breaches of obligations of international law outside of Chapter Eleven of NAFTA. Essentially, through its broad interpretation of Articles 1110 and 1105, Claimant is trying to expand this Tribunal's jurisdiction to include other international law obligations. This attempt must be rejected.

3. Articles 1116 and 1117 of NAFTA create a limited right on behalf of an investor of one NAFTA Party to bring a claim against another NAFTA Party. Specifically, Article 1116 provides[1]:

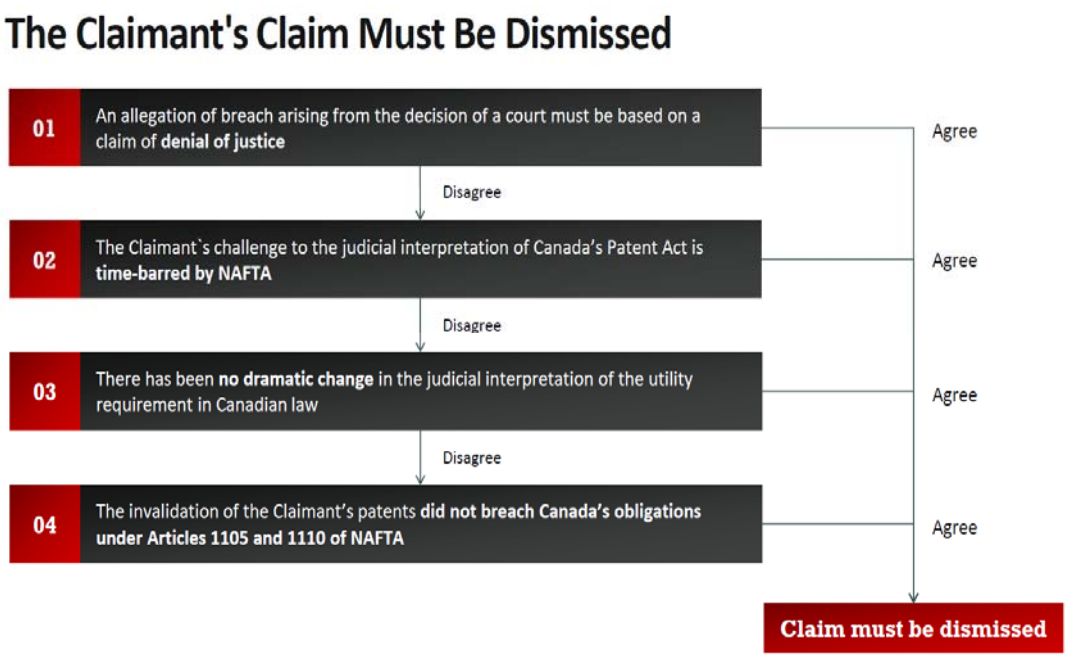
[1] Article 1117 provides an identical right for an investor to bring a claim on the same grounds, and with the same limitations, "on behalf of an enterprise of another Party that is a juridical person that the investor owns or controls directly or indirectly."

> 1. An investor of a Party may submit to arbitration under this Section a claim that another Party has breached an obligation under:
>
> > (a) Section A or Article 1503(2) (State Enterprises), or
> > (b) Article 1502(3)(a) (Monopolies and State Enterprises) where the monopoly has acted in a manner inconsistent with the Party's obligations under Section A,
>
> and that the investor has incurred loss or damage by reason of, or arising out of, that breach.
>
> 2. An investor may not make a claim if more than three years have elapsed from the date on which the investor first acquired, or should have first acquired, knowledge of the alleged breach and knowledge that the investor has incurred loss or damage.

4. Accordingly, when an investor brings a dispute to arbitration under Chapter Eleven of NAFTA, it bears the burden of proving two things: (1) that its allegations, even if assumed to be true, constitute a "claim" that may be brought to arbitration under paragraphs 1 and 2 of Article 1116 or Article 1117 of NAFTA; and (2) that the challenged conduct does in fact breach one or more of the obligations in Section A of Chapter Eleven, or in either Article 1503(2) or Article 1502(3)(a).

5. Claimant has failed to meet its burdens. In its oral submissions, Canada introduced a decision tree (pictured below), that outlines the four separate and alternate reasons why this Tribunal should dismiss this claim. Claimant expressly agreed that this decision tree represented the fundamental issues that the Tribunal must address in this dispute.[2]

[2] Closing Statement of Claimant, June 8, 2016, pp. 2007:18 – 2008:5 ("SIR DANIEL BETHLEHEM: May I just clarify? Do you agree with this decision tree? MS. CHEEK: Well, we will take the time bar issue first, which I will address very briefly. Then we will look at the denial-of-justice question, which Mr. Berengaut will address. We will look at the dramatic change of the law, which Ms. Wagner will address, and then we will look at the violations of 1110 and 1105. SIR DANIEL BETHLEHEM: Apart from inverting 1 and 2, are you otherwise in agreement with this? MS. CHEEK: Yes, we are.") Claimant later submitted its own decision tree which further amended the order of the issues, but did not disagree on any point of substance: Closing Presentation of Claimant, Slide 149.



6. In accordance with this decision tree, in Part II of this submission, Canada will summarize the evidence and argument that show why Claimant has failed to state a legally cognizable "claim" of a breach of Articles 1110 and 1105 because it has not alleged a denial of justice. Claimant has challenged measures of the Canadian judiciary, and specifically the alleged radical change in the interpretation of Canadian domestic law by the Canadian judiciary in a six-year period between 2002 and 2008. The Tribunal has the competence to consider whether judicial measures are consistent with a NAFTA Party's obligations under Articles 1110 and 1105 of NAFTA. The judiciary is an organ of government, and hence its measures constitute measures of a Party subject to the obligations of Chapter Eleven pursuant to Article 1101.

7. However, the fact that a NAFTA Party is responsible for the conduct of the judiciary provides no insight into the content of the substantive obligations that the NAFTA Parties accepted with respect to judicial measures in Articles 1110 and 1105 of NAFTA. The primary question the Tribunal must adjudicate in this arbitration is: what is the role of a Chapter Eleven tribunal when it is the acts of a State's domestic courts interpreting domestic laws that are alleged to be the source of a violation of Articles

1110 and 1105 of NAFTA? All three NAFTA Parties agree that under the treaty that they negotiated and signed, the answer to this question is straightforward. When it is the acts of a neutral and independent judiciary that are being challenged under Articles 1110 and 1105, a Chapter Eleven tribunal is limited to considering whether there has been a denial of justice. Claimant has not and could not allege that any of the judicial decisions that it challenges amount to a denial of justice. Hence, even if Claimant's factual allegations were accepted as true, those allegations would be manifestly without legal merit. Put simply, even if true, Claimant's allegations would not amount to a "claim" of a breach under Article 1116(1) or Article 1117(1) of NAFTA because Claimant does not allege the denial of justice that is necessary to ground a claim in this context. Accordingly, the Tribunal should dismiss this claim on this ground alone, before it is necessary to consider any of the other grounds for dismissal.

8. In Part III, Canada will summarize the argument and the evidence before the Tribunal that establish that Claimant's challenge to the alleged "promise utility doctrine" is time-barred under Articles 1116(2) and 1117(2). Those Articles require an investor to bring a claim to NAFTA Chapter Eleven arbitration within three years of when an investor knows of the allegedly breaching measure and of a loss resulting from that measure. In short, NAFTA does not allow an investor to sit on its hands and bring a challenge to the most recent application to it of an older doctrine or law.

9. The evidence before the Tribunal is clear that Claimant knew of what it characterizes as the promise utility doctrine, and of a loss it suffered as a result of that doctrine, by 2008. Indeed, Claimant expressly admitted at the hearing that the alleged judicial doctrine it challenges had crystalized by no later than 2008 in a decision involving Claimant's patent related to raloxifene.[3] However, Claimant did not bring its claim until 2013, more than four years later. As such, its claim that the alleged radical change in the judicial interpretation by the Canadian courts of the term "useful" in Canada's *Patent Act* is time-barred and should be dismissed.

[3] Closing Statement of Claimant, June 8, 2016, pp. 1994:2 – 1995:19.

10. In Part IV, Canada will summarize the evidence and argument before the Tribunal that show that even if Claimant is not required to prove a denial of justice, and even if its claim is not time-barred, Claimant's claim fails because it necessarily relies on a false factual predicate that is vital to the Tribunal's jurisdiction in this matter. Claimant's allegation is that after its patents for olanzapine and atomoxetine were granted, Canadian courts dramatically changed their interpretation of the utility requirement in Canada's *Patent Act*, and that this dramatic change breaches Article 1110 and Article 1105. Claimant had to allege a dramatic change in law after the grant of its patents because the Tribunal has no jurisdiction *ratione temporis* to consider measures that pre-exist the date of Claimant's alleged investments.

11. As expressly clarified by Claimant at the hearing, its allegation is that there were three changes in the interpretation of Canada's patent law, all of which serve to form a "unitary" promise utility doctrine, and none of which are sufficient in and of themselves to breach Canada's obligations under NAFTA. Accordingly, as Claimant itself admits, if it cannot prove that each one of these alleged elements of the alleged promise utility doctrine is a dramatic change in the way the Canadian courts have interpreted Canadian law since the grant of its patents, its claim must fail.

12. The evidence before the Tribunal is clear: Claimant has not established that any of the courts' interpretations of the law, let alone all of them, represent such a dramatic change. The challenged aspects of Canadian law all find their roots in decades of Canadian jurisprudence and legal doctrine. All of the interpretations of Canadian law that Claimant bundles together as the promise utility doctrine existed prior to Claimant making its investments in Canada. As a result, Claimant cannot challenge these interpretations. The claims fail for this reason as well.

13. Finally, in Part V of this submission, Canada will summarize the evidence and argument in this arbitration that demonstrate that even if the Tribunal accepts Claimant's view of the applicable law under Articles 1110 and 1105, Claimant has failed to prove the facts necessary to establish that Canada is in breach of its obligations.

14. In Part V.A, Canada will summarize the evidence and argument that show that Claimant has not established the facts necessary to prove a breach of Article 1110, even on Claimant's own theory of how that Article must be interpreted. First, the Canadian courts did not take Claimant's property – to the contrary, the Canadian courts found that as a matter of Canadian law, that property simply did not exist. Second, the decisions of the Canadian courts in question are consistent with Chapter Seventeen, and thus protected by the shield that the NAFTA Parties created in Article 1110(7). Finally, Claimant has not submitted evidence sufficient to establish that the invalidation of its patents amounted to a substantial deprivation of the value of its investment for which compensation is due.

15. In Part V.B, Canada will summarize the evidence and argument before the Tribunal that show that Claimant has failed to prove the facts that it wrongly claims would be sufficient to establish a breach of Canada's obligations under Article 1105. In particular, Claimant has failed to prove that Canada's measures are discriminatory, arbitrary, and contrary to its legitimate expectations. Claimant's allegations of discriminatory treatment rely on a statistical analysis that was based on a biased data set assembled by Claimant so that there could be only one mathematical result. Once that data set is corrected, the analysis reveals that there is no evidence of any disparate impact on the pharmaceutical sector, let alone discriminatory treatment. Claimant also has not made out its case that either the specific decisions with respect to its olanzapine and atomoxetine patents, or the interpretation of the term "useful" in Canada's *Patent Act* in a series of decisions between 2002 and 2008, is in any way arbitrary. Claimant's allegations of arbitrariness amount to nothing more than a request that this Tribunal review the decisions of Canadian courts on the merits, without the evidence and factual record that those courts had before them, and hold that Canada should have different laws and policies than it does. Unsurprisingly, the laws and policies for which Claimant advocates would allow it almost unfettered access to patents and the ability to obtain patent protection for old inventions indefinitely based on speculation, guesswork, and unsound predictions rather than innovation. Such an approach would fundamentally

unbalance the *quid pro quo* of patent bargain and eliminate the "*quid*" that the public gets for the offered "*quo*" of a patent monopoly. Finally, Claimant has failed to prove, as a matter of fact, that it had any legitimate expectations on which it relied in making its patents investments that were somehow violated by the judicial decisions in question.

16. For all of these reasons, Claimant's allegation that a radical change in the judicial interpretation of the term "useful" in Canada's *Patent Act* since 2002 violates Canada's obligations in Articles 1110 and 1105 of NAFTA must be dismissed. Canada should be awarded its costs, as well as pre-Award and post-Award interest at a rate to be established by the Tribunal.

II. CLAIMANT HAS FAILED TO STATE A CLAIM UNDER ARTICLES 1116(1) AND 1117(1) FOR A BREACH OF ARTICLES 1110 AND 1105 BECAUSE IT ADMITS THAT THERE HAS BEEN NO DENIAL OF JUSTICE

17. Claimant alleges that a radical change in the way that the Canadian courts have interpreted the word "useful" in Canada's *Patent Act* since 2002 has resulted in a violation of Canada's obligations under two specific articles of chapter eleven of NAFTA: Articles 1110 and 1105. As such, the Tribunal must interpret these particular articles of Chapter Eleven and determine the substantive obligations that they impose upon Canada with respect to the acts of the Canadian judiciary.

18. In undertaking this task, Article 1131(1) requires the Tribunal to decide this dispute in accordance "with this Agreement and applicable rules of international law."[4] This language is not an invitation for the Tribunal to apply substantive obligations beyond those contained in Section A of Chapter Eleven of NAFTA. In particular, it does not permit a tribunal to consider a NAFTA Party's compliance with other international

[4] Article 102(2) of NAFTA similarly requires that the NAFTA Parties themselves "interpret and apply the provisions of this Agreement in the light of its objectives set out in paragraph 1 and in accordance with applicable rules of international law." Whether or not a NAFTA Party complies with this obligation is beyond the jurisdiction of a Chapter 11 Tribunal. Nevertheless, similar to Article 1131(1), the applicable rules of international law here are merely the secondary rules of international law. This article is not an umbrella article through which the NAFTA Parties obligated themselves in NAFTA to comply with any other relevant international legal obligation. *See also*, Opening Presentation of Canada, Slides 17-18.

law obligations, including obligations found in other Chapters of NAFTA.[5] As Canada explained at the hearing, the "applicable rules of international law" referred to in Article 1131(1) are secondary rules of international law.[6] Such rules include, for example, the rules of treaty interpretation found in customary international law and in the Vienna Convention on the Law of Treaties ("VCLT"), and the rules on State responsibility.

19. As explained in detail in Canada's previous submissions[7] and as summarized again below, the only substantive obligation that Articles 1110 and 1105 contain with respect to judicial measures is an obligation to ensure that the investments of an investor from another NAFTA Party are not denied justice. Claimant has asserted that this is at odds with the principle of State responsibility for judicial actions and that it amounts to an immunity for acts of the judiciary. There is no merit to such an argument. It is not in dispute that under the applicable rules of international law, Canada is responsible for the actions of its judiciary. The judiciary is an organ of government.[8] However, the fact that Canada is responsible for acts of its judiciary does not determine what the applicable substantive obligations are in Articles 1110 and 1105 or how those obligations apply in the context of judicial measures. To be clear, if there were a specific provision in NAFTA Chapter Eleven that obligated the courts of the NAFTA Parties to make or refrain from making certain decisions or taking certain actions, and the courts of a NAFTA Party undertook such prohibited actions, it would not be necessary to prove a

[5] Second US 1128 Submission, para. 2. ("This Article requires the Tribunal to apply international law both in interpreting the provisions of Chapter Eleven, Section A, and as a rule of decision for claims of breach of Chapter Eleven, Section A. Article 1131 (1) does not give the Tribunal jurisdiction to hear claims of breach of any obligations other than the obligations listed in Chapter Eleven, Section A. For example, Article 1131(1) does not expand the obligations listed in Article 1105 beyond any protections recognized as a part of the minimum standard of treatment under customary international law. We also note that Article 1110(1) reflects customary international law with respect to expropriation.")

[6] Closing Statement of Canada, June 8, 2016, pp. 2170:21–2177:5.

[7] Respondent's Counter Memorial ("Resp. CM"), paras. 230-245, 316-325 and 331-343; Respondent's Rejoinder ("Resp. Rejoinder"), para. 213-222, 236-237 and 244-255; Respondent's Observations on Issues Raised in 1128 Submissions, paras. 12-14, 19-21 and 30-33.

[8] Opening Statement of Canada, May 30, 2016, p. 215:15-24. *See also*, Resp. CM, para. 230, FN 416; Resp. Rejoinder, para. 245.

denial of justice.[9] There would be a breach of that provision of Chapter Eleven, and the relevant NAFTA Party would be responsible. However, NAFTA Chapter Eleven contains no such provision. The only question before the Tribunal is whether Articles 1110 and 1105 can form the basis of a breach when it is the acts of the judiciary of a NAFTA Party that have been challenged and there is no denial of justice. The answer is that they cannot.

20. Claimant has not, and indeed, could not allege a denial of justice in this case. Accordingly, the Tribunal need not decide any of the factual issues in dispute between the parties. Even if the Tribunal accepts all of the factual allegations made by Claimant, its claim is manifestly without legal merit. In light of the fact that Claimant has failed to allege a denial of justice, it has failed to state a claim of a breach of an obligation in Section A of Chapter Eleven of NAFTA as a matter of law.

A. The Application of Article 1110 (Expropriation) With Respect to Judicial Measures

21. Article 1110(1) of NAFTA provides:

> 1. No Party may directly or indirectly nationalize or expropriate an investment of an investor of another Party in its territory or take a measure tantamount to nationalization or expropriation of such an investment ("expropriation"), except:
>
> (a) for a public purpose;
>
> (b) on a non-discriminatory basis;
>
> (c) in accordance with due process of law and Article 1105(1); and
>
> (d) on payment of compensation in accordance with paragraphs 2 through 6.

[9] *See also*, Closing Statement of Canada, June 8, 2016, pp. 2207:25 – 2208:9 ("MR. SPELLISCY: 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.")

22. NAFTA does not define "expropriation," but the NAFTA Parties have consistently taken the position that Article 1110(1) reflects the customary international law rules on expropriation.[10] NAFTA tribunals interpreting Article 1110(1) have agreed.[11] As such, for there to be an expropriation under Article 1110(1), there must be a "taking" of property rights that causes a substantial deprivation of the economic value of an investment.[12]

23. In undertaking an analysis under Article 1110, there are, thus, three questions to be addressed: (1) are there actual property rights that could be expropriated? (2) have such property rights been directly or indirectly expropriated? (3) did the expropriation violate Article 1110?[13]

[10] *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Second Submission of Canada Pursuant to NAFTA Article 1128 dated 6 July 2001, ("*Mondev Second Submission of Canada*"), paras. 64 and 65 (defining "expropriation" in Article 1110 with reference to international law) (**RL-021**); *Methanex Corporation v. The United States of America*, (UNCITRAL), Mexico Fourth Submission per Article 1128, 30 January 2004, para. 13 ("Article 1110, which must be interpreted in accordance with the applicable rules of customary international law, incorporates the principle that States generally are not liable to compensate aliens for economic loss resulting from non-discriminatory regulatory measures taken to protect the public interest, including human health.") (**RL-042**); *Metalclad Corporation v. The United Mexican States*, ICSID Case No. ARB(AF)/97/1, Submission of the United States pursuant to Article 1128, 9 November 1999, para. 10 (stating that the United States "believes that it was the intent of the Parties that Article 1110(1) reflect customary international law as to the categories of expropriation.") (**RL-055**). *See also*, Resp. CM, para. 308; US 1128 Submission, para. 28; Mexico 1128 Submission paras. 17 and and 18; Second US 1128 Submission, para. 2.

[11] *Glamis Gold Ltd. v. United States of America*, (UNCITRAL), Award, 8 June 2009 ("*Glamis Award*"), para. 354 (holding that "inclusion in Article 1110 of the term "expropriation" incorporates by reference the customary international law regarding that subject") (**RL-006**); *Archer Daniels Midland Company v. The United Mexican States*, ICSID Case No. ARB(AF)/04/05, Award, 21 November 2007 ("*Archer Daniels Award*"), para. 237 ("The key terms in Article 1110 –"nationalization," "expropriation," and "measures tantamount thereto" – are not defined in the NAFTA. The interpretation of these terms requires an analysis of the applicable rules of international law, in accordance with Article 1131 of the NAFTA.") (**RL-074**).

[12] *Glamis Award*, para. 357 (**RL-006**); *Grand River Enterprises Six Nations, Ltd. et al v. United States of America*, (UNCITRAL), Award, 12 January 2011 ("*Grand River Award*"), para. 148 ("Other NAFTA Tribunals have regularly construed Article 1110 to require a complete or very substantial deprivation of owners' rights in the totality of the investment…") (**RL-010**); *Pope & Talbot v. Government of Canada*, (UNCITRAL), Interim Award, 26 June 2000, para. 102 ("…under international law, expropriation requires a 'substantial deprivation ['']") (**RL-056**).

[13] *See for example*, *Chemtura Corporation (formerly Crompton Corporation) v. Government of Canada*, Award, 2 August 2010, ("Chemtura Award"), para. 240 (**RL-057**).

1) Article 1110 Can Apply Only If Valid Property Rights Exist At Domestic Law

24. Claimant alleges that its patents for the use of atomoxetine and olanzapine constitute "investments" pursuant to the definition of that term in NAFTA Article 1139(g) because they are intangible property "acquired in the expectation or used for the purpose of economic benefit or other business purposes".[14]

25. Answering the question of whether Claimant's patents with respect to atomoxetine and olanzapine constitute intangible property that could be taken by Canada requires a *renvoi* to domestic Canadian law. It is "for the host State to define the nature and extent of property rights that a foreign investor can acquire."[15] If there is no property right at domestic law, then there is nothing that can be taken.[16] International arbitral tribunals have affirmed this principle, explaining that "for there to have been an expropriation of an investment or return … the rights affected must exist under the law which creates them…".[17] International legal scholars have also recognized this principle,[18] including in the particular context of intellectual property rights.[19]

---

[14] Claimant's Reply ("Cl. Reply"), para. 163; North American Free Trade Agreement, Article 1139(g). *See also*, Opening Presentation of Canada, Slides 90 and 136.

[15] Campbell McLachlan, Laurence Shore & Matthew Weiniger, *International Investment Arbitration: Substantive Principles*, Oxford University Press 2007, para. 8.65 (**R-328**); Monique Sasson, *Substantive Law in Investment Treaty Arbitration The Unsettled Relationship Between International and Municipal Law*, Wolter Kluwers 2010, pp. 81-82 (stating that "international law classifies the property rights that are protected, while municipal law supplies the substantive aspects of these rights. The substantive aspects include the existence as well as the legality of a property right… An investor's legal entitlement is based on a 'legal' interest which must be assessed under a set of rule. International Law does not provide these rules") (**R-333**); Andrew Newcombe, *Law and Practice of Investment Treaties, Standards of Treatment*, February 2009, para. 7.19 (stating that the "rights associated with any investment are normally determined by local law. Thus, the nature and scope of property rights are determined by the law of the State in which the property is located (the *lex situs*).") (**R-334**); Sonarajah, *The International Law on Foreign Investment*, Third Edition, p. 383, FN 67 ("There is no indication of a theory of property in international law itself. International law does not create property on an individual. It relies upon municipal law for the recognition of property rights.") (**R-335**). *See also*, Opening Presentation of Canada, Slides 91-94.

[16] *Robert Azinian, Kenneth Davitian & Ellen Baca v. United Mexican States*, ICSID Case No. ARB(AF)/97/2, Award, 1 November 1999, ("*Azinian Award*") (**RL-002**).

[17] *Emmis International Holding, B.V. Emmis Radio Operationg, B.V. Mem Magyar Electronic Media Kereskedelmi Es Szolgaltato KT v. Hungary*, ICSID Case No. ARB/12/2, Award, 16 April 2014, ("*Emmis Award*"), paras. 161-162 (**RL-060**); *EnCana Corporation v. Republic of Ecuador*, (UNCITRAL), Award, 3 February 2006, para. 184 (**RL-061**). *See also, George W. Cook (USA) v. United Mexican States*, Award,

2) A Judicial Determination that Property Rights Do Not Exist at Domestic Law Is Not a Taking Absent a Denial of Justice

26. If a tribunal determines that there are property rights at domestic law, it must then address whether the challenged measures have expropriated those property rights. As is clear from the language of Article 1110, an expropriation can be either direct or indirect. A direct expropriation involves "a State sanctioned compulsory transfer of property from the foreigner to either the government or a State-mandated third party."[20] A measure that does not involve a transfer of property does not constitute a direct expropriation even if it destroys all of the value of the investment. In such circumstances, the question is solely whether the measure amount to an indirect expropriation. Determining whether a measure constitutes an indirect expropriation requires a contextual inquiry that goes beyond purely the effects of a measure and considers its character to determine whether it can amount to a taking that obligates a State to pay compensation.[21] In an indirect expropriation analysis, the Tribunal should

3 June 1927, p. 215 (*per* Commissioner Nielson holding that "it is necessary to have clearly in mind the particular law applicable to the different aspects of the case. The nature of such contractual rights or rights with respect to tangible property, real or personal, which a claimant asserts have been invaded in a given case is determined by the local law that governs the legal effects of the contract or other form of instrument creating such rights.") (**RL-062**). *See also*, Opening Presentation of Canada, Slide 95.

[18] Andrew Newcombe, *Law and Practice of Investment Treaties, Standards of Treatment*, February 2009, para. 7.19 (explaining in State the context of contractual rights that "where the investment in question is a contract governed by host law and the contract is invalid or otherwise nullified based on the host State law, in principle there can be no expropriation because there has been a judicial determination that there is no contract to expropriate.") (**R-334**).

[19] Zachary Douglas, "*The International Law of Investment Claims*", Cambridge: CUP, 2009, p. 187 (**R-336**). *See also*, Zachary Douglas, *The Foundations of International Investment Law*, Oxford University Press, 2014, p. 402 (explaining that rights over intellectual property "can only exist by reference to their proper law – the national system of law that created them. This is the exclusive object of an expropriation claim…") (**R-337**).

[20] Andrew Newcombe, *Law and Practice of Investment Treaties, Standards of Treatment*, February 2009, para. 7.3 (**R-334**).

[21] *Methanex Corporation v. United States of America*, (UNCITRAL), Final Award of the Tribunal on Jurisdiction and Merits, 3 August 2005, IV, Chap. C ("*Methanex Final Award on Jurisdiction*"), Part IV, Chapter D, p. 4, para. 7 (**RL-011**); *Technicas Medioambientales Tecmed, S.V. v. United Mexican States*, ICSID ARB(AF)/00/2, Award, 29 May 2003, paras. 115 and 122 (**RL-049**); *Marvin Feldman v. Mexico*, ICSID Case No. ARB(AF)/99/1, Award, 16 December 2002 ("*Feldman Award*"), para. 103 (**RL-058**); *Archer Daniels Award*, para. 250 (**RL-074**); *S.D. Myers, Inc. v. Government of Canada*, (UNCITRAL), Partial Award ("*S.D. Myers*, Partial Award"), paras. 281 and 285 (holding that "international law makes it appropriate for tribunals to examine the purpose and effect of government measures.") (**RL-076**); Andrew

consider: (1) the economic impact of the measure or series of measures; (2) the extent to which the measure or series of measures interferes with distinct, reasonable investment-backed expectations; and (3) the character of the measure or series of measures.[22] None of these factors, alone or in combination, is determinative. Further, non-discriminatory measures of a Party that are designed and applied to protect legitimate public welfare objectives do not constitute indirect expropriations, except where they are so severe in light of their purpose that they cannot be reasonably viewed as having been adopted and applied in good faith.[23]

Newcombe, *Law and Practice of Investment Treaties, Standards of Treatment*, February 2009, para. 7.7 (writing that "…the case-by-case, fact-based inquiry for indirect expropriation focusing on economic impact, legitimate expectations and the character of the government action is generally consistent with customary international law authorities on the scope of expropriation and the developing IIA jurisprudence on the scope of expropriation under IIAs.") (**R-334**); M. Kinnear, A. Bjorklund and J. Hannaford, *Investment Disputes under NAFTA: An Annotated Guide to NAFTA Chapter 11*, Kluwer: 2006, p. 1110, para. 17 (noting that many observers have concluded "that the best approach is a fact-based, case-by-case assessment which draws on various factors discussed above [the effect of the measure, the context of government action and the purpose of the measure, legitimate investor expectations and the intent of the host State]") (**R-343**). *See also*, Opening Presentation of Canada, Slide 107.

[22] *Free Trade Agreement between Canada and the Republic of Panama*, 14 May 2010 (entered into force 1 April 2013), Can. T.S. 2013/9, Chapter Nine, Annex 9.11(b)(i)-(iii), Available at: http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/panama/chapter-chapitre-9.aspx?lang=eng (**R-349**); *Agreement Between Canada and the Hashemite Kingdom of Jordan for the Promotion and Protection of Investments*, 28 June 2009 (entered into force 14 December 2009), Annex B.13(1)(b)(i)-(iii), Available at: http://www.treaty-accord.gc.ca/text-texte.aspx?id=105176&lang=eng (**R-350**); 2012 U.S. Model Bilateral Investment Treaty, s. 4(a)(i)-(iii), Available at: http://www.ustr.gov/sites/default/files/BIT%20text%20for%20ACIEP%20Meeting.pdf (**R-351**); *Treaty Between the Government of the United States of America and the Government of the Republic of Rwanda Concerning the Encouragement and Reciprocal Promotion of Investment*, 19 February 2008 (entered into force 1 January 2012), Annex B, s. 4(a)(i)-(iii), Available at: http://www.state.gov/documents/organization/101735.pdf (**R-352**). *See Glamis Gold, Ltd. v. United States of America*, (UNCITRAL), Counter-Memorial of the United States of America, 19 September 2006, pp. 159-160 (**RL-105**); *Methanex Corporation v. United States of America*, (UNCITRAL), Amended Statement of Defence of Respondent United States of America, 5 December 2003, para. 405, FN 636 (**RL-106**); *Grand River Enterprises v. United States of America*, (UNCITRAL), Counter-Memorial of the United States of America, 22 December 2008, p. 147 (**RL-107**); Andrea J. Menaker, *Benefiting From Experience: Developments in the United States' Most Recent Investment Agreements* (2006), 12:1 U.C. Davis J. Int'l L. Pol'y, p. 122, Available at: http://jilp.law.ucdavis.edu/issues/volume-12-1/menaker1-19.pdf (**R-353**); Andrew Newcombe, "Canada's New Model Foreign Investment Protection Agreement" (Aug. 2004), p. 6 (**R-356**). *See also*, Resp. CM., paras. 407 and 413; Resp. Rejoinder, paras. 224-226; Closing Presentation of Canada, Slide 34.

[23] *Id.*

27. If the alleged taking is a revocation or invalidation of a property right by a court adjudicating whether the property right actually exists in domestic law, it is well-accepted in international law that such a decision cannot amount to an expropriation unless it constitutes a denial of justice. The NAFTA Parties all agree that this is the proper interpretation of Article 1110.[24] Every NAFTA tribunal to consider a challenge to judicial measures has also agreed that this is the proper interpretation of Article 1110.[25] Even outside of the NAFTA context, international tribunals[26] and international law scholars[27] have also found this to be the proper interpretation of the expropriation

[24] Closing Presentation of Canada, Slides 43-45; Respondent's Observations on Issues Raised in 1128 Submissions, paras. 30-33; US 1128 Submission, para. 29 ("decisions of domestic courts, acting in the role of neutral and independent arbiters of the legal rights of litigants do not give rise to an expropriation"); Second US 1128 Submission, para. 5; Mexico 1128 Submission, para. 19, ("when legal rights are declared a nullity…a disputing investor would have to establish a claim of denial of justice under Article 1105").

[25] *Azinian Award*, para. 99 (holding "The possibility of holding a State internationally liable for judicial decisions does not, however, entitle a claimant to seek international review of the national court decisions as though the international jurisdiction seised has plenary appellate jurisdiction. This is not true generally and it is not true for NAFTA. What must be shown is that the court decision itself constitutes a violation of the treaty. Even if the Claimants were to convince this Arbitral Tribunal that the Mexican courts were wrong with respect to the invalidity of the Concession Contract, this would not per se be conclusive as to a violation of NAFTA. More is required; the Claimants must show either a denial of justice, or a pretence of form to achieve an internationally unlawful end.") (emphasis added) (**RL-002**); *The Loewen Group Inc. and Raymond Loewen v. United States of America*, ICSID ARB(AF)/98/3, Award on Merits, 26 June 2003, ("*Loewen Award*"), para. 141 (holding "a claim alleging an appropriation in violation of Article 1110 can succeed only if *Loewen* establishes a denial of justice under Article 1105.") (**RL-013**). *See also*, Opening Presentation of Canada, Slides 100-101.

[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, ("*Liman Award*"), para. 430 (holding that the "mere fact that decisions of the Kazakh courts declared that Claimants did not prevail and were not holders of rights they claimed to have, therefore, is not sufficient to find an expropriatory measure" under the Energy Charter Treaty.) (**RL-027**); *Encana Award*, para. 200, FN 138 (**R-061**); *Mr. Franck Charles Arif v. Republic of Moldova*, ICSID Case No. ARB/11/23, Award, 8 April 2013 ("*Arif Award*"), paras. 415-416 (holding that since "the agreements have been found [by domestic courts] to be invalid under Moldovan law this Tribunal is not persuaded that there can be deprivation of invalid rights. The invalidity of these agreements … resulting from the application of Moldovan law by the Moldovan courts as a result of lawsuits filed by private competitors cannot be interpreted as an expropriation of Mr. Arif's rights, as Claimant pretends.") (**RL-063**); *Affaires Du Chemin De Fer Panevezys-Saldutiskis Railway* Cases, PCIJ series A/B. No. 76 (1939), p. 18 (observing, in a dispute concerning the non-recognition of a claimed property right and contractual right that "[i]n principle, the property rights and the contractual rights of individuals depend in every State on municipal law and fall therefore more particularly within the jurisdiction of municipal tribunals.") (**RL-066**). *See also*, Opening Presentation of Canada, Slide 102.

[27] Martins Paparinskis, *The International Minimum Standard and Fair and Equitable Treatment*, (Oxford University Press, 2013, p. 208 (stating "while taking of property through the judicial process could be said to constitute expropriation, the rules and criteria to be applied for establishing the breach should come

obligation at international law. This is hardly surprising since the customary international law of expropriation has, for centuries, concerned only executive, legislative, military, and police actions.[28] When the NAFTA Parties used the term expropriation in Article 1110 of NAFTA, they certainly would not have understood it to apply to decisions by neutral and independent courts regarding property rights. That was just not how expropriation would have been understood in its ordinary meaning. Tellingly, the concept of a judicial expropriation has still not even been recognized in either domestic Canadian or U.S. law.[29]

28. Claimant resiles from this well-established principle, claiming that it need not establish a denial of justice in order to show that a court decision invalidating property rights constitutes an expropriation under Article 1110. It asserts that denial of justice is

from denial of justice") (**R-340**); *Loewen Group and Another v. United States of America*, Opinion of Christopher Greenwood Q.C, 26 March 2001, p. 10 (explaining "Although the Loewen claim also alleges an expropriation in violation of Article 1110, an award of damages, including an award of punitive damages, can amount to an expropriation only if the court proceedings are so flawed as to amount to a denial of justice. As Sir Robert [the claimant's expert witness] says, in the present case the expropriation claim "is another aspect of the denial of justice.") (**RL-025**).

[28] G.C. Christie, *What Constitutes a Taking of Property under International Law?*, 38 British Yearbook of International Law 307 (1962) (**R-463**); *See, e.g*., these seminal cases of the customary international law of expropriation: *Oscar Chinn Case (UK v. Belgium)*, Judgment, 12 December 1934, PCIJ Ser A/B, No. 63 (1934) (**R-464**); *Norwegian Shipowners' Claims (Norway v. USA)*, Permanent Court of Arbitration, Award of 13 October 1922, 1 RIAA 307 (**R-465**); *German Interests in Polish Upper Silesia (Germany v. Poland)*, Judgment, 25 May 1926, PCIJ Ser A, No. 7 (1926) (**R-466**); *Chorzow Factory Case* (Jurisdiction) (1927), Ser. A, no. 9 (**R-467**); *Barcelona Traction Light and Power Company Limited (Belgium v. Spain)*, 1970 ICJ 3 (**R-468**); *Restatement of the Law Third: The Foreign Relations of the United States*, Vol. 2 (St. Paul, MN: American Law Institute, 1987) (**R-472**). *See also*, Resp. Rejoinder, para. 214; Respondent's Observations on Issues Raised in 1128 Submissions, para. 31.

[29] Elizabeth B. Wydra, *Constitutional Problems with Judicial Takings Doctrine and the Supreme Court's Decision in Stop the Beach Renourishment* (2011) *UCLA Journal of Environmental Law and Policy* 29:109, p. 128 ("For now, at least, it seems that the theory of judicial takings will continue to be a concept that remains unrecognized as a matter of viable doctrine.") (**R-469**); Laura S. Underkuffler, *Judicial Takings: A Medley of Misconceptions*, (2011) *Syracuse Law Review*, 61:203, p. 204 ("In addressing [the question of judicial takings], the Court splintered. On the result, all eight justices agreed that the petitioners should lose.") (**R-470**); John D. Echeverria; *Stop the Beach Renourishment: Why the Judiciary is Different*, *Vermont Law Review*, Vol. 35:475, p.493 (Describing the Supreme Court's ruling as "inconclusive" and arguing that "the Court should reject the judicial takings concept, if and when it revisits the issue") (**R-341**); *Stop the Beach Renourishment, Inc. v. Florida Department of Environmental Protection et al*., 560 U.S., (2010) (**RL-046**). *See also*, Resp. CM, para. 414; Resp. Rejoinder, para. 214; Respondent's Observations on Issues Raised in 1128 Submissions, para. 31; US 1128 Submission, para 29.

only the relevant standard if the allegation is that there has been a breach of procedural fairness in judicial proceedings, or an allegation of a misapplication of national law.[30] It alleges that in order to prove that the invalidation of its patent rights amounts to a violation of Article 1110 in this case, all it must establish is that it has suffered a substantial deprivation and that there has been a violation of Chapter Seventeen of NAFTA.[31] In order to connect the legal dots between a breach of Article 1110 and a breach of Chapter Seventeen, Claimant puts forward "two alternative paths": (1) Article 1110(7); and (2) the reasoning in *Saipem*.[32]

29. There are no grounds in Article 1110, interpreted in accordance with the VCLT, that allow the legal dots to be connected in either way that Claimant suggests. Nothing in the ordinary meaning of the term "expropriation", as that term is understood at customary international law, in the subsequent practice of the NAFTA Parties, or in any subsequent agreement between them, supports Claimant's interpretation of the obligations in Article 1110. To the contrary, the NAFTA Parties have agreed in their submissions in this arbitration that inconsistency with Chapter Seventeen does not assist a claimant in proving a breach of Article 1110.[33]

30. With respect to the first proposed path from Article 1110(1) to Chapter Seventeen – through Article 1110(7) – there is nothing in the language of that provision that suggests that it can be read as expanding the competence of the Tribunal beyond that clearly stated in Articles 1116(1) and 1117(1). Nor is there any language that could

[30] Closing Statement of Claimant, June 8, 2016, pp. 2016:21 – 2017:4.

[31] Closing Statement of Claimant, June 8, 2016, pp. 2082:15 – 2083:23; Closing Statement of Claimant, June 8, 2016, pp. 2097:20 – 2098:2.

[32] Opening Statement of Claimant, May 30, pp. 106:3 – 108:22; Closing Statement of Claimant, June 8, 2016, pp. 2083:2 – 2084:14.

[33] Opening Presentation of Canada, Slides 104-106; Closing Presentation of Canada, Slide 37; US 1128 Submission, para. 33 ("Article 1110(7) therefore should not be read as an element of an investor's claim under Article 1110(1) or as a jurisdictional hook that allows a Chapter Eleven tribunal to examine whether alleged breaches of Chapter Seventeen by a NAFTA Party constitute an expropriation of intellectual property rights. Nor should Article 1110(7) be read as an invitation to review a NAFTA Party's measures, each time they arise, for consistency with Chapter Seventeen."); Mexico 1128 Submission, para. 22; Second US 1128 Submission, paras. 8-12.

reasonably be interpreted as rendering a breach of Chapter Seventeen a component of a breach of Article 1110(1).

31. Article 1110(7) provides:

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

32. By its clear terms, Article 1110(7) gives the Tribunal the competence to consider whether measures are consistent with Chapter Seventeen where a respondent raises such consistency as a defence to an allegation of a violation of Article 1110. However, the fact that consistency with Chapter Seventeen means there has been no breach of Article 1110 does not allow one to infer the inverse, that inconsistency with Chapter Seventeen means inconsistency with Article 1110. Such an interpretation is a logical fallacy.[34]

33. Claimant seems to recognize the difficulty with the interpretation it proposes, and thus admits that "there's a few other examples of breaches of Chapter Seventeen that would not probably amount to a violation of Article 1110."[35] In an attempt to make its arguments seem more reasonable, Claimant offers a "limiting principle" – that there must also be a substantial deprivation for a breach of Chapter Seventeen to amount to an expropriation.[36] However, it also argues that a revocation or invalidation of a patent always amounts to a substantial deprivation.[37] Hence, in the context of a revocation or

[34] *See also*, Resp. Rejoinder, paras. 219-221.

[35] Closing Statement of Claimant, June 8, 2016, p. 2097:13-16.

[36] Closing Statement of Claimant, June 8, 2016, p. 2097:14-22 ("MS. CHEEK: there's a few other examples of breaches of Chapter 17 that would not probably amount to a violation of Article 1110, precisely because you don't have a substantial deprivation as well. And we cited to some of those -- I believe it's paragraph 32 of our comments on the amicus and 1128 submission. So there is a limiting principle there as well in that not every breach of Chapter 17 would be sufficient…")

[37] Closing Statement of Claimant, June 8, 2016, pp. 2082:18 – 2083:1 ("MS. CHEEK: As we've explained, because this is a judicial expropriation, it's necessary, but not sufficient, that there's been a substantial deprivation. We've quickly moved beyond substantial deprivation in this case more or less

invalidation of a patent, Claimant is asserting that a breach of Chapter Seventeen is sufficient in and of itself to prove a breach of Article 1110. In short, Claimant's so called limiting principle collapses upon itself.

34. Claimant's interpretation of Article 1110(7) does violence to the structure and language of that provision. By its terms, Article 1110(7) is only a shield, safe-harbour, and defence.[38] Contrary to what Claimant argues,[39] the fact that judicial invalidations fall within the ambit of the broad term "revocation," which is used in Article 1110(7), does not signal an intention by the NAFTA Parties to displace the rule that judicial determinations regarding the existence of property rights are not capable of being expropriations in the absence of a denial of justice. As the United States noted in its Second Article 1128 submission, "the NAFTA Parties drafted the provision mindful of a situation that could arise if a party were to allege that certain measures taken by patent authorities rise to the level of an expropriation under Article 1110."[40] They were not intending to capture court decisions on patent validity.

35. In fact, the NAFTA Parties have agreed in their submissions in this arbitration that Claimant's attempt to use Article 1110(7) in the manner it proposes relies on a

because Lilly's patent rights, the bundle of exclusive rights that it was granted, have been revoked, and so we would posit that that substantial deprivation is clear.")

[38] U.S. 1128 Submission, para. 32 ("The ordinary meaning of Article 1110(7) is that it excludes the listed measures from the scope of Article 1110, establishing a "safe harbor," to the extent those measures are consistent with Chapter Seventeen. Specifically, the provision preserves the ability of the NAFTA Parties to adopt or maintain intellectual property laws, consistent with Chapter Seventeen, even where those measures might be claimed to contravene Article 1110. As some commentators have recognized, in the absence of such a provision, investors might allege that any revocation of a patent under domestic law constitutes an expropriation requiring compensation or restitution. 'The mischief that such a claim would cause domestic intellectual property regimes is evident.'"); Mexico 1128 Submission, para. 31; Respondent's Observations on Issues Raised in 1128 Submissions, paras. 34-37; *See also*, Opening Statement of Canada, May 30, 2016, pp. 301:23 – 302:1; Resp. CM, paras. 344-347; Resp. Rejoinder, paras. 219-222.

[39] Cl. Reply, paras. 254-255.

[40] Second US 1128 Submission, para. 9 (emphasis added).

significant misinterpretation of the clear meaning of the provision.[41] As the United States noted in its submissions:

> If the provision were intended to be invoked by a claimant as an element of its expropriation claim or as a basis for jurisdiction for review of the host State's conduct under Chapter 17, the NAFTA Parties would have drafted Article 1110(7) in a positive form, as an inclusion. For example, the Parties could have drafted Article 1110(7) to provide that the listed measures presumptively constitute an expropriation where taken *inconsistently* with Chapter 17. The NAFTA Parties did not draft 1110(7) as an inclusion. The NAFTA Parties expressly sought to avoid the mischief of Chapter 11 claims arising from, for example, routine patent revocations or other actions otherwise consistent with Chapter 17.[42]

36. Put simply, Article 1110(7) does not bring any of the obligations in Chapter Seventeen into the scope of Chapter Eleven. Indeed, where the NAFTA Parties wished to expand the jurisdiction of Chapter Eleven tribunals to review the NAFTA Parties' conduct for consistency with the obligations in other Chapters of NAFTA (e.g. Articles 1503(2) and 1502(3)(a)), they expressly did so in Articles 1116(1) and Articles 1117(1).[43] There is no such relationship between Chapter Seventeen and Articles 1116(1), 1117(1), or 1110(1). Accordingly, Claimant's effort to incorporate an alleged breach of Chapter Seventeen into the Tribunal's analysis of whether Canada has acted consistently with its obligations under Article 1110(1) must fail.

37. With respect to its second pathway from Article 1110(1) to Chapter Seventeen – through the reasoning in the *Saipem* decision – Claimant argues that even if Article

[41] Closing Presentation of Canada, Slides 37-38; Resp. CM, paras. 344-347; Resp. Rejoinder, paras. 219-222; Respondent's Observations on Issues Raised in 1128 Submissions, paras. 34-37; US 1128 Submission, para. 33 ("Article 1110(7) therefore should not be read as an element of an investor's claim under Article 1110(1) or as a jurisdictional hook that allows a Chapter Eleven tribunal to examine whether alleged breaches of Chapter Seventeen by a NAFTA Party constitute an expropriation of intellectual property rights. Nor should Article 1110(7) be read as an invitation to review a NAFTA Party's measures, each time they arise, for consistency with Chapter Seventeen."); Mexico Article 1128 Submission para. 22; Second US1128 Submission, paras. 8-12.

[42] Second US 1128 Submission, para. 10 (emphasis in original).

[43] *See also*, Closing Statement of Canada, June 8, 2016, pp. 2197:24 – 2198:24.

1110(7) cannot be read in the way it suggests, this Tribunal must find a violation of Article 1110 if it determines that a judicial decision results in the substantial deprivation of its property rights and that the decision in question has an internationally "unlawful character."[44] Claimant's argument fails because it misinterprets cases that have no relevance here, and suggests a principle that even Claimant realizes leads to an absurd result that does not respect the limited nature of a Chapter Eleven tribunal's jurisdiction.

38. First, the cases Claimant relies upon to support its proposed interpretation of Article 1110 do not concern Article 1110. All are interpreting language in other treaties. Moreover, all of the cases, including *Saipem*, are ones in which the courts interfered with or extinguished rights that were acknowledged to be valid at domestic law.[45] Not a single one addressed the situation where a court was determining whether or not a property right at domestic law actually existed in the first place. Moreover, all of the cases cited by Claimant involved serious procedural irregularities on the part of the domestic judiciary.[46] In essence, all of the cases could be construed to be denial of justice claims on the facts as they were found by those tribunals.

[44] Closing Statement of Claimant, June 8, 2016, p. 2083:2-10.

[45] *Saipem S.p.A v. The People's Republic of Bangladesh*, ICSID Case No. ARB/05/7, Award, 30 June 2009 ("*Saipem Award*"), paras. 128-129 and 202 (while the Bangladeshi courts declared the ICC Award "a nullity," it was not contested that the underlying contractual rights existed) (**RL-064**); *ATA Construction, Industrial and Trading Company v. The Hashemite Kingdom of Jordan*, ICSID Case No. ARB/08/02, Award, para. 126 (the tribunal found a treaty breach on the basis of a court decision triggering retroactive application of new legislation that "extinguished a valid right to arbitration".) (**RL-068**); *Oil Field of Texas, Inc. v. Iran*, 12 Iran-U.S. C.T.R. 308, 318 (1986) ("*Oil Field of Texas*"), paras. 41 and 43 ("NIOC has retained possession of the three existing blowout preventers leased pursuant to the Lease Agreement despite the fact that the Claimant demanded their return if rent was not paid on them … NIOC confirmed that this Court order prevented NIOC not only from making payments, but also from returning the equipment to Oil Field … The interference with the use of the three blowout preventers as caused by the Ahwaz Court order amounts to a taking of this equipment.") (emphasis in original removed) (**CL-59**); *Sistem Muhendislik Insaat Sanayi Ve Ticaret A.S. v. Kyrgyz Republic*, ICSID Case No. ARB(AF)/06/1, Award, 9 September 2009 ("*Sistem Award*"), paras. 69-73 (there was no dispute as to actual title and ownership of the hotel in question – it had even been confirmed in an agreement between the respondent Kyrgyz Republic and the claimant's home State Turkey.) (**CL-146**).

[46] *Saipem Award*, para. 121 (noting that the claimant Saipem argued that it did "consider that the misconduct of the domestic courts did also amount to a denial of justice") and para. 155 (finding that the conduct of the Bangladeshi courts amounted to an abuse of right and that the decision "can only be viewed as a grossly unfair ruling" that "lacks any justification") (**RL-064**); *Oil Field of Texas*, para. 43 (expressly noting "the Claimant's impossibility to challenge the Court order in Iran") (**CL-59**); *Sistem Award*, paras.

39. Second, the interpretation of Article 1110 that Claimant alleges these decisions support is untenable as a matter of law. Such an approach would turn NAFTA Chapter Eleven tribunals into courts of general international jurisdiction able to sit in judgment of the compliance of the NAFTA Parties with any and all of their international obligations. This is absurd.[47] Claimant recognizes this, and once again manufactures several untenable and unsupported limiting principles. First, it says that the violation that gives the judicial act its unlawful character must be of some other "substantive rule of international law."[48] It uses this invented limiting principle to say that this is why it is no longer claiming that a breach of the Patent Cooperation Treaty ("PCT") leads to a violation of Article 1110(1). The PCT, it says, is a treaty that creates only procedural obligations, and thus cannot perform the required function in Claimant's proposed approach.[49] However, Claimant offers no explanation as to why it matters, for the purposes of its proposed interpretation of Article 1110(1), that the obligations in the PCT are procedural rather than substantive. Nor does it offer any explanation as to why it believes that the obligations in Chapter Seventeen are of a different character than those found in the PCT. Its proposed limiting principle is transparently self-serving.

97 and 128 (involving a loss of control of its property following an armed seizure of the hotel in which it was alleged that the State had colluded.) (**CL-146**); Compare *GEA Group Aktiengesellschaft v. Ukraine*, ICSID Case No. ARB/08/16, Award, 31 March 2011 ("*GEA Award")*, para. 236 ("[T]he Claimant has provided the Tribuanl with no reason to believe that the courts of Ukraine were 'applying a discriminatory law,'only that the Ukraine courts came to a conclusion different to what GEA had hoped. Moreover, contrary to Saipem, the Tribunal has been presented with no evidence that the actions taken by the Ukrainian court were 'egregious' in any way.") (**RL-026**).

[47] Mexico 1128 Submission, paras, 21-30; U.S. 1128 Submission, para. 23. *See also*, Resp. CM, paras. 331-334; Resp. Rejoinder, paras. 215-218; Respondent's Observations on Issues Raised in 1128 Submissions, para. 15-17.

[48] Closing Statement of Claimant, June 8, 2016, p. 2083:2-10.

[49] Closing Statement of Claimant, June 8, 2016, pp. 2079:15 – 2081:20 ("MS. CHEEK: …it is our view that the underlying violation which the Tribunal needs to address its attention is a violation of a substantive rule of international law…The PCT, it's common ground, is a procedural treaty and does not get to substantive rules of international law. That's a limiting principle here, and so while Mr. Erstling is of the firmly held view that Canada is in violation of its PCT commitments, Lilly does not rest its allegations of a breach of Article 1110 on a violation of the PCT in that it's agreed that that is a procedural treaty that does not embody substantive rules – substantive rules of -- and international obligations as between the parties."); Closing Statement of Claimant, June 8, 2016, pp. 2083:2 – 2084:14 ("MS. CHEEK: And as I said, consistent with that view that the focus is on a violation of substantive obligations, the PCT, as a procedural treaty, is out of bounds.")

40. Further, Claimant recognizes that its position, even with its first limiting principle in place, still leads to the absurd result that it would open up to Chapter Eleven arbitration the universe of international legal obligations. As a result, Claimant suggests a second limiting principle. It states that there must be some sort of "nexus" or direct relationship between the challenged measure and the international obligation outside of Chapter Eleven.[50] However, not only does Claimant provide no suggestion as to what sort of nexus is required, or how close the relationship must be, it is clear that its nexus argument is not actually a limiting principle at all. While such a rule might potentially limit what any particular NAFTA tribunal can consider in the context of a particular dispute, it does not operate as an overall limitation on Claimant's expansion of the competence of NAFTA Chapter Eleven tribunals. Which international obligations have a nexus or direct relationship with a challenged measure will vary from case to case. Thus, even with this proposed limiting principle, NAFTA tribunals would have potentially unlimited jurisdiction to consider any breach of any international law obligation of the NAFTA Partys – in essence, the limits of their competence to consider a NAFTA Party's international obligations would depend not on the text the NAFTA Parties agreed to, but on the facts of a particular dispute. That cannot be right.

[50] Opening Statement of Claimant, May 30, 2016, pp. 106:16 – 108:15 ("MS. CHEEK: …We think those are two alternative paths that the Tribunal could follow, that you could follow the logic in the Saipem case, whereas you could find that there is an independent breach of international law where the government measures at hand are directly related to that international breach and there's a nexus, just like there was in Saipem there's a nexus here, so you can follow the independent logic that that Tribunal did." Secondly, there is an alternative avenue to take, and that is through specifically the provision of 1110(7), which I'll also come to address in a moment. THE PRESIDENT: Thank you. MS. CHEEK: I guess the one thing I would say in follow-up, Mr. President, is that we don't think it's strictly necessary, as in Saipem, that the Treaty rule be found in the same arbitration agreement. It happens to be found in the same arbitration agreement in our case. It's chapter 17 of the NAFTA free trade agreement. But we would argue that there is some limit. Like I said, the rule needs to apply to the government measures at issue and there needs to be some nexus. For us perhaps it's simpler than in the Saipem case because chapter 17 is part of the North American Free Trade Agreement, and those intellectual property rights provisions apply to Canada and Canada has not objected to that notion, so I think it's common ground that Canada has obligations…THE PRESIDENT: Maybe you will address it later. If you take that route and you take the Saipem route, as argued by the Claimant in this case, would you not import an entire universe of international law into potential violations leading to an expropriation? MS. CHEEK: No, I don't think that that's the case. I think that there are limiting principles. For example, in Saipem, in ATA v Jordan, they look to the New York Convention. The issue was an underlying arbitration award, and there was relevance between the two in that the international treaty at issue, the New York Convention, specifically applied to the ICC Award the investment that was the subject matter of this dispute. So here you would have a similar nexus.")

41. All of the NAFTA Parties agree that such an expansion of the competence of Chapter Eleven tribunals flies in the face of the clear language of NAFTA Articles 1116(1) and 1117(1).[51] The Tribunal should definitively reject Claimant's argument that it is entitled to find a breach of Article 1110 on the basis of a breach of some other obligation of international law. Instead, it should agree with the NAFTA Parties as to the meaning of the treaty they negotiated, signed, and are implementing: absent a denial of justice, a judicial measure determining that property does not exist at domestic law is not an expropriation subject to Article 1110.

3) The Revocation of an Intellectual Property Right That Is Consistent With Chapter Seventeen Is Not Subject To Article 1110

42. Regardless of whether the Tribunal agrees with Canada or Claimant as to when a court decision regarding the existence of property at domestic law can amount to a violation NAFTA Article 1110(1), as seen above, Article 1110(7) clarifies that an expropriation claim cannot be brought for the revocation of intellectual property rights if such revocation is consistent with Chapter Seventeen. Article 1110(7) is an additional safeguard or shield that the NAFTA Parties put in place to guard against the potential for abusive expropriation claims in the context of intellectual property.[52] In short, consistency with Chapter Seventeen of NAFTA is a complete defence to any assertion of a violation of Article 1110.

[51] Resp. CM, para. 210; US 1128 Submission, para. 36, FN 64 ("Chapter Eleven tribunals have jurisdiction only to assess claims of a breach of a NAFTA Party's obligations under Chapter 11 Section A (or Article 1503(2), or 1502(3)(a) where a monopoly has acted in a manner inconsistent with a Party's obligations under Section A). *See* NAFTA, Articles. 1116(1) and 1117(1)"); Mexico 1128 Submission, para. 23; Second US 1128 Submission, para. 8.

[52] M. Kinnear, A. Bjorklund and J. Hannaford, *Investment Disputes under NAFTA: An Annotated Guide to NAFTA Chapter 11* (Kluwer: 2006), pp. 1110-57 ("Absent a provision such as Article 1110(7) one can imagine an investor claiming that the issuance of a compulsory license or the revocation, limitation or creation of intellectual property rights effectively expropriated its investment, resulting in an obligation on the host government to compensate for the loss caused by its measures or to provide restitution of the intellectual property rights. The mischief that such a claim would cause domestic intellectual property regimes is evident. Presumably, the drafters of NAFTA included Article 1110(7) to avoid any such argument.") (**R-343**); US 1128 Submission, para. 33; Mexico 1128 Submission, para. 22; Respondent's Observations on Issues Raised in 1128 Submissions, paras. 34-37. *See also*, Opening Statement of Canada, May 30, 2016, p. 236:16-22; Closing Presentation of Canada, Slides 37-38; Resp. CM, para. 345.

B. The Application of Article 1105 (Minimum Standard of Treatment) With Respect to Judicial Measures

43. NAFTA Article 1105(1) states:

> Article 1105: Minimum Standard of Treatment
>
> (1) Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security.

44. The proper interpretation of Article 1105(1) was confirmed by the NAFTA Free Trade Commission ("FTC") in its binding Note of Interpretation of July 31, 2001 ("FTC Note"). The FTC Note states:

> 1. Article 1105(1) prescribes the customary international law minimum standard of treatment of aliens as the minimum standard of treatment to be afforded to investments of investors of another Party.
>
> 2. The concepts of "fair and equitable treatment" and "full protection and security" do not require treatment in addition to or beyond that which is required by the customary international law minimum standard of treatment of aliens.
>
> 3. 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).[53]

45. The FTC Note represents the definitive meaning to be given to Article 1105(1) and is binding on all arbitration tribunals constituted under NAFTA Chapter Eleven.[54] As the tribunal in *ADF v. United States* observed, "[n]o more authentic and authoritative source of instruction on what the Parties intended to convey in a particular provision of NAFTA is possible."[55] Since the FTC Note, NAFTA tribunals have consistently

[53] NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter Eleven Provisions, 31 July 2001, s. 2 (**RL-009**); Opening Presentation of Canada, Slide 63; Closing Presentation of Canada, Slide 21.

[54] NAFTA, Article 1131(2) states ("[a]n interpretation by the Commission of a provision of this Agreement shall be binding on a Tribunal established under this Section.")

[55] *ADF Group Inc. v. United States of America*, ICSID Case No. ARB(AF)/00/1, Award, 9 January 2003, ("*ADF Award*"), para. 177 (**RL-005**).

recognized its binding effect.[56] Claimant acknowledges that the FTC Note is binding on this Tribunal.[57]

1) The Customary International Law Minimum Standard of Treatment of Aliens Is the Only Source of Obligations in Article 1105

46. The FTC Note makes clear that the only source of obligations in Article 1105(1) is the customary international law minimum standard of treatment of aliens. Pursuant to Article 38(1)(b) of the Statute of the International Court of Justice, customary international law has two constitutive elements: (1) extensive, uniform and consistent general practice by States; and (2) belief that such practice is required by law (*opinio juris*).[58] NAFTA tribunals have long recognized this double requirement to identifying whether a rule of customary international law exists.[59]

[56] *International Thunderbird Gaming Corporation v. United Mexican States*, (UNCITRAL), Arbitral Award, 26 January 2006 ("*Thunderbird Award*"), paras. 192-193 (**RL-003**); *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Final Award, 11 October 2002 ("*Mondev Award*"), paras. 100, 120-5 and ff. (**RL-004**); *ADF Award*, paras. 175-178 (**RL-005**); *Glamis Award*, para. 599 (**RL-006**); *Mobil Investments Canada Inc. and Murphy Oil Corporation v. Government of Canada*, ICSID Case No. ARB(AF)/07/4, Decision on Liability and on Principles of Quantum, 22 May 2012 ("*Mobil Decision on Liability*"), para. 135 (**RL-007**); *Methanex Final Award on Jurisdiction*, p. 9, para. 21 (**RL-011**); *Loewen Award*, para. 126 (**RL-013**); *Waste Management, Inc. v. United Mexican States*, ICSID ARB(AF)/00/3, Award, 30 April 2004 ("*Waste Management II Award*"), paras. 90-91 (**RL-014**); C*argill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, 18 September 2009 ("*Cargill Award*"), paras. 267-268 (**RL-015**). *See also*, *Apotex Holdings Inc., Apotex Inc. v. United States of America*, ICSID Case No. ARB(AF)/12/1, Award, 25 August 2014, ("*Apotex Award*"), Part IX, p. 1, para. 9.4 (**RL-016**).

[57] Cl. Mem., para. 253, FN 453.

[58] United Nations, *Statute of the International Court of Justice*, 18 April 1946, Article. 38(1)(b) (providing that in making decisions in accordance with international law, the Court shall apply, *inter alia*, "international custom, as evidence of a general practice accepted as law.") (**RL-034**); *North Sea Continental Shelf Cases (Federal Republic of Germany v. Denmark; Federal Republic of Germany v. The Netherlands)*, Judgment [1969] ICJ, p. 43 (it is an "indispensable requirement" to show that "State practice, including that of States whose interests are specially affected, should have been both extensive and virtually uniform in the sense of the provision invoked; -- and should moreover have occurred in such a way as to show a general recognition that a rule of law or legal obligation is involved") (**RL-035**); *Case Concerning the Continental Shelf*, (*Libyan Arab Jamahiriyah v. Malta*) [1985] ICJ Rep., p. 29, para. 27 ("it is of course axiomatic that the material of customary international law is to be looked for primarily in the actual practice and *opinio juris* of states…") (**RL-036**); *Case of Nicaragua v. United States* (Merits), ICJ Rep. 14 (1986), p. 108, para. 207 ("For a new customary rule to be formed, not only must the acts concerned "amount to settled practice," but they must be accompanied by the *opinio juris sive necessitates*. Either the States taking such action or the other States in a position to react to it, must have

47. The threshold to establish a breach of Article 1105 is high.[60] Generally, to reach that threshold it is necessary to establish that "an investor has been treated in such an unjust or arbitrary manner that the treatment rises to the level that is unacceptable from the international perspective."[61] Such a determination must be made in the light of the high measure of deference that international law generally extends to the right of domestic authorities to regulate matters within their own borders.[62] In short, egregious

behaved so that their conduct "is evidence of a belief that this practice is rendered obligatory by the existence of a rule of law requiring it.") (**RL-037**). *See also*, Closing Presentation of Canada, Slide 22.

[59] *Glamis Award*, para. 602 (**RL-006**); *Cargill Award*, para. 274 (**RL-015**); *United Parcel Service of America Inc. v. Canada*, (UNCITRAL), Award on Jurisdiction, 22 November 2002 ("*UPS Jurisdiction Award*"), para. 84 (**RL-038**). *See also*, Closing Presentation of Canada, Slide 23.

[60] *Glamis Award*, para. 627 ("[A] violation of the customary international law minimum standard of treatment, as codified in Article 1105 of the NAFTA, requires an act that is sufficiently egregious and shocking – a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons – so as to fall below accepted international standards and constitute a breach of Article 1105.") (**RL-006**); *Waste Management II Award*, para. 98 (for there to be a breach of Article 1105, the impugned conduct must have been "arbitrary, grossly unfair, unjust or idiosyncratic" or "involve[d] 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[…]") (**RL-014**); *Cargill Award*, para. 296 ("To determine whether an action fails to meet the requirement of fair and equitable treatment, a tribunal must carefully examine whether the complained-of measures were grossly unfair, unjust or idiosyncratic; arbitrary beyond merely inconsistent or questionable application of administrative or legal policy or procedure so as to constitute an unexpected or shocking repudiation of a policy's very purpose and goals, or to otherwise grossly subvert a domestic law or policy for an ulterior motive; or involve an utter lack of due process so as to offend judicial propriety.") (**RL-015**). *See also*, Closing Presentation of Canada, Slide 66.

[61] *S.D. Myers* Partial Award, paras. 261 and 263 (**RL-076**).

[62] *Id*; *Mondev Award*, para. 127 (**RL-004**); *ADF Award*, para. 184 (**RL-005**); *Mobil Decision on Liability*, paras. 138-153 and *see* paras. 152-153 (**RL-007**); *Loewen Award*, paras. 132-134 (**RL-013**); *Waste Management II Award*, para. 98 ("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.") (**RL-014**). *See also*, *Apotex Award*, para. 9.47 (endorsing the statement that "a high threshold of severity and gravity is required in order to conclude that the host state has breached any of the elements contained within the FET standard under Article 1105." *citing* Patrick Dumberry, "The Fair and Equitable Treatment Standard", Netherlands: Kluwer Law, 2013, p. 262. (R-320)) (**RL-016**); *See S.D. Myers* Partial Award, para. 263 (Article 1105 only protects against treatment that is "arbitrary, grossly unfair, unjust or idiosyncratic, or is discriminatory and exposes a claimant to section or racial prejudice, or involves a lack of due process leading to an outcome that offends judicial propriety […] those standards are set, as we

conduct will be required to breach Article 1105. However, to be clear, merely establishing egregiousness does not establish a violation of a substantive obligation contained in Article 1105. To understand the content of Article 1105, it is necessary to determine the rules of customary international law that are part of the minimum standard of treatment of aliens.[63]

48. Article 1105 does not invite an assessment of what the Tribunal simply feels might be fair or equitable.[64] The FTC Note makes clear that the NAFTA Parties rejected an ordinary meaning interpretation of the terms "fair and equitable" and the subjective determination of fairness it would entail.[65] Instead, they made clear that the requirement of "fair and equitable treatment" does not require anything more than treatment in accordance with customary international law.[66]

49. Article 1105 also does not invite the Tribunal to question the policy decisions made by the government. As the tribunal in *Mesa Power Group, LLC v. Canada* explained, "it is not for this Tribunal to second-guess a government's policy choices, or to ascertain whether the policy goals of the government would have been better served by resorting to other means."[67]

---

have noted above, at a level which protects against egregious behavior.") (**RL-076**). *See also*, Opening Presentation of Canada, Slides 76 and 86; Closing Presentation of Canada, Slide 27.

[63] *Mesa Power Group LLC v. Government of Canada*, Submission of the United States of America, 25 July 2014, paras. 5-6 (**RL-051**). US 1128 Submission, para. 6; US Second 1128 Submission, para. 4; Resp. Rejoinder, paras. 266-267. *See also*, Opening Statement of Canada, May 30, 2016, pp. 211:14 – 212:15; Closing Statement of Canada, June 8, 2016, pp. 2178:19 – 2179:14.

[64] *See also*, Closing Statement of Canada, June 8, 2016, pp. 2179:15 – 2180:1.

[65] NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter Eleven Provisions, 31 July 2001, para. 2 (**RL-009**). *See also*, Opening Presentation of Canada, Slide 63; Closing Presentation of Canada, Slide 21.

[66] NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter Eleven Provisions, 31 July 2001, para. 2 (**RL-009**). *See also*, Opening Presentation of Canada, Slide 63; Closing Presentation of Canada, Slide 21.

[67] *Mesa Power Group, LLC v. Canada*, (NAFTA/UNCITRAL), (PCA Case No. 2012-17), Award, March 24, 2016 ("*Mesa Award*"), para. 632 (**RL-159**). *S.D. Myers*, Partial Award, paras. 261-263 (**RL-076**); *See also*, Opening Presentation of Canada, Slide 135; Closing Presentation of Canada, Slide 24; Closing Statement of Canada, June 8, 2016, p. 2180:2-8; Resp. Rejoinder, para. 267.

50. As made clear by paragraph three of the FTC Note, Article 1105 also does not allow a tribunal to find a breach of Article 1105 based on the breach of another provision of NAFTA.[68] Thus, establishing that a NAFTA Party is in breach of an obligation in Chapter Seventeen does not establish a breach of Article 1105.[69] The only source of obligations in Article 1105 is the customary international law minimum standard of treatment of aliens. In order for a breach of an obligation in Chapter Seventeen to also breach Article 1105, the obligation in question must form part of the customary international law minimum standard of treatment of aliens.[70] Claimant did not, and could not, allege that any of the obligations in Chapter Seventeen are also part of the customary international law minimum standard of treatment. Indeed, customary international law does not require a State to provide patent protection for inventions. This is a choice that States make for themselves, in the same way that they choose their substantive conditions of patentability.[71] As a result, a breach of Chapter Seventeen is not relevant to whether there has been a breach of Article 1105.

51. Article 1105 also does not allow the Tribunal to find a breach based on the standards contained in other treaties. In particular, the NAFTA Parties have agreed that autonomous fair and equitable treatment provisions in other treaties do not form a rule of customary international law relevant to the interpretation of Article 1105.[72] As noted by

[68] NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter Eleven Provisions, 31 July 2001, para. 2 (**RL-009**). *See also*, Opening Presentation of Canada, Slide 63; Closing Presentation of Canada, Slide 21.

[69] *Mobil Decision on Liability* (**RL-007**). The Tribunal unanimously rejected the claim that Canada had acted in violation of Article 1105(1) even though it determined that the measure in question was inconsistent with Article 1106(1)(c) (Performance Requirements) and, by majority, decided that the measure was not covered by Canada's NAFTA Annex I reservation. Resp. CM, paras. 228-229; Resp. Rejoinder, para. 262; US 1128 Submission, para. 19; US Second 1128, para 6.

[70] *See also*, Closing Statement of Canada, June 8, 2016, pp. 2180:11-2181:4 and 2199:24 – 2202:24.

[71] Gervais Second Report, paras. 11 and 12-17.

[72] *Mercer International Inc. v. Government of Canada*, ICSID Case No. ARB(AF)/12/(3), Submission of Mexico Pursuant [to] Article 1128 of NAFTA, 8 May 2015 ("*Mercer Submission of Mexico*"), paras. 18-19 (**RL-089**); *Mercer International Inc. v. Government of Canada*, ICSID Case No. ARB(AF)/12/(3), Submission of the United States of America, 8 May 2015 ("*Mercer Submission of United States*"), paras. 19-20 (**RL-097**); *The Loewen Group, Inc. and Raymond L. Loewen v. United States of America*, ICSID ARB(AF)/98/3, Second Submission of the Government of Canada Pursuant to NAFTA Article 1128, 27 June 2002, paras. 18 and 26 (**RL-110**); *The Loewen Group, Inc. and Raymond L. Loewen v. United States*

the Special Rapporteur to the International Law Commission, "when a State says that something is not a rule of customary international law, that is evidence of the absence of an *opinio juris*."[73] NAFTA tribunals have also recognized that standards found in other treaties are not necessarily relevant to interpreting NAFTA.[74] The reason is simple – the content of an investment treaty negotiated between States is a matter of policy, not necessarily a reflection of rules of customary international law. It is true that at international law, treaties may contribute to the crystallization or development of a rule of customary international law, but not all treaties do so, and there should be no presumption that they do. As the International Court of Justice noted in *Diallo*, the fact that certain provisions are often included in investment treaties "is not sufficient" to

of America, ICSID ARB(AF)/98/3, Response of the United States of America to the June 27 and July 2, 2002 Submissions of the Governments of Canada and Mexico Pursuant to NAFTA Article 1128, 19 July 2002, pp. 3-6 (**RL-111**); *The Loewen Group, Inc. and Raymond L. Loewen v. United States of America*, ICSID ARB(AF)/98/3, Third Article 1128 Submission of the United Mexican States, 2 July 2002 ("*Loewen Group Third Article 1128 Submission of Mexico*"), paras. 32-40 (**RL-112**); *Bilcon of Delaware Inc. v. Government of Canada*, (PCA/UNCITRAL), Canada's Counter-Memorial, 9 December 2011 ("*Bilcon Canada's Counter-Memorial*"), paras. 313-318 (**RL-113**); *Windstream Energy LLC v. Government of Canada*, (UNCITRAL), Counter-Memorial of Canada, 20 January 2015 ("*Windstream Counter-Memorial of Canada*") paras. 372-379 (**RL-114**). Closing Statement of Canada, June 8, 2016, pp. 2181:5 – 2183:7; Resp. CM, paras. 228-229; Resp. Rejoinder, paras. 258-259; U.S. 1128 Submission, paras. 15, 19; U.S. Second 1128 Submission, para. 4; Mexico 1128 Submission, para 14; Respondent's Observations on Issues Raised in 1128 Submissions, para. 25.

[73] Michael Wood, *Second report on identification of customary international law*, para. 75 (stating that "Such assertions by States of rights or obligations under (customary) international law (or lack thereof) could, *inter alia*, take the form of … claims and legal briefs before court and tribunals …") (**R-449**).

[74] *Mondev Award*, para. 121 (noting "Article 1105(1) refers to a standard existing under customary international law, and not to standards established by other treaties of the three NAFTA Parties….Chapter 11 arbitration does not even extend to claims concerning all breaches of NAFTA itself, being limited to breaches of Section A of Chapter 11 and Articles 1503(2) and 1502(3)(a). If there had been an intention to incorporate by reference extraneous treaty standards in Article 1105 and make Chapter 11 arbitration applicable to them, some clear indication of this would have been expected) (**RL-004**); *Glamis Award*, para. 602 (**RL-006**); *Cargill Award*, para. 274 (**RL-015**).

show customary international law exists on a point.[75] In the words of the court, "it could equally show the contrary."[76]

52. Finally, Article 1105 does not allow the Tribunal to find a breach based solely on the principles enunciated in other arbitral awards. Arbitral decisions do not create customary international law.[77] They do not constitute sufficient evidence of State practice[78] and *opinio juris*.[79] All three NAFTA Parties agree on this fact.[80] NAFTA

[75] *Case Concerning Ahmadou Sadio Diallo* (*Republic of Guinea v. Democratic Republic of The Congo*), Judgment on Preliminary Objections, ICJ, 24 May 2007, para. 90 (**RL-041**). *See also*, Closing Presentation of Canada, Slide 26.

[76] *Case Concerning Ahmadou Sadio Diallo* (*Republic of Guinea v. Democratic Republic of The Congo*), Judgment on Preliminary Objections, ICJ, 24 May 2007, para. 90 (**RL-041**). *See also*, Closing Presentation of Canada, Slide 26.

[77] *See also*, Sir Hersch Lauterpacht, *The Development of International Law by the International Court*, (London: Stevens, 1958), pp. 20-21 ("[d]ecisions of international courts are not a source of international law… [t]hey are not direct evidence of the practice of States or of what States conceive to be the law.") (**R-331**); Mohamed Shahabuddeen, *Precedent in the World Court* (Cambridge University Press, 1996), pp. 71-72 ("The development of customary international law depends on State practice. It is difficult to regard a decision of the Court as being in itself an expression of State practice….A decision made by it is an expression not of the practice of the litigating States, but of the judicial view taken of the relations between them on the basis of legal principles which must necessarily exclude any customary law which has not yet crystallised. The decision may recognise the existence of a new customary law and in that limited sense it may no doubt be regarded as the final stage of development, but, by itself, it cannot create one. It lacks the element of repetitiveness so prominent a feature of the evolution of customary international law.") (**R-332**); *See Case Concerning Ahmadou Sadio Diallo* (*Republic of Guinea v. Democratic Republic of The Congo*), Judgment on Preliminary Objections, ICJ, 24 May 2007, paras. 88-91 (holding that reliance on investor-State arbitration awards and foreign investment protection agreements could not substitute for evidence of State practice and *opinio juris* to show a change in the customary international law rules governing diplomatic protection.) (**RL-041**). *See also*, Closing Presentation of Canada, Slide 26.

[78] *See* Michael Wood, *Second report on identification of customary international law*, paras. 40-42 (identifying a non-exhaustive list of examples of what constitutes State practice, such as acts of the executive branch, including "positions expressed by States before national or international courts and tribunals (including in *amicus curiae* briefs of States") (**R-449**).

[79] *See* Michael Wood, "Second report on identification of customary international law", paras. 60-69 (**R-449**).

[80] *Mercer Submission of Mexico*, paras. 18-19 (**RL-089**); *Mercer Submission of* United States, paras. 19-20 (**RL-097**); *Loewen Group Third Article 1128 Submission of Mexico*, paras. 32-40 (**RL-112**); *Bilcon Canada's Counter-Memorial*, paras. 313-318 (**RL-113**); *Windstream Counter-Memorial of Canada*, paras. 372-379 (**RL-114**). *See also*, Resp. Rejoinder, paras. 257-259, U.S. 1128 Submission, para. 15; Mexico 1128 Submission, para. 14; Respondent's Observations on Issues Raised in 1128 Submissions, para. 24.

tribunals have also agreed.[81] To hold otherwise would fundamentally confuse Articles 38(1)(b) and 38(1)(d) of the Statute of the International Court of Justice. Of course, arbitral awards may contain valuable analysis of State practice and *opinio juris* in relation to a particular rule of custom, and can be informative to the extent they do.[82] However, to the extent that they do not contain such an analysis, they offer no assistance in understanding the content of the customary international law minimum standard of treatment. It is for this reason that NAFTA tribunals have consistently warned that awards interpreting autonomous fair and equitable treatment clauses are not relevant in the context of interpreting NAFTA Article 1105(1).[83]

53. In short, neither the fact that States choose to include the autonomous fair and equitable treatment standard in their treaties, nor the arbitral decisions interpreting such clauses, are relevant for understanding the content of the customary international law minimum standard of treatment of aliens. There is no evidence to support Claimant's allegation that the FTC Note has become superfluous because the minimum standard of treatment has converged with the autonomous fair and equitable treatment standard. This

[81] *Glamis Award*, para. 611 (holding arbitral awards under treaties with autonomous FET standards provide no guidance in determining the content of the minimum standard of treatment at customary international law.) (**RL-006**); *Cargill Award* para. 276 (holding "significant evidentiary weight should not be afforded to autonomous clauses inasmuch as it could be assumed that such clauses were adopted precisely because they set a standard other than that required by custom.") (**RL-015**). *See also*, Closing Presentation of Canada, Slides 27 and 28.

[82] *Cargill Award*, para. 277 (The tribunal cautioned that "the evidentiary weight to be afforded [arbitral awards] … is greater if the conclusions therein are supported by evidence and analysis of custom.") (**RL-015**); *Glamis Award*, para. 611 (The tribunal affirmed the same: "The Tribunal therefore holds that it may look solely to arbitral awards – including BIT awards – that seek to be understood by reference to the customary international law minimum standard of treatment, as opposed to any autonomous standard") (**RL-006**).

[83] *Cargill Award*, paras. 276-278 (stating that "significant evidentiary weight should not be afforded to autonomous clauses inasmuch as it could be assumed that such clauses were adopted precisely because they set a standard other than that required by custom.") (**RL-015**). *See also*, Dolzer and Schreuer, *Principles of International Investment Law*, Oxford: Oxford University Press, 2008, pp. 16 and 126 (holding that "In contrast to the NAFTA practice, arbitral awards applying treaties that do not contain statements about the relationship of FET to customary international law have interpreted the relevant provisions in BITs autonomously on the basis of their respective wording.") (**R-327**). *See also*, Closing Presentation of Canada, Slide 27.

exact proposition has been consistently raised by claimants in NAFTA arbitrations and it has not been accepted.[84]

2) The Content of the Customary International Law Minimum Standard of Treatment of Aliens Is More Limited Than Claimant Alleges

54. The NAFTA Parties accept that the customary international law minimum standard of treatment of aliens protects against denial of justice, and obligates the NAFTA Parties to ensure the physical protection and security of investors and investments from other NAFTA Parties.[85] However, Claimant does not base its allegation of a breach of Article 1105 on these grounds. Rather, it argues that there has been a breach of Article 1105 because Canada's alleged promise utility doctrine discriminates against pharmaceutical companies, is arbitrary, and is contrary to its legitimate expectations.

55. Canada does not disagree with Claimant's submission that the content of the international minimum standard may evolve over time with the development of customary international law.[86] However, to the extent that Claimant asks the Tribunal recognize other forms of conduct prohibited by the customary international law

[84] *See e.g. Glamis Award*, para. 609 ("Claimant has agreed with this distinction between customary international law and autonomous treaty standards but argues that, with respect to this particular standard, BIT jurisprudence has 'converged with customary international law in this area.' The Tribunal finds this to be an over-statement.") (**RL-006**); *Cargill Award*, paras. 241 and 276 ("the Tribunal does not find it prudent to accord significant weight to even widespread adoption of such [fair and equitable treatment] clauses.") (**RL-015**); *Mesa Award*, paras. 484 and 503 ("There is thus no scope for autonomous standards to impose additional requirements on the NAFTA Parties.") (**RL-159**).

[85] Resp. CM, para. 230; Resp. Rejoinder, para. 256; Respondent's Observations on Issues Raised in 1128 Submissions, para. 19; US 1128 Submission, para. 6; Mexico 1128 Submission, para.10.

[86] *ADF Group Inc. v. United States*, Second Submission of Canada Pursuant to NAFTA Article 1128, ICSID ARB(AF)/00/1, 19 July 2002, para. 33 ("Canada's position has never been that the customary international law regarding the treatment of aliens was "frozen in amber" at the time of the *Neer* decision. Obviously, what is shocking or egregious in the year 2002 may differ from that which was considered shocking or egregious in 1926. Canada's position has always been that customary international law can evolve over time, but that the threshold for finding violation of minimum standard of treatment is still high.") (**RL-077**); Resp. CM, para. 288.

minimum standard of treatment of aliens, it bears the burden of establishing that the relevant rules exist.[87] It has not met its burden.

56. First, its allegation that discrimination against the pharmaceutical sector in patent laws violates Article 1105 is legally baseless. As an initial matter, customary international law does not prohibit States from differentiating their treatment of nationals and aliens,[88] at least outside of the context of court proceedings.[89] It is for this reason that NAFTA contains protections against nationality-based discrimination in Articles 1102 and 1103 – neither of which Claimant alleges were breached here. In this light, to suggest that there is a rule of customary international law that protects against

[87] Nguyen, Quoc Dinh, Dallier & Pellet, *Droit International Public*, 6th ed., (LGDJ 1999), p. 330 (writing that the burden is on the party "who relies on a custom to establish its existence and exact content.") ("c'est à [la partie] qui s'appuie sur une coutume d'en établir l'existence et la portée exacte.") (**R-329**); Ian Brownlie, *Principles of Public International Law*, Seventh Edition, 2008, p. 12 ("In practice, the proponent of a custom has the burden of proof the nature of which will vary according to the subject-matter and the form of the pleadings.") (**R-330**); *ADF Award*, paras. 183-184 ("We are not convinced that the Investor has shown the existence, in current customary international law, of a general and autonomous requirement (autonomous, that is, from specific rules addressing particular, limited, contexts) to accord fair and equitable treatment and full protection and security to foreign investments" (emphasis added)) (**RL-005**); *Glamis Award*, paras. 601-603 ("If, as Claimant argues, the customary international law minimum standard of treatment has indeed moved to require something less than the "egregious," "outrageous," or "shocking" standard as elucidated by *Neer*, then the burden of establishing what the standard now requires is upon Claimant […] it is necessarily the Claimant's place to establish a change in custom") (**RL-006**); *Mobil Decision on Liability* (**RL-007**); *Cargill Award*, paras. 271-273 ("The burden of establishing any new elements of this custom is on Claimant. The Tribunal acknowledges that the proof of change in a custom is not an easy matter to establish. However, the burden of doing so falls clearly on Claimant. If Claimant does not provide the Tribunal with the proof of such evolution, it is not the place of the Tribunal to assume this task. Rather the Tribunal, in such an instance, should hold that Claimant fails to establish the particular standard asserted.") (**RL-015**); *Apotex Award*, para. 9.17 (**RL-016**); *UPS Jurisdiction Award*, para. 84 ("[R]elevant practice and the related understandings must still be assembled in support of a claimed rule of customary international law.") (**RL-038**). *See also*, *Case Concerning Rights of Nationals of the United States of America in Morocco* (*France v. United States*), [1952] ICJ Rep. 176, p. 200 (quoting Asylum (Colom. v. Peru), 1950 ICJ 266) (**RL-039**).

[88] *Grand River Award*, paras. 208-209 ("The language of Article 1105 does not state or suggest a blanket prohibition on discrimination against alien investors' investments, and one cannot assert such a rule under customary international law. States discriminate against foreign investments, often and in many ways, without being called to account for violating the customary minimum standard of protection […] Thus, neither Article 1105 nor the customary international law standard of protection generally prohibits discrimination against foreign investments.") (**RL-010**); *Methanex Final Award on Jurisdiction*, para. 25 (**RL-011**). *See also*, Opening Presentation of Canada, Slide 81.

[89] *Loewen Award*, para. 123 (**RL-013**); *Waste Management II Award*, para. 130 (**RL-014**); *Loewen Group and Another v. United States of America*, Opinion of Christopher Greenwood Q.C, 26 March 2001, para. 64 (**RL-025**). *See also*, Opening Presentation of Canada, Slides 73 and 77; Closing Presentation of Canada, Slide 47 and 54.

discrimination between fields of technology or between brand and generic pharmaceutical companies is absurd. Claimant points to no State practice or *opinio juris* evidencing such a rule. Nor could it, for such a rule does not exist. In fact, the sovereign right of States to make independent decisions about the sort of patent protection they will make available is a bedrock principle in international intellectual property law.[90] As such, the fact that an obligation not to discriminate based on field of technology is contained in another Chapter of NAFTA does not prove that such an obligation also exists at customary international law. To the contrary, the NAFTA Parties included Article 1709(7) precisely because there is no such obligation at customary international law. Hence, Article 1709(7) is irrelevant for the purposes of an Article 1105 analysis (as is expressly made clear by the FTC Note).[91]

57. Second, Claimant failed to undertake the required analysis of State practice and *opinio juris* to identify the content of a rule prohibiting arbitrariness in the context of judicial decisions. Claimant simply refers to jurisprudence, which itself contains no analysis of customary international law. Thus, it has failed to meet its burden in this regard.

58. Moreover, even the decisions that do address arbitrariness make clear that government measures are not arbitrary if they are merely unreasonable or involve the inconsistent application of administrative or legal policy or procedure.[92] Customary international law does not protect against merely arbitrary, unpredictable or inconsistent treatment, even in cases where the well-reasoned and impartial decisions of a State's

[90] Gervais Second Report, paras. 11-17; *Paris Convention for the Protection of Industrial Property*, World Intellectual Property Organization, (1883), Article 4*bis* (**R-036**); Philippe Baechtold, Tomoko Miyamoto and Thomas Henninger, "International patent law: Principles, major instruments and institutional aspects", in D. Gervais (ed), *International Intellectual Property: A Handbook of Contemporary Research* (Cheltenham, Edward Elgar, 2015), p. 53 (**R-402**).

[91] NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter Eleven Provisions, 31 July 2001, para. 2(3) (**RL-009**). *See also*, Opening Presentation of Canada, Slide 68; Closing Presentation of Canada, Slide 25.

[92] *See, e.g.*, *Cargill Award*, para. 293 (**RL-015**). *See also*, Opening Presentation of Canada, Slide 83.

highest courts are not at issue.[93] Tribunals considering arbitrariness at international law have explained that "arbitrariness is not so much something opposed to a rule of law, as something opposed to the rule of law." [94] Arbitrariness in international law means that "prejudice, preference or bias is substituted for the rule of law."[95] Thus, in order to be arbitrary, a measure must have no legitimate purpose, must not be based on legal standards or must have intentionally ignored due process and proper procedure.[96] A measure is not "arbitrary" merely because a private party (or an international tribunal) would have preferred a different outcome or disagrees with the interpretation of a domestic law given by a domestic court. Applying a standard of arbitrariness in the context of court decisions could lead to a Chapter Eleven tribunal undertaking the functions of a domestic court in conducting a judicial review or hearing an appeal. This is not the role of a Chapter Eleven tribunal. A reasoned and rational court decision based on a good faith interpretation of the statute and jurisprudence and an assessment of the facts at trial cannot be arbitrary in international law.[97]

59. Third and finally, Claimant's allegation that Article 1105 protects an investor's legitimate expectations is false. The NAFTA Parties agree that Article 1105 does not

[93] *Thunderbird Award*, para. 194 (**RL-003**); *Mondev Award*, para. 127 (**RL-004**); *Glamis Award*, paras. 625-626 (**RL-006**); *Loewen Award*, para. 131 (**RL-013**); *Cargill Award*, para. 293 (**RL-015**); *Elettronica Sicula SpA (ELSI) United States v. Italy*, International Court of Justice, Judgment, 20 July 1989, p. 76, para. 128 (**RL-031**). *See also*, Resp. CM., paras. 247-253.

[94] *Elettronica Sicula SpA (ELSI) United States v. Italy*, International Court of Justice, Judgment, 20 July 1989 ("*ELSI Judgment*"), paras. 124-128 (**RL-031**).

[95] *Joseph Charles Lemire v. Ukraine*, ICSID Case No. ARB/06/18, Decision on Jurisdiction and Liability, 14 January 2010 ("*Lemire Decision on Jurisdiction and Liability*"), para. 263 (**RL-029**). *See also*, *LG&E Energy Corp. v. The Argentine Republic*, Decision on Liability, ICSID ARB/02/1, 3 October 2006 ("*LG&E Liability*"), para. 157 (in order for a measure to be arbitrary, a measure must be "depending on individual discretion; (…) founded on prejudice or preference rather than on reason or fact." citing *Lauder v. Czech Republic* and Black's Law Dictionary) (**RL-030**).

[96] *Lemire Decision on Jurisdiction and Liability*, para. 262 (**RL-029**), citing *EDF (Services) Limited v. Romania*, ICSID ARB/05/13, Award, 8 October 2009 ("*EDF Award*"), para. 303 (the *EDF* tribunal accepted the definition of "arbitrary" as described in the expert opinion of Professor Christoph Schreuer).

[97] *See e.g.*, *LG&E Liability*, para. 162 (finding that Argentina's measures not to be arbitrary because they "were the result of reasoned judgment rather than simple disregard of the rule of law.") (**RL-030**).

incorporate such protection.[98] Previous NAFTA tribunals have also agreed, concluding that mere failure to meet an investor's expectations does not breach Article 1105(1).[99] Moreover, the tribunals that have considered legitimate expectations as a relevant, though not determinative, factor in assessing whether there has been a breach of Article 1105 have required that such expectations: (1) be reasonable objective expectations, rather than the subjective expectations of the investor;[100] (2) derive from a specific assurance or promise by the State to induce the investment which was relied on by the investor;[101] (3) exist at the time the investor decided to make the investment;[102] and (4) be reasonable in light of all of the circumstances.[103] Even non-NAFTA arbitral tribunals interpreting autonomous fair and equitable treatment provisions have insisted on these conditions.[104]

[98] *Mesa Power Group LLC v. Government of Canada*, Submission of the United States of America, 25 July 2014, para. 8 (**RL-051**); *TECO Guatemala Holdings LLC v. Republic of Guatemala*, ICSID Case No. ARB/10/23, 23 November 2012, para. 6 (**RL-052**); *Merrill & Ring Forestry LP v. Government of Canada*, Canada's Counter-Memorial, 13 May 2008, paras. 507-509 (**RL-108**); *Mobil Investments Canada Inc. and Murphy Oil Corporation v. Government of Canada*, ICSID Case No. ARB(AF)/07/4, Canada's Rejoinder, 9 June 2010, paras. 140-142 and 149 (**RL-109**); *Bilcon*, Canada's Counter-Memorial, paras. 389 and 391 (**RL-113**); *Windstream*, Counter-Memorial of Canada, para. 405 (**RL-114**); *Mesa Power Group LLC and Government of Canda*, (UNCITRAL), Second Submission of the United States of America, 12 June 2015, para. 14 (**RL-117**); *Mesa Power Group LLC and Government of Canda*, (UNCITRAL), Second Submission of Mexico Pursuant to NAFTA Article 1128, 12 June 2015, para. 10 (**RL-118**); Resp. CM, paras. 269-283, Resp. Rejoinder, paras. 264-265; US 1128 Submission, para. 13; Mexico 1128 Submission, paras. 15-16; Respondent's Observations on Issues Raised in 1128 Submissions, para. 26.

[99] *Thunderbird Award*, paras. 147 and 194 (**RL-003)**; *Glamis Award*, paras. 620, 627 and 761-762 (**RL-006**); *Mobil Decision on Liability*, para. 153 (**RL-007**); *Waste Management II Award*, para. 98 (**RL-014**).

[100] *Glamis Award*, para. 627 ("Creation by the state of objective expectations in order to induce investment…") (**RL-006**); *Mobil Decision on Liability*, para. 125 (**RL-007**).

[101] *Glamis Award*, para. 620 ("Merely not living up to expectations cannot be sufficient to find a breach of Article 1105 of the NAFTA. Instead, Article 1105(1) requires the evaluation of whether the State made any specific assurance or commitment to the investor so as to induce its expectations.") (**RL-006**); *Mobil Decision on Liability*, para. 125 (**RL-007**); *Waste Management II Award*, para. 98 (noting the relevance of a "breach of representations made by the host State which were reasonably relied on by the claimant.") (**RL-014**).

[102] *Mobil Decision on Liability*, para. 125 (**RL-007**).

[103] *Mobil Decision on Liability*, para. 125 (**RL-007**).

[104] *EDF Award*, paras. 217-219 (emphasis added) (**RL-008**); *Parkerings-Compagniet AS v. Republic of Lithuania*, (ICSID ARB/05/8), Award, 11 September 2007, para. 332 (**RL-040**); *Duke Energy Award*, para. 340 (**RL-048**), cited with approval in *Bayindir Award*, para. 192 (**RL-054**). *See also*, *Saluka Partial Award*, para. 304 ("This Tribunal would observe, however, that while it subscribes to the general thrust of

3) Judicial Measures Cannot Breach the Customary International Law Minimum Standard of Treatment of Aliens Absent a Denial of Justice

60. Where the challenged measures are the judgments of national courts interpreting national laws, the only basis for a finding of a breach under Article 1105 is denial of justice. The NAFTA Parties agree that this is the correct interpretation of the customary international law minimum standard of treatment of aliens contained in Article 1105.[105] Every NAFTA Tribunal to consider a challenge to the measures of the judiciary of one of the NAFTA Parties has also ruled the same and required proof of a denial of justice.[106] Tribunals outside of the NAFTA context have found the same.[107] Finally,

---

these and similar statements, it may be that, if their terms were to be taken too literally, they would impose upon host States' obligations which would be inappropriate and unrealistic. Moreover, the scope of the Treaty's protection of foreign investment against unfair and inequitable treatment cannot exclusively be determined by foreign investors' subjective motivations and considerations. Their expectations, in order for them to be protected, must rise to the level of legitimacy and reasonableness *in light of the circumstances.*") (**RL-050**).

[105] *Mondev Second Submission of Canada*, paras. 57-62 (**RL-021**); *ADF Group Inc. v. United States of America*, ICSID Case No. ARB(AF)/00/1, Article 1128 Submission of the United Mexican States, 18 January 2002, p. 4 (**RL-022**); *The Loewen Group Inc. and Raymond Loewen v. United States of America*, ICSID ARB(AF)/98/3, Second Submission of the United Mexican States, 9 November 2001, pp. 5-6 (**RL-023**); *The Loewen Group Inc. and Raymond Loewen v. United States of America*, ICSID ARB(AF)/98/3, Response of the United States of America to the November 9, 2001 Submissions of the Governments of Canada and Mexico Pursuant to NAFTA Article 1128, 7 December 2001, p. 6 (**RL-024**). *See also*, Opening Statement of Canada, May 30, 2016, pp. 162:18 – 163:1; Opening Presentation of Canada, Slides 52-64; Closing Statement of Canada, June 8, 2016, pp. 2177:6-17; Closing Presentation of Canada, Slides 20-31; Resp. CM, para. 213; Resp. Rejoinder paras. 243-247; Respondent's Observations on 1128 Submissions, para. 19; US Article 1128 Submission, para. 23; Mexico 1128 Submission, para. 14.

[106] *Azinian Award*, paras. 99 and 102-103 (there must be a denial of justice or "malicious misapplication of the law.") (**RL-002**); *Mondev Award*, para. 127 ("The test is not whether a particular result is surprising, but whether the shock or surprise to an impartial tribunal leads, on reflection, to justified concerns as to the judicial propriety of the outcome, bearing in mind on the one hand that international tribunals are not courts of appeal, and on the other hand that Chapter 11 of NAFTA (like other treaties for the protection of investments) is intended to provide a real measure of protection. In the end the question is whether, at an international level and having regard to generally accepted standards of the administration of justice, a tribunal can conclude in the light of all the available facts that the impugned decision was clearly improper and discreditable, with the result that the investment has been subjected to unfair and inequitable treatment.") (**RL-004**); *Grand River Award*, para. 234 ("As before, the Tribunal is loath to purport to address these delicate and complex questions of U.S. constitutional and Indian law…these issues of national law belong in national courts, not in an international tribunal. If a national court system fails to address these questions in a proper way, there may be grounds for a true claim of denial of justice within the ambit of the customary minimum standard under NAFTA Article 1105. That is not what is presented here.") (**RL-010**); *Loewen Award*, para. 123 (holding that "the responsibility of the State under international law and, consequently, of the courts of a State, to provide a fair trial of a case to which a foreign investor is a party.") (**RL-013**); *Waste Management II Award*, paras. 129-130 ("Turning to the actual reasons given by the federal courts, the Tribunal would observe that it is not a further court of

international scholars also agree. As Professor Douglas aptly summarizes: "Denial of justice is the sole form of international delictual responsibility towards foreign nationals for acts or omissions within an adjudicative procedure for which the State is responsible."[108]

61. This rule stems from recognition of the independence of the judiciary and the great deference afforded to domestic courts acting in their *bona fide* role of adjudication and interpretation of a State's domestic law.[109] In contrast to executive or legislative

appeal, nor is Chapter 11 of NAFTA a novel form of *amparo* in respect of the decisions of the federal courts of the NAFTA Parties. […] [T]he Tribunal does not discern in the decisions of the federal courts any denial of justice".) (**RL-014**).

[107] *Barcelona Traction, Light and Power Company Limited (Belgium v. Spain),* Judgement of 5 February 1970, Separate Opinion of Judge Tanaka, p. 158 (Issues of municipal law "do not belong to the realm of international law. If an international Tribunal were to take up these issues and examine the regularity of the decisions of municipal courts, the international Tribunal would turn out to be a 'cour de cassation', the highest court in the municipal law system…the incorrectness of a judgement of a municipal court does not have an international character.") (**RL-020**). *See also, GEA* Award, paras. 306-324 (**RL-026**); *Liman Award*, paras. 268, 274-279 (citing *Mondev*, para. 275) (**RL-027**); *Jan de Nul N.V. Dredging International NV v. Egypt*, ICSID Case No. ARB/04/13, Award, 6 November 2008, paras. 191-254 (citing *Mondev*, paras. 193-194) and specifically para. 191 ("the relevant standards to trigger State responsibility for the [judicial proceedings] are the standards of denial of justice…holding otherwise would allow to circumvent the standards of denial of justice.") (**RL-028**).

[108] Zachary Douglas, *International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed*, International and Comparative Law Quarterly (ICLQ), p. 34 and also p. 29 ("acts or omissions attributable to the State within the context of a domestic adjudicative procedure can only supply the predicate conduct for a denial of justice and not for any other form of delictual responsibility towards nationals.") (**R-323**); *Loewen Group and Another v. United States of America*, Second Opinion of Christopher Greenwood Q.C, 16 August 2001, para. 94 ("error on the part of the national court is not enough, what is required is 'manifest injustice' or 'gross unfairness.'") (**RL-018**); *Ida Robinson Smith Putnam (U.S.A.) v. United Mexican States*, (United States-Mexico Cl. Commission 1927) Reports of International Arbitral Awards, vol. IV (15 April 1927) ("The Commission, following well-established international precedents, has already asserted the respect that is due to the decisions of the highest courts of a civilized country (Case of Margaret Roper, Docket No. 183, para. 8). A question which has been passed on in courts of a different jurisdiction by the local judges, subject to protective proceedings, must be presumed to have been fairly determined. Only a clear and notorious injustice, visible, to put it thus, at a mere glance, could furnish ground for an international Tribunal of the character of the present, to put aside a national decision presented before it and to scrutinize its grounds of law and fact") (**RL-019**).

[109] Zachary Douglas, *International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed*, International and Comparative Law Quarterly (ICLQ), p. 11 ("International law is deferential to the particular virtues of adjudication by respecting the integrity of the process and the outcomes it produces. This deference is manifest in the finality rule and the idea that denial of justice focuses upon the procedural aspects of the adjudication rather than the substantive reasons for the decision.") (**R-323**); J.L. Brierly, *The Law of Nations* (Oxford: 1963), p. 287 ("It will be observed that even on the wider interpretation of the term 'denial of justice' which is here adopted, the misconduct must be extremely gross. The justification of this strictness is that the independence of courts is an accepted

acts, adjudicative acts produce outcomes with moral and legal authority independent of the State's coercive powers. This authority is rooted in the particular form of affected party participation (submission of argument and evidence), and in the demand for heightened rationality in the process and in the result.[110]

62. Claimant again finds itself forced to turn its back on this well-established rule in international law. Citing to arbitral decisions, it alleges that denial of justice is "*just one part* of the protection afforded by the Minimum Standard of Treatment in respect of judicial measures".[111] It claims that denial of justice is only the standard if the allegation is one of a lack of procedural unfairness, or misapplication of domestic law. It seeks to distinguish every single NAFTA case considering judicial measures on these grounds. Its attempts are unsustainable.

63. First, Claimant's attempt to differentiate its claim from previous NAFTA cases is unavailing. Claimant is alleging nothing more than a misapplication or an error in the interpretation of Canadian law by the Canadian courts. Even accepting its representation that it is not doing so in the context of the specific court challenges invalidating its patents, it is clear that it is doing so with respect to the series of decisions between 2002 and 2008, which it claims radically deviated from existing Canadian law.[112] Further, its claim of a radical change in the jurisprudence is in fact one that other NAFTA tribunals have considered. Indeed, the tribunal in *Mondev* considered the exact same type of allegation as Claimant makes here – that a significant and serious departure from previous jurisprudence amounts to a violation of Article 1105. That tribunal agreed with the well-established principle of international law that proof of a breach of Article 1105

canon of decent government, and the law therefore does not lightly hold a State responsible for their faults. It follows that an allegation of a denial of justice is a serious step…") (**R-324**). *See also*, Closing Presentation of Canada, Slide 51.

[110] *See* Zachary Douglas, *International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed*, International and Comparative Law Quarterly (ICLQ), p. 10 (**R-323**); LL Fuller and KI Winston, *The Forms and Limits of Adjudication*, (1978) 92 Harvard Law Review 353, p. 367 (**R-448**).

[111] *See* Cl. Reply., para. 326.

[112] *See also*, Closing Statement of Canada, June 8, 2016, p. 2233:2– 2236:1.

in these circumstances requires proof of a denial of justice.[113] This Tribunal should do the same.

64. Second, Claimant's suggestion that there is a ground of liability for the measures of the judiciary other than denial of justice at customary international law is wrong as a matter of substance. In support of its arguments, Claimant does not cite to State practice and *opinio juris* but rather solely to arbitral decisions. As noted above, arbitral decisions do not constitute evidence of customary international law.[114] Further, the cases cited by Claimant involve the application of the autonomous fair and equitable treatment standard, lack any analysis of customary international law,[115] or involve seriously egregious conduct on the part of the State manifested in a judicial decision.[116]

65. Finally, the decisions cited recognized the need to "take into account the different functions held by administrative organs and judicial organs of a State and the resulting differences in their discretion when applying the law and in the appeals against their decisions."[117] Indeed, they generally dealt with the investor's complaints about treatment by courts as being claims for a denial of justice in substance, if not in name.[118] In sum, none of the decisions cited by Claimant provides any support for its claim as to the content of the customary international law minimum standard of treatment of aliens.

---

[113] *Mondev*, Second Submission of Canada, para. 62 (**RL-021**).

[114] *See* para. 52 below.

[115] *Liman Award*, para. 263 (**RL-027**); *Frontier Petroleum Services Ltd. v. The Czech Republic*, (UNCITRAL), Final Award, 12 November 2010, ("*Frontier Petroleum Final Award*"), para. 529 (denying the claim by explaining "Claimant's requests were entertained by four levels of courts and Claimant had several opportunities to submit legal arguments on the proper interpretation and application of…Article V of the *New York Convention*.") (**RL-067**); *White Industries Australia Ltd. v. India*, (UNCITRAL), Award, 3 November 2011, ("*White Industries*"), para. 4.3.1 (**CL-157**).

[116] Subsequent tribunals have observed that the *Rumeli* tribunal's finding was based on "collusion between the State and the claimants' competitor, which collusion was then effected through court proceedings." *See Swisslion Doo Skopje v. The Former Yugoslav Republic of Macedonia*, ICSID Case No. ARB/09/16, Award, 6 July 2012 , para. 313, FN 377 (**RL-065**). *Rumeli Telekom A.S. and Telsim Mobil Telekomunikasyon Hizmetleri A.S. v. Republic of Kazakhstan*, ICSID Case No. ARB/05/16, Award, 29 July 2008, paras. 702 and 707 (**RL-070**).

[117] *Liman Award*, para. 268 (**RL-027**).

[118] Ibid.

C. Claimant Has Not Alleged and Could Not Allege a Denial of Justice

66. Claimant has not alleged that there has been a denial of justice in this case. In fact, it has repeatedly stressed that this is not its claim.[119] It is not the role of this Tribunal to reassert Claimant's claim so as to make it cognizable under Article 1110 or 1105 of NAFTA. As a result, because it is challenging the measures of the Canadian courts under Articles 1110 and 1105, but has not alleged a denial of justice, Claimant has failed to state a legally cognizable claim. Its case must be dismissed on this ground alone.

67. However, even if Claimant had alleged a denial of justice, that claim would fail as a matter of substance because the challenged conduct of the Canadian courts does not breach the standard set by customary international law. In order to rise to the level of denial of justice, the conduct of the judiciary would have to amount to a refusal to entertain a suit or a serious failure to adequately administer justice.[120] As Professor Paulsson has explained, "[d]enial of Justice is always procedural."[121] Professor Douglas similarly commented:

> International law is deferential to the particular virtues of adjudication by respecting the integrity of the process and the outcomes it produces. This deference is manifest in the finality rule and the idea that denial of justice focuses upon the procedural aspects of the adjudication rather than the substantive reasons for the decision.[122]

[119] *See e.g.* Cl. Reply, para. 17 (it states "Lilly's claims do not rest on denial of justice, but rather on a completely separate and equally well-established basis for liability: the Canadian judiciary's *substantive* violations of international law.")

[120] Jan Paulsson, *Denial of Justice in International Law*, (Cambridge: 2005), p. 98 (**R-321**); Christopher Greenwood, *State Responsibility for the Decisions of National Courts*, in *Issues of State Responsibility before International Judicial Institutions*, Fitzmaurice and Sarooshi (eds.) (Oxford: 2004), pp. 55-73 (**R-322**); Zachary Douglas, *International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed*, International and Comparative Law Quarterly (ICLQ), pp. 1-34 (**R-323**); *Azinian v. Mexico*, paras. 102-103 (**RL-002**).

[121] Jan Paulsson, *Denial of Justice in International Law*, (Cambridge: 2005) (**R-321**). *See also*, Closing Presentation of Canada, Slide 50.

[122] Zachary Douglas, *International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed*, International and Comparative Law Quarterly (ICLQ) (**R-323**). *See also*, Closing Presentation of Canada, Slide 51.

68. Canada agrees that a tribunal assessing whether there has been a denial of justice must look beyond whether there were superficially fair procedures.[123] The question is whether the party has actually been afforded a fair procedure (i.e. due process) in front of a neutral and independent judiciary. A State has not afforded justice to an investment in accordance with the customary international law minimum standard of treatment merely by offering the pretence of due process.[124]

69. As such, in order to determine whether there has been a denial of justice, an international tribunal must primarily examine the procedure of the domestic proceedings to ensure that the parties had an opportunity to present their case. In addition, a tribunal might consider whether there is any rational basis in law for the decision, whether it appears bereft of any reason, or whether it is malicious. Such evidence might be *indicia* that there was no real due process afforded.[125]

[123] *See also*, Closing Statement of Canada, June 8, 2016, p. 2209:14-17.

[124] *Azinian Award*, para. 99 ("Even if the Claimants were to convince this Arbitral Tribunal that the Mexican courts were wrong with respect to the invalidity of the Concession Contract, this would not per se be conclusive as to a violation of NAFTA. More is required; the Claimants must show either a denial of justice, or a pretence of form to achieve an internationally unlawful end.") (**RL-002**).

[125] Rudolf Dolzer and Christoph Schreuer, *Principles of International Law*, (Oxford: Oxford University Press), 2008, pp. 165-166 ("Concerning the outcome of a case before a local court, it is clear that an investment Tribunal will not act as an appeals mechanism and will not decide whether the court was in error or whether one view of the law or the other would be preferable. Nevertheless, a line will have to be drawn between an ordinary error and a gross miscarriage of justice, which may no longer be considered as an exercise of the rule of law. This line will be crossed especially when it is impossible for a third party to recognize how an impartial judge could have reached the result in question.") (**R-327**). *See also*, Campbell Mclachlan, Laurence Shore & Matthew Weiniger, *International Investment Arbitration: Substantive Principles*, (Oxford Univeristy Press 2007), p. 229 ("An attack on the substantive outcome of the national court decision can only succeed if it is clear that there has been judicial impropriety, rather than merely a mistake of law.") (**R-328**); *Mondev Award*, para. 127 ("The test is not whether a particular result is surprising, but whether the shock or surprise to an impartial tribunal leads, on reflection, to justified concerns as to the judicial propriety of the outcome…[i]n the end the question is whether, at an international level and having regard to generally accepted standards of the administration of justice, a tribunal can conclude in the light of all the available facts that the impugned decision was clearly improper and discreditable, with the result that the investment has been subjected to unfair and inequitable treatment.") (emphasis added) (**RL-004**); *Loewen Group and Another v. United States of America*, Opinion of Christopher Greenwood Q.C, 26 March 2001, para. 64 ("The international tribunal is not a court of appeal from the national court (as Loewen accepts), nor is its task to review the findings of the national court. In the absence of clear evidence of bad faith on the part of the relevant court…the claimant must demonstrate that either it was the victim of discrimination on account of its nationality or that the

70. However, neither simple defects in procedure nor errors with respect to either rulings of law or findings of fact are enough. States do not incur liability in international law for erroneous decisions or misapplications of national law.[126] In this case, there is no allegation that Canada's courts are not a fair and independent judiciary.[127] There is no allegation of any defect in procedure let alone anything that would amount to a denial of justice.[128] There is not even an allegation that the Canadian courts incorrectly applied

administration of justice was scandalously irregular. Defects in procedure or a judgement which is open to criticism on the basis of either rulings of law or findings of fact are not enough.") (**RL-025**).

[126] Jan Paulsson, *Denial of Justice in International Law*, (Cambridge: 2005), pp. 73-81 (**R-321**); Christopher Greenwood, *State Responsibility for the Decisions of National Courts*, in *Issues of State Responsibility before International Judicial Institutions*, Fitzmaurice and Sarooshi (eds.) (Oxford: 2004), p. 61 ("it is well established that a mistake on the part of the court or an irregularity in procedure is not in itself sufficient to amount to a violation of international law; there must be a denial of justice.") (**R-322**); Zachary Douglas, *International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed*, International and Comparative Law Quarterly (ICLQ) (**R-323**); J.L. Brierly, *The Law of Nations* (Oxford: 1963), pp. 286-287 (defining denial of justice as "an injury involving the responsibility of the State committed by a court of justice" and stating that "no merely erroneous or even unjust judgment of a court will constitute a denial of justice…the misconduct must be extremely gross.") (**R-324**); G.G. Fitzmaurice, *The Meaning of the Term 'Denial of Justice*, 13 Brit. Y.B Int'l L. 93 (1932), pp. 93-114 (**R-325**); A.V. Freeman, *The International Responsibility of States for Denial of Justice* (Longmans: 1970) p. 319 ("In a word, no domestic judgment may be attacked merely because it is unsound in the light of applicable principles of local law and justice.") (**R-326**); *Azinian Award*, paras. 102-103 (**RL-002**); *Thunderbird Award*, para. 120 ("it is not the Tribunal's function to act as a court of appeal or review in relation to the Mexican judicial system regarding the subject matter of the present claims…")(**RL-003**); *ADF Award*, para. 190 (endorsing the position of the *Azinian* Tribunal and stating that a NAFTA Tribunal "does not sit as a court with appellate jurisdiction with respect to the United States measures" and whether they have legal validity under United States domestic law) (**RL-005**); *Loewen Award*, para. 134 ("a NAFTA claim cannot be converted into an appeal against the decisions of municipal courts.") (**RL-013**). *See also*, *Barcelona Traction, Light and Power Company Limited (Belgium v. Spain)*, Judgement of 5 February 1970, Separate Opinion of Judge Tanaka, p. 158 ("If an international tribunal were to take up these issues and examine the regularity of the decisions of municipal courts, the international tribunal would turn out to be a "cour de cassation", the highest court in the municipal law system…the incorrectness of a judgment of a municipal court does not have an international character.") (**RL-020**).

[127] Siebrasse, May 31, 2016, p. 573:1-4; Reddon, June 1, 2016, pp. 892:20 – 893:10; Reddon, June 1, 2016, pp. 886:16-19.

[128] Cl. Reply, para. 217 ("Canada emphasizes the procedural history of each case…Canada recites the number of witnesses each trial included and the number of days each trial spanned…maintaining that the judges "carefully weigh[ed]" and "extensively analyzed" the evidence through months of deliberation. Canada does this because it would prefer to litigate whether the proceedings in Canada were procedurally fair. But that is not Lilly's case…").

existing Canadian law in the decisions invalidating Claimant's patents, let alone engaged in merely a pretence of form or a malicious misapplication of Canadian law.[129]

71. Accepted at face value, Claimant's concern is merely that the Canadian courts allegedly changed the interpretation that they had previously given to the term "useful" in Canada's *Patent Act*. Even if such a change did occur, it does not amount to a denial of justice at international law.

72. Common law courts evolve and develop the law – including in fields with broad governing statutes, like patent law. As Claimant's own expert Professor Merges explained, in any doctrinal area that has a single word in a statute like "useful", it is necessary to "take off from [that] single word…and develop a body of law to apply to the specific technologies and specific situations…common law elaboration and application of the basic concept is necessary."[130]

73. In short, it is the role of the courts as part of the process of common law elaboration to interpret, to evolve, and sometimes to "reach into their treasure chest of old discarded principles" to decide the case in front of them."[131] Further, higher level courts are often called upon to look to a series of past decisions, discern a rule and express that rule in a synthesized way that will ensure that the previous jurisprudence, appropriately understood, will be correctly applied by the lower courts.[132] Higher courts are also often called upon to correct the lower courts, even if the lower courts have adjudicated certain cases in particular ways for significant periods of time. Indeed, in this regard, a country's highest court is sometimes called upon to correct its own earlier jurisprudence even though such jurisprudence may have stood as the law of the land, and

[129] Cl. Reply, para. 334 ("Lilly has not alleged that the Federal Court and Federal Court of Appeal misapplied Canadian law as it stood in 2010 and 2011.")

[130] Merges, June 3, 2016, p. 1286:2-18; Siebrasse, June 1, 2016, p. 749:6-9; Siebrasse, June 1, 2016, pp. 751:24 – 752:5.

[131] Robert P. Merges & John F. Duffy, Patent Law and Policy (6th ed. 2013), pp. 291-292 (**C-272**).

[132] Merges, June 3, 2016, p. 1332:2-8.

been relied upon, for decades. None of this amounts to a denial of justice or a breach of the customary international law minimum standard of treatment.[133]

74. As the U.S. explained in its second Article 1128 submission, "[n]either the evolution nor development of 'new' judge-made law that departs from previous jurisprudence within the confines of common law adjudication may provide the basis for claiming a State has committed a denial of justice."[134] Similarly, the *Mondev* tribunal explained in response to an allegation of a "serious" and "significant" departure from previous jurisprudence that even if the U.S. court had actually "made new law" in its judgments, "its decision would have fallen within the limits of common law adjudication. There is nothing here to shock or surprise even a delicate judicial sensibility."[135]

75. In order to escape these conclusions, Claimant attempts to draw an untenable distinction between "minor and evolutionary" changes that would fall within the limits of common law adjudication, and "radical" and "dramatic" changes.[136] However, the claimant in *Mondev* also claimed a "significant and serious departure" from previous jurisprudence.[137] The *Mondev* tribunal found that this was irrelevant.[138] A court's extension of existing principles to new situations is the very core of common law adjudication. Merely affixing the label "radical" or "dramatic" to a specific instance of principled extension does not suffice to remove it from the limits of common law adjudication.

[133] *See also*, Closing Statement of Canada, June 8, 2016, pp. 2212:7 – 2217:12.

[134] Second US 1128 Submission, para. 5.

[135] *Mondev Award*, para. 133 (emphasis added) (**RL-004**).

[136] *See* Cl. Reply, para. 219.

[137] *Mondev Award*, para. 131.

[138] *Mondev Award*, para. 133.

76. In sum, without an allegation of a denial of justice, there is no allegation of a breach of Article 1110 or 1105. Accordingly, Claimant has failed to state a claim as a matter of law, and this action should be dismissed as manifestly without legal merit.

III. PURSUANT TO ARTICLES 1116(2) AND 1117(2), CLAIMANT'S CLAIM THAT THE ALLEGED PROMISE UTILITY DOCTRINE VIOLATES CANADA'S OBLIGATIONS IS TIME-BARRED

77. Articles 1116(2) and 1117(2) establish a strict three-year statute of limitations for claims to be brought alleging that the measures of a NAFTA Party breach its obligations under Chapter Eleven. Claimant's allegation is that the Canadian courts radically changed their interpretation of the term "useful" in Canada's *Patent Act* between 2002 and 2008, creating the "promise utility doctrine" in breach of Canada's obligations under Articles 1110 and 1105. However, Claimant admits that the doctrine was fully crystallized and developed by 2008,[139] when the Canadian courts applied it in a case under the *Patented Medicines Notice of Compliance* (PM(NOC)) regulations involving Claimant's patent with respect to raloxifene. Further, it does not contest that it suffered loss as a result of that decision. Nor could it. After that PM(NOC) decision, a generic version of raloxifene was able to enter the market.[140] Claimant chose not to bring a

[139] Opening Statement of Claimant, May 30, 2016, pp. 47:17 – 48:12 ("THE PRESIDENT: Before we do that, you pointed us to the court decisions which is at C-160 and Paragraph 121, Slide 37. You see in 121, in the penultimate line, it says -- let me read the full sentence – 'The disclosure issue, however, has been determined by earlier decisions that are binding upon me and to the extent that it may be amenable to reconsideration, it must be examined elsewhere.' Which are the earlier decisions which the judge says are 'binding upon me'? You need not answer now. You may wish to do that through your expert testimony. MS. CHEEK: That is not a specific reference to the Strattera litigation itself; it's a reference to the fact that there is earlier case law that's been applying the disclosure rule that was first articulated in Raloxifene in 2008, and then courts have been applying that since then. THE PRESIDENT: Those are the earlier decisions? MS. CHEEK: Yes."); Closing Statement of Claimant, June 8, 2016, pp. 1994:2 – 1995:19 ("But what we are looking at is what was the utility test in Canada that was applied to our patents, and that would include all three of the elements that we've discussed over the course of the last week, 2002, 2005 and 2008… The utility standard that was applied to these patents invalidate them in 2010 and 2011 was crystallized in 2008 with the Raloxifene decision. However, there were decisions even before the Raloxifene decision that were applying the promise utility doctrine. So you will recall a question that came up at the opening, which is at what point did Canada have this new and different test. And in our view, that's 2005. But this latent component of it, the disclosure requirement, does not come to fruition or crystallize until 2008.")

[140] Health Canada, *Drugs and Health Products, Notice of Compliance Information*, "Apo-Raloxifene" (**R-473**). *See also*, Resp. Rejoinder, paras. 105-107.

NAFTA challenge to the allegedly new promise utility doctrine within three years of these measures and its loss. It has never adequately answered the question of why it did not.[141] Regardless, under the clear language of Articles 1116(2) and 1117(2), it was not permitted to simply wait, to bide its time while its alleged loss grew, and then challenge the most recent application of the judicial doctrine to its patents. Its challenge to the judicial doctrine itself as a violation of Canada's obligations under Articles 1110 and 1105 is beyond this Tribunal's jurisdiction.

A. Canada's Jurisdictional Objection on the Basis of Articles 1116(2) and 1117(2) Is Not Untimely and Must Be Considered

1) Canada Brought Its Jurisdictional Objection As Early As Possible

78. Article 21(3) of the UNCITRAL Arbitration Rules (1976) provides: "A plea that the arbitral tribunal does not have jurisdiction shall be raised not later than in the statement of defence or, with respect to a counter-claim, in the reply to the counterclaim." While the Rules themselves do not contain the express statement found in the UNCITRAL Model Law that a tribunal can admit later objections to jurisdiction if it finds the delay justified, such a textual distinction is not relevant here.[142] UNCITRAL Arbitration Rule 21(3) must be understood to apply only to the extent that the respondent was or should have been aware of the jurisdictional objection at the time of

[141] When asked by the Tribunal "if we accept everything that you say about the newness of the Canadian, as you describe it, promise utility doctrine, does that mean that in response to the judgment of Hughes J. in 2008 in respect of Raloxifene, that you would have had a cause of action in respect of the Raloxifene patent?", Claimant's response was "Technically probably no, although we didn't have to contend with this issue, because it was not finally invalidated in those proceedings…The patent was not revoked…These were PM(NOC) proceedings." Closing Statement of Claimant, June 8, 2016, pp. 2067:17 – 2068:2. This response is both surprising and unresponsive. It is surprising because Claimant argued in every other context that there was no meaningful difference between invalidation proceedings and PM(NOC) proceedings in terms of outcomes. Indeed, it cross-examined Dr. Brisebois in an effort to establish this point. Brisebois, May 31, 2016, pp. 482:23 – 488:25. It is irrelevant because Claimant admits that the doctrine it now wishes to challenge was crystallized by 2008, and the fact is undisputed that after the PM(NOC) decision in 2008, Claimant's competitor was allowed to enter the market, causing Claimant loss. These are the only two conditions in Articles 1116(2) and 1117(2) for the limitations period to begin running.

[142] *See also*, Closing Statement of Canada, June 8, 2016, pp. 2236:22 – 2238:18.

the filing of the statement of defence. Otherwise, it would be unfairly prejudicial to the respondent.

79. As Canada noted at the hearing, UNCITRAL Arbitration Rule 21(3) has to be read in the context of the Rules as a whole.[143] The UNCITRAL Arbitration Rules contemplate that, by the statement of claim, the claimant will have fully laid out its claims, positions and arguments.[144] As Article 22 of the Rules makes clear, a claimant has no presumptive right to make another written submission following the statement of claim. If a claimant is authorized by a tribunal to make further written statements, and if such further written statements reorient the claim in a way that gives rise to a new jurisdictional objection, the claimant cannot be permitted to rely on Article 21(3) to prevent that objection from being considered. If the rule were interpreted in any other way, it would cause serious prejudice to a respondent who acted in good faith in not raising a jurisdictional objection to a claim that it was not aware was actually at issue.

80. This is the situation in this arbitration.[145] Canada brought its objection to the jurisdiction of the Tribunal based on Articles 1116(2) and 1117(2) in its Rejoinder because it only became clear in Claimant's Reply Memorial that Claimant was challenging the alleged judicial doctrine, not the specific application of that alleged doctrine to Claimant's patents.[146] Prior to its Reply, Claimant appeared to challenge the particular judicial invalidations of its olanzapine and atomoxetine patents. This was evident from its pleadings and written submissions,[147] as well as the evidence that Claimant submitted in support of its case. In particular, the witness statement of Mr. Armitage, Claimant's General Counsel at the time it first decided to bring this case to

[143] Opening Statement of Canada, May 30, 2016, pp. 253:8 – 255:4.

[144] UNCITRAL Arbitration Rules (1976), s. 21 (3).

[145] Resp. Rejoinder, paras. 63-65.

[146] Ibid.

[147] Notice of Arbitration, dated September 12, 2013, designated as the Statement of Claim ("NOA"), para. 81; Cl. Mem., paras. 8, 13, 19, 57, 61, 64, 65, 218, 258, 262, 263 and 264.

arbitration,[148] makes clear that Claimant's concern was with the application of the alleged doctrine to it, not just the alleged doctrine itself.[149] In light of the way that Claimant pled its case, Canada did not raise a jurisdictional objection based on time-bar. Instead, Canada responded to the claim regarding the application of the alleged doctrine by detailing the fairness of the proceedings and the opportunity Claimant had to present its case.[150]

81. After Canada filed its Counter-Memorial, during the document production phase of the arbitration, Claimant began to reorient its claims, clearly alleging for the first time that the measure it was challenging was "Canada's development of a new utility doctrine (the promise utility doctrine)."[151] Canada immediately objected to this reorientation, noting that Canada had not objected to jurisdiction because of the way that Claimant had previously pled its claims.[152] In its Reply, Claimant definitively moved away from its previous claims, agreeing that it received a fair process in the Canadian courts, and that the courts properly applied Canadian law to its atomoxetine and olanzapine patents.[153] For the first time, Claimant specifically challenged the three aspects of Canadian

[148] Armitage, May 31, 2016, pp. 364:1 – 366:1; Armitage Statement, para. 2; Claimant's Notice of Intent, para. 115.

[149] Armitage Statement, para. 13 ("The doctrine was especially egregious as applied to the '113 patent"), para. 16 ("we were quite simply incredulous when, on remand, the trial judge invalidated our patent solely on the ground of inutility") and para. 22 ("When Canada invalidated the '735 patent solely on the grounds of inutility in 2010, we found this development outrageous… It was inconceivable to us that the Canadian courts could fairly adjudicate the inutility issue without considering the most salient facts…").

[150] *See* Resp. CM., paras. 246-264.

[151] Procedural Order No. 2, Annex B: Tribunal's Decisions on Respondent's Document Requests, No. 1, Reply to Objections to Document Request ("Procedural Order No. 2, Annex B") (**R-434**).

[152] Procedural Order No. 2, Annex B (explaining "In order to establish jurisdiction in this matter, Claimant stated the measures to be the invalidation of two of its patents by the Federal Court. Having asked the Tribunal to assert jurisdiction on the basis of these two specific measures, Claimant cannot now recast the measure as "Canada's development of a new utility doctrine. This goes beyond the Tribunal's jurisdiction, extending to an undefined time period and cases involving unspecified patents that did not form any part of Claimant's investment.)." (emphasis added) (**R-434**).

[153] Cl. Reply, paras. 13 ("Canada asserts, the Federal Courts are simply engaged in the standard process of adjudication, including by applying settled rules of construction and weighing evidence with the assistance of expert testimony. This might be a relevant response if Lilly were claiming a lack of procedural fairness, but it is not.") and para. 22 ("[Claimant] is not asking this Tribunal to assess *at all* whether the court decisions were correctly decided under *Canadian* Law.") (emphasis added).

jurisprudence that it called the promise utility doctrine.[154] Canada made its jurisdictional objection in its next submission to the Tribunal, its Rejoinder. Such a jurisdictional objection was, accordingly, timely even under Article 21(3) of the UNCITRAL Arbitration Rules.

2) Claimant Suffered No Prejudice From Canada Raising Its Objection in Its Rejoinder

82. Article 21(3) establishes the statement of defence as the time for known jurisdictional objections to be made because of the structure of the UNCITRAL Arbitration Rules. As noted above, and in Canada's oral submissions, under the 1976 UNCITRAL Arbitration Rules, the presumption is that the statement of defence will be the only written submission from the respondent prior to oral submissions at the hearing. Article 21(3) of the Rules must be understood in this context. It operates to prevent surprise and prejudice to a claimant at the hearing by ensuring that a claimant is on notice of, and can respond to, jurisdictional objections in its oral submissions.[155]

83. Claimant was not prejudiced by Canada submitting its jurisdictional objection in its Rejoinder. Canada raised its jurisdictional objection six months before the hearing.[156] Moreover, Claimant was given an opportunity by the Tribunal to make a further written submission, to which Canada was not permitted to respond in writing.[157] Tellingly, when seeking to explain at the hearing the prejudice it allegedly suffered, all Claimant could argue was that Canada's submission of its jurisdictional objection in its Rejoinder "prejudiced Lilly by creating the need for additional briefing, of course, which was granted by this Tribunal, increasing arbitration costs and compromising efficiency."[158] This argument is meritless. Regardless of when Canada raised its objection, additional

[154] Cl. Reply, paras. 70, 173 and 211.

[155] *See also*, Opening Statement of Canada, May 30, 2016, pp. 254:21 – 255:4.

[156] Canada's Rejoinder was filed on December 8, 2015 and the hearing commenced on May 30, 2016, five months and three weeks later.

[157] Procedural Order No. 3, paras.1-2.

[158] Closing Statement of Claimant, June 8, 2016, p. 2009:21-24.

briefing would have been required by the parties. The fact that such briefing came later and in a separate submission is not evidence of any sort of prejudice, especially given how far in advance of the hearing such briefing occurred. In light of the above, even if the Tribunal finds that Canada could and should have raised its jurisdictional objection earlier in the process, Article 21(3) cannot be read to prevent the Tribunal from considering it in these particular circumstances.

3) An Objection to the Jurisdiction of the Tribunal Pursuant to Articles 1116(2) and 1117(2) Cannot Be Waived

84. Finally, even if the Tribunal finds that Canada could and should have raised this jurisdictional objection in its earlier pleadings, the Tribunal must still address it and determine whether it in fact has jurisdiction under NAFTA Chapter Eleven to consider Claimant's claims.

85. It is undisputable that the jurisdiction of an arbitral tribunal extends only so far as the extent of the consent of the parties to the arbitration agreement. In a commercial arbitration, the consenting parties are both before the arbitral tribunal. Accordingly, the parties can agree at any point, if they so desire, to vary the terms of the tribunal's jurisdiction as long as such variation is consistent with applicable mandatory law.[159]

86. However, in the context of treaty-based investment arbitration, variation of the terms of a State Party's consent to arbitration in the context of any particular dispute is not possible, unless allowed for in the treaty, because it would amount to an amendment of the terms of the underlying treaty itself. Therefore, in a treaty-based investor-State arbitration, in order to ascertain the limits of its jurisdiction, the Tribunal must look not to the conduct or agreement of the particular disputing parties before it, but rather to the terms of the treaty by which it is governed and the agreement of the States that are Parties to it.[160]

[159] *See also*, Closing Statement of Canada, 2238:19-2239:19.

[160] *See also*, Closing Statement of Canada, June 8, 2016, pp: 2175:3 – 2176:16 ("…MR. BORN: Why exactly is it that you think that the substantive rules of State responsibility would be applicable but that

87. The UNCITRAL Arbitration Rules do not alter this fundamental fact. Indeed, even in the context of commercial arbitration, the subsidiarity of the UNCITRAL Arbitration Rules is acknowledged in the Rules themselves. Article 1(2) of the Rules provides "These Rules shall govern the arbitration except that where any of these Rules is in conflict with a provision of the law applicable to the arbitration from which the parties cannot derogate, that provision shall prevail." This subsidiarity is also made clear in NAFTA Article 1120(2), which expressly states that the "applicable arbitration rules shall govern the arbitration except to the extent modified by this Section."

88. In NAFTA Article 1122(1), the NAFTA Parties provided that "Each Party consents to the submission of a claim to arbitration in accordance with the procedures set out in this Agreement" (emphasis added). Article 1116(2) sets out one of the several limits on the consent of the NAFTA Parties to arbitration – specifically that the NAFTA Parties agree to arbitrate claims only if the claims are brought to arbitration within three years of the claimant knowing about the measures in question and loss. Nothing in the UNCITRAL Arbitration Rules, including Article 21(3), can expand the jurisdiction of a Chapter Eleven tribunal contrary to the express restrictions on that jurisdiction contained in Chapter Eleven of NAFTA. The temporal limit on this Tribunal's jurisdiction is clear and it cannot be waived or otherwise altered by the actions of the parties in this arbitration.

B. Claimant Did Not Bring Its Claim Within the Time Limit Established By Articles 1116(2) and 1117(2)

89. Claimant submitted this claim to arbitration on September 12, 2013 – nearly four years after the judicial doctrine it alleges breaches Canada's obligations under NAFTA was first applied to it causing it loss in the litigation relating to its raloxifene patent. As such, Claimant failed to satisfy the preconditions to Canada's consent to arbitrate

other substantive rules, like say estoppel or jurisdictional limitations, wouldn't be? … MR. SPELLISCY: I think that the question there would be a little bit confined by what is the treaty saying, so some of the rules of estoppel, some of the rules of waiver might be applicable on certain things, but it really would come down to, when we talk about Article 1116(1), that there are things that the treaty itself will trump in that.")

articulated in NAFTA Articles 1116(2) and 1117(2). Its challenge to the interpretations given to the term "useful" in Canada's *Patent Act* in decisions rendered by the Canadian courts between 2002 and 2008 is, therefore, beyond the jurisdiction of the Tribunal.

1) NAFTA Articles 1116(2) and 1117(2) Establish a Strict Three-Year Statute of Limitations for NAFTA Claims

90. The consent of the NAFTA Parties to arbitrate disputes is conditioned upon compliance with the procedures established in NAFTA Chapter Eleven.[161] Adherence to the time limits for filing a claim that are set out in Articles 1116(2) and 1117(2) is one of the preconditions to Canada's consent.

91. Article 1116(2) states:

> An investor may not make a claim if more than three years have elapsed from the date on which the investor first acquired, or should have first acquired, knowledge of the alleged breach and knowledge that the investor has incurred loss or damage.

92. Similarly, Article 1117(2) provides:

> An investor may not make a claim on behalf of an enterprise described in paragraph 1 if more than three years have elapsed from the date on which the enterprise first acquired, or should have first acquired, knowledge of the alleged breach and knowledge that the enterprise has incurred loss or damage.

[161] NAFTA Article 1122 (Consent to Arbitration) states: "Each Party consents to the submission of a claim to arbitration in accordance with the procedures set out in this Agreement." *Apotex Award*, para. 335 (concluding that the tribunal had no jurisdiction *rationae temporis* over measures that fell outside NAFTA Chapter Eleven's three-year limitations period) (**RL-016**); *Methanex Corporation v. United States of America*, (UNCITRAL), Partial Award, 7 August 2002, para. 120 ("In order to establish the necessary consent to arbitration, it is sufficient to show (i) that Chapter 11 applies in the first place, i.e. that the requirements of Article 1101 are met, and (ii) that a claim has been brought by a claimant investor in accordance with Articles 1116 and 1117 (and that all pre-conditions and formalities required under Articles 1118-1121 are satisfied) (**RL-088**). Where these requirements are met by a claimant, Article 1122 is satisfied; and the NAFTA Party's consent to arbitration is established."); *Bilcon of Delaware Inc. v. Government of Canada*, (PCA/UNCITRAL), Award, 17 March 2015 ("*Bilcon Award*"), paras. 266-282 and 742 (finding that events that occurred outside the three-year limitations period were beyond the tribunal's jurisdiction) (**CL-166**).

93. Articles 1116(2) and 1117(2) impose a strict three-year limitations period on NAFTA Chapter Eleven claims.[162] The word "first" means "earliest in occurrence, existence."[163] Accordingly, the NAFTA Parties have consistently agreed that the limitations period for an alleged breach starts from the moment the claimant *first* acquires (1) knowledge of the breach and (2) knowledge that it has suffered some type of cognizable loss or damage.[164]

2) Claimant Had Knowledge of the Alleged Breach More than Three Years Prior to Submitting its Claim to Arbitration

94. Claimant challenges three aspects of Canadian law as violations of Canada's obligations under NAFTA Articles 1110 and 1105. First, Claimant alleges that in 2005, Canadian law changed such that patents are now required to meet promises of utility found in the disclosure. Second, it alleges that in 2002, Canadian law changed to impose a heightened evidentiary burden, notably by refusing to admit post-filing evidence to prove utility. Third, it alleges that Canadian law changed in 2008 to require that the basis for a sound prediction be disclosed in the patent. Claimant alleges that these three aspects together form the so-called "promise utility doctrine", and admits that the

[162] *Apotex Award*, paras. 314-335 (finding that the FDA's 11 April 2006 decision could not be the basis for a NAFTA claim because it occurred more than three-years prior to when Apotex filed its Notice of Arbitration (4 June 2009)) (**RL-016**). *See also*, *Feldman Award*, para. 63 (**RL-058**); *Grand River Decision on Objections to Jurisdiction*, paras. 24, 29, 38 and 103-104 (**RL-090**); *Bilcon Award*, paras. 258-282 (**CL-166**); W. Michael Reisman, *Opinion with Respect to the Effect of NAFTA Article 1116(2) on Merrill & Ring's Claim, April 22, 2008*, para. 28 ("Reisman Expert Opinion") ("It takes great effort to misunderstand Article 1116(2). It establishes that the challenge of the compatibility of the measure must be made within three years of first acquiring (i) knowledge of the measure and (ii) that the measure carries economic cost for those subject to it. If the challenge is not made within those three years, it is time-barred.") (**R-431**). *See also*, U.S. 1128 Submission, paras. 2-4; Mexico 1128 Submission, paras. 4-8.

[163] *Shorter Oxford English Dictionary*, 5th ed. (Oxford University Press, 2002), p. 965 (**R-432**).

[164] *Merrill & Ring Forestry L.P. v. Canada*, (UNCITRAL), 1128 Submission of the United States, 14 July 2008, para. 10 (**RL-091**); *Merrill & Ring Forestry L.P. v. Canada*, (UNCITRAL), 1128 Submission of Mexico, 2 April 2009, (**RL-092**); *William Ralph Clayton,William Richard Clayton, Douglas Clayton, Daniel Clayton, and Bilcon Of Delaware Inc. v. Government of Canada*, (UNICTRAL), Submission of the United States of America, 19 April 2013, para. 12 (**RL-094**); *Detroit International Bridge Company v. Canada*, (UNCITRAL), Submission of the United States of America, 14 February 2014, para. 3 (**RL-095**); *Detroit International Bridge Company v. Canada*, (UNCITRAL), Reply of the Government of Canada to the NAFTA Article 1128 Submission of the Governments of the United States of America and the United Mexican States, 3 March 2014, para. 29 (**RL-154**); Resp. Rejoinder, paras. 72-80; U.S. 1128 Submission, para. 4; Mexico 1128 Submission, para. 5.

doctrine was fully crystallized in Canadian law no later than 2008.[165] Further, the evidence confirms that Claimant was aware of the alleged radical change in Canadian law that it claims violates Canada's NAFTA obligations by no later than 2008.[166]

95. Specifically, all three aspects of Canadian law that Claimant now alleges violate Canada's obligations were applied by the Canadian Federal Court in 2008 in a

[165] Opening Statement of Claimant, May 30, 2016, pp. 47:17 – 48:12 ("THE PRESIDENT: Before we do that, you pointed us to the court decisions which is at C-160 and Paragraph 121, Slide 37. You see in 121, in the penultimate line, it says -- let me read the full sentence – 'The disclosure issue, however, has been determined by earlier decisions that are binding upon me and to the extent that it may be amenable to reconsideration, it must be examined elsewhere.' Which are the earlier decisions which the judge says are 'binding upon me'? You need not answer now. You may wish to do that through your expert testimony. MS. CHEEK: That is not a specific reference to the Strattera litigation itself; it's a reference to the fact that there is earlier case law that's been applying the disclosure rule that was first articulated in Raloxifene in 2008, and then courts have been applying that since then. THE PRESIDENT: Those are the earlier decisions? MS. CHEEK: Yes."); Closing Statement of Claimant, June 8, 2016, pp. 1994:2 – 1995:19 ("But what we are looking at is what was the utility test in Canada that was applied to our patents, and that would include all three of the elements that we've discussed over the course of the last week, 2002, 2005 and 2008… The utility standard that was applied to these patents invalidate them in 2010 and 2011 was crystallized in 2008 with the Raloxifene decision. However, there were decisions even before the Raloxifene decision that were applying the promise utility doctrine. So you will recall a question that came up at the opening, which is at what point did Canada have this new and different test. And in our view, that's 2005. But this latent component of it, the disclosure requirement, does not come to fruition or crystallize until 2008.")

[166] Armitage, May 31, 2016, pp. 348:16 – 349:8 ("MR. SPELLISCY: But then it goes on, "I also received regular reports from attorneys" – the sentence goes on -- "on significant changes to patent law and policy in each of Lilly's major markets." MR. ARMITAGE: That's correct. MR. SPELLISCY: So those briefings, then, would have related to changes in patent law and how they would affect Lilly's patents in those major markets, correct. MR. ARMITAGE: That would be correct, yes."); Armitage, May 31, 2016, pp. 380:12 – 388:1; Postlethwait, May 31, 2016, pp. 425:15 – 426:22 ("MS. ZEMAN: And you worked closely with Lilly's legal team for this aspect of the product launch. Is that right? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And you expected them to monitor changes in the patent systems of launch countries? MR. POSTLETHWAIT: Yes. MS. ZEMAN: Including in Canada? MR. POSTLETHWAIT: Yes…I did presume that they would be totally informed and very competent in this space and be attuned to any material changes, yes. 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. POSTLETHWAIT: Yes"); Nobles May 31, 2016, pp. 444:1 – 444:23 ("MS. ZEMAN: And you expected the patent attorneys to monitor developments in the patent law framework of your launch countries. Is that right? MS. NOBLES: …I relied on and what our team relied on was the information from that lawyer assessing patents where that was appropriate, the probability or likelihood that we would get a patent, and so forth. MS. ZEMAN: And, in that reliance, you would expect the information that was provided to you by the patent attorney to be up-to-date and current? MS. NOBLES: That's correct. MS. ZEMAN: And if there was a fundamental change that presented a potential risk to the validity of your patents, you would expect your patent attorney to advise you of that? MS. NOBLES: That's correct.") *See also*, Armitage Second Statement, paras. 5 ("…I received regular reports from the attorneys in my office on litigation risks across Lilly's global patent portfolio, as well as on significant changes to patent law and policy in each of Lilly's major markets.") and 44 ("…risks associated with validity challenges can generally be accounted for in advance.")

PM(NOC) proceeding involving Claimant's patent with respect to raloxifene.[167] The decision was affirmed by the Federal Court of Appeal in March 2009,[168] and leave to appeal to the Supreme Court was denied in October 2009.[169] As a result, there can be no dispute that Claimant was aware of the exact alleged judicial doctrine that it alleges violates Canada's obligations under NAFTA by 2008 (when the decision was rendered by the Federal Court) or, in the alternative, no later than October 2009 (when the final leave to appeal that decision was denied).

3) Claimant Had Knowledge of Loss Arising From the Alleged Breach More than Three Years Prior to Submitting its Claim to Arbitration

96. On March 30, 2009, five days after the Federal Court of Appeal affirmed the decision of the Federal Court in the raloxifene litigation, the Canadian Minister of Health issued a Notice of Compliance ("NOC") to Apotex.[170] As a result, Apotex was allowed to enter the market with its generic raloxifene product. Consequently, on this date, Claimant suffered a loss as a result of the exact same law and jurisprudence that it is challenging as a breach of NAFTA in this arbitration. The fact that the raloxifene decision was rendered in the context of a PM(NOC) proceeding, and not in an impeachment or an infringement proceeding, is irrelevant to the issue of loss.[171] While a

[167] *Eli Lilly Canada Inc. v. Apotex Inc. et al*, 2008 FC 142 ("*Raloxifene FC*"), paras. 1-5 and 74-78 (finding promises in the patent, including in the disclosure), para. 126 (considering the question to be whether the evidence existing at the time of filing was sufficient to have demonstrated or soundly predicted the promised utility) and paras. 156-157, 160-164 (finding that while a study that existed on the filing date was sufficient to ground a sound prediction of utility, that study could not be relied upon because it had not been disclosed) (**R-200**). S*ee generally*, Patent Specification 2,101,356 (**R-429**).

[168] *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97 ("*Raloxifene FCA*"), paras. 18, 37 and 71 (**R-354**).

[169] *Eli Lilly Canada Inc. v. Apotex Inc.*, [2009] SCCA No. 219 (**R-447**).

[170] Health Canada, Drugs and Health Products, Notice of Compliance Information, "Apo-Raloxifene" (**R-473**).

[171] c*f.* Closing Statement of Claimant, June 8, 2016, pp. 2067:1 – 2068:11("SIR DANIEL BETHLEHEM: …I'm just trying to establish whether if we accept everything that you say about the newness of the Canadian, as you describe it, promise utility doctrine, does that mean that in response to the judgment of Hughes J. in 2008 in respect of Raloxifene, that you would have had a cause of action in respect of the Raloxifene patent? MS. WAGNER: Technically probably no, although we didn't have to contend with this issue, because it was not finally invalidated in those proceedings. The patent was not revoked, if you will. There were PM(NOC) proceedings. The leave to appeal that was sought to the Supreme Court of Canada was in the context of PM(NOC) proceedings. Had Lilly continued down a path of litigation, they would have been entitled to bring an infringement action, and then that would have -- if the same doctrine had

PM(NOC) proceeding does not result in the invalidation of a patent,[172] the fact is that Apotex was allowed to enter the market, causing Claimant loss, because of the application of the exact same judicial doctrine which Claimant now alleges violates NAFTA.

4) The Fact that the Doctrine Was First Applied to a Different Patent Held by Claimant in 2008 is Irrelevant

97. It is not relevant that in 2008 the allegedly breaching measures were applied to Claimant's raloxifene patent, rather than its patents with respect to atomoxetine and olanzapine. The language of Article 1116(2) is that the limitations period commences when the "investor first acquire[s]…knowledge of the alleged breach and knowledge that the investor has incurred loss or damage" (emphasis added).[173] Thus, for the limitations period to commence, the "investor" must only have "knowledge that the investor has incurred loss or damage." There is no requirement that the loss or damage be specific or certain as to amount.[174] The Tribunal should not read any of these requirements into the plain text of Article 1116(2) and Article 1117(2).

98. Claimant has not alleged any change in the judicial doctrine that it challenges since the decision of the Federal Court in the case involving its raloxifene patent.[175]

been applied there and that had gone before the courts, of course it would be the same claim as exists today. But that was not the case. The decision was not a revocation of the patent.")

[172] Dimock Report, para. 44. *See also,* Resp. CM., para. 141.

[173] Similarly, the equivalent language in Article 1117(2) states that the limitations period commences when the "the enterprise first acquire[s] … knowledge of the alleged breach and knowledge that the enterprise has incurred loss or damage."

[174] *Mondev Award* (**RL-004**); *Grand River Decision on Objections to Jurisdiction*, paras. 77-78 (**RL-090**). *See also,* Resp. Rejoinder, para. 76; Opening Statement of Canada, May 30, 2016, p. 260:13:18.

[175] Closing Statement of Claimant, June 8, 2016, p. 1995:1-19 ("SIR DANIEL BETHLEHEM: Can I just follow up on that? Are you then saying that in your view, the utility standard crystallized the Raloxifene decision? I appreciate you say the breach occurred in 2011 and following with the decisions in respect of Zyprexa and Strattera, but are you saying the utility standard crystallized in 2008 with the last of the trilogy as it were in the sequence. MS. CHEEK: The utility standard that was applied to these patents invalidate them in 2010 and 2011 was crystallized in 2008 with the Raloxifene decision. However, there were decisions even before the Raloxifene decision that were applying the promise utility doctrine. So you will recall a question that came up at the opening, which is at what point did Canada have this new and

Indeed, Claimant is not claiming that the alleged promise utility doctrine was merely developing in 2008. As was made clear at the hearing, Claimant's allegation is that the doctrine was complete and fully crystallized by that date.[176] The allegation is that since 2008, Canadian courts have simply continued to apply the same allegedly breaching promise utility doctrine to the different patents that have come before them.

99. The NAFTA Parties agree in their submissions in this arbitration,[177] and in all previous Chapter Eleven arbitrations where the issue has arisen,[178] that the limitations

different test. And in our view, that's 2005. But this latent component of it, the disclosure requirement, does not come to fruition or crystallize until 2008.")

[176] Opening Statement of Claimant, May 30, 2016, pp. 47:17 – 48:12; Closing Statement of Claimant, June 8, 2016, pp. 1994:1 – 1995:18.

[177] Resp. CM., para. 72 ("The use of the word "first" … mark[s] the beginning of the time when knowledge of breach and a loss existed, and not the middle or end of a continuous event or series of events. In other words, once the investor first acquires knowledge of the alleged breach and that it has suffered damage, the limitations period for filing a claim commences and will end at the three-year mark regardless of whether the impugned measure continues thereafter."); US 1128 Submission, para. 4 ("under Articles 1116(2) and 1117(2), knowledge is acquired as of a particular "date." Such knowledge cannot first be acquired at multiple points in time or on a recurring basis …once a claimant first acquires (or should have first acquired) knowledge of breach and loss, subsequent transgressions by the State Party arising from a continuing course of conduct do not renew the limitations period under Articles 1116(2) or Article 1117(2)."; Mexico 1128 Submission, para. 7 ("neither a continuing course of conduct nor the occurrence of subsequent acts or omissions can renew or interrupt the three-year limitation period once it has commenced to run.")

[178] *Merrill & Ring Forestry L.P. v. Canada*, (UNCITRAL), 1128 Submission of the United States, 14 July 2008 ("*Merrill & Ring Submission of the United States*"), para. 5 ("An investor first acquires knowledge of an alleged breach and loss at a particular moment in time: under Article 1116(2), that knowledge is acquired on a particular 'date'. Such knowledge cannot first be acquired on multiple dates, nor can such knowledge first be acquired on a recurring basis...[O]nce an investor first acquires knowledge of breach and loss, subsequent transgressions by the State arising from a continuing course of conduct do not renew the limitations period under Article 1116(2)."") (**RL-091**); *See Merrill & Ring Forestry L.P. v. Canada*, (UNCITRAL), 1128 Submission of Mexico, 2 April 2009 ("*Merrill & Ring Submission of Mexico*"), para. 5 ("concurring 'in its entirety' with the United States Article 1128 submission") (**RL-092**); *Merrill & Ring Forestry L.P. v. Government of Canada*, (UNCITRAL), Rejoinder Memorial, 27 March 2009, ("*Merrill & Ring Rejoinder Memorial*"), paras. 24-51 (**RL-093**); *William Ralph Clayton,William Richard Clayton, Douglas Clayton, Daniel Clayton, and Bilcon Of Delaware Inc. v. Government of Canada* (UNICTRAL), Submission of the United States of America, 19 April 2013, para. 12 (stating in the footnote that "The United States' views on the interpretation of NAFTA Articles 1116(2) and 1117(2) are reflected in the attached non-disputing Party submission of July 14, 2008 in the NAFTA Chapter Eleven case *Merrill & Ring Forestry, L.P. v. Canada*.") (**RL-094**); *Detroit International Bridge Co. v. Canada*, (NAFTA/UNCITRAL), (PCA Case No. 2012-25) Submission of the United States of America, 14 February 2014, ("*DIBC Submission of the United States*"), para. 3 (**RL-095)**; *Detroit International Bridge Co. v. Canada* (NAFTA/UNCITRAL), (PCA Case No. 2012-25), Submission of Mexico Pursuant to Article 1128 of NAFTA, 14 February 2014, para. 21 (**RL-096**); *Mercer Submission*, paras. 4-6 (**RL-097**); *Marvin Feldman v. Mexico*, ICSID Case No. ARB(AF)/99/1, Respondent's Counter-Memorial on

period they negotiated in Articles 1116(2) and 1117(2) does not start in the middle or end of a continuous event or series of events, and it is not renewed simply because of the continuing application of the allegedly breaching measures.

100. Tribunals and scholars interpreting these provisions have appropriately accepted the NAFTA Parties' shared views on the interpretation and application of Articles 1116(2) and 1117(2).[179] The only NAFTA tribunal to suggest that the continued application or effect of an impugned measure extends the limitations period until the measure is revoked is *UPS v. Canada*.[180] All three NAFTA Parties agree that the *UPS* tribunal was incorrect on this issue.[181] No other NAFTA tribunal has endorsed the *UPS* tribunal's notion that a continuing breach tolls the three-year limitations period.

Preliminary Questions, 8 September 2000, paras. 189 and 199 (**RL-098**); *Bilcon of Delaware Inc. v. Government of Canada*, (PCA/UNCITRAL), Rejoinder, 21 March 2013, paras. 54-60 (**RL-099**); *Detroit International Bridge Co. v. Canada* (NAFTA/UNCITRAL), (PCA Case No. 2012-25), Canada's Memorial on Jurisdiction and Admissibility, 15 June 2013, paras. 206-214 (**RL-100**); *Detroit International Bridge Co. v. Canada* (NAFTA/UNCITRAL), (PCA Case No. 2012-25), Canada's Reply Memorial on Jurisdiction and Admissibility, 6 December 2013, paras. 153-156 (**RL-101**); *Detroit International Bridge Co. v. Canada* (NAFTA/UNCITRAL), (PCA Case No. 2012-25), Canada's Reply to NAFTA Article 1128 Submissions, 3 March 2014, ("DIBC Canada's Reply to NAFTA Article 1128 Submissions"), paras. 26-33 (**RL-102**).

[179] As Professor Reisman has explained, "an investor does not and logically cannot 'first acquire' knowledge of the allegedly incompatible measure that constitutes the challenged 'breach' *repeatedly*." Reisman Expert Opinion, para. 29 (emphasis in original) (**R-431**); *Feldman Award*, para. 63 (describing the provisions as a "clear-cut" three-year limitations period and "a clear and rigid limitation defense, which, as such, is not subject to any suspension…, prolongation or other qualification.) (**RL-058**); *Grand River Decision on Objections to Jurisdiction*, paras. 29 and 81 (holding that another interpretation would "render the limitations provisions ineffective in any situation involving a series of similar and related actions by a respondent State, since a claimant would be free to base its claim on the most recent transgression, even if it had knowledge of earlier breaches and injuries.") (**RL-090**).

[180] *United Parcel Service v. Canada*, (UNCITRAL), Award on the Merits, 24 May 2007 ("*UPS Merits Award*") (**RL-103**).

[181] *Merrill & Ring Submission of the United States*, 14 July 2008, paras. 5 and 10 (explaining "Under the UPS tribunal's reading of Article 1116(2), for any continuing course of conduct the term 'first acquired' would in effect mean 'last acquired,' given that the limitations period would fail to renew only after an investor acquired knowledge of the State's final transgression in a series of similar and related actions. Accordingly, the specific use of the term 'first acquired' under Article 1116(2) is contrary to the UPS tribunal's finding that a continuing course of conduct renews the NAFTA Chapter Eleven limitations period.") (**RL-091**). *See also*, *Merrill & Ring Submission of Mexico*, p. 5 (**RL-092**). *See also*, Resp. Rejoinder, para. 79; US 1128 Submission, para. 4; Mexico 1128 Submission, para.5.

101. Similar to the conclusion of the tribunal in the *Grand River* arbitration, allowing this case to proceed with respect to the application of the same measures to different patents would render the limitations provisions ineffective "because it would allow Claimant to base its claim on the most recent transgression, even if it had knowledge of earlier breaches and injuries."[182] Indeed, allowing Claimant to proceed here would mean that there is no statute of limitations at all with respect to judicial doctrines because courts only ever decide the specific disputes in front of them.

102. In short, Claimant cannot have first acquired knowledge of the alleged NAFTA breach in the raloxifene proceedings with respect solely to its raloxifene patent, and then again first acquired knowledge of the alleged breach years later with respect to its atomoxetine and olanzapine patents. The fact that the impugned "promise utility doctrine" continued to affect Claimant's other investments is irrelevant for the purpose of the limitations period imposed by NAFTA.

103. However, in the alternative, even if the Tribunal were to consider the challenged judicial doctrine solely with respect to Claimant's patents for atomoxetine and olanzapine, the conclusion it should reach here as to the application of Article 1116(2) and Article 1117(2) is no different. Claimant lost the PM(NOC) proceeding with respect to its raloxifene patent in 2008. Claimant appealed the decision both to the Federal Court of Appeal and the Supreme Court of Canada. Neither reversed the decision of the Federal Court. Claimant knew of the content of Canadian law and the existence of what it alleges to be the promise utility doctrine by certainly no later than October 22, 2009, when its leave to appeal to Canada's Supreme Court was considered, but denied.

104. Mr. Armitage, Claimant's former General Counsel, explained during his testimony that "as patent laws develop and to the extent they're material," Claimant evaluated legal risks to its existing patents.[183] He further confirmed that "there's an

[182] *Grand River Decision on Objections to Jurisdiction*, para. 81 (**RL-090**).

[183] Armitage, May 31, 2016, pp. 391:19 – 392:20 ("SIR DANIEL BETHLEHEM: … You testified about the economic value of patents in the context of the acquisition of patents by Lilly. Counsel for Canada

entire due diligence process within Lilly in all other countries to look at material assets, patents being most material in our industry, and attempting to do regulatory assessments of risk to the extent that they're material to the company."[184] He also confirmed that this was not limited to matters in which Claimant was in litigation,[185] and that the atomoxetine and olanzapine patents "were material to our Canadian business and our Canadian affiliate."[186]

105. In light of this testimony, there can be no doubt that after the raloxifene decision in 2008, and especially after leave to appeal was denied by the Supreme Court in 2009, Claimant would have assessed the risk of the allegedly newly crystallized promise utility doctrine with respect to its patents for atomoxetine and olanzapine. Because Claimant has not alleged that the promise utility doctrine was improperly applied in the proceedings related to its patents for atomoxetine and olanzapine,[187] it must be assumed that Claimant, who employed an array of Canadian patent lawyers,[188] understood how that doctrine would affect those patents. For example, with respect to atomoxetine, Claimant knew that it had disclosed nothing at all in its patent regarding the factual basis

took you to the Raloxifene decisions of 2008 and 2009. Insofar as you can respond to this question from your knowledge as senior vice-president of Lilly, would Lilly have been required to have made any regulatory or financial filings following the Raloxifene decision indicating a risk associated with its subsequent patents in Canada? MR. ARMITAGE: As patent laws develop and to the extent they're material, we actually do -- and there's an entire due diligence process within Lilly in all other countries to look at material assets, patents being the most material in our industry, and attempting to do regulatory assessments of risk to the extent that they're material to the company. So we report not only individual litigation matters but material developments otherwise. So I'd have to go back and actually look at our regulatory filings to determine whether these would have been material to the company as a whole. Clearly they were material to our Canadian business and our Canadian affiliate.")

[184] Armitage, May 31, 2016, pp. 391:19 – 392:20.

[185] Armitage, May 31, 2016, pp. 391:19 – 392:20.

[186] Armitage, May 31, 2016, pp. 391:19 – 392:20.

[187] Cl. Reply, para. 221.

[188] Armitage, May 31, 2016, p. 344:14-19 ("MR. ARMITAGE: Absolutely. If there had been material developments in the Canadian law on utility, there would have been any number of communications back and forth between Lilly's in-house patent attorneys and its Canadian patent agents.")

and sound line of reasoning needed to support a sound prediction of utility.[189] Thus, it would have known after raloxifene that, if challenged, its patent for atomoxetine could not rely on the doctrine of sound prediction and, thus, was at greater risk of being invalidated. Accordingly, with respect to atomoxetine and olanzapine, given the lack of data supporting those patents when they were filed, Claimant knew of at least some loss of value after the decision in raloxifene.[190] In short, in light of the facts of this case, it was not necessary for Claimant to have the specific patents at issue in this arbitration invalidated for the statute of limitations in Articles 1116(1) and 1117(1) to commence running.

[189] Patent Specification CA 1,181,430 ("'430 Patent"), p. 20, line 5 ("[t]he compound of this invention is used as an antidepressant in the method of this invention, which comprises administering to a human suffering from depression an effective antidepressant dose of the compound") (**R-269**).

[190] Armitage, May 31, 2016, p. 356:1-14 ("MR. SPELLISCY: Right. Which is why I asked my question, first of all, domestic litigation. I assume this was a practice Lilly was doing in every jurisdiction. If it lost a patent in any jurisdiction, it would consider the implications of that decision for the other patents it held in that jurisdiction, correct? MR. ARMITAGE: Yes. And again, there's no general rule here. I mean there are situations in which you receive an adverse decision that, for example, you believe is wrong and won't be replicated and, therefore, the decision taken is no decision, that this anomaly need not affect our strategy or our practices.") and May 31, 2016, pp. 358:16 – 359:16 ("MR. SPELLISCY: And if you thought, in doing that due diligence, that there was a risk that the patent would not survive an invalidity challenge, that would affect the price that you were willing to pay for that patent, correct? MR. ARMITAGE: Well, in -- you're getting now into an area where you want my opinions and how to do market value assessments for intellectual property, which I'm a little reluctant to do, but let me just make this observation. By and large, these assets have a binary character. If you buy a piece of property, either you get a valid title or you don't. And if you're going to build your business on the assumption that you're going to have a valid title, then you basically need to have assurance that you can defend that title. So to a certain degree you have to, in a due diligence assessment, make that binary assessment, we're going to build a business on the assumptions the patent is valid and can be enforced. And then it's very difficult to get in a real world economic negotiation some discount based on some hypothetical probability that that patent might be invalidated. So there's a real world context to this that is sort of at a disconnect given the binary nature of the acquisition of most assets.") *See also*, Armitage Second Statement, para. 44 ("…neither Lilly nor any other firm I am aware of would put off the acquisition of a patent owned by another company until after someone brings litigation to challenge the validity of the patent.")

IV. CLAIMANT'S CLAIM FAILS BECAUSE THERE HAS BEEN NO DRAMATIC CHANGE IN THE WAY THE CANADIAN COURTS INTERPRET THE TERM "USEFUL" IN CANADA'S *PATENT ACT* SINCE CLAIMANT MADE ITS INVESTMENTS

106. Even if the Tribunal determines that this claim should not be dismissed for the reasons above, it still fails because it necessarily relies on a false factual predicate.[191] Claimant stakes its claims in this arbitration on the allegation that there was a dramatic change in how the Canadian courts interpreted the utility requirement in Canada's *Patent Act* after its olanzapine and atomoxetine patents were granted.[192] As Canada explained at the hearing, Claimant has done so because if such dramatic change did not occur, this Tribunal would not have jurisdiction *ratione temporis* over Claimant's claim.

107. Claimant only advances claims under NAFTA Articles 1110 and 1105, both of which address the treatment of investments rather than investors. NAFTA tribunals have repeatedly held that they do not have jurisdiction over measures that existed prior to the establishment of the investment which has been accorded the allegedly breaching treatment.[193] Claimant is clear that the only investments at issue in this arbitration are the specific patents for olanzapine and atomoxetine.[194] Those investments did not exist

[191] *See also*, Opening Statement of Canada, May 30, 2016, p. 276:8 – 279:20; Opening Presentation of Canada, Slides 133-137; Closing Statement of Canada, June 8, 2016, p. 2160:13-21.

[192] Cl. Mem, paras. 56 ("In the mid-2000s, after the patents for Zyprexa and Strattera had been examined and granted, but prior to their invalidation by the courts, Canada's patent utility law underwent a dramatic transformation."), 76, 185, 228 and 230 ("There is a material difference between nuanced developments in common law relating to existing patentability requirements and the creation of entirely new and additional grounds for revocation that did not exist when the Zyprexa and Strattera patents were granted.").

[193] *Mesa Award*, para. 236 ("As a consequence investment arbitration tribunals have repeatedly found that they do not have jurisdiction *ratione temporis* unless the claimant can establish that it had an investment at the time that the challenged measure was adopted.") (**RL-159**); *Gami Investments Inc. v. Government of the United Mexican States* (NAFTA/UNCITRAL), Award (15 November 2004), para. 93 ("NAFTA arbitrators have no madate to evaluate laws and regulations that predate the decision of a foreigner to invest.") (**CL-108**). *See also*, Opening Statement of Canada, May 30, 2016, pp. 277:18 – 278:1; Opening Presentation of Canada, Slides 134-135; Closing Statement of Canada, June 8, 2016, p. 2160:17-20;

[194] Opening Statement of Claimant, pp. 10:5-9, 102:9-14 ("The fact that Lilly can produce and sell Zyprexa and Strattera does not mean that the protected investments in this arbitration, the '113 and '735 patents, have not been substantially or really in this case completely, deprived of value."); Cl. Mem., para. 4; Cl. Reply, para. 10; Claimant's Opposition to Respondent's Jurisdictional Objection, para. 3 ("Lilly has consistently sought redress under NAFTA Chapter 11 for the revocation of two specific investments in Canada: its patents for Zyprexa and Strattera.")

until the patents were issued by the Canadian patent office.[195] The olanzapine patent was granted on July 14, 1998,[196] and the atomoxetine patent was granted on October 1, 2002.[197]

108. As a result, Claimant has had to accept that if it cannot show that there was a dramatic change in Canadian law after the last of its patents was granted, then its claim should be dismissed.[198] The dramatic change in Canadian law alleged by Claimant is the creation of the so-called "promise utility doctrine". Claimant casts this as a "unitary doctrine" with the three parts identified above.[199]

109. Importantly, at the hearing Claimant clarified that its allegation of breach of Articles 1110 and Article 1105 is based only on all three of these alleged changes acting in concert. It made clear that it is not alleging a breach of Chapter Eleven based upon any single one of these parts taken separately.[200] Again, it is not the Tribunal's job to

[195] Cl. Mem., para. 286 ("Lilly's patents were legally enforceable the moment they were issued by the Canadian Intellectual Property Office.") (emphasis added); Reddon Report, para. 27 ("Canadian law explicitly recognizes that patents are legally enforceable immediately upon issuance and confer certain rights and obligations. Section 42 of the *Patent Act* establishes that, from the time of grant, the patent confers "the exclusive right, privilege and liberty or making, constructing and using the invention and selling it to others to be used". Other provisions of the *Act* and other aspects of Canadian law recognize that patents are legally enforceable on issuance. … As a practical matter, patentees can and often do exploit valuable rights in their patents following issuance … the parties to the contract consider that there is a property right to license upon issuance.") (emphasis added). *See also*, Opening Statement of Canada, May 30, 2016, pp. 278:18 – 279:1; Closing Statement of Canada, June 8, 2016, p. 2160:13-21.

[196] Patent Specification CA 2,041,113, ("'113 Patent") (**R-030**); Cl. Mem., para. 286 ("Respondent granted patents to Lilly on 14 July 1998 for Zyprexa … "). *See also*, Opening Presentation of Canada, Slide 137; Resp. CM, para. 43.

[197] Cl. Mem., para. 286 ("Respondent granted patents to Lilly … on 1 December 2002 for Strattera"); Patent Specification CA 2,209,735 ("735 Patent"), (**R-026**). *See also*, Opening Presentation of Canada, Slide 137; Resp. CM, para. 25.

[198] Closing Statement of Claimant, p. 2144:6-9 ("SIR DANIEL BETHLEHEM: You have to succeed on each one. MS. CHEEK: Yes, the Claimant would need to succeed on each of these."); Closing Presentation of Claimant, Slide 140, "The Tribunal's Decision Tree" ("2. Whether there has been a dramatic change in the utility requirement in Canada").

[199] *See* infra Section V.B., para. 239.

[200] Closing Statement of Claimant, June 8, 2016, p. 1997:4-11 ("MS. CHEEK: So it is not our case that each element taken separately would, on its own, constitute a violation, nor is it our view that that is the appropriate level of analysis, if you will. And the reason that that's not the appropriate level of analysis is because those are three components of a single holistic legal standard, the utility test in Canada.") Compare with Closing Statement of Claimant, June 8, 2016, p. 2033:16-23 ("MS. WAGNER: I just

rewrite Claimant's claim; rather, it must consider the claim as presented by Claimant. Accordingly, under Claimant's theory of its case, for this Tribunal to have jurisdiction, Claimant must establish that all three of these alleged interpretations of Canada's *Patent Act* are dramatically different from how the utility requirement was interpreted by the Canadian courts prior to 2002. If it fails to do so with respect to any single element, its entire claim must fail.

110. The evidence before the Tribunal, summarized below, shows that there has been no dramatic change in any – let alone all – of these aspects of Canadian law since Claimant made its investment. Specifically, for decades prior to Claimant making its investments, Canadian law required that (A) patentees must meet promises of utility in the disclosure, (B) utility must be established before filing for a patent, and (C) the basis for a sound prediction of utility must be disclosed in the patent.

A. The Canadian Courts Did Not Radically Alter their Interpretation of Canada's Utility Requirement in 2005 to Require Patentees to Meet Promises of Utility

1) Claimant Concedes that Patentees Have Always Been Held to Promises in the Claims

111. The central plank of Claimant's alleged "promise utility doctrine" is the idea that, beginning in 2005, Canadian law changed such that the courts began to hold patentees to promises of utility. However, Claimant has put forward inconsistent accounts of the change that it alleges occurred.

112. Claimant argued that before 2005, the sole standard of utility was that an invention must possess a "mere scintilla" of utility.[201] Claimant accepts that this standard

wanted to address, Sir Bethlehem, your opening question. I think I would say that hypothetically each element could possibly sustain a breach and maybe different breaches if we're looking at Chapter 17, but it's hypothetical and it's not possible to know, because the fact is that this is applied as a single construct, as a single test.").

[201] Opening Statement of Claimant, May 30, 2016, pp. 10:13-15 and 15:20-24; Cl. Mem., para. 45.

still exists in Canadian law today,[202] but alleges that the second branch of Canada's utility requirement, holding patentees to promises of utility, was completely new in 2005.

113. However, over the course of the arbitration, Claimant narrowed its allegations, conceding that patentees have always been held to promises of utility in the patent, so long as those promises were found in the claims.[203] The dramatic change that it now alleges occurred in 2005 is not holding patentees to promises of utility *per se*, but holding them to promises found in the disclosure portion of the patent.[204]

[202] Opening Statement of Claimant, May 30, 2016, p. 21:6-9 ("MS. CHEEK:…Canada's simple, mere scintilla, utility requirement that is a statutory test that existed at the time these patents were granted and continues to exist under Canadian law today..."); Cl. Mem., para. 57 ("…the traditional mere scintilla test for utility described above still exists under Canadian law …").

[203] Closing Statement of Claimant, June 8, 2016, p. 2056:2-6 ("MS. WAGNER: For the promise element, before the change in the law, courts had actually rejected the idea that utility could be defined or ought to be defined by statements in the disclosure if not claimed."); Closing Statement of Claimant, June 8, 2016, p. 2046:4-12 ("MS. WAGNER: At most, we'd argue that prior to 2005, the phrase "or more broadly, that it will not do what the specification promises that it will do "might be taken to mean that if the invention claims a particular result, it must be operable for that purpose. Because there is not always a use that is specifically claimed. There were certainly cases that we saw that stood for this unremarkable proposition..."); Siebrasse, May 31 2016, p. 560:13-16 ("MR. JOHNSTON: So does he include this case [*New Process Screw*] in his section on promise utility? PROFESSOR SIEBRASSE: Right, but the promise in this case was in the claims."); *Norman Siebrasse Form and Function in the Law of Utility: A Reply to Gold & Shortt* Canadian Intellectual Property Review, p. 49, ("To be sure, 'promises' found in the claims must be enforced, but this is a function of the actual utility and sufficiency requirements, not the promise doctrine.") (**R-497**); Cl. Reply, paras. 85-85; Siebrasse Second Expert Report, paras. 4 ("(1) under the promise of the patent, utility is assessed against a promise or promises derived from the disclosure of the patent") and 36 ("New Process Screw is not an example of the promise of the patent, because the 'promise' (which was not satisfied) was made in the claims, and no higher promise was construed from the disclosure (i.e. the 'promise' was simply the claimed use of the invention).")

[204] Reddon, June 1, 2016, p. 911:4-19 ("MR. REDDON: In my report, and I think I'm very clear, it's not so much suddenly we're going to take promises. It's we're going to stop looking in the claims for promises and start pulling them out of the disclosure … it really arose when we changed from the claims to the disclosure …"); Siebrasse, May 31, 2016, pp. 555:22 – 556:24 ("MR. JOHNSTON: As we've been discussing, on your view for a case to be an example of the promise utility doctrine, the promise must be derived from the disclosure, not from the claims. PROFESSOR SIEBRASSE: That's right. That's correct."); *Aventis Pharma Inc. v. Schering Corp.*, Memorandum of Fact and Law of Schering Corp., Federal Court File No. T-1742-03, 2005 IP Pleading 4297, 24 January 2005, p. 47 ("…it is not enough that the utility against which the patent is measured is set out in the specification; it must be set out in the disclosure.") (**R-487**). *See also*, Opening Statement of Canada, May 30, 2016, pp. 185:22 – 186:20; Opening Presentation of Canada, Slide 30.

114. Yet confusion persists about the precise change alleged by Claimant, since it continues to invoke as examples of the alleged promise utility doctrine cases where the promise was based on the language of the claims, not the disclosure. This includes the atomoxetine patent,[205] and cases such as that involving a patent for latanoprost.[206] In testimony, Professor Siebrasse attempted to characterize the latanoprost case as one where the promise was derived from the disclosure rather than the claims,[207] but this is flatly contradicted by his own previous academic writing. Professor Siebrasse previously described the latanoprost case as one where, in "construing the patent, the Court of Appeal made no reference whatsoever to the disclosure."[208] Professor Siebrasse in fact

[205] Claimant even argued that the outcome of the atomoxetine could be regarded as an improper application of the principles of claims construction: Closing Statement of Claimant, June 8, 2016, p. 2063:17-23 (MS. WAGNER: And even if the court's analysis has been presented as a matter of claim construction, it would still have to be considered as a claim construction exercise that is a marked departure from settled claim construction principles, including that resort to the disclosure is not permitted to vary the scope or ambit of the claims.); *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, para. 32, ("The 16 patent claims involve the use of atomoxetine for treating ADHD in three of its manifestations among all age groups (children, adolescents and adults).") (**R-027**); *Eli Lilly & Co. v. Teva Canada Ltd.*, 2011 FCA 220, para. 21 (holding that the trial judge "was simply interpreting what "treatment" means in this patent in the context of ADHD, a chronic disorder requiring sustained treatment.") (**C-163**). *See also*, Opening Statement of Canada, May 30, 2016, p. 203:8-21; Resp. CM, para. 27; Dimock First Report, para. 189 ("Based on the above, as well as the clear language of the claim itself, which refers to treating ADHD in a patient, it is not surprising that the inventive promise of the invention was construed as clinical use of atomoxetine to treat ADHD.").

[206] Opening Statement of Claimant, May 30, 2016, pp. 58:8 – 59:15; Cl. Mem., para. 64; Cl. Reply, para. 176; Siebrasse First Report, paras. 48-50; Reddon Report, para. 15 ("The *Latanoprost* litigation is an example of a case where the innovative company lost because of the Court's construction of the promise and other aspects of the promise utility doctrine.").

[207] Siebrasse, May 31, 2016, p. 623:20 ("PROFESSOR SIEBRASSE: I believe it was interpreting the disclosure."), Siebrasse, May 31, 2016, p. 630:3-4 ("PROFESSOR SIEBRASSE:…they court construed the promise by reading the disclosure through the eyes of a skilled person."); Siebrasse, May 31, 2016, pp. 630:23 – 631:5 ("MR. JOHNSTON: And the words they were interpreting were "treatment" and "glaucoma"? PROFESSOR SIEBRASSE: Yes. MR JOHNSTON: And those words appeared both in the claims in *Latanoprost*? PROFESSOR SIEBRASSE: Well, they do appear in the claims, but my recollection of the case is that they were construing it from the disclosure.")

[208] Norman V. Siebrasse, *The False Doctrine of False Promise*, (2013) 29 Can IP Rev 3, p. 22, FN 91, p. 43 ("… in so construing the patent, the Court of Appeal made no reference whatsoever to the disclosure. The Court of Appeal consequently concluded that the claimed invention was invalid on the sole basis that it lacked utility.") (**C-205**); Norman Siebrasse, *Sufficient Description Blog Excerpts*, p. 32 ("I have gone through these details to show that the FCA established its view of the promise of the patent without making any reference to what is said in the description …") (**R-476**).

criticized this aspect of the decision and testified that if a court is going to consider promises of utility, it should consider the language of the disclosure.[209]

115. However, whether Claimant is arguing that looking to promises of utility *per se* was new in Canadian law in 2005, or whether it is only arguing that looking to promises in the disclosure was new in 2005, neither version of Claimant's account holds up to the historical record. Even Claimant acknowledged the longstanding place of the promise standard in submissions to the Supreme Court of Canada in the course of the olanzapine proceedings.[210] Claimant's expert, Professor Siebrasse, also acknowledged the existence of the promise standard under prior Canadian law in his earlier academic publications.[211] Furthermore, he conceded in testimony that other leading Canadian patent law scholars do not consider that the promise standard was new in 2005, as Claimant alleges.[212]

[209] Siebrasse, May 31, 2016, pp. 627:25 – 628:3 ("PROFESSOR SIEBRASSE:… yes, it's my position that, given the promise of the patent doctrine we should at least look at the disclosure and look at the words in the disclosure …").

[210] In Claimant's submissions to the Supreme Court of Canada opposing Novopharm's application for leave to appeal from the first decision of the Federal Court of Appeal, Claimant argued that the Federal Court of Appeal "did nothing more than follow established principles of patent law and the jurisprudence of this Court" in its decision that instructed the trial judge to apply the promise utility standard and cited *Consolboard* as authority: Canada Opening Statement, May 30 2016, pp. 200:17 – 201:13; Canada Opening Presentation, Slide 49: *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197 ("*Olanzapine FCA I*"), para. 76 ("However, where the specification set out an explicit "promise", utility will be measured against that promise [citing *Consolboard*]") (**R-015**); *Novopharm Limited v. Eli Lilly and Company*, Supreme Court of Canada Case No. 33870, Memorandum of Argument of the Respondent, Application for Leave to Appeal, October 26, 2010, para. 2 ("… a review of the Reasons for Judgment of the Federal Court of Appeal shows that it did nothing more than follow established principles of patent law and the jurisprudence of this Court.") (**R-034**).

[211] Norman V. Siebrasse, *Must the Factual Basis for Sound Prediction Be Disclosed in the Patent?* (2012) 28 Can IP Rev 39, p. 11, FN 30 ("It has a long, but sporadic, history in Anglo-Canadian patent law … but it has recently become a much more important feature of Canadian patent law…") (emphasis added) (**C-206**); Norman Siebrasse, (2012) *2011 in Review: Patent Law*, 24 Intellectual Property Journal 119, p. 127 ("This is the result of the increased prominence of the doctrine that utility is measured by the promise of the patent…") (emphasis added) (**R-498**); Norman V. Siebrasse, *The False Doctrine of False Promise*, (2013) 29 Can IP Rev 3, p. 3 ("Even in Canada, the doctrine was almost entirely quiescent for decades.") (emphasis added) (**C-205**). *See also*, Closing Presentation of Canada, Slide 95.

[212] Siebrasse, June 1, 2016, pp. 762:19 – 763:1 ("PROFESSOR SIEBRASSE: … There is Mr. Gold, of course, who has written on this particular issue, and he, as I understand -- well, he takes the contrary view … in terms of a mainstream or consensus view, there just aren't enough patent academics to really say there's a consensus one way or the other.") *See also*, Closing Presentation of Canada, Slide 96.

116. Despite Claimant's attempts to rewrite history in this arbitration, the reality of the historical record is that, for at least sixty years, Canadian law has recognized the promise standard of utility, and it has never been limited to promises found in the claims.

2) The Promise Standard Has Been Part of Canadian Law Since At Least the Mid-20th Century

117. There is extensive historical evidence demonstrating the existence of the promise standard in Canadian law long before Claimant filed its patents or NAFTA entered into force.[213] The meaning of "useful" in Canadian patent law has long been understood as a contextual consideration that asks the question, "useful for what?" If the patent contains a promise as to the usefulness of the invention, then the invention will only be considered useful if it meets that promise. [214] If a patent does not contain a promise of usefulness, then a "mere scintilla" of utility will suffice. This utility standard was recognized by the Supreme Court of Canada in *Consolboard* in 1981:[215]

> There is a helpful discussion in *Halsbury's Laws of England*, (3rd ed.), vol. 29, at p. 59, on the meaning of "not useful" in patent law. It means "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do.
> …
>
> Canadian law is to the same effect. …[216]

[213] Opening Statement of Canada, May 30, 2016, pp. 185:6 – 189:7; Closing Statement of Canada, June 8, 2016, pp. 2250:12 – 2260:18; Resp. CM, paras. 88-107; Resp. Rejoinder, paras. 152-156; Dimock First Report, paras. 53-91; Dimock Second Report, paras. 7-86, Annex B.

[214] Resp. CM, para. 90; Resp. Rejoinder, para. 152; Dimock First Report, para. 58; Dimock Second Report, para. 10.

[215] Opening Statement of Canada, May 30, 2016, pp. 186:21 – 187:8; Closing Statement of Canada, June 30, 2016, p. 2251:7 – 17; Resp. CM, paras. 92-93; Resp. Rejoinder, para. 156.

[216] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] SCR 504, 1981 CarswellNat 582, para. 36 (**R-011**). *See also*, Opening Presentation of Canada, Slide 31; Closing Presentation of Canada, Slide 97.

118. Claimant's attempt to argue that *Consolboard* is not authority for the promise standard of utility ignores the plain words of that decision which refers to the two branches of Canada's utility requirement.[217] The first half refers to a situation in which the patent makes no promise, the second addresses situations where a promise is made. *Consolboard* is clear. If you make a promise of utility, you will be held to it.[218] Practitioners, including Claimant's own expert Mr. Reddon, understood that this was the law.[219]

119. In an effort to find a way around this clear wording, Claimant's experts gave conflicting accounts of how this passage in *Consolboard* should be read. Professor Siebrasse attempted to read out the second half of the *Consolboard* standard altogether, arguing that the case does not represent a bifurcated standard,[220] despite recognizing that the sentence has a bifurcated structure.[221] Mr. Reddon contradicted Professor Siebrasse by recognizing the bifurcated nature of the *Consolboard* standard, and agreeing that practitioners had to regard the second branch as having legal effect independent from the

[217] Dimock First Report, para. 56; Dimock Second Report, para. 26 ("…the law of utility – including the promise standard – was accurately described by the Supreme Court of Canada in 1981 in *Consolboard* …") and paras 29-32 (explaining that utility was not a "non-issue" in *Consolboard* as suggested by Professor Siebrasse).

[218] E. Richard Gold and Michael Shortt, *The Promise of the Patent in Canada and Around the World*, 30:1 Canadian Intellectual Property Review, p. 54 ("Understanding this bifurcated structure is crucial: writers who characterize *Consolboard* as standing for a "very low threshold" of utility overlook its explicit endorsement of the promise of the patent.") (**R-050**). *See also*, Closing Statement of Canada, June 8, 2016, p. 2251:12-17; Dimock First Report, para. 77; Dimock Second Report, para. 44.

[219] Reddon, June 1, 2016, p. 910:2-20 ("MR. REDDON…the practitioner, has to take those kinds of statements and live with them, as if a judge is some day going to apply them, even though it had never happened … As a practitioner you have to contend with the words after the "or" and be ready to deal with them if it ever is applied, and what practitioners thought was that you needed to show some promise in the claims.") *See also*, Closing Statement of Canada, June 8, 2016, pp. 2252:22 – 2253:4; Closing Presentation of Canada, Slide 104.

[220] Closing Presentation of Canada, Slide 103; Siebrasse, May 31, 2016, p. 592:14-16 ("As I stated in my response to your question about Consolboard, that statement does not state a bifurcated standard."); Siebrasse, May 31, 2016, p. 598:22-25 ("And that's not a bifurcated standard. It's a lower standard. It's not saying that you have to meet any purpose; its saying it's enough that it works.")

[221] Siebrasse, May 31, 2016, pp. 587:14 – 588:13. *See also*, Closing Statement of Canada, June 8, 2016, p. 2252:17-23; Closing Presentation of Canada, Slide 98.

first branch.[222] His argument that the second branch refers only to promises made in the claims is without merit, as explained below.[223]

120. Claimant's argument on the meaning of *Consolboard* also second-guesses the settled interpretation of *Consolboard* by Canada's Federal Court and Federal Court of Appeal.[224] Even Claimant's expert, Professor Siebrasse, recognizes that the Federal Court and Federal Court of Appeal's interpretation of *Consolboard* as authority for the promise standard is plausible.[225]

121. To cast doubt on the authority of *Consolboard*, Claimant also argued that *Consolboard* was seldom cited for utility prior to 2005 and never cited for the promise standard. This is contradicted by the evidence.[226] Numerous pre-2005 courts cited *Consolboard* for the utility standard, reproducing the two branches of the standard, including the promise branch.[227] Even Professor Siebrasse cited *Consolboard* and its

[222] Reddon, June 1, 2016, p. 910:2-20 ("MR. REDDON…the practitioner, has to take those kinds of statements and live with them, as if a judge is some day going to apply them, even though it had never happened … As a practitioner you have to contend with the words after the "or" and be ready to deal with them if it ever is applied, and what practitioners thought was that you needed to show some promise in the claims.") *See also*, Closing Statement of Canada, June 8, 2016, pp. 2252:23 – 2253:5; Closing Presentation of Canada, Slide 104.

[223] *See infra* Section V.A., para. 121; Closing Presentation of Canada, June 8, 2016, pp. 2253:5 – 2254:15.

[224] Siebrasse, May 31, 2016, p. 589:5-6 ("…that's how the current Canadian courts read that …"); Dimock First Report, para. 60 ("… *Consolboard* is generally considered to be the leading authority concerning the basic utility requirements of Canadian patent law. The case continues to be applied by judges and was applied to Claimant's patents. In a decision rendered October 30, 2014 the Federal Court of Appeal referred to *Consolboard* was 'the source of the promise doctrine in Canadian law'.")

[225] Siebrasse, May 31, 2016, pp. 588:24 – 589:8 ("MR. JOHNSTON: Your view is that this passage in Consolboard cannot reasonably be interpreted as acknowledging the existence of the promise doctrine in prior law? PROFESSOR SIEBRASSE: Well, this one sentence out of the whole decision could be read as supporting that, yes, and that's how the current Canadian courts read that and they're not being ridiculous in reading it, but you have to read the whole decision."); Norman V. Siebrasse, *The False Doctrine of False Promise*, (2013) 29 Can IP Rev 3, pp. 24-25 ("The passage in *Halsbury's* quoted in *Consolboard* cites *Alsop's Patent* and *Hatmaker* for the key proposition that an invention lacks utility if 'it will not do what the specification promises that it will do,' so the approval of this passage from *Halsbury's* could be taken as indirect approval of those decisions.") (**C-205**). *See also*, Closing Presentation of Canada, Slide 100.

[226] Dimock First Report, para. 70 ("*Consolboard* and the promise of the patent were inextricably linked together long before 2005."); Dimock Second Report, paras. 33-39. *See also* Resp. CM, para. 94.

[227] *See Goldfarb v. W.L. Gore & Associates Inc.* (2001), 11 CPR (4th) 129, para. 109 (**R-187**); *Feherguard Products Ltd. v. Rocky's of B.C. Leisure Ltd.* (1994), 53 PCR (3d) 417 (FCTD), para. 23 (**R-360**); *Almecon*

two-branch utility standard when he needed a single leading authority for the law of utility in a 2003 publication.[228] The Canadian government also expressly identified the two-branch *Consolboard* test as stating the utility standard in Canada in 2001 and 2003 submissions to WIPO, expressly labelling the second branch "false promise".[229]

122. Numerous other Canadian court decisions, in the years before and after *Consolboard*, recognize the existence of the promise standard.[230] Notably, in 1995 – just after NAFTA entered into force and around the time Claimant filed its patents – the Federal Court of Appeal in *Wellcome v. Apotex* held:

> Since the utility of a patent must ultimately be judged against its promise, the exercise requires that the specification be carefully construed to determine exactly what the promise is.[231]

Industries Ltd. v. Anchortek Ltd. (2001), 17 CPR(4th) 74 (FCTD), paras. 45 and 46 (**C-230**); Siebrasse, May 31, 2016, p. 592:8-19; Dimock First Report, paras. 70-71; Dimock Second Report, paras. 33-40. *See also*, Closing Statement of Canada, June 8, 2016, p. 2252:1-3; Closing Presentation of Canada, Slide 103.

[228] Siebrasse, May 31, 2016, p. 595:10-15 ("MR. JOHNSTON:…you have quoted from *Consolboard* in your 2003 paper. It is the only authority that you've quoted for the meaning of "not useful" in Canadian patent law in 2003. Is that right? PROFESSOR SIEBRASSE: Yes."); Norman Siebrasse (2004) *A Remedial Benefit-Based Approach to the Innocent-User Problem in the Patenting of Higher Life Forms* 20(1) CIPR 79-134, p. 95 ("As the Supreme Court of Canada has affirmed, lack of utility means 'that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do … the practical usefulness of the invention does not matter, nor does its commercial utility, unless the specification promises commercial utility …', citing at FN 85 'Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd., [1981] 1 S.C.R. 504, at 525, quoting with approval Halsbury's Laws of England, 3d ed., vol. 29, at 59.'") (**R-489**). *See also*, Closing Statement of Canada, June 8, 2016, p. 2252:3-5.

[229] Thomas, June 4 2016, pp. 1715:17-18 ("MR. THOMAS: Canada replied in response to a survey saying what its law was."); Thomas, June 4, 2016, pp. 1734:20 – 1736:2; WIPO, *The Practical Application Of Industrial Applicability/Utility Requirements Under National And Regional Laws*, April 2001, para. 13 ("An invention lacks utility if it is not operable or it will not do what the specification promised it will do ("false promise").") (**R-407**); WIPO, *Industrial Applicability" and "Utility" Requirements: Commonalities and Difference*, document SCP/9/5, 17 March 2003, para. 41 ("A finding that the alleged invention is not useful may be expressed in a way that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promised it would do ('false promise').") (**R-230**). *See also*, Closing Statement of Canada, June 8, 2016, p. 2252:5-11; Closing Presentation of Canada, Slide 101.

[230] Dimock First Report, paras. 61-64 and 70-71; Dimock Second Report, paras. 33-40, 48-51, Annex B.

[231] *Wellcome Foundation Ltd. v. Apotex Inc*., [1995] FCJ No 226, 60 CPR (3d) 135 (FCA), p. 154 (**R-401**). *See also*, Dimock Second Report, para. 84; Opening Statement of Canada, p. 188:8-16; Opening Presentation of Canada, Slide 32.

123. In academic writing prior to being retained by Claimant in this matter, Professor Siebrasse described *Wellcome v. Apotex* as "the clearest support for the promise of the patent doctrine" and as a case in which the "court considered a heightened utility requirement based on the promise of the specification".[232] He also confirmed in his testimony that where the Federal Court refers to "specification" in this context, it is referring to the disclosure rather than the claims.[233]

124. Canadian legal literature from the mid-to late-20th century is also replete with references to the promise standard of utility.[234] These include publications by esteemed patent practitioners such as Dr. Harold Fox,[235] Mr. Donald Hill,[236] Mr. Gordon

[232] Norman V. Siebrasse, *The False Doctrine of False Promise*, (2013) 29 Can IP Rev 3, p. 22, FN 91 (**C-205**). *See also*, Siebrasse, May 31, 2016, p. 621:18-22 ("MR. JOHNSTON: Just to be clear, is this the case we discussed earlier that you described as the clearest support for the promise of the patent doctrine? PROFESSOR SIEBRASSE: Yes."); Closing Presentation of Canada, Slide 108.

[233] Siebrasse, May 31, 2016, p. 621:14-17 ("MR. JOHNSTON: … Now, here you understand the court in using the word "specification" to be referring to the disclosure? PROFESSOR SIEBRASSE: Yes.").

[234] Dimock First Report, paras. 49, 62-69 and 84; Dimock Second report, para. 3, Annex B. *See also*, Resp. CM, paras. 95-96 and 103; Resp. Rejoinder, para. 153.

[235] Siebrasse, May 31, 2016, pp. 578:18 – 579:5 (describing Dr. Fox's text as a "very well known text and regularly cited by the courts" and as "the first text I'd look for" if he were looking for a statement of the law in the late 1960s); Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969), p. 152 ("But a distinction must be drawn here between a case where a patentee claims a result and bases his claim for a patent on the production of that result, and a case where a patentee merely points to certain advantages that will accrue for this use of his invention. In the former case failure to perform the promise of the specification is fatal to the patent.") and p. 153 ("Cases of this type are of importance in that a distinction must be made between them and those cases where the specification contains no promise of results. In the latter case no particular quantum of utility is necessary; and a mere scintilla is sufficient for validity. But in those cases of patents that are based upon a promise of results contained in the specification it is not sufficient that the patent be useful for a part only of the result, or for that result only in a manner inferior to that claimed.") (**R-019**). *See also*, Resp. CM, paras. 96 and 103; Resp. Rejoinder, FNs 274 and 287; Opening Statement of Canada, May 30, 2016, p. 187:19-25; Opening Presentation of Canada, Slide 31; Closing Statement of Canada, June 8, 2016, p. 2294:14-20; Closing Presentation of Canada, Slide 107; Dimock First Report, paras. 66, 68 and 84, FN 70; Dimock June 2 2016, pp. 1040:9 – 1041:1.

[236] Donald Hill, "Claim Inutility" (1960), 35 CPR 185, p. 188 ("Where, however, the patentee has promised in his specification results of a certain kind or order, and these are not yielded when the invention is put into practice, the patent of course will be invalid. This is so obvious that it hardly need stating; it is referred to here, however, to warn against a lack of candour in a patent specification concerning the limitation of one's invention. There are of course no positive requirements for reciting in the disclosure disadvantages or limitations of one's invention.") (**R-160**). *See also*, Resp. CM, para. 95; Resp. Rejoinder, para. 152; Dimock First Report, paras. 49 and 65; Dimock Second Report, p. 45; Dimock, June 2, 2016, p. 1037:4-15.

Henderson,[237] Mr. William Hayhurst,[238] and Mr. Donald MacOdrum.[239] Even Claimant had to admit that the writings of these practitioners acknowledge the promise standard of utility.[240] Professor Siebrasse attempted in his expert reports to disregard the writings of these esteemed Canadian practitioners in a single three-sentence paragraph,[241] but had to admit in testimony that these authors were aware of and expressly considered the promise standard of utility to be part of Canadian law decades ago.[242]

[237] *New Process Screw Corp. v. PL Robertson Mfg Co. Ltd.*, (1961), 39 CPR 31 (Ex Ct) pp. 33 and 34 ("These findings illustrate the different senses in which utility has been used in patent law. It has been used in the sense of quantum of usefulness. In the absence of a promise or representation of a specific usefulness, it is clear that only a limited degree of usefulness is required. If the patentee makes a specific promise in the specification, the promise must be fulfilled or the patent is invalid…") (**R-162**). *See also*, Dimock First Report, paras. 62-62; Dimock, June 2, 2016, pp. 1039:11 – 1040:8.

[238] W.L. Hayhurst, *Disclosure Drafting*, (1971), 28 PTIC Bull (7th) 64, p. 73 ("In the introductory parts of the specification one must be chary of promising advantages that are not achieved by everything that falls within the broadest claim. If you make false promises you may get an invalid patent.") (**R-164**); W.L. Hayhurst, Q.C., *Survey of Canadian Law – Industrial Property: Part I*, (1983), 15 Ottawa L. Rev. 38, pp. 68-69 ("Also it is trite law that, as long as that which is disclosed has some practical utility, the quantum of utility may be slight unless the specification promises more. For this reason, the patent agent should be chary of making promises and of reciting objects in the specification …") (**R-199**); William L. Hayhurst, Q.C., *The Art of Claiming and Reading a Claim*, in Gordon F. Henderson, *Patent Law of Canada* (Toronto: Carswell, 1994), p. 217 ("To avoid problems of false suggestion and inutility, the patent agent should be chary of promising results in the descriptive portion where those results may not be achieved by things that arguably fall within the claims.") (**R-201**). *See also*, Resp. CM, para. 106; Resp. Rejoinder, para. 153; Opening Statement of Canada, May 30, 2016, p. 188:1-7; Opening Presentation of Canada, Slide 31; Closing Statement of Canada, June 8, 2016, p. 2294:14-15; Closing Presentation of Canada, Slide 107; Dimock First Report, paras. 69 and 79; Dimock, p. 1041:2-16.

[239] Donald H. MacOdrum, *Patent Law in Canada: Cases and Materials* (Lang Michener LLP, 1995), p. 5-1 ("In general, the level of utility is not high … However, the situation is different where some specific utility is promised by the disclosure.") (**R-361**); Closing Presentation of Canada, Slide 107; Dimock Second Report, para. 40; Dimock, June 2, 2016, p. 1042:6-14.

[240] Closing Statement of Claimant, June 8, 2016, p. 2052: 7-12 ("MS. WAGNER: So the interaction between the elements of the test brings us back to the prior law commentators, some of whom did seem to suggest that Canada had or potentially could adopt a false promise doctrine similar to that which was abolished in the UK in the 1970s.")

[241] Siebrasse Second Report, para. 40.

[242] Siebrasse, May 31, 2016, p. 588:15-23 ("MR. JOHNSTON: And the leading Canadian practitioners of the day like Dr. Fox, publishing in the years preceding *Consolboard*, did consider the promise standard to be part of Canadian law. PROFESSOR SIEBRASSE: Well, that's not clear to me. They quote the Canadian cases. They say you should worry about this. Whether they considered it part of Canadian law – they may have but it's not clear to me that they did.")

3) Early Promise Authorities Show that Patentees were Held to Promises in the Disclosure as well as the Claims

125. Nothing in any of the early promise authorities identified above supports Claimant's, and Mr. Reddon's, view that patentees would only be held to promises found in the claims. Canadian jurisprudence and legal texts have recognized for decades that it is appropriate to have regard to the patent specification as a whole – meaning both the disclosure and the claims – when determining whether the utility requirement is met.[243]

126. The language used by the Supreme Court in *Consolboard* indicates that promises can be found in either the disclosure or the claims. The *Consolboard* test refers to promises in the "specification",[244] which means under Canadian law both the claims and the disclosure (as noted by the Court in *Consolboard* itself),[245] and is often used in common parlance among patent lawyers to mean only the disclosure—but never means

[243] Dimock First Report, paras. 67-69 and 83-91 ("It has long been known that the specification as a whole (both the disclosure and claims) is to be construed in an informed manner through the eyes and mind of the person skilled in the art. This means that reference may be had to the descriptive portion of the patent in construing its promise." (para. 88)); Dimock Second Report, paras. 83-86 ("Professor Siebrasse contends that courts have changed their practice by looking to the disclosure to determine whether the patent promises a particular utility. I disagree …" (para. 83)); *Feherguard Products Ltd. V. Rocky's of B.C. Leisure Ltd.*, [1995] F.C.J. No. 620, para. 19 ("The patent as a whole, and not only the claims, must be considered when assessing the utility of an invention") (**R-488**); *Wellcome Foundation Ltd. v. Apotex Inc*., [1995] FCJ No 226, 60 CPR (3d) 135 (FCA), p. 154 ("Since the utility of a patent must ultimately be judged against its promise, the exercise re1quires that the specification be carefully construed to determine exactly what the promise is.") (**R-401**); Siebrasse, May 31, 2016, p. 621:6-17 (stating his understanding that the reference to "specification" in the FCA's decision *Wellcome v. Apotex* (R-401) refers to the disclosure); *Hoechst Pharmaceuticals of Canada Limited et al. v. Gilbert & Company et al.*, (1964), Fox Pat C 28 (Ex Ct), para. 29 (**R-195**); E. Richard Gold and Michael Shortt, *The Promise of the Patent in Canada and Around the World*, 30:1 Canadian Intellectual Property Review, p. 57 ("Based on our review of the 20th-century patent jurisprudence, we conclude that, for at least the last 60 years, Canadian law has held a patent invalid if the skilled reader, looking at the specification as a whole, would find that the patent promised a certain utility that the patent holder did not possess on the filing date.") (**R-050**). *See also*, Resp. CM, paras. 101-107.

[244] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] SCR 504, 1981 CarswellNat 582, para. 36 ("…it will not do what the specification promises that it will do") (**R-011**).

[245] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] SCR 504, 1981 CarswellNat 582, para. 26 ("In essence, what is called for in the specification (which includes both the "disclosure", *i.e.* the descriptive portion of the patent application, and the "claims") is a description of the invention and the method of producing or constructing it, coupled with a claim or claims which state those novel features in which the applicant wants an exclusive right.") (**R-011**).

only the claims.[246] The passage from *Halsbury's* quoted in *Consolboard* was based in part on old English false promise cases, which Professor Siebrasse concedes stood for the proposition that a patentee could be held to promises in the disclosure.[247]

127. Mr. Reddon's attempt to argue that the Supreme Court in *Consolboard* was referring only to promises made in the claims[248] lacks any support in the language of that judgment or in Canadian law.[249] Notably, Professor Siebrasse's expert reports and

[246] Dimock First Report, FN 60 ("Although the "specification" of a patent is defined as the combination of both the "disclosure" and the "claims" of the patent, it is used interchangeably with "disclosure" in some cases."); Dimock, June 2, 2016, p. 1038:12-17 ("MR. DIMOCK: In normal practice the specification is really the disclosure. There are two parts to a patent, the claims and the disclosure. Technically the specification is both the claims and the disclosure, but people invariably refer to the disclosure as the specification or vice versa."); Dimock, June 2, 2016, p. 1079:6-12 ("MR. DIMOCK: …Under the Patent Act the specification is defined to include the disclosure and the claims. However, in normal parlance between patent lawyers, people tend to use specification to mean disclosure … but never would the specification be the claims only.") *See also*, Opening Statement of Canada, May 30, 2016, p. 185:14-21; Closing Statement of Canada, June 8, 2016, p. 2254:2-9; Closing Presentation of Canada, Slide 106.

[247] Siebrasse, May 31, 2016, p. 588:9-14 ("MR. JOHNSTON: In substance, would you agree that the quoted passage from Halsbury did rely in part on old English false promise cases that held patentees to promises made in the disclosure? PROFESSOR SIEBRASSE: Halsbury does footnote such cases, yes."); Norman Siebrasse "Form and Function in the Law of Utility: A Reply to Gold & Shortt" Canadian Intellectual Property Review, p. 63, "…Halsbury's did quote true promise cases, in particular *Hatmaker* and *Alsop's Patent* …" (**R-497**); Closing Presentation of Canada, Slide 99.

[248] Reddon, June 1, 2016, p. 826:2-25 ("MR. REDDON:… that tag line in *Consolboard* … where it said a "promise in the specification," was clearly understood and I believe to this day clearly means at least that it has to be in the claims." (p. 826:17-21). *See also*, Closing Presentation of Canada, Slide 105.

[249] *See* Closing Statement of Canada, p. 2253:9-25. Mr. Reddon provided no authority to support his view that the reference to promises in the "specification" in *Consolboard* "clearly means at least that it has to be in the claims": Reddon, June 1, 2016, p. 826:16. As Mr. Reddon conceded, *Consolboard* itself expressly recognizes that the word "specification" under the *Patent Act* means both the disclosure and the claims: Reddon, June 1 2016, p. 826:5-7, referring to *Consolboard Inc v MacMillan Bloedel (Sask) Ltd.*, (1981) 1 SCR 504, p. 520 (…"the specification (which includes both the "disclosure", *i.e.* the descriptive portion of the patent application and the "claims")…") (**C-118**). Mr. Reddon could point to nothing in *Consolboard* to suggest that the Supreme Court had a narrower meaning in mind when it used the word "specification" in relation to promises of utility. Mr. Reddon then argued that what the Supreme Court intended in *Consolboard* should be read in light of *Free World Trust v. Électro Santé Inc.*, [2000] 2 SCR 1024 (**R-018**), a Supreme Court decision issued nineteen years later and that related to claims construction rather than utility. He did not cite any passages from *Free World Trust* to support his *post-hoc* interpretation of *Consolboard*: Reddon, June 1, 2016, p. 826:2-25. In fact, Mr. Reddon condeded that *Free World Trust* provides that there can be recourse to the disclosure even for the purpose of claims construction: Reddon, June 1, 2016, pp. 895:21 – 8961. Mr. Reddon did not offer any other evidence to support his interpretation of *Consolboard*.

testimony did not corroborate Mr. Reddon's reading of the word "specification" in *Consolboard*.[250]

128. Similarly, the leading Canadian 20th century practitioners writing on the promise standard made clear that they were not only talking about promises made in the claims.[251] Practitioners like Dr. Fox,[252] Mr. Hayhurst,[253] and Mr. MacOdrum[254] all referred to promises found outside of the claims.

129. Contrary to Claimant's assertion,[255] there are also a number of pre-2005 cases where the court expressly recognizes that a patentee may be held to promises in the

[250] Siebrasse First Report, paras. 74-77; Siebrasse Second Report, paras. 19-32. *See also*, Siebrasse, May 31 2016, p. 621:6-17. *See also*, Closing Statement of Canada, pp. 2253:20 – 2254:1; Closing Presentation of Canada, Slide 105.

[251] *See* Closing Statement of Canada, June 8, 2016, p. 2254:10-15; Closing Presentation of Canada, Slide 107.

[252] Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969), p. 150 ("The invention must, subject to the qualification above mentioned, be useful as specified and for the purpose stated in the specification and claims …") and p. 153 ("…It necessarily involved a construction of the specification in order to ascertain what the ordinary workman would apprehend by its disclosure. It is, therefore of the utmost importance to decide whether the specification makes a promise of a result and whether the ordinary workman would understand that that particular result is promised.") (emphasis added) (**R-019**). *See also*, Dimock, June 2, 2016, p. 1040:20-22 (stating with reference to Dr. Fox's 1969 treatise "So here specification is used as a disclosure …").

[253] William L. Hayhurst, Q.C., *The Art of Claiming and Reading a Claim*, in Gordon F. Henderson, *Patent Law of Canada* (Toronto: Carswell, 1994), p. 217 ("To avoid problems of false suggestion and inutility, the patent agent should be chary of promising results in the descriptive portion where those results may not be achieved by things that arguably fall within the claims.") (emphasis added) (**R-201**); W.L. Hayhurst, *Disclosure Drafting*, (1971), 28 PTIC Bull (7th) 64, p. 73 ("In the introductory parts of the specification one must be chary of promising advantages that are not achieved by everything that falls within the broadest claim. If you make false ·promises you may get an invalid patent …") (emphasis added) (**R-164**). *See also*, Dimock, June 2, 2016, p. 1041:6-11 ("… "In the introductory parts of the specification" – so that's the disclosure … So there he is distinguishing between the specification and the claim.")

[254] Donald H. MacOdrum, *Patent Law in Canada: Cases and Materials*, (Lang Michener LLP, 1995), p. 1 ("There are three broad ways in which issues relating to utility arise: (1) Issues relating to the utility of the "invention" itself; (2) Issues relating to the utility of the subject matter embraced by the claims; and (3) Issues relating to particular utility "promised" in the disclosures") (emphasis added) (**R-361**).

[255] Closing Statement of Claimant, June 8, 2016, p. 2047:4-8 ("MS. WAGNER: And we know this because we have here Mr. Dimock's chart, and he put up a lot of decisions, but not one sets the requirement for utility by reference to additional promises that go beyond the basic use of the claimed invention.")

disclosure, including *Wellcome v. Apotex*,[256] *New Process Screw*,[257] and *Corning Glass Works*.[258] Still other cases show debate over whether particular statements in the disclosure were, on the facts, promises of utility.[259]

[256] *Wellcome Found. Ltd. v. Apotex Inc.* 39 C.P.R. (3d) 289, 292 (FC 1991), p. 349 ("The focus of the main criticism by the defendant was the passage at p. 19 of the description … … I am not satisfied that the claims of the plaintiffs were inoperable, or that they lacked the utility claimed in the patents…") (emphasis added) (**C-041**); *Wellcome Foundation Ltd. v. Apotex Inc.* (1995), 60 CPR (3d) 135 (FCA), p. 154 (affirming the Federal Court's utility analysis and stating "Since the utility of a patent must ultimately be judged against its promise, the exercise requires that the specification be carefully construed to determine exactly what that promise is.") (**R-401**); Siebrasse, May 31, 2016, p. 621:6-17 (stating his understanding that the reference to "specification" in the FCA's decision *Wellcome v. Apotex* (**R-401**) refers to the disclosure); Siebrasse, May 31, 2016, p. 621:18-22 (describing *Wellcome v. Apotex* (1991) as the "clearest support for the promise of the patent doctrine"); Norman V. Siebrasse, *The False Doctrine of False Promise*, (2013) 29 Can IP Rev 3, p. 22 (describing *Wellcome v. Apotex* (1991) as a case where the "court considered a heightened utility requirement based on the promise of the specification" and as "the clearest support for the promise of the patent doctrine") (**C-205**). Professor Siebrasse testified that if *Wellcome v. Apotex* (1991) had been a promise case, there would have been debate over whether particular statements in the disclosure were promises that had to be satisfied: Siebrasse, May 31, 2016, p. 532:8-17. Precisely this kind of debate occurred in *Wellcome v. Apotex* (1991). There was extensive debate between the parties over the promised utility of the invention: *Wellcome Found. Ltd. v. Apotex Inc.* 39 C.P.R. (3d) 289, 292 (FC 1991), *rev'd on other grounds* 60 C.P.R. (3d) 135 (FCA), p. 348 ("The utility of the inventions was characterized quite differently by the two learned counsel, as might be expected.") (**C-041**). *See also*, Closing Statement of Canada, June 8, 2016, pp. 2254:22 – 2255:19; Closing Presentation of Canada, Slides 108-109 and 112.

[257] In *New Process Screw*, the patent was invalidated for failure to deliver a utility specified in the claim, but the court also recognized that failure of a promise in the disclosure was fatal to the patent. The disclosure – not the claims – stated that the invention would produce a commercially good product. The evidence was that the invention did not produce a commercially good product. The court held that this alone was enough to invalidate the patent: *New Process Screw Corp. v. PL Robertson Mfg Co. Ltd.*, (1961), 39 CPR 31 (Ex Ct), p. 46 ("He also said that dies with a pitch angle of 22° would roll a double threaded No. 18 screw, but it would not be a good one but would be rough and not a good commercial product. This statement was enough in itself to destroy the patent.") (**R-162**); Dimock, June 2, 2016, p. 1039:4-10 ("…they were looking at the disclosure, not to the claims in looking for the promise of the patent."); Siebrasse, May 31, 2016, pp. 558:23-559:1 ("MR. JOHNSTON: The term "commercial results" was in the patent. PROFESSOR SIEBRASSE: In the disclosure, yes."). *See also*, Closing Presentation of Canada, Slides 115-116. The headnote to the case in the Canadian Patent Reporter confirms that the decision recognizes the promise standard of utility, expressly linking it to the old English false promise cases, which hold patentees to promises in the disclosure: *New Process Screw Corp. v. PL Robertson Mfg Co. Ltd.*, (1961), 39 CPR 31 (Ex Ct), p. 34, "If the patentee makes a specific promise in the specification, the promise must be fulfilled or the patent is invalid: *Re Alsop's patent* (1907), 36 R.P.C. 231 at p.237. However, commercial utility may become a requirement as in the present case, if it is found by the Court to be part of the promise. If the specification promises a commercial advantage over the prior art then commercial utility would be a requisite." (**R-162**); Closing Presentation of Canada, Slide 116.

[258] In *Corning Glass Works*, the court found that the patent did not lack utility, stating that "neither in the disclosures nor in the claims" does the patent "promise any particular result". This statement only makes sense if the patent could have been held to a promise of utility made in the disclosure: *Corning Glass Works v. Canada Wire & Cable Ltd*. (1984), 81 CPR (2d) 39 (FCTD), p. 18 (**R-375**). *See also*, Closing Presentation of Canada, Slide 110. In academic writing prior to being retained by Claimant in this matter,

130. Looking to the disclosure to determine whether the patentee promises a particular utility is consistent with other aspects of patent interpretation.[260] Even Claimant's own expert, Mr. Reddon, has urged courts to look to the disclosure when assessing non-obviousness, another key patentability requirement.[261] Courts have done so, and this has been determinative of patent validity in some cases.[262] Even for claims construction, the language of the claims must be read in light of the patent as a whole, including the disclosure, through the eyes of a skilled reader.[263] As Professor Siebrasse has previously

Professor Siebrasse described *Corning Glass Works* as a case in which the "court considered a heightened utility requirement based on the promise of the specification": Norman V. Siebrasse, *The False Doctrine of False Promise*, (2013) 29 Can IP Rev 3, p. 22, FN 91 (**C-205**); Siebrasse, June 1, 2016, p. 572:1-24. *See also*, Closing Presentation of Canada, Slide 111.

[259] *See, e.g., Mobil Oil Corp. v. Hercules Canada Inc.*, (1994), 57 CPR (3d) 488, p. 513 ("The defendant argues that the only teaching the patent to assist the addressee, in what he is not to do, is found in the table of test results at p. 6 of Patent '228. Counsel argues that the invention's promise of enhanced adhesion is only achieved when a bond strength measurement of at least 250 g/in., with no metal lift-off is obtained.") (**R-165**); *Unilever PLC. v. Procter & Gamble Inc.*, (1995), 61 CPR (3d) 499 (FCA), p. 512 ("The argument here is that one of the Patent's stated objectives is to reduce staining by the addition of a 'distributing agent', and that if it does not do so, the Patent fails to fulfil its promise and it invalid.") (**R-172**); TRW Inc. v. Walbar of Canada Inc. (1991), 39 CPR (3d) 176 (FCA), para. 31, (stating that the defendant argues that "the Patent is invalid because it contains two failed promises, *viz.*, that the process would avoid repeated handling and processing of separate work blanks …") (**R-376**). *See also*, Closing Presentation of Canada, Slide 114.

[260] Dimock First Report, paras. 85-89 and 220 ("Canadian courts … identify whether a patent contrains a promise using interpretive principles … applicable to all aspects of patent construction." (para. 220)); Dimock Second Report, paras. 58 and 84. *See also*, Resp. CM, para. 102.

[261] Dimock Second Report, paras. 15-19; *Allergan Inc.. v. Minister of Health and Sandoz Inc.*, Memorandum of Fact and Law of the Applicants (Redacted), Federal Court File No. T-154-10, 18 July 2011, para. 20 ("The law is clear that the inventive concept need not be readily discernible from the claims alone. Rather, the inventive concept in the claims is to be understood based on a review of the patent as a whole.") (**R-485**); Reddon, June 1, 2016, pp. 900:21 – 901:4 ("MR. REDDON: Yes, I acted for brand. Yes, the generic argued that there should be no reference to the disclosure. So that's your first and third question. Your second question is whether I argued that an advantage in the disclosure should be what? MR. JOHNSTON: Should be understood as part of the inventive concept. MR. REDDON: Yes.")

[262] Reddon, June 1, 2016, p. 896:9-18 ("MR. JOHNSTON: In this process of identifying the inventive concept, is it the case that there may be advantages of the invention stated in the disclosure that may be relevant to determining what the inventive concept it? MR. REDDON: It may be so, yes. MR. JOHNSTON: And that the existence of these advantages may, in fact, be what distinguishes an obvious invention from a non-obvious invention? MR. REDDON: Yes. …"); Reddon June 1, 2016, p. 901:11-23, explaining that where the achievement of an advantage stated in the disclose is the invention, patentees have argued that advantages from the disclosure should be considered as part of the inventive concept; Reddon, June 1, 2016, p. 897:15-18 ("MR. REDDON: There are cases where the brand, the patent holder, has argued that the achievement of those advantages is part of the inventive step, the inventive concept.")

[263] Dimock First Report, para. 85; *Whirlpool Corp. v. Camco Inc., [2000] 2 SCR 1067, para. 52* ("In *Consolboard* supra, as mentioned, Dickson J. considered that the whole specification (including the

written, it is always necessary to have regard to the disclosure in order to construe the claims,[264] and it is generally necessary to do so to identify the inventive concept for non-obviousness.[265] The longstanding practice of construing promised utility in light of the patent as a whole is no anomaly.

4) Claimant Ignores that Patentees Were Also Held to Promises Under Other Doctrines such as Overbreadth

131. Claimant asks the Tribunal to examine Canada's utility requirement in isolation from all other patent law requirements. This also creates a false picture of change in the law by obscuring the historical role of other patent law requirements in holding patentees to promises of utility. The doctrine of overbreadth has for decades held patentees to promises of utility by prohibiting claims that are broader than the invention made or disclosed.[266] The overlapping nature of overbreadth and promise utility has

disclosure and the claims) should be looked at "to ascertain the nature of the invention"). To the same effect is the statement of Taschereau in *Metalliflex Ltd. v. Rodi & Wienenberger AG* (1960), [1961] S.C.R. 117 (S.C.C.), p. 122 ("The claims, of course, must be construed with reference to the entire specifications, and the latter may therefore be considered in order to assist in apprehending and construing a claim …") (**R-022**); Reddon, June 1, 2016, pp. 895:21 – 896:8 ("MR. REDDON: The law from the Supreme Court of Canada in *Whirlpool* and in *Free World Trust* mandates that the court read the patent, the specification including primarily the claims, but also the disclosure, through the eyes of a skilled person. And to that end, unless the court has the expertise itself, which is not the case in the Federal Court of Canada because we do not have technical expert judges, it is necessary in most cases for the court … to consider expert evidence to understand the words in the patent.")

[264] Norman Siebrasse, *Sufficient Description Blog Excerpts*, p. 85, writing that in *Pfizer Canada Inc. v. Pharmascience Inc.*, 2013 FC 120, p. 70, "We might as well simply say that it is always necessary to have recourse to the specification in interpreting the claims." (**R-476**); Norman Siebrasse, *Sufficient Description Blog Excerpts*, p. 85, writing that in *Pfizer Canada Inc. v. Pharmascience Inc.*, 2013 FC 120, p. 81 ("… the words of the claim cannot be properly understood without recourse to the specification as a whole … The same is true of the inventive concept.") (**R-476**). *See also*, Siebrasse, May 31 2016, p. 618:2-20.

[265] Norman Siebrasse, *Sufficient Description Blog Excerpts*, p. 85, writing that in *Pfizer Canada Inc. v. Pharmascience Inc.*, 2013 FC 120, p. 80 ("… it is generally necessary to have recourse to the disclosure to construe the inventiove concept, not only in the case of a *per se* compound claim … it is the information in the disclosure which must be non-obvious in order to justify the monopoly.") (**R-476**). *See also*, Siebrasse, May 31, 2016, pp. 619:14 – 620:1.

[266] *Amfac Foods Inc. v. Irving Pulp & Paper, Ltd.*, (1986), 12 CPR (3d) 193 (FCA) (**R-168**); *Unilever PLC. v. Procter & Gamble Inc.*, (1995), 61 CPR (3d) 499 (FCA) (**R-172**); *Hoechst Pharmaceuticals of Canada Limited et al. v. Gilbert & Company et al.*, (1964), Fox Pat C 28 (Ex Ct) (**R-195**); *Apotex Inc. v. Wellcome Found. Ltd*., (1998) 79 CPR (3d) 193 (**C-116**); Opening Statement of Canada, June 8, 2016, p. 177:12-17; Opening Presentation of Canada, Slide 18; Resp. Rejoinder, para. 174; Dimock First Report, paras. 125-126; Dimock Second Report, paras. 52-72; Dimock Second Report, para. 69.

been recognized by Canadian courts.[267] Even Claimant[268] and Professor Siebrasse[269] ultimately acknowledged the overlapping nature of overbreadth and promise utility, retreating from their earlier position that overbreadth is "quite distinct" from utility.[270]

5) MOPOP and Patent Office Practice Do Not Indicate that the Promise Standard Was Created in 2005

132. Claimant attempts to buttress its argument that the promise standard was new in 2005 by pointing to revisions to MOPOP in 2009 and 2010, and to certain comments made by examiners during internal consultations leading up to those revisions. Claimant's reliance on these sources is misplaced. They do not provide the evidence of change that Claimant suggests.

133. In particular, Claimant seeks to draw an inference of change in the law from the alleged omission of specific references to the promise standard from MOPOP in the 1990s, and its addition to MOPOP in 2009.[271] Claimant's argument is flawed because MOPOP is neither an authoritative statement of the law nor a comprehensive summary of either Canadian patent law or Patent Office practice.[272] MOPOP is only a high-level

[267] *Olopatadine*, para. 225 (stating that an "allegation of overbreadth is simply another way of articulating the utility argument, but from the perspective of claims drafting rather than from the perspective of the demonstration or sound prediction of utility.") (**C-353**). *See also*, Resp. Rejoinder, para. 174; Dimock Second Report, para. 61.

[268] Opening Statement of Claimant, May 30, 2016, p. 63:7-14 ("MS. WAGNER:… you just don't see any cases in prior law where a claim was held to be overbroad because it encompassed subject matter that didn't meet a promise utility, because the courts weren't looking for a promise utility. So although there's overlap between the concept, there's not overlap in the prior law between utility as we see it today with utility as we see it today.") (emphasis added).

[269] Siebrasse, May 31, 2016, p. 534:3-10 ("PROFESSOR SIEBRASSE: So overbreadth can overlap with any of the other grounds of invalidity; it can overlap with utility, or anticipation, or obviousness. Prior to 2005, whenever overbreadth overlapped with utility, it overlapped with the scintilla branch because that was the only branch there was. Since 2005 it's possible that overbreadth could overlap with either of the branches of utility.").

[270] Siebrasse Second Report, para. 37 ("Overbreadth as a ground of objection is quite distinct from utility.").

[271] Opening Statement of Claimant, May 30, 2016, p. 22:17-20 ("MS. CHEEK: So the MOPOP, the patent examination manual of the Canadian IP office, is the authoritative and comprehensive reference guide that's used by patent office examiners.")

[272] Dimock, June 2, 2016, p. 1070:4-5 ("MR. DIMOCK: No, I don't use MOPOP as a source of authority in any case I've argued."); "*Manual of Patent Office Practice*", Consumer and Corporate Affairs Canada,

overview of Patent Office practice.[273] Furthermore, updates to MOPOP to reflect Patent Office practice have often been slow and incomplete.[274]

134. For these reasons, the omission or addition of an important case or concept in MOPOP does not indicate that Canadian law or Patent Office practice have changed. MOPOP is not the only tool relied upon by patent examiners in conducting examinations.[275] Indeed, Mr. Wilson admitted under examination that even cases that were important in examination, such as *Monsanto*, were not listed in MOPOP.[276] The Patent Office has at times expanded, clarified and improved sections of MOPOP in areas where it is uncontested that there was no change in the law.[277] Moreover, the language used to describe the utility requirement in MOPOP in the 1990s did not exclude the promise standard, and indeed, is consistent with it.[278]

Patent Office (August 1989, January 1990, March 1998, September 2004, February 2005, April 2006, January 2009, December 2009, November 2013, December 2013 and May 2014), Foreword, para. 4 ("This Manual is to be considered solely as a guide, and should not be quoted as an authority. Authority must be found in the Patent Act, the Patent Rules, and in decisions of the Courts interpreting them.") (**R-025**); Dimock First Report, paras. 23-24; Gillen, First Statement, paras. 17-18 and 24 ("I am unaware of any examiner, patent applicant, or patent agent who would consider the MOPOP to be a complete and authoritative guide on Patent Office practice or patent law in Canada at any given point in time." (para. 24)). *See also*, Opening Statement of Canada, May 30, 2016, pp. 193:14 – 194:8; Opening Presentation of Canada, Slide 38; Resp. CM, paras. 73-76; Resp. Rejoinder, para. 230.

[273] Wilson, June 1, 2016, p. 791:5-8 ("MR. WILSON: It doesn't provide instructions on how to examine each specific application, no, but it gives principles on how to examine all applications."); Gillen, First Statement, para. 18.

[274] Gillen, June 1 2016, p. 924:9-10; Gillen, First Statement, para. 20 ("An inherent weakness of the MOPOP … is that it cannot be relied upon to be completely up to date.")

[275] Gillen, First Statement, para. 19 ("Examinations are not governed by the MOPOP but by the *Patent Act*, *Patent Rules*, and relevant jurisprudence.")

[276] Wilson, June 1, 2016, pp. 794:14 – 795:1 ("MS. ZEMAN: You explained that Monsanto was an important case that impacted examination. Is that right? MR. WILSON: Yes. MS. ZEMAN: And you also stated that MOPOP is an up-do-date reflection of the jurisprudence? MR. WILSON: Yes. MS. ZEMAN: But MOPOP is not listed here in this chapter? MR. WILSON: Monsanto is not listed. MS. ZEMAN: Monsanto, yes. What did I say? MOPOP?")

[277] Gillen Second Statement, para. 31 ("For example, there is a section added to Chapter 9 (Description) in 2010 that discusses in detail the person of ordinary skill in the art (POSITA) … There were no changes to the POSITA analysis in the 1990s or 2000s.")

[278] Wilson, June 1, 2016, pp. 801:25 – 801:15. Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 12 (January 1990) (Excerpts), Art. 12.02.02 ("Utility must be disclosed"), p. 4 ("operation or use of the invention must, of course, show the purpose for which the

135. Apart from pointing to changes in the language of MOPOP, Claimant also argues that Patent Office practice did not involve consideration of promises of utility until after 2005. This is false. As Dr. Gillen explains, in the 1990s "patent examiners assessed inventions on the basis of the language employed by applicants, including the description and what an applicant says the alleged invention will do."[279]

136. Finally, Claimant places great emphasis on isolated comments made by patent examiners during internal CIPO consultations leading up to the 2009 and 2010 MOPOP revision. These isolated comments of individual patent examiners do not establish any change in law or in Patent Office practice. Claimant misleadingly takes the comments out of context. In certain instances, Claimant invokes comments that were not even directed to the MOPOP's presentation of the elements of the alleged "promise utility doctrine", but to other issues altogether.[280] In other instances, Claimant selectively quotes from the document in question, distorting the examiner's specific comment or

invention was intended") and p. 7 ("The claims must be drafted to an invention having the utility disclosed. If the claims cover only things that have utility other than that disclosed or if they include inoperable and therefore useless embodiments, they are bad.")) (emphasis added) (**C-54**). *See also,* Resp. Rejoinder paras. 230-231.

[279] Gillen Second Report, para. 13. *See also,* Gillen, June 1, 2016, p. 925:5-10 ("MICHAEL GILLEN:…Utility is what the applicant will assert it to be in the application. That is how we, as examiners, approach the notion of utility. Applications are examined on the basis of the language employed by the applicant, including what the applicant says the invention will do"). *See also,* Closing Presentation of Canada, Slide 102, Resp. CM, para. 98; Resp. Rejoinder, para. 42; Gillen, First Report, paras. 27-32.

[280] For example, Claimant quotes comments from patent examiner Rob Rymerson that "the draft of Chapter 12 contains information that is not our current examination practice": Cl. Reply, para. 133. However, the original document shows that Mr. Rymerson's complaint was directed at the contribution analysis approach to patentable subject matter, not to any element of the alleged promise utility doctrine. Claimant omits Mr. Rymerson's further explanation that "There have been no internal or external (with the agents) discussion, training or practice notices regarding Contribution Analysis. Where has this approach come from?": "Comments on MOPOP Chapter 12 Compiled from Section C5 Biotech," Comments from Rob Rymerson, (17 March 2008) [Canada Doc. No. 910, at 065383] (**C-358**). Similarly, Claimant alleges that "Another examiner asked: 'Chapter 12 underwent a major revision, which included discussion and consultation, resulting in the version of February 2005. Why, three years later is the entire chapter being revised again?' The reason for the changes was, of course, the emergence of the promise utility doctrine starting in 2005": Cl. Reply, para. 133. This is a complete mischaracterization of the examiner's comment. She in fact wrote that "The 'contribution approach' seems to be the major new feature in this revision" and in contrast that the "utility section was well received": "Comments on MOPOP Chapter 12 Compiled from Section C5 Biotech," Comments of Linda Brewer, (17 March 2008) [Canada Doc. No. 910, at 065407, 065413].

omitting other comments that undermine Claimant's allegations of change in the law.[281] Still other examiner comments relied upon by Claimant were directed to which section of the *Patent Act* should be used to address a particular issue, rather than suggesting that substantive principles involved are new.[282]

B. The Canadian Courts Did Not Radically Alter their Interpretation of Canada's Utility Requirement So As to Impose a Heightened Evidentiary Burden in 2002

137. Claimant alleges that after its patents were filed and granted, Canadian courts began to interpret the term "useful" as imposing a heightened evidentiary burden to satisfy the utility requirement. Specifically, it alleges that the Supreme Court of Canada in the 2002 *AZT* decision drastically changed the law by prohibiting "post-filing evidence," such as evidence of commercial success or testing after the filing date. These allegations are false.[283] No heightened evidentiary burden has been imposed since 2002. In fact, Canadian law has never allowed applicants to file speculative patent applications, and then justify the patent with "after-the-fact" testing to establish utility. Similarly, contrary to Mr. Armitage's testimony, it has never been the law in Canada that Health Canada approval of a drug is in any way relevant to whether it is useful

[281] For example, Claimant alleges that "The prohibition against post-filing evidence was also new to examiners": Cl. Reply, para. 136. The example that it provides is actually a comment related to pre-filing evidence, "Can they provide evidence after the fact of data obtained before the filing date (supported by affidavit) in support of their claims?" But it also omits comments which make clear that examiners understood post-filing evidence of utility was inadmissible. One examiner expressed concern that the proposed language of the Chapter suggested that post-filing evidence was acceptable, contrary to Office practice. The examiner wrote: "This seems to be implying that the description need not disclose the invention, that post-filing experimentation is acceptable support and that obvious inventions are allowable. None of these is Office practice.": "Comments on Chapter 12 – 12.08 [Canada Doc No. 891, at 065256].

[282] *See*, *e.g.*, Email "RE: Chapter 17 questions" (16 January 2009), [Canada Doc. No. 794, at 063529] ("1. There were a number of questions about applying subsection 27(3) when an assertion is made in the description that lacks utility (17 .03). Questions varied from "Is this based on a court case?", "Should such a case be brought to a Final Action if they do not amend?", "How will the applicant be able to amend the description without adding new matter?" (i.e. would changing "compound X is useful... " to "compound X may be useful. .. " be considered new matter"?). There was also some concern as to why this part of the PA is being used for this objection.").

[283] Dimock First Report, paras. 92-113 and 221; Dimock Second Report, paras. 87-109. *See also* Opening Statement of Canada, May 30, 2016, pp. 190:5 – 193:14; Opening Presentation of Canada, Slides 35-36; Closing Statement of Canada, June 8, 2016, pp. 2260:19 – 2269:16; Resp. CM, paras. 108-124; Resp. Rejoinder, para. 161.

under the *Patent Act*.[284] Even Claimant's own experts on Canadian law have never taken that position.[285]

1) The Patent Act and Early Jurisprudence Show that Utility Must be Established Before Filing

138. Establishing the utility of an invention has always been an essential element of inventorship under the *Patent Act*.[286] It is not, and never has been, permissible to patent now and invent later. As the Supreme Court of Canada explained in *Consolboard*, the utility requirement "is a condition precedent to an invention".[287] Without first establishing utility, a patent applicant has not made an invention and has no claim to priority for patent rights over other prospective applicants.[288]

[284] Armitage, May 31, 2016, p. 387:2-11 ("MR. ARMITAGE: …The larger part of what I think was gotten wrong by Canadian law was the fact that Health Canada actually approved this compound as safe and effective for the treatment of ADHD and, therefore, there was no factual issue, no factual dispute – no possible factual dispute that this compound was, in fact, useful."); Armitage, May 31, 2016, pp. 393:25 – 395:4 ("THE PRESIDENT: So is it your testimony that once Health Canada has given this approval, if we may call it that way, safe and effective, that it is therefore also useful in the terms of Section 2 of the Patent Act? MR. ARMITAGE: Right. And so you can look at a regulatory approval for a medicine as sufficient to demonstrate it's useful but not necessary to demonstrate it's useful, and so usefulness, particularly in the international way in which that term utility is used, generally refers to some practical real-world value. And largely for many medicines -- for olanzapine, for example, as soon as we did the initial pharmacology testing, we knew the compound was useful. It had useful pharmacological properties. We could typically go ahead and seek a patent on that basis. But once you know a drug is safe and effective in humans, it's hard to say that in a patent sense, the drug can't even be useful."). *See also*, Resp. CM, paras. 165-169; Barton Statement, paras. 22-25; Cl. Reply, FN 434.

[285] Siebrasse First Report; Siebrasse Second Report; Reddon Report.

[286] Resp. CM, para. 108; Dimock Second Report, paras. 88 ("… it has never been permissible under Canadian law to obtain a patent for an invention whose utility had not been established by the time of filing the application.") and para. 94 ("A large body of case law developed on the point that the utility of the invention had to be established before it could be said that any invention had been made"). Section 2 of the *Patent Act* provides that an invention is something that is "new and useful." *See also*, Patent Act, RSC 1985, c P-4 (**R-001**).

[287] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] SCR 504, 1981 CarswellNat 582, para. 40 ("…the Federal Court of Appeal has confused the requirement of s. 2 of the *Patent Act* defining an invention as new and 'useful', with the requirement of s. 36(1) of the *Patent Act* that the specification disclose the 'use' to which the inventor conceived the invention could be put. The first is a condition precedent to an invention, and the second is a disclosure requirement, independent of the first.") (**R-011**).

[288] Dimock First Report, para. 221 ("…a "file now, invent later" approach would be inconsistent with the *Patent Act* and its policy objectives. The patent bargain is made at the time of filing, not later. The court decisions invalidating Claimant's patents for atomoxetine and olanzapine were consistent with this rule, which has not changed since those patents were filed."); Dimock Second Report, paras. 107-109; Under

139. Contrary to Claimant's assertion, Canadian law has never permitted patents to be filed first and then later justified with research conducted after the fact.[289] Indeed, the Supreme Court of Canada's adoption of the doctrine of sound prediction in Canadian law in the 1979 *Monsanto* case confirms that the utility of an invention must be established before filing for a patent.[290] There would have been no need for this permissive approach to establishing utility if applicants could simply patent based on speculation and then justify their claims with testing done after-the-fact.

140. Patent Office practice and the language of MOPOP in the 1990s similarly reflect the longstanding requirement to establish utility by demonstration or sound prediction before filing for a patent. As Dr. Gillen explains, in the 1990s, the Patent Office always required that an invention be fully realized before applying for a patent, including

Canada's "first-to-file system", patent rights are award to the first person to file a patent for an invention. That is the critical date at which exclusive monopoly rights come into existence: Wilson, June 1, 2016, p. 787:7-21. Under Canada's old "first-to-invent" system, patent rights were awarded to the first person to make the invention, irrespective of who filed first. In both systems, the invention must have been made, including establishing utility, to assert priority for patent rights.

[289] Dimock, June 2, 2016, pp. 1166:27 – 1167:5 ("MR. DIMOCK: If you know by just having made the device, for example, that it was obvious that it would have the utility, then you don't have to test it. But if it is not so obvious that what you've made has the utility, then you've got to test it. And that's what the Procter & Gamble and Bristol Myers case stands for in the Court of Appeal …"); *Wandscheer et al. v. Sicard Ltd*., [1948] SCR 1, pp. 3-4 ("It is not sufficient, in order to obtain a valid patent, as Viscount Cave said in *Permutit Co. v. Borrowman*, 'for a man to say that an idea floated through his brain; he must at least have reduced it to a definite and practical shape before he can be said to have invented a process.'") (**R-181**); *Procter & Gamble Co. v. Bristol-Myers Canada Ltd.*, (1979) 42 CPR (2d) 33, para. 15 ("Knowing a new process without knowing its utility is not in my view knowledge of an 'invention'.") (**R-183**); *Goldfarb v. W.L. Gore & Associates Inc.* (2001), 11 CPR (4th) 129, para. 112 ("Proving actual utility at the claimed date of invention is not the only way of establishing it. Canadian patent law holds, in certain circumstances, sufficient if the inventor had soundly predicted the utility of the invention at that date.") (**R-187**); Opening Statement of Canada, May 30, 2016, pp. 191:21 – 192:9; Opening Presentation of Canada, Slide 35; Rep. CM, para. 108-110 and 114; Dimock First Report, para. 102 ("Whether utility is established by demonstration or sound prediction, it has long been understood in Canadian patent law that post-filing evidence is not available to prove that an inventor had made the invention by the filing date of the patent application (including satisfaction of the utility requirement).")

[290] Dimock First Report, paras. 98-101 and 103 ("Indeed, the whole purpose of the introduction of the doctrine of sound prediction was to permit patentees to satisfy the utility requirement at the time of filing without having actually demonstrated utility at that point."); Dimock Second Report, paras. 54 and 68-72. *See also*, Opening Statement of Canada, May 30, 2016, pp. 190:20 – 191:12; Resp. CM, paras. 110-111.

establishing its utility.[291] Post-filing evidence of utility was not accepted.[292] This is consistent with the direction in the 1990 version of MOPOP.[293]

2) Nothing in AZT Suggests that the Court was Changing the Law Regarding How Utility Could Be Proved

141. Nothing in the Supreme Court's 2002 *AZT* decision indicates that the Court considered that it was changing the law on the evidence admissible to establish utility.[294] This was a unanimous judgment of the Court,[295] penned by Justice Binnie, a highly esteemed jurist[296] with particular expertise in patent law.[297] There was not a single dissent from any other judge. There was not even a word of doubt expressed in a concurring opinion that Justice Binnie's decision would depart from the letter or purpose of the *Patent Act*, disrupt settled patent law, or intrude on the legislature's role of making new law.[298] Mr. Reddon testified that he did not doubt that the Supreme Court of Canada's decision in *AZT* was rendered entirely in good faith,[299] and Professor Siebrasse

[291] Gillen First Statement, paras. 33-41 ("The Patent Office has always required that utility be established as at the date an application is filed."), ("This is consistent with the longstanding Patent Office requirement that an applicant must have realized its invention as of the filing date"). *See also*, Resp. CM, para. 119.

[292] Gillen First Statement, para. 41 ("The Patent Office has never accepted post-filing evidence to support "predicted" utility … The only situation in which an examiner would accept evidence of utility after filing was one in which the examiner had doubts as to the credibility of an allegedly demonstrated (not predicted) utility. However, even then the evidence would be required to have pre-dated the filing of the application in question."). *See also*, Resp. CM, para. 119.

[293] *Manual of Patent Office Practise, Consumer and Corporate Affairs Canada, Patent Office* (1990), Art. 18.20.02 ("An invention, such as that relating to a new substance, may not be said to be invented until such date as the utility for it is known.") (**R-309**).

[294] Dimock First Report, paras. 110 ("This was not a reversal of Canadian law, but a confirmation of a well-established rule.") and para. 221. *See also*, Resp. CM, para. 113; Resp. Rejoinder, para. 161.

[295] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153 (**R-004**).

[296] Reddon, June 1, 2016, p. 887:8-9 ("MR. REDDON: I think he's a great judge.").

[297] Dimock First Report, FN 142 ("Justice Binnie also wrote the decisions for the Court in *Whirlpool* and *Free World Trust*, the two seminal cases on patent claim construction in Canada. As a lawyer, he was lead counsel for Unilever in the *Unilever v. Procter & Gamble* patent litigation referred to earlier.")

[298] Reddon, June 1, 2016, pp. 887:22 – 888:19. *See also*, Closing Statement of Canada, June 8, 2016, p. 2263:16-25; Closing Presentation of Canada, Slide 124.

[299] Reddon, June 1, 2016, p. 886:17-19 ("MR. REDDON:…Of course I'm not suggesting that the Supreme Court of Canada was acting in anything but good faith …").

admits that *AZT* pursued, and was rationally connected to, the same policy objective of preventing premature patenting that the utility requirement had served since at least the mid-20th century.[300] Indeed, Professor Siebrasse has elsewhere written that the "similarity of the language is striking" between *AZT* and the Supreme Court's 1948 decision in *Wandscheer*.[301]

142. Rather than making new law, the Court interpreted provisions of the *Patent Act* and jurisprudence that had existed for decades. It canvassed the relevant provisions of the *Patent Act*[302] and noted that the *Act* "does not postpone the requirement of utility to the vagaries of when such proof might actually be demanded."[303] The Court also relied

[300] Siebrasse, June 1, 2016, p. 659:21-24 ("MR. JOHNSTON: …Would you agree that, under prior law, preventing premature patenting was a function served by the utility requirement? PROFESSOR SIEBRASSE: Yes."); Siebrasse, June 1, 2016, p. 667:20-24 ("MR. JOHNSTON: You say that Wandscheer was an early decision illustrating that purpose of the utility requirement in preventing patenting too far upstream? PROFESSOR SIEBRASSE: Yes."); Siebrasse, June 1, 2016, p. 665:19-22 ("MR. JOHNSTON:. ..Would you say having read this that the court in AZT was concerned with the problem of patenting too far upstream? PROFESSOR SIEBRASSE: Yes."); Siebrasse, June 1, 2016, pp. 665:24 – 666:5 ("MR. JOHNSTON: …And would you say that the court's statement that utility must be demonstrated or soundly predicted at the time of filing is rationally connected to the objective of patenting too far upstream? PROFESSOR SIEBRASSE: I would say it's rationally connect, yes."); Norman Siebrasse "Form and Function in the Law of Utility: A Reply to Gold & Shortt" Canadian Intellectual Property Review, p. 15 ("I will show below that the function of preventing premature patents is and has long been served by the actual utility requirement.") (**R-497**). *See also*, Closing Statement of Canada, June 8, 2016, p. 2264:1-15; Closing Presentation of Canada, Slide 126.

[301] Norman Siebrasse "Form and Function in the Law of Utility: A Reply to Gold & Shortt" Canadian Intellectual Property Review, p. 37 ("Thus *Wandscheer* [decided in 1948] is explicitly a case refusing to grant a patent prematurely. This exactly reflects the standard justification for the requirement of actual utility set out in … *Wellcome /AZT*, as discussed above; the similarity of language is striking.") (**R-497**). *See also*, Closing Presentation of Canada, Slide 125.

[302] Dimock First Report, para. 111; Reddon, June 1, 2016, p. 885:4-12; *Apotex Inc. v. Wellcome Foundation Ltd*., [2002] 4 SCR 153, para. 46 ("Utility is an essential part of the definition of an invention (*Patent Act*, s. 2). A policy of patent first and litigate later unfairly puts the onus of proof on the attackers to prove *invalidity*, without the patent owner's ever being put in a position to establish validity. Unless the inventor is in a position to establish utility as of the time the patent is applied for, on the basis of either demonstration or sound prediction, the Commissioner 'by law' is required to refuse the patent (*Patent Act*, s. 40)."), para. 80 (stating that after-the-fact validation is not consistent with the *Act* 'which does not postpone the requirement of utility to the vagaries of when such proof might actually be demanded'"), and para. 84 ("In the broader context of the *Patent Act*, as well, there is good reason to reject the proposition that bare speculation, even if it afterwards turns out to be correct, is sufficient. An applicant does not merit a patent on an almost-invention…") (**R-004**). *See also*, Closing Presentation of Canada, Slide 127.

[303] *Apotex Inc. v. Wellcome Foundation Ltd*., [2002] 4 SCR 153, para. 80 (**R-004**); ("In my view, with respect, Glaxo/Wellcome's proposition is consistent neither with the Act (which does not postpone the requirement of utility to the vagaries of when such proof might actually be demanded) nor with patent

upon decades-old jurisprudence on inventorship and utility,[304] including the 1979 *Procter and Gamble*[305] case and its 1930 *Rice v. Christiani*[306] decision. Finally, it clarified that *Ciba-Geigy*, a 1981 decision of the Federal Court of Appeal,[307] did not stand for the proposition that utility could be proved with post-filing evidence because, on the facts of *Ciba-Geigy*, the Federal Court of Appeal found that there was enough evidence at the filing date to make a sound prediction.[308] The Supreme Court further

policy (which does not encourage the stockpiling of useless or misleading patent disclosures). Were the law to be otherwise, major pharmaceutical corporations could (subject to cost considerations) patent whole stables of chemical compounds for all sorts of desirable but unrealized purposes in a shot-gun approach hoping that, as in a lottery, a certain percentage of compounds will serendipitously turn out to be useful for the purposes claimed. Such a patent system would reward deep pockets and the ingenuity of patent agents rather than the ingenuity of true inventors.") (emphasis added); Dimock First Report, para. 102 ("As observed by the Supreme Court of Canada in *AZT*, the *Patent Act* does not postpone the requirement of utility … to the time when utility may be challenged, which could be any time up to and even beyond the end of the twenty-year patent term.").

[304] Reddon, June 1, 2016, p. 885:13-19. *See also*, Closing Statement of Canada, June 8, 2016, pp. 2264:17 – 2265:1; Closing Presentation of Canada, Slide 127.

[305] *Apotex Inc. v. Wellcome Foundation Ltd*., [2002] 4 SCR 153, para. 52 citing *Procter & Gamble Co. v. Bristol-Myers Canada Ltd.*, (1979) 42 CPR (2d) 33 ("Knowing a new process without knowing its utility is not in my view knowledge of an "invention"".") (**R-004**).

[306] *Apotex Inc. v. Wellcome Foundation Ltd*., [2002] 4 SCR 153, para. 54 citing *Christiani v. Rice*, [1930] SCR 443, para. 31 ("it is not enough for a man to say that an idea floated through his brain; he must at least have reduced it to a definite and practical shape before he can be said to have in-vented a process.") (**R-004**).

[307] Notably, when *Ciba-Geigy* was decided, it was not established in Canadian law that new use patents – the types of inventions that were before the court in *AZT* and atomoxetine - were even patentable under the *Patent Act*. The patentability of these types of inventions was subsequently established by the Supreme Court of Canada in *Shell Oil Company v. Commissioner of Patents*, [1982] 2 SCR 536, paras. 24 and 34 (**R-046**); Closing Statement of Canada, June 8, 2016, p. 2267:6-20.

[308] Dimock, June 2, 2016, pp. 1143:1-21, 1146:8-20; Reddon, June 1, 2016, p. 890:15-16 (MR. REDDON: So he's basically saying the laws articulated in *Ciba-Geigy* may be obiter …); *Apotex Inc. v. Wellcome Foundation Ltd*., [2002] 4 SCR 153, para. 84 ("Moreover, on the facts of *Ciba-Giegy* itself, Thurlow C.J. says, as quoted above, that '[e]ven at the time it was made it is not improbable [i.e., it is probable] that it [the invention] would have been considered well founded [i.e., a sound prediction.'") (**R-004**); *Ciba-Geigy AG. v. Canada (Commissioner of Patents)*, (1982), 65 CPR (2d) 73 (FCA), pp. 76-77 ("In this context the use by the author of the word 'possible' does not appear to me to support the view that what was being asserted was speculation … Even at the time it was made it is not improbable that it would have been considered well founded.") (**R-190**); Closing Statement of Canada, June 8, 2016, pp. 2266:12 – 2269:16; Closing Presentation of Canada, Slides 131-135; Resp. CM, paras. 117-119; Dimock First Report, paras. 108-110 ("…there was no need to consider post-filing evidence in *Ciba-Geigy*) (para. 110).

explained that reading *Ciba-Geigy* as endorsing after-the-fact validation of speculation would be inconsistent with its own earlier holding in *Monsanto*.[309]

143. Nor did *AZT* overturn any other prior case law endorsing the notion that utility could be established using post-filing evidence. Claimant argues that post-filing evidence was, until 2002, routinely used by courts to assess the utility of an invention. This is incorrect. As Mr. Dimock explained, Claimant relies on cases concerning the operability (or utility in fact) of the invention, which is a different question from whether utility was established at the filing date.[310] Post-filing evidence always has been, and still is, admissible to show the operability of the invention; but post-filing evidence was never, and still is not, admissible to show that the inventor had actually made an invention, including establishing its utility, when it filed for a patent.[311]

3) The Legal Community Did Not Regard AZT as a Dramatic Change in Law

144. Evidence contemporaneous to the release of the Supreme Court's decision in *AZT* shows that its treatment of proof of utility was not regarded as a dramatic change in the law. Mr. Reddon's claim that he and other practitioners regarded the decision as a

[309] *Apotex Inc. v. Wellcome Foundation Ltd*., [2002] 4 SCR 153, para. 84 ("Thurlow C.J. purported to be applying *Monsanto*, *supra*, and in the passage from *Monsanto* that he quotes Pigeon J. says it is central to the analysis that he is dealing with '…a matter which is not of speculation but of exact science …' The point of Pigeon J.'s reasons is that a wide gulf separates speculation from 'exact science' and it is the latter that may (or may not, depending on the expert evidence) permit sound prediction.") (**R-004**). *See also*, Closing Statement of Canada, June 8, 2016, p. 2268:10-17; Closing Presentation of Canada, Slide 133.

[310] Dimock First Report, paras. 104-105 ("The post-filing "evidence" used by Canadian courts does not relate to whether an invention was demonstrated or soundly predicted at the time of filing (thus, whether one has actually made an invention) but rather relates to the utility-in-fact (operability) of the invention described in the patent.") (emphasis in original); Dimock Second Report, paras. 90 and 100-106. *See also*, Resp. CM, para. 11.

[311] Dimock, June 2, 2016, pp. 1042:17 – 1043:4; Dimock, June 2, 2016, pp. 1167:23 – 1168:17; Dimock, June 2, 2016; p. 1169:11-15; Dimock, June 2, 2016, pp.1132:17 – 1133:2; Dimock First Report, para. 105 ("Post-filing evidence has long been admissible, and continues to be so today, with respect to issues of operability.") *See also*, Closing Statement of Canada, June 8, 2016, p. 2269:1-15; Closing Presentation of Canada; Slide 136; Resp. CM, para. 115;

"radical change" was not supported by any documentary evidence.[312] In fact, Claimant conceded that no impact of the alleged promise utility doctrine was observed until 2005, years after *AZT* was decided.[313] Mr. Reddon corroborated this, and further testified that he observed no impact on the volume of cases that raised utility issues in his own practice until 2008, six years after *AZT* was decided.[314]

145. Contrary to Claimant's characterization of *AZT*, contemporaneous commentary by Canadian law firms shows that the decision affirmed, rather than changed, Canadian law. In February 2003, the leading Canadian intellectual property law firm Smart & Biggar wrote that *AZT* "reaffirmed a long-standing position" that the prediction must be sound at the filing date, "confirmed" that after-the-fact validation of speculation is not enough to establish utility, and rejected the mere "suggestion" from the Federal Court of Appeal to the contrary.[315]

[312] Reddon, June 1, 2016, pp. 874:22 – 875:8 ("MR. JOHNSTON: Now, you've described this decision and this aspect of the decision today in your presentation as really important, really significant, really surprising, radical change. Are these all words that you would use to describe the requirement as stated in *AZT*, that utility must be established by a demonstration or sound prediction prior to filing? MR. REDDON: I used them deliberately and in a considered way because that's exactly how they landed on the practitioners at the time, of which I was one.") *See also*, Closing Presentation of Canada, Slide 118.

[313] Closing Statement of Claimant, June 8, 2016, p. 2036:2-6 ("MS. WAGNER: So again, if you're looking at discrimination and you're looking at impact, you don't see that impact until a few years after 2005 when things really get rolling or as of 2005 and then really picking up around 2008.")

[314] Reddon, June 1, 2016, p. 912:12-18 ("MR. REDDON: My opinion, based on my experience and what I know of other practices and cases, is that it really – if I can use the word – started to bite in 2005, but my personal experience with it really only saw the cases start to hit after Raloxifene in 2008. That's when my practice went from zero of these cases to half.); Reddon, June 1 2016, p. 841:5-12 ("MR. REDDON: …Before the Raloxifene decision, I received notices of allegation on behalf of clients and engaged in litigation under the NOC regulations which follow upon a notice of allegation in 37 cases. With one minor exception that isn't relevant, zero of those cases made allegations that engaged any of the rules that Lilly is complaining about here. Zero out of 37."). *See also*, Closing Statement of Canada, June 8, 2016, pp. 2261:24 – 2262:9; Closing Presentation of Canada, Slide 120.

[315] *Supreme Court of Canada Reaffirms the Doctrine of Sound Prediction in Canadian Patent Law, IP Perspectives Intellectual property & Technology Newsletter*, Smart & Biggar /Fetherstonhaugh, February 2003, pp. 2-3 ("The Court reaffirmed a long-standing position that sound prediction will not successfully support a patent claim if either the prediction at the date of the application was not sound or, irrespective of the soundness of the prediction, there is evidence of lack of utility in respect of some of the areas covered by the claim." "After-the-fact-Validation: The Court confirmed that bare speculation, even if it afterwards turns out to be correct, will not amount to sound prediction. It 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.") (**R-191**); Dimock First Report, para. 110 ("This was not

146. Claimant points to two post-*AZT* court decisions as allegedly acknowledging that *AZT* changed the law on the admission of post-filing evidence. They do not. In one case, decided in 2010, a generic pharmaceutical company argued that *AZT* had changed the law so that it would be allowed to amend its pleadings, and the trial court appeared to take that argument at face value.[316] But that decision was reversed by the Federal Court of Appeal, which did not acknowledge any change in the law.[317] The other case, a 2005 decision, simply noted that under the binding authority of *AZT*, after-the-fact validation is impermissible, and made no comment on whether *AZT* changed the law whatsoever.[318]

4) No Other Heightened Evidentiary Burden Has Been Imposed in Canadian Law

147. Claimant alleges that beyond the exclusion of post-filing evidence, Canadian law has also changed by somehow demanding more evidence of utility than under prior law. This vague allegation does not even specify the date at which such a change is alleged to have occurred or the alleged cause. In any case, it has no merit.[319]

---

a reversal of Canadian law, but a confirmation of a well-established rule.") *See also*, Closing Statement of Canada, June 8, 2016, p. 2261:13-23; Closing Presentation of Canada of Canada, Slide 119; Resp. CM, para. 119.

[316] *Bristol-Myers Squibb Company v. Apotex Inc*., 2010 FC 1304, paras. 30-31 (**C-532**); *Written Representations of the Defendant Apotex Inc., Bristol-Myers Squibb Company v. Aptoex Inc*., T-2078-00 (29 November 2010), para. 16 (**C-533**). *See also*, Closing Statement of Canada, June 8, 2016, pp. 2262:17 – 2263:6; Closing Presentation of Canada, Slides 122-123; Opening Statement of Claimant, May 30, 2016, p. 18:13-20.

[317] Apotex Inc. v. Bristol-Myers Squibb Company, 2011 FCA 34, para. 23 ("Today, Apotex tells us that the decision of the Supreme Court in *Apotex Inc. v. Wellcome Foundation Ltd*, 2002 SCC 77, [2002] 4 S.C.R. 153 changed the law and, therefore, necessitated the 2004 amendments to its pleadings. If that was the case, it could have addressed *Wellcome* with specific and well-particularized amendments, but did not do so.") (emphasis added) (**C-545**). *See also*, Cl. Closing, para. 123.

[318] Opening Statement of Claimant, May 30, 2016, p. 69:4-15; *Aventis Pharma Inc v. Apotex Inc*, 2005 FC 1283, para. 157 ("There is no question that the '206 patent turned out to be a very useful invention. However, this sort of "after the fact validation" was specifically rejected by the Supreme Court of Canada in *Wellcome*.") (**C-209**).

[319] *See* Opening Statement of Canada, May 30, 2016, p. 181:12-24; Opening Presentation of Canada, Slide 24; Closing Statement of Canada, June 8, 2016, p. 2261:2-5; Resp., CM, paras. 121-124; Resp. Rejoinder, para. 274.

148. Claimant's argument that patentees face a heightened evidentiary burden completely overlooks the doctrine of sound prediction, and indeed attempts to mischaracterize sound prediction as part of the alleged problem of a heightened evidentiary burden. To the contrary, sound prediction is a permissive rule for establishing utility that has been part of Canadian law since 1979 and is still available to patentees today.[320] It enables patentees to satisfy the utility requirement even when they do not know with certainty that the invention will be useful, so long as they can soundly predict that it is useful. This doctrine permits patenting further upstream in the research process. In short, it allows patentees to secure and defend patents with less evidence than would otherwise be required, not more. Patentees in the pharmaceutical field have relied, and continue to rely, on this permissive rule to secure patents for pharmaceutical inventions based only on testing done on animals (*in vivo*) or in a petri dish (*in vitro*). This is not a heightened, but a relaxed, evidentiary burden.

149. Contrary to Claimant's allegation, there is no new requirement for clinical trials for pharmaceutical inventions to meet Canada's utility requirement.[321] Canadian patent law does not require clinical trials for pharmaceutical inventions to meet the utility requirement.[322] As Mr. Dimock explains, "[n]umerous pharmaceutical patents have been upheld in the absence of clinical trials, including on the basis of sound prediction."[323] For example, in *AZT*, *in vitro* tests were sufficient to support a sound prediction of utility of a compound for the treatment of HIV in humans.[324] This undermines Claimant's

[320] Dimock First Report, paras. 98-101 and 103 ("Indeed, the whole purpose of the introduction of the doctrine of sound prediction was to permit patentees to satisfy the utility requirement at the time of filing without having actually demonstrated utility at that point.") (para. 103); Dimock Second Report, paras. 54 and 68-72. *See also*, Opening Statement of Canada, May 30, 2016, pp. 190:20 – 191:12; Resp. CM, paras. 110-111.

[321] Dimock First Report, para. 100. *See also*, Resp. CM, para. 124.

[322] *Pfizer Canada Inc. v. Novopharm Ltd.*, 2009 FC 638, paras 86-87 (**R-188**); *Allergan Inc. v Canada (Minister of Health)*, 2011 FC 1316, para. 69 (**R-189**); Dimock First Report, para. 100 ("I disagree with Claimant's suggestion that a pharmaceutical invention cannot meet Canada's utility requirement in the absence of clinical trials.")

[323] Dimock First Report, para. 100.

[324] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153 (**R-004**). *See also*, Resp. CM, para. 124; Respondent's Observations on Issues Raised in Amicus Submissions, FN 115.

baseless allegation that patentees find themselves in a "Catch-22", unable to delay filing for fear that clinical study results will render the invention anticipated or obvious, while unable to file before clinical trials because of the utility requirement.

150. Claimant's allegation of heightened evidentiary scrutiny also overlooks the role of the court in an adversarial system of patent litigation. The court is a neutral arbiter that hears and adjudicates on the evidence put forward by the parties.[325] Any increase in scrutiny of evidence of utility is due in part to the litigation strategy of the parties, who decide how many expert witnesses they wish to put forward and the rigour with which they interrogate the evidence put forward by the other side.[326] The parties, and not the courts, drive the scrutiny of the evidence in the adversarial process.

C. The Canadian Courts Did Not Radically Alter their Interpretation of Canada's Utility Requirement And Create a New Disclosure Requirement for Sound Prediction in 2008

151. Claimant alleges that the raloxifene case in 2008 imposed a new disclosure rule when patentees rely on a sound prediction of utility, requiring disclosure in the patent of the factual basis and line of reasoning supporting the prediction. Claimant and its expert, Mr. Reddon, contend that the Supreme Court's 1979 *Monsanto* decision set out "clear law" permitting a sound prediction to be justified based on evidence not disclosed in the patent.[327] They argue that the Federal Court in its 2008 raloxifene decision departed from the rule in *Monsanto*. Claimant's position is untenable and is contradicted by the historical evidence.[328]

[325] Dimock First Report, para. 29; *See also*, Opening Statement of Canada, May 30, 2016, p.181:12-25; Opening Presentation of Canada, Slide 24; Resp. CM, para. 122.

[326] Dimock First Report, paras. 90-91. *See also*, Opening Statement of Canada, May 30, 2016, p.181:12-25; Opening Presentation of Canada, Slide 24; Resp. Rejoinder, paras. 47-48.

[327] Reddon, June 1, 2016, p. 829:19-21.

[328] Dimock First Report, paras. 114-152; Dimock Second Report, paras. 110-131; Opening Statement of Canada, May 30, 2016, pp. 194:9 – 196:19; Opening Presentation of Canada, Slides 39-41; Closing Statement of Canada, June 8, 2016, pp. 2269:17 – 2275:23; Closing Presentation of Canada, Slides 137-149; Resp. CM, paras. 125-134; Resp. Rejoinder, paras. 162-165.

1) The Need to Disclose the Basis for Predictions of Utility Has Been Recognized Since the 1970s

152. As early as 1970, Canadian patent practitioners were aware that if they relied upon a mere prediction of utility to secure a patent, they must include adequate support for that prediction in the patent disclosure.[329] Claimant attempts to dismiss such practitioner publications as not on point,[330] but that is demonstrably false. For example, in 1970, the esteemed practitioner Mr. William Hayhurst wrote in a publication of the Patent and Trademark Institute of Canada, used for the training of patent agents: "You must include sufficient examples to justify a sound prediction that everything falling within the scope of the claims will have the promised utility."[331]

153. Contrary to what Claimant argues, the need to disclose the basis for a sound prediction was affirmed by the Supreme Court of Canada in *Monsanto* in 1979.[332] That case stands for the proposition that a patentee can rely on sound prediction where the sound prediction is supported by information disclosed in the patent.[333] In *Monsanto*, the

[329] *See* Dimock First Report, paras. 123, 135 and 149-152. *See also*, Resp. CM, para. 128.

[330] Opening Statement of Claimant, May 30, 2016, p. 79: 9-14 ("MS. WAGNER: Again, secondly, Canada points to certain statements made by commentators, most of whom just repeat this same type of language, consideration given by the disclosure, which doesn't mean that you had to include proof or evidence to support utility within the patent itself."); *contra* Dimock, June 2 2016, p. 1101:7-9 ("When you say a "proper disclosure," that means a disclosure in the patent. It can't mean anything else but that.")

[331] W.L. Hayhurst, *Disclosure Drafting* (1971), 28 PTIC Bull (7th) 64, (**R-164**); Opening Presentation of Canada, Slide 40. *See also*, W.L. Hayhurst, Q.C., *Annual Survey of Canadian Law – Industrial Property* (1979), 11 *Ottawa L. Rev*. 391, p. 427. (emphasis added) (writing that "The public is adequately protected by two other principles… and secondly, that the claim is invalid, for covering more than was invented, where it covers more useful territory than could soundly have been predicted to be useful on the basis of what is disclosed.") (**R-198**); William L. Hayhurst, Q.C., *The Art of Claiming and Reading a Claim* in Gordon F. Henderson, *Patent Law of Canada* (Toronto: Carswell, 1994), p. 206 (emphasis added) (stating "It was noted earlier in the discussion of disclosure of the invention that a patent specification must be read as a whole to determine what invention is disclosed, and that for this purpose the claims cannot be ignored, subject to the caveat that claims must not extend beyond sound prediction of what is suggested by the descriptive portion of the specification.") (**R-201**).

[332] Dimock First Report, paras. 126-137 and 147-152; Dimock Second Report, paras. 70, 121-125 and 131. *See also*, Opening Statement of Canada, May 30, 2016, p. 195:1-9; Opening Presentation of Canada, Slides 40-41; Closing Statement of Canada, June 8, 2016, pp. 2271:25 – 2273:6; Closing Presentation of Canada, Slides 145-147; Resp. CM, paras. 129-131 and 133; Resp. Rejoinder, para. 162.

[333] Dimock, June 2, 2016, p. 1083:2-17 ("MR. DEARDEN: 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. Monsanto had

Supreme Court of Canada allowed a claim to a group of compounds on the basis of sound prediction. The only evidence of utility supporting the sound prediction were three examples disclosed in the patent and evidence of the common general knowledge.[334] As Professor Siebrasse confirmed, the two types of evidence considered in *Monsanto* – the three examples and affidavit evidence of the common general

before it, the Supreme Court of Canada had in the patent application, reference to three examples to support the claim for 126 chemicals. That was the factual basis. And the common general knowledge, which was as of the date of the patent application gave the basis, the reasoning, for being able to claim all 126 chemicals. So it 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."); *Monsanto Company v. Commissioner of Patents*, [1979] 2 SCR 1108 ("…all that is said to reject it as not being based on a sound prediction is: "We are not satisfied that three specific examples are adequate support for the breadth of the claim". On what basis is it so? The Board gives absolutely no indication …") (**R-023**); W.L. Hayhurst, Q.C., *Survey of Canadian Law – Industrial Property: Part I*, (1983), 15 Ottawa L. Rev. 38, p. 69 ("In *Monsanto Co. v. Commissioner of Patents*, discussed in the last Survey… [t]he Supreme Court of Canada reversed these decisions having regard to the applicant's evidence of undoubted experts that the disclosure of the three compounds provided a sound basis for predicting the promised utility of the others.") (**R-199**); Adrian Zahl, *Covetous Patent Claims* (2004) 21 CIPR 141, p. 147 (writing that "The Supreme Court in *Monsanto* ruled that a patent is justified by the "consideration" of the patent disclosure if a person skilled in the art could make a "sound prediction" based on the disclosure that the subject matter of the claim could be made by using the teachings in the disclosure and that it would have the utility promised by the disclosure.) (emphasis added) (**R-310**). *See also*, Opening Statement of Canada, May 30, 2016, p. 195:1-9; Opening Presentation of Canada, Slides 40-41; Closing Statement of Canada, June 8, 2016, pp. 2272:16 – 2273:5; Closing Presentation of Canada, Slide 145; Resp. CM, paras. 130 and 133; Resp. Rejoinder, para. 162; Dimock First Report, paras. 126-127 and 135; Dimock Second Report, paras. 70, 121 and 131.

[334] Dimock, June 2, 2016, p. 1086:2-5 ("MR. DIMOCK: They accepted the fact that the three examples given and what was said by the two experts about the common general knowledge was sufficient to make the sound prediction."); Siebrasse, June 1, 2016, p. 699:16-18 ("…a factual basis was disclosed and the sound line of reasoning was common general knowledge…"); Siebrasse, June 1, 2016, p. 697:12-15 ("MR. JOHNSTON: And you would understood those three examples to have constituted, in this case, the factual basis for the sound prediction? PROFESSOR SIEBRASSE: Yes."); Siebrasse June 1, 2016, p. 695:2-3 ("The sound line of reasoning was in the form of affidavits given by experts …"); Siebrasse, June 1, 2016, p. 699:11-16 ("PROFESSOR SIEBRASSE: Yes, so it's fair to say that this passage indicates that, in fact, the sound line of reasoning would have been common general knowledge and so would not have had to have been disclosed either under – even under current Canadian law.") (emphasis added); *Monsanto Co. v. Commissioner of Patents* (The Board), (1977), 34 CPR (2d), pp. 7-8 ("He has submitted affidavits from undoubted experts in this field to show that in their view both that skilled chemists would have received adequate direction from the specification so that they could have prepared all the compounds covered by the claim, and further to suggest that it would have been equally apparent to them what utility the compounds would have possessed.") (**R-197**); *Monsanto Company v. Commissioner of Patents*, [1979] 2 SCR 1108, para. 7 ("The Patent Appeal Board had before it elaborate affidavits from persons skilled in the art …") (**R-023**). *See also*, Resp. CM, para. 130; Resp. Rejoinder, para. 162; Opening Statement of Canada, May 30, 2016, p. 195:1-9; Opening Presentation of Canada, Slides 40-41; Closing Statement of Canada, June 8, 2016, p. 2272:5-12; Closing Presentation of Canada, Slide 146; Dimock First Report, paras. 126-127 and 151; Dimock Second Report, para. 70.

knowledge – are still admissible to support sound predictions in Canadian law today.[335] The law has not changed.

154. Patent Office practice in the 1990s also shows that examiners understood that the basis for a sound prediction of utility needed to be disclosed in the patent.[336] The fact that examiners have at times raised these concerns under different provisions of the *Patent Act* (notably ss. 2 and 27(3)) and *Patent Rules* (notably Rule 84), which may at times overlap,[337] makes no difference to the underlying principle that patentees have always been required to support sound predictions of utility with information in the patent.[338] Even Patent Office comments quoted by Claimant to suggest change in Patent

[335] Siebrasse, June 1, 2016, pp. 699: 24 – 700:4 ("MR. JOHNSTON: But in Monsanto the court did not admit any evidence that would not still be admissible under Canadian law to justify a sound prediction. PROFESSOR SIEBRASSE: Well, yes, that's right."); Siebrasse, June 1, 2016, p. 681:11-15 ("MR. JOHNSTON: On the current state of the law, the line of reasoning, or whatever is within the common general knowledge need not be disclosed in the patent. PROFESSOR SIEBRASSE: Yes."); Siebrasse, June 1, 2016, p. 682:21-25 ("MR. JOHNSTON: And, as a practical matter, in court, how does the court come to know what is within the common general knowledge? PROFESSOR SIEBRASSE: Through the testimony of expert witnesses."). *See also*, Closing Statement of Canada, June 8, 2016, p. 2272:12-16; Closing Presentation of Canada, Slide 146.

[336] Gillen, June 1, 2016, p. 927:1-6 ("DR. GILLEN:…prior to the Apotex decision, this same kind of information was what examiners looked for in a patent application where the utility was based on a sound prediction. Apotex gave us some terminology but it was the same kinds of information …); Gillen, June 1, 2016, p. 939:15-20 ("DR. GILLEN: Well, the AZT decision gave us a three-part test and the terminology that we would use in assessing whether or not a prediction was sound. It didn't actually change, as I said, what the examiners looked for in a patent application …"); Gillen First Statement, para. 44 ("… the examiner would determine whether or not the prediction appeared to be sound based on the type of research disclosed in the application, the results obtained, and the explanation provided in the specification as to how those results could predict the utility of a subject compound.") and para. 47 (AZT "effectively confirmed the practice that had been employed by the Patent Office since the 1990s in allowing patents based upon a sound prediction of utility, assuming some basis for that prediction was set out in the patent"); Gillen Second Statement, para. 14 ("… since the Supreme Court decided the *Monsanto* case in 1979, patent examiners have applied the same principles of disclosure in sound prediction cases as they have more recently."); Dimock First Report, para. 137. *See also*, Closing Presentation of Canada, Slide 147; Resp. CM, para. 134; Resp, Rejoinder, para. 164.

[337] Dimock First Report, para. 81; Dimock Second Report, paras. 52-72. *See also*, Resp. Rejoinder, paras. 34-173.

[338] Gillen, June 1 2016, pp. 947:4-14 ("So there was discussions at that time in the office about what section of the rules, or the *Act*, should be used when dealing with claims of broad scope. And it may be that discussion is still going on to this day. I don't know. The underlying fact with both of these applications was that there's a claim of broad scope. It's not a change in the law. It's what section of the *Act* or the rules should be used in making the objection to the scope of the claim."); Gillen Second Statement, para. 18 ("…the Patent Office historically preferred to issue an Office Action on the basis of Rule 84, which requires that the claims shall be "fully supported by the description" … The claims would

Office practice regarding the disclosure requirement for sound prediction actually show consistency in the underlying substantive patent law principles.[339]

2) The Need to Disclose the Basis for Sound Prediction was Affirmed in AZT in 2002

155. Claimant's own theory of when Canadian law first required disclosure of the basis for a sound prediction is confused and contradictory. At the hearing, Claimant[340] and its expert, Professor Siebrasse,[341] acknowledged that the disclosure requirement for sound prediction was recognized in the 2002 *AZT* decision. Claimant's expert, Mr. Erstling, also traced the disclosure requirement to *AZT*.[342] Yet Claimant has previously argued that *AZT* does not even suggest the disclosure requirement for sound prediction,[343] and Mr. Reddon testified that he "never considered" that there was a

need to be supported by the description, meaning both the basis for, and the soundness of, the prediction would need to be discloed.") and para. 16 ("While the Commissioner refused to grant a patent … on the basis of now-subsection 27(3) … it is clear 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.") *See also*, Closing Presentation of Canada, Slide 278.

[339] Cl. Reply, para. 141, quoting *CIPO, Final Action for Application* 2, 248,228, at 3 (1 February 2011) ("The claims were previously considered defective from noncompliance with section 84 of the *Patent Rules* , on the basis that the lack of proper disclosure of a sound prediction implied a lack of proper support for the claims. Following current Office practice, this objection is now presented as non-compliance with section 2 of the Patent Act (lack of utility).") (**C-414**); Wilson, June 1, 2016, pp. 806:10 – 807:17.

[340] Opening Statement of Claimant, May 30, 2016, p. 49:1-5 ("MS. WAGNER:…the AZT decision basically stated an additional disclosure rule, or what might have looked like an additional disclosure rule, but didn't actually apply it in that case because it wasn't at issue..."); Opening Statement of Claimant, May 30, 2016, p. 68:15-20 ("MS. WAGNER:...the disregarding of post-filing evidence, does absolutely date to AZT 2002. It's the extra disclosure requirement that's uncertain because the court alluded to it but then never applied it, and then it wasn't until 2008 that it actually was applied.")

[341] Siebrasse, June 1, 2016, pp. 684:11 – 685:2 ("PROFESSOR SIEBRASSE: It made some statements that certainly could be interpreted as supporting this disclosure … those words are amenable to that interpretation, although they're amenable to other interpretations as well.") *See also*, Closing Presentation of Canada, Slide 139.

[342] Erstling, June 4, 2015, p. 1602:18-21 ("PROFESSOR ERSTLING: This was my understanding that it was a requirement brought into effect relatively recently … I believe it was the *AZT* case.") *See also*, Closing Presentation of Canada, Slide 140.

[343] Cl. Reply Memorial, para. 111 ("*AZT* did not establish or endorse a heightened disclosure rule for sound prediction … *AZT* does not suggest, much less hold, that courts must disregard evidence of soundly predicted utility that is not disclosed in the patent.")

requirement to disclose the basis for a sound prediction until the raloxifene decision in 2008, affirmed by the Federal Court of Appeal in 2009.[344]

156. Claimant's position – in all of its permutations – is without merit. The Supreme Court in *AZT* clearly affirmed that the doctrine of sound prediction requires disclosure of the basis for the prediction in the patent.[345] The Court explained that in this sort of case, "the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly."[346] It reiterated three times in the judgment that the patent in issue disclosed the factual basis and the sound line of reasoning supporting the prediction, enabling the patentee to rely on a sound prediction.[347] Moreover, in recognizing this requirement, the Supreme Court did not change Canadian law, but affirmed the same principle reflected in its 1979 *Monsanto* decision.

157. Canadian patent practitioners understood that *AZT* clearly reiterated the requirement to disclose the basis for a sound prediction in the patent. This is evident in

[344] Reddon, June 1, 2016, pp. 864:17 – 865:15; Closing Presentation of Canada, Slide 138; Reddon Report, para. 10 ("Prior to *Raloxifene*, I had never considered that there was any need to establish that an inventor had met a "heightened" obligation to disclose facts supporting a prediction in the patent.")

[345] Dimock First Report, paras. 124-125; Dimock Second Report, paras. 126-131. *See also*, Opening Statement of Canada, May 30, 2016, p. 195:10-22; Opening Presentation of Canada, Slide 41; Closing Statement of Canada, June 8, 2016, pp. 2270:6 – 2271:24; Closing Presentation of Canada, Slides 139-144; Resp. CM, paras. 132-133; Resp. Rejoinder, para. 162.

[346] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153, para. 70 (**R-004**); Opening Presentation of Canada, Slide 41.

[347] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153, paras. 3, 70 and 75 ("It was sufficient that at the time the Glaxo/Wellcome scientists disclosed in the patent a rational basis for making a sound prediction that AZT would prove useful in the treatment and prophylaxis of AIDS, which it did." "In this sort of case, however, the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly. Precise disclosure requirements in this regard do not arise for decision in this case because both the underlying facts (the test data) and the line of reasoning (the chain terminator effect) were in fact disclosed, and disclosure in this respect did not become an issue between the parties. I therefore say no more about it." "The trial judge has found that the inventors possessed and disclosed in the patent both the factual data on which to base a prediction, and a line of reasoning (chain terminator effect) to enable them to make a sound prediction at the time they applied for the patent.") (**R-004**); Siebrasse, June 1 2016, p. 689:23 – 690:10 ("MR. JOHNSTON: You recognize certainly the plain language of paragraph 70 and 75. The Supreme Court of Canada is saying that the factual data on which to base a prediction was disclosed in the patent. That's what the Supreme Court of Canada said PROFESSOR SIEBRASSE: Well, the question is – well, they said that but I'm telling you that the beses itemized … these are not in the patent.") *See also*, Closing Statement of Canada, June 8, 2016, p. 2271:5-14; Closing Presentation of Canada, Slides 143-144.

publications by the leading Canadian law firm Smart and Biggar in 2003[348] and Claimant's own law firm, Gowlings.[349] Both clearly identify *AZT* as requiring disclosure of the basis for a sound prediction. Other practitioners also expressly recognized the continuity in the disclosure requirement for sound prediction from *Monsanto* through to *AZT*.[350] Mr. Reddon simply disagreed with these interpretations.[351]

158. It is implausible for Claimant to allege that it did not understand that there was a need to disclose the basis for a sound prediction in the patent until the raloxifene decision in 2008. Claimant itself received CIPO office actions prior to raloxifene raising the need for disclosure of the basis for a sound prediction in the patent, and citing *AZT* for this requirement.[352] Claimant also blatantly misstates the factual record by arguing

[348] "Supreme Court of Canada Reaffirms the Doctrine of Sound Prediction in Canadian Patent Law," *IP Perspectives Intellectual property & Technology Newsletter*, Smart & Biggar /Fetherstonhaugh, February 2003, pp. 2-3 ("The Court identified a three-component requirement of the doctrine: 1. There must be a factual basis for the prediction; 2. The inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis; and 3. There must be proper disclosure of the foregoing.") (emphasis added) (**R-191**). *See also*, Closing Statement of Canada, June 8, 2016, p. 2270:6-20; Closing Presentation of Canada, Slide 141.

[349] Gowling Lafleur Henderson LLP, *Pharmacapsules @ Gowlings*, May 4, 2009, p. 5 ("The Court [in *Raloxifene*] reiterated the test articulated by the Supreme Court in *AZT* namely that when an invention had not yet been reduced to practice, the disclosure must give both the underlying facts and the sound line of reasoning to justify the prediction.") (**R-494**). *See also*, Closing Statement of Canada, June 8, 2016, p. 2270:11-19; Closing Presentation of Canada, Slide 141.

[350] Adrian Zahl, *Covetous Patent Claims* (2004) 21 CIPR 141, p. 158 ("in cases such as *Monsanto* and *Apotex v. Wellcome Foundation* … the question is whether the patent specification provides sufficient information to enable a skilled reader to both produce everything within the scope of the patent claims and to predict that they will probably achieve the desired goal.") (**R-310**); Dimock Second Report, paras. 124-125. *See also*, Opening Statement of Canada, May 30, 2016, p. 195:18-22; Opening Presentation of Canada, Slide 41.

[351] Reddon, June 1, 2016, p. 873:12-13 ("MR. REDDON: I never considered that this passage means what Mr. Bochnovic thought [referring to the Smart & Biggar comment on AZT]"); Reddon, June 1, 2016, p. 867:15-22 ("MR. JOHNSTON: You disagree with the characterization given about *AZT* by Claimant's law firm in 2009? … MR. REDDON: … I disagree with it [referring to the Gowlings comment on *AZT*]"). *See also*, Closing Statement of Canada, June 8, 2016, p. 2270:10-18; Closing Presentation of Canada, Slide 142.

[352] Gillen Second Report, paras. 26-27, citing CIPO Office Action dated October 23, 2003, Application No. CA2304657 ("Claims 1 to 20 do not comply with Section 84 of the Patent Rules. The description fails to provide a sound line of reasoning for the utility claimed. The factual support described does not lead to the conclusion that the subject matter of these claims would have the predicted utility") (**R-382**). *Apotex v. Wellcome Foundation Ltd.*, 2002 SCC 77 (**C-213**), and CIPO Office Action dated October 7 2004, Application No. CA2248873 ("Claim 6 does not comply with section 2 of the *Patent Act*. The description fails to provide a sound line of reasoning for the utility of olanzapine for treating inflammation. The

that the Federal Court of Appeal in the atomoxetine litigation found that the disclosure rule traced only as far back as the decision in raloxifene rather than the decision in *AZT*.[353] This is false. The Federal Court in atomoxetine specifically cited and considered itself bound by *AZT*.[354]

3) There was No Precedent in Canadian Law for Allowing a Sound Prediction on the Facts of Atomoxetine

159. Ironically, given Claimant's allegations about change in the law, the real change in Canadian law would have come if a sound prediction was allowed on the facts of the atomoxetine case.[355] In all of the leading Canadian authorities on sound prediction, such as *Monsanto* and *AZT*, the patent disclosed support for the sound prediction of utility.[356] Professor Siebrasse acknowledged on cross-examination that he was unaware of any Canadian case where a sound prediction was upheld in the absence of any factual basis disclosed in the patent.[357]

160. The atomoxetine patent differed from all prior patents that were upheld on the basis of sound prediction in Canadian law, because the atomoxetine patent disclosed no

factual support described does not lead to the conclusion that the subject matter of these claims would have the predicted utility") (**R-383**). *See also*, Resp. Rejoinder, para. 164.

[353] Opening Statement of Claimant, May 30, 2016, pp. 47:25 – 48:9 and 48:13-19 ("THE PRESIDENT: They don't go back in time prior to 2008? MS. CHEEK: That's correct … MR. BORN: It's AZT? MS. CHEEK: For the disclosure rule it's the 2008 Raloxifene decision.")

[354] *Novopharm v. Eli Lilly*, 2010 FC 915, para. 117 ("In a case involving a claimed sound prediction of utility, it is equally beyond debate that an additional disclosure obligation arises. According to Justice Binnie in *AZT*, above, this obligation is met by disclosing *in the patent* both the factual data on which the prediction is based and the line of reasoning followed to enable the prediction to be made.") (**R-027**).

[355] *See* Closing Statement of Canada, June 8, 2016, p. 2275:8-23; Closing Presentation of Canada, Slide 149.

[356] Dimock First Report, para. 127 (*Monsanto*) and para.125 (*AZT*); Dimock Second Report, para. 71 (*Monsanto*) and para. 127 (*AZT*). *See also*, Resp. CM, para. 133.

[357] Siebrasse, June 1, 2016, p. 700:5-11 ("MR. JOHNSTON: Professor Siebrasse, are you aware of any Canadian case in which a sound prediction of utility was upheld in the absence of any disclosure of a factual basis for the prediction in the patent? PROFESSOR SIEBRASSE: Not whether – well, I mean I'm not aware of any.") *See also*, Closing Presentation of Canada, Slide 149.

information whatsoever to support a sound prediction of utility.[358] There was no precedent in Canadian law for allowing a sound prediction in these circumstances.

D. Claimant's Statistical Evidence Does Not Support its Theory of a Dramatic Change in the Law

161. Claimant attempts to prop-up its theory of change Canada's law of utility with anecdotal statistical evidence of changes in litigation volumes and outcomes. Claimant's statistics are of no assistance to its argument that there has been a dramatic change in Canadian law.[359]

162. As an initial matter, Claimant's statistics do not even correspond to its theory of the alleged change in Canadian law. Claimant alleges three changes occurring at three different points in time: a prohibition on post-filing evidence to establish utility in 2002, the introduction of a promise standard of utility in 2005, and the introduction of a heightened disclosure requirement for sound prediction in 2008. It also argues that the doctrine is a unitary one, that crystallized with all three elements in 2008. Yet Claimant only presents statistical analyses that divide the data at 2005.[360] There is no attempt whatsoever to isolate and measure the effect of the alleged changes in Canada's law of utility in 2002 and 2008. In contrast, Dr. Brisebois did conduct such analyses and found no statistically significant difference in pharmaceutical patent invalidation rates on the basis of utility before and after either 2002 or 2008.[361]

---

[358] *Novopharm Ltd. v. Eli Lilly and Co.*, 2010 FC 915, para. 36 ("the '735 Patent offers no information about the nature or sources of the evidence relied upon by the inventors to support the promise of atomoxetine's utility to treat ADHD by demonstration or by sound prediction.") (**R-027**). *See also*, Resp. CM, para. 34.

[359] Brisebois First Statement, paras. 11-22; Brisebois Second Statement. *See also* Opening Statement of Canada, May 30, 2016, p. 326:4-17; Closing Statement of Canada, pp. 2247:6 – 2250:11 and 2278:14 – 2281:18; Closing Presentation of Canada, Slides 82-93 and 153-160; Resp. Rejoinder, paras. 189-202.

[360] Brisebois Second Statement, para. 35 ("However, all of its statistical analyses are centered on 2005.") *See also*, Resp. Rejoinder, para. 201.

[361] Brisebois Second Statement, paras. 35-39 ("If the alleged new post-filing evidence and "heightened disclosure" rules began to be applied against pharmaceutical patents in a new way after 2002 and 2008, respectively, one might expect to see a statistically significant increase in pharmaceutical patent invalidation rates in the periods following the *AZT* and *Raloxifene* decisions. This is not the case.");

163. Even the statistics that Claimant puts forward to draw comparisons before and after 2005 are purely anecdotal. Conspicuously absent from Claimant's "rigorous" statistical analysis is any claim of a statistically significant difference in utility challenge volumes or outcomes before and after 2005.[362] Dr. Brisebois did conduct this analysis,[363] and found no statistically significant change in the rate of invalidity findings for pharmaceutical patents on the basis of inutility before and after any of the changes in law alleged by Claimant.[364]

164. The purely anecdotal statistics that Claimant puts forward are also methodologically flawed. Claimant divides the data at a date that is inconsistent with its theory of the case, skewing numbers in its favour.[365] On Claimant's theory of the case,

Brisebois, Errata and Updates, May 29, 2016, p.4, Adjusted tables 8-11.Brisebois Presentation, Slide 20. *See also*, Resp. Rejoinder, para. 201.

[362] Levin Report, para. 5; Levin, June 3, 2016, pp. 1263:24 – 1264:3 ("PROFESSOR LEVIN: … So my primary affirmative point, Question No. 1 that I was asked, was to compare pharmaceutical and non-pharmaceutical cases post-2005. That has nothing to do with what happened pre.") and 1264:11-1264:24 ("SIR DANIEL: But as regards the change over time, simply as regards pharmaceutical patents, that is relevant, isn't it? PROFESSOR LEVIN: Yes. It would alter the proportions of inutility cases in the pharmaceutical sector pre versus post. However, as I testified in regard to table 2 of my report, that is a very treacherous, shall we say, comparison, because of the small numbers involved. If we're going to rely, as I believe the Respondent might, on the lack of statistical significance between those two proportions and draw from that conclusion, therefore, that they were identical in truth, that's problematic because of low power."); Levin, June 3 2016, pp. 1276:23 – 1277:8 ("THE PRESIDENT: Is that because the sheer number you have is not too sensitive to make actually a meaningful – you say statistically significant analysis here? PROFESSOR LEVIN: The point you're raising is exactly the point I drew as an important caveat when I testified about table 2. If you recall, I said I draw no conclusion from the lack of significance between pre and past, and the reason is precisely that. The number of cases pre-2005 challenged on utility was too small."). *See also*, Resp. Rejoinder, para. 201; Brisebois, Second Statement, para. 33 ("Dr. Levin has not assessed the statistical significance of this difference."); Cl. Reply, para. 300.

[363] Brisebois Second Statement, paras. 33-34 ("…there is no statistical evidence of a difference in utility-based invalidation rates for pharmaceutical patents before and after 2005."); Brisebois, Errata and Updates May 25, 2016, p.3, Adjusted tables 6 and 7. *See also*, Resp. Rejoinder, para. 201.

[364] Even if Claimant had found a statistically significant result, when comparing pre- and post-2005 litigation outcomes, which it did not, this would only show a correlation, not causation. Levin, June 3, 2016, p. 1266:9-10 ("PROFESSOR LEVIN: … I'm not opining about causality as a statistician in this case.") and 1266:24-1267:6 ("PROFESSOR LEVIN: … First on the general point I am not opining on causality. I was not asked to do that; I am not qualified to offer an opinion … I agree there could be other causes; I'm not here to say one way or the other."), 1269:22-23 ("PROFESSOR LEVIN: … Causality and correlation are actually two different things.")

[365] *See* Closing Statement of Canada, June 8, 2016, pp. 2247:6 – 2248:22; Closing Presentation of Canada, Slides 82-86.

September 2, 2005[366] is the origin of the promise standard in Canadian law.[367] Dr. Levin testified that it would therefore be logical to conduct the statistical analysis based on that date.[368] Claimant did not do so. Claimant divided the data at January 1, 2005, a full nine months before it says that the promise standard was even created.[369] Correcting for this flaw, the anecdotal statistics and charts presented by Claimant to support its case look very different. Where Claimant suggested a 0% rate of inutility findings for pharmaceutical patents prior to the alleged introduction of the promise standard in 2005,[370] the rate is actually 40%.[371] The rate is in fact slightly lower after the alleged introduction of the promise standard.

[366] Confidential reasons for judgment were rendered in *Pfizer* on September 2, 2005, *Pfizer Canada Inc. v Apotex Inc.*, 2005 FC 1205 (**C-250**).

[367] Siebrasse, May 31, 2016, pp. 561:18 – 562:1; Siebrasse First Report, para. 72, FN 98 ("The original Federal Court cases were *Bristol-Myers Squibb Co v. Apotex Inc*, 2005 FC 1348 [C-520], *Pfizer Canada Inc v Apotex Inc*, 2005 FC 1205 (C-250) and *Aventis Pharma Inc v Apotex Inc*, 2005 FC 1283 (C-209)". The first Court of Appeal decision affirming the promise of the patent analysis was *Atorvastatin* 2008 FCA 108, *supra* note 51 (C-234)"). *See also*, Closing Statement of Canada, June 8, 2016, pp. 2247:11 – 19; Closing Presentation of Canada, Slide 82.

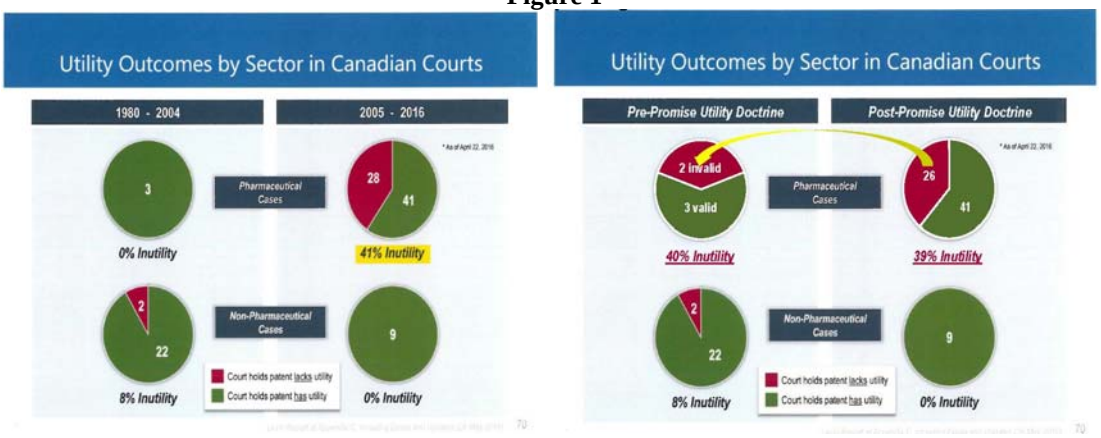
[368] Levin, June 3, 2016, p. 1253:14-21 ("MS. ZEMAN: Let me put it this way: If you were interested in measuring the impact of the promise utility doctrine and it came into existence at a certain moment in time, it would be logical to conduct your analysis as of the date that it came into existence. Would you agree with that? PROFESSOR LEVIN: It would be logical, yes."). *See also*, Closing Statement of Canada, June 8, 2016, p. 2247:22-24; Closing Presentation of Canada, Slide 83.

[369] Levin, June 3, 2016, p. 1255:12-15 ("PROFESSOR LEVIN: Mr. President, may I also correct one thing that you stated a moment ago? I did not draw the line at the year 2005. That was a legal decision."). *See also*, Closing Statement of Canada, June 8, 2016, pp. 2247:24-2248:3; Closing Presentation of Canada, Slide 84; Levin Report, para. 4; Levin Report, para. 4.

[370] Cl. Mem., Appendix 3, Figure 3; Opening Presentation of Claimant, Slide 70.

[371] Closing Statement of Canada, June 8, 2016, pp. 2248:3-8; Closing Presentation of Canada, Slide 85.

Figure 1 [372]



165. Claimant's anecdotal statistics also systematically overstate any impact of the alleged "promise utility doctrine." Claimant has not justified any of its decisions to count any of the cases in its dataset where inutility findings were made as applications of the alleged promise utility doctrine, despite bearing the evidentiary burden to do so. In fact, it inappropriately counts every inutility finding as an application of the promise utility doctrine.[373] But not every inutility finding can be attributed to the alleged promise utility doctrine, as Professor Siebrasse admitted in testimony.[374] Many of the cases counted by Claimant as applications of the promise utility doctrine[375] are not in fact promise cases.[376] Professor Siebrasse has specifically disagreed with several of

[372] Opening Presentation of Claimant, Slide 70; Closing Presentation of Canada, Slide 85.

[373] Levin, June 3, 2016, p. 1248:14-21 ("MS. ZEMAN: The dataset provided to you does not make any distinction between utility and promise utility outcomes. Is that right? PROFESSOR LEVIN: Not to my knowledge. MS. ZEMAN: So you also did not make any distinction between utility and promise utility outcomes in your analysis. Is that right? PROFESSOR LEVIN: I did not, no."). *See also*, Closing Presentation of Canada, Slides 87-88; Cl. Mem., Appendix 2, Figure 2.

[374] Siebrasse, May 31, 2016, p. 550:20-25 ("MR. JOHNSTON: There's certainly other reasons in the law that a patent could be found to lack utility... PROFESSOR SIEBRASSE: Yes, absolutely."). *See also*, Closing Statement of Canada, June 8, 2016, pp. 2248:23 – 2249:13; Closing Presentation of Canada, Slide 89; Resp. Rejoinder, para. 190.

[375] Levin Report, Appendix C; Cl. Mem., App. 2, Fig. 2.

[376] *See, e.g., Abbott Laboratories v. Canada (Minister of Health)*, 2005 FC 1332 (aff'd 2007 FCA 153) (**C-113**); *Merck v. Apotex*, 2005 FC 755 (**C-354**); *Abbott v. Ratiopharm*, 2005 FC 1095 (**C-441**). *See also*, Resp. Rejoinder, para. 190. The testimony of Mr. Reddon corroborates that neither *Abbott Laboratories v. Canada (Minister of Health)*, 2005 FC 1332 (aff'd 2007 FCA 153) (**C-113**) nor *Abbott v. Ratiopharm*, 2005 FC 1095 (**C-441**) should have been included in Claimant's dataset. These *PM(NOC)* cases were decided in 2005, and Mr. Reddon testified that "zero" of his *PM(NOC)* cases prior to 2008 raised any

Claimant's coding decisions,[377] and has more generally argued that far from every inutility finding being an example of the promise doctrine, "[w]hen the patentee is held to a higher standard of utility, this higher standard has been determinative of utility roughly half the time …".[378]

166. Claimant's narrow focus on inutility findings also places blinders on the analysis, and ignores the broader context of trends in Canadian patent litigation.[379] Claimant simply ignores that the "spike" in utility-based invalidity findings was symptomatic of a larger trend of increased litigation and invalidity findings on all patentability criteria, including where utility was not even at issue.[380] Clearly, something other than a change in the way that Canadian courts have interpreted the term "useful" in Canada's *Patent Act* has been driving changes in pharmaceutical patent litigation outcomes.[381]

aspects of Claimant's alleged promise utility doctrine. Reddon, June 1 2013, p. 912:12-18 ("MR. REDDON: My opinion, based on my experience and what I know of other practices and cases, is that it really -- if I can use the word -- started to bite in 2005, but my personal experience with it really only saw the cases start to hit after Raloxifene in 2008. That's when my practice went from zero of these cases to half.")

[377] For example, Claimant attributes both *Pfizer Canada Inc. v. Pharmascience Inc.*, 2013 FC 120 and *Alcon Canada Inc. v. Cobalt Pharm. Co.*, 2014 FC 149 to the promise utility doctrine: Cl. Mem., Appendix 2, Figure 2; Levin Report, Appendix C. Professor Siebrasse rejects that these are promise cases, Norman Siebrasse, *Sufficient Description Blog Excerpts*, p. 85 (writing that in *Pfizer Canada Inc. v. Pharmascience Inc.*, 2013 FC 120 "The false promise doctrine was not in issue.") (**R-476**); Norman Siebrasse, *Sufficient Description Blog Excerpts*, p. 121 (writing of *Alcon Canada Inc. v. Cobalt Pharm. Co.*, 2014 FC 149 that "I do not see it as truly a promise case") (**R-476**). *See also*, Closing Statement of Canada, June 8, 2016, p. 2249:7-13; Closing Presentation of Canada, Slide 90.

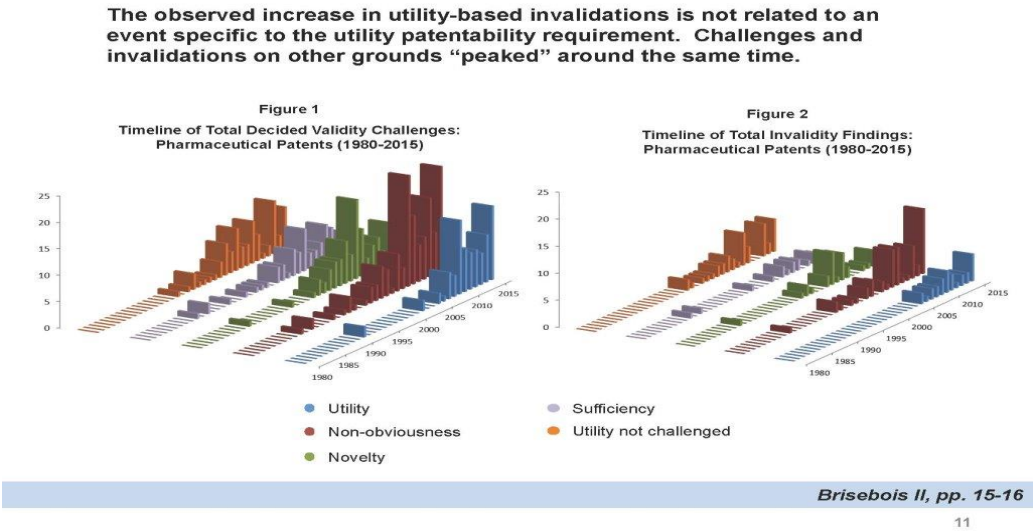
[378] Norman V. Siebrasse, *The False Doctrine of False Promise*, (2013) 29 Can IP Rev 3, p. 2 (emphasis added) (**C-205**). *See also*, Closing Presentation of Canada, Slide 90.

[379] *See* Closing Statement of Canada, June 8, 2016, pp. 2249:14 – 2250:11; Resp. Rejoinder, paras. 189-198.

[380] Brisebois Presentation, Slides 10-11; Resp. Rejoinder, paras. 192-193; Brisebois Second Statement, paras. 40-47 ("… the same "spike" occurred around the same period for all of the main grounds of invalidity"), Figures 1 and 2; Brisebois, May 31, 2016, p. 473:18-20. *See also*, Closing Statement of Canada, June 8, 2016, p. 2250:3-8.

[381] Brisebois Second Statement, para. 47 ("As the data shows, the increase was certainly not related to an event specific to the utility patentability requirement.").

Figure 2[382]



167. Finally, other contextual factors that Claimant ignores may also have impacted litigation patterns over time, such as the introduction of *PM(NOC)* proceedings,[383] the increasing prevalence of secondary patents that may be more susceptible to challenge,[384] market dynamics in the pharmaceutical sector,[385] and shifts in the use of substantively

[382] Brisebois Second Statement, Figures I and II; Brisebois presentation, Slide 11.

[383] Dimock, June 2 2016, p. 1061:7-11 ("MR. DIMOCK: Up until 1995 we had no pharmaceutical litigation to speak of, and it took a number of years for both the pharmaceutical and the generic side of the industry to understand the proper procedures."); Siebrasse, June 1 2016, p. 760:15-18 ("PROFESSOR SIEBRASSE: Yes. So there was pharmaceutical litigation even under the compulsory licensing regime, but the abolition of the regime has contributed to the increase, no doubt."); Closing Statement of Canada, June 8, 2016, pp. 2249:20 – 2250:2; Closing Presentation of Canada, Slide 92; Resp. CM, paras. 138-141; Dimock First Report, paras. 39, 43-45, 154, 156 and 159-161.

[384] Brisebois First Statement, paras. 41-46, Figure 6; Brisebois, Errata and Updates, May 26, 2016, p.1, Errata.2.; Resp. Rejoinder, para. 31; Bouchard et al., "Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals", Northwestern Journal of Technoglogy and Intellectual Property, vol. 8, issue 2 (Spring 2010) (**R-421);** European Commission (2009) Pharmaceutical Sector Inquiry: Final Report, paras. 476-506, 523-527 (**R-243 amended**); A. Kapczynski, C. Park, and B. Sampat, "Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of 'Secondary' Pharmaceutical Patents," *PLOS One*, vol. 7, Issue 12 (December 2012), p. 1 (**R-422**). *See also* Opening Statement of Canada, May 30, 2016, pp. 178:6 – 180:9; Resp. CM, para. 145; Resp. Rejoinder, para. 191; Dimock Second Report, paras. 20-25.

[385] Merges, June 3 2016, pp. 1322:19 – 1323:3 ("PROFESSOR MERGES: … There are multiple reasons why companies engage in patent litigation … They may be using patent litigation for strategic purposes to slow down a new entrant or to sort of harass a competitor. There's a lot of different scenerios under which patents are litigated."); Holbrook, June 3 2015, pp. 1557:18 – 1558:3 ("PROFESSOR HOLBROOK: So the absence of litigation, to me, doesn't tell us much because it becomes a business decision as to whether

overlapping patent law doctrines by litigants over time (such as utility and overbreadth).[386] Claimant's flawed statistics are of no assistance to its argument that there has been a dramatic change in Canadian law.[387]

E. Claimant's Own Corporate Practice and Records in the mid-2000s Show that There Was No Dramatic Change in the Law

168. Given the dramatic and fundamental changes that Claimant alleges occurred in Canadian law in 2002, 2005, and 2008,[388] one would expect to see some evidence of these changes in Claimant's own corporate records or in the recollections of its executives responsible for Canadian patent filings during that period. There is a total dearth of such evidence from Claimant.[389] Not a single document or recollection in testimony supports its allegation of a dramatic and fundamental change in the law. This lack of evidence has a simple explanation – there was no dramatic change in Canadian patent law in 2002, 2005, or 2008. Claimant's allegations to the contrary are false and belied by its own corporate practice during the relevant period.

169. Claimant emphasizes that intellectual property rights are the lifeblood of its business,[390] and its executives consistently testified that they would have been briefed on any material patent law changes in markets where Claimant held patents, including Canada.[391] In short, if there were dramatic changes in Canadian law in the mid-2000s,

to sue … So the failure to challenge a patent or the failure to sue on a patent, its hard to read anything about the validity of that patent based off of that decision.")

[386] Dimock First Report, paras. 125-126; Dimock Second Report, paras. 52-72 ("The case law on overbreadth and utility cannot be neatly divided into distinct categories, as Professor Siebrasse suggests. The courts have expressly warned against treating patent law concepts as watertight compartments.") *See also*, Opening Statement of Canada, May 30, 2016, pp. 177:12-17 and 180:10-20; Opening Presentation of Canada, Slide 18; Resp. Rejoinder, paras. 173-174.

[387] The flaws in Claimant's statistical arguments are further discussed in paras. 222-229 below.

[388] Cl. Mem, para. 56; Cl. Reply, paras. 219 and 324.

[389] *See also*, Resp. Rejoinder, paras. 154-155; Closing Statement of Canada, June 8, 2016, p. 2161:6-19.

[390] Cl. Mem., para. 25.

[391] Armitage, May 31, 2019, p. 343:18-21; Armitage, May 31, 2019, p. 344:14-19 ("MR. ARMITAGE: Absolutely, if there had been material developments in the Canadian law on utility, there would have been any number of communications back and forth between Lilly's in-house patent attorneys and its Canadian patent agents."); Armitage, May 31, 2019, p. 349:4-8; Postlethwait, May 31, 2019, p. 426:19-22 ("MS.

Claimant would have been made aware of these changes, and its executives and documentary records from that period would corroborate that it was aware.[392] Mr. Armitage explained during direct examination that although there were regular communications between Lilly's in-house patent attorneys and its Canadian patent agents, he would have been shocked if there were evidence of such communications regarding the utility requirement from the mid-1990s "since it was so well understood" that the utility requirement was "so low" during that period. It stands to reason that if in the mid-2000s there were dramatic changes in Canada's utility requirement, especially if such changes resulted in a higher standard, such communications would have occurred.

170. Yet, Claimant has adduced no evidence whatsoever showing that during the mid-2000s it considered that there had been any change in Canadian law. The witness statements and testimony of Claimant's executives did not indicate that any change in Canadian law was brought to their attention during the relevant period. Their evidence does not indicate any briefing on the 2002 *AZT* decision,[393] on the cases that allegedly

ZEMAN: And you expected your legal team to raise with you any issues they identified that might affect the products in your portfolio? MR. POSTLETHWAIT: Yes."); Nobles, May 31, 2019, p. 444:19-23 ("MS. ZEMAN: And if there was a fundamental change that presented a potential risk to the validity of your patents, you would expect your patent attorney to advise you of that? MS. NOBLES: That's correct."); Nobles, May 31 2016, p. 446:7-15; Stringer, May 31 2016, pp. 409:23 – 410:7 ("MR. SPELLISCY: So I understand, then, that if there were significant and dramatic changes in the way Canada – in the law in Canada, it would have been your responsibility to understand those changes and to brief senior Eli Lilly management on them, correct? MR. STRINGER: Yes. I mean, the expectation would be that our local patent attorney would advise us as to an important change in the law.") *See also*, Closing Statement of Canada, June 8, 2016, pp. 2160:22 – 2161:5; Closing Presentation of Canada, Slides 70-73.

[392] Armitage, May 31 2016, p. 344:14-25 ("MR. ARMITAGE: Absolutely. If there had been material developments in the Canadian law on utility, there would have been any number of communications back and forth between Lilly's in-house patent attorneys and its Canadian patent agents. However, on this particular issue I'd be actually 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").

[393] Nobles, May 31, 2016, p. 450:6-7 ("MS. NOBLES: I don't recall any discussion of this [*AZT*]"); Armitage, May 31, 2016, p. 373:18-19 ("MR. ARMITAGE: I have no recollection whatsoever…[regarding briefing on *AZT*]"); Stringer, May 31 2016, p. 412:5-11 ("MR. SPELLISCY: Do you recall, Mr. Stringer, briefing on this issue [*AZT*], on this decision, to senior management? MR. STRINGER: Do I recall – excuse me. Do I recall briefing senior management? MR. SPELLISCY: Yes. MR. STRINGER: No."). *See also*, Closing Statement of Canada, June 8, 2016, p. 2262:10-16; Closing Presentation of Canada, Slide 121.

adopted the promise doctrine in 2005,[394] or on the alleged change in law arising from the 2008 raloxifene case.[395]

171. Moreover, Claimant has not produced or entered in evidence a single document from its corporate records during the mid-2000s expressing concern at, or noting any change in, Canadian patent law.[396] No memos, no meetings notes or agendas, no legal opinions, no updates, not even a single email. Nothing from 2002; nothing from 2005; nothing from 2008. Indeed, Claimant produced no such documents to Canada either, despite Canada's request that it do so during the document production phase of this arbitration.[397] Again the reason for such a failure is clear -- Claimant has put no relevant documents into the record because no such materials exist. No briefing and no discussions occurred. And no briefing or discussions occurred because there was no dramatic change in law during this period on which briefing or discussion was required.

F. The Lack of Concerns from Other States in the Relevant Period is Evidence that There Has Been No Dramatic Change in the Law

172. Given that Claimant alleges dramatic changes in Canada's utility requirement in 2002, 2005, and 2008 that violate Canada's international intellectual property obligations under treaties like NAFTA, TRIPS and the PCT, Claimant should be able to point to some evidence of other States or international organizations voicing concerns

[394] Stringer, May 31 2016, p. 412:13-19 ("MR. SPELLISCY: … In 2005 the Claimant has alleged there was a change, another dramatic change in Canadian patent law. Do you recall providing any briefings to Eli Lilly senior management in 2005 as your role of executive director of International Patents on those changes? MR. STRINGER: No."); Armitage, May 31 2016, pp. 373:23 – 374:3 ("MR. ARMITAGE: Sometime before 2011, I would have been briefed at least generally on developments in Canadian patent law, and I don't have a specific recollection of whether that briefing would have gone into the details of individual decisions and holdings.")

[395] Nobles, May 31 2016, p. 451:23-25 ("MS. ZEMAN: You were advised about this decision [*Raloxifene*]? MS. NOBLES: I was not."); Armitage, May 31 2016, pp. 373:23 – 374:3 ("MR. ARMITAGE: Sometime before 2011, I would have been briefed at least generally on developments in Canadian patent law, and I don't have a specific recollection of whether that briefing would have gone into the details of individual decisions and holdings.").

[396] *See also*, Resp. Rejoinder, paras. 154-155.

[397] *See also*, Resp. Rejoinder, para. 154; Procedural Order No. 2, Annex B, Requests 4 and 5 (**R-434**).

about, or at least commenting on, the alleged changes in law during the relevant period. In fact, there is none, prior to Claimant initiating this arbitration.

173. The only evidence that Claimant adduced indicating any concern expressed by any State or international organization regarding Canada's utility requirement are the 2014[398] and 2015[399] editions of the Special 301 Report published by the US Trade Representative ("USTR"). [400] While these two publications refer to Canada's utility doctrine as a concern, neither alleges any breach of NAFTA Chapter Seventeen or other international obligations.[401] Further, there is no evidence before this Tribunal of any concerns regarding the utility requirement in Special 301 Reports prior to 2014, over a decade after the Supreme Court of Canada's *AZT* decision in 2002 and five years after Claimant alleges that all elements of the promise utility doctrine crystallized in 2008. The timing of concerns in the Special 301 Reports is no coincidence. It is important to recall that Claimant initiated this arbitration in 2013, and that the Special 301 Report is based not on empirical evidence and analysis, but on industry allegations made to USTR, including representations made by the Claimant and its industry associations.[402] Claimant would have had ample opportunity to lobby during the Special 301 process in an attempt to bolster its claim in this arbitration.

174. During the hearing, the Tribunal also asked whether Canada was aware of any complaints or comments received in the PCT, WIPO, or WTO context regarding

[398] Office of the United States Trade Representative, *Special 301 Report* (2014) (**C-331**).

[399] Office of the United States Trade Representative, *Special 301 Report* (2015) (**C-332**).

[400] Sir Daniel Bethlehem, June 8, 2016, pp. 2320:20 – 2321:10 ("SIR DANIEL BETHLEHEM: Perhaps I could just put down a marker that it would be helpful for both parties to address this in post-hearing briefs, particularly since this was an issue that Ms. Cheek raised in her submissions. And I think at least the two documents in the record that I'm aware of and have in front of me are 341 and 332 , and I don't know whether it's relevant but it's interesting that the language changes from 2014 to 2015. In 2014, the U.S. describes the Canadian doctrine as this amorphous and evolving standard by which courts invalidate a patent, and that language of "amorphous and evolving standard" is noticeably absent from the 2015 report. So I make no further observation other than it would be, I think, interesting to hear more about that.")

[401] Office of the United States Trade Representative, *Special 301 Report* (2014) pp. 49-50 (**C-331**); Office of the United States Trade Representative, *Special 301 Report* (2015), pp. 66-67 (**C-332**).

[402] Canada does not recognize the validity of the Special 301 process and considers it to be methodologically flawed.

Canada's utility requirement in the relevant period.[403] Canada is not aware of any complaints regarding its utility requirement from any State or international organization prior to Claimant's initiation of this arbitration, nor has Claimant adduced any such evidence. To the contrary, the witnesses presented by Claimant, like Mr. Erstling[404] and Mr. Thomas[405] to whom complaints of this kind would have been raised, all confirmed that they heard no concerns during the relevant period. Further, there has been no challenge to Canada's utility requirement under the PCT brought to the ICJ, no

[403] Closing Statement of Canada, June 8, 2016, p. 2322: 3-18 ("SIR DANIEL BETHLEHEM: Perhaps while we're on this point -- and again, not for response now, but Professor Erstling mentioned that in the period of his tenure between 2002 and 2007, there were incompatibility complaints, and I think the language that he used was "mostly by applicants." We also had, I think from Mr. Gervais, some discussion about whether in the context both of WIPO and the WTO, these issues have been raised. I suppose the Claimant here would be aware whether it made any complaints to the PCT office in the period 2002-2007, but Canada would be aware whether it was the recipient of any complaints or comments both in PCT, WIPO or WTO context in respect of this. So if there is anything more that we should be informed about, I think that would be helpful.")

[404] Erstling, June 4, 2016, pp. 1627:17 – 1628:3 ("SIR DANIEL: But there's nothing – in case I've sort of missed it – in your reports which puts a sort of finger on any communication or internal consideration or anything of that nature which would indicate that what you said in your report – which is much more contemporaneous with this dispute – had a reference back to concerns which were expressed at the time that you were the director of the Office? PROFESSOR ERSTLING: Yes. That's correct. There's nothing in particular that I could point to.")

[405] Mr. Thomas testified that no concerns were raised about Canada's utility requirement during his tenure at WIPO, despite also testifying that Canada actively disclosed the existence of the promise standard in submissions to WIPO that were circulated to all member States. Thomas, June 4, 2016, pp. 1719:3 – 1720:4 ("MR. SPELLISCY: And, as you've said today – and in your report as well – you can recall no other State raising any concerns about the consistency of this statement with the core utility requirement, correct? … MR. THOMAS: There were no concerns raised, nor was there any approval raised. It simply wasn't discussed. MR. SPELLISCY: And no one raised any concerns to you on the Secretariat, even outside of the plenary session, that wouldn't be reflected in the minutes, correct? MR. THOMAS: No one said anything to me, to my recollection, at all about this study. I would venture to say it would have been of passing interest."); WIPO, *The Practical Application Of Industrial Applicability/Utility Requirements Under National And Regional Laws*, April 2001, para. 13 ("An invention lacks utility if it is not operable or it will not do what the specification promised it will do ("false promise").") (**R-407**); WIPO, *Industrial Applicability" and "Utility" Requirements: Commonalities and Difference*, document SCP/9/5, 17 March 2003, para. 41 ("A finding that the alleged invention is not useful may be expressed in a way that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promised it would do ('false promise').") (**R-230**). *See also*, Closing Statement of Canada, June 8, 2016, p. 2252:5-11; Closing Presentation of Canada, Slide 101.

challenge under TRIPS brought to the WTO, and no challenge brought by the United States or Mexico under NAFTA Chapter Twenty.[406]

V. THE INVALIDATION OF CLAIMANT'S PATENTS DID NOT BREACH CANADA'S OBLIGATIONS UNDER EITHER ARTICLE 1110 OR ARTICLE 1105

175. Even if Claimant is not required to plead a denial of justice in order to establish a breach of Articles 1110 and 1105 when the challenged measures are judicial interpretations of domestic law, even if this claim is not time-barred, and even if there has been a change in the law which brings this claim within the jurisdiction *ratione temporis* of the Tribunal, Claimant has still failed to meet its burden to make out a claim of breach on the facts. For this reason as well, its claim must be dismissed.

A. Claimant Has Failed to Prove a Breach of Article 1110

176. Claimant alleges that Canada has breached its obligations under Article 1110 of NAFTA because the decisions of the Canadian courts substantially deprived it of its property rights in the atomoxetine and olanzapine patents in violation of Canada's obligations under NAFTA Chapter Seventeen. Even if Claimant were correct that this is the appropriate legal test under Article 1110 with respect to judicial measures (it is not), it has failed to prove the facts necessary to support its claim. First, there has been no taking of property.[407] The court invalidations of Claimant's patents *ab initio* means that

[406] *See* Closing Statement of Canada, June 8, 2016, p. 2203:12-24 ("SIR DANIEL BETHLEHEM: So is the only recourse for a patent owner, patentee, if it is concerned about consistency of practice with Chapter 17, to go along to its NAFTA party and try and push that NAFTA party to raise it at the level of an interstate party discussion or Chapter 20 case, is that the avenue of recourse? MR. SPELLISCY: Certainly in our view Chapter 20 tribunals are set up to resolve disputes under chapters like Chapter 17. So if there is a concern about a breach of the obligations of Chapter 17, it is to be resolved between the State Parties to NAFTA under Chapter 20."); Closing Statement of Canada, June 8, 2016, p. 2320: 5-10 ("We would note that there has been no challenge by the United States against Canada under Chapter 20 alleging a breach of Chapter 17. Chapter 17 is the exclusive means by which a breach of that chapter, including 1709(1), can be established.") *See also*, US 1128 Submission, paras. 23 and 36; Mexico 1128 Submission, paras. 24-25 and 30; Respondent's Observations on Issues Raised in 1128 Submissions, paras. 15-17 and 36; Resp. CM, para. 210, FN 399.

[407] *See generally*, Opening Statement of Canada, May 30, 2016, pp. 298:2 – 301:6; Closing Statement of Canada, June 8, 2016, pp. 2298:12 – 2300:20; Resp. CM, paras. 326-330; Resp. Rejoinder, paras. 116-131.

the property did not ever exist at Canadian law, and therefore could not be expropriated. Second, Claimant has failed to prove a breach of Canada's obligations under NAFTA Chapter Seventeen. In fact, to the contrary, the measures here are consistent with Chapter Seventeen and thus, NAFTA Article 1110(7) excludes the application of Article 1110.[408] Third, Claimant has not proven that there has been an unlawful substantial deprivation of its investment.[409]

1) There Has Been No Taking of Property

177. As discussed above, all three NAFTA Parties agree[410] that to have an expropriation, there must be property that exists under the domestic law of the NAFTA Party.[411] Claimant has identified its two invalidated patents as its allegedly expropriated property.[412]

178. Patents are created and granted in accordance with domestic law.[413] While they are, in general, property capable of being expropriated,[414] and are protected under

[408] *See generally*, Opening Statement of Canada, May 30, 2016, pp. 313:14 – 327:20; Closing Statement of Canada, June 8, 2016, pp. 2303:19 – 2325:19; Resp. CM, paras. 334-402; Resp. Rejoinder, paras. 132-211; Respondent's Observations on Issues Raised in 1128 Submissions, paras. 38-47.

[409] *See generally*, Resp. CM, paras. 403-416; Resp. Rejoinder, paras. 223-242.

[410] *See also*, Opening Presentation of Canada, Slides 96-97; Resp. CM, paras. 312-315; Resp. Rejoinder, para. 116; US 1128 Submission, para. 26 ("Thus, the first step in any expropriation analysis must begin with an examination of whether there is an investment capable of being expropriated. Moreover, it is appropriate to look to the law of the host State for a determination of the definition and scope of the 'property right' at issue."); Mexico 1128 Submission, para. 18 ("A claim of expropriation under Article 1110(1), first requires the claimant … to establish that it has an 'investment' … in the territory of the host Party. An investment can only be based on vested legal rights under the legal system of the host Party."); Respondent's Observations on Issues Raised in 1128 Submissions, paras. 28-29.

[411] Campbell McLachlan, Laurence Shore & Matthew Weiniger, *International Investment Arbitration: Substantive Principles*, (Oxford Univeristy Press 2007), para. 8.65 (**R-328**); Monique Sasson, *Substantive Law in Investment Treaty Arbitration The Unsettled Relationship Between International and Municipal Law*, Wolter Kluwers 2010, pp. 81-82 (**R-333**); Andrew Newcombe, *Law and Practise of Investment Treaties*, "Standards of Treatment", February 2009, para. 7.19, (**R-334**); Sornarajah, *The International Law on Foreign Investment*, Third Edition, p. 383 FN 67 (**R-335**); *Emmis Award*, para. 162 (**RL-060**). *See also*, Opening Statement of Canada, May 30, 2016, p. 298:4-7; Opening Presentation of Canada, Slides 91-95.

[412] *See, e.g.*, Closing Statement of Claimant, June 8, 2016, p. 2238:13-22; Cl. Mem., para. 163.

[413] Dimock First Report, para. 13 ("There is no common law right to a patent. The patent system is entirely rooted in legislation."); Siebrasse First Report, para. 3 ("Patent rights in Canada are wholly a creature of statute"). *See also*, Opening Presentation of Canada, Slide 97; Resp. CM, para. 301 ("Nothing

Article 1105 as well, it must be recalled that they are solely a legal construct. Without the *Patent Act* in Canada, they would not exist. Courts are often called upon to decide issues with respect to title to property like real estate, or a chattel (i.e. a physical thing). However, the issue before the courts in such disputes is never whether the property does or does not exist. It is simply a question of "to whom does it belong?" Patent validity challenges are different. A declaration by a domestic court that a patent is void *ab initio* means that the patent should not have issued in the first place.[415] In short, a declaration of invalidity means that there is no, and never was, property at domestic law. As Claimant's expert, Mr. Reddon, explained, "the effect of a declaration of invalidity is that the patentee can no longer sue for past infringements – anyone – even during the time when the patent was extant."[416] Thus, in making such a determination, courts do not consider whether to take property; rather, they determine whether there was any property

in NAFTA determines whether an asserted property right actually exists at domestic law, or the nature and scope of such rights."); Resp. Rejoinder, para. 19 ("A patent is a purely domestic legal construct."); US 1128 Submission, para. 27, FN 58 (noting that "Patents properly granted in accordance with domestic law are intellectual property rights …" under NAFTA, and explaining that patents are properly granted in cases in which an invention meets the domestic statutory requirements); Mexico 1128 Submission, para. 18 ("An investment can only be based on vested legal rights under the legal system of the host Party."); Respondent's Observations on Issues Raised in 1128 Submissions, para. 38 ("In the specific context of patents, the United States observes that patents are intellectual property rights protected by Article 1110 only if they conform to the substantive conditions of patentability under domestic law.")

[414] *See also*, Opening Statement of Canada, May 30, 2016, p. 299:4-5; Resp. CM, para. 311; Resp. Rejoinder, para. 119 ("Canada does not dispute that intellectual property rights may qualify as investments under NAFTA").

[415] Dimock, June 1, 2016, p.818:7-9; Dimock Second Report, paras. 135-139 ("Validity, which is at issue in most patent cases, is not a question of title but a question of the very existence of the rights. To my knowledge, this is very different than most other forms of property where the existence of the property is not an issue.") *See also*, Closing Presentation of Canada, Slide 198; Resp. CM, para. 327; Resp. Rejoinder, para. 117 ("Under Canadian law, if the court determines that a patent right is invalid, it determines that the property in question never existed in accordance with section 60 of the *Patent Act*.")

[416] Reddon, June 1, 2016, p. 818:7-16 ("When a patent is declared invalid by a court, it is treated as if it were void ab initio. That is from the outset. … So it is rolled back to the date of grant for the purpose of precluding the patentee from suing …"); Dimock Second Report, para. 139 ("Once a patent is invalid, there are no rights to exploit whatsoever. This does not mean 'a patentee cannot obtain damages for infringement', it means they cannot make *any* recovery under the patent, including for the period prior to the invalidation of the patent.") This is distinct from disputes over title in other property contexts: *see* Opening Presentation of Canada, Slide 152; Closing Presentation of Canada, Slide 198; Dimock Second Expert Report, para. 37; Resp. Rejoinder, para. 117.

that could be taken under Canadian law.[417] Such a determination cannot amount to an expropriation.[418]

2) Claimant Has Not Proved a Breach of Canada's Obligations Under Chapter Seventeen

179. Claimant has argued in this arbitration that the invalidation of its patents amounts to a breach of Article 1110 because such invalidation violates Canada's obligations under Chapter Seventeen of NAFTA. As discussed above, this is wrong as a matter of law. But even accepting Claimant's incorrect theory that a breach of Chapter Seventeen results in a breach of Article 1110, because it has made such a breach part of its claim, Claimant bears the burden of showing that such a breach occurred. It has failed to meet this burden. To the contrary, as Canada has shown, the measures in question here are fully consistent with Canada's obligations under Chapter Seventeen. Specifically, Canada's law on utility is consistent with the obligations Canada owes to the United States and Mexico under Articles 1701(1), 1709(1), 1709(7), and 1709(8). Thus, not only has Claimant failed to prove the breach of Chapter Seventeen that it alleges to be an essential element of its claim, but NAFTA Article 1110(7) also expressly excludes the application of Article 1110 to Claimant's patents because Canada's conduct was consistent with Chapter Seventeen.

[417] *See Apotex Inc. v. Pfizer Ireland Pharmaceuticals*, 2012 FC 1339, para. 27 (holding that a "declaration of invalidity is a declaration that a patent is, and has been void all along (*i.e. ab initio*)") (**R-153**); Dimock First Report, para. 28 ("A successful claim [under s. 60 of the *Patent Act*] will result in a declaration of invalidity. Such declaration means that the patent is, and has always been void (*i.e.* void *ab initio*)." Contrast with other instances specifically provided for in the *Patent Act* where a valid patent can be revoked: *see, e.g.*, Patent Act, RSC 1985, c P-4, s. 66 ("…the Commission shall order the patent to be revoked …") (**R-001**); Opening Statement of Canada, May 30, 2016, pp. 298:15 – 299:3; Opening Presentation of Canada, Slides 12 and 150; Resp. Rejoinder, para. 118.

[418] All three NAFTA Parties agree: US 1128 Submission, para. 26 ("it is appropriate to look to the law of the host State for a determination of the definition and scope of the 'property right' at issue."); Mexico 1128 Submission, para. 19 ("When legal rights are declared a nullity, or void *ab initio*, by a court of competent jurisdiction, there cannot be a claim of expropriation. Mexico agrees with Canada that in such a case, as a matter of domestic law, the alleged investment never existed for the purposes of Article 1110."); Opening Presentation of Canada, Slide 96; Resp. CM, paras. 326-330; Respondent's Observations on Issues Raised in 1128 Submissions, para. 30.

a) Canada's Law on Utility is Consistent with NAFTA Article 1701(1)

180. Article 1701(1) articulates a general statement of principle for Chapter Seventeen that requires the Parties to ensure (1) that legal protection is available for intellectual property rights, and (2) that such rights are supported by an adequate enforcement mechanism, namely a full and fair procedure before their domestic courts.[419] The obligation is further clarified in Article 1701(2), which explains that each Party shall, "at a minimum, give effect to this Chapter" and to the provisions of specified international treaties (none of which are alleged to have been breached here) to meet its obligations under Article 1701(1).[420]

181. Canada is in full compliance with Article 1701(1). It has a professional and effective patent office,[421] a robust system of law that protects patent rights, and an efficient and fair court system for the adjudication of patent disputes.[422] Since 2005, Canada has granted over 13,000 pharmaceutical patents.[423] In that same period, even

[419] *See also*, Opening Statement of Canada, May 30, 2016, p. 314:4-18; Resp. CM, para. 401; Resp. Rejoinder, paras. 133-135.

[420] *See also*, Opening Statement of Canada, May 30, 2016, p. 314:4-18; Resp. Rejoinder, para. 135.

[421] Cl. Reply, para. 30 ("Examiners at CIPO are skilled and well-trained. All CIPO examiners must have scientific degrees, such as engineering, chemistry, physics, or biotechnology."); Gillen Second Statement, para. 2 ("…patent examiners are well-trained."); Wilson Second Report, para. 10 ("Examiners are highly trained to ensure that each application meets all of the requirements of patentability, including utility, before a patent application is allowed and a patent granted.")

[422] Reddon, June 1, 2016, p. 837:15-16 ("Our courts are very rigorous and scrupulous and the decisions are theirs."); Reddon, June 1, 2016, p. 886:17-19 ("Of course I'm not suggesting that the supreme Court of Canada was acting in anything but good faith…"); Resp. CM, para. 374 (explaining that Canada maintains a "world-class system of patent registration and sophisticated, specialised courts before which parties may seek to defend and enforce their patent rights."); Resp. Rejoinder, para. 87 ("Claimant now agrees that it received a fair process in the Canadian courts, and that the courts properly applied Canadian law to its atomoxetine and olanzapine patents."); Dimock First Report, paras. 180, 194 (illustrating this point by reference to the courts' "fair and reasonable" consideration of Claimant's olanzapine and atomoxetine patents) and para. 220 ("Courts construe patents purposively, having regard to the whole of the patent, in an informed manner on the basis of expert evidence, that is rational and fair to both the patentee and the public.")

[423] WIPO Database, *Patent Grants by Technology – Pharmaceutical, Total Count by Filing Office – Canada* (1980 – 2013) (**R-436**). *See also*, Opening Presentation of Canada, Slide 159; Resp. Rejoinder, para. 190.

using Claimant's flawed data set,[424] fewer than 30 pharmaceutical patents have been found to lack utility,[425] resulting in less than half of one percent of pharmaceutical patents found to lack utility in almost a decade.[426]

182. The evidence at the hearing confirmed that despite its legal pleadings, Claimant's business practices show that it believes that Canada has strong protection of intellectual property rights. As Claimant's witnesses explained, Claimant stopped filing patent applications in jurisdictions that it believed no longer had adequate protection of IP rights,[427] even going so far as to close down its affiliates in certain countries because of its views on the adequacy of IP protection.[428] In contrast, Claimant has continued filing patent applications in Canada.[429] Its local subsidiary remains active and in operation.[430]

[424] *See* paras. 161 - 167 and 222-230; Brisebois, May 31, 2016, pp. 475:1 – 477-21; Brisebois Second Statement; Resp. Rejoinder, paras. 188-203; (all explaining the numerous ways in which Claimant's data set is flawed).

[425] Levin Report – Errata and Additional Case Coding updated Tables 1 through 3 (through 22 April 2016), Table 1 (Updated): Patent Cases in the Post-2005 Period Involving a Decided Challenge on Grounds of Utility (showing 28 pharmaceutical patents "found invalid on utility grounds"); Levin Demonstrative Slide 3. While Claimant counted PM(NOC) cases as "invalidations" for the purposes of its statistical arguments, it stated explicitly in closing argument that a PM(NOC) decision is not a "revocation"; Closing Statement of Claimant, June 8, 2016, pp. 2067:23 – 2068:11. If one was to count exclusively what Claimant now appears to view as "revocations", there have been only 6 such invalidations of pharmaceutical patents since 2005: Brisebois, Errata and Updates, 25 May 2016, Table 3, p. 3.

[426] *See also*, Resp. Rejoinder, para. 137 (explaining that invalidity findings were made with respect to 0.003% of all pharmaceutical patents granted in Canada between 1980 and 2013).

[427] Stringer, May 31, 2016, p. 416:15-24 ("MR. SPELLISCY: And you say that in the last sentence of Paragraph 8, 'Depending on the circumstances, I would sometimes decide not to file in a particular foreign jurisdiction if the patent protection was not adequate.' And I think this gets to your next sentence where you're talking about, I guess, the inverse in Czechoslovakia. But if the patent protection was not adequate sometimes you would decide not to file in that jurisdiction. MR. STRINGER: That's correct."); Stringer Statement, para. 8.

[428] Postlethwait, May 31, 2016, p. 423:11-18 ("MS. ZEMAN: And Lilly closed its Argentina affiliate in 1985. Is that right? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And inadequate patent protection there was an important part of the decision to close? MR. POSTLETHWAIT: Yes, it was an important part over there."); Postlethwait Statement, para. 21 ("In fact, weaknesses in Argentina's patent regulatory framework were an important consideration in the company's decision to close our affiliate in that country in 1985.")

[429] Nobles, May 31, 2016, p. 447:11-19 ("MS. ZEMAN: And so just to go back one job time frame, when you were VP Corporate Affairs, Lilly continued to file for patents in Canada, to your knowledge. Is that right? MS. NOBLES: You mean related to Strattera specifically? MS. ZEMAN: Other products. MS. NOBLES: Other products? I would assume so"); Stringer, May 31, 2016, p. 417:6-11 ("MR.

Claimant's own behaviour thus proves that even it does not believe in the merit of its allegations of a breach of Article 1701(1).

b) Canada's Law on Utility is Consistent with NAFTA Article 1709(1)

183. Claimant argues that Canada's alleged promise utility doctrine is in violation of Canada's obligations under Article 1709(1). As discussed above, Claimant has alleged that the promise utility doctrine is a "unitary" standard that requires that (1) inventions meet the promise of the patent, (2) the utility of the invention be demonstrated or soundly predicted by evidence that exists on the date of application, and (3) if relying on sound prediction, the factual basis and sound line of reasoning be disclosed in the patent.

184. Claimant's argument requires the Tribunal to drastically enlarge the NAFTA Parties' obligations under Article 1709(1). First, it asks the Tribunal to transform Article 1709(1) into an obligation that governs not only the utility standard in terms of patentability, but also the evidence required to establish utility and the disclosure required in the patent. Second, it asks the Tribunal to lock in a highly specific meaning for the utility standard. Claimant characterizes the standard it proposes to read into Article 1709(1) as a baseline, but it is actually a harmonized standard that sets an exceptionally low bar and leaves the NAFTA Parties no room for flexibility in their domestic laws. Claimant's arguments lack any basis in the language Article 1709(1) and

SPELLISCY: And, to your knowledge, Eli Lilly filed patents for pharmaceutical products in Canada all the way up through when you retired in 2006, correct? MR. STRINGER: Yes. Canada was regarded as a very important country."). *See also*, Closing Presentation of Canada, Slide 200.

[430] Claimant has brought this claim on its own behalf, and on behalf of its enterprise Eli Lilly Canada, claiming specific damages to its enterprise, NOA, p. 1, para. 73; Cl. Mem., FN 317 ("Pursuant to NAFTA Article 1117, the Tribunal also has jurisdiction to consider Lilly's claim brought on behalf of its wholly-owned subsidiary, Eli Lilly Canada Inc.") *See also*, Cl. Mem., para. 24 ("Canada has long been an important market for Lilly. … Lilly founded Eli Lilly Canada, Inc. 15 years later, in 1938, making it one of Lilly's longest-running foreign enterprises.")

would require the Tribunal to drastically transform the obligation into something contrary to its plain meaning.[431] Claimant's argument should, thus, be wholly rejected.

i. Article 1709(1) Does Not Restrict What Evidence and Disclosure the NAFTA Parties Can Require for a Patent to Be Granted to a New, Useful and Non-Obvious Invention

185. Claimant's argument is that Article 1709(1) regulates not only the standard of utility for an invention to be patentable, but also the evidence of utility and the disclosure that can be required. In particular, Claimant argues that the alleged promise utility doctrine as a whole, meaning all three elements together, breaches Article 1709(1). Claimant clarified at the hearing that it is not alleging that any one of the elements of the alleged doctrine could alone constitute a breach of NAFTA.[432] The second and third elements of Claimant's alleged doctrine relate not to the standard of utility in Canadian law, but rather to its implementation, and specifically to the admissible evidence that the courts require to establish utility and to disclosure requirements. Accordingly, for Claimant's argument to succeed, Article 1709(1) must be read to cover such requirements as well.

186. On its face, neither Article 1709(1) nor anything else in Chapter Seventeen says anything at all about the evidentiary or disclosure requirements that the NAFTA Parties can impose on patents. Thus, in order to connect the legal dots, Claimant is forced to twist the language in Article 1709(1). Its position is that the obligation in Article 1709(1) that the NAFTA Parties "shall make patents available" to inventions that are new, non-obvious and useful, must be interpreted to be "an obligation to grant and maintain patents as long as the three enumerated criteria are met."[433]

[431] *See generally* Resp. CM, paras. 348-382; Resp. Rejoinder, paras. 138-185; Respondent's Observations on Issues Raised in 1128 Submissions, paras. 39-42.

[432] Closing Statement of Claimant, June 8, 2016, p. 1997:4-11. Compare with Closing Statement of Claimant, June 8, 2016, p. 2033:16-23.

[433] Cl. Mem., paras. 189,190; Opening Statement of Claimant, May 31, 2016, p. 119:4-11.

187. This is why Claimant spent considerable time extolling the actual benefits and usefulness today of its olanzapine and atomoxetine products for the uses promised in the patents.[434] It is why Claimant has argued that Canadian courts are wrong to refuse to consider commercial success.[435] Further, it is why Mr. Armitage, Claimant's former General Counsel and Vice President, testified that Claimant is entitled to a patent because its olanzapine and atomoxetine products have now been deemed useful and safe by Health Canada for the treatment of the conditions specified in the patents.[436] Claimant has made these arguments because it believes that Article 1709(1) requires the NAFTA Parties to grant and maintain patents if an invention is new, non-obvious and *useful in fact* at the date of challenge, irrespective of evidentiary or disclosure rules.

188. Not only does Claimant's argument improperly conflate the real-world use of a product (evidenced by commercial success or Health Canada regulatory approval) with utility in the patent law sense, there is no support for this reading in the text of Article 1709(1). Article 1709(1) says nothing about the evidentiary and disclosure requirements that are ubiquitous in patent law. It leaves entirely to the discretion of the NAFTA Parties what evidentiary standards and disclosure requirements they may have in order for a patent to be granted, and leaves it open to the NAFTA Parties to withhold patents

[434] Opening Statement of Claimant, May 30, 2016, pp. 11:14 – 13:12.

[435] Cl. Mem., paras. 69, 209 and 210; Cl. Reply, paras. 80, 103, 115 and 201.

[436] Armitage, May 31, 2016, pp. 387:3-11, 394:9-14 ("PRESIDENT: So is it your testimony that once Health Canada has given this approval, if we may call it that way, safe and effective, that it is therefore also useful in the terms of Section 2 of the Patent Act? MR. ARMITAGE: Right."); Opening Statement of Claimant, May 30, 2016, p. 82:12-15. Claimant and its witnesses maintain that once Health Canada has issued its approval for a drug, it goes without saying that the utility requirement under patent law has been met: *see, e.g.*, Cl. Notice of Intent, para. 41; NOA, paras. 34 and 81 .This is a non sequitur. Health Canada approval and satisfaction of the utility requirement are distinct inquiries, imposing requirements at distinct points in time: *see* Barton Statement paras. 22-24 ("I can confirm that these two processes are entirely distinct."); Resp. CM, para. 166. The distinct nature of these two processes is underscored by the fact that, for both atomoxetine and olanzapine, the studies upon which Claimant relied to justify its invention in the patent law context played no role in Health Canada's approval process: Resp. CM, para. 167; Barton Statement, paras. 25, 30, and para. 50.

to inventions that are useful if they do not comply with evidentiary and disclosure rules.[437]

189. Claimant's efforts to twist the wording of Article 1709(1) should be rejected. The phrase "shall make patents available" in Article 1709(1) does not mean "shall grant."[438] These words contemplate that there may be further conditions for a new, non-obvious and useful invention to satisfy before a patent can be granted. Had the NAFTA Parties meant "shall grant", they could very easily have used those words. That they did not, and opted instead for more complex language structure, indicates that that is not what they meant. Both the French[439] and Spanish[440] language versions of Article 1709(1) also confirm that Article 1709(1) does not impose an obligation on the NAFTA Parties to grant patents to any particular alleged invention even if that invention meets the three criteria in Article 1709(1).

190. Instead, the text of Article 1709(1) sets out only the necessary conditions for patentability in the Parties' systems. The context of Articles 1709(2) and (3) confirms this interpretation of Article 1709(1). Article 1709(1) begins with "Subject to paragraphs 2 and 3, and each of these paragraphs begins with "A Party may exclude from

[437] *See* Gervais Second Report, paras. 21-25. Claimant's expert, Professor Siebrasse, has also recognized the importance of distinguishing between the threshold of utility and the evidence required to show that the threshold has been met: Siebrasse First Report, FN 21, para. 19. *See also* Opening Statement of Canada, p. 183:15-22; Resp. CM, paras. 86, 112 and 125; Resp. Rejoinder, paras. 146-147; Respondent's Observations on Issues Raised in Article 1128 Submissions, paras. 41-42; Respondent's Observations on Issues Raised in *Amicus* Submissions, para. 22; US 1128 Submission, para. 40.

[438] *See* Opening Statement of Canada, May 30, 2016, p. 316:16-22 ("MR. SPELLISCY: I think one thing is clear. It doesn't mean what the Claimant said this morning it means."); Resp. Rejoinder, para. 140.

[439] The French version reads: "chacune des Parties pourra accorder un brevet", or "can grant" or "will be able to grant". It does not say "shall grant." *See also*, Opening Statement of Canada, May 30, 2016, p. 317:2-7; Opening Presentation of Canada, Slide 162.

[440] The Spanish version reads: "las Partes dispondrán el otorgamiento de patentes", or "will determine the grant of patents". Again, it does not say "shall grant". *See also*, Opening Statement of Canada, May 30, 2016, p. 317:8-14; Opening Presentation of Canada, Slide 163.

patentability."[441] These two paragraphs' exclusions to "patentability" confirm that paragraph 1 was included precisely to set out the necessary conditions for patentability.

191. While Article 1709(1) establishes the three necessary conditions for patentability, it does not mean that meeting these conditions will be sufficient for a patent to be granted in the NAFTA Parties. The fact that an invention is patentable (i.e. the fact that it is new, non-obvious and useful) does not mean it is entitled to a patent. Other conditions apply in accordance with each NAFTA Party's domestic laws, including requirements related to the "quid pro quo" of the patent bargain – the disclosure.[442] Indeed, each NAFTA Party's system includes other conditions that must be met for a patent to issue.[443] What is sufficient for each of the Parties to grant a patent with respect to both the core criteria and other criteria is clearly and unequivocally left to the Parties' domestic laws. It is not regulated by Chapter Seventeen of NAFTA.

192. As a result, Article 1709(1), properly interpreted, has nothing to say about the second and third elements of Claimant's alleged promise utility doctrine. It simply does not regulate what evidence Canada can require to establish utility, nor does it regulate

[441] *See also*, Opening Statement of Canada, May 30, 2016, pp. 319:2 – 320:23 (discussing the context of Articles 1709(2) and (3)).

[442] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153, para. 37 ("Disclosure is the *quid pro quo* for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*.") (**R-004**); Dimock First Report, paras. 19 ("Disclosure lies at the core of the bargain."), para. 74 (describing disclosures as the "consideration that the public receives in exchange for the patent monopoly"), para. 114 ("Disclosure lies at the 'very heart of the patent bargain.'") and paras. 124-125. *See also*, Resp. CM, paras. 7 and 84; Resp. Rejoinder, para. 7 ("Patents reward and encourage innovation in exchange for disclosure that advances the state of the art."), para. 20 ("The *Patent Act* represents the desire of Canada's Parliament to craft a fair 'patent bargain' through which an inventor is given a time-limited monopoly in exchange for innovation and the disclosure of an invention that improves the general state of knowledge."), para. 24 ("[Disclosure] lies at the core of the patent bargain."), and para. 275 ("…disclosure of the basis for the prediction is the *quid pro quo* offered in exchange for the monopoly.")

[443] For example, Canada requires sufficient disclosure of the invention and its operation or use as contemplated by the inventor: Dimock First Report, para. 19. Similarly, the U.S. imposes written description and enablement requirements: Holbrook First Report, paras. 9 and 41 (explaining that enablement requires that "the patent specification shall provide sufficient detail to allow one of ordinary skill in the art to both make and use the claimed invention") and para. 56 ("Section 112(a) requires '[t]he specification shall contain a written description of the invention'."); Merges First Report, para. 15 ("Section 112(a) requires adequate disclosure of an invention."). Mexico also requires compliance with a "sufficient description" requirement: Lindner Second Report, paras. 18-20. *See also* Opening Statement of Canada, May 30, 2016, p. 317:7-23; Resp. CM, para. 68; Resp. Rejoinder, paras. 24 and 140.

what disclosure Canada can require for a patent to be granted.[444] Other than wrongly trying to shoehorn these two aspects of Canadian law into an allegedly "unitary" Canadian utility requirement,[445] Claimant has offered no explanation of how Article 1709(1), interpreted in accordance with the VCLT, can be seen as regulating the latter two aspects of Canada's alleged promise utility doctrine.

193. At most, Article 1709(1) applies to how Canada defines utility at its domestic law (*i.e.* the *Consolboard* standard); that is, it could only apply to the first element of the alleged promise utility doctrine. Because Claimant is not alleging a breach of NAFTA based solely on the application of only this element of the doctrine,[446] there is no need for the Tribunal to engage in an analysis of whether Canada's requirement that a patent meet its promised utility is in fact consistent with Article 1709(1). However, even if it did, as shown below, the interpretation by the Canadian courts of the utility standard in Canada's *Patent Act* is consistent with Canada's obligations in Article 1709(1).

[444] Gervais, June 4, 2016, p. 1749:5-17 ("PROFESSOR GERVAIS: I think other criteria always apply … but basically there was a clear understanding that the three patentability criteria were not the entire list of conditions that an applicant must comply with to obtain a patent. In the case of TRIPS, we see this explicitly in Article 29, which in part resembles Article 5 PCT, and in Professor Holbrook's report we also see quite clearly that the U.S. has specific requirements in terms of written description and enablement.") *See also*, Opening Statement of Canada, May 30, 2016, p. 318:1-14 ; Resp. Rejoinder, paras. 146-147, 159, and 172; US 1128 Submission, para. 40 ("Article 1709(1) provides each NAFTA Party with the flexibility to determine the appropriate method of implementing the requirements of Chapter Seventeen, including the utility requirement in Article 1709(1), within its own legal system and practice."); Respondent's Observations on Issues Raised in Amicus Submissions, para. 22.

[445] Dimock First Report, para. 51 ("The individual changes or components which Professor Siebrasse has combined and characterized as the "Promise Utility Doctrine", are really three distinct aspects of Canadian patent law which have remained virtually unchanged for as long as I have been a lawyer.") Even Claimant's expert Professor Siebrasse recognizes that the various elements of the alleged "Promise Utility Doctrine" are independent of one another: Siebrasse, June 1, 2016, p. 742:7-12 ("PROFESSOR SIEBRASSE: Well, there has to be a factual basis for the prediction and a sound line of reasoning linking the factual basis to the promised utility or scintilla utility if the scintilla standard is applied, but normally to a promised utility."). *See also*, Opening Statement of Canada, May 30, 2016, pp. 182:10 – 184:10; Opening Presentation of Canada, Slides 26-27; Closing Statement of Canada, June 8, 2016, p. 2245:7-14; Closing Presentation of Canada, Slide 81; Resp. CM, para. 86; Resp. Rejoinder, para. 160.

[446] Closing Statement of Claimant, June 8, 2016, p. 1993:6-21.

ii. Article 1709(1) Does Not Prohibit Canada From Requiring Patentees to Meet the Promise of the Patent

194. A proper analysis under VCLT Articles 31 and 32 illustrates that Article 1709(1) leaves to each NAFTA Party the flexibility to define and implement the specific legal standard under each of the enumerated criteria of novelty, non-obviousness or inventiveness, and utility or industrial applicability.[447] This flexibility means that Article 1709(1) does not prohibit Canada from having the promise standard under Canadian law; moreover, Article 1709(1) not only permits, but plans for, evolution in each Party's domestic law system.

195. Claimant incorrectly argues that Canada's position means that "the terms in Chapter 17 have no meaning and that Canada is free to interpret its obligations as it sees

[447] *See generally*, Kathleen Liddell and Michael Waibel, *Fair and Equitable Treatment and Judicial Patent Decisions*, Legal Studies Research Paper Series, University of Cambridge, Paper No.4/2016 January 2016 ("Liddell Waibel Paper"), pp. 7-11, (discussing the flexibility retained by States, even after TRIPS, "to interpret and implement the TRIPS standards in different ways to advance their own technological and development needs.") (**R-474**). *See also* Closing Presentation of Canada, Slide 215; Resp. CM, paras. 188 and 348-382; Resp. Rejoinder, paras. 138-185; Respondents Observations on Issues Raised in *Amicus* Submissions, paras. 4, 17 ("CIPPIC/CIPP correctly submits that it is in fact necessary to view Chapter Seventeen as incorporating a flexible approach because all patent systems are required to adapt to changing technologies and business approaches to technology."), para. 22 ("Instead, the NAFTA Parties all recognized the flexibility given to each system to implement the broad standards articulated in the Chapter, as well as more broadly in TRIPs.") and para. 36 ("Instead, the Parties' choice 'reflect[ed] continuing differences of substantive law,' and demonstrates the flexibility inherent in Article 1709(1)."); US 1128 Submission, para. 40 ("Article 1709(1) provides each NAFTA Party with the flexibility to determine the appropriate method of implementing the requirements of Chapter Seventeen, including the utility requirement in Article 1709(1)."); Respondent's Observations on Issues Raised in 1128 Submissions, paras. 39-42.

fit."[448] The terms in Chapter Seventeen have meaning,[449] but as set out below, that meaning is not the singular and exacting meaning Claimant would prefer.[450]

196. **VCLT Article 31(1)**: The first step of the VCLT analysis is to look at the ordinary meaning of the terms of the treaty "in their context and in the light of its object and purpose."[451] The term "useful" in Article 1709(1) must be viewed in its patent law context.[452] Recourse to dictionary definitions alone, as advocated by Claimant, strips the terms of their context.[453]

[448] Cl. Reply, para. 261.

[449] *See also*, Opening Statement of Canada, May 30, 2016, p. 321:2-5 ("MR. SPELLISCY: The Claimant alleges that the term 'useful' in 1709(1) must mean something, and on this, the parties are agreed. Of course it must have meaning."); US 1128 Submission, para. 41 ("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."); Respondent's Observations on Issues Raised in 1128 Submissions, para. 40 ("Canada agrees with the United States that Article 1709(1) cannot be devoid of meaning, but also agrees that it confers discretion on the NAFTA Parties.")

[450] Cl. Mem., para. 192 (arguing "a good faith interpretation of 'capable of industrial application' and 'useful' in accordance with the ordinary meaning of those terms leads to a straightforward conclusion: an invention with the capacity to be put to specific use in industry meets the standard articulated in NAFTA Article 1709(1)"); Cl. Reply, paras. 260 and 282. In contrast, *see* Gervais, June 4, 2016, p. 1747:4-7 ("PROFESSOR GERVAIS: NAFTA, like TRIPS, does not require one way of defining these criteria. 1709(1), which corresponds to TRIPS 27.1, is not harmonizing this terminology."); Closing Presentation of Canada, Slide 268; Gervais, June 4, 2016, p. 1759:9-12 ("PROFESSOR GERVAIS:…these treaties confine, they don't define, so there are confines, there are limits to the leeway, otherwise, the Treaty means nothing, but the question is where is that limit.") *See also* Opening Statement of Canada, May 30, 2016, p. 321:5-7 ("the Claimant's suggestion as to how the Tribunal should understand the meaning of the phrase 'useful' suffers from numerous flaws"); Resp. CM, para. 352 ("The bare listing of patentability criterion in Article 1709(1) was never meant to impose on the NAFTA Parties a unique and specific obligation to grant patents whenever an applicant met the threshold of 'capacity to be put to a specific use in the industry', under whatever circumstances."); Resp. Rejoinder, para. 149 ("Indeed, there is no evidence that the NAFTA parties intended to constrain themselves in Article 1709(1) to any particular definitions, and certainly not the highly specific and restrictive meaning that Claimant advocates.")

[451] United Nations, *Vienna Convention on the Law of Treaties*, 23 May 1969 ("VCLT"), p. 340 , Article 31(1) (**RL-072**). *See also*, Closing Presentation of Canada, Slide 204.

[452] Olivier Dörr and Kirsten Schmalenbach, *Vienna Convention on the Law of Treaties, A commentary*, Springer, New York, 2012, p. 542 ("…thus the test is not so much any layman's understanding, but what a person reasonably informed on the subject matter of the treaty would make of the terms used.") (**R-344**); Richard Gardiner, *Treaty Interpretation*, Oxford University Press, UK, 2011, p. 174 ("Thus the test is not necessarily what the ordinary person would understand a term to mean but could take account of the subject matter of the treaty so as to seek what a person reasonably informed in that subject, or having access to evidence of what a reasonably informed person would make of the terms as a starting point.") (**R-345**). In the case of Article 1709(1), this context is the patent law context: Resp. CM, paras. 360-364

197. Neither the text of Article 1709(1) nor any other text in Chapter Seventeen provides a definition of any of the patentability terms, including "useful" or "capable of industrial application".[454] Nor does it say that "useful" is a high standard or a low standard. Not even the Canadian, American or Mexican patent statutes indicate whether utility or capable of industrial application is a high or low bar.[455] The absence of a specific definition suggests that the NAFTA Parties wanted to maintain flexibility on the meaning and implementation of these obligations.[456] Had they intended "useful" to mean

(arguing that the term "utility" can "reasonably be informed by the various national definitions recognized by WIPO, including Canada's"); Resp. Rejoinder, para. 150.

[453] Gervais, June 4, 2016, pp. 1833:24 – 1834:11 ("PROFESSOR GERVAIS: Well, the ordinary meaning of technical terms in the patent field is an interesting question to begin with. So you have terms that over time have evolved in two different systems to be used and have been defined by courts in those systems because most statutes do not define utility and industrial applicability very clearly, so you leave it up to a large degree to courts. So you're already looking at a moving target in terms of ordinary meaning on the domestic front, and so if you look at dictionaries here, I don't think they would help you very much. So the text doesn't give you very much.") *See also*, Closing Presentation of Canada, Slide 210; Resp. CM, para. 359; Resp. Rejoinder para. 150.

[454] Gervais, June 4, 2016, p. 1747:4-7 ("PROFESSOR GERVAIS: NAFTA, like TRIPS, does not require one way of defining these criteria. 1709(1), which corresponds to TRIPS 27.1, is not harmonizing this terminology.") *See also*, Closing Statement of Canada, June 8, 2016, p. 2305:4-15 ("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. That tells you something immediately, that the NAFTA parties didn't want to have a definition and they wanted to have flexibility on the meaning and the implementation of those obligations. As Professor Gervais testified, there is no obligation in the NAFTA or the TRIPS to use a specific definition or application of any substantive patentability criteria, including utility."); Closing Presentation of Canada, Slides 206 and 215; Resp. CM, para. 353; Resp. Rejoinder, paras. 149 and 169-170; US 1128 Submission, para. 40 ("The NAFTA does not prescribe any particular definition of the terms, 'capable of industrial application,' or 'useful,' but the text notes that these two terms may be deemed to be synonymous."); Respondent's Observations on Issues Raised in 1128 Submissions, para. 40.

[455] Siebrasse, May 31, 2016, p. 555:7-15 ("MR. JOHNSTON: It does not specify any particular meaning in the Act for the word "useful"? PROFESSOR SIEBRASSE: That's right. MR. JOHNSTON: It does not say that "useful" is a high bar? PROFESSOR SIEBRASSE: No. MR. JOHNSTON: It does not say that it is a low bar? PROFESSOR SIEBRASSE: No. Not in the Act."); Siebrasse, June 1, 2016, p. 759:7-12 ("THE PRESIDENT: My question is simply when you state 'this requisite standard under the Act is low', where do I see that the requisite standard under the Act is low or, for that matter, high? Where do I read that in the Act? PROFESSOR SIEBRASSE: Yes. So the word is only 'useful'…"); Merges, June 3, 2016, p. 1348:12-17 ("MR. LUZ: Those words 'substantial', 'specific' and 'credible' do not appear in the statute itself? PROFESSOR MERGES: They may at disparate locations but not together referring to utility, so I don't want to be coy. No."); *Patent Act*, s. 2 (**R-001**); Title 35, United States Code (Excerpts), § 101 (**C-073**). *See also*, Closing Presentation of Canada, Slides 208-209.

[456] Gervais First Report, para. 58 ("PROFESSOR GERVAIS: The fact that NAFTA (like TRIPS) contains no definitions suggests that the intention of the NAFTA Parties was to keep the same flexibility for domestic implementation as they have under the TRIPS Agreement. If there had been any ambition to add further substance to the concept of utility, it would in my opinion be reflected in the NAFTA text.") *See*

"mere scintilla," "specific, substantial, and credible", or even "have the capacity or ability to put to a specific or practical use in industry"[457], those words could have been added to the text. That they were not is significant.

198. The fact that Article 1709(1) refers to two possible standards for two of the three patentability criteria is equally telling about the flexibility intended by the NAFTA Parties.[458] The Parties expressly acknowledged the reality of differences in their national systems by referring to "capable of industrial application" and "useful", as well as "inventive step" and "non-obvious".[459] To read a single standard into the text, as Claimant asks the Tribunal to do, ignores the express intention of the Parties.

also Resp. CM, para. 367; Resp. Rejoinder, para. 169 ("If the NAFTA Parties had wanted such a specific and restrictive meaning, they could have included a precise definition of 'capable of industrial application' or 'useful' in the NAFTA Intellectual Property Chapter. They did not.")

[457] *See* Cl. Reply, para. 260.

[458] Gervais, June 4, 2016, p.1747:4-12 ("PROFESSOR GERVAIS: NAFTA, like TRIPS, does not require one way of defining these criteria. 1709(1), which corresponds to TRIPS 27.1, is not harmonizing this terminology. There is, as I say, in my report a negotiation. Some countries wanted industrial applicability; others wanted utility. They could not agree. They could not agree to state that these were synonymous terms for, I believe, the simple reason that they're not."); Gervais First Report, para. 57; Gervais Second Report, paras. 19-20; Lindner First Report, para. 20. *See also*, Closing Presentation of Canada, Slide 206; Resp. CM, para. 366; Resp Rejoinder, para. 170 ("In fact, Article 1709(1) does not even require the NAFTA Parties to have the same basic patentability requirements … The distinct nature of these concepts was well-known a the time NAFTA was drafted.")

[459] Gervais First Report, paras. 54 and 58; Gervais Second Report, para. 11 ("The idea that significantly different understandings of core patentability requirements and variations of the definitions as defined by courts or legislators over time are compatible with both NAFTA and TRIPS is demonstrated by years of state practice.") *See also*, Opening Presentation of Canada, Slide 31; Closing Statement of Canada, June 8, 2016, p. 2316:1-5 ("The definition of useful in the NAFTA is one that allows for different – not different interpretations, but ones that have substantive content that are determined by the courts and within its own legal jurisdictions."); Closing Presentation of Canada, Slide 97; Resp. Rejoinder, para. 168 ("There was no harmonized or agreed standard or method of implementation between them. There is no evidence to suggest that the NAFTA Parties intended to impose restrictions on the implementation of their utility standards which would have required substantial changes to each of their domestic laws. The ordinary meaning of the term 'useful' in Article 1709(1) must therefore correspond with the concept of utility that existed individually in each of the NAFTA Parties' law."); Resp. CM, para. 358 (indicating the terms "utility" and "industrial applicability" "bear a range of meanings, reflecting their diverse usages in various national patent law systems.") and para. 362 ("neither 'utility' no[r] 'industrial applicability' are harmonized terms, and instead bear a range of distinct technical meanings in various national patent law systems.")

199. The meaning of "useful", considered in its context, must therefore be read to include the Supreme Court of Canada's articulation in *Consolboard*.[460] In patent law, that meaning is just as acceptable as anything Claimant has put forward. Indeed, it forms part of the relevant context of the meaning of "useful" in Article 1709(1) because this standard formed part of Canadian law at the time of NAFTA's conclusion.[461] Claimant inaccurately argues that all three NAFTA Parties' systems provided for a more-or-less harmonized understanding of utility when NAFTA was signed. It ignores that the promise standard did in fact form part of Canadian law[462] and that other differences existed between the Parties.[463]

200. The meaning of the term "useful" must also be considered in light of the other patentability criteria contained in Article 1709(1).[464] Accordingly, it must be considered

[460] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] SCR 504, 1981 CarswellNat 582, para. 36 (explaining that, under Canadian patent law, "not useful" means "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do ") (**R-011**). *See also*, Opening Presentation of Canada, Slide 31; Closing Presentation of Canada, Slide 97.

[461] See section IV. A.2, para. 111 to 136. Claimant itself recognized *Consolboard* as part of "established principles of patent law" in Canada when it opposed Novopharm's leave to appeal to the Supreme Court in 2010: *Novopharm's Limited v. Eli Lilly and Company*, Supreme Court of Canada Case No. 33870, Memorandum of Argument of the Respondent, Application for Leave to Appeal, October 26, 2010, para. 2 (**R-034**); *compare with* Federal Court of Appeal's instructions on promise, citing to *Consolboard* for premise that utility will be measured against a promise if made: *Olanzapine FCA I*, para. 76 (**R-015**). *See also*, Opening Presentation of Canada, Slide 49; Resp. CM, paras. 91-96; Resp. Rejoinder, paras. 152-153, and 156-157 ("There is no reason to think that when the drafters of NAFTA made reference to 'useful' in Article 1709(1), they decided to ignore the pronouncement of the highest court of one of the three NAFTA Parties on the meaning of that term or the scholarship of Canada's preeminent patent law specialists examining the Canadian law of utility.")

[462] Section IV.A. para 111-136, Dimock, June 2, 2016, pp. 1034:19 – 1035:2 ("MR. DIMOCK: The Claimant's experts say that as of 2005 this promise standard was new. They also allege that reading the patent through the mind and eyes of a person of skill in the art was new as of 2005. My opinion, as I've indicated, is that these alleged changes have been part of our Canadian law since before the 1970s, and it's always been that the patentees are held to their side of the bargain. The promise secures the patent.") *See also*, Resp. CM, paras. 91-100; Resp. Rejoinder, paras. 152, 153 and 158; Dimock First and Second Reports.

[463] *See generally*, Dimock First and Second Reports; Holbrook First and Second Reports; Lindner First and Second Reports. *See also*, Resp. Rejoinder, paras. 151-158 (on differences in Parties' standards at NAFTA signing); Resp. CM, paras. 170-172 (on differences in US law), paras. 176-178 (on differences in Mexican law), and paras. 375-377 (laws in place at NAFTA's signing belie Claimant's argument).

[464] Gervais Second Report, paras. 7-11 ("The logical implication of Claimant's argument on utility is that a baseline must also have been established for novelty and non-obviousness. If that were the case, then

in light of the patent bargain that underpins the patent law systems of all three NAFTA Parties, and the reality that that same bargain is enforced through different mechanisms.[465] Other relevant context includes the remainder of NAFTA Chapter Seventeen, which places each Party's courts at the centre of their patent systems.[466] Similarly, Article 1701(1) incorporates the *Paris Convention*, which establishes the principle of independence of patents under which countries may apply the patent bargain differently.[467] These provisions confirm that the Parties expected a dynamic approach to

one would expect that the current requirements in U.S. law now fall below a notional baseline by increasing the obligations imposed on inventors. I do not believe this is the case.") *See also*, Resp. Rejoinder, paras. 171-172 . The overlapping nature of patentability criteria is equally relevant context: *see, e.g.*, Dimock First Report, para. 81; Dimock Second Report, paras. 12-25 and 53; Holbrook Second Report, paras. 26 and 49; Resp. Rejoinder, paras. 20-25 and 173-174; Opening Statement of Canada, May 30, 2016, pp. 176:13 – 180:9 (describing the interlocking nature of patentability requirements); Opening Presentation of Canada, Slides 17-20.

[465] Holbrook, June 3, 2016, pp. 1446:6 – 1447:1 (describing that similar tensions and issues "pervade all patent systems, but countries may vary in which doctrinal bucket they use to address these concerns"); Gervais, June 4, 2016, p. 1749:18-25 ("PROFESSOR GERVAIS: How the patent bargain, therefore, is applied will change and evolve from jurisdiction to jurisdiction, and over time I would submit that this is the nature of the common law process, when the policy is mostly made in and by courts, and I would also stress that the disclosure and enablement obligations that are not mentioned in 27 or 1709(1) are core in implementing the bargain".); Gervais First Report, para. 61 ("The principle that the patent bargain may be applied differently by countries is notably recognized by the most widely adhered to instrument in the field of industrial property (including patents): the *Paris Convention for the Protection of Industrial Property*."); Dimock Second Report, para. 53 ("In my experience, distinguishing promised utility, overbreadth, and other staples of patent law based on form and labels does not recognize that aspects of patent law often overlap."); Holbrook First Report, paras. 7-8; Holbrook Second Report, para. 5 ("a proper comparative analysis does not myopically focus on a utility-to-utility doctrine comparison. Because countries have flexibility in how they implement various policy options, the proper comparison is a holistic one."); Lindner Second Report, para. 22 ("The procedural requirements of Article 47.I, patentability requirements, and the substantive requirements of Article 12.IV cannot be understood in isolation from one another."); Gervais Second Report, para. 6 ("As Professor Holbrook explains, the U.S. accomplishes many of the goals of Canada's utility requirement through other closely-related doctrines (such as enablement and written description.") *See also*, Closing Presentation of Canada, Slides 59, 211 and 217; Resp. CM, paras. 170-174 (arguing that the utility requirement in the US cannot be accurately assessed in isolation from the rest of United States patent law), and paras. 176-180 (explaining that Mexico "addresses utility in its own distinct manner"); Resp. Rejoinder, paras. 141-143 and 173-174; Respondent's Observations on Issues Raised in *Amicus* Submissions, para. 3 ("The systems are designed in such a way that all of the criteria work together to maintain the patent bargain") and para. 28 ("a proper comparative analysis requires 'comparison of rules that possess similar functions,' rather than similar labels or precise rules.")

[466] NAFTA Articles 1714-1717. *See also*, Resp. Statement of Defence, para. 90; Resp. CM, paras. 369-372; Resp. Rejoinder, para. 209.

[467] Gervais Report, para. 61; Gervais Second Report, paras. 13-16. *See also*, Resp. CM, para. 368.

patent law, and built in flexibility for evolution.[468] Finally, the object and purpose of NAFTA as it relates to intellectual property supports a view of the flexible meaning of "useful."[469]

201. **VCLT Article 31(2)**: **VCLT** Article 31(2) explains that instruments relating to the conclusion or implementation of the Agreement are relevant context in determining the meaning of treaty terms.[470] While each Party enacted implementing legislation to bring NAFTA into force, no Party altered or specified the meaning of "useful" or "capable of industrial application" or the other two substantive patentability criteria of Article 1709(1).[471] The absence of changes under domestic law with respect to the patentability criteria points to the NAFTA Parties' understanding that they were not

[468] Gervais, June 4, 2016, pp. 1747:24 – 1748:5 ("PROFESSOR GERVAIS: Utility will continue to vary as either new types of inventions or new understandings of new technologies evolve; how lawyers approach these issues in courts, how courts make policy, because most patent policy is made by courts, very few patent laws are amended on the level of how to define these criteria."); Gervais, June 4, 2016, p. 1830:7-13 ("PROFESSOR GERVAIS: What is different is the fact that very often the patent statute doesn't say very much, and so then it's left to courts to apply it. And then they see this technology and hear new arguments and they see, well, yes or no, and then it goes to Supreme Court. That's the process. That's the way these things work."); Merges, June 3, 2016, p. 1286:16-18 ("PROFESSOR MERGES: So common law elaboration and application of the basic concept is, of course, necessary.") *See also*, Closing Statement of Canada, June 8, 2016, pp. 2308:11 – 2309:16 (highlighting that the Parties have left the terms undefined "precisely because they will evolve and emerge in the context of legal systems."); Closing Presentation of Canada, Slides 212-214; Resp. CM, para. 365 (noting the Parties' intention to leave these terms to be applied in a flexible and principled manner, in accordance with national law) and para. 377 ("Nor have the three NAFTA Parties taken the position that their domestic patent law cannot evolve as courts interpret and apply such criteria"); Respondent's Observations on Issues Raised in 1128 Submissions, para. 38 ("In particular, both Canada and the United States affirm the flexibility of the NAFTA Parties to evolve and develop their patent law over time.")

[469] NAFTA Article 102(d), which tracks closely the language of Article 1701(1), reads: "the objectives of this Agreement are to … Provide adequate and effective protection and enforcement of intellectual property rights in each Party's Territory." This is not a harmonization objective. *See* Resp. CM, para. 374. *See also*, paras. 180 to 182 above (Article 1701(1)).

[470] United Nations, VCLT, 23 May 1969, p. 340 (**RL-072**).

[471] Gonzalez, June 6, 2016, p. 1871:8-11 ("MS. MONTPLAISIR: In 1994, Mexico did not amend its terminology to adopt the terminology used in the U.S. and Canada for patentability requirements, correct? MS. GONZALEZ: Correct."); Lindner First Report, para. 11. *See also* Closing Presentation of Canada, Slide 248; Resp. CM, para. 373; Resp. Rejoinder, para. 175 ("Claimant has adduced no evidence to show that Mexico, Canada, and the United States changed their respective practices when NAFTA came into force to bring their legislation into line with the alleged single restrictive standard adopted in Article 1709(1)."). In contrast, Canada did amend its legislation to remove compulsory licensing: Dimock First Report, para. 40 ("Canada eliminated the compulsory licensing scheme in 1993 in response to lobbying by the innovator pharmaceutical companies. In addition, the change was made to recognize Canada's international obligations under the [TRIPS] and NAFTA, in particular NAFTA Article 1709(10).")

accepting international obligations that required them to make substantive changes to their patent laws. Instead, they were agreeing that Chapter Seventeen contained sufficient flexibility to allow each system to continue its particular evolution within the confines of maintaining a "useful" or "capable of industrial application" requirement.

202. **VCLT Article 31(3)(b)**: The VCLT dictates that subsequent practice of the treaty parties in the application of the treaty can be a helpful interpretive tool. Here, two aspects of subsequent practice have been raised: first, the manner in which the courts and legislatures of each Party have implemented and applied its patent law since NAFTA came into force; and second, any communications or complaints among the Parties with respect to the others' implementation and application of the treaty. An analysis of the first shows that the Parties have all acted in a manner consistent with an understanding that NAFTA accords them flexibility in implementing their obligations and in continuing to evolve their laws. Consideration of the second shows that there have been no specific complaints raised, nor disputes commenced, by either the United States or Mexico with respect to Canada's implementation of Article 1709(1).

203. With respect to the first, Claimant places an arbitrary temporal restriction on its assessment of the subsequent practice of the NAFTA Parties in their application of the treaty.[472] It argues that one decade of implementation, from 1995 to 2005, is sufficient to establish an agreement, and that any implementation following that is irrelevant.[473] There is simply no basis in the VCLT or in NAFTA for such an interpretation.

204. The NAFTA Parties' implementation of Article 1709(1) over the past two decades actually supports Canada's interpretation, not Claimant's. Indeed, the United States agreed with Canada in its Article 1128 submission that the Parties retain the discretion to change or refine their domestic law and to implement the utility

[472] Closing Statement of Claimant, June 8, 2016, p. 2106:11-21.

[473] Closing Statement of Claimant, June 8, 2016, p. 2107:11-13.

requirements within their own legal systems and practices.[474] Claimant has shown no State practice to the contrary. It could not.[475]

205. The utility requirement continues to evolve in U.S. jurisprudence, just as other patentability requirements have changed.[476] For example, Claimant's own experts agree that the utility requirement has become more rigorous and stringent in the years since NAFTA in the United States.[477] Similarly, the "non-obviousness" requirement has been

[474] US 1128 Submission, para. 40 ("Article 1709(1) provides each NAFTA Party with the flexibility to determine the appropriate method of implementing the requirements of Chapter Seventeen, including the utility requirement in Article 1709(1), within its own legal system and practice."). *See also*, Closing Presentation of Canada, Slide 215; Respondent's Observations on Issues Raised in 1128 Submissions, para. 40 ("As the United States expressly contemplates, Article 1709(1) does not prevent change or refinements in the patent laws of the NAFTA Parties.")

[475] *See, generally*, Resp. CM, paras. 173 and 375-377; Resp. Rejoinder, paras. 175-176.

[476] Robert P. Merges, Justifying Intellectual Property, (London, 2011) Harvard University Press, p. 182 (noting "Courts are of course especially well suited to assess these sorts of changes and to adjust rules accordingly" and using as an example "The updating of the utility requirement in patent law to obviate the patenting of gene snippets aimed at capturing the value of later-discovered genes") (**R-450**); Holbrook Second Report, paras. 7 ("the Federal Circuit's expansion of the written description requirement as an independent basis for invalidating patents represents a significant shift in patent law") and para. 45 (discussing the "dramatic impact" of developments in US law such as *Alice Corp Pty. Ltd. V. CLS Bank Int'l*, and *Ariad*, and concluding that these "significant changes to Untied States patent law … suggest U.S. courts do not feel constrained by NAFTA in their development of patent law'); Merges, June 3, 2016, p. 1330:20-23 ("PROFESSOR MERGES: […] As with patentable subject matter, the law of utility has been developed largely by the courts in a common law fashion, without detailed guidance from Congress.")

[477] Robert Patrick Merges & John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* (LexisNexis, 6th ed. 2013), p. 241 (explaining the "2001 [PTO] Guidelines indicated a tightening of agency policy on utility") (**R-056**); Robert P. Merges, Peter S. Menell, & Mark A. Lemley, *Intellectual Property in the New Technological Age* (Wolters Kluwer 6th Ed 2012), p. 175 (identifying the two "novel" aspects of utility introduced in the 2001 PTO Guidelines as defining "specific" utility and adding the "substantial" utility requirement) (**R-055**); Stephen J. Kunin, *Written Description Guidelines and Utility Guidelines*, 82 J. Pat. & Trademark Off. Soc'y (2000), p. 100 (writing in 2000 that the PTO is "applying a more stringent test for utility than in its earlier set of guidelines") (**R-119**); Janice Mueller, *Patent Law* (Wolters Kluwer, 4th ed. 2013), pp. 330-331 (characterizing the 2005 result in *In re Fisher* as a "return by the federal Circuit … to the rigorous utility criteria announced almost 40 years earlier", and questioning the scope of application of the "heightened utility requirement") (**R-120**); Holbrook First Report, para. 11 ("In reality, however, practitioners and academics recognize that the USPTO utility guidelines, subsequently embraced by the Federal Circuit, effectively raised the U.S. utility standard, precluding most patents on gene fragments."). *See also*, Closing Statement of Canada, June 8, 2016, pp. 2312:23 – 2314:15; Closing Presentation of Canada, Slides 226-228 and 230.

tightened since NAFTA was concluded.[478] This kind of evolutionary dynamic is unsurprising.

206. Mexico, too, understands that it retains discretion to implement the patent bargain in the context of its own domestic legal system.[479] Claimant's argument that Mexico's "capable of industrial application" standard is a *de minimis* one and has not changed since NAFTA was signed failed completely.[480] In 2010, Mexico implemented reforms to its patent laws to impose stricter requirements, including by tightening the definition of industrial application.[481]

207. Claimant's attempt[482] to extrapolate the subsequent practice of the NAFTA Parties in the application of Article 1709(1) from the different outcomes of patent validity challenges in different Parties' courts is also futile. Such a comparison is dangerous because, even if the same patent were challenged in multiple jurisdictions, different outcomes may simply be the result of courts disagreeing on the facts based on the evidence and argument before them.[483] For example, in comparing the Canadian and

[478] Holbrook First Report, paras. 72-74; Gervais Second Report, para. 9. *See also*, Resp. CM, para. 173.

[479] Lindner First Report, paras. 20-21 (noting that "the text of NAFTA left flexibility in its implementation for Parties to use, at their discretion, different basic terms reflecting their respective domestic legal system."); Lindner Second Report, para. 14. *See also*, Resp. CM, paras. 175-180; Resp. Rejoinder, para. 158 ("The Mexican law of industrial applicability contained none of the promise language found in Canadian law, or of substantial utility found in American law.") and para. 177.

[480] Cl. Mem., paras. 200-201; Cl. Reply, paras. 161-172. *Contrast* Lindner Second Report, paras. 16-18.

[481] Gonzalez, June 6, 2016, p. 1890:1-16 ("MS. MONTPLAISIR: …The commissions noted that the including of the term 'for the purposes described in the application' would limit the practice of submitting patent applications that have yet to complete the development of industrial application, correct? MS. GONZALEZ: Correct. MS. MONTPLAISIR: In other words, the commissions were concerned about the practice of prematurely filing a patent application to secure a filing date without having specified the utility of the invention. Is that correct? MS. GONZALEZ: It was a situation that existed in Mexico, and legal scholars and regulations established that. This comes from the application, yes. That's correct."); Lindner Second Report, paras. 12-22. *See also*, Closing Presentation of Canada, Slides 248-249.

[482] Closing Statement of Claimant, June 8, 2016, p. 2110:1-14.

[483] Holbrook, June 3, 2016, pp. 1535:18 – 1536:8 (explaining that looking to litigation outcomes to assess patentability requirement across jurisdictions "would be troubling because it assumes that the doctrines are exactly the same. It assumes the fact finders would be exactly the same. It assumes the evidence would be exactly the same. All of these cases are very fact intensive, and how a given fact finder, a given tribunal, weighs those facts in light of their own -- I'm not willing to say that you're going to expect uniform decisions across jurisdictions."); Holbrook, June 3, 2016, p. 1543:16 – 23 ("My take-away would be that

American atomoxetine proceedings, one finds that the testifying experts, the lawyers, the parties, the judges, the relevant case law, and the legal arguments were all different.[484] Moreover, the fact that at least one lower court in the U.S. did see fit to invalidate the patent on the basis of "lack of enablement utility", even if it was overturned on appeal, shows that Canada's approach is not an "extreme outlier" as Claimant suggests.[485] Similarly, the fact that patents in Mexico are seldom invalidated on the basis of industrial application is not evidence of State practice that supports Claimant's interpretation of the meaning of Article 1709(1).[486]

208. With respect to the second element of relevant subsequent practice between the NAFTA Parties, the absence of specific complaints or allegations by Canada's NAFTA partners that Canada is in breach of Chapter Seventeen is telling. Neither the United

on the factual issues in this case, the courts disagree. That doesn't necessarily tell me that there is systemic differences in the utility standards."); Holbrook, June 3, 2016, pp. 1557:21 – 1558:6 (noting the absence of litigation "doesn't tell us much because it becomes a business decision as to whether to sue"); Merges, June 3, 2016, pp. 1322:20 – 1323:4 ("There are multiple reasons why companies engage in patent litigation. Unfortunately, sometimes the patents are not particularly valuable. They may be initiating litigation simply to try to negotiate a settlement and, in fact, the patents are not very valuable. They may be using patent litigation for strategic purposes to slow down a new entrant or to sort of harass a competitor. There's a lot of different scenarios under which patents are litigated.") *See also*, Closing Presentation of Canada, Slides 242-245.

[484] *See* Holbrook, June 3, 2016, pp. 1539:21 – 1542:4 (noting that "you'd have to take into account what different evidence was available. I think you have to take into account the context of the case, the context of the fact finders" and that it was a "close case" in the US). *Compare* trial level decision in *Eli Lilly and Co. v. Actavis Elizabeth LLC*, 731 F. Supp. 2d 348 (DNJ 2010), p. 385 **(R-029)** with trial level decision in *Novopharm Ltd. v. Eli Lilly and Co.*, 2010 FC 915 (**R-027**).

[485] Holbrook, June 3, 2016, p. 1540:2-15 ("The evidence in the case showed that the inventor didn't actually seem to know that the invention would work when it field. The inventor in the case testified that at the time they filed, there were studies that were going to start, but they weren't certain that the inventions as going to work, the method was going to work. So the facts are close. In a close case, even with a similar standard, you may get differing outcomes because reasonable minds can disagree on what's the salience of those particular patents."); Holbrook, June 3, 2016, p. 1541:19-25 ("So when an inventor is testifying that they're not convinced that it's going to work at the time they're filing the application, that, to me suggests that this is a close case. When the U.S. case law talks about not patenting hypotheses or not patenting research proposals, that type of evidence suggests that you're getting close to that line."); *Eli Lilly and Co. v. Actavis Elizabeth LLC*, 731 F. Supp. 2d 348 (DNJ 2010) (**R-029**).

[486] Lindner, June 6, 2016, p. 1973:1-10 ("MR. SMITH: And there was no litigation challenge of any kind to this patent during that period, right? MS. LINDNER: For that to happen, someone has to be interested in the product, and there should be an evaluation of the cost benefit of attacking a patent in this way."); Lindner First Report, para. 89. *See also*, Resp. CM, para. 180; Closing Presentation of Canada, Slides 245-246.

States nor Mexico has launched a challenge against Canada under Chapter Twenty, the exclusive means by which a breach of Chapter Seventeen, including Article 1709(1), can be established.[487] Nor is there evidence that either has made such an allegation in any other way. In this regard, it is noteworthy that the 2014 and 2015 Special 301 Report published by USTR and relied upon by Claimant do not allege any breach of NAFTA Chapter Seventeen or of any of Canada's other international obligations.

209. **VCLT Article 31(3)(c)**: Consideration of other relevant rules of international law further confirms that NAFTA Article 1709(1) does not impose the specific meaning of utility that Claimant proposes. TRIPS is a relevant rule of international law under VCLT Article 31(3)(c) because NAFTA and TRIPS emerged at the same time.[488] The text of TRIPS Article 27 and NAFTA Article 1709(1) is virtually the same.[489] It is well established that WTO Member States are left to define and implement the various criteria prescribed by TRIPS Article 27 into their national laws.[490] It is difficult to see how the NAFTA Parties could have intended anything else.

[487] Mexico 1128 Submission, paras. 24-25 and 30; US 1128 Submission, paras. 23 and 36. *See also*, Closing Statement of Canada, June 8, 2016, p. 2303:12-24 ("SIR DANIEL BETHLEHEM: So is the only recourse for a patent owner, patentee, if it is concerned about consistency of practice with Chapter 17, to go along to its NAFTA party and try and push that NAFTA party to raise it at the level of an interstate party discussion or Chapter 20 case, is that the avenue of recourse? MR. SPELLISCY: Certainly in our view Chapter 20 tribunals are set up to resolve disputes under chapters like Chapter 17. So if there is a concern about a breach of the obligations of Chapter 17, it is to be resolved between the state parties to NAFTA under Chapter 20."); Closing Statement of Canada, June 8, 2016, p. 2320:4-9 ("We would note that there has been no challenge by the United States against Canada under Chapter 20 alleging a breach of Chapter 17. Chapter 17 is the exclusive means by which a breach of that chapter, including 1709(1), can be established."); Resp. CM, para. 210, FN 399; Respondent's Observations on Issues Raised in 1128 Submissions, paras. 15-17 and 36.

[488] Gervais First Report, paras. 56-62. *See also*, Resp. CM, paras. 185-188; Resp. Rejoinder, paras. 178-181.

[489] Gervais, June 4, 2016, p. 1819:10-22 ("… the point I make is that when the same parties use the same language in an agreement which has a very similar object and purpose, which is a trade agreement with an IP chapter, there is definitely relevance in the fact that they have this common origin, and if you look at 1709(1) and 27(1), you see very similar language, the real difference being the footnote in 27 being moved to the text in 1709. In 1709(2) the paragraphs are formatted differently, but the words are almost identical in 22 that section.") *See also*, Closing Presentation of Canada, Slide 251.

[490] Marney L. Cheek, *The Limits of Informal Regulatory Cooperation in International Affairs: A review of the Global Intellectual Property Regime*, the Geo. Wash. Int'l L. Rev., Vol. 33, (2000), pp. 292-293 ("the TRIPS Agreement is not intended to be a harmonization agreement, meaning that countries are not

210. Claimant argues that the PCT, rather than TRIPS, is a relevant rule of international law because it "has a definition of utility that's well accepted."[491] This argument does not withstand scrutiny. Not only is the PCT recognized by WIPO (and by Claimant)[492] as a merely procedural treaty,[493] but the definition Claimant focuses on was expressly intended only for the preliminary and non-binding assessment portion of the PCT international phase.[494] The PCT has nothing to say about the substantive patentability criteria of Member States.[495] As such, it is not a relevant rule of

required to create identical regimes") (**R-314**); Gervais Second Report, para. 21 ("The TRIPS Agreement does not prohibit a state from defining its substantive patentability criteria. This flexibility on how TRIPS is to be implemented is noted in the very first article of the Agreement, and has been recognized by cases from the WTO Appellate Body and various dispute-settlement panels that have interpreted TRIPS and other WTO instruments."); TRIPS, Article 1(1) ("Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice"). *See also* Resp. CM, para. 186.

[491] Closing Statement of Claimant, June 8, 2016, p. 2110:18-25; Cl. Reply, para. 276.

[492] Closing Statement of Claimant, June 8, 2016, p. 2111:23-24.

[493] WIPO, *WIPO-Administered Treaties*, (listing the PCT under a group of treaties ensuring one international registration or filing, in contrast to the IP Protection group of treaties that define internationally agreed basic standards of IP protection) (**R-255**); Reed First Report, para. 12 (noting that PCT brings "enhanced procedural convenience" to users); Reed Second Report, paras. 8 and 12; Gervais First Report, paras. 78 ("The PCT itself is a procedural treaty"). *See also* Resp. CM, paras. 378-382; Resp. Rejoinder, para. 181 ("The PCT is recognized by WIPO as a merely procedural treaty.")

[494] Gervais First Report, para. 74, ("The definition of 'industrial applicability' which the Claimant points to in PCT Article 33(4) is expressly intended only for the purpose of the PCT's international examination procedure."). *See also* Resp. CM para. 380 ("Although the PCT defines capable of industrial application, it does so broadly and expressly only for the purposes of the 'preliminary and non-binding' assessment of patentability conducted during the 'international phase' of the PCT to provide an application with preliminary information about the apparent patentability of an invention claimed in an international application.").

[495] Gervais, June 4, 2016, p. 1748:16-23 ("NAFTA does not require the parties adopt the PCT definition of industrial applicability. The PCT and the Paris Convention were both well-known at the time that NAFTA was signed and TRIPS. Neither one of those agreements incorporated the PCT, but they both incorporated the Paris Convention. Therefore, not being in the "must comply" list of treaties in NAFTA is, I think, relevant."); Erstling, June 4, 2016, p. 1620:4 ("MR. SPELLISCY: And the PCT has nothing to say on what those substantive conditions are, correct? PROFESSOR ERSTLING: That's correct."); Ertsling, June 4, 2016, p. 1574:11-13 ("To be clear, there is nothing in the PCT that is an effort to create substantive patent law …"); Reed Second Report, paras. 8 and 12 ("Article 27(5) makes clear that the freedom of states to prescribe substantive conditions of patentability is absolute – it is not affected in any way by other provisions of the PCT). *See also*, Closing Presentation of Canada, Slide 59 and 194; Resp. Rejoinder, para. 181 ("the PCT has nothing to say about the substantive patentability criteria applied by Contracting States.")

international law helpful in ascertaining the substantive meaning of "useful" or "capable of industrial application" in NAFTA Article 1709(1).

211. **VCLT Article 31(4)**: Claimant has failed to establish that the NAFTA Parties intended a special meaning under VCLT Article 31(4) that would deviate from the ordinary meaning analysis Canada has done above.[496] Had the NAFTA Parties intended to ascribe singular content or special meaning to a word like "useful" in Article 1709(1) that is "pregnant with ambiguity",[497] they would have done so in the text. They have not, and Claimant has offered no evidence to prove otherwise.

212. **VCLT Article 32**: Finally, a review of relevant supplemental means of interpretation pursuant to VCLT Article 32 shows that: (1) there is no core agreement on the definition of utility or industrial applicability; and (2) there have been no complaints about Canada's promise standard in terms of any of Canada's international intellectual property law obligations. Both points support an interpretation of NAFTA Article 1709(1) that recognizes the NAFTA Parties' flexibility to articulate and apply the patentability criteria in their own domestic systems, and that includes Canada's promise standard.

213. First, as Claimant's expert, Mr. Thomas agreed there is neither core agreement on how utility or industrial application should be defined[498] nor substantial

[496] Gervais First Report, paras. 59-62 ("I have seen no credible evidence that the NAFTA Parties intended to give a special meaning of the term utility that confirms what the Claimant argues.") *See also*, Resp. CM, paras. 353-357.

[497] *See Brenner v. Manson*, 383 US 519 (1966), p. 529 (**R-053**). *See also*, Opening Statement of Canada, May 30, 2016, p.175:14-17 ("MR. JOHNSTON: And as the U.S. Supreme Court noted with respect to the word 'useful' in U.S. patent law, 'a simple everyday word can be pregnant with ambiguity when applied to the facts of life.) Opening Presentation of Canada, Slide 15.

[498] Thomas, June 4, 2016, p. 1720:16-24 ("I don't think there's a core agreement on utility, if that means that there's a core agreement on how it should be defined or elaborated in national legislation. In that respect there's no core agreement.") *See also*, Closing Presentation of Canada, Slide 253; Resp. CM, para. 185 ("the negotiation of TRIPS showed no serious attempt to agree on, or even consider including, definitions of the patentability requirements in the text of the agreement. Definitions of patentability requirements were instead left to each Member, allowing ample room for national variations and approaches.") and para. 366 ("The absence of substantive harmonization between the Parties is embedded in the basic terms of NAFTA Article 1709(1) itself").

harmonization in the manner in which the industrial applicability and utility standards are applied.[499] Failed attempts to achieve substantive harmonization confirm this view.[500] The failure of States to agree on how to define and implement the core patentability standards supports Canada's view that Article 1709(1) was not meant to solve this as-of-yet internationally intractable issue. Indeed, the better interpretation of Article 1709(1) is one that is consistent with the lack of international consensus, and which acknowledges the NAFTA Parties' recognition of the need for, and adoption of, flexibility in their agreement.

214. Second, there is evidence in the record that Canada's trading partners were both aware of Canada's promise standard, and raised no concerns or complaints about it. Claimant's allegation is that Canada's utility standard is an international outlier – that it is internationally aberrant. If this were so, one would expect Claimant to be able to introduce that other States, even outside of the NAFTA context, have raised concerns and complaints. However, the evidence in this case is the exact opposite. For example, in WIPO documents from 2001 and 2003, Canada's promise doctrine was given as a

[499] Thomas, June 4, 2016, p. 1732:4-17 ("MR. SPELLISCY: there's significant variance in the standard, correct? MR. THOMAS: There most certainly is."); Gervais, June 4, 2016, p. 1776:19-23 ("they overlap to a large degree but they're not identical. The WIPO documents made that quite clear. They're not identical and within both families there are divergences as well."); WIPO, "The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws, April 2001, p. 1 ("there is a wide range of differences among [Standing Committee on the Law of Patents] members concerning the interpretation and practice relating to the 'industrial applicability/utility' requirement.") (**R-407**); 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.pdf, paras. 25, 49 (noting that, even between countries adopting the "industrial applicability" standard, "national and regional laws and practices ...vary significantly." The same held true of jurisdictions adopting "utility") (**R-230**); Gervais Report, para. 54. *See also*, Closing Presentation of Canada, Slides 254-255; Resp. CM, para. 18 ("It is notorious that technical patent law terms such as 'utility' are not internationally harmonized."), para. 362 ("In the international context, relevant international organizations and States have recognized that neither 'utility' not [*sic*] 'industrial applicability' are harmonized terms, and instead bear a range of distinct technical meanings in various national patent law systems.") and para. 382 ("all later attempts at substantive harmonization have failed."); Respondent's Observations on Issues Raised in Amicus Submissions, para. 24.

[500] Gervais, June 4, 2016, p. 1745:13-21 (noting that "there have been a series of efforts to harmonize all patentability criteria and they have, as we've seen before, all failed. The lack of agreement is there. The reason for lack of agreement is partly because countries want to keep the ability to define these criteria. They know that their courts will continue to change the way that these criteria are applied and defined."); Gervais First Report, paras. 17-54; Gervais Second Report; Reed First Report, paras. 49-56. *See also*, Resp. CM, paras. 182-199; Closing Presentation of Canada, Slide 252; Resp. Rejoinder, para. 185.

"definition and example" of "utility" alongside the standard in the United States.[501] As Claimant's own expert acknowledged, no State raised any concerns with Canada's approach to utility in the WTO context.[502]

215. Even as late as 2014, the evidence in the record – the Tegernsee Report which Claimant highlighted in its cross-examination of Dr. Gervais[503] – shows that Canada's major trading partners had no concerns about Canada's allegedly "aberrant" and "outlier" approach to utility more than a decade after Canada allegedly began to deviate from its international obligations in 2002 and over five years after its allegedly deviant doctrine had crystallized in 2008.[504] In short, there is no evidence of formal or informal complaints from Canada's trading partners with respect to utility in this arbitration.

216. These facts support an interpretation of "utility" in Article 1709(1) that includes flexibility for Canada to maintain the promise standard. In sum, Canada's utility

[501] Thomas, June 4, 2016, p. 1717:13-17 ("MR. SPELLISCY: So this would have been, then, Canada informing the SCP of what its law was, correct? MR. THOMAS: Canada replied in response to a survey saying what its law was."); Thomas, June 4, 2016, p. 1718:16-20 ("MR. SPELLISCY: This paper was dated April 2001, so you would agree with me, then, that this information must have been provided by Canada prior to that date, correct? MR. THOMAS: Yes."); WIPO, *The Practical Application Of Industrial Applicability/Utility Requirements Under National And Regional Laws*, April 2001, paras. 13 and 24 (**R-407**); WIPO, *Industrial Applicability" and "Utility" Requirements: Commonalities and Difference*, document SCP/9/5, 17 March 2003, paras 34-35 and 40-41 (also noting that utility "relates to other substantive requirements of patentability" and "cannot be considered separately from other requirements") (**R-230**). *See also*, Closing Presentation of Canada, Slides 257-263.

[502] Thomas, June 4, 2016, pp. 1719:3 – 1720:4 (admitting there were "no concerns raised, nor was there any approval raised" about the consistency of Canada's statement with the core utility requirement in the 2001 WIPO Paper); Thomas, June 4, 2016, pp. 1734:22 – 1736:2 ("MR. SPELLISCY: And no concerns, to your knowledge, as a member of the secretariat there attending every meeting, no concerns, to your knowledge, were ever raised about this Canadian standard, correct? MR. THOMAS: That is correct.") *See also*, Closing Presentation of Canada, Slides 263 and 264.

[503] Gervais, June 4, 2016, pp. 1802:21 – 1809:16; *Consolidated Report on the Tegernsee User Consultation on Substantive Patent Law Harmonization* (May 2014) (**R-240**).

[504] Gervais, June 4, 2016, pp. 1805:7 – 1806:4 (noting no concern about practical differences in utility/industrial applicability requirements across jurisdictions in the Tegernsee Group report); Gervais, June 4, 2016, p. 1809:5-10 (similar conclusions with respect to Germany); *Consolidated Report on the Tegernsee User Consultation on Substantive Patent Law Harmonization* (May 2014) (**R-240**); Japan Patent Office, *Report on Consultations with Users* (2013), p. 21 (showing absence of utility as a "main issue" from the Japanese Patent Office's perspective) (**C-340**); European Patent Office, Evaluation of the Tegernsee Questionnaires for Germany (Executive Summary) (2013), p. 2 (showing "no other obvious topics deemed to be similarly important by the applicants" for harmonization) (**C-483**). *See also*, Closing Presentation of Canada, Slides 265 and 267.

requirement is fully consistent with its obligations to the United States and Mexico in Article 1709(1).

iii. Article 1709(1) Neither Prohibits Canada from Requiring that an Invention be Made at the Time of Filing Nor from Requiring Disclosure for Sound Prediction

217. Even if the Tribunal reads Article 1709(1) to include evidentiary and disclosure rules, Canada's law is still consistent with its obligations in Article 1709(1). The VCLT analysis conducted above remains germane, and leads to the same result: NAFTA Article 1709(1) allows the NAFTA Parties flexibility to implement the patent bargain in their own way in their own domestic laws, and to evolve those laws over time.[505]

218. In this regard, relevant context includes the fact that all three NAFTA Parties have their own rules to address the question of when to grant a patent. In Canada, utility must be demonstrated or soundly predicted by the time the applicant filed for a patent.[506] In the United States, utility has to be established at the time that a patent application was filed.[507] In Mexico, patentees need to establish at the time of filing that their inventions are capable of industrial applicability.[508] In all systems, post-filing evidence is too late.[509]

---

[505] *See* Resp. Rejoinder, paras. 159 and168 (on differences in Parties' implementation practices at NAFTA signing).

[506] *Manual of Patent Office Practice, Consumer and Corporate Affairs Canada*, Patent Office (1990), s. 18.20.02 ("An invention, such as that relating to a new substance, may not be said to be invented until such date as the utility for it is known.") (**R-309**); Dimock First Report, para. 93; Dimock Second Report, para. 94. *See also*, Resp. Rejoinder, para. 161.

[507] Holbrook First Report, para. 32; Holbrook Second Report, para. 44. *See also*, Resp. Rejoinder, para. 166.

[508] Lindner Second Report, paras. 18-22. *See also*, Resp. Rejoinder, para. 167.

[509] For Canada, *see* Dimock First Report, para. 112; Dimock Second Report, para. 89 (explaining that a patentee in Canada cannot "file now and invent later"); Gillen Second Statement, paras. 18-22. *See also*, Resp. Rejoinder, para. 161. For the United States, *see*: Robert Patrick Merges & John Fitzgerald Duffy, Patent Law and Policy: Cases and Materials (LexisNexis, 6th ed. 2013), p. 213 (**R-056**); *Rasmusson v. SmithKline Beecham Corp.*, 413 F3d 1318, (Fed Cir 2005) (**R-063**). *See also*, Resp. Rejoinder, para. 166; Resp. Rejoinder, para. 166; Closing Presentation of Canada, Slide 231 (discussing the *Rasmusson v. SmithKline Beecham Corp.* case, in which it was found that "evidence obtained after the filing date was 'too late'."). For Mexico, *see* Lindner Second Report, para. 18-22; Lindner First Report, para. 52 ("If an

219. All three NAFTA Parties equally have rules relating to disclosure. In Canada, patentees relying on sound predictions of utility need to disclose the factual basis and sound line of reasoning underpinning their predictions of utility.[510] In the United States, patentees need to provide convincing data to support the utility requirement, including to show that the asserted utility has a substantial use that is not merely hypothetical.[511] Such requirements were largely imposed by the enablement requirement, which is closely connected to utility.[512] In Mexico, patentees need to provide a sufficient description of the invention, particularly for pharmaceutical and chemical products where the industrial applicability of the invention is not necessarily self-evident.[513]

220. Underlying all of these rules are similar policy rationales. All three systems are concerned with issues of speculation and premature filing, though they often deal with those issues through different lenses.[514] For example, the policy concerns articulated in the 2005 *Rasmusson* case in the United States, cited in the 2009 '*318* patent judgment,[515]

applicant produces information showing that the applicant had not completed the invention process, including establishing that the invention was capable of industrial application, before the filing date, the patent should be held invalid.").

[510] Dimock First Report, para. 41; Dimock Second Report, para. 130; Gillen First Statement, para. 54; Gillen Second Statement, paras. 16 and 24. *See also*, Resp. CM, paras. 125-134; Resp. Rejoinder, paras. 162-164.

[511] Timothy R. Howe, *Patentability of Pioneering Pharmaceuticals: What's the Use?*, 32 San Diego L. Rev. 819 (1995), p. 826 (**R-445**) *Brenner v. Manson*, 383 US 519, (1966), para. 529 (**R-053**) Holbrook First Report, para. 64. *See also*, Resp. Rejoinder, para. 166.

[512] Holbrook Second Report, paras. 5 and 25 (writing that the enablement, written description and utility requirements are inextricably linked).

[513] Lindner Second Report, paras. 19-20. *See also*, Resp. Rejoinder, para. 167.

[514] For example, the United States polices these policy concerns in part through the doctrines of enablement and written description: Holbrook Second Report, para. 9 ("these three doctrines are meant to address concerns with premature patenting and overly broad claim scope, as do the Canadian utility requirements. U.S. law simply places these policy concerns in different doctrinal 'buckets' than in Canada."); Holbrook, June 3, 2016, pp. 1445:23 – 1447:10 (explaining that "you have to ensure sufficient protection to the patentee to maintain the incentives of the patent system, but you don't want to give too much protection, rewarding a windfall for work that that inventor did not actually accomplish", and that these tensions and issues "pervade all patent systems, but countries may vary in which doctrinal bucket they use to address these concerns," including through the utility, enablement, written description and obviousness doctrines in US law.); Holbrook Presentation, Slides 3-4. *See also*, Closing Presentation of Canada, Slides 231 and 232.

[515] *Rasmusson v. SmithKline Beecham Corp.*, 413 F3d 1318, (Fed Cir 2005), p. 6 ("If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions"

are strikingly similar to those articulated by the Supreme Court of Canada in *AZT*.[516] Mexico, too, is concerned with speculative patenting, as was shown by the explanation of the drafters of its 2010 amendments.[517]

221. The subsequent practice of the NAFTA Parties illustrates that Canada, the United States, and Mexico all understand that they retain flexibility to enforce the patent bargain in different ways in their domestic legal systems.[518] For example, the United States introduced, after NAFTA came into force, written description as a requirement that is separate and distinct from enablement.[519] As Claimant's expert, Professor

consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis.") (**R-063**); *In re '318 Patent Infringement Litigation*, 583 F.3d 1317 (Fed. Cir. 2009), p. 1327 (**C-279**). *See also*, Closing Presentation of Canada, Slides 234-235.

[516] *Apotex Inc. v. Wellcome Foundation Ltd*., [2002] 4 SCR 153, para. 84 ("In the broader context of the Patent Act, as well, there is good reason to reject the proposition that bare speculation, even if it afterwards turns out to be correct, is sufficient. An applicant does not merit a patent on an almost-invention, where the public receives only a promise that a hypothesis might later prove useful; this would permit, and encourage, applicants to put placeholders on intriguing ideas to wait for the science to catch up and make it so. The patentee would enjoy the property right of excluding others from making, selling, using or improving that idea without the public's having derived anything useful in return.") (**R-004**). *See also*, Closing Presentation of Canada, Slide 236.

[517] Lindner, June 6, 2016, p. 1931:9-13 ("MS. LINDNER:… the motivation of the proposed amendment, which aims to limit the practice of filing patent applications for which the development of the industrial applicability has not been concluded."); Lindner, June 6, 2016, p.1928:10-20 ("MS. LINDNER: Here it's noted that in practice, industrial application has been distorted. It's often -- oftentimes there are applications that don't specify this requirement. There are -- well, if there are delays in defining industrial applicability for subsequent stages, this gives rise to an imbalance in the system as to -- or concerning possible future developments one would be breaching the social contract of granting a patent for something that turns out to be speculative and thereby impede or obstruct parallel development.)"; Gonzalez, June 6, 2016, pp. 1891:25 – 1892:9 ("MS. MONTPLAISIR: The intention of the drafters was to avoid speculative patenting, correct? … MS. GONZALEZ: That is what the report says, yes, that's correct."); Gonzalez, June 6, 2016, p. 1892:7-16 ("MS. MONTPLAISIR: The intention of the drafters was to avoid speculative patenting, correct? … MS. GONZALEZ: That is what the report says, yes, that's correct."); Gonzalez, June 6, 2016, p. 1890:15-23. *See also*, Closing Presentation of Canada, Slide 247-248.

[518] *See*, *e.g.*, Holbrook Second Report, para. 9; Holbrook, June 3, 2016, pp. 1446:2 – 1447:13; Holbrook Presentation, Slides 3-4; Gervais First Report, paras. 63-70.

[519] Robert Patrick Merges & John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* (LexisNexis, 6th ed. 2013), p. 292 (identifying that "more stringent written description requirements" had been developed in recent cases) (**R-056**); Janice Mueller, *Patent Law* (Wolters Kluwer, 4th ed. 2013), p. 154 (writing that the question of whether a patent application provides an enabling disclosure is "a completely separate inquiry" from that of written description) (**R-120**); Holbrook First Report, paras. 68-

Merges, agreed, there has been movement between doctrinal headings that impacts the patent bargain as a whole, including the utility requirement.[520] These developments had a "dramatic impact" on patent law in the United States.[521] Similarly, Mexico amended its patent laws to address concerns about speculative patenting.[522] These developments further confirm the inappropriateness of Claimant's binary utility-to-utility comparison.[523] The label attached to a measure in domestic law cannot be a legitimate basis to distinguish compliance from non-compliance with NAFTA Chapter Seventeen.[524]

69 ("Due in large part to Eli Lilly's own efforts, the law of written description in the United States has evolved into a doctrine distinct from enablement that assesses the adequacy of a patent disclosure…"); Holbrook Second Report, paras. 45 and 47 (explaining that *Ariad*, which full recognized the written description and "stands alone in the world", "represents a dramatic unilateral alteration of United States patent law, creating a doctrine that is unique to the United States.") *See also*, Closing Presentation of Canada, Slide 237; Resp. CM, para. 163; Resp. Rejoinder, para. 176.

[520] Merges, June 3, 2016, p. 1303:13-20 ("PROFESSOR MERGES: … So we've moved a little among doctrinal headings and that, of course, has an impact to some degree on practitioners, who may have to couch their arguments differently."); Holbrook, June 3, 2016, p. 1517:7-21 (confirming "changes in the invalidations that have arisen" since the written description doctrine was embraced by the Federal Circuit).

[521] Holbrook Second Report, para. 7 ("the Federal Circuit's expansion of the written description requirement as an independent basis for invalidating patents represents a significant shift in patent law") and para. 45 (discussing the "dramatic impact" of developments in US law such as *Alice Corp Pty. Ltd. V. CLS Bank Int'l*, and *Ariad*, and concluding that these "significant changes to Untied States patent law … suggest U.S. courts do not feel constrained by NAFTA in their development of patent law").

[522] Gonzalez, June 6, 2016, p. 1890:8-23 ("MS. MONTPLAISIR: …The commissions noted that the including of the term 'for the purposes described in the application' would limit the practice of submitting patent applications that have yet to complete the development of industrial application, correct? MS. GONZALEZ: Correct. MS. MONTPLAISIR: In other words, the commissions were concerned about the practice of prematurely filing a patent application to secure a filing date without having specified the utility of the invention. Is that correct? MS. GONZALEZ: It was a situation that existed in Mexico, and legal scholars and regulations established that. This comes from the application, yes. That's correct."); Lindner Second Report, paras. 12-22. *See also* Closing Presentation of Canada, Slide 248.

[523] Gervais First Report, para. 67 ("Given that each country generates its own 'mix', comparisons of single points in different systems will be misleading."); Holbrook Second Report, paras. 7-8 ("The Claimant inappropriately focuses narrowly on a comparison of U.S. and Canadian utility requirements. Such a myopic focus fails to capture the true picture because U.S. law uses other doctrines in addition to utility to police the concerns identified above.") *See also* Resp. CM, paras. 170-172.

[524] *See also* Resp. Rejoinder, paras. 141-143.

c) Canada's Law on Utility is Consistent with NAFTA Article 1709(7)

222. Claimant argues that Canada's promise utility doctrine discriminates against pharmaceutical patents[525] in contravention of Canada's obligation under NAFTA Article 1709(7) to make patents available and patent rights enjoyable without discrimination as to the field of technology.[526] Claimant's arguments have neither factual nor legal merit, and must be dismissed.[527]

223. First, Claimant grounds its discrimination claim in the flawed evidence of Professor Levin, who concluded based on the data set coded and provided to him by Claimant[528] that there was a statistically significant difference between utility-based invalidity rates for pharmaceutical and non-pharmaceutical patents post-2005.[529] This difference, he concluded, was "consistent with a disproportionate impact of the utility doctrine on pharmaceutical patents."[530]

224. Claimant provided Professor Levin with a data set that was fundamentally flawed in several respects.[531] Claimant's defence to these flaws is that "the data set to see the discriminatory effects of the application of the promise utility doctrine is the universe of all cases that have applied the promise utility doctrine to patents since 1980."[532]

[525] Cl. Mem., para. 185; Cl. Reply, paras. 12, 21, 299 and 324; Opening Presentation of Claimant, Slides 62 and 70; Closing Presentation of Claimant, Slides 21, 104 and 115.

[526] Article 1709(7) of NAFTA reads: "Subject to paragraphs 2 and 3, patents shall be available and patent rights enjoyable without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced."

[527] *See generally*, Resp. CM, paras. 135-149, and 383-388; Resp. Rejoinder, paras. 186-203.

[528] Levin, June 3, 2016, p. 1232:12-14, and p. 1241:12-18; Respondent's Closing Presentation, Slide 154.

[529] Levin Report, para. 5; Levin, June 2, 2016, p. 1204:3-9. *See also*, Levin Report, Errata and Additional Case Coding, Updated Tables 1 through 3 (through 22 April 2016), Table 1 (Updated): Patent Cases in the Post-2005 Period Involving a Decided Challenge on Grounds of Utility; Levin Demonstrative, Slide 3.

[530] Levin Report, paras. 5, 7 and 9; Levin, June 2, 2016, p. 1199:19-22. This was the alternative hypothesis provided to Professor Levin by Claimant: *see* Levin, June 3, 2016, pp. 1265:25 – 1266:1.

[531] Brisebois Second Statement, paras. 2-26; Brisebois presentation, Slides 12-19; Brisebois, May 31, 2016, pp. 474:12 – 478:1.

[532] Closing Statement of Claimant, June 8, 2016, p. 2337:3-9. It is absurd to suggest that Canada has "not provided any contrary dataset" when Dr. Brisebois has provided his more appropriate way of presenting

However, this ignores the reality that there are many ways of presenting the universe of all cases. Claimant selected coding and counting rules that led it to the specific outcome of statistical significance that it desired.[533] Specifically, Claimant chose:

- To count outcomes by court judgments instead of patents. As Dr. Brisebois explained, this methodological approach skews the outcomes in cases in which utility challenges were decided with respect to more than one patent;[534]

- To include outcomes in PM(NOC) cases to compare treatment between pharmaceutical and non-pharmaceutical patents. As Dr. Brisebois explained,[535] not only do PM(NOC) outcomes not determine the validity of the patent at issue,[536] but including them also leads to double-counting[537] and

and coding utility outcomes in all pharmaceutical patent litigation since 1980: *see* Brisebois II, Annex B, as updated by Brisebois, Errata and Updates, May 25, 2016; Brisebois First Statement, para. 26 ("To verify the validity of Lilly's statistical allegations, I assembled a database of all Canadian pharmaceutical patent litigation in which validity was challenged, comparing overall outcomes and specific outcomes for each challenged patentability criterion between the two time frames identified by Claimant, *i.e.* 1980 – 2004 and 2005-2014 (*see* Annex A)." [Annex A in Brisebois First Statement was updated and became Annex B in Brisebois Second Statement.]) Moreover, to suggest that the dataset "is the universe of all cases that have applied the promise utility doctrine to patents since 1980" is contrary to Claimant's own theory of the case, under which the "promise utility doctrine" did not exist in Canadian law until at least 2005.

[533] Levin, June 2, 2016, p. 1232:15-18 ("MS. ZEMAN: And you did not do any independent verification of the accuracy or appropriateness of the dataset. Is that right? PROFESSOR LEVIN: Correct."); Levin, June 2, 2016, p. 1232:12-14 ("MS. ZEMAN: You did not code the dataset. Is that correct? PROFESSOR LEVIN: Correct."); Levin, June 3, 2016, p. 1241:12-18 ("MS. ZEMAN: And it was the Claimant who gave you this rule. Is that correct? PROFESSOR LEVIN: They were the ones who decided on the coding rules. I did have a conversation on statistical grounds to make sure that was a statistically appropriate coding rule, but the substance of the rule was Claimant's decision.") *See also* Closing Statement of Canada, June 8, 2016, pp. 2278:23 – 2279:6; Closing Presentation of Canada, Slide 154.

[534] Brisebois, May 31, 2016, p. 475:2-9 ("…one of my observations was that the data counts court judgments rather than individual patent challenges. I consider this to be inappropriate because the data set includes cases wherein multiple pharma patents were challenged on the same grounds, and that only one outcome is counted if you count court judgments rather than patent challenges) Brisebois presentation, Slide 15 (illustrating by example the effects of counting judgments rather than patents); Brisebois Second Statement, paras. 14-19. *See also*, Resp. Rejoinder, para. 200.

[535] Brisebois Second Statement, paras. 20-26. *See also* Resp. Rejoinder, paras. 197-199.

[536] Brisebois, May 31, 2016, p. 477:10-11 ("PRESENTATION OF MR. BRISEBOIS: First, like I said previously, PM(NOC) proceedings do not invalidate a pharma patent."); Brisebois presentation, Slide 18; Brisebois Second Statement, para. 22; Dimock First Report, para. 40. *See also* Resp. CM, paras. 148 and 388. Claimant agreed at the hearing: Closing Statement of Claimant, June 8, 2016, p. 20167:23 – 2068:11.

[537] Brisebois, May 31, 2016, p. 477:12-18 ("PRESENTATION OF MR. BRISEBOIS: 2, there is an interim problem of double counting associated with the inclusion of PM(NOC) proceedings, because the same pharma patent can be challenged in one or more PM(NOC) proceedings and subsequently

introduces an inappropriate differentiation between the pharmaceutical and non-pharmaceutical patent populations beyond the pharmaceutical/non-pharmaceutical distinction.[538]

- To adopt an inconsistent coding rule that allowed it to select the outcomes most favourable to its theory.[539] Each judgment was given one coding value for utility, regardless of how many findings on utility were included in the judgment.[540] In pharmaceutical cases such as *Novartis*, where there were findings of both utility and inutility in a single case,[541] Claimant applied its rule to select the "not useful" outcome to code the case.[542] Conversely, in the non-pharmaceutical cases of *Eurocopter* and *Uponor*, where there were again findings of both utility and inutility in a single case,[543] Claimant applied its

challenged in an impeachment action. In my view recording the same outcome more than one time for the same patent is problematic."); Brisebois presentation, Slide 18; Brisebois Second Statement, paras. 23-24. *See also*, Resp. Rejoinder, para. 199.

[538] Brisebois, May 31, 2016, p. 477:18-21 ("PRESENTATION OF MR. BRISEBOIS: Also, the only invalidations that are equally comparable between the pharma and non-pharma sectors are invalidation under impeachment actions."); Brisebois presentation, Slide 18; Brisebois Second Statement, para. 21; Resp. Rejoinder, para. 198; Brisebois First Statement, para. 33. The PM(NOC) mechanism is available exclusively to pharmaceutical patents: Brisebois First Statement, para. 33. *See also*, Resp. Rejoinder, para. 198.

[539] Levin Annex C, p. 1 ("Where rulings were split by claim within a patent, such that some claims were found valid and others invalid, a coding of "Y" was applied for the relevant ground. … Where a case involved multiple patents challenged on the same ground, and at least one patent was invalidated on a given ground, a coding of "N" was applied for the relevant ground.")

[540] Levin Annex C; Levin, June 3, 2016, p. 1234:13-22 ("MS. ZEMAN: each unit or lawsuit has a single code for 'useful.' Is that right? PROFESSOR LEVIN: Well, there are actually three codes. There's a 'yes' for 'useful,' a 'no' or an 'N' for 'not useful,' and a dash for 'not challenged on that ground.' MS. ZEMAN: Three possible codes for 'useful'? PROFESSOR LEVIN: Yes. MS. ZEMAN: But each unit is assigned one code. Is that right? PROFESSOR LEVIN: Yes.")

[541] Levin, June 3, 2016, pp. 1235:23 – 1236: 24 (identifying the opposite conclusions with respect to utility); *Novartis Pharmaceuticals Canada Inc. v. Teva Canada*, 2013 FC 283, paras. 170 ("I find that Teva's allegations as to lack of utility of claim 14 of the '895 patent are justified.") and 172 ("I find that Teva's allegations as to lack of utility in respect of claims 1 and 2 of the '937 patent not to be justified.") (**C-244**).

[542] Levin, June 3, 2016, p. 1235:13-18 ("MS. ZEMAN: And this case is coded as a pharmaceutical case. Is that right? PROFESOR LEVIN: Yes. MS. ZEMAN: And it is coded as 'N' for 'utility.' Is that correct? PROFESSOR LEVIN: Yes. MS. ZEMAN: Meaning that a validity challenge to utility was sustained, if I take the language from your presentation. Is that accurate? PROFESSOR LEVIN: Yes."); Levin Annex C, p. 18 (*Novartis*, coded "N" for "Useful").

[543] Levin, June 3, 2016, pp. 1242:3 – 1243:17 (identifying the many invalid conclusions with respect to utility in *Uponor*); Levin, June 3, 2016, pp. 1239:20 – 1241:18 (identifying the opposite conclusions with respect to utility in *Eurocopter*); *Uponor AB v. Heatlink Group Inc.*, 2016 FC 320, paras. 164 and 166, and 168 (invalidating 35 of the patent's claims on the basis of utility) (**R-484**); *Eurocopter v Bell Helicopter Textron Canada Ltd.*, 2012 FC 112, para. 360 ("…the Court finds that the utility of an embodiment in claim 15 (offset forwards) has been demonstrated at the Canadian filing date; however,

rule to select the "useful" outcome to code the case.[544] Its rationale that there were infringement findings in both cases[545] is irrelevant to the fact that the purpose of its statistical exercise was to assess the impact of inutility findings,[546] which existed in both cases, but whose impact was ignored.[547] Claimant made much of its allegation that Dr. Brisebois "double counted" the patents at issue in these two cases,[548] but even coding these cases exclusively as outcomes for which there was a negative utility finding leads to the same result: no statistical significance.[549]

there is a lack of demonstrated utility or sound prediction with respect to an embodiment included in claim 16 (offset backwards).") (**C-120**).

[544] *See* Levin Annex C, p. 17 (*Eurocopter*, coded "Y" for "Useful"); Levin, Appendix C – Errata and Additional Case Coding, Federal Court Patent Validity Cases from 1980-Present (through 22 April 2016), 3. Levin Appendix C Case Coding for Decisions 11 August 2015 to 22 April 2015 (cases after Levin Expert Report) (*Uponor*, coded "Y" for "Useful").

[545] Closing Statement of Claimant, June 8, 2016, pp. 2119:1-10; Brisebois, May 31, 2016, p. 500:6-13 (questioning Dr. Brisebois on the infringement findings in *Eurocopter*); Brisebois, May 31, 2016, p. 501:10-21 (questioning Dr. Brisebois on the infringement findings in *Uponor*).

[546] Cl. Reply, para. 195; Levin Presentation, Slide 3 ("I was asked by counsel for Eli Lilly to assess the statistical significance of certain differences in the proportions of patent lawsuits in which courts sustained validity challenges: on the grounds of utility or on other grounds…" [emphasis added]); Levin Report, para.7; Table 1, entitled "Patent Cases in the Post-2005 Period Involving a Decided Challenge on Grounds of Utility". *See also*, Brisebois, May 31, 2016, pp. 497:14 – 498:4 ("MR. BRISEBOIS: The fact that the infringer was infringing the valid claim has no relevance to what I was doing, and to acknowledge that there was a finding of lack of utility for a non-pharma patent in my opinion should be acknowledged…"); Brisebois, May 31, 2016, p. 499:5-13 ("MR. BRISEBOIS: Again, not part of my work. Same as – I never distinguished the outcomes based on the commercial value of the claims. It was with regard to whether or not a finding of invalidity was present or not. So if we want to look at the impact and the impact is being invalid, I think this should be acknowledged that one of the embodiments had been found invalid for lack of utility."); Brisebois, May 31, 2016, pp. 476:8 – 477:3 ("PRESENTATION OF MR. BRISEBOIS, explaining that "counting this case exclusively as a case where a non-pharma patent was held valid on utility grounds, as Claimant did in Appendix C to Dr. Levin's report, is not an accurate reflection of the outcomes of this case."); Brisebois Presentation, Slide 17; Brisebois Second Statement, para. 8.

[547] Levin, June 2, 2016, pp. 1240:24 – 1241:4 ("MS. ZEMAN: And so when there's a claim held invalid, you ignore the finding of inutility and code this case as 'Y' for utility. Is that correct? PROFESSOR LEVIN: Well, I didn't ignore anything. Others were doing the coding.") Note that the study Claimant relies on for US litigation outcome statistics (*see* Cl. Mem., paras. 150, 199 and 222; Merges First Report, para. 6; Merges Second Report, para. 6; Opening Presentation of Claimant, Slide 67), adopted Dr. Brisebois' methodological approach of counting distinct legal outcomes with respect to distinct embodiments of a single patent: Allison & Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLAQ.J. 185 (1998), p. 205, FN 51 ("Although there were 299 litigated patents reported, one of those patents produced two different final validity results for two different sets of claims. We have therefore counted that patent twice, as both a final valid and a final invalid result. In other cases, where *n* = 300, it is for the same reason.") (**C-167**).

[548] Levin, June 2, 2016, p. 1216:4-23; Closing Statement of Claimant, June 8, 2016, p. 2118:1-25.

[549] Levin, June 3, 2016, p. 1244:12-19 ("MS. ZEMAN: Now, if Eurocopter and Uponor had been coded 'N' in your data set instead of 'Y' and everything else remained the same, your conclusion would lose its

225. Correcting for all of these errors, there is no evidence of a statistically significant difference in the utility-based invalidity rates for pharmaceutical and non-pharmaceutical patents.[550]

226. However, even if there was a statistically significant difference in the utility outcomes in validity challenges to pharmaceutical and non-pharmaceutical patents, Claimant's statistics do not prove discrimination. As the United States pointed out in its Article 1128 submission, differential effects of a measure on a particular sector do not necessarily prove discrimination.[551] Thus, even if the Tribunal accepts that there is a statistically significant difference in the utility outcomes of litigated pharmaceutical and non-pharmaceutical patents, Claimant's argument must nonetheless be dismissed.

227. Claimant asserts a causal relationship between Professor Levin's evidence of statistical significance and its own legal hypothesis of discrimination[552] where there is

statistical significance, too, wouldn't it? PROFESSOR LEVIN: If one used that invalid coding, as I testified yesterday, the P-value would be greater than .05, yes.")

[550] Brisebois Second Statement, paras. 4, 12-13,18-19 and 26. *See also*, Closing Presentation of Canada, Slide 155 (showing only two corrections: consistent coding of *Eurocopter* and *Uponor*, and dividing the data set as of September 2005 in accordance with the Claimant's theory of the case). In an attempt to maintain its conclusion of statistical significance, Claimant asked Professor Levin to selectively and inconsistently apply the corrections pointed out by Dr. Brisebois: *see, e.g.*, Levin Demonstrative Slides 6-8; Levin June 2, 2016, pp. 1212:5 – 1218:4 (explaining tables on direct examination); Levin, June 3, 2016, pp. 1244:20 – 1248:13 (highlighting inconsistencies in approaches to the tables on cross-examination). However, these errors are cumulative. Applying all of the corrections leads to a finding of no statistical significance: *see* Opening Statement of Canada, May 30, 2016, p. 326:3-16; Opening Presentation of Canada, Slide 171; Closing Statement of Canada, June 8, 2016, pp. 2279:9 – 2280:10; Resp. Rejoinder, paras. 195-200.

[551] US 1128 Submission, para. 43 ("Differential effects of a measure on a particular sector, even if shown, do not necessarily prove discrimination as to the field of technology within the meaning of Article 1709(7).") *See also*, Respondent's Observations on Issues Raised in 1128 Submission, para. 3 ("Article 1709(7) is not violated by the mere fact that a measure has differential effects on a particular field of technology.") and para. 43 ("Canada agrees with the United States that the mere existence of differential effects of a measure on a particular sector does not establish discrimination under Article 1709(7).") Claimant's own expert acknowledged that there "is a distinction" between statistical and legal significance: Levin, June 3, 2016, p. 1261:9-14 ("MS. ZEMAN: One final question. You agree that conclusions of statistical significance are not the same as conclusions as to legal significance? PROFESSOR LEVIN: There is a distinction."); Opening Statement of Canada, May 30, 2016, p. 326:17-23; Opening Presentation of Canada, Slide 172; Closing Presentation of Canada, Slide 157.

[552] Closing Statement of Claimant, June 8, 2016, p. 2121:2-7; Cl. Mem., para. 223; Cl. Reply, paras. 300 and 367.

evidence, at most, of correlation.[553] Claimant attributes all utility outcomes to its alleged promise utility doctrine.[554] As explained above, not all utility outcomes are promise utility outcomes.[555] Claimant did not even attempt to identify in its statistical analysis which cases were subject to application of the promise utility doctrine.[556] It has not demonstrated causation.

228. Even if Claimant had done the analysis required, litigation outcomes cannot possibly tell the whole story.[557] Only a small fraction of patents are ultimately litigated,[558] and "great care must therefore be taken when interpreting data from any

[553] Professor Levin acknowledged that he was not offering an opinion on causality: Levin, June 3, 2016, pp. 1266:24 – 1267:6 ("First on the general point I am not opining on causality. I was not asked to do that; I am not qualified to offer an opinion. I offered a statistical opinion which is the rejection of the null hypothesis was consistent with a causal hypothesis, that of Claimants. I agree there could be other causes; I'm not here to say one way or the other.") *See also*, Closing Statement of Canada, June 8, 2016, p. 2280:9-20; Resp. Rejoinder, para. 192; Resp. CM, paras. 263-264.

[554] *See* Cl. Mem., p. 104 (Figure 2, entitled "Canada's Promise Utility Doctrine Discriminates Against Pharmaceutical Patents"), para. 222 ("Moreover, as Figure 3 indicates, since the Federal Courts' application of the promise utility doctrine began in 2005, inutility findings have jumped from *zero* to 40 percent for pharmaceutical patents, while inutility findings for non-pharmaceutical patents have actually declined, from eight to zero percent.") Figure 3 (entitled "Utility Outcomes by Sector in Canadian Courts").

[555] *See* para. 165. *See also*, Resp. Rejoinder, para. 190.

[556] Levin, June 3, 2016, p. 1248:14-21 (acknowledging the data set provided to him did not make any distinction between utility and promise utility outcomes); Levin, June 3, 2016, pp. 1248:22 – 1250:13 (admitting that he "would have to look at the particular data" to make a determination about the relationship between utility outcomes and promise utility outcomes, and that he did not look at that data in this case). *See* Chronological List of Canadian Utility Decisions from 1980 to Present" (showing that the basis for the Claimant's Memorial Figures did not identify which cases were promise cases); Levin, Annex C (showing a single category for "Useful" outcomes) (**C-305**).

[557] John R. Allison and Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185 (1988), p. 204 (**C-167**). *See also*, Closing Presentation of Canada, Slide 156; Closing Statement of Canada, June 8, 2016, pp. 2280:21 – 2281:11.

[558] WIPO Database, *Patent Grants by Technology – Pharmaceuticals, Total Count by Filing Office – Canada* (1980-2013) (**R-436**); Brisebois Second Satement, Annex F; Mark A. Lemley and Carl Shapiro, *The Journal of Economic Perspectives, Probabilistic Patents*, Vol 19. No. 2 (American Economic Association, 2005), p. 79 ("The vast majority of patents are never asserted in litigation. Only 1.5 percent of all patents are ever litigated, and only 0.1 percent are litigated to trial") (**R-437**); Merges, June 3, 2016, p. 1322:9-13 ("MR. LUZ: Most patents are never ultimately litigated. Is that right? Thousands are issued – tens of thousands are issued every year. Most of them never end up in court. PROFESSOR MERGES: True."). *See also*, Closing Presentation of Canada, Slides 157 and 162; Resp. Rejoinder, para. 190.

sample of litigated patent cases."[559] In addition, counting litigation outcomes does not account for a number of factors that inform those outcomes, including the facts, reasonable people's assessment of facts, the skill of counsel, the quantum and quality of evidence presented, and the quality of the patents themselves.[560]

229. The most these data show is that the utility requirement has more relevance in the field of pharmaceuticals. That increased relevance is unsurprising. Patentees in the pharmaceutical field are the ones frequently making sound predictions of utility and patenting upstream.[561] It is also a field in which there is a high prevalence of "secondary

[559] Mark A. Lemley and Carl Shapiro, *The Journal of Economic Perspectives, Probabilistic Patents*, p. 79 (**R-437**); Holbrook First Report, para. 39 ("It is typical for fact-finders to view the evidence differently and to reach inconsistent results. … As a factual issue, differences about the sufficiency of a single patent disclosure do not reflect systemic, legal inconsistencies between the patent laws of the two countries. Reasonable minds can often disagree on what factual conclusions to draw based on the evidence. Indeed, within the United States, one judge found the disclosure insufficient, while two others disagreed.") *See also,* Closing Presentation of Canada, Slides 157 and 201. This is especially important in an area that is well-recognized as highly fact-dependent: *see, e.g., Eli Lilly and Company v. Apotex Inc.*, 2009 FC 991, paras. 5-8 and 25 (**R-475**); Merges, June 3, 2016, p. 1373:13-20 ("Of course, it all depends on the nature of the claimed invention and the level of skill in the field, level of skill in the art, and the content of the prior art. These cases are all very fact intensive…") *See also,* Resp. Rejoinder, para. 270; Resp. Comments on Issues Raised in *Amicus* Submissions, para. 2, FN 5 (citing to Liddell-Waibel Paper, p. 23 (**R-474**).

[560] Holbrook, June 3, 2016, pp. 1534:18 – 1535:8 ("… facts can differ. People of reasonable minds can disagree about what the facts of the case are. At a super abstract level, yes, I would agree, but when you actually talk about how these decisions are made on the ground, I would not agree with that. Particularly if the evidence is different, how people characterize the evidence is different. Now we're talking about dealing with specific facts of cases, and reasonable minds can disagree on those kind of outcomes -- and that's okay."); John R. Allison and Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185 (1988), p. 204 (**C-167**); Michael Burdon and Kristie Sloper, *The Art of Using Secondary Patents to Improve Protection*, Vol. 3 International Journal of Medical Marketing (2003) <http://www.olswang.com/pdfs/secondary_patents_jun03.pdf>, p. 4, (noting that "there may be differences in the outcome of patent litigation in different jurisdictions. Such differences in outcome may result from a number of factors including differences in the substantive legislation (e.g. between the UK and the US); differences in the procedural requirements of each jurisdiction; differences in the evidence put before the courts in each jurisdiction, and differences in the approach of the courts to interpretation of the relevant provisions of the legislation.") (**R-477**). *See also,* Closing Presentation of Canada, Slides 158-159; Resp. CM, para. 64; Respondent's Observations on Issues Raised in *Amicus* Submissions, FN 17.

[561] Merges, June 3, 2016, pp. 1380:8 – 1381:18 (explaining that patents are sometimes "put together very quickly" because "there are always other people breathing down your neck." Pharmaceutical patentees "know the standard quite well but they try to get something in early because they know other people are racing for the same result, and sometimes you end up putting it in too early and it is characterized as speculation or an educated guess but, again, that comes from the high-risk context that we're talking about, which is multiple researchers in pharmaceutical companies, and in some cases universities. They're all circling around these hot prospects and priority, being first, is absolutely crucial. So that's the tension that leads you to a case where the court might call it speculation."); Dimock First Report, paras. 100 and 160-161 ("innovator litigants have frequently sought, often successfully, to uphold the validity of their patents

patents", for which the utility requirement has more salience.[562] As recognized by both parties' experts in this case, certain doctrines may be more salient for certain industries.[563] An increased relevance or salience does not establish discrimination; it is a legally irrelevant point.

d) Canada's Law on Utility is Consistent NAFTA Article 1709(8)

230. Claimant argues that Canada breached Article 1709(8) because it retroactively applied a "new and additional test for utility that did not exist" when the atomoxetine and olanzapine patents were granted as the basis to invalidate them.[564] Both Canada's law on utility, and its specific application to Claimant's atomoxetine and olanzapine patents, are wholly consistent with NAFTA Article 1709(8).

231. **VCLT Article 31(1)**: By its ordinary meaning, NAFTA Article 1709(8) provides that if a patent should not have been granted in the first place, it may be revoked.[565] The

through [the application of sound prediction]"); Holbrook First Report, para. 5 ("2) … Sound prediction will be particularly helpful for pharmaceutical inventions, allowing companies to file despite lacking conclusive evidence that a new use of a pharmaceutical compound will 'work' as promised."); Gillen Second Statement, para. 7 ("…inventions in the chemical and biotechnology arts frequently rely on sound predictions to establish utility.") *See also*, Closing Statement of Canada, June 8, 2016, pp. 2281:20 – 2282:1; Closing Presentation of Canada, Slide 160; Resp. CM, para. 137.

[562] Brisebois First Statement, para. 43, Figure 6 (as updated in Errata point 2 of Brisebois, Errata and updates, May 25, 2016, p. 1); Hemphill, *When Do Generics Challenge Drug Patents?*, pp. 613-649 (**R-245**); European Commission (2009) *Pharmaceutical Sector Inquiry: Final Report*, p. 221 (**R-243 amended**). *See also*, Opening Statement of Canada, May 30, 2016, pp. 178:6 – 180:9; Opening Presentation of Canada, Slide 20; Resp. CM, para. 145; Resp. Rejoinder, para. 191; Respondent's Observations on Issues Raised in *Amicus* Submissions, paras. 21 and 37.

[563] Holbrook Second Report, para. 12 ("even though the utility threshold is the same for all technologies, utility has more 'bite' in the context of pharmaceutical, chemical, and biological inventions. … It is well accepted that, while patent law is technology-neutral in theory, it is technology-specific in application."); Merges Second Report, paras. 12 (explaining utility "may have greater relevance in the pharmaceutical field") and para. 13 (explaining that "the use requirement is more salient" in pharmaceutical contexts). *See also*, Dan L. Burk and Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 Berkeley Tech. L.J. 1155 (2002) at 1156-1157 (**R-386**); Resp. Rejoinder, para. 237; Respondent's Observations on Issues Raised in *Amicus* Submissions, para. 21.

[564] Opening Statement of Claimant, May 30, 2016, p. 126:7-15; Cl. Reply, paras. 301-305; Cl. Mem., paras. 227-231.

[565] *See also*, Resp. CM, para. 390; Resp. Rejoinder, para. 206;Opening Statement of Canada, May 30, 2016, pp. 292:7 – 294:7 (responding to President Van den Berg's questions on Article 1709(8)); Closing

NAFTA Parties did not intend to constrain the ability of the courts to interpret and elaborate patentability criteria set out in legislation over time.[566] Evolution in jurisprudence on a particular patentability requirement between the grant and the revocation of a patent does not amount to a breach of Article 1709(8), even if it is a "significant" change.[567]

232. The interpretive context of Article 1709(8) confirms the flexibility provided for in Article 1709(8). NAFTA Chapter Seventeen places the courts at the centre of the adjudication of intellectual property rights.[568] There is nothing to suggest the Parties intended to limit their ability to evolve principles over time and in response to new technological situations.[569]

233. **VCLT Article 31(3)(b)**: Looking to the subsequent practice of the NAFTA Parties further confirms that even court interpretations that significantly alter past

Statement of Claimant, June 8, 2016, p. 2324:16-19; Opening Presentation of Canada, Slide 173; Closing Presentation of Canada, Slide 270.

[566] *See also,* Opening Statement of Canada, May 30, 2016, p. 327:5-10; Opening Presentation of Canada, Slide 174; Resp. CM, paras. 395-398; Resp. Rejoinder, paras. 205, and 209; Respondent's Observations on Issues Raised in 1128 Submissions, para. 45; US 1128 Submission, para. 44. Furthermore, Article 1709(8)(a) cannot be interpreted to adopt a patent-by-patent analysis: *see* Opening Statement of Canada, May 30, 2016, pp. 294:18 – 295:16; Closing Statement of Canada, June 8, 2016, pp. 2324:18-2325:17.

[567] Gervais First Report, para. 69 ("Evolution in the interpretation and application of patentability criteria, particular as novel issues arise, are part and parcel of any system… indeed, the court can go further, reversing prior interpretations of patent law previously upheld by the courts. This is inherent in the system and is nothing new.") *See also,* Opening Statement of Canada, May 30, 2016, p. 327:10-20; Opening Presentation of Canada, Slide 174; Resp. CM, paras. 395-399; Resp. Rejoinder, paras. 205 and 207 US 1128 Submission, para. 44. Claimant recognizes that at least some evolution in the law is permissible under Article 1709(8), but seeks to draw a distinction between "sea changes" and incremental steps that is simply unsupported by the ordinary meaning, interpretive context and subsequent practice of the NAFTA Parties: *see* Resp. Rejoinder, para. 208; Respondent's Observations on Issues Raised in 1128 Submissions, para. 45. Nonetheless, Canada has shown throughout this arbitration that there has not been a "sea change" in the law of utility: *see* Section IV above.

[568] NAFTA Articles 1714-1717. *See also,* Resp. Statement of Defence, para. 90; Resp. CM, paras. 369-371; Resp. Rejoinder, para. 209.

[569] *See also,* Opening Presentation of Canada, Slide 174; Resp. Rejoinder, para. 209; Respondent's Observations on Issues Raised in 1128 Submissions, para. 45; US 1128 Submission, para. 44 ("Article 1709(8) does not mean that courts are limited to reviewing the specific grounds of refusal before the patent examiner; the use of the present tense 'exist' in Article 1709(8) confirms this interpretation.")

jurisprudence do not breach NAFTA Article 1709(8).[570] Significant changes in U.S. patent law have occurred after the introduction of NAFTA – such as the U.S. Supreme Court's decision in *Alice v. CLS Bank*,[571] the reappearance of the written description doctrine in *Ariad*,[572] and the increased rigour of the obviousness requirement.[573] Similar significant changes were made to Mexican legislation in the 2010 amendments to Mexico's patent law.[574] Such changes demonstrate that the NAFTA Parties do not believe that Article 1709(8) prevents the invalidation of patents based on the law as it stands when the challenge was made, rather than when the patent was granted.[575]

3) The Claimant Has Failed to Prove That There Has Been An Unlawful Substantial Deprivation

234. Finally, even if the Tribunal finds that Canada's utility requirement is inconsistent with its NAFTA Chapter Seventeen obligations, under Claimant's (incorrect) interpretation of Article 1110, it must still show that there has been a substantial deprivation of its investment.

235. Claimant has failed to show that the invalidation of its patents resulted in a total or near total deprivation of its investment.[576] Claimant has provided no evidence that it

[570] *See also,* Resp. CM, paras. 397-399; Resp. Rejoinder, para. 210.

[571] Holbrook Second Report, paras. 45-46 ("the Supreme Court decision in *Alice v. CLS Bank* represents a dramatic sea change in the law of patentable subject matter that has invalidated thousands of patents."); Merges, June 3, 2016, p. 1304:8-9 ("The Alice case was I'll certainly say noteworthy.")

[572] Holbrook Second Report, para. 45 (explaining that *Ariad* "standards alone in the world and has had a dramatic impact in biotechnology and software cases.")

[573] Holbrook First Report, paras. 73-75; *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 92007) (**R-130**). *See also*, Gervais Second Report, paras. 10-11.

[574] Lindner Second Report, paras. 12-22. *See also,* Closing Presentation of Canada, Slide 248.

[575] *See* US 1128 Submission, para. 44; Opening Statement of Canada, May 30, pp. 293:13 – 294:17 and 296:4-10; Opening Presentation of Canada, Slide 174; Resp. Rejoinder, para. 207; ; Respondent's Observations on Issues Raised in 1128 Submissions, paras. 45-47.

[576] *See also,* Opening Statement of Canada, May 30, 2016, pp. 329:21 – 330:3.

was substantially deprived of the value of its investment, including of the value attributable to licensing or other rights associated with its patent.[577]

B. Claimant Has Not Proved a Breach of Article 1105

236. Claimant argues that Canada's promise utility doctrine is in violation of Canada's obligations under Article 1105 because it is discriminatory, arbitrary, and inconsistent with its legitimate expectations. As set out above, Claimant has failed to prove that those standards form part of the customary international law minimum standard of treatment of aliens that applies to judicial measures under NAFTA Article 1105.[578]

237. However, even on its own standard, Claimant has failed to establish its case on the facts. Its burden of proof does not shift.[579] Therefore, if the Tribunal determines that Claimant's allegations are relevant to the legal issues it must consider, it must nonetheless dismiss the case.

1) Canada's Law on Utility is Not Discriminatory

238. As set out in section V.a.2 (c) above, Claimant has not established that the promise utility doctrine it has articulated discriminates against pharmaceutical patents.[580]

[577] As Claimant's expert, Mr. Reddon, explained at the hearing, "there are many other rights associated with the patent that are not erased by a declaration of invalidity": Reddon, June 1, 2016, p. 818:16-18. Reddon, June 1, 2016, p. 820:14-17. *See also*, Reddon, June 1, 2016, pp. 819:15 – 820:17; Dimock First Report, para. 140 ("Under Canadian law, where a licenced patent is subsequently held invalid or expires, the licence will not automatically terminate unless expressly outlined in the licence. …Any licence in this context is thus akin to a licence to 'know how' and is also enforceable as between the parties through contract law, not against the world as in the case of a patent.") *See also,* Closing Presentation of Canada, Slides 271-272.

[578] See paras. 54-59 above.

[579] *See also,* Resp. Rejoinder, para. 266.

[580] *See* Brisebois First Statement, paras. 11-16 and 23-46; Brisebois Second Statement. *See also*, Opening Statement of Canada, May 30, 2016, pp. 281:18 – 282:9 and 325:17 – 327:4; Closing Statement of Canada, June 8, 2016, pp. 2278:14 – 2 282:17; Resp. CM, paras. 135-149, 261-264 and 383-388; Resp. Rejoinder, paras. 186-203 and 277-280.

Neither has Claimant established that the alleged promise utility doctrine discriminates on the basis of nationality.[581] Its argument is without merit.

2) Canada's Law on Utility is Not Arbitrary

239. Claimant argues that the promise utility doctrine is arbitrary, and that it "cannot be defended by any legitimate policy rationale."[582] As an initial matter, Claimant has invented the "promise utility doctrine" concept for the purposes of this arbitration. What Claimant describes as a "unitary doctrine" is in fact several distinct, longstanding rules of Canadian patent law with respect to both the meaning of utility in Canada's *Patent Act* and how to prove and properly disclose such utility.[583] Not only do Claimant's experts agree,[584] but Claimant's own opportunistic behaviour in changing the definition of the doctrine over the course of the arbitration illustrates the point.[585] Claimant's

[581] *See also,* Resp. CM, paras. 261-264; Resp. Rejoinder, paras. 261-263 and 277-280.

[582] *See, e.g.*, Closing Statement of Claimant, June 8, 2016, p. 2131:9-12.

[583] Dimock First Report, para. 51. *See also,* Opening Presentation of Canada, pp. 182:10 – 184:10; Opening Presentation of Canada, Slides 26-27; Closing Statement of Canada, p. 2245:7-14; Closing Presentation of Canada, Slide 81; Resp. CM, para. 86; Resp. Rejoinder, para. 160.

[584] Siebrasse First Report, FN 23 ("Lilly has referred to as (*sic*) the law of utility in all of its aspects as currently applied by the courts as the "Promise Utility Doctrine", which is a convenient phrase to describe the law pertaining to utility as applied in a given case."); Reddon Report, FN 6 ("In the Claimant's Memorial and Export Report of Norman V. Siebrasse … these changes are referred to in the collective as Canada's "Promise Utility Doctrine". For ease of reference, I will use this same phrase when referring to Canada's utility requirement, which includes all of these elements.") Professor Siebrasse also recognizes that the various elements of the alleged "promise utility doctrine" are independent of one another: Siebrasse, June 1, 2016, p. 742:7-12 ("PROFESSOR SIEBRASSE: Well, there has to be a factual basis for the prediction and a sound line of reasoning linking the factual basis to the promised utility or scintilla utility if the scintilla standard is applied, but normally to a promised utility.") *See also,* Resp. Closing, Slide 81.

[585] Claimant in its Notice of Intent characterized the promise doctrine as a departure from the Supreme Court's 2002 decision in *AZT*, but subsequently decided that it better served its interests to cast *AZT* as part of the promise utility doctrine: *compare*, Notice of Intent, November 7, 2012, para. 39 ("The adoption of the "promise Doctrine" by the Federal Courts marks a departure from the law established by the Supreme Court of Canada in *Apotex Inc. v. Wellcome Foundation Ltd.*"), *with* Cl. Reply, para. 93 ("Second, since the *AZT* ruling of the Supreme Court in 2002, Canadian judges no longer admit evidence of utility that post-dates the patent application. This new evidentiary exclusion overturned decades of settled law allowing patentees to offer post-filing evidence of the fact that an invention had utility as of the filing date.") *See also*, Opening Statement of Canada, May 30, 2016, pp. 182:10 – 184:10; Opening Presentation of Canada Presentation, Slides 26-27. Similarly, Professor Siebrasse previously described the *AZT* decision as "functionally distinct" from the promise doctrine, but accepted it as part of Claimant's "promise utility doctrine" for the purposes of this arbitration: Siebrasse, June 1, 2016, p. 675:8-14; Norman Siebrasse "Form and Function in the Law of Utility: A Reply to Gold & Shortt" Canadian

repeated and incorrect assertions that the courts applied all elements of the alleged "promise utility doctrine" to invalidate its olanzapine and atomoxetine patents further elucidate the imperfection of its doctrinal invention.[586] Only two of the three elements applied to invalidate Claimant's olanzapine patent; the disclosure requirement for sound prediction had no bearing.[587]

240. Nevertheless, Claimant focuses on the doctrine as a unitary whole and argues that it is only when all three aspects are applied together that it becomes arbitrary.[588] Not

Intellectual Property Review), p. 15 ("…the utility requirement as defined in Wellcome / AZT is functionally distinct from the promise doctrine.") (**R-497**). *See also,* Closing Statement of Canada, June 8 2016, p. 2245:8-13; Closing Presentation of Canada, Slide 81.

[586] *See* Opening Statement of Claimant, May 30, 2016, p. 15:13-17 ("MS. CHEEK:… the three elements that Lilly has identified comprise a unitary patent test that was applied by the courts to invalidate these patents under the utility requirement in Canada."); Closing Statement of Claimant, June 8, 2016, p. 1994:20-24 ("MS. CHEEK: But what we are looking at is what was the utility test in Canada that was applied to our patents, and that would include all three of the elements that we've discussed over the course of the last week, 2002, 2005 and 2008."); Closing Statement of Claimant, June 8, 2016, p. 1995:9-12 ("MS. CHEEK: The utility standard that was applied to these patents invalidate them in 2010 and 2011 was crystallized in 2008 with the Raloxifene decision."); Closing Statement of Claimant, June 8, 2016, p. 1996:11-19 ("MS. CHEEK:… the reason we challenge the elements as a whole is because as a matter of fact, those elements as a whole are the utility tests in Canada that is applied to determine whether or not a patent is valid or invalid for lack of utility … That's the law in Canada that was applied to our patents and it had all three elements when it was applied to our patents.") *See also,* Closing Presentation of Canada, Slide 81.

[587] Dimock First Report, para. 222 (writing that the disclosure requirement for sound prediction "did not bear on the validity of Claimant's patent for olanzapine."); Siebrasse First Report, para. 98 ("In summary, the olanzapine patent would have been valid under prior law, and was invalid under the Promise Utility Doctrine because of the exclusion of post-filing evidence and the heightened utility requirement established by the promise of the patent.") *compare with* Siebrasse First Report, para. 104 ("In summary, the atomoxetine patent would have been valid under the prior law. The invalidity of the patent turned on three novel rules of Canadian law, namely the heightened standard for utility under the promise doctrine; the exclusion of post-filing evidence; and the requirement that evidence of sound prediction must be disclosed in the patent."); *See also,* Cl. Reply, paras. 212-213 (alleging that the "Canadian courts applied all three aspects of the promise utility doctrine in invalidating Lilly's patent for Zyprexa [olanzapine]", but only enumerating two aspects (the promise standard (para. 212) and the prohibition on post-filing evidence (para. 213)."). *See also,* Closing Statement of Canada, June 8, 2016, pp. 2245:18 – 2247:5; Closing Presentation of Canada, Slide 274.

[588] Closing Statement of Claimant, June 8, 2016, p. 1997:5-12 ("So it is not our case that each element taken separately would, on its own, constitute a violation, nor is it our view that that is the appropriate level of analysis, if you will. And the reason that that's not the appropriate level of analysis is because those are three components of a single holistic legal standard, the utility test in Canada.") *Compare with* Closing Statement of Claimant, June 8, 2016, p. 2033:16-23 ("MS. WAGNER: I just wanted to address, Sir Bethlehem, your opening question. I think I would say that hypothetically each element could possibly sustain a breach and maybe different breaches if we're looking at Chapter 17, but it's hypothetical and it's not possible to know, because the fact is that this is applied as a single construct, as a single test.")

only should Claimant's efforts to create a doctrine, only to then argue that this fictional doctrine is arbitrary, fail as a matter of principle, as a matter of fact its argument is also untenable.

241. First, even if arbitrariness was part of the customary international law minimum standard of treatment, it would not give this Tribunal license to act as an appellate court for the decisions of the Canadian courts in the way Claimant seeks here.[589] Whether it is the Supreme Court of Canada's decision in *AZT*, the trio of cases in 2005, the decision in raloxifene, or the decisions in olanzapine and atomoxetine, the Tribunal must be careful not to engage in a second-guessing of the policy rationale for the Canadian courts' interpretation of the *Patent Act*.[590] Similarly, the Tribunal must be careful not to act as a

[589] Armitage, May 31, 2016, pp. 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 … 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."); Armitage, May 31, 2016, p. 372:11-19 ("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. And, as applied to Zyprexa, in my view for good reason I remain to this day incredulous that the doctrine could apply to Zyprexa and still be a rational doctrine of patent law."); Armitage, May 31, 2016, pp. 377:24 – 378:9 (Spelliscy: "And your concern was – your view was that the Canadian court, you say, made its decision without considering those facts?" Armitage: "Without considering the dispositive evidence that Strattera was useful to treat ADHD in attempting to determine whether the requirement for utility was met. That was why, indeed, I think I used the intemperate word 'outrageous' and again continued by saying I didn't believe that this could be part of a rational patent law."); Armitage, p. 385:13-22 ("In any event, with respect to atomoxetine, 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 believed showed statistical significance, it should have been accepted without being disclosed in the Canadian patent application, actually not as a matter of sound prediction but as a matter of a demonstration that, in fact, Strattera had been shown to be effective to treat ADHD."); Armitage, p. 387:3-9 ("The larger part of what I think was gotten wrong by Canadian law was the fact that Health Canada actually approved this compound as safe and effective for the treatment of ADHD and, therefore, there was no factual issue, no factual dispute – no possible factual dispute that this compound was, in fact, useful."). *See also*, Closing Statement of Claimant, June 8, 2016, p. 2063:17-23 ("And even if the court's analysis has been presented as a matter of claim construction, it would still have to be considered as a claim construction exercise that is a marked departure from settled claim construction principles, including that resort to the disclosure is not permitted to vary the scope or ambit of the claims.").

[590] *See Glamis Award*, paras. 762 and 779 (**RL-006**); *S.D. Myers Partial Award*, paras. 261 and 263 (**RL-076**); *Chemtura Award*, para. 134 (**RL-057**); *Mondev Award*, para. 126 (**RL-004**); *Azinian Award*, para. 99 (**RL-002**); *Arif Award*, paras. 398, 416 and 440-441 (**RL-063**). *See also*, Opening Presentation of Canada, Slide 75; Closing Presentation of Canada, Slides 46 and 49; Resp. Rejoinder, para. 267.

re-trier of fact or of Canadian law.[591] The absence of all underlying factual records[592] before this Tribunal, in a highly fact-specific area of the law,[593] demands particular caution.

242. Second, the evidence before this Tribunal shows clearly that all three aspects of the promise utility doctrine Claimant alleges are arbitrary fulfill important policy functions in Canada's patent law system. Claimant's preference for different policies cannot, and does not, render them arbitrary. Similarly, the courts' specific application of Canadian law to Claimant's olanzapine and atomoxetine patents was well-reasoned and grounded in findings of fact rendered after careful consideration of extensive adversarial records, records not before the Tribunal here. Claimant's preference for different litigation outcomes cannot, and does not, render those outcomes arbitrary.

[591] *Loewen Award*, para. 242 ("Far from fulfilling the purposes of NAFTA, an intervention on our part would compromise them by obscuring the crucial separation between the international obligations of the State under NAFTA, of which the fair treatment of foreign investors in the judicial sphere is but one aspect, and the much broader domestic responsibilities of every nation towards litigants of whatever origin who appear before its national courts. … [T]hese latter responsibilities are for each individual state to regulate according to its own chosen appreciation of the ends of justice. As we have sought to make clear, we find nothing in NAFTA to justify the exercise by this Tribunal of an appellate function parallel to that which belongs to the courts of the host nation.") (**RL-013**).

[592] Siebrasse, May 31, 2016, pp. 648:24 – 649:1 ("The Court of Appeal had the whole record. I don't have the whole record.") Even with the whole record, the Court of Appeal exercises caution with respect to the factual findings of the trial judge: *Eli Lilly and Co. v. Teva Canada Limited*, 2011 FCA 220 ("*Atomoxetine FCA"*), para. 8 ("This is an essentially factual issue that turned on the Judge's assessment of the evidence which, in turn, depended in large part on his credibility findings. I am not persuaded that the Judge made any palpable and overriding error in his findings of fact or in his application of the law to the facts.") (**R-028**). *See also*, Opening Presentation of Canada, Slide 16; Closing Presentation of Canada, Slide 171.

[593] Merges, June 3, 2016, p. 1323:16-19 ("So it's a very, very fact specific inquiry when you're asking what is the risk of a particular patent invalidation. It's very specific."); Merges, June 3, 2016, p. 1373:13-17 ("Of course, it all depends on the nature of the claimed invention and the level of skill in the field, level of skill in the art, and the content of the prior art. These cases are all very fact intensive…"); Reddon, June 1, 2016, p. 903:10-15 ("…so it's not a question of law to look at the first case where there's one patent and one resultant second case where there's a different patent and a different result, and say that there's a logic or illogic. The patents are different."); Holbrook, June 3, 2016, pp. 1534:18 – 1535:8 ("MR.SMITH: Same patent, same evidence, same fact finders. Assume it's all the same. You would expect the same result, would you not? PROFESSOR HOLBROOK: I personally wouldn't because facts can differ. People of reasonable minds can disagree about what the facts of the case are. At a super abstract level, yes, I would agree, but when you actually talk about how these decisions are made on the ground, I would not agree with that. Now we're talking about dealing with specific facts of cases, and reasonable minds can disagree on those kinds of outcomes – and that's okay.") *See also*, Resp. CM, para. 79; Resp. Rejoinder, para. 46; Respondent's Observation on Issues Raised in *Amicus* Submissions, para. 2.

a) Holding a Patentee to the Promise of Its Patent is Not Arbitrary

243. Claimant argues that the Canadian courts arbitrarily (1) identify promises in patents;[594] (2) look to a patent's disclosure to identify promises;[595] and (3) "scour" patents to identify promises.[596] Claimant's arguments must all be dismissed.

244. First, it is not arbitrary to hold patentees to promises. The bargain theory of patent law underpins the entire system,[597] and enforcing promises encourages accuracy while discouraging overstatement in patent disclosures.[598] Patentees know they will be held to their promises, and they know they must be very precise.[599] Claimant itself recognizes that holding patentees to promises is a legitimate part of the patent bargain, so long as those promises are found in the claims.[600]

[594] Opening Statement of Claimant, May 30, 2016, p. 152:22-24; Cl. Mem., para. 61; Cl. Reply, para. 339.

[595] *See, e.g.*, Cl. Mem., para. 65.

[596] Cl. Mem., para. 60; Cl. Reply, para. 177.

[597] Dimock First Report, para. 12 ("The bargain is the foundation of the Canadian patent system. The inventor discloses to the public a new, useful and unobvious invention, and in return the public offers the inventor exclusive monopoly rights for a finite period of time. The goal of the bargain is the public benefit from the improvement in the state of knowledge."), paras. 72-73 and 219 ("This rule ensures that the public receives its end of the patent bargain, particularly for patents such as 'new use' patents and 'selection patents,' where a particular promised utility is the only consideration that the public receives in exchange for the monopoly that it confers."). *See also*, Resp. CM, paras. 84; Resp. Rejoinder, paras. 18-27 and 273.

[598] Dimock First Report, para. 74 ("Holding patentees to their promises also promotes the quality and accuracy of patent disclosures, which are the consideration that the public receives in exchange for the patent monopoly."). *See also*, Resp. CM, para. 100.

[599] Dimock Second Report, para. 12 ("A statement of utility included in a patent specification does not typically appear by accident."); Siebrasse, May 31, 2016, p. 633:5-6 ("Patentees know they must be very precise."); *Kirin-Amgen Inc and others v. Hoechst Marion Roussel Limited and others*, [2004] UKHL 46, para. 34 ("the specification is a unilateral document in the words of the patentee's own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document *inter rusticos* for which broad allowances must be made.") (**R-425**). *See also*, Opening Statement of Canada, May 30, 2016, p. 181:2-5; Closing Presentation of Canada, Slide 173; Resp. Rejoinder, paras. 38 and 40.

[600] Reddon, June 1, 2016, p. 911:4-10 ("In my report, and I think I'm very clear, it's not so much suddenly we're going to take promises. It's we're going to stop looking in the claims for promises and start pulling them out of the disclosure or – and I say this with the greatest respect to the court – sometimes out of thin air on the basis of expert opinion.") *See also*, FNs Supra, paras. 113 and 130.

245. Second, it is not arbitrary to locate promises in the disclosure. To the contrary, Claimant's experts agreed that it is often both necessary and desirable to go to the disclosure to understand what the invention is and what it does.[601] Claimant's expert also agreed that the courts are using sound principles of claims construction to identify promises.[602] If the exercise of using sound principles of claims construction to interpret the words of a patent is arbitrary, then all statutory interpretation is arbitrary. Such a conclusion is untenable.

246. Third, it is not arbitrary for judges to decide between competing evidence on what the promise of a patent is. Contrary to Claimant's arguments, the courts do not "scour" patents in search of promises; private parties have placed utility front and centre.[603] It is amply clear that private parties drive both the drafting and prosecution of patent applications[604] and the challenge of those patents later in the courts.[605] A patentee

[601] Siebrasse, June 1, 2016, pp. 735:18 – 736:1 ("And the underlying point is that an invention has to be useful, but for a chemical compound, for example, to be useful, people have to know what it's good for, because if the thing cures cancer but nobody who uses it knows that it's not useful, so it's necessary that a skilled person would know what it's useful for. If they wouldn't know for other reasons, it may be necessary to look to the disclosure."); Reddon, June 1, 2016, pp. 900:13 – 901:4 (agreeing that there are circumstances where he encourages the courts to look to the disclosure); *Allergan Inc.. v. Minister of Health and Sandoz Inc.*, Memorandum of Fact and Law of the Applicants (Redacted), Federal Court File No. T-154-10, 18 July 2011, para. 20 ("The law is clear that the inventive concept need not be readily discernible from the claims alone. Rather, the inventive concept in the claims is to be understood based on a review of the patent as a whole.") (**R-485**); Dimock Second Report, paras. 15-19 (explaining the practice of "reading up the invention" by arguing that passages from the disclosure asserting the advantages of invention should be read into the claims). *See also*, Closing Presentation of Canada, Slide 174; Resp. Rejoinder, paras. 33-36.

[602] Siebrasse, May 31, 2016, pp. 633:21 – 634:12 ("PROFESSOR SIEBRASSE: Yes, yes. The principles are sound principles. I mean, they're applying the same principles that are applied to claim construction."); Dimock First Report, paras. 85-88; *Gold and Shortt*, p. 42 ("interpreting the promise of the patent is an aspect of construing the patent, and thus courts are to approach promises by employing purposive construction.") (**R-050**). *See also*, Closing Presentation of Canada, Slide 175; Resp. CM, paras. 102-103 and 106.

[603] Reddon, June 1, 2016, pp. 891:23 – 892:3 ("MR. JOHNSTON: Did the court in any of those instances embark on a section of its judgment entitled 'Scouring the patent'? MR. REDDON: Never. And the three instances that I can recall weren't in this exact context either."); Dimock Second Report, paras. 73-78. *See also,* Opening Statement of Canada, May 30, 2016, p.180:13-19; Opening Presentation of Canada, Slides 21-24; Resp. CM, paras. 254-256; Resp. Rejoinder, paras. 48-50, 160 and 271.

[604] Gillen, June 1, 2016, p. 921:22-24 ("Examiners do not draft patent applications; they rely on what the applicant has put in the application to carry out their examination."); Dimock First Report, para. 13 ("To obtain and maintain patent rights in Canada, an applicant must comply with the provisions of the *Patent Act*."). *See also*, Opening Presentation of Canada, Slides 22-23; Closing Presentation of Canada, Slide

is not required to identify a particular utility – Canada continues to make patents available for inventions with a mere scintilla of utility.[606] Patentees make promises because, in some cases, it is necessary to satisfy another concept of patent law.[607] For example, the advantages of a selection over a genus or the specified new use of a known compound form the basis of these types of inventions.[608] This was evident in both the olanzapine and atomoxetine cases at issue here.

247. The olanzapine patent at issue here (the '113 Patent) was a selection patent from the '687 genus patent.[609] The '687 patent disclosed the potential use of the group of

186; Resp. CM, paras. 107 and 292; Resp. Rejoinder, paras. 38-40; Respondent's Observations on Issues Raised in *Amicus* Submissions, FN 118.

[605] Reddon, June 1, 2016, pp. 892:20 – 893:2 ("As I said in my opening statement, the way all litigation works, the lawyers put the case together, they present it to the court, they lead the court through the approach that they want, and the court adopts the approach that is most attractive to it …"); Dimock Second Report, para. 75 ("Rather it is the parties in pharmaceutical litigation – and not the courts – that are now placing promises made in the patents front and centre before the courts."). *See also,* Opening Statement of Canada, May 30, 2016, p. 181:2-25; Opening Presentation of Canada, Slide 24; Closing Presentation of Canada, Slide176; Resp. CM, paras. 414-415; Resp. Rejoinder, paras. 46-50; Respondent's Observations on Issues Raised in *Amicus* Submissions, para. 14.

[606] Dimock First Report, para. 58 ("The standard of utility required is a contextual consideration dependant on the disclosure of the patent and particularly on whether it is silent about utility or whether it promises a result or certain level of utility. In the former case, the invention simply needs to have a 'mere scintilla' of utility…"); Dimock Second Report, para. 10 ("Where there is no indication of the utility of the invention in the disclosure or claims in the nature of a promise, all that it [*sic*] is required is some utility (i.e., a 'mere scintilla')."). *See also,* Resp. Rejoinder, para. 23.

[607] Dimock, June 2, 2016, p. 1035:3-22 ("Why does a patent applicant make a promise of utility when, according to Consolboard, there's no need to make reference to the utility or the novelty in the patent? Well, in some cases it is a necessity to satisfy another concept of law or an incentive, as the case may be, where there's a particular utility at the core of the invention."); Dimock First Report, para. 59; Dimock Second Report, paras. 12-25. *See also,* Closing Presentation of Canada, Slide 177; Resp. CM, paras. 97 and 100; Resp. Rejoinder, paras. 39-40 and 143.

[608] Dimock First Report, para. 73 ("In these types of situations, a promise of utility is the basis for the grant of a patent. Failure to deliver the promised utility breaches the patent bargain."); Dimock Second Report, para. 21 ("In these cases, a particular utility is the essence of the invention – that is, without the promised utility, the named inventor has not invented anything at all."); Gillen Second Statement, para. 9 ("Examiners working in these areas (including pharmaceuticals) typically spend more time assessing utility for new use and selection patents than for new compound and genus patents. This is because the specified new use, or newly identified advantages of the selection over the genus, forms the basis for the invention.") *See also,* Resp. Rejoinder, para. 32.

[609] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 1018 ("*Olanzapine FC I*"), para. 23 ("One of the vast number of compounds covered by the '687 patent (15 trillion) was olanzapine.") (**R-033**). *See also,* Resp. CM, paras. 39 and 41; Resp. Rejoinder, para. 52.

compounds containing olanzapine to treat schizophrenia.[610] Thus, to warrant a further monopoly, the Claimant had to have discovered surprising advantages of olanzapine over the genus. The Claimant understood this requirement under Canadian law,[611] and highlighted the advantages of olanzapine over the genus in its patent application,[612] as well as before the Patent Office during prosecution.[613]

248. The trial judge later concluded that the '113 patent promised that "olanzapine treats schizophrenia patients in the clinic in a markedly superior fashion with a better side effects profile than other known antipsychotics."[614] This was neither subjective nor

[610] *Compare* Patent Specification CA 1,075,687, p. 21, lines 17-22 (**R-292**), *with* Patent Specification CA 2,041,113, p. 4 (**R-030**).

[611] Response to Office Action re Canadian Patent Application No. 2,041,113 (Zyprexa/Olanzapine), p. 4 ("There may well be invention in the selection of one member (or a few members) out of a number of substances for a particular purpose, even though others of this class may have been used before, even perhaps for the same purpose, provided there is a special advantage to be derived from the use of the selected substance or substances and its selection constitutes a definite advance upon existing knowledge (see Fox, *Canadian Patent Law and Practice*, 4th Edition, Carswell Company Limited, Toronto, (1969) pages 89-92.)") p. 6 ("In Applicant's view, therefore, patentability of the compound of the present invention depends on proving that the compound has exceptional properties that could not be predicted from the prior art; and this, it is believed, is adequately established by evidence already included in the Applicant's specification.") (**C-064**).

[612] Patent Specification CA 2,041,113, p. 6, lines 2-5 ("Overall, therefore, in clinical situations, the compound of the invention shows marked superiority, and a better side effects profile than prior known antipsychotic agents, and has a highly advantageous activity level.") (**R-030**). *See also*, Opening Presentation of Canada, Slide 45; Closing Presentation of Canada, Slide 178.

[613] Response to Office Action re Canadian Patent Application No. 2,041,113 (Zyprexa/Olanzapine), p. 6 ("The compound of the invention is both very active and surprisingly free from the disadvantages of the neighbouring prior art compounds. None of the properties of the compound could have been predicted, especially in view of the small structural differences involved."), p. 7 ("The present invention is based on the discovery of the compound [olanzapine] and the fact that it has exceptional and unexpected properties, giving it the potential to be used as a relatively safe and side effect-free effective treatment for schizophrenia and related disorders.") and pages 7-8 ("In summary, therefore, although drug therapy can provide some degree of management of schizophrenia, there is still a great need for a compound which not only has efficacy against both the positive and negative symptoms of the disease but which is also free from the presently experienced extremely negative extrapyramidal side effects and blood toxicity. Following the discovery of the compound of the present invention, it has been found surprisingly to show every potential to meet these very exacting and long-sought requirements, in the extensive research and trailing that have been carried out. In this respect it appears unique against the prior art background.") (**C-064**). *See also*, Opening Presentation of Canada, Slide 46.

[614] *Eli Lily Canada Inc. v. Novopharm Limited*, 2011 FC 1288 ("*Olanzapine FC II"*), para. 209 (construing the promise as "Olanzapine treats schizophrenia patients in the clinic in a markedly superior fashion with a better side effects profile than other known antipsychotics.") (**R-016**). *See also*, Opening Presentation of Canada, Slide 50, Closing Presentation of Canada, Slides 167 and 178; Resp. CM, paras. 44-47 and 54-58.

arbitrary – it directly tracked the language Claimant itself used in its patent.[615] This holding was affirmed on appeal; there was not a single dissent.[616]

249. Claimant argues that the promise that the court read was "different from what might be needed to support a patent to make it non-obvious."[617] It argues that the court construed the promise as "marked superiority over all known other anti-psychotics", which was broader than what would be required to meet the obviousness requirement for a selection patent.[618] Since the court found the patent overcame the non-obviousness hurdle, Claimant reasons, the utility requirement should also have been met.[619]

250. Claimant's argument ignores that the courts determined that there was no evidence that olanzapine was superior *either* to any other compounds in the genus class,[620] or to other known antipsychotics.[621] These findings of fact, which were not

[615] Patent Specification CA 2,041,113, p. 6 ("Overall, therefore, in clinical situations, the compound of the invention shows marked superiority and a better side effects profile than prior known antipsychotic agents, and has highly advantageous activity level.") (**R-030**). *See also*, Resp. CM, paras. 59-60; Opening Presentation of Canada Presentation, Slides 45 and 50 Resp. Closing Presentation of Canada, Slide 178.

[616] *See* Resp. CM, paras. 53 and 61; *Olanzapine FC I*, 2010 FCA 197, p. 20 (**R-015**); *Novopharm Limited v. Eli Lilly Canada Inc. et al*., 2011 CanLII 6307, (SCC) No. 33870, 10 February 2011 (**R-300**); *Olanzapine FCA II*, 2012 FCA 232 (**R-035**); *Eli Lilly Canada Inc., et al. v. Novopharm Limited*, 2013 CanLII 26762 (SCC) (**R-002**). *See also*, Opening Presentation of Canada, Slides 47 (roadmap of olanzapine litigation) and 52.

[617] Opening Statement of Claimant, May 30, 2016, p. 67:2-4.

[618] Opening Statement of Claimant, May 30, 2016, p. 67:5-10. In contrast, in 2012, Professor Siebrasse commented that the olanzapine case was "a selection case in which it is difficult to disentangle the unexpected additional advantages necessary to support a selection patent from the heightened utility requirement derived from the promise of the patent.": Norman V. Siebrasse, *The False Doctrine of False Promise*, (2013) 29 Can IP Rev 3 p. 37, FN 163 (**C-205**).

[619] *See, e.g.*, Siebrasse Second Report, para. 49.

[620] *Olanzapine FC II*, paras. 260-261 ("More particularly, the evidence does not support a prediction that the alleged advantages of olanzapine over two '687 compounds, flumezapine and ethyl olanzapine, are substantial. To the extent they existed at all, their magnitude was insignificant. In addition, there is no evidence that olanzapine was superior to any other compounds in the '687 class in respect of the characteristics described in the '113 patent. The comparisons did not relate to the class as a whole and I have no evidence that any advantage was peculiar to olanzapine. None of the comparisons in the '113 patent was supported by evidence suggesting that olanzapine was a peculiar or special member of the '687 class. …") (**R-016**).

[621] *Olanzapine FC II*, para. 259 ("In sum, the evidence before me simply does not support a *prima facie* reasonable inference that olanzapine would treat schizophrenia in a markedly superior manner with a better side-effects profile than other antipsychotics."), and para. 264 ("The evidence before me suggests

overturned on appeal, would equally have led to invalidity if made under another heading of patentability – such as non-obviousness. Claimant's focus on "other known antipsychotics" ignores that even if the promise was limited to other compounds in the genus class, the patent was still found invalid.

251. In atomoxetine, the promise of the patent was found in the claims,[622] construed in light of the disclosure from the perspective of the skilled person in the art and possessing common general knowledge. This is a basic principle of claims construction.[623] The trial judge found as a fact that in the context of a patent claiming "treatment" of ADHD – which is a chronic disorder – a skilled reader would understand "treatment" to require sustained treatment.[624] Indeed, Claimant's counsel in this proceeding underscored the long-term use of atomoxetine in treating ADHD.[625] Yet, Claimant maintains that the court's factual finding is unfair, arbitrary, and unexpected. There is no merit to such a claim. Claimant appealed to the Federal Court of Appeal, which upheld the trial court decision, describing it as "careful and thorough".[626] There was not a single dissent.[627]

---

that Lilly filed the '113 patent before it had a basis on which to found a sound prediction of olanzapine's advantages, if any, over the '687 compounds or other antipsychotics.") (**R-016**).

[622] Patent Specification CA 2,209,735, p. 8 ("[Claim] 1. The use of tomoxetine for treating attention-deficit/hyperactivity disorder in a patient in need thereof.") (**R-026**). *See also*, Opening Presentation of Canada, Slide 55; Closing Presentation of Canada, Slide 179.

[623] *See* FN 600 above.

[624] *Novopharm Ltd. v. Eli Lilly and Co.*, 2010 FC 915 ("*Atomoxetine FC*"), para. 111 (referencing expert evidence that that long-term treatment is "generally required in the management of ADHD symptoms) and para. 112 ("In the case of the '735 Patent, the inventors claimed a new use for atomoxetine to effectively treat humans with ADHD. What is implicit in this promise is that atomoxetine will work in the longer term.") (**R-027**).

[625] Closing Statement of Claimant, June 8, 2016, p. 2006:18-22 ("To the contrary, [atomoxetine and olanzapine are] valuable, useful medicines to treat ADHD and schizophrenia. They provide effective long-term treatment for those conditions, and they continue to do so to this day for Canadian patients…." [emphasis added]).

[626] *Atomoxetine FCA*, para. 7 ("In my view, the Judge's careful and thorough reasons reveal no reversible error.") (**R-028**). *See also*, Opening Presentation of Canada, Slides 54 (roadmap of atomoxetine litigation) and 58; Resp. CM, para. 35.

[627] *Atomoxetine FCA*, p. 9 (**R-028**); *Eli Lilly Canada Inc., et al. v. Novopharm Limited*, 2013 CanLII 26762 (SCC) (**R-002**).

The mere fact that Claimant did not obtain the interpretation of the claims that it thinks is the better one, is not arbitrary

b) Requiring Patentees to Have Made an Invention by the Time of Filing Is Not Arbitrary

252. The requirement that utility must be demonstrated or soundly predicted at the time of filing exists to prevent patenting for bare speculation.[628] Determining at which point speculation becomes invention is a difficult question in any patent system, and there is no ideal place to draw this line.[629]

253. Canada has decided that the time of application is the point at which the bargain must be fulfilled.[630] Patents are granted to the first inventor to file an application.[631] The

[628] Dimock First Report, paras. 111-112; Dimock, June 2, 2016, pp. 1160:22 – 1161:3 ("Well, if you can show that your prediction was wrong, that if you predict that a particular drug X would treat disease Y and it turns out it doesn't, then why should you be able to get a patent if your hunch turned out to be right? You have to be able to give more as part of the bargain to the government to get the monopoly."); Reddon, June 1, 2016, p. 880:4-6 ("…I think the Supreme Court did say mere speculation is not enough to found an invention."); Siebrasse, June 1, 2016, p. 665:19-22 ("MR. JOHNSTON: Would you say having read this that the court in AZT was concerned with the problem of patenting too far upstream? PROFESSOR SIEBRASSE: Yes.); Siebrasse, June 1, 2016, p. 660:9-12 ("MR. JOHNSTON: Now, do you consider that this objective of preventing speculative patenting is a legitimate objective in the patent system? PROFESSOR SIEBRASSE: Yes.); Siebrasse, June 1, 2016, p. 706:16-20 ("You've raised this point on post-filing evidence, what's the policy on post-filing evidence. You've given me policies that persuaded the court in AZT to actually change the law. Those policies weren't foolish….). *See also,* Resp. CM, paras. 84, 114, 120 and 294; Resp. Rejoinder, para. 25.

[629] Professor Siebrasse agrees: Siebrasse, June 1, 2016, pp. 660:20 – 661:2 (MR. JOHNSTON: Would you agree that there is no absolute ideal place to draw that line of patentability between speculation and invention? PROFESSOR SIEBRASSE: Well, theoretically it's not entirely clear. There are competing considerations on how far upstream. Then there are a variety of practical considerations that narrow down the appropriate range substantially."); Siebrasse, June 1, 2016, p. 708:17-20 ("…There's a sharp distinction in the type of evidence that can be admitted. But arbitrary in this context, I meant there isn't a theoretically perfect place to draw the line."); Norman V. Siebrasse, *Must the Factual Basis for Sound Prediction Be Disclosed in the Patent?* (2012) 28 Can IP Rev 39, p. 12 ("That means the line between speculation and utility is important – we must draw a line somewhere – and yet difficult – because there is no natural line in the real world. Consequently, the three part test for sound prediction provides useful guidance as to where to draw that line. Put another way, we may consider the doctrine of sound prediction to be an elaboration of an overarching utility requirement that is intended to provide guidance in the most difficult cases, on the borderline between speculation and utility.") (**C-206**).

[630] Dimock First Report, paras. 15-17 and 103("Put simply, the patent bargain is made at the time of filing, not later."); Dimock Second Report, paras. 107 and 109; Gillen First Statement, para. 34 ("The Patent Office has always required that utility be established at the date an application is filed."). *See also,* Resp. Rejoinder, para. 25.

patent monopoly runs from the date the applicant, as the presumed first inventor, files her patent application.[632] It is not arbitrary to require the bargain to be met at that time.

254. Tellingly, the Claimant's own expert, Professor Siebrasse, agrees that the rule in *AZT* is rationally connected to the objective of preventing patenting too far upstream.[633] The fact that Claimant would prefer to draw the line elsewhere[634] does not make the place that Canadian patent law draws the line arbitrary. Nor is it the role of this Tribunal to decide where Canada should draw that line.

255. Claimant attempted to limit the scope of this policy rationale at the hearing by arguing that "the type of speculation that the traditional utility requirement is designed to address" is limited to perpetual motion machines and gene snippets because they "have

[631] Dimock Second Report, paras. 107-109 ("Under this new ['first-to-file'] regime, patents are awarded to the first inventor to file a patent application, even if someone else actually invented earlier but filed later…. The system is therefore best described as a 'first (inventor) to file' system. A patentee cannot claim a monopoly before having made an invention – including establishing its utility."); Gillen First Statement, para. 37 ("In 1989, amendments to the *Patent Act* replaced the first-to-invent system with a first-to-file system … It was understood by applicants, and assumed by examiners, that an applicant would only file first because that applicant had actually realized their invention at the time of filing." [emphasis in original]). *See also,* Resp. Rejoinder, para. 25.

[632] *Patent Act*, RSC 1985, c P-4, s. 44 ("Subject to section 46, where an application for a patent is filed under this Act on or after October 1, 1989, the term limited for the duration of the patent is twenty years from the filing date.") (**R-001**); Wilson, June 1, 2016, p. 787:13-21 ("MS. ZEMAN: So your monopoly begins running form the date you filed your application? MR. WILSON: Yes. MS. ZEMAN: And not from the date of the patent grant? MR. WILSON: No. MS. ZEMAN: And not from the date of commercialization of your product? MR. WILSON: No.") *See also*, Resp. CM, FN 115.

[633] Siebrasse, June 1, 2016, pp. 665:24 – 666:5 ("MR. JOHNSTON: And you would say that the court's statement that utility must be demonstrated or soundly predicted at the time of filing is rationally connected to the objective of patenting too far upstream? PROFESSOR SIEBRASSE: I would say it's rationally connected, yes."); Norman Siebrasse, Sufficient Description Blog Excerpts, p. 54 ("The principle that a patent may be granted for a speculative invention is sound, and it may be that Lilly patented too soon.") (**R-476**). *See also*, Closing Presentation of Canada, Slides 165 and 168.

[634] *See, e.g.*, Reddon, June 1, 2016, p. 916:13-16 ("The articulated policy to effectively require inventors to wait longer before they file, to file further downstream, I don't think is a good policy."); Siebrasse, June 1, 2016, pp. 678:12 – 679:3 ("MR. JOHNSTON: My question is, if I've fairly captured what you're saying here, am I right in reading this sentence to say there are two extremes. One of them is consideration of post-published evidence; the other would be limiting consideration to what is actually disclosed in the patent, and that you characterize as a middle ground between these two extremes limiting your consideration to evidence that exists at the relevant date, even though it is not disclosed in the specification. That's what you're characterizing as a middle between two extremes. PROFESSOR SIEBRASSE: Well, I will point out that I say the law as recently developed in the Federal courts, and it is a middle ground, but I'm not saying the middle ground is, therefore, the correct answer.")

no articulated real-world use."[635] This argument is baseless. The invention at issue in *AZT*, where the Supreme Court of Canada articulated its concern with upstream patenting, was a new use of a known compound.[636] Claimant's attempt to limit the Supreme Court of Canada's articulation is without merit. Moreover, Claimant's argument leaves no room for doubt: it asks this Tribunal to choose a different policy for Canada. The Tribunal cannot do so under the guise of an arbitrariness analysis.[637]

256. Claimant further argues that the courts' application of the rule to its patents for olanzapine and atomoxetine produced unfair results because those patents "were not speculative. They were extraordinarily supported by human clinical studies at the date of filing."[638] The undisputed fact is that the same claims were made by Claimant to the Canadian courts, and the Canadian courts disagreed based on the extensive evidentiary records before them.[639] Claimant asks this Tribunal to decide that the Canadian courts got it wrong, and to do so without any of the evidence. The Tribunal should not do so.[640]

257. In olanzapine,[641] the courts determined that there was no evidence that olanzapine was superior to any other compounds in the genus class in respect of the

[635] Closing Statement of Claimant, June 8, 2016, pp. 2006:1 – 2007:2.

[636] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153, para. 2 ("The appeals therefore require us to consider the statutory requirement for an invention in the context of a new use for an old chemical compound…"), para. 52 ("It is important to reiterate that the *only* contribution made by Glaxo/Wellcome in the case of AZT was to identify a new *use*. The compound itself was not novel.") and para. 56 ("Where the new use is the *gravamen* of the invention, the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available.") (**R-004**).

[637] *Azinian Award*, paras. 83 and 99 (**RL-002**); *Mondev Award*, para. 126 (**RL-004**); *Glamis Award*, paras. 762 and 779 (**RL-006**); *Loewen Award*, para. 242 (**RL-013**); *Apotex Award*, paras. 9.37-9.40 (**RL-016**); *Chemtura Award*, para. 134 (**RL-057**); *Arif Award*, paras. 398, 416 and 440-441 (**RL-063**); *S.D. Myers Partial Award*, paras. 261 and 263 (**RL-076**); *Mesa Award*, paras. 632 and 579 (**RL-159**). *See also*, Resp. CM, para. 223; Resp. Rejoinder, para. 267; Respondent's Observations on Issues Raised in *Amicus* Submissions, para. 11.

[638] Opening Statement of Claimant, May 30, 2016, p. 80:1-4; Closing Presentation of Canada, Slide 160; Cl. Mem., para. 267.

[639] *See* Resp. CM, paras. 26, 48 and 54.

[640] *See* Resp. CM, paras. 26, 48, and 54.

[641] *See* Opening Presentation of Canada, Slide 47 for roadmap of olanzapine litigation history.

surprising advantages described in the '113 patent.[642] While there may be disagreement about which doctrinal heading is best suited to deal with advantages in a selection context, it is undisputed that selections must, in fact, have advantages.[643] These findings of fact even if made under another heading of patentability, would equally have led to invalidity.[644] Indeed, Claimant's own expert, Professor Siebrasse, acknowledges that objecting to the approach of dealing with the advantages necessary for a selection under the heading of utility rather than non-obviousness in cases such as this is "inconsequential."[645]

258. In atomoxetine,[646] the court found, as a matter of fact, that the MGH study, whose qualities Claimant extols,[647] was not sufficient to demonstrate the claimed

[642] See *Olanzapine FC I*, para. 127 ("Further, there is no evidence that olanzapine was superior to any other compounds in the '687 class in respect of the characteristics described in the '113 patent.") (**R-033**); *Olanzapine FC II*, para. 264 ("The evidence before me suggests that Lilly filed the '113 patent before it had a basis on which to found a sound prediction of olanzapine's advantages, if any, over the '687 compounds or other antipsychotics.") (**R-016**). *See also*, Opening Presentation of Canada, Slides 48 and 167.

[643] Reddon, June 1, 2016, p. 897:15-18 ("There are cases where the brand, the patent holder, has argued that the *achievement of those advantages* is part of the inventive step, the inventive concept." [emphasis added]); Siebrasse, May 31, 2016, p. 643:6-10 ("And a selection patent has to have advantages over the other compounds in the genus. And if the selection patent doesn't actually have the advantages, then it's not an invention."); Norman Siebrasse, *Sufficient Description Blog Excerpts*, p. 92 ("It is also clear that in order to be valid, a selection patent must possess some unexpected property as compared with the genus, be it the presence of an advantage or the avoidance of a disadvantage.") (**R-476**); Dimock First Report, para. 119 ("Such patents are directed to a subset or 'selection' of members of a previously known group, based on the discovery that those members have a previously unidentified advantage over the other members in the group.").

[644] Claimant and Professor Siebrasse conclude that the olanzapine patent would have been valid under prior law: Siebrasse First Report, para. 98; Cl. Mem., paras. 111, and 235. This argument relies on the following logic: the '687 class satisfied the utility requirement; olanzapine is part of the '687 class; therefore, olanzapine satisfies the utility requirement: Siebrasse First Report, para. 97. The argument also relies on an assumption that the courts would have come to the same conclusions with respect to the other patentability requirements, particularly obviousness: Siebrasse, June 1, 2016, p. 702:2-5 ("MR. JOHNSTON: So you take the court's findings on those other challenges to validity essentially at face value?… PROFESSOR SIEBRASSE: Essentially, yes.") However, given that everyone agrees that the basis for obtaining a selection patent in Canada is the achievement of advantages over the genus (see FN 262 above) it is illogical to assume that the court's factual finding that there was no evidence of olanzapine's advantages over the genus would not have affected the court's findings under other doctrinal headings. As Claimant has failed to consider this possibility (*see, e.g.*, Siebrasse, June 1, 2016, pp. 702:24 – 703:6), its conclusions cannot be accepted.

[645] Siebrasse, June 1, 2016, pp. 637:4 – 638:2.

[646] *See* Opening Presentation of Canada, Slide 54 for roadmap of atomoxetine litigation history.

utility.[648] Nor did the patent disclose a factual basis for a sound prediction of utility.[649] Contrary to Claimant's arguments,[650] the court did not make a finding of fact to the effect that the MGH study would have provided adequate support for a sound prediction absent the disclosure rule. Indeed, the court found that the inventors themselves had reservations about the study,[651] which suggests instead that the court may well have found the patent to lack utility in any event. Claimant's inability to convince the court that it had established the utility of its inventions at the filing date – that is, at the moment its patent monopolies began to run – does not render the application of the rule arbitrary.[652]

[647] *See, e.g.*, Cl. Mem., paras. 129 and 137 (describing the "statistically significant, positive results of a placebo-controlled, double-blind, crossover human trial that merited publication in the *American Journal of Psychiatry*," a "prestigious peer-reviewed journal."); *Atomoxetine FC*, para. 114 ("Lilly's primary utility argument is that the results of the MGH Study were sufficiently robust to constitute a demonstration of utility.") (**C-160**).

[648] *Atomoxetine FC*, para. 113 ("For the most part, I accept Dr. Virani's evidence about the limitations of the MGH Study and find that its reported results do not demonstrate the clinical utility of atomoxetine to treat ADHD in adults let alone in children and adolescents.") (**C-160**).

[649] *Atomoxetine FC*, para. 120 ("It follows inevitably from the authorities that to the extent that the '735 Patent is based on a sound prediction from the MGH Study that atomoxetine is useful in the treatment of ADHD, the patent fails for want of disclosure because some reference to those findings was required to be set out in the patent.") (**C-160**).

[650] Claimant argues that, but for the promise utility doctrine, the atomoxetine patent would have been valid: Siebrasse First Report, para. 104; Cl. Mem., para. 140; Opening Presentation of Claimant, Slide 43. *Contrast with* Opening Statement of Canada, May 30, 2016, p. 181:12-19.

[651] *Atomoxetine FC*, paras. 2, 9, 19 and 103-105 (showing that Dr. Heiligenstein, one of the named inventors, characterized the MGH study as a preliminary study, a "'pilot' designed to test the hypothesis that atomoxetine 'might be useful in treating ADHD,' and that his view was shared with others in Lilly's later study of atomoxetine to treat ADHD.) (**C-160**). *See also*, Opening Presentation of Canada, Slide 56; Closing Presentation of Canada, Slides 169 and 170.

[652] Under Professor Siebrasse's view, it is sufficient to establish utility in the context of a new use patent by simply writing down the previously disclosed compound and stating a new use for it in the patent: Siebrasse, June 1, 2016, p. 670:13-25, and p. 671:17 – 672:19. The Supreme Court of Canada expressly rejected this notion, finding that "there is good reason to reject the proposition that bare speculation, even if it afterwards turns out to be correct, is sufficient.": *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153, para. 84 (**R-004**). Claimant's preference for a different policy approach does not render this well-reasoned policy choice arbitrary: *see* Siebrasse, June 1, 2016, p. 672:10 – 15 ("MR. JOHNSTON: But the fact that it was a wild guess would not change your assessment of whether it had been reduced to a definite and practical shape? PROFESSOR SIEBRASSE: Well, it certainly seems counter-intuitive that that should be allowed"). *See also*, Closing Presentation of Canada, Slides 129, 133, 164 and 235.

259. Even if Article 1105 allowed for the kind of review of court decisions that Claimant advocates here – and it does not– this Tribunal is in no position to conduct any sort of review of the courts' factual findings. The courts had the whole record, and the advantage of the ability to question witnesses and probe the evidence at a hearing. This Tribunal does not have such an opportunity.[653]

260. Finally, Claimant argues that preventing speculative patenting is not a legitimate policy rationale underlying the promise utility doctrine because the doctrine puts pharmaceutical patentees in a "catch-22 type of situation."[654] To make this argument, Claimant argues that Canada is "holding patentees to a requirement to have large-scale clinical trials" before filing for patents,[655] and that this "dramatically elevated standard that applies today may actually make it impossible for patentees to obtain or maintain pharmaceutical patents at all."[656] Claimant's argument is simply unsupported by the facts.

261. First, Canadian law does not require "large-scale clinical trials" to support patents. Patent applications for drugs are routinely filed and granted in Canada on the basis of *in vitro* and *in vivo* animal studies.[657] As just one example, the patent granted and upheld in *AZT* – the case articulating concerns about patenting too far upstream – was supported only by *in vitro* tests.[658]

[653] Siebrasse, May 31, 2016, p. 648:21-23 ("The Court of Appeal had the whole record. I don't have the whole record."). *See also*, Closing Presentation of Canada, Slide 171.

[654] Opening Statement of Claimant, May 30, 2016, p. 82:5-22; Closing Statement of Claimant, June 8, 2016, pp. 2043:21 – 2044:2; Cl. Mem., paras. 32, 266, FNs 34 and 252; Cl. Reply, paras. 11 and 192.

[655] Opening Statement of Claimant, May 30, 2016, p. 82:12-15. Claimant and its witnesses maintain that once Health Canada has issued its approval for a drug, it goes without saying that the utility requirement under patent law has been met. This is a non sequitur. Health Canada approval and satisfaction of the utility requirement are distinct inquiries, imposing requirements at distinct points in time. *See* FN 284 above.

[656] Opening Statement of Claimant, May 30, 2016, p. 82:5-11.

[657] *See also*, Respondent's Observations on Issues Raised in *Amicus* Submissions, para. 29; CGPA Amicus Brief, para. 69.

[658] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153, paras. 72, 73, and 93 (**R-004**). *See also*, *GlaxoSmithKline Inc. v. Pharmascience Inc.*, 2011 FC 239, paras. 115-117 (**C-249**). *See also*, Norman

262. Second, if it was in fact impossible for patentees to obtain or maintain pharmaceutical patents at all, one would expect to see a decline in the number of patents granted by the Canadian Patent Office since the doctrine came into being – in 2005, under Claimant's theory of the case. However, the opposite has been true. The number of pharmaceutical patents granted in Canada has increased steadily every year since 2005.[659] Claimant's argument must be dismissed.

c) Requiring the Basis for a Sound Prediction of Utility To Be Disclosed in the Patent is Not Arbitrary

263. Requiring applicants to disclose the factual basis and sound line of reasoning of their sound predictions is an essential part of the patent bargain.[660] Contrary to Claimant's arguments, the Supreme Court of Canada was clear about the rationale for this rule. Justice Binnie explained in *AZT*: "In this sort of case, however, the sound prediction is to some extent the quid pro quo the applicant offers in exchange for the patent monopoly."[661]

264. Sound prediction is a permissive doctrine that allows patentees to obtain a monopoly for something more than they have already made.[662] The *quid pro quo* is

---

Siebrasse, *Sufficient Description Blog Excerpts*, p. 13 ("It is well-established that 'an inventor is not require to meet regulatory testing standards in order to demonstrate utility": *Pfizer v. Novopharm / sildenafil (NOC)* 2010 FCA 242 [C-464].") (**R-476**);Respondent's Observations on Issues Raised in *Amicus* Submissions, FN 118.

[659] WIPO Database, *Patent Grants by Technology – Pharmaceutical, Total Count by Filing Office – Canada*, (1980 – 2013) (2005:686 patents; 2006: 844 patents; 2007: 1,091 patents; 2008: 1,349 patents; 2009: 1,524 patents; 2010:1,583 patents; 2011: 1,996 patents; 2012: 1,943 patents; and 2013: 2,041 patents) (**R-436**). This is compared to the 538 patents granted in 1980: Resp. Rejoinder, para. 137, FN 230.

[660] Dimock First Report, para. 114 ("Disclosure lies at the 'very heart of the patent bargain'.") and para. 146. *See also*, Resp. CM, para. 127; Resp. Rejoinder, para. 275.

[661] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153, para. 70 (**R-004**). *See also*, Closing Presentation of Canada, Slide 181.

[662] Dimock First Report, paras. 99-100 ("Under this doctrine, a patentee is entitled to frame a claim which does not go beyond the limits within which the prediction remains sound. This provides a more flexible test whereby utility will be presumed where the patentee makes a sufficient disclosure … in the patent from which the invention can be soundly predicted by the person of ordinary skill in the art."). *See also*, Closing Presentation of Canada, Slide 181; Resp. CM, paras. 110-111 and 137; Respondent's Observations on Issues Raised in *Amicus* Submissions, para. 29.

telling the public what it is that makes its prediction a sound one.[663] A skilled reader cannot discern whether a prediction is sound, or mere speculation, unless it knows the factual basis and the sound line of reasoning.

265. The Federal Court of Appeal articulated the same rationale when it upheld the trial court's decision to invalidate Claimant's atomoxetine patent. It found that "if disclosure in the patent of the factual basis of the prediction of utility was not required for sound prediction, it would be difficult to see what Lilly could be said to have given to the public, in exchange for the grant of the monopoly, that it did not already have."[664] Thus, requiring such disclosure is not arbitrary.

266. To underscore this point, one need look no further than to the United States District Court of New Jersey decision regarding the atomoxetine patent.[665] Issued one month prior to the Canadian Federal Court's decision, the District Court found the identical patent to be invalid for "lack of enablement/utility under 35 U.S.C. s. 112."[666] Specifically, the Court examined whether the patent "properly disclosed the patent's utility at the time of the filing date," and concluded that the patent did not contain test data and a person of skill in the art "would [not] have recognized the method of treatment's utility in view of the specification and prior art."[667] The District Court explained that "'usefulness' in the context of a clinical study … is not the same as 'utility' for the purposes of patentability."[668] While the decision was overturned on appeal, it shows that the Canadian outcome is not arbitrary.

[663] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153, para. 70 (**R-004**); *Atomoxetine FCA*, para. 51 ("When utility is based on sound prediction, disclosure of its factual foundation goes to the essence of the bargain with the public underlying patentability.") (**R-028**). *See also*, Closing Presentation of Canada, Slide 181.

[664] *Atomoxetine FCA*, para. 51 (**R-028**).

[665] *Eli Lilly v. Actavis et al.*, August 12, 2010 (**R-272**).

[666] *Eli Lilly v. Actavis et al.*, August 12, 2010, p. 49 (**R-272**).

[667] *Eli Lilly v. Actavis et al.*, August 12, 2010, p. 48 (**R-272**).

[668] *Eli Lilly v. Actavis et al.*, August 12, 2010, p. 48 (**R-272**). The court also summarized its findings in an earlier Opinion denying a motion for summary judgment as to non-enablement: "Although this Court

3) Canada's Law on Utility is Not Inconsistent with Claimant's Legitimate Expectations

267. Claimant argues that it had "legitimate expectations that its Zyprexa and Strattera patents would not be invalidated on the basis of a radically new utility requirement."[669] As shown above, Claimant has failed to show that such a radical change in the law of utility in fact occurred.[670] Even if such a change had occurred, it is trite to say that the common law evolves over time. Any sophisticated investor expects developments in the law, particularly in the area of patent law. It simply cannot be that every time a court overrules a precedent, it violates customary international law. This point underscores why the Tribunal should be very cautious to consider legitimate expectations regarding Canadian patent law as a relevant element here.

268. Even if Claimant's legal arguments with respect to legitimate expectations could be accepted (and they cannot be), Claimant has not established that it had legitimate expectations for three reasons. First, there has been no specific representation. While Claimant argues that a patent grant in Canada is a specific representation upon which investors ground their expectations, the Patent Office's grant of a patent and a court's assessment of its validity are distinct exercises. As Claimant itself recognizes in its annual securities filings, the grant of a patent is no guarantee of validity.[671] It is not

recognized the utility in fact of the invention, the Court determined that these results (or the initiation of the trials) could not serve to demonstrate utility because the materials were not disclosed to the patent office. … That is, the Court found that although non-disclosed materials could be relied upon to confirm a patent's disclosure of utility when challenged (e.g., to later demonstrate that the asserted utility was accurate), such non-disclosed materials could not make the initial demonstration of utility that is required in the first instance" (see p. 42).

[669] Closing Statement of Claimant, June 8, 2016, p. 2135:12-15.

[670] *See* Section IV above.

[671] Eli Lilly Annual Reports, Fiscal Years 1999 to 2008 ("There is no assurance that the patents we are seeking will be granted or that the patents we have been granted would be found valid if challenged.") (**R-303**). *See also* Merges, June 3, 2016, pp. 1326:20 – 1327:8 ("There's no guarantee."); Merges, June 3, 2016, pp. 1317:12 – 1318:7; Dimock First Report, para. 27 ("The exclusive rights of a patentee are not unreviewable or irrevocable following the initial grant.") and para. 29; Dimock Second Report, para. 137 ("I advise my clients that asserting their patent rights is an uncertain and risky endeavour."); Mark A. Lemley and Carl Shapiro, *The Journal of Economic Perspectives, Probabilistic Patents,* p. 76 ("The risk that a patent will be declared invalid is substantial. Roughly half of litigated patents are found to be

surprising that the review conducted by the Patent Office and the courts may lead to different results.[672] Indeed, as Claimant's witness explained, patents are valued based on their assessed risk of invalidation.[673] This fact shows that the market understands that the fact that a patent has been granted does not mean that it is a valid patent or that there is a legitimate expectation of validity.

269. Second, Claimant has not shown that it had legitimate expectations. While Claimant argued that its fact witnesses provided "uncontroverted evidence of Lilly's robust processes for identifying patent-related risk,"[674] the record shows that the decision-makers were not informed about what Claimant now alleges were "sea changes" in Canadian law.[675] Notwithstanding Claimant's officials' lack of briefing, the

invalid, including some of great commercial significance") (**R-437**). *See also*, Closing Presentation of Canada, Slide 185; Resp. CM, paras. 66-68, 78, 219 and 294.

[672] Wilson, June 1, 2016, p. 786:4-21; Gillen, June 1, 2016, p. 930:5-11 ("The court can examine evidence not found in the patent specification. It can ask the applicant, or the patentee as the case may be, to provide evidence of the demonstrated utility or evidence to support the sound prediction, and the court can come to a different conclusion than did the patent examiner."); Gillen First Statement, paras. 11-16; Gillen Second Statement, para. 5. *See also*, Resp. CM, paras. 65-80; Resp. Rejoinder, para. 43.

[673] Armitage, May 31, 2016, p. 363:8-23 (explaining that he would give "yes" or "no" answers to the business about acquiring patents based on his assessment of whether they could be defended); Closing Statement of Claimant, June 8, 2016, p. 2072:3-14.

[674] Opening Statement of Claimant, May 30, 2016, p. 148:7-9. *See also*, Closing Presentation of Canada, Slide 187.

[675] Claimant's witnesses testified that they would have received legal advice about Canadian law when they filed their patents, and that they would expect their legal teams to be familiar with Canadian law: Armitage, May 31, 2016, pp. 343:18 – 344:1 ("Lilly maintained a network of patent agents whose responsibilities 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."); Stringer, May 31, 2016, pp. 405:22 – 406:1 ("MR. SPELLISCY: I take it, then, that you were familiar with Canadian law because you would receive briefings and advice from qualified Canadian lawyers, correct? MR. STRINGER: That's correct."); Nobles, May 31, 2016, p. 443:21-25 ("MS. ZEMAN: And you would expect them to be familiar with patent law in Canada. Is that right? MS. NOBLES: That would be correct, for purposes of the Canadian launch"); Postlethwait, May 31, 2016, p. 426:2-11 ("MS. ZEMAN: And you worked closely with Lilly's legal team for this aspect of the product launch. Is that right? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And you expected them to monitor changes in the patent systems of launch countries? MR. POSTLETHWAIT: Yes. MS. ZEMAN: Including in Canada? MR. POSTLETHWAIT: Yes."). And yet, when confronted with questions about specific and relevant cases, such as the 1981 *Consolboard* decision and the 1995 Federal Court of Appeal decision in *Apotex v Wellcome*, Mr. Stringer, the individual responsible for deciding where in the world to file patent applications, admitted that he had never seen those decisions: Stringer, May 31, 2016, pp. 406:8-23 and 408:10-24. Moreover, there was no evidence

record is full of Canadian patent law publications by such practitioners and scholars as Fox[676] and Hayhurst,[677] warning about including promises in your patent, and of disclosing a sufficient basis for a sound prediction long before Claimant filed its patent applications. These publications are consistent with Mr. Dimock's recollections of his understanding and practice at the time.[678] That Claimant was not briefed is no fault of Canada's. It cannot form the basis of a legitimate expectations claim.

---

that Claimant's officials were in fact briefed on changes in the law, despite claiming that they would have been: Armitage, May 31, 2016, p. 349:4-8 ("MR. SPELLISCY: So those briefings, then, would have related to changes in patent law and how they would affect Lilly's patents in those major markets, correct? MR. ARMITAGE That would be correct, yes."); Nobles, May 31, 2016, p. 446:7-15 ("MS. ZEMAN: And if there was a fundamental change in the patent framework of one of your major markets, would you have expected them to advise you about that? MS. NOBLES: …certainly if they considered it a major change from the basis on which we'd been proceeding previously, I think it's very likely that they would have talked to me about that"); Postlethwait, May 31, 2016, p. 427:4-13 ("MS. ZEMAN: And if Canada or another launch country fundamentally changed its approach to a major patentabilty criterion, you expected to be informed about that? MR.POSTLETHWAIT: Your question is regarding subsequent to filing of the patent, or what? MS. ZEMAN: Or during patent prosecution. At both stage.s MR.POSTLETHWAIT: Yes, I would."); Postlethwait, May 31, 2016, p. 426:19-22 ("MS. ZEMAN: And you expected your legal team to raise with you any issues they identified that might affect the products in you r portfolio? MR. POSTLETHWAIT: Yes.") Not a single document was produced, or registered in Claimant's privilege log, to demonstrate that any Lilly official was, in fact, briefed: *see, e.g.*, Resp. Rejoinder, paras. 154-155; Nobles, May 31, 2016, p. 449:3-6. *See also*, Closing Presentation of Canada, Slides 70-71 and 188-189.

[676] Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969), p. 153 ("But in those cases of patents that are based upon a promise of results contained in the specification it is not sufficient that the patent be useful for a part only of the result, or for that result only in a manner inferior to that claimed.") (**R-163**). *See also*, Opening Presentation of Canada, Slide 31; Closing Presentation of Canada, Slide 190.

[677] W.L. Hayhurst, *Disclosure Drafting*, (1971), 28 PTIC Bull (7th) 64, p. 78 ("You must include sufficient examples to justify a sound prediction that everything falling within the scope of the claims will have the promised utility.") (**R-164**); W.L. Hayhurst, Q.C., *Survey of Canadian Law – Industrial Property: Part I*, (1983), 15 Ottawa L. Rev. 38, pp. 68-69 ("Also it is trite law that, as long as that which is disclosed has some practical utility, the quantum of utility may be slight unless the specification promises more" [emphasis added]) (**R-199**); William L. Hayhurst, Q.C., *The Art of Claiming and Reading a Claim*, in Gordon F. Henderson, *Patent Law of Canada* (Toronto: Carswell, 1994), p. 217 ("To avoid problems of false suggestion and inutility, the patent agent should be chary of promising results in the descriptive portion where those results may not be achieved by things that arguably fall within the claims.") (**R-201**). *See also*, Opening Presentation of Canada, Slides 31-32 and 40-41; Closing Presentation of Canada, Slide 190.

[678] *See, e.g.*, Dimock First Report, para. 70 ("[Professor Siebrasses's] statement is entirely inconsistent with my own experience in litigating and reading patent cases; *Consolboard* and the promise of the patent were inextricably linked together long before 2005.") and paras. 77-79 ("Shortly after the [*Amfac* Foods] decision, in a newsletter of my law firm, Sim Hughes Dimock, I warned against the dangers of including object clauses in patents and that such clauses should be avoided altogether, or if their inclusion was absolutely necessary, to draft them very carefully. … Mr. Hayhurst's comments were virtually identical to mine in that *Consolboard* had previously warned against such statements."); Dimock, June 2, 2016, pp.

270. Claimant nonetheless maintains that the "fact that Lilly's team was not briefed does not detract from the basic proposition that Lilly had a robust process to identify patent-related risk and that this process worked in this case."[679] Its argument must be rejected, particularly in light of its own expert's testimony that practitioners must take statements of law and "live with them, as if a judge is some day going to apply them, even though it had never happened."[680] If legitimate expectations were at all applicable in this context, this is the only reasonable expectation an investor could hold.

271. Claimant also argues that, if examiners in Canada's Patent Office were "surprised by the radical change in Canada's utility requirement," its own surprise was legitimate.[681] Even setting aside the fact that mere surprise does not form the basis of a breach of Article 1105, Claimant's argument takes examiner comments out of context and accords them undue weight. As noted above, Claimant attributes comments about a "surprising change in the law" to utility when the examiners directed them specifically to patentable subject matter.[682] Claimant also attributes disagreement over the most appropriate words to use to articulate a standard in a draft version of MOPOP – which is not on the record – to evidence of a "surprising" change in the law. [683] The examiner's comments are not evidence of a surprising or radical change in the law.

1028:24 – 1029:4 ("My early experience that's relevant, among other experience in this case, to the issues before you is that I acted as a junior lawyer with Donald Sim on the Consolboard and Monsanto cases. I didn't appear as counsel in either of those cases, but I did work as a junior lawyer supporting him."); Dimock, June 2, 2016, pp. 1029:24 – 1030:7 ("My opinion today, and in those two reports, is based on my own patent practice experience over these last 40 years and my historical review of the legislation, case law, and legal doctrine. My conclusion ultimately is that the law which was applied in the two cases to invalidate the Claimant's two patents predates the NAFTA and the respective patent filing dates for those two drugs.")

[679] Closing Statement of Claimant, June 8, 2016, pp. 2136:22 – 2137:1.

[680] Reddon, June 1, 2016, pp. 909:24 – 910:5. *See also*, Closing Presentation of Canada, Slides 104 and 191.

[681] Closing Statement of Claimant, June 8, 2016, p. 2138:19-22.

[682] *See* para. 136 above.

[683] For example, Claimant uses one particular examiner's comments to support its argument that Canada's utility requirement may be "unethical": Cl. Reply, paras. 135 and 192; Opening Presentation of Claimant, Slide 10; *MOPOP Chapter 12 feedback C14 - part 2*, Comments of Nancy Trus, (17 March 2008) [Canada Doc. No. 921 at 065459] (**C-361**). This examiner suggested a change in the proposed language to

272. Third, Claimant argues that it grounded its expectations, with respect to its patent for atomoxetine, in the PCT's form and contents requirements. Claimant ignores that the PCT has nothing to say about the substantive conditions of patentability,[684] leaving that assessment to each country.[685] Moreover, Claimant did not make efforts to address country-specific concerns about validity,[686] despite clear warnings from WIPO to do

avoid a possible misinterpretation that she identified: *see* "MOPOP Chapter 12 feedback C14 - part 2,"Comments of Nancy Trus, (17 March 2008), pp. 065458 ("I have chosen to interpret certain paragraphs within the chapter and apply them to things that I see in my art in an effort to indicate how this document will impact my examination"), 065459 (explaining her interpretation based on the draft text of the utility part of the chapter: "As written it would appear that most biotech applications directed 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." [emphasis added]) (**C-361**).

[684] Patent Cooperation Treaty, Article 27(5) ("Nothing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires") (**R-037**); Erstling, June 4, 2016, p. 1620:1-4 ("MR. SPELLISCY: And the PCT has nothing to say on what those substantive conditions of patentability are, correct? PROFESSOR ERSTLING That's correct."); Gervais First Report, paras. 72-78 ("There is no basis to claim an expectation on the part of an applicant that any or all PCT Contracting States will apply the same notion of industrial applicability (or utility), and that that notion will not evolve in each jurisdictions [*sic*]."); Reed First Report, paras. 31-33 ("Understanding 'form and contents' in the manner suggested by Mr. Erstling would lead to the conclusion that the PCT somehow harmonizes substantive criteria for patentability, which it expressly does not do."); Reed Second Report, paras. 8 and 12; *Raloxifene FCA*, para. 19 ("However, this *Treaty* specifically contemplates the supremacy of national law in setting the rules for substantive conditions of patentability (see Article 27(5) of the *Treaty*). We are concerned here with substantive conditions of patentability.") (**R-354**). *See also*, Closing Presentation of Canada, Slide 193; Resp. CM, paras. 182, 200-208 and 297; Resp. Rejoinder, paras. 103- 104, 181 and 241.

[685] Erstling, June 4, 2016, p. 1619:3-10 ("The drafter of the application, in order to meet the form and conditions requirement, needs to include, where it's not inherent, an explicit statement of the way in which the invention can be exploited industrially, or the way in which it can be made and used. It's then up to the examiner to determine whether that statement meets the substantive condition of patentability."); Reed First Report, para. 25 ("I was always aware, and expected, that regardless of the outcome of the prior art search and preliminary examination under the PCT, decision on patentability would be left solely to each country based upon the application of domestic patent law."); Gervais First Report, para. 76 ("The determinations made in the national phase of the PCT are made by each PCT Contracting State independently of the outcome preliminary and non-binding examination."); Gillen First Statement, para. 55 ("From a Patent Office perspective, the PCT did not change the examination practices of the Office. This is because the PCT does not impose substantive patentability requirements on PCT Contracting States."). *See also*, Resp. Rejoinder, paras. 27 and 241-242.

[686] Stringer, May 31, 2016, p. 416:8-12 ("MR. SPELLISCY: So you weren't making efforts to address country-specific concerns about validity. It was about allowability of patents. Is that – MR. STRINGER: It's more allowability.") Mr. Stringer also testified that the Foreign Patent Committee, which had responsibility for making decisions about where to file patent applications, did not include any patent lawyers or agents from Canada: Stringer, May 31, 2016, pp. 404:21-405:2. Mr. Stringer also admitted it was "probably true, yes" that when the initial patent application was filed in one jurisdictions, the persons filing that application would have had no idea in which other jurisdictions the patents might be filed: Stringer, May 31, 2016, p. 415:6-11. *See also*, Closing Presentation of Canada, Slide 194.

so.[687] Finally, even if the PCT's form and contents requirements were relevant here, Canada has acted consistently with them.[688] The most telling evidence of this is that despite being allegedly in violation of what Claimant asserts is a fundamental obligation in the PCT, there is no evidence that there have been any complaints – either formal or informal – by Canada's treaty partners.[689]

[687] Erstling, June 4, 2016, p. 1608:8-13 ("MR. SPELLISCY: So the PCT WIPO is warning applicants when they're drafting disclosure that due account be taken of national practice. We agree on that, right? PROFESSOR ERSTLING: Yes, that's correct.") *See also,* Closing Presentation of Canada, Slide 192.

[688] Reed First Report, paras. 30-48; Reed Second Report, paras. 35-40.

[689] Erstling, June 4, 2016, p. 1601:13-17 ("MR. SPELLISCY: So the answer is no, none of Canada's Treaty partners under the PCT have brought a dispute complaining that Canada is violating the PCT, correct? PROFESSOR ERSTLING: That is correct."); Erstling, June 4, 2016, p. 1627:2-11 ("SIR DANIEL BETHLEHEM: In the light of what you've just said, and given that you were the director of the Office between 2002 and 2007, which covers a very important part of the period that we're looking at, would you have expected to receive, or to your recollection did you receive, from applicants, from the United States, from other states, any complaints about Canada's sound prediction law? PROFESSOR ERSTLING: I can't point to anything in particular that I recall,…"). *See also,* Closing Presentation of Canada, Slides 195-196.

VI. REQUEST FOR RELIEF

273. For all of the above reasons, Canada respectfully asks the Arbitral Tribunal to issue an order:

- dismissing Claimant's claim in its entirety;
- awarding Canada its costs, with applicable interest, pursuant to NAFTA Article 1135(1) and Article 40 of the UNCITRAL Rules; and
- granting any other relief that may seem just.

July 25, 2016

Respectfully submitted

[signed]

Sylvie Tabet
Shane Spelliscy
Mark A. Luz
Adrian Johnston
Krista Zeman
Mariella Montplaisir

Trade Law Bureau
Departments of Justice and of Foreign Affairs, Trade and Development
125 Sussex Drive
Ottawa, Ontario
CANADA K1A 0G2

On behalf of the Respondent the Government of Canada