

**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

RESPONSE TO POST-HEARING MEMORIAL OF CLAIMANT

August 8, 2016

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I. PRELIMINARY STATEMENT

1. Three years of evidence and argument, including hundreds of pages of written pleadings and dozens of hours of oral hearings, have revealed that Claimant's case relies on a set of internally inconsistent positions. In its Post-Hearing Memorial, Claimant confirmed its agreement that the Tribunal must make four separate factual and legal findings in its favour for its claim to succeed. However, Claimant's arguments on these separate points do not work together. If the Tribunal finds for Claimant on one point, it must find against it on another. Thus, the whole claim must fail.

2. Not only is Claimant's approach replete with internal contradictions, but it also requires the Tribunal to disagree with the NAFTA Parties as to the meaning of the treaty they negotiated, signed and are implementing. Further, it requires the Tribunal to disagree with the Supreme Court of Canada, the Federal Courts, and numerous Canadian lawyers and scholars as to the meaning of Canadian law prior to 2002. The Tribunal should decline to do either. Claimant has failed to prove any of the elements necessary to its claim, let alone all of them. The legal authorities and the evidentiary record before the Tribunal compel the conclusion that Claimant has both failed to state a claim as a matter of law and to make out its case on the facts.

3. In a rather transparent attempt to divert the Tribunal from this conclusion, and from the dearth of evidence that it has been able to put into the record to support its allegations, Claimant has resorted to focusing on what Canada allegedly did not prove. Such arguments are both unfounded and misguided. Canada has no burden in this case—it is not presumed to be in violation of its obligations and forced to prove its compliance with NAFTA. The burden to prove that Canada has breached its obligations, and thus to introduce legal authority and factual evidence in support of its claims, is entirely on Claimant. Moreover, Canada has in fact submitted ample evidence and authority to support each of its positions. In contrast, Claimant has failed to meet both its legal and evidentiary burdens and its claims should be dismissed.

4. In the remainder of this Response, Canada will address some of the primary contradictions, misstatements and errors in Claimant’s Post-Hearing Memorial. In light of its brief nature, this Response is not comprehensive. The fact that something is unaddressed in this Response is not a concession or an indication that Canada agrees with Claimant’s position. Canada reiterates and incorporates herein its previous arguments and evidence which show that Claimant’s claims are without merit.

II. DENIAL OF JUSTICE IS THE ONLY BASIS FOR A CLAIM UNDER ARTICLES 1110 AND 1105 IN THIS ARBITRATION

5. The NAFTA Parties and the various relevant authorities all agree that when the acts of a neutral and independent judiciary are challenged under Articles 1110 and 1105, a claimant must establish that there has been a denial of justice in order to prove a breach.¹ Claimant’s response to this is a confused tangle of legally untenable and factually irrelevant distinctions, contradictory positions, and a straw man argument.

6. First, Claimant argues that denial of justice is only applicable where courts are exercising an adjudicative function, but that because of its procedural nature, it does not apply where courts are exercising a legislative function.² Claimant presented no evidence or authority to support the existence of such a distinction. Nor could it, as there is no basis for such a distinction in law. As Canada has explained,³ and as echoed by the United States in its Second Article 1128 Submission,⁴ even when a court does evolve or develop “new” law as part of the process of common law adjudication, the only applicable legal standard under Articles 1110 and 1105 against which such evolution or development can be judged is denial of justice.

7. Further, even if one were to accept Claimant’s distinction as a matter of law, it is irrelevant. In the decisions between 2002 and 2008 to which the Claimant appears to

¹ Respondent’s Post-Hearing Submission (“Resp. PHS”), paras. 7, 26-41 and 60-65.

² Claimant’s Post-Hearing Memorial, (“Cl. PHM”), para. 180.

³ Resp. PHS, paras. 60-65; Closing Statement of Canada, June 8, 2016, pp. 2212:17-2217:17.

⁴ Second US 1128 Submission, para. 5.

point, the Canadian courts did not rewrite Canada's *Patent Act*. Every single Canadian court in question, and every single judge on those courts, was clear that the decisions were no more than an interpretation of the *Patent Act*, consistent with past interpretations, and applied to the facts.⁵ Nor has Claimant pointed to any independent Canadian lawyer or scholar, actually practicing or studying Canadian patent law prior to 2002, who believes that the challenged decisions were anything other than a principled interpretation of existing Canadian law. As Claimant's own legal experts admitted,⁶ interpreting the broad terms of a statute is a core function of any court carrying out its adjudicatory role.

8. Moreover, even if the Tribunal accepted Claimant's distinction in principle, and even if it accepted that the Canadian courts evolved new law between 2002 and 2008, Claimant's argument actually would mandate the dismissal of its claim. Claimant argues that it is challenging only the application of the alleged promise utility doctrine to invalidate two specific patents – olanzapine and atomoxetine.⁷ Everything else is, it says, merely factual background and context.⁸ But Claimant agrees that the Canadian courts in olanzapine and atomoxetine did nothing more than act as expositors of what the law is, and neutral adjudicators of how it applies. Indeed, Claimant does not claim that the courts in the olanzapine and atomoxetine cases legislated new law. It admits that those courts merely applied existing and binding Canadian law.⁹ Rather, Claimant's position is that it was in proceedings years earlier, specifically those related to its raloxifene patent, that the Canadian courts acted as a legislator and crystallized new law in the form of the

⁵ *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153 (“AZT”), paras. 51-62 (**R-004**); *Bristol-Myers Squibb Co v. Apotex Inc.*, 2005 FC 1348 (“*Bristol-Myers Squibb*”), paras. 18-20 (**C-520**); *Pfizer Canada Inc. v. Apotex Inc.*, 2005 FC 1205 (“*Pfizer*”), paras. 68-82 (**C-250**); *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283 (“*Aventis*”), paras. 270-275 (**C-209**); *Eli Lilly Canada Inc. v. Apotex Inc. et al*, 2008 FC 142 (“*Raloxifene FC*”), paras. 64-75 (**R-200**).

⁶ Merges, June 3, 2016, p. 1286:2-18.

⁷ Cl. PHM, para. 33.

⁸ See, e.g., Cl. PHM, para. 39.

⁹ Claimant's Reply (“Cl. Reply”), para. 334.

promise utility doctrine.¹⁰ Claimant did not challenge that decision. If Claimant is correct that different standards apply depending on how one characterizes a court decision, the atomoxetine and olanzapine decisions could only be challenged as a denial of justice because they merely applied settled and existing law. Claimant has made no such claim; thus, this case must be dismissed.

9. Second, Claimant's arguments about the denial of justice standard are inconsistent with how it presents its claims in other sections of its submissions. Claimant accepts, as it must, that this Tribunal is not a court of appeal that can sit in judgment of the correctness of the decisions of the Canadian courts on Canadian law. It argues that it is not limited to a denial of justice claim in this case because it is not alleging that the Canadian courts misapplied Canadian law in the decisions invalidating its patents related to atomoxetine and olanzapine.¹¹ However, as Canada has pointed out,¹² it is alleging that Canadian courts misapplied the existing Canadian law on utility in the decisions between 2002 and 2008 when they allegedly created the promise utility doctrine. Indeed, that existing Canadian law was wrongly applied in these decisions is the very foundation of Claimant's case. Claimant's arguments cannot be reconciled with each other.

10. Claimant's admission that the only applicable standard is denial of justice when the allegation concerns a misapplication of domestic law is also inconsistent with its own created distinction between the applicable standard when a court is exercising adjudicative versus legislative functions. An argument that a court has "legislated" new domestic law is nothing more than a misapplication argument in disguise. There is no theoretical line to be drawn between a court ignoring previous law and making a new rule, and a court misapplying existing domestic law and thereby imposing a legal rule that does not accurately reflect existing law. It cannot be that a claim for a violation of

¹⁰ Cl. PHM, para. 42; *see also* Closing Statement of Claimant, June 8, 2016, p. 1995:1-19.

¹¹ Cl. PHM, para. 334.

¹² Opening Statement of Canada, May 30, 2016, pp. 277:13-279:20; Closing Statement of Canada, June 8, 2016, p. 2160:13-20.

Articles 1110 and 1105 must be based on an alleged denial of justice if the measure is viewed from one angle, but not from another. Claimant's position is self-contradictory.

11. Finally, Claimant's response is ultimately to a straw man argument, rather than to Canada's positions. Canada has never said that courts cannot breach any substantive rule of international law absent a denial of justice.¹³ But that is not the question in this case. Rather the question is: how do Articles 1110 and 1105 apply with respect to the decisions of neutral and independent courts adjudicating the rights of litigants? All NAFTA Parties agree on the answer: those specific Articles only protect against a denial of justice.¹⁴ As Canada explained at the hearing, this means that Articles 1110 and 1105 require that NAFTA Parties ensure that investments of investors of the other NAFTA Parties are able to have true and meaningful due process in front of a neutral and independent judiciary.¹⁵

12. There is no dispute between the parties here. Claimant had due process. It had a meaningful "day in court". Its claims were decided by a neutral and independent judiciary. It simply lost. Now, unhappy with the result, it seeks an appeal in this Tribunal. But this Tribunal is not a supra-national court of appeal. In the absence of an allegation of a denial of justice, Claimant has failed to state a legal claim that Canada has breached its obligations under Articles 1110 and 1105.

III. CLAIMANT'S CHALLENGE TO THE ALLEGED PROMISE UTILITY DOCTRINE IS TIME-BARRED

13. Even if the Tribunal were to decide that Claimant's claim is not manifestly without legal merit, its challenge to the alleged promise utility doctrine is time-barred pursuant to Articles 1116(2) and 1117(2). Claimant's arguments are plagued by contradictory assertions, inconsistent positions, and the inappropriate use of authorities.

¹³ See Canada's Closing Statement, June 8, 2016, pp. 2225:10-2226:1 and 2207:25-2208:9.

¹⁴ Resp. PHS, paras. 26-41 and 60-65.

¹⁵ Canada's Closing Statement, June 8, 2016, pp. 2205:11-2210:10; US Second Article 1128 submission, para. 5.

14. First, Claimant's assertion for the purposes of time bar that it is challenging the application of the promise utility doctrine to its patents for olanzapine and atomoxetine¹⁶ is inconsistent with how it presents its claims of breach of Articles 1110 and 1105. For example, Claimant's arguments that Canada's alleged promise utility is arbitrary and discriminatory in violation of Articles 1110 and 1105 are not based on how the alleged doctrine was applied to Claimant's atomoxetine and olanzapine patents. Indeed, many of the Canadian court decisions to which Claimant cites do not even involve Claimant's patents, let alone the specific patents Claimant alleges are at issue here. Claimant cannot have it both ways. It cannot on the one hand claim to be challenging the application of the doctrine to its patents in order to show that it satisfies the limitations period in NAFTA, and then on the other hand base its claims of breach not on the application of the doctrine to those patents but on the doctrine itself, which Claimant admits was crystallized in the decision with respect to its raloxifene patent in 2008 – a decision it did not challenge.

15. Second, contrary to what Claimant asserts, Article 21(3) of the UNCITRAL Arbitration Rules cannot give this Tribunal jurisdiction where none exists because of a claimant's failure to respect the limitations period in Articles 1116(2) and 1117(2). Claimant's reliance on the Federal Court's 2004 decision in the *S.D. Myers* set-aside motion¹⁷ and on the NAFTA tribunal's decision in *Feldman v. Mexico*¹⁸ is misplaced. Unlike here, where Canada raised its objection six months before the hearing, the Federal Court in *S.D. Myers* found as a matter of fact that no objection to jurisdiction was raised at all during the arbitration proceedings.¹⁹ Moreover, irrespective of that distinction, as a matter of principle, a treaty-based investor-State arbitral tribunal must assure itself that it has jurisdiction over the dispute based on the language of the governing treaty, not based on the conduct of the parties to the dispute.

¹⁶ Cl. PHM, para. 33.

¹⁷ Cl. PHM, para. 38.

¹⁸ Cl. PHM, FN 17.

¹⁹ *Canada (Attorney General) v. S.D. Myers, Inc.*, 2004 FC 38 ("*S.D. Myers*"), paras. 51-52 (C-1).

16. The decision in *Feldman* does not hold otherwise. In fact, Article 21(3) was not even an issue. The question in that case was whether Mexico would be estopped from raising a limitations defence because it allegedly gave the claimant assurances that the breaching measures would be rectified.²⁰ Further, the tribunal in *Feldman* actually held that anything short of “formal and authorized recognition” of a claim could only in exceptional circumstances estop a respondent State from raising a limitation defence.²¹ Claimant can point to no such formal and authorized recognition of its claim, or exceptional circumstances of the sort contemplated in *Feldman*, here. If anything, *Feldman* stands for the proposition that it takes more than merely failing to raise it in a Statement of Defence for a State to be estopped from raising a jurisdictional defence under Articles 1116(2) and 1117(2).

17. Finally, Claimant argues that Canada has offered no legal support for its position.²² It is Claimant’s burden to establish that the Tribunal has jurisdiction over the dispute. Moreover, the legal support for Canada’s position is clear from the plain meaning of Articles 1116(2) and 1117(2). Those Articles refer to “a loss” suffered by an investor, not to the specific loss an investor seeks to recover.²³ Canada’s position is also supported by numerous authorities holding that NAFTA does not permit a claim to be brought more than three years after it was first applied and caused loss merely because the State continues to apply the same measure to the investor.²⁴

18. Claimant’s challenge to the alleged promise utility doctrine itself is time-barred in light of the decisions of the Federal Court in relation to Claimant’s patent on raloxifene in 2008. The only claim that Claimant could bring is that the manner in which

²⁰ *Marvin Feldman v. Mexico*, ICSID Case No. ARB(AF)/99/1, Award, 16 December 2002 (“*Feldman Award*”), para. 53 (**RL-058**).

²¹ *Feldman Award*, para. 63 (**RL-058**).

²² Cl. PHM, paras. 32-44.

²³ Resp. PHS, para. 97; Respondent’s Rejoinder (“Resp. Rejoinder”), para. 76; Opening Statement of Canada, May 30, 2016, p. 260:13:18.

²⁴ Resp. PHS, paras. 97-105.

the doctrine was applied to its patents for olanzapine and atomoxetine constituted a denial of justice. It did not bring such a claim, and hence, this case must be dismissed.

IV. CANADIAN LAW HAS NOT DRAMATICALLY CHANGED SINCE 2002

19. Claimant accepts that, as a jurisdictional matter, it must show that there was a radical change in the Canadian courts' interpretation of the term "useful" in Canada's *Patent Act* after 2002.²⁵ The evidence shows that no such "sea change" in Canadian law has occurred.²⁶ The Tribunal should not accept Claimant's contradictory arguments, inconsistent treatment of the evidence, and attempt to "whitewash" the historical record.

20. First, Claimant's arguments in this part of its submissions are inconsistent with its submissions on other topics. Claimant has insisted in its submissions regarding denial of justice that it is not asking this Tribunal to act as an appellate court to determine the correctness of judicial decisions under Canadian law.²⁷ However, that is what Claimant asks the Tribunal to do in its submissions on change in Canadian law. Claimant asks this Tribunal to conclude that the Canadian courts erred in their interpretation and application of Canada's *Patent Act* and of their own precedents in decisions such as *AZT* in 2002, *Aventis*, *Pfizer* and *Bristol-Myers* in 2005, and *raloxifene* in 2008.²⁸ Claimant actually goes so far as to ask that the Tribunal find that each element of the alleged promise utility doctrine is a "complete and surprising reversal from prior [Canadian] law."²⁹ That is the role of an appellate court, not a Chapter Eleven tribunal. Claimant cannot explain this inherent contradiction in its arguments.

21. Second, Claimant asks the Tribunal to treat the existence or absence of evidence as notable in a transparently opportunistic and inconsistent manner. For example, it

²⁵ Cl. PHM, para. 1.

²⁶ See Resp. PHS, paras. 106-174.

²⁷ See, e.g., Cl. Reply, para. 334; Cl. Opening Statement, May 30, 2016, p. 148:16-18; Cl. PHM, Answer to Tribunal question 28.

²⁸ *AZT (R-004)*; *Bristol-Myers Squibb (C-520)*; *Pfizer (C-250)*; *Aventis (C-209)*; *Raloxifene FC (R-200)*.

²⁹ Cl. PHM, Answer to Tribunal question 29.

points to the absence of discussion or controversy with respect to utility in the WIPO context as evidence that Canada had a “traditional utility test” pre-2005.³⁰ But the evidence Claimant relies on to support this argument includes not only evidence from 2001 and 2003, but also evidence from 2013 and 2014.³¹ Claimant does not, and indeed, cannot, explain how evidence of no controversy five and six years after the raloxifene decision supports its allegation of a sea change in law in that decision. Further, Claimant cannot have it both ways. It cannot argue that the absence of controversy prior to 2005 shows that Canada had a “traditional utility test”, and that the same absence of controversy after 2005 confirms that Canada is now an outlier.

22. Similarly, Claimant points to the absence of internal legal advice it received on Canadian law on utility prior to 2002 as evidence of Canada’s “traditional utility” standard.³² However, Claimant has also submitted into the record no evidence of specific internal legal advice on Canada’s utility standard after 2002, and all of its witnesses confirmed that they had not received such advice.³³ Again, Claimant cannot have it both ways. It cannot point to the absence of legal advice prior to 2002 as evidence that Canada had what it calls a traditional legal standard, and then claim that the same absence of advice after 2002 is consistent with its arguments of a “sea change” in Canadian law.

23. Claimant’s statistical arguments suffer from similar inconsistencies. For example, its statistical analysis is based on a “pre-2005” and “post-2005” division. But that is inconsistent with its argument that the promise utility doctrine “crystallized” with raloxifene in 2008.³⁴ According to Claimant, only the doctrine as a “unitary whole” is relevant for its allegations of a Chapter Eleven breach.³⁵ Yet, Claimant never performed

³⁰ Cl. PHM, para. 174.

³¹ Cl. PHM, paras. 166-170, 173-174

³² Cl. PHM, para. 289.

³³ See Resp. PHS, paras. 170-171 and 269.

³⁴ Cl. Closing Statement, June 8, 2016, p. 1995:9-12.

³⁵ Cl. PHM, Answer to Tribunal question 27.

a statistical analysis based on a pre- and post-crystallization division.³⁶ Claimant's statistical evidence is also inconsistent with the evidence of Professor Siebrasse, who has testified and written that not all of the cases Claimant counts in its statistics are promise utility cases,³⁷ and that the first alleged application of the promise doctrine was not in January 2005, but in September 2005.³⁸ Correcting for these inconsistencies alone invalidates Claimant's statistical analysis. Claimant cannot have it both ways – it cannot describe the breach in one way, and then claim that the breach is evidenced by a statistical analysis that does not correspond with that description.

24. Third, Claimant misrepresents and ignores the relevant historical evidence with respect to all three aspects of the alleged promise utility doctrine. With respect to the promise standard of utility, Claimant tries to distract the Tribunal from the plain language used by the Supreme Court of Canada in 1982 in *Consolboard*. For example, Claimant strangely leads its arguments with the high-level and non-authoritative MOPOP guide.³⁹ Even Claimant's own witnesses admitted that the MOPOP, especially in past versions, does not always contain references to all relevant cases.⁴⁰ Claimant next misleadingly and inaccurately extracts individual comments from patent examiners on a draft version of MOPOP that is not even in the record.⁴¹ None of this changes what the Supreme Court said in *Consolboard*.

³⁶ See Resp. PHS, para. 162.

³⁷ See, e.g., Siebrasse, May 31, 2016, p. 550:20-25. Claimant acknowledged as much in its Post-Hearing Memorial at FN 201. The other case it attempts to argue is an application of the promise doctrine is inconsistent with its theory of breach as set out above.

³⁸ Siebrasse First Report, para. 72, FN 98; Siebrasse, May 31, 2016, pp. 561:10 – 562:1.

³⁹ Cl. PHM, paras. 50-68.

⁴⁰ Wilson, June 1, 2016, pp. 791:23 – 793:1 and 794:14 – 795:1. See also Resp. PHS, para. 134. Claimant ignores that *Consolboard* was in fact cited for utility in the 1996 and 1998 versions of MOPOP: Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice (October 1996) (Excerpts), s. 16.10 (C-55); Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 16 (March 1998) (Excerpts), s. 16.10 (C-57).

⁴¹ See Resp. PHS, paras. 136 and 271.

25. Equally telling of the weakness of Claimant's arguments is its reliance on Professor Siebrasse's interpretation of *Consolboard*. Claimant goes so far as to tout Professor Siebrasse as the "only scholar of Canadian law" to give evidence in this arbitration.⁴² More accurately, Professor Siebrasse is the only current Canadian law professor, who began examining Canadian patent law long after the relevant judicial decisions and even after Claimant commenced this arbitration, who gave *viva voce* evidence.⁴³ Professor Siebrasse identified only one other current Canadian law scholar, Professor Gold, as writing on the alleged promise utility doctrine, a dearth of interest which is itself good evidence that there has been no sea change in Canadian law. Further, as Professor Siebrasse acknowledged, Professor Gold disagrees with his analysis.⁴⁴ Moreover, the Tribunal has evidence on the record from Canadian patent law practitioners and scholars who actually worked, studied, and practiced Canadian patent law during the relevant period, including Dr. Fox, Mr. Hayhurst, Mr. Henderson, Mr. Hill, and Mr. MacOdrum.⁴⁵ It also has the evidence of Mr. Dimock, who worked as one of the Canadian lawyers on the *Consolboard* case.⁴⁶ Professor Siebrasse's recent, post-hoc opinion on how to read *Consolboard* is insufficient to make Claimant's case, especially in light of the historical authority to the contrary.

26. Claimant also inappropriately attempts to narrow the historical record. It asks the Tribunal to look only at cases where a patent was invalidated on the basis of a promised utility found in the disclosure. This approach suffers from three fatal flaws. First, the fact that a patent's utility was upheld on the promise standard, or that a promise was found but was not dispositive, is not evidence that the standard does not exist as a matter of

⁴² Cl. PHM, para. 14 [emphasis in original].

⁴³ Siebrasse, May 31, 2016, p. 546:3-14.

⁴⁴ Siebrasse, May 31, 2016, p. 762:8-763:10; see E. Richard Gold and Michael Shortt, The Promise of the Patent in Canada and Around the World, 30:1 Canadian Intellectual Property Law Review 35, June 2014, (RL-050)

⁴⁵ See Resp. PHS, para. 124.

⁴⁶ Dimock, June 2, 2016, pp. 1028:24-1029:4.

law.⁴⁷ Second, there were in fact early cases in which a promise was found in the disclosure.⁴⁸ Third, the fact that, in many instances, a promise is found in the claims, is not evidence of the absence of a broader principle that patentees will be held to their promises in the entire specification as *Consolboard* says. To the contrary, the promise analysis is, and always has been, based on a construction of the patent as a whole.⁴⁹

27. With respect to the post-filing evidence rule, Claimant's position is similarly riddled with inconsistencies. Claimant alleges that this rule was articulated for the first time in the 2002 Supreme Court decision in *AZT*,⁵⁰ and as noted above, asks that the Tribunal find this rule to be a "complete and surprising reversal"⁵¹ of prior Canadian law. In fact, it asks the Tribunal to proclaim that the Supreme Court of Canada was wrong in interpreting what the *Patent Act* required to establish utility, was wrong about the real holding in *Ciba-Geigy*, and was wrong about the relationship between the utility requirement and inventorship. Leaving aside the improper nature of such a request, Claimant offers no explanation as to why, if its current claims are true, it did not even consider *AZT* to form part of the alleged promise utility doctrine at the outset of this arbitration, a decade after *AZT* was decided.⁵² Moreover, it offers no explanation of how it can make its claims while simultaneously arguing in its submission that Canada's utility requirement was "uncontroversial" until 2005, three years after *AZT* was decided.⁵³ Nor does it explain why, if it is correct as to the nature of the Supreme

⁴⁷ Mr. Dimock's timeline of historical authority shows that there are a number of older cases where the courts: (1) held patentees to promises in the patent – *New Process Screw (R-384)*, *Consolboard (R-359)*, *Wellcome (R-397)*, *Hoechst (R-379)*, and *Mobil (R-165)*; (2) looked for a promise but did not find one – *Corning Glass (R-375)*; (3) applied a promise approach under the label of overbreadth – *Amfac (R-168)*; (4) expressly stated the promise standard but did not find it necessary to apply it on the facts – *Consolboard (R-359)*, *Metalliflex (R-009)*, *Feherguard (R-360)*, *Almecon (C-230)*, *Goldfarb (R-187)*; and (5) did not reject arguments on promise made by counsel as being unfounded in law – *Unilever (R-172)*, *TRW (R-376)*.

⁴⁸ See, e.g., *New Process Screw (R-384)*; *Consolboard (R-359)*; *Wellcome (R-397)*; *Hoechst (R-379)*.

⁴⁹ See, e.g., Resp. PHS, paras. 125 and 130.

⁵⁰ Claimant's Memorial, para. 70; Cl. PHM, Answer to Tribunal question 9.

⁵¹ Cl. PHM, Answer to Tribunal question 29.

⁵² See Resp. PHS, FN 585.

⁵³ Cl. PHM, para. 157.

Court's decision in *AZT*, its own expert, Professor Siebrasse, had never, prior to his retention by Claimant, criticized the post-filing evidence rule in *AZT*,⁵⁴ and in fact still agrees that the *AZT* rule pursues the longstanding objectives of the utility requirement.⁵⁵ As Canada has explained, the evidence compels the conclusion that Canadian law has never allowed a patentee to file now and invent later.⁵⁶

28. Finally, with respect to what patentees must disclose when relying on sound prediction, not only are Claimant's arguments inaccurate,⁵⁷ they are irrelevant here. The thrust of Claimant's argument now seems to acknowledge that a disclosure requirement always existed in Canadian law. It claims that the 2008 raloxifene decision changed how much disclosure is required in a patent to support a sound prediction of utility.⁵⁸ Claimant fails to recognize that this change, even if it did occur (and it did not), is irrelevant in the context of Claimant's patents for olanzapine and atomoxetine. With respect to olanzapine, the disclosure rule was not applied – nor would it have mattered because that patent disclosed everything upon which it relied.⁵⁹ With respect to atomoxetine, the alleged change is irrelevant because Claimant disclosed nothing at all.⁶⁰ There has never been a case in Canadian law in which a sound prediction was upheld in the absence of any disclosure of a factual basis for the prediction in the patent.⁶¹ The invalidation of the atomoxetine patent is fully consistent with the earlier authorities.

⁵⁴ Siebrasse, June 1, 2016, pp. 676:19-677:5.

⁵⁵ Siebrasse, June 1, 2016, pp. 659:21-24, 665:19-22 and 665:24-666:5. *See also* Resp. PHS, para. 141.

⁵⁶ Resp. PHS, paras. 137-146.

⁵⁷ *See* Resp. PHS, paras. 151-158. Claimant also mischaracterizes Dr. Gillen's testimony from the hearing.

⁵⁸ *See, e.g.*, Cl. PHM, para. 115.

⁵⁹ Cl. PHM, para. 76.

⁶⁰ *See* Resp. PHS, paras. 159-160. Notably, Claimant confirmed the lack of consistency in its filing practices in its Post-Hearing Memorial, *compare e.g.* paras. 76 and 308.

⁶¹ Siebrasse, June 1, 2016, p. 700:5-11.

V. THE INVALIDATION OF CLAIMANT’S PATENTS DID NOT BREACH CANADA’S OBLIGATIONS UNDER ARTICLES 1110 OR 1105

29. Even if Claimant’s allegations of a breach of Articles 1110 and 1105 absent a denial of justice are not manifestly without legal merit, and even if a claim challenging the promise utility doctrine is not time-barred, and even if there has been a dramatic change in Canadian law since 2002, Claimant has not proved a breach of Articles 1110 and 1105. Claimant’s allegations in support of its claims are rife with inconsistencies, rely on mischaracterization of Canada’s arguments, and misrepresent the relevant facts.

A. Claimant Has Not Proved a Breach of Article 1110

30. Article 1110 does not apply to a determination by a neutral and independent judiciary that property rights do not exist at domestic law absent a denial of justice.⁶² Such decisions do not take property, they determine that there was no property to take.⁶³ The NAFTA Parties agree that this is the proper interpretation of Article 1110.⁶⁴

31. Claimant continues to reject this simple proposition. It argues that NAFTA Article 1110 “does not create any special rules for judicial measures.”⁶⁵ However, in explaining how the Canadian courts breached Article 1110, Claimant contradicts itself, and urges the Tribunal to adopt precisely such a special rule. Claimant argues that “a judicial measure is expropriatory when it substantially deprives an investment of value while violating a rule of international law.”⁶⁶ Canada has explained at length why Claimant has failed to demonstrate that this special rule exists,⁶⁷ but Claimant’s arguments should also be rejected because they are inconsistent with each other.

⁶² See Resp. PHS, paras. 26-41.

⁶³ See Resp. PHS, paras. 176-178.

⁶⁴ See Resp. PHS, paras. 27 and 177.

⁶⁵ Cl. PHM, Answer to Tribunal question 13; Claimant’s Opening Statement, May 30, 2016, p. 105:9-11.

⁶⁶ See, e.g., Cl. PHM, p. 110 (heading IV.B.3.a), paras. 221, 235 and 272, Answers to Tribunal questions 20 and 23.

⁶⁷ Resp. PHS, paras. 28-41.

32. Further, when describing the substantive rule of international law that it alleges has been breached, Claimant's arguments become more inconsistent. It claims that the relevant substantive rule of international law in this case is found in Chapter Seventeen. It then argues that Canada has been in breach of its obligations under Chapter Seventeen "since 2005" through the promise utility doctrine.⁶⁸ However, in other parts of its submissions, it makes clear that the promise utility doctrine did not crystallize until 2008 when the final component (disclosure) was adopted, and that it is only the doctrine as a whole, not its individual parts, that amounts to a breach of Chapter Eleven.⁶⁹ Claimant's position on when the alleged breach occurred in this case is inherently contradictory.

33. Finally, the evidence and argument compel the conclusion that Canada is not in breach of its obligations under Chapter Seventeen. As an initial matter, Canada notes that Claimant has relegated its Article 1701(1) arguments to footnotes in its Post-Hearing Memorial.⁷⁰ Further, Claimant's arguments with respect to Article 1709(1) can do nothing more than attempt to knock down a straw man. Canada has never argued that Article 1709(1) is not an obligation "at all"⁷¹ or that Canada has "unfettered discretion to interpret 'useful'."⁷² Canada's position is that this Tribunal need not pronounce a universal and comprehensive definition for a term the NAFTA Parties left undefined. In fact, the Tribunal need answer only one question: has Claimant established that Canada's promise standard is not within the meaning of "useful" as that term is found in Article 1709(1)? As Canada has shown, Claimant has not.⁷³

34. Claimant's attempts to show otherwise fail. For example, its attempt to portray Canada as an outlier misrepresents U.S. and Mexican law as being wholly indifferent to the issues that the Canadian courts address under the heading of utility. In doing so,

⁶⁸ Cl. PHM, Answer to Tribunal question 9.

⁶⁹ Cl. PHM, Answer to Tribunal questions 11, 27 and 29.

⁷⁰ Cl. PHM, FNS 380 and 440.

⁷¹ See Cl. PHM, paras. 237 and 254.

⁷² See Cl. PHM, paras. 237, 242 and 251. Compare Resp. PHS, paras. 189-191.

⁷³ See Resp. PHS, paras. 183-221.

Claimant disregards judicial decisions that have had major effects on existing patents in the United States⁷⁴ and ignores actual legislative changes in Mexico in favour of focusing on rejected legislative proposals.⁷⁵ For example, the strictness with which utility has been applied by U.S. Courts has fluctuated and several decisions (including *Rasmussen* and *In re '318*) demonstrate that even valuable and successful patents can be invalidated many years after they were issued because the evidence in support was obtained after the filing date and was consequently too late.⁷⁶ Claimant also inappropriately focuses exclusively on the utility criterion to compare litigation outcomes,⁷⁷ when a proper comparison across jurisdictions takes into account both its interaction with other patentability requirements and divergences in factual contexts.⁷⁸

B. Claimant Has Not Proved a Breach of Article 1105

35. Claimant continues to disagree with the relevant authorities and with the NAFTA Parties that the customary international law minimum standard of treatment only protects against judicial measures that amount to a denial of justice. It alleges that the customary international law minimum standard of treatment also obligates Canada to ensure that the patent law decisions of its courts are not discriminatory with respect to pharmaceutical products, arbitrary or contrary to Claimant's legitimate expectations. Its Post-Hearing Memorial betrays how baseless its claims are both as a matter of law, and as a matter of fact.

36. With respect to its discrimination claim, Claimant has not pointed to a single instance of state practice or *opinio juris* supporting the existence of a rule of customary international law that prohibits discrimination against a particular field of technology in

⁷⁴ See, e.g., *In re Brana*, 51 F.3d (R-073); *In re Fisher*, 421 F.3d 1365 (Fed Cir 2005) (R-064); *Rasmussen v. SmithKline Beecham Corp.*, 413 F.3d 1318, (Fed Cir 2005) (R-063); *In re '318 Patent Infringement Litigation*, 583 F.3d 1317 (Fed Cir 2009) (R-054).

⁷⁵ Cl. PHM, paras. 23 and 143.

⁷⁶ Robert Patrick Merges and John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials*, (LexisNexis, 6th ed. 2013), p. 213 (R-056).

⁷⁷ Cl. PHM, paras. 144-146; Kunin, June 3, 2016, p. 1428:3-16.

⁷⁸ See Resp. PHS, paras.199-200 and 217-221.

patent law. Claimant's references to an arbitral award in a case involving Venezuela under a different treaty,⁷⁹ and to separate obligations in a different chapter of NAFTA,⁸⁰ are simply irrelevant. Neither concerns whether customary international law prohibits the type of discrimination Claimant alleges.

37. In an apparent recognition of the likely failure of its field of technology discrimination claim,⁸¹ Claimant resorts to asserting that the promise utility doctrine also discriminates "in favor of a prominent domestic [generic pharmaceutical] industry at the expense of foreign [brand pharmaceutical] patent holders."⁸² Not only does customary international law generally not prohibit nationality-based discrimination,⁸³ Claimant has not meaningfully attempted to provide evidence to support such a claim. In fact, Claimant dropped its Article 1102 nationality-based discrimination claim.⁸⁴ Further, as Canada pointed out in its Counter-Memorial, there is no nationality-based line between generic and brand pharmaceuticals.⁸⁵ As Claimant's own expert Mr. Reddon explained, the lines between "generic" and "brand" pharmaceutical companies are not always clear cut, and patent cases are sometimes fought between brand pharmaceutical companies.⁸⁶

38. With respect to its arbitrariness claim, Claimant has not established that what it describes as arbitrary conduct is prohibited by Article 1105.⁸⁷ Moreover, it has not established as a matter of fact that the judicial decisions with respect to olanzapine and atomoxetine, which it admits simply followed binding precedent, even meet its own

⁷⁹ Cl. PHM, para. 319.

⁸⁰ Cl. PHM, para. 320.

⁸¹ See Resp. PHS, paras. 222-229. Claimant continues to maintain that "none of Canada's proposed changes to Professor Levin's data set had a material effect on his findings": Cl. PHM, para. 259. Dr. Brisebois' evidence shows the opposite. See Brisebois Second Statement, paras. 2-26; Brisebois Errata and Updates, May 25, 2016, pp. 2-3.

⁸² Cl. PHM, para. 321.

⁸³ See Resp. PHS, para. 56.

⁸⁴ Compare Claimant's Notice of Intent, paras. 116-118, with Notice of Arbitration, paras 73-84.

⁸⁵ Resp. CM, para. 264.

⁸⁶ Reddon, June 1, 2016, pp. 852:15-854:9.

⁸⁷ Resp. PHS, paras. 57-58.

definition of arbitrary conduct. Tellingly, Claimant relegates its discussion of those court decisions to the very end of its submissions in this section.⁸⁸ It then characterizes those specific decisions as merely illustrating the arbitrary nature of the doctrine, rather than being arbitrary in and of themselves.⁸⁹ This is inconsistent with its claim that it is challenging those specific decisions here.

39. Further, Claimant's argument that the requirement to establish utility at the time of filing has "had apparently unintended consequences" relies on a mischaracterization of the Supreme Court's discussion of a hypothetical patent for the Wright brothers' airplane.⁹⁰ Claimant's argument, like Glaxo/Wellcome's in *AZT*, "presupposes that the date to establish utility is the state of knowledge when the patent is attacked."⁹¹ The Supreme Court rejected this view as consistent neither with the *Patent Act* nor with patent policy.⁹² Claimant improperly asks this Tribunal to determine that the Supreme Court of Canada got Canadian law wrong. The Tribunal cannot do so.

40. Claimant also argues that liability attaches under Article 1105 if a judicial decision is "unpredictable, incoherent, and totally irrational".⁹³ Its allegation that the court decisions at issue here were devoid of all rationality simply cannot be sustained. In arguing that the outcomes of the atomoxetine and olanzapine cases demonstrate the arbitrariness of the "promise utility doctrine's application" to those patents, Claimant once again asks this Tribunal to decide that the Canadian courts reached the wrong result as both a matter of fact and of Canadian law. The Tribunal cannot do so.

⁸⁸ See Cl. PHM, paras. 295-309 (discussion of olanzapine and atomoxetine at paras. 307-309).

⁸⁹ Cl. PHM, para. 307.

⁹⁰ Cl. PHM, para. 302.

⁹¹ *AZT*, para. 78 (**R-004**).

⁹² *AZT*, para. 80 (**R-004**).

⁹³ Cl. PHM, Answer to Tribunal question 28.

41. Claimant also argues that the promise utility doctrine is arbitrary because it lacks a policy rationale and “does not produce consistent results.”⁹⁴ Claimant’s argument rests on the faulty premise that assessing utility is like applying a mathematical formula – the result should always be the same. However, patent cases are intensely fact-specific,⁹⁵ and reasonable people can disagree.⁹⁶ The internal CIPO wiki document Claimant points to highlights this reality.⁹⁷ Reasonable disagreement as to facts is evidence neither of arbitrary outcomes nor of an arbitrary doctrine.⁹⁸

42. Finally, while acknowledging that the utility requirement exists to prevent speculative patenting,⁹⁹ Claimant argues that the rationale does not extend to the pharmaceutical sector apparently because Canada has not shown Claimant’s specific patents to be speculative.¹⁰⁰ Canada has never argued that the rationale underlying the utility requirement in Canada is tied specifically to Claimant’s patents. To the contrary, one need look no further than the Supreme Court of Canada’s decision in *AZT* to understand that the rationale applies to all kinds of patents, including new uses of known chemical compounds.¹⁰¹ Claimant’s arguments to the contrary are not credible.

43. With respect to Claimant’s legitimate expectations claim, Claimant has again failed to establish that the customary international law minimum standard of treatment protects an investor’s expectations. Further, its proposed distinction between the “clarification of previously unsettled law” and the “adoption of a completely new doctrine in a well-settled area”¹⁰² is inconsistent with its assertion that it is challenging

⁹⁴ Cl. PHM, para. 310.

⁹⁵ See, e.g., Cl. PHM, para. 76.

⁹⁶ See Resp. PHS, paras. 207, 228, 241 and 252.

⁹⁷ See, e.g., Cl. PHM, para. 66.

⁹⁸ See Resp. PHS, para 241; Holbrook, June 3, 2016, pp. 1534:18-1535:8.

⁹⁹ Cl. PHM, para. 314.

¹⁰⁰ Cl. PHM, paras. 314-317.

¹⁰¹ *AZT*, paras. 52 and 56 (**R-004**); Resp. PHS, para. 255.

¹⁰² Cl. PHM, para. 279.

only the application of the promise utility doctrine to its olanzapine and atomoxetine patents. Claimant admits those decisions did not adopt a new doctrine, but merely applied settled law. Moreover, in making its arguments, Claimant is doing nothing more than arguing that the domestic courts got “well-settled” domestic law wrong. It also argues, based on Mr. Armitage’s testimony, for this Tribunal to correct what it views as factual errors by the Canadian courts.¹⁰³ This Tribunal cannot review Canadian court decisions for errors of law or fact.

44. Claimant also asks the Tribunal to find it “notable” for its legitimate expectations claim that Lilly received no specific advice on Canadian utility law prior to 2002.¹⁰⁴ However, it then inconsistently asks the Tribunal to completely ignore the same absence of specific advice with respect to Canadian utility law in the period following 2002. Claimant cannot have it both ways. If an absence of advice is notable to show that Canadian law was as Claimant expected it to be prior to 2002, the same absence of advice after 2002 should also be considered notable to show that Canadian law continued to be as Claimant expected it to be after 2002.

VI. REQUEST FOR RELIEF

45. For all of the above reasons, Canada respectfully asks the Arbitral Tribunal to issue an order dismissing this claim in its entirety and granting the relief Canada has previously requested.

¹⁰³ Cl. PHM, para. 291.

¹⁰⁴ Cl. PHM, para. 289.

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Respectfully submitted

[signed]

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