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

COUNTER MEMORIAL

January 27, 2015

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CANADA

COUNTER MEMORIAL

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I. PRELIMINARY STATEMENT

1. Through this arbitration Eli Lilly and Company ("Claimant" or "Lilly") attempts to re-litigate two Federal Court proceedings that determined that atomoxetine and olanzapine patents held by Claimant were invalid under Canadian law.[1] These decisions were the outcome of two lengthy trials during which Claimant had ample opportunity to present extensive factual evidence, witness and expert testimony and legal arguments in favour of its claim to valid patents. The Federal Court, having thoroughly examined the facts and applying precedents based upon long-standing principles of Canadian patent law, did not agree with Claimant's position. Both judgments were ultimately upheld by the Federal Court of Appeal. The Supreme Court of Canada declined to review either ruling. There can be no doubt that Canada's courts fulfilled their duty to rule on patent disputes in accordance with Canadian law, with full due process given to the disputing parties.

2. Claimant believes that NAFTA allows this Tribunal to act as court of *de novo* review from these two reasoned and procedurally just decisions of Canada's Federal Court interpreting and applying Canadian law. Claimant believes that its own views of what Canadian patent law provides and its self-serving position on what NAFTA requires with respect to "utility" gives it the right to assail the reasoning of Canada's federal judiciary as "profoundly arbitrary" and "illogical and absurd."[2]

3. It is Claimant that is profoundly wrong. Nothing in these judgments offends any of Canada's obligations under NAFTA. Claimant's Memorial is rife with misrepresentations about Canadian patent law and misstatements of Canada's NAFTA obligations under Chapters Eleven and Seventeen and of international law generally.

[1] As in the Statement of Defence, Canada refers throughout to Claimant's two patents by the chemical compounds which they sought to monopolize, *i.e.* olanzapine and atomoxetine, as opposed to Claimant's brand-name drug products using these same compounds, *i.e.* Zyprexa (active ingredient olanzapine) and Strattera (active ingredient atomoxetine).

[2] Claimant's Memorial, paras. 8 and 258.

Nothing in Claimant's Memorial comes even close to establishing a breach of NAFTA. This Tribunal should reject this claim and award full costs to Canada.

4. There is no dispute that the court proceedings at issue, which are described in Part II.A below, were conducted fairly, and afforded Claimant full due process. Claimant's complaint is that, in its view, the Federal Court "promulgated" a "new" "promise doctrine" which did not comport with its "expectations" of how the concept of "utility" in the *Patent Act* would be interpreted and applied to its atomoxetine and olanzapine patents. The judgments also allegedly failed to reflect Claimant's understanding of what NAFTA Chapter Seventeen and the Patent Cooperation Treaty ("PCT") require.

5. This Tribunal only has jurisdiction to rule on alleged violations of Chapter Eleven obligations. In any event, this Counter-Memorial will demonstrate that Claimant's alleged "expectations" and its interpretation of both Canadian law and what is required by NAFTA Chapter Seventeen and the PCT are all unfounded.

6. As set out in Part II.B below, every inventor seeking a patent in Canada is well aware (because the *Patent Act* makes this clear) that the decision of the Patent Office to grant a patent is always subject to review by the Federal Court for actual compliance with the *Patent Act*. No reasonable patentee expects the grant of a patent (which is done on the basis of a limited record and presumptions in favour of patentees) to be unassailable. In Canada, as in the United States, the United Kingdom and other jurisdictions, courts regularly correct Patent Office grants, including by invalidating the grant altogether when litigation reveals a latent invalidity – that is, the courts confirm that the patent never complied with the *Patent Act* in the first place.

7. Part II.C of this Counter-Memorial corrects Claimant's misleading account of Canadian law with respect to an invention's "utility." What Claimant alleges to be an extra-statutory creation of Canadian courts as of 2005 is, in reality, a series of distinct doctrines, each of them principled, rational, based upon statutory requirements, and with

deep roots in Canadian law. Claimant calls in question a series of specific rules regarding the interpretation of patents, regarding the type and timing of evidence that may be relied upon, and upon the nature of disclosure required, complaints going far beyond the mere threshold of "utility" received under Canada's *Patent Act*. Claimant ignores the policy impetus for such rules. These rules are intended to ensure that patentees provide the consideration they promised in exchange for the grant of a 20-year monopoly. They seek to ensure that patents are filed on the basis of true invention, rather than of speculation. They verify that disclosure obligations in the patent, which is the basis for the "patent bargain" with the public, are fulfilled. These rules are fundamental to the integrity of the patent system. That Canada should seek to uphold such rules in the administration of its domestic patent system is as legitimate and lawful as it is unsurprising.

8. The application of such rules has not resulted in any "systemic discrimination" against Claimant, or against participants in the patent system more generally. As set out in Part II.D below, Claimant's statistics, suggesting that Canada's "new" utility criteria has led to a surge in pharmaceutical patent invalidation rates since 2005, are misleading. Claimant fails to acknowledge that enhancements in pharmaceutical patent-holders' substantive and procedural rights in the 1990s led to a dramatic increase in patent litigation that was unique to this sector. Despite this, the proportion of overall patent invalidations has not changed in the referenced period, and challenges on the basis of utility since 2005 have typically been unsuccessful. Most cases Claimant relies upon simply denied patent holder's attempts pre-emptively to exclude competitors from the pharmaceutical market, leaving the patents at issue valid and the patent holder free to pursue infringements proceedings. Out of hundreds of patent challenges in the 2005-2014 period, only three pharmaceutical patents have been invalidated on the sole basis of lack of "utility," two of which are Claimant's atomoxetine and olanzapine patents which are the subject of this arbitration. Claimant concocts a systemic problem that does not exist.

9. Indeed, Claimant's own patenting behaviour demonstrates the rationality of Canadian rules. As described in Part II.E, as of the 1990s Claimant filed over two dozen of patents for different "uses" of olanzapine and atomoxetine, only to abandon virtually all of these applications either during prosecution or post-grant. Close study of these patent applications suggests that they were filed when Claimant had little or no basis to claim the alleged new uses. This suggests Claimant's patent applications were filed to monopolize whole areas of research and potential innovation, in advance of any adequate basis for its claims. Regardless of its intentions, Claimant's patent filing practice had the effect of diminishing rather than increasing innovation, by discouraging competing research efforts in this same sector. Canadian patent law rules exist to check such behaviour, linking patent validity to the existence of a sound prediction of promised utility of inventions at filing, and proper disclosure of the basis of such predicted utility.

10. Claimant's argument that its patents should have been declared valid because its drug products using olanzapine and atomoxetine later received Health Canada approval is a red herring. As set out in Part II.F, Health Canada's approval of related drug products years after Lilly's patent filings, on the basis of altogether different scientific evidence, is irrelevant for purposes of determining whether Claimant had sufficient grounds to claim a patent monopoly at the time it filed. Patents are granted in Canada (as in most other jurisdictions) on the basis of invention, not on the basis of speculation. Moreover, Claimant's touting of the research it had performed prior to filing its patents, suggesting it was later used by Health Canada to approve its drug products, is groundless. Given its preliminary and inconclusive nature, the research Claimant had in fact conducted as at the time of its patent filings, and on which it based its patent claims, was immaterial to Health Canada's subsequent approval.

11. As stated in Part II.G, Claimant's references to the contents of U.S. law also fail to assist its claim. Claimant cites to the U.S. utility standard – which it portrays as low – as confirmation of the low "utility" threshold the Parties allegedly "enshrined" in NAFTA. Yet Claimant's portrayal of U.S. law misleads. U.S. law on utility is more

nuanced and stringent than Claimant suggests, particularly for pharmaceutical inventions. Claimant also fails to acknowledge that U.S. law reaches many of the same results as do Canada's utility rules, through its analogous "enablement" and "written description" requirements. To be properly compared, legal systems must be considered as a whole. Moreover, Claimant's portrayal of U.S. patent law as fixed and unchanging post-NAFTA is belied by the significant and often dramatic evolution of substantive U.S. patent law since 1994, changes effected through the interpretative power of U.S. courts.

12. Claimant's reference to Mexican law is equally unsound. As Part II.H shows, Claimant awkwardly asserts substantive harmonization on the "utility" standard between the NAFTA Parties, despite that Mexico continues to apply a different and alternative technical criterion, "industrial applicability", in the post-NAFTA period. Moreover, Claimant understates the significance of "industrial applicability" in Mexican law, and again fails to acknowledge how this criterion interacts with other legal tests. Claimant also glosses over substantial reforms to Mexican substantive law post-NAFTA – specifically addressing the issue of speculative patent filings, in 2010 – again contradicting the notion that the Parties "enshrined" any fixed, low definition of either "utility" or "industrial applicability" in NAFTA Chapter Seventeen.

13. Nor does Claimant find any support in other international treaties, including the *Agreement on Trade-Related Aspects of Intellectual Property Rights* ("TRIPS") and the PCT. To the contrary, as described in Part II.I, it is notorious that there has been no international harmonization of substantive patent law and in particular with respect to establishing the utility of a patent. Nothing in the NAFTA or TRIPS requires Canadian courts to adopt the interpretation of utility Claimant advocates. For its part the PCT (addressed in Part II.J) is irrelevant, as it does not deal with substantive patent law issues at all.

14. In all of these circumstances, Claimant's allegations of a NAFTA Chapter Eleven breach are not made out.

15. Article 1105(1) requires the NAFTA Parties to afford investors the minimum standard of treatment of aliens in customary international law. Canada complied with that obligation. As set out in Part IV below, nothing in the record even remotely resembles the type of egregious behaviour which past NAFTA tribunals have said must be evident in order to breach Article 1105(1). And since this Tribunal cannot act as a court of appeal to the domestic law decisions of Canada's Federal Courts, the only basis in customary international law to impugn the reasoning of domestic courts interpreting domestic law is to prove a denial of justice. Nothing of the sort occurred here. Nor are any of Claimant's allegations of alleged "arbitrary" or "discriminatory" rulings made out. Claimant merely redefines these notions to mean judgments with which it disagrees.

16. Claimant tries to elevate the standard of treatment owed under NAFTA Article 1105(1) by arguing that Canadian court decisions violated its "legitimate expectations" regarding the interpretation and application of Canadian patent law. Even if enforcement of "expectations" were a rule of customary international law (it is not), or applicable with respect to judgments rendered by domestic courts acting in their *bona fide* adjudicative function of domestic statutory interpretation (it is not), Claimant could not have had the expectations it claims. It was fully aware that its patents were granted contingent upon further review by the Federal Court, which could reveal latent defects in the patent grant through its full adversarial process. Claimant could not reasonably expect Canadian courts to ignore longstanding principles and rules of Canadian law, whether or not Claimant itself was properly advised in this regard. Claimant could not reasonably expect Canadian courts to apply some purported "harmonized" approach to utility, when efforts at such harmonization have all notoriously failed, nor *a fortiori* that they would apply U.S. patent law rules.

17. As set out in Part V below, there has also been no expropriation under NAFTA Article 1110. In order to apply the customary international law of expropriation, which is encapsulated by Article 1110, an international tribunal must first consider whether a property right exists at all under the applicable domestic law. When a domestic court has

determined through the good faith application of domestic law that a property right is invalid, the expropriation analysis has nowhere to go: there is no "taking" of a property right which did not properly exist in the first place. Judicial decisions can only be treated as an "expropriation" where the decision itself amounted to a denial of justice. Mere disagreement with the court's decision is not an expropriation under customary international law.

18. Application of Article 1110(7) leads to the same result. Chapter Seventeen, like the TRIPS, requires the NAFTA Parties to have a patent system. It lists (but does not define) basic criteria of patentability. Claimant seeks to impose upon one of these criteria – that of "utility" – a specific, self-serving and radically restrictive definition, one which it fails to establish, and which contradicts the plain and ordinary meaning of this term. It is notorious that technical patent law terms such as "utility" are not internationally harmonized. The plain and ordinary meaning of patent criteria such as "utility", when stated but left undefined in a treaty, is that the Parties are free to adopt at their election one of the range of national technical approaches to this specialised criterion, in accordance with the requirements and policies of their respective patent laws. Canada's approach to "utility" is simply one of several internationally-acknowledged approaches, and is fully consistent with Chapter Seventeen. That Chapter otherwise calls on the Parties to have in place functional judicial systems, through which issues concerning patent rights can fairly be determined. That is precisely what Canada has provided: a patent system which judges patentability on, *inter alia*, the "utility" criterion, as interpreted and applied in Canada, and where Claimant was granted full due process before specialised courts. As such, applying the express terms of NAFTA, Article 1110 does not even apply to this case.

19. Even if this conclusion was ignored and the Tribunal decided to apply Article 1110 to these court decisions, there would still be no expropriation. Certainly a court decision declaring a patent invalid is not a "direct" taking, as there is no transfer of property, but rather a recognition that no property exists. Analysis of the measure as an "indirect" expropriation also fails. Claimant's investment in Canada was and remains a

complex assemblage of real and personal property, including intellectual property, through which it pursues business in Canada. Despite the invalidation of Claimant's patents, it continues to enjoy its investment in Canada, including substantial profits from the sales of its drug products "Zyprexa" and "Strattera." Even if the law of expropriation treated court decisions as a "taking" (which it does not), there has been no "substantial taking" of Claimant's overall investment in Canada, and therefore no indirect expropriation.

20. Together with this Counter-Memorial, Canada submits the following expert reports and witness statements:

- the expert report of Mr. Ronald Dimock, one of Canada's most senior and experienced patent litigators. Mr. Dimock contests Claimant's flawed account of Canadian patent law. He describes Canadian law regarding the "utility" of an invention as deeply-rooted in longstanding principles that would have been known to Claimant at the time that it filed its patents and were fairly applied by the courts in the two patent cases at issue;

- the witness statement of Dr. Michael Gillen, former Chair of the Canadian Intellectual Property Office ("CIPO") Patent Appeal Board. Dr. Gillen explains that Patent Office review of patent applications is conducted on a time-limited basis with a limited record and making several assumptions in favour of the patentee. Its Manual of Patent Office Practice is a general guide that on its express terms is non-binding. The Federal Court is the ultimate arbiter of the validity of all patent grants. In any event, Dr. Gillen confirms that current Federal Court interpretations of the "utility" criteria are consistent with Patent Office practice at the time Claimant's patents were filed;

- the witness statement of Ms. Kimby Barton, Director, Bureau of Cardiology, Allergy and Neurological Sciences of the Therapeutic Products Directorate of

Health Canada. As her evidence shows, Health Canada's determination to approve a drug as safe for human use in Canada is irrelevant to the validity of Claimant's patent applications: Health Canada approvals are based upon different, later, and far more extensive research than Claimant relied upon when filing its patents. Responding to Claimant's attempt to exaggerate the state of its research at the time it filed its patents (an issue already fully addressed by Canadian courts), Ms. Barton confirms that the studies Claimant disclosed in its patent applications (or for atomoxetine, had performed but not disclosed in the patent), played no part in Health Canada's ultimate approval of Claimant's drug products.

- the witness statement of Dr. Marcel Brisebois, a senior examiner at the Canadian Intellectual Property Office, and currently senior policy analyst in the Strategic Policy Sector of Industry Canada. Dr. Brisebois corrects Claimant's misleading account of patent invalidation rates before Canadian courts. Dr. Brisebois also describes his investigation of Claimant's historic patent filing behaviour. His analysis reveals that the two patents at issue in this matter were among dozens Claimant applied for in a scattershot manner, for a broad range of alleged "new uses" of these two compounds. Claimant abandoned virtually all of these applications, either during prosecution or following the patent grant. Its behaviour reflects speculative patent filing, precisely what Canada's utility rules seek to discourage.

- the expert report of Professor Timothy Holbrook of Emory University, a leading expert on U.S patent law. Professor Holbrook describes how Claimant misstates the content of U.S law on utility and fails to note how U.S. patent law adopts analogous rules under related "enablement" and "written description" of the invention, making comparisons based upon the sole utility criteria misleading. He describes how interpretation of substantive patentability criteria has and continues to fluctuate substantially

under U.S. law since NAFTA, including in a manner that has led to the invalidation of thousands of previously-granted patents;

- the expert report of Ms. Heidi Lindner, a senior member of the Mexican patent bar. Ms. Lindner objects to Claimant's suggestion that Mexican law was substantively harmonized with United States and/or Canadian law under NAFTA. She highlights how Mexican law both incorporates a distinct substantive requirement of industrial applicability, applied in connection with other patent law requirements, and has undergone significant change since NAFTA, belying any notion that a particular standard was "enshrined" in NAFTA. Like Canadian rules on utility, such reforms have notably sought to address the problem of patent applications filed on the basis of insufficient research;

- the expert report of Professor Daniel Gervais of Vanderbilt University, one of the world's leading experts in international intellectual property law. Professor Gervais describes the lack of harmonization of substantive patent law at the international level and refutes Claimant's argument that TRIPS, NAFTA or and PCT imposes a particular definition of utility upon Canada;

- the expert report of Mr. David Reed, patent consultant with decades of experience filing thousands of PCT applications on behalf of a major United States multinational company and instructor with the World Intellectual Property Organization ("WIPO"). Mr. Reed confirms that while PCT facilitates international filings, it does not "harmonize" domestic laws, whose requirements must still be respected in order to gain patent protection. Mr. Reed confirms that in his experience of filing thousands of patents in jurisdictions around the world, substantive requirements for patentability vary widely, and it is courts that have the authority to determine their interpretation and application.

II. FACTS

A. Canadian Courts Reached Just and Principled Decisions and Granted Full Due Process to Claimant

21. The "measures" at issue in this matter are two court proceedings that invalidated Claimant's atomoxetine and olanzapine patents. These proceedings were just, principled, and provided Claimant extensive due process. The conclusions reached by the Canadian courts were within their specialized legislative mandate and in application of existing precedent. In total, nine different Canadian judges in the context of these two cases found that Claimant's patents were invalid.[3]

1) Claimant's atomoxetine patent

22. The chemical compound atomoxetine has been in the public domain for many years. Pre-clinical research conducted by Claimant in the 1970s led it to believe that atomoxetine would be useful for the treatment of depression.[4] In 1979, Claimant sought and obtained a first patent for a genus group of compounds, including atomoxetine, for that use.[5] In 1985, Claimant filed for a second patent, this time only claiming atomoxetine, again for use as an antidepressant.[6] Claimant failed to develop any marketed product for this use.[7]

23. As atomoxetine was not itself a "new" compound, having been already subject to the two previous patents, Claimant could not monopolize the chemical formulation of atomoxetine *per se*. It had to claim a "new use" in order to warrant a third patent over the same compound.[8] Therefore, as of the mid-1990s, Claimant filed a dozen patent

[3] For Atomoxetine: Justices Barnes, Noel, Evans and Dawson. For Olanzapine: Justices O'Reilly, Nadon, Sharlow, Trudel and Hughes.

[4] *Novopharm Ltd. v. Eli Lilly and Co.*, 2010 FC 915, ("*Atomoxetine FC*"), para. 13 (**R-027**).

[5] Patent Specification CA 1,051,034 (**R-247**).

[6] Patent Specification CA 1,181,430, ("'430 Patent"), p. 20, line 5 (**R-269**): "[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".

[7] *Atomoxetine FC*, para. 17 (**R-027**).

[8] Dimock Report, para. 183.

applications for atomoxetine, each time claiming that it had discovered a separate "new use".[9]

24. Among these was a patent application in which Claimant claimed the use of atomoxetine for the treatment of attention deficit/hyperactivity disorder ("ADHD"). Claim 1 of the patent, upon which all other claims depended, stated that "the present invention provides a method of treating attention-deficit/hyperactivity disorder" and the patent asserted that atomoxetine "is a notably safe drug, and its use in ADHD, in both adults and children, is a superior treatment for that disorder."[10]

25. On the basis of Claimant's representations in the patent specification,[11] the Patent Office granted Canadian Patent No. 2,209,735 on October 1, 2002 (the "'735 Patent").[12] Years after filing the '735 Patent, and based upon different and much more extensive and later research, Claimant on December 24, 2004 obtained Health Canada approval for a formulation of atomoxetine to treat ADHD.[13]

26. In 2008, Novopharm Limited (now Teva Canada Limited) ("Novopharm"), commenced an action before the Federal Court seeking a declaration that the '735 Patent was void for, *inter alia*, lack of "utility". Novopharm argued that, as at the time of filing, Claimant had insufficient basis to claim the new "use" for atomoxetine that was the essence of its alleged invention. The trial was heard in Toronto over 19 days before Justice Hughes of the Federal Court. Testimony was received from six witnesses, including three experts on behalf of Novopharm and one expert on behalf of Claimant.[14]

[9] In addition to these patent applications, Claimant also filed applications for use in combination with other drugs, see Brisebois Statement, para. 52 and at footnote 17.

[10] Patent Specification CA 2,209,735, ("'735 Patent"), p. 2, line 7 (**R-026**).

[11] Gillen Statement, para. 48 and FF.

[12] '735 Patent, p. 1 (**R-026**).

[13] Barton Statement, paras. 29-31.

[14] *Atomoxetine FC*, para. 4 (**R-027**).

27. Both parties acknowledged that the '735 Patent claimed that it was useful for the treatment of ADHD.[15] With respect to "utility", the main issue was whether "at the Canadian filing date of the '735 Patent, there was sufficient evidence that atomoxetine was clinically useful in treating some patients with ADHD or, alternatively, that such efficacy could be soundly predicted".[16]

28. At trial, Claimant relied exclusively (and not only "principally" as it now suggests[17]) on the results of a small, short term study conducted in 1995 by researchers of the Massachusetts General Hospital (the "MGH Study") to show that it had demonstrated or soundly predicted the utility of its invention at the time of filing.[18] For reasons that are still unknown, Claimant decided not to secure the attendance of any witness with direct knowledge of the MGH Study at trial, including its only living author (Dr. Heiligentein). As a result, Justice Barnes held that he was "left in the unsatisfactory position of assessing the merits of the MGH Study in the absence of evidence from any of the several witnesses who were best placed to defend it and to discuss the significance of its data."[19]

29. Justice Barnes heard the expert evidence presented by each party regarding the value that ought to be given to the MGH Study. Dr. Virani, retained by Novopharm, described the MGH Study as a "pilot study with so many methodological limitations that its data were only preliminary and, at best, interesting".[20] Dr. McGough, on behalf of Claimant, opined that the MGH Study data were "proof of atomoxetine's efficacy

[15] *Atomoxetine FC*, para. 32 (**R-027**).

[16] *Atomoxetine FC*, para. 93 (**R-027**).

[17] Claimant's Memorial, para. 128.

[18] *Atomoxetine FC*, para. 94 (**R-027**).

[19] *Atomoxetine FC*, para. 5 (**R-027**).

[20] *Atomoxetine FC*, para. 9 (**R-027**).

because they showed […] that atomoxetine had worked to treat several of the patients studied for at least the duration of the trial".[21]

30. After carefully weighing the evidence before him, the trial judge made credibility findings in favour of Novopharm's expert, Dr. Virani.[22] In its detailed reasons, the trial judge criticised at length Claimant's expert, Dr. McGough. Among other things, Justice Barnes held that Dr. McGough "effectively ignored the reservations expressed by the study authors about its methodological limitations", that his responses were "simplistic" to certain issues which involved "considerably more nuanced" and "meaningful answer"[23], that he made an "extraordinary statement that [was] simply not correct"[24], and that, as compared to Dr. Virani's testimony, Dr. McGough's evidence was "less than compelling" and "not persuasive."[25] Justice Barnes's findings stand in stark contrast to Claimant's characterization of the MGH Study in this arbitration as being "successful,"[26] as do comments by Claimant's witnesses in this NAFTA proceeding who attempt to rehabilitate the MGH Study.[27]

31. Overall, Justice Barnes accepted the evidence regarding the limitations of the MGH Study.[28] Among other things, he noted that both authors of this study and one of the inventors of Claimant's patent characterized it as a "pilot" and conceded that it had a "number of limitations."[29] These limitations included: (i) the small size and uniformity of the patient sample; (ii) the short duration of the trial; (iii) the absence of an active control; (iv) the potential for design bias; (v) dosing restrictions; and (vi) the use of

[21] *Atomoxetine FC*, para. 9 (**R-027**).

[22] *Atomoxetine FC*, para. 113 (**R-027**).

[23] *Atomoxetine FC*, para. 107 (**R-027**).

[24] *Atomoxetine FC*, para. 110 (**R-027**).

[25] *Atomoxetine FC*, para. 106 (**R-027**).

[26] Claimant's Memorial, paras. 119, 121.

[27] Although none of them were involved in any way in the research leading to the MGH Study, *see* Armitage Statement, para. 22; Nobles Statement, paras. 8-9.

[28] *Atomoxetine FC*, para. 102 (**R-027**).

[29] *Atomoxetine FC*, paras. 19, 101, and 104 (**R-027**).

crossover design.[30] Unpublished earlier drafts of the MGH Study included statements by its authors to the effect that "before final conclusions can be drawn about the role of [a]tomoxetine in the treatment of ADHD, more information is needed with a longer duration study."[31] Those reservations were also recognized by studies conducted by Claimant subsequent to obtaining its patent. For instance, the authors of a 2003 study on atomoxetine characterized the MGH Study as "preliminary" and noted its "small sample size and methodological limitations."[32]

32. The trial judge also noted Claimant's reaction after receiving the results of the MGH Study: it did not immediately proceed with the development of atomoxetine; rather, Claimant decided to form an "ADHD working group" to review atomoxetine and compare it with two other candidates that Claimant considered for the treatment of ADHD.[33]

33. Based on these factual determinations, Justice Barnes ruled that Claimant had failed to demonstrate at the time of filing for the '735 Patent that it was useful to treat ADHD:

> 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. This was a clinical trial that was too small in size and too short in duration to provide anything more than interesting but inconclusive data. With a patient sample of this uniformity and size, an exposure to atomoxetine of only three weeks and a degree of subjectivity in the testing, one can only conclude, as the researchers

[30] *Atomoxetine FC*, paras. 99 and 113 (**R-027**).

[31] *Atomoxetine FC*, para. 101 (**R-027**). The trial judge held in this regard: "I also have no doubt that the reservations more fully expressed by the MGH Study authors in their initial draft report more accurately reflect their views about the study design and the resulting data than their later published version" *Atomoxetine FC*, para. 103 (**R-027**).

[32] *Atomoxetine FC*, para. 105 (**R-027**).

[33] *Atomoxetine FC*, para. 21 (**R-027**). This is fact that is entirely overlooked by Ms. Nobles in her witness statement: para. 9.

> themselves stated, that the study had "limitations" and the results were promising but only preliminary.[34]

34. The Federal Court also found that there was no disclosure of anything supportive of a prediction of utility in the patent specification,[35] as Claimant chose not to disclose or refer to the MGH Study in the '735 Patent (again for reasons that remain unclear).[36] In fact, the trial judge found that the '735 Patent offered "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."[37]

35. Claimant appealed from this trial decision. The three judges of the Federal Court of Appeal ("FCA") unanimously endorsed the trial judgment as "careful and thorough."[38] The FCA confirmed that utility had to be established as of the date the '735 Patent was filed and reiterated that the main issue was "whether the single study on which Lilly relied was sufficient to demonstrate that atomoxetine was an effective treatment of ADHD."[39] The FCA confirmed that this is a question of fact that turned on the trial judge's assessment of the evidence.[40] The FCA reviewed the record in detail, including witness testimony,[41] and ruled that the trial judge made no "palpable and overriding error in concluding that the evidence was insufficient, for patentability purposes, to demonstrate the effectiveness of atomoxetine as a clinical treatment for ADHD."[42] The FCA also noted that no error of law had been made in applying the test

[34] *Atomoxetine FC*, para. 113 (**R-027**).

[35] *Atomoxetine FC*, para. 120 (**R-027**).

[36] Indeed, had Lilly referred to the MGH Study, it may have been able to support the validity of its patent by relying on Canada's permissive doctrine of sound prediction, which, as explained in more detail below, allows patent applicants, particularly in the pharmaceutical sector, to claim patent monopolies based upon sound prediction rather than full demonstration, as long as that prediction is well-founded.

[37] *Atomoxetine FC*, para. 36 (**R-027**).

[38] *Eli Lilly and Co. v. Teva Canada Limited.*, 2011 FCA 220, ("*Atomoxetine FCA*"), para. 7 (**R-028**).

[39] *Atomoxetine FCA*, para. 8 (**R-028**).

[40] *Atomoxetine FCA*, para. 8 (**R-028**).

[41] *See* for instance, *Atomoxetine* FCA, paras. 13, 24, 25, and 37 (**R-028**).

[42] *Atomoxetine FCA*, para. 43 (**R-028**).

of "sound prediction", noting that "when utility is based on sound prediction, disclosure of its factual foundation goes to the essence of the bargain with the public".[43]

36. Claimant's application for leave to appeal of this FCA decision was denied by the Supreme Court of Canada on December 8, 2011.[44]

37. Claimant seeks to portray the invalidation of its atomoxetine patent by the Federal Court as an outlier, noting that it held atomoxetine patents in a total of 36 jurisdictions, yet the validity of these patents was challenged in only three jurisdictions, and Canada was the only country where it was invalidated. Such comments are misleading. Claimant fails to note that its patent for atomoxetine was in fact invalidated by the U.S. District Court of New Jersey one month prior to the equivalent Federal Court decision, on grounds of lack of utility.[45] While that decision was later overturned on appeal, it means that judges in two out of three of the countries in which challenges were pursued questioned the validity of the patent on analogous grounds. Beyond this, Claimant's own witness Ms. Nobles admits that atomoxetine was marketed in very few countries where it held patents, because ADHD "was not widely recognized as a disease or condition in many countries."[46] She further confirms that there were only four major markets for Claimant's atomoxetine-based product (Japan, Europe, the US and Canada) and that in two of them, there was scepticism about the ability to treat ADHD with pharmaceuticals.[47] The better conclusion to draw from such evidence is that no one

[43] *Atomoxetine FCA*, para. 51 (**R-028**).

[44] *Eli Lilly and Company v. Teva Canada Limited*, 2011 CanLII 79177 (SCC) ("*Atomoxetine SCC*") (**R-003**).

[45] The decision of the Canadian court was preceded by one month by a decision of the United States District Court for the District of New Jersey which, like the Federal Court, invalidated Claimant's patent citing many of the same deficiencies. Noting that the patent specification "does not disclose any data or testing regarding the efficacy of atomoxetine to treat ADHD", that "there's no rationale provided, [in the 590 patent] explaining the compounds utility in treating ADHD", the court held that it "cannot conclude that a person of skill in the art would have recognized the method of treatment's utility in view of the specification and prior art": *Eli Lilly and Company v. Actavis Elizabeth LLC, et al*., 731 F. Supp. 2d 348, 2010, pp. 35, 48 (**R-272**). While this decision was reversed on appeal, the Federal Circuit decision was non-precedential and so does not have the binding effect of precedent: Holbrook Report, para 38.

[46] Armitage Statement, para. 20.

[47] Nobles Statement, paras. 13 and 20.

bothered to challenge Claimant's patents in other jurisdictions because the indicated use of atomoxetine had no market there.

38. Finally, Ms Lindner raises a further issue with regard to the Mexican market, where Claimant similarly cited the absence of any challenge.[48] As she notes, due to the length and cost of patent proceedings and limited patent experience of judges, full patent trials in Mexico are rare.[49] Domestic producers often do not have the resources to take on major foreign multinationals such as Claimant in court.[50] As a result, many patents (such as that for atomoxetine) go unchallenged, despite the inherent weakness of the patent grant.[51] Overall, Claimant's attempt to impugn the Canadian outcome by comparison with that in other countries falls flat.

2) Claimant's olanzapine patent

39. In 1975, Claimant filed an application for a "genus patent" that covered 15 trillion compounds[52] claiming that they were "useful in the treatment of mild anxiety states and certain kinds of psychotic conditions such as schizophrenia."[53] Olanzapine was mentioned as one of the "most preferred compounds" for that purpose.[54] Claimant obtained Canadian Patent No. 1,075,687 in 1980 (the "'687 Patent").

40. By the mid-1990s, as its existing monopoly over olanzapine was getting close to expiry, Claimant began filing multiple patent applications relating to the compound.[55] As it had already enjoyed a monopoly over the class of chemicals to which olanzapine belonged, between 1995 and 1998, Claimant filed no fewer than 16 separate patent

[48] Claimant's Memorial, paras. 113 and 141.

[49] Lindner Report, paras. 79, 85, and 86.

[50] Lindner Report, para. 74.

[51] Lindner Report, para. 83.

[52] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 1018, ("*Olanzapine FC I*"), para. 3 (**R-033**).

[53] Patent Specification CA 1,075,687, ("'687 Patent"), p. 21, line 20 (**R-292**).

[54] *Olanzapine FC I*, para. 23 (**R-033**).

[55] *Olanzapine FC I*, para. 29 (**R-033**).

applications covering olanzapine, alleging the discovery of a distinct unexpected new use for the compound, all of which were ultimately abandoned.[56]

41. In 1991, Claimant had also filed a patent application which it characterized as a "selection patent", *i.e.* a patent claiming the selection of a compound from a previously patented class of compounds (the '687 Patent).[57] In Canada, "selection patents" are allowed if, among other things, the selected compound possesses a substantial advantage (or avoids a substantial disadvantage) over the other compounds covered by the "genus patent."[58]

42. Unlike the '735 Patent (atomoxetine), Claimant did not file its patent application for olanzapine using the PCT.[59] Instead, it filed the patent application directly with Canada's Patent Office. Claimant represented in its patent application that:

> 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.[60]

43. Based on these representations, the Patent Office in 1998 granted Claimant a second monopoly, including both olanzapine *per se* (as a selection from the genus of compounds of the '687 Patent) and the use of olanzapine for the treatment of schizophrenia, under Canadian Patent No. 2,041,113 (the "'113 Patent"). [61]

44. In 2004, litigation between Novopharm and Claimant arose regarding the validity of the '113 Patent. In the context of the *Patented Medicines (Notice of Compliance)*

[56] Brisebois Statement, paras. 57-61.

[57] *Eli Lilly Canada Inc. v. Novopharm*, 2007 FCA 359, ("*Olanzapine NOC FCA*"), para. 8 **(R-208)**.

[58] *Olanzapine FC I*, para. 49 **(R-033)**.

[59] Patent Specification CA 2,041,113, ("'113 Patent"), p. 1 **(R-030)**. As discussed below, Claimant could have had no "expectation" relating to the PCT regarding this patent as it was not filed under this treaty.

[60] Patent Specification CA 2,041,113, ("'113 Patent"), p. 6 **(R-030)**.

[61] *Olanzapine FC I*, para. 31 (**R-033**); Gillen Statement, paras. 49, 50, and 52.

Regulations,[62] Claimant sought an order from the Federal Court prohibiting the Minister of Health from issuing a Notice of Compliance ("NOC") to Novopharm that would have allowed the latter to make and sell olanzapine before the expiry of the '113 Patent, though subject to the risk of being pursued for patent infringement.[63] In response, Novopharm alleged that the '113 Patent was invalid for reasons of anticipation, obviousness, double patenting, intention to mislead, insufficient disclosure and inutility.[64]

45. Decisions under the *PM(NOC) Regulations* relate to the Minister's ability to issue a NOC and apply solely to the generic company seeking the NOC. Such rulings cannot invalidate the patent. If the court decides in favour of the generic and the NOC is issued, the patent-holder can nevertheless immediately launch proceedings against that same party seeking damages for infringement.[65]

46. At the '113 Patent *PM(NOC)* hearing, Claimant filed affidavit evidence from 13 witnesses, including 10 expert reports, and Novopharm provided affidavit evidence from eight witnesses, including seven expert reports.[66] After a 6-day hearing, Justice Hughes (who was a leading patent law practitionner for more than 30 years before being appointed to the bench) found that "no data was given" to support Claimant's representations that the '113 Patent had "surprising and unexpected" properties in comparison to the other compounds.[67] In the circumstances, Justice Hughes rejected Claimant's attempts to block the issuance of an NOC for Novopharm's competing product.

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[62] *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, ("*PM(NOC) Regulations*") **(R-031)**.

[63] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596, ("*Olanzapine* NOC"), para. 1 **(R-032)**.

[64] *Olanzapine* NOC, para. 2 **(R-032)**.

[65] Dimock Report, para. 44.

[66] *Olanzapine* NOC, paras. 3, 4 **(R-032)**.

[67] *Olanzapine NOC*, para. 162 **(R-032)**.

47. Claimant's appeal from this decision was dismissed as moot by the Federal Court of Appeal given that an NOC had, by then, already been issued to Novopharm.[68] Leave to appeal to the Supreme Court of Canada was refused in March 2008.[69] Having failed to pre-emptively block the entrance of a competitor, Claimant remained free to pursue Novopharm in infringement under its still-valid patent under the *Patent Act.*

48. Shortly after the Federal Court decision, Claimant therefore commenced a patent infringement action before the Federal Court. Again, issues of utility and sufficiency of disclosure were raised. At trial, Justice O'Reilly heard evidence from approximately 30 fact witnesses over 44 days.[70] More than 650 trial exhibits were marked, which aggregated to more than one million printed pages and 42 gigabytes of database information. This amounted to far more discovery than had been disclosed in any other cases involving the '113 Patent in Canada or patents for olanzapine elsewhere in the world.[71]

49. As in the atomoxetine trial hearing, Claimant decided not to call any witness directly involved in any of the olanzapine clinical trials that had taken place or were ongoing at the time the '113 Patent application was filed.[72] Instead, Claimant opted to call as expert witnesses persons not involved in the trials and failed to provide them with relevant documentary evidence prior to their testimony. One of Claimant's witnesses conceded that he learned of the existence of some of the most relevant documents while sitting in Court waiting to testify.[73]

[68] *Olanzapine NOC FCA* (**R-208**).

[69] *Eli Lilly Canada Inc. v. Novopharm*, 386 NR 381 (**R-203**).

[70] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197, ("*Olanzapine FCA I*"), para. 3 (**R-015**).

[71] *Eli Lilly Canada Inc. and al. v. Novopharm*, Respondent's Memorandum of Fact and Law, Court file A-454-09, para. 15 and FN 9 (**R-298**).

[72] *Eli Lilly Canada Inc. and al. v. Novopharm*, Respondent's Memorandum of Fact and Law, Court file A-473-11, para. 24 (**R-299**).

[73] *Ibid.*, para. 25 (**R-299**).

50. After deliberating for seven months, Justice O'Reilly found that Claimant had assembled insufficient evidence regarding the advantages identified in the '113 Patent at the time when its patent application was filed. The trial judge determined that "the stated advantages were not substantial and peculiar," that "a person skilled in the art" ("POSITA") would not be able to appreciate any inventive difference between the '687 Patent and the '113 Patent," and that "Lilly had very little idea about what olanzapine's effect was likely to be" when it filed for its patent.[74] In Justice O'Reilly's words, "the '113 patent was clearly drafted with a view of justifying a fresh patent. But the evidence just was not there, yet."[75] Not a single one of the alleged advantages disclosed in the patent were found to be substantiated by the evidence. Thus, the '113 Patent did not meet the requirements for a valid "selection patent" and was held invalid for insufficiency, lack of utility, anticipation and double patenting.

51. The reasons of the trial judge confirm that the question of "promise" was not controversial or debated at trial. Rather, the main issue was a factual one, namely, whether the compound possessed the advantages claimed in the patent specification at the time of filing. The trial judge ruled that it did not.

52. Claimant appealed that decision. The FCA allowed the appeal on the basis that Justice O'Reilly had incorrectly treated the notion of "selection patents" as a free-standing ground of invalidity.[76] On the basis of the trial record, the FCA disposed of the grounds for invalidity of anticipation, obviousness and double-patenting.[77] However, given that issues of "utility" and "sufficiency of disclosure" are questions of fact, the FCA remanded them to the trial court for re-determination in accordance with its

[74] *Olanzapine FCA I*, para. 15 (**R-015**).

[75] *Olanzapine FC I*, para. 154 (**R-033**).

[76] *Olanzipine FCA I*, para. 4 (**R-015**).

[77] *Olanzapine FCA I*, paras. 53, 64, and 73 (**R-015**).

directions.[78] In doing so, the FCA provided guidance to the Federal Court on the issue of "promise". Among other things, the FCA stated:

> …where the specification sets out an explicit "promise", utility will be measured against that promise… The question is whether the invention does what the patent promises it will do…
>
> The promise of the patent must be ascertained. Like claims construction, the promise of the patent is a question of law. Generally, it is an exercise that requires the assistance of expert evidence…
>
> Ultimately, for the purpose of utility regarding a selection patent, the question to be determined is whether, as of the date of filing, the patentee had sufficient information upon which to base the promise…
>
> The promise of the patent is fundamental to the utility analysis.[79]

53. Novopharm sought leave to appeal from the FCA's decision to the Supreme Court of Canada. Claimant opposed its request, arguing that the Federal Court of Appeal "did nothing more than follow established principles of patent law and the jurisprudence of this court" [80] (a position diametrically opposed to what claimant argues before this Tribunal.). The SCC denied leave to appeal. [81] The matter was therefore sent back to the Federal Court.

54. A second hearing before Justice O'Reilly took place over three days, based on the same record by agreement of the parties. The parties were given the opportunity to file additional submissions on the impact of the decision of the FCA on the utility and sufficiency grounds of invalidity.[82] After deliberating for an additional 10 months,

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[78] *Olanzapine FCA*, para. 104 (**R-015**): "In summary on this issue, the assessment and weighing of the evidence are the domain of the trial judge."

[79] *Olanzapine FCA I*, paras. 76, 80, 81, and 93 (**R-015**).

[80] *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, 26 October 2010, para. 2 (our emphasis) (**R-034**).

[81] *Novopharm Limited v. Eli Lilly Canada Inc. et al*., 2011 CanLII 6307, (SCC) No. 33870, 10 February 2011 (**R-300**).

[82] *Eli Lilly Canada Inc. v. Novopharm Limited*, 2011 FC 1288 ("*Olanzapine FC II*"), para. 5 (**R-016**).

Justice O'Reilly again found the '113 Patent to be invalid for lack of utility. He carefully followed the FCA's directions and provided a detailed review of the extensive documentary and witness evidence. He construed the "promise" based on the "broad assertion" found in the patent specification, namely that olanzapine shows "marked superiority and a better side effects profile than prior known [drugs] and has highly advantageous activity level."[83]

55. Justice O'Reilly concluded that the evidence available at the time Claimant applied for its patent did not suggest that olanzapine had any of the alleged advantages over the compounds included in the '687 Patent[84] or over other antipsychotic drugs.[85] To arrive at this conclusion, the trial judge extensively analysed the opinions expressed by experts on both sides regarding the result of the studies conducted by Claimant. Claimant had only disclosed *in vitro* studies and one human study, the so-called "E001 Study", in the patent application – this E001 Study proved to be Claimant's main evidence in support of "utility."[86]

56. Contrary to Claimant's allegations in the NAFTA proceeding, expert evidence adduced at trial suggested that the E001 study was far from being "successful."[87] For instance, it was revealed that its "sample size was very small and [its] duration very short" and that it was "susceptible to bias" and "hypothesis-generating" only.[88] In addition, several experts testified that the E001 Study "would not even support a conclusion that olanzapine was active"[89] and that it "doesn't establish anything one way

[83] *Olanzapine FC II,* para. 120 (**R-016**).

[84] Namely, lower incidence of liver enzyme elevations compared to flumezapine; lower CPK levels than flumezapine; lower EPS than flumezapine; and no increase in cholesterol to ethyl olanzapine: *Olanzapine FC II*, para. 48 (**R-016**).

[85] Namely, a high level of efficacy at low doses; lower elevation of prolactin; lower EPS liability; and no alteration of white blood cell count: *Olanzapine FC II*, para. 42 (**R-016**).

[86] Dimock Report, para. 173.

[87] Claimant's Memorial, paras. 84, 86. In making this statement, Claimant relies on the evidence submitted by its witnesses in this matter, who are not scientists and were not involved in this study.

[88] *Olanzapine FC II*, paras. 153, 155, and 156 (**R-016**).

[89] Expert testimony of Dr. Newcomer, *Olanzapine FC II*, para. 157 (**R-016**).

or another."[90] In sum, when Claimant applied for the '113 Patent, it had at most "a hope that these statements might someday turn out to be true."[91] The authors of the E001 Study themselves stated that it would be "difficult to make conclusions on the efficacy of [olanzapine] on the basis of an open study with so small a sample of patients."[92]

57. Confronted with this abundant evidence of the limitations and flaws of the E001 Study, Justice O'Reilly held:

> In my view, Novopharm has shown that evidence available to Lilly in 1991 was clearly insufficient to demonstrate olanzapine's capacity to treat schizophrenia patients in the clinic in a superior fashion and with fewer side effects than other known antipsychotics.[93]

58. Justice O'Reilly reached a similar conclusion with respect to the more permissive "sound prediction" of utility threshold. He held that the evidence did not support a *prima facie* reasonable inference of utility from the information available in 1991 to the promise of the '113 patent.[94]

59. Attempting to re-write the trial record and its own patent application, Claimant now argues that what it represented in the '113 Patent is only that olanzapine "is a relatively safe and effective anti-psychotic", and not that it has advantages over other known compounds.[95] Yet, this was precisely the utility that was set out for the genus of compounds, including olanzapine, in the '687 Patent. Claimant cannot secure an additional monopoly for a selection of one of the compounds covered by the genus '687

[90] Expert testimony of Dr. Young, *Olanzapine FC II*, para. 158 **(R-016)**.

[91] Expert testimony of Dr. Healy, *Olanzapine FC II*, para. 159 **(R-016)**.

[92] *Olanzapine FC II*, para. 156 **(R-016)**.

[93] *Olanzapine FC II*, para. 213 (our emphasis) **(R-016)**.

[94] *Olanzapine FC II*, para. 219 (our emphasis) **(R-016)**. *See also Olanzapine FC II*, para. 265 **(R-016)**: "[i]n sum, at the time the patent was filed in April 1991; Lilly had not found any special qualities of olanzapine that would justify a fresh monopoly. Lilly had carried out routine testing of olanzapine's properties. It had some early signals of safety and efficacy in a few small studies of healthy volunteers and patients. While Lilly scientists showed persistence, diligence and sound science in getting olanzapine that far, that is not necessarily enough for a patent. There must be an invention. And, in the context of a selection patent, the invention is the discovery of a substantial advantage over the genus compounds."

[95] Claimant's Memorial, para. 100 and ff.

Patent by promising exactly the same results. Without providing any advantage over the other compounds of the genus patent, the selection of olanzapine would be considered an arbitrary and obvious selection from the compounds covered by the genus patent.[96] It is difficult to criticise Justice O'Reilly's construction of the utility set out in the '113 Patent when it essentially replicates the language used by Claimant:

Representations made in the '113 Patent	The utility as construed by the trial judge
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.	Olanzapine treats schizophrenia patients in the clinic in a markedly superior fashion with a better side effects profile than other known antipsychotics

60. Claimant itself confirmed in statements contemporary to its patent application filing that it understood it could not simply reassert the utility set out in its genus patent. When Claimant applied for the '113 Patent, it explained to the Patent Office that the '113 Patent "can properly be considered as a selection invention within a broader class of compounds" and that "[i]n the Applicant's view… 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."[97]

61. Claimant appealed the second trial decision to the FCA. After a full-day hearing, the FCA dismissed the appeal, noting that the trial judge had not erred in its application of the law to the facts.[98] Claimant sought leave to appeal to the Supreme Court of

[96] Dimock Report, para. 119.

[97] Letter from Gowling, Strathy & Henderson to The Commissioner of Patents, September 5, 1997, pp. 4, 6 (emphasis added) (**R-301**).

[98] *Olanzapine FCA II* (**R-035**).

Canada. After exceptionally granting a hearing on the leave application, the Supreme Court of Canada declined to grant leave.[99]

62. One of the core claims Claimant made with regard to olanzapine in support of its claim to a valid patent is that it had a better side-effect profile than prior known antipsychotic agents. Yet since it brought olanzapine to market under the brand name "Zyprexa", Claimant has faced multiple lawsuits from people claiming they suffered from many side effects from its use, including weight gain, heart disease, increased levels of blood sugar and cholesterol.[100]

63. Claimant argues that it held olanzapine patents in eighty-one jurisdictions around the world and that, out of twenty-four validity challenges, only Canadian courts invalidated its patent on the ground of inutility.[101] The point is again to portray Canada as an outlier.

64. Yet no firm conclusions can be drawn from Claimant's numbers. First, Mr. Armitage acknowledged that there was "some variation in claim drafting" between these different patents across jurisdictions.[102] It is well-recognized that patents may stand or fall based upon their specific language, making comparison of outcomes between differently-drafted patents of little probative value. In addition, given variations in national substantive laws, the basis upon which a patent may be held valid or invalid will inevitably vary between countries: each patent grant is national, and will stand or fall on the relevant national grounds. Finally, it is well-recognized that litigation outcomes may differ based upon the arguments presented before the court, the quality of counsel, the issues raised, and the evidence filed. As described above, the Federal Court proceedings took place on the basis of an evidentiary record far more complete than that

[99] *Eli Lilly Canada Inc., et al. v. Novopharm Limited*, 2013 CanLII 26762 (SCC) ("*Olanzapine SCC*") **(R-002)**.

[100] Alex Berenson, "Mother Wonders if Psychosis Drug Helped Kill Son", The New York Times, 4 January 2007, online: http://www.nytimes.com/2007/01/04/business/04drug.html?_r=0 **(R-302)**.

[101] Claimant's Memorial, paras. 114 and 115.

[102] Armitage Statement, para. 11.

in any other jurisdiction. Thus, rather than being an "outlier", another reasonable conclusion to draw is that the Canadian court was more careful and thorough than courts in other jurisdictions, and upon this basis reached the most trustworthy result.

B. The Federal Court Performed Its Expected Statutory Role as Ultimate Arbiter of Patent Validity

65. In declaring invalid the patents at issue in this proceeding, the Federal Court did nothing more than fulfil its statutory role under the *Patent Act* as the ultimate arbiter of patent validity. In Canada, as in other jurisdictions around the world, the Patent Office has the responsibility of initially examining applications and granting patents. However it is the courts which have the ultimate responsibility of interpreting and applying the law in deciding whether those patents were validly granted.

66. Claimant's Memorial ignores this distinction. In arguing that "a patent constitutes a commitment to the patentee that it will have exclusive rights to make, use, and sell its invention until the expiry of the patent",[103] and that it "relied on the [olanzapine] and [atomoxetine] patents themselves, which were issued after a careful review by Canada's patent examiners in light of Canada's utility requirements at the time,"[104] Claimant omits to mention that a patent granted by the Patent Office is presumptive and explicitly conditional on its validity being subject to possible future review by the Federal Court. As Canada will set out below, Claimant is well aware that the patent grant is never the final word. Indeed, Claimant confirms this understanding in its own corporate Annual Reports, where it writes that "[t]here is no assurance that the patents [Eli Lilly is] seeking will be granted or that the patents we have been granted would be found valid if challenged".[105]

[103] Claimant's Memorial, para. 286.

[104] Claimant's Memorial, para. 20.

[105] *Eli Lilly Annual Reports*, Fiscal Years 1999 to 2008 (**R-303**). Since 1999, Claimant's Annual Reports have recognized the presumptive nature of the patent grant and that it is subject to adjudication by the courts: "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." (Eli Lilly Annual Report, Fiscal Years 1999, 2000, 2001, 2002, and 2003, "There is no assurance that the patents we are seeking will be granted or that the

1) The Patent Office makes an initial determination of patentability

67. The Patent Office administers the patent system in Canada, including through oversight of the patent application process, the collection of patent-related fees, and the maintenance of patent records.[106] Responsibility for granting and issuing patents lies with the Commissioner of Patents and is carried out on his behalf by Patent Office officials, notably patent examiners.[107]

68. The purpose of the patent examination process is to determine *prima facie* whether an application meets basic legislative requirements for patentability under the *Patent Act*, namely novelty, non-obviousness, utility, patentable subject matter and sufficient disclosure.[108] If an examiner has reasonable grounds to believe that the application complies with these requirements, then the application will be allowed and a patent must be granted by the Commissioner.[109] A decision to reject a patent application can be appealed to the Patent Appeal Board ("PAB"), which will make a recommendation to the Commissioner whether to issue the patent or not.[110] A patent

patents we have been granted would be found valid and enforceable if challenged (Eli Lilly Annual Report, Fiscal Years 2004, 2005, 2006, 2007, 2008).

[106] Dimock Report, para. 20, citing *Patent Act,* s. 3, and Gillen Statement, para. 11. *See* also Canadian Intellectual Property Office, A Guide to Patents, 2 September 2014, online: http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr03652.html (**R-304**). The Guide identifies the main functions of the Patent Office as: "receiv[ing] and examin[ing] applications for patents and grant[ing] patents to qualifying applicants; record[ing] assignments of patents' maintain[ing] search files of Canadian and other patent documents and a search room for public use in researching patent documents and records; and publish[ing] and distribut[ing] patent information."

[107] *Patent Act*, RSC 1985, c P-4, ("*Patent Act*"), ss. 4(2), 4(4), and 6 (**R-001**). *See* also Dimock Report, para. 21.

[108] Gillen Statement, para. 11; and Dimock Report, para. 14, citing *Patent Act*, ss. 2, 27(3), 27(8), 28.2(1), and 28.3; and 21.

[109] *Patent Act*, s. 27(1) (**R-001**); *Patent Rules,* SOR/96-423, ("*Patent Rules*"), s. 30(1) (**R-206**). *See also* Dimock Report, para. 21. In reaching a decision as to the allowability of an application, a series of exchanges may take place between the patent examiner and the application, through Office Actions. An Office Action is an examiner's report to the applicant identifying defects in the application which prevent it from being considered legislatively compliant (*see* Gillen Statement, FN 7; and Dimock Report, paras. 21 and 25).

[110] Gillen Statement, para 4; and Dimock Report, para. 26. Prior to the rejection of an application by an examiner, the examiner will send the applicant a Final Action, inviting the applicant to correct the defects in their application within a specified time period or to provide arguments why the application does

grant awards the applicant (now a "patentee") presumptive intellectual property rights, expressly subject to the terms of the *Patent Act*.[111] The *Patent Act* provides that:

> 42. Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.[112]
>
> […]
>
> 43(2). After the patent is issued, it shall, in the absence of any evidence to the contrary, be valid and avail the patentee and the legal representatives of the patentee for the term mention in section 44 or 45, whichever is applicable.[113]
>
> […]
>
> 60.(1) A patent or any claim in a patent may be declared invalid or void by the Federal Court at the instance of the Attorney General of Canada or at the instance of any interested person.[114]

69. In addition to possible invalidation by the court, the *Patent Act* establishes several other grounds upon which patent rights may be lost prior to the end of the patent term.[115] For example, patent rights will expire if an applicant fails to pay annual

comply with the *Act* and *Rules*. The examiner will then decide whether to accept or reject the application; if rejected, the applicant can appeal to the PAB. (*See* Gillen Statement, FN 4; and Dimock Report, paras. 25-26).

[111] Dimock Report, para. 27, and Gillen Statement, para. 14. *See also* Robert Mitchell, "The Role of the Patent Office in Canada and the International Patent System in Gordon F. Henderson, *Patent Law of Canada* (Toronto: Carswell, 1994), p. 89 **(R-305)** ("Even though the Patent Office may grant the patent, with the seal of the Patent Office, and is considered *prima facie* valid there is no guarantee that the patent is valid.").

[112] *Patent Act*, s. 42 (emphasis added) **(R-001)**.

[113] *Patent Act*, s. 43(2) (emphasis added) **(R-001)**.

[114] *Patent Act*, s. 60(1) (emphasis added) **(R-001)**.

[115] The term of a patent granted in Canada is addressed in the *Patent Act*, ss. 44 and 45. Under s. 44 of the *Act*, patent applications filed on or after October 1, 1989 are given a term of 20 years from the filing date.

maintenance fees following the patent grant or if the Patent Office determines that there has been an abuse of patent rights.[116] Specific claims in a patent may be cancelled or amended by the Patent Office following a request for re-examination made by any interested person who raises "a substantial new question of patentability affecting any claim of the patent".[117]

2) The determination of the Patent Office is based on a limited record and adopts assumptions in favour of the applicant

70. Patent examiners operate under time and informational limitations. The Patent Office receives tens of thousands of applications and requests for examinations each year: in 2012-2013, approximately 36,000 new patent applications and approximately 28,000 requests for examination of previously submitted patent applications were received.[118] Although the number of examiners employed by the Patent Office has risen since the late 1980s, the number is still small in comparison to the huge volume of applications and examination requests received annually.[119] As a result, the amount of time spent by patent examinations on individual applications is necessarily compressed. Patent examiners also have limited information available to them during the examination process. They have only the benefit of the information included in the patent application itself, information obtained through a prior art search conducted by the examiner, and, if

Under s. 45 of the Act, patent applications filed before October 1, 1989 are given a term of 17 years from the date the patent is issued.

[116] Dimock Report, paras. 30-31 and 33, citing *Patent Act*, ss. 46, 66, and 71.

[117] Dimock Report, paras. 30 and 32, citing *Patent Act*, ss. 48.1, 48.2, 48.4, and 48.5.

[118] Canadian Intellectual Property Office, CIPO Annual Report 2012-2013, 2 September 2014, online: http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03785.html#patents) **(R-306)**. Of the new patent applications received in 2012-2013, 11,758 were filed in the combined fields of biotechnology and organic or other chemistry. Of the requests for examination of previously submitted patent applications received in the same year, 9,827 were made with regards to applications filed in the combined fields of biotechnology and organic or other chemistry.

[119] Gillen Statement, para. 12.

the application was filed under the PCT, a prior art search report and preliminary and non-binding written opinion on patentability generated under the PCT.[120]

71. Examiners may also obtain additional information from the applicant during the examination process to help them determine whether an application appears to comply with the *Patent Act* and *Patent Rules.*[121] However, such information is not exhaustive and is usually one sided, as the applicant has an obvious incentive to have the patent granted. Patent examination is not an adversarial inquiry into patent validity like a trial.[122] If the Patent Office afforded review equivalent to that performed in a trial, "the entire system would grind to a halt and no patents would issue."[123]

72. Consistent with these limitations and the Patent Office's administrative role, the patent examination is a *prima facie* assessment of an application's apparent compliance with the *Patent Act* and *Patent Rules.* The analysis applied by patent examiners is notably deferential to the applicant. Examiners seek to determine whether reasonable grounds exist to believe that an invention meets legislative requirements, and, unless it is clearly without substantial foundation, the examiner will allow the application.[124] During the examination, many assumptions are adopted in favour of the applicant. As Dr. Gillen explains:

> […] examiners rel[y] on the language of the patent application itself in looking for evidence of the demonstration or sound prediction of utility. If such evidence [is] found in the application, the examiner [will]

[120] Gillen Statement, para. 13. The search report and written opinion on patentability generated under the PCT process are preliminary and non-binding on PCT Contracting States. (*See* Reed Report, paras. 20, 24-25, and Gervais Report, para. 74). National Patent Offices are not required to defer to the results of the search report or the written opinion, but may consider it in their evaluation of whether an invention appears to be novel and non-obvious (Gillen Statement, para. 60).

[121] Gillen Statement, para. 13.

[122] Dimock Report, para. 22.

[123] Gillen Statement, para. 15.

[124] Dimock Report, para. 22; *Vanity Fair Silk Mills v. Canada (Commissioner of Patents)*, [1939] SCR 245, para. 3 (**R-149**); *Monsanto Company v. Commissioner of Patents*, [1979] 2 SCR 1108, ("*Monsanto 1979*"), para. 20 (**R-023**).

necessarily apply assumptions in the applicant's favour, by accepting that evidence as credible.

For example, where a patent application stated in unequivocal terms that a molecule or compound had been confirmed to achieve a particular pharmacological effect - giving the impression that the compound had been tested and proven to work - and that pharmacological effect was not completely implausible, an examiner would apply an assumption in favour of the applicant and accept that the invention's utility had been "demonstrated" as at the time of filing. Examiners would do this with the understanding that if challenged in court, the applicant would be required to produce evidence predating the application's filing, to prove that the applicant had indeed been able to demonstrate the alleged utility as of the filing date".[125]

3) The Patent Office lacks authority to issue binding interpretations of patent law

73. In addition to mischaracterising the nature of the rights granted by the Patent Office, Claimant also wrongly suggests that Patent Office examination guidelines are authoritative on Canadian patent law and legislation.[126] Claimant argues that the Manual of Patent Office Practice ("the MOPOP") was only recently modified to require examiners to consider the promise of a patent, whether a patent disclosed the basis for a sound prediction of utility, and whether the utility of an alleged invention had been established as at the date of filing. Claimant alleges that these elements were not part of

[125] Gillen Statement, paras. 42-43. *See* also Gillen Statement, paras. 13 ("Examiners have neither the time nor the means to confirm the scientific validity of every statement made in an application […]Although examiners have the authority to request specimens from applicants in order to carry out post-filing experiments, this is generally not done. It is not practicable to obtain 'specimens' for certain types of inventions, including chemical inventions."); and Robert Mitchell, "The Role of the Patent Office in Canada and the International Patent System in Gordon F. Henderson, *Patent Law of Canada* (Toronto: Carswell, 1994), p. 89 **(R-305)** ("The Patent Office further does not test the invention to be sure that is operable as described in the patent specification. If the examiner has doubt as to whether or not the invention will work, the application is rejected. Otherwise, the applicant's description of the invention is accepted at face value.").

[126] Wilson Statement, para. 22 ("Although MOPOP is to be considered solely as a guide, in my experience, MOPOP recorded the Patent Office's practice and was tantamount to a rulebook to be followed by patent examiners and patent agents during the prosecution of applications filed with the Patent Office.")

Patent Office practice when Claimant's patents for olanzapine and atomoxetine were filed in the 1990s, because they were not in the MOPOP at that time.[127]

74. These arguments are unfounded. The MOPOP is not a comprehensive guide to Canadian patent law.[128] It is a high level guide, prepared by the Patent Office as a reference tool for patent examiners and other participants in the patent system.[129] It is not binding and does not have the force of law. It has no statutory basis in the *Patent Act* or *Patent Rules*.[130]

75. The MOPOP itself expressly indicates that it is non-authoritative. In its first publication in 1977, the MOPOP cautioned that it 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."[131] That same warning, or some variation thereof, has been included in every edition of the MOPOP published by the Patent Office since, including those editions that were in place when Claimant's patents for olanzapine and atomoxetine were filed and examined in the 1990s and early 2000s.[132]

76. The Patent Office seeks to keep the MOPOP as current as possible, but as Dr. Gillen explains "[…] it is impractical and unreasonable to expect that it will always exactly reflect Office practise […]".[133] Updates to the MOPOP require significant time

[127] Wilson Report, paras. 48, 49.

[128] Gillen Statement, paras. 18, 24; Dimock Report, para. 24.

[129] Gillen Statement, paras. 17, 18; Dimock Report, para. 23.

[130] Dimock Report, paras. 23-24, citing *Belzberg v. Canada (Commissioner of Patents)*, 2009 FC 657, para. 10 (**R-150**); *Bayer AG v. Apotex Inc.*, (1998), 84 CPR (3d) 23 (FCTD), para. 49 (**R-151**).

[131] "Manual of Patent Office Practice", Consumer and Corporate Affairs Canada, Patent Office (December 1977), Forward ("MOPOP December 1977") (**R-024**). *See* also Gillen Statement, para. 18.

[132] "Manual of Patent Office Practice", Consumer and Corporate Affairs Canada, Patent Office (December 1977, August 1989, January 1990, March 1998, September 2004, February 2005, April 2006, January 2009, December 2009, November 2013, December 2013, May 2014), Forward ("*MOPOP*") (**R-025**); "Manual of Patent Office Practice", Consumer and Corporate Affairs Canada, Patent Office, September 2014, Forward (**R-045**). *See* also Gillen Statement, para. 18.

[133] Gillen Statement, para. 20; Dimock Report, para. 24.

and resources, the availability of which has varied at the Patent Office over time.[134] Furthermore, the law itself is constantly developing. Consequently, patent examinations are not themselves governed by the MOPOP, but by the *Patent Act, Patent Rules*, and relevant patent jurisprudence.[135]

4) The Federal Court has sole authority to interpret the law

77. In Canada's patent system, as in many jurisdictions around the world, the courts are tasked with confirming or rejecting patents granted by the Patent Office.[136] In fulfilling its statutory responsibilities as ultimate arbiter of patent validity in Canada, only the Federal Court may issue binding interpretations of the *Patent Act*.[137]

78. The authoritative role the Federal Court plays in Canada's patent system is reflected in the analysis the court applies and in the resources available to it. [138] Conducting its review in the context of adversarial civil proceedings, the Federal Court applies a far more rigorous analysis of patent validity than the Patent Office. Assumptions adopted in favour of applicants during the Patent Office examination process no longer apply.[139] While the court must recognize the statutorily imposed presumption of validity in place after a patent is granted by the Commissioner, this "weakly worded" presumption no longer applies once evidence to the contrary is

[134] Gillen Statement, para. 21.

[135] Gillen Statement, para. 19; Dimock Report, para. 21.

[136] The Federal Court is the "court of competent jurisdiction" under the *Patent Act*, s. 42 (**R-001**). *See* the *Federal Courts Act*, RSC 1985 c. F-7, s. 20(1) (**R-307**), which gives the Federal Courts exclusive original jurisdiction (a) in all cases of conflicting applications for any patent of invention, or for the registration of any copyright, trade-mark, industrial design or topography within the meaning of the Integrated Circuit Topography Act; and (b) in all cases in which it is sought to impeach or annul any patent of invention or to have any entry in any register of copyrights, trade-marks, industrial designs or topographies referred to in paragraph (a) made, expunged, varied or rectified."

[137] *Patent Act*, s. 60(1) (**R-001**); *See* also Dimock Report, para. 28.

[138] Gillen Statement, para. 16.

[139] Gillen Statement, para. 53.

presented at trial. The court will then make its determination on a balance of probabilities.[140]

79. The Federal Court has the benefit of assessing patent validity in light of extensive expert and fact evidence put forward in adversarial private party litigation. This includes substantial document production and the ability to assess first-hand the credibility of fact and expert witnesses through cross-examination. Validity hearings are lengthy, often lasting weeks or even months.[141]

80. Finally, it is the responsibility of the courts, as it is in any legal system founded on a separation of powers and the rule of law, to interpret what the law is and declare the legal rights and obligations of litigants who come before it. The mere grant of a patent by the Patent Office is not a guarantee that the patent is legally valid. Any participant in the patent system is aware of the Federal Court's statutory role in confirming the Patent Office grant and knows that decision-making outcomes between the Patent Office and the court can be and often are different. Patentees also know that for a patent to be confirmed valid, it must ultimately bear and withstand the scrutiny of not just the Patent Office, but the Federal Court.[142]

C. Claimant's Patents Were Invalidated on the Basis of Long-Standing Patent Law Rules That Are Grounded in the Patent Act and Serve Rational Policy Objectives

81. Nothing in the NAFTA prohibits the domestic law of the Parties from changing over time, including with respect to intellectual property. Evolution in the law is an inevitable feature of any legal system. So too is clarification of the law over time by the courts, as broad legal principles are applied in different circumstances. Such elaboration

[140] Dimock Report, para. 29.

[141] As Mr. Dimock explains in his Report, the first trial in which the patent for olanzapine was challenged lasted for 44 days and included testimony from over 30 witnesses. The first trial for the atomoxetine patent lasted for 18 days and included testimony from 6 witnesses. Dimock Report, paras. 213 and 216.

[142] Gillen Statement, para. 16 and Reed Report, paras. 58-59.

occurs in patent law, which must constantly be adapted and applied to new technologies. No sophisticated participant in the patent system expects the contrary.

82. Claimant alleges that Canada's patent law underwent a "sea change" in the mid-2000s, with the development of a previously unknown "promise utility doctrine," which it characterizes as extra-statutory, subjective, arbitrary, unpredictable, and discriminatory. It contends that the introduction of this "promise utility doctrine" has caused the invalidation of its patents, which would have been valid under "prior law".[143]

83. Claimant's account is misleading and incorrect. Claimant's patents were invalidated on the basis of longstanding, rational, and fair rules of Canadian patent law that have not changed since Claimant filed its patents.

84. These longstanding rules and principles go to the heart of the "patent bargain" that provides the foundation for the Canadian patent system, the goal of which is public benefit from improvement in the state of knowledge. Under the patent bargain, the public confers a time-limited monopoly in exchange for the "hard coinage" of the disclosure of new, useful, and non-obvious inventions.[144] As the Supreme Court of Canada explained in *AZT*, the costs of conferring monopoly rights through a patent cannot be taken lightly, and the patent bargain demands more than mere speculation in return:

> The grant of a patent monopoly for 17 years (20 years after October 1, 1989) creates, and is intended to create, serious anti-competitive effects. Once the subject matter of the patent is fenced in by the claims, others trespass (advertently or inadvertently) on the forbidden territory at their peril. The boundary is defended by a considerable arsenal of remedies conferred by the Patent Act, including an accounting of the infringer's profits in an appropriate case. Patent litigation is usually protracted and costly [...] There is in the meantime a chilling effect on other researchers. They will tend to invest their talents in less litigious areas. Parliament considered this chilling effect to be a worthwhile price for

[143] Claimant's Memorial, paras. 10, 56, 57, 79, and 208.

[144] Dimock Report, para. 14.

> the disclosure of a "new and useful" invention, bringing into the public domain information that might otherwise remain a trade secret, but there is nothing in the Act to suggest that Parliament was prepared to accept the chilling effect in exchange for nothing but speculation.[145]

85. It is against the backdrop of the "patent bargain" that Canada will debunk the many misrepresentations Claimant makes with respect to Canadian patent law.

1) Claimant's so-called "promise utility doctrine" is in fact several distinct patent law rules, all of which were part of Canadian law when Claimant filed its patents

86. What Claimant describes as the "promise utility doctrine," allegedly contrary to the definition of "utility" in NAFTA Article 1709(1), is actually a series of distinct patent law rules.[146] Only one of these rules actually addresses the amount of utility required for patentability in Canadian law: (1) the rule that patentees are held to promises of utility. The remaining patent law rules attacked by Claimant extend to diverse patent law issues going far beyond the amount of utility required: (2) the principles of construction followed by courts to interpret patents; (3) the date at which the patentee must have established the invention's utility, and the evidence that can be used to prove that utility was established; (4) the manner in which courts receive and consider evidence in patent trials; and (5) what constitutes proper disclosure of the invention. Needless to say, these are nuanced aspects of the patent law that are not governed by the high level framework for intellectual property rights in NAFTA Chapter Seventeen. Yet Claimant attempts to cram them all into the "ordinary meaning" of utility.

87. Claimant's allegations with respect to each of the discrete rules it attacks are unfounded. They were all part of Canadian patent law when Claimant filed its patent

[145] *Apotex Inc. v. Wellcome Foundation Ltd*., [2002] 4 SCR 153 ("*AZT*"), para. 45 (**R-004**).

[146] Dimock Report, para. 51. Professor Siebrasse effectively acknowledges both that Claimant has invented the term "Promise Utility Doctrine" and that this concept invoked by Claimant extends beyond the standard for utility and into rules concerning its application by the courts. He writes: "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." (emphasis added). Siebrasse Report, para. 17, FN 23.

applications, and all serve important policy objectives at the heart of the *Patent Act*. This will be demonstrated in the following sub-sections (2) through (6) addressing each aspect of Claimant's complaint.

2) Promises in the patent must be met for an invention to have utility

88. Claimant alleges that Canadian court have, since 2005, created a new "judge-made" and "extra-statutory" utility requirement by holding patentees to the utility promised in their patents. Claimant alleges that this rule dramatically departs from the standard that applied when Claimant filed its patents for atomoxetine and olanzapine.[147] Claimant's account is completely unfounded.

89. Under Canadian law, a patentable invention must be new, useful, non-obvious, constitute patentable subject matter, and be properly disclosed. The requirement of usefulness, synonymous with utility in the *Patent Act*, is set out in s. 2:

> "invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.[148]

90. The term "useful" in s. 2 is undefined in the *Patent Act*, but has been interpreted and clarified through a long line of Canadian jurisprudence.[149] Canadian courts have long held that the utility requirement under the *Patent Act* is a contextual consideration dependent on the language of the patent specification itself.[150] If the patent is silent on the issue of utility, then the invention simply needs to have a "scintilla of utility." However, if the patent promises a specific result, then the invention must achieve the result promised, or it will lack utility under the *Act*.[151] This was the rule applied in both

[147] Claimant's Memorial, paras. 45, 229.

[148] *Patent Act*, s. 2 (our emphasis) (**R-001**).

[149] Dimock Report, para.55.

[150] Dimock Report, para. 58.

[151] Dimock Report, para. 58; *See* also E. Richard Gold and Michael Shortt, "The Promise of the Patent in Canada and Around the World", 30:1 Canadian Intellectual Property Review 35, June 2014, ("*Gold and*

the atomoxetine and olanzapine matters. The patents contained promised levels of utility, and were held to those promises.[152]

91. Claimant alleges that Canada's utility standard did not require that promises in the patent be met when it filed its patents in the 1990s, and that the "mere scintilla" standard was the only utility requirement.[153] This is not true. As Mr. Ronald Dimock explains, "the well-established rule in Canadian jurisprudence and legal literature for at least the past sixty years is that if a patent promises a certain utility then such utility must be attainable by the claimed invention."[154]

92. The leading case on the law of utility, including the promise requirement, is the Supreme Court of Canada's 1981 decision in *Consolboard v. MacMillan Bloedel (Sask.) Ltd.* The Supreme Court's decision was penned by Justice Dickson, who went on to become Chief Justice of Canada. Justice Dickson wrote:

> 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". There is no suggestion here that the invention will not give the result promised. The discussion in Halsbury's Laws of England, ibid., continues:
>
> … the practical usefulness of the invention does not matter, nor does its commercial utility, unless the specification promises commercial utility, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested. [Footnotes omitted.]

Shortt"), p. 42 (explaining that Canadian law "holds a patent claim invalid for lack of utility if the patented invention fails to achieve a promise made in the specification, even if the invention may otherwise possess a scintilla of usefulness.") **(R-050)**.

[152] Dimock Report, para. 165.

[153] Claimant's Memorial, para. 45.

[154] Dimock Report, para. 219; *See* also *Gold and Shortt*, p. 57 **(R-050)** (writing that "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.").

and concludes:

> … it is sufficient utility to support a patent that the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice. [Footnotes omitted.]
>
> Canadian law is to the same effect.[155]

93. This is the utility test that was applied to invalidate Claimant's patents.[156] In other words, the "promise of the patent", as applied to invalidate Claimant's patents, was recognized as an integral part of Canadian law by the Supreme Court of Canada long before Claimant filed its patent applications.

94. Claimant contends that *Consolboard* has simply been misread by Canadian courts since 2005, and cannot reasonably be taken to mean that the utility requirement in the *Patent Act* holds patentees to promises of utility.[157] Apart from engaging this Tribunal in a fine debate about the proper interpretation and application of Supreme Court of Canada precedent, this argument is baseless. Not only is Claimant's argument inconsistent with the express direction given by the Supreme Court in the above quoted passage, but as Mr. Dimock explains, "*Consolboard* and the promise of the patent were inextricably linked together long before 2005".[158]

95. Moreover, Canadian jurisprudence and legal literature since at least the 1960s is replete with warnings that patents may be invalidated if they fail to fulfil promises of

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[155] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] SCR 504, 1981 CarswellNat 582, ("*Consolboard*"), para. 36-37 (emphasis added) **(R-011)**; *See* also *Gold and Shortt*, p. 54 **(R-050)** (writing that the definition of utility in *Consolboard* has two components: "First, where the patent document itself makes no promise of utility, a mere "scintilla of utility" will suffice; this requirement has normally been interpreted as requiring that the invention produce some minimally useful result. Second, where the inventor makes a promise, the patent will have utility only if it fulfills that promise, regardless of whether it possesses a scintilla of utility. 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.").

[156] Dimock Report, paras. 168 and 187.

[157] Siebrasse Report, para. 73.

[158] Dimock report, para. 70.

utility.[159] For example, a 1960 article by Donald Hill, a highly respected Canadian patent lawyer, explained that it was "so obvious that it hardly needs stating" that a patent will be invalid if the invention fails to achieve the promised utility:

> 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…[160]

96. Similarly, the well-known 1969 treatise of Dr. Harold G. Fox set out the role of promise in its chapter on "Utility" as follows:

> **Promised Results**: 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 from the use of his invention. In the former case failure to perform the promise of the specification is fatal to the patent.
>
> …
>
> 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 of utility 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.[161]

97. Promises of utility will often be made where a specific utility is at the core of the invention.[162] Some inventions must make a promise of utility in order to be patentable. Two examples of this are "new use" patents (such as Claimant's patent for atomoxetine) and "selection patents" (such as Claimant's patent for olanzapine). As Mr. Dimock

[159] Dimock Report, paras. 56-82.

[160] Donald Hill, "Claim Inutility" (1960), 35 CPR 185, p. 188 (**R-160**); Dimock Report, para. 65.

[161] Dimock Report, para. 66; Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969), pp. 152-153 ("our emphasis") (**R-163**).

[162] Dimock Report, para. 59.

explains, in "these types of situations, a promise of utility is the basis for the grant of a patent".[163] For "new use" patents, a patent on an already known substance is merited by identifying a previously unknown use. Failure to deliver the promised new use would break the patent bargain. For "selection" patents a secondary patent on a selection from an already known and patented genus of compounds is justified by that selection offering some substantial advantage over the genus.[164] Claimant contends that its selection patent for olanzapine must have met the "mere scintilla" standard on the basis that if the previously patented genus of compounds was useful, then so too must be the selection.[165] However, this ignores that patents must meet their promised utility, and that a selection patent will necessarily involve a promise of utility beyond the genus.[166]

98. Patent examiners considering patents such as Claimant's, for new uses or for selection inventions based upon relatively superior effectiveness, have long assessed utility on the basis of what was asserted in the patent application.[167] Claimant is incorrect that in the 1990s, patent examiners looked only for "any utility"[168] and "did not consider advantages in the invention that were stated in the disclosure to be equivalent to the utility of the invention".[169]

[163] Dimock Report, para. 73.

[164] Dimock Report, paras. 118-119.; *See* also W.L. Hayhurst, "Disclosure Drafting" (1971), 28 PTIC Bull (7th) 64, p. 73 (**R-164**) (explaining that "[g]enerally speaking there is no need to set out the advantages of an invention. Exceptions to this general rule seem to be as follows: If no advantage is stated, and if because of that an expert would not, on reading the specification, understand that something special had been achieved, it may be possible to say that no disclosure of the invention has been made: this applies in the "selection" cases where patentability turns on the unexpected utility of one or more members of a previously known class, but the point can apparently arise in other cases where it is necessary to understand the advantage in order to understand what the invention is."). This is why Claimant's witnesses' statements to the effect that olanzapine as of filing showed some utility are beside the point. Olanzapine had to show greater utility than the genus to warrant additional patent protection. Cite to witness statements.

[165] Claimant's Memorial, para. 98.

[166] Dimock Report, para. 195.

[167] Gillen Statement, paras. 199-201.

[168] Wilson Report, para. 46.

[169] Wilson Report, para. 29; Gillen Statement, paras. 27-29.

99. Beyond its claim that promise is a new development in Canadian law, Claimant argues that this standard is "judge-made" and "extra-statutory" in contrast to the "mere scintilla" standard required by the *Patent Act*.[170] In reality, neither "scintilla" nor "promise" is found in the letter of the *Patent Act*. Both aspects of the utility requirement are the result of judicial interpretation of the meaning of "useful" in the context of the *Patent Act*.[171]

100. Holding patentees to promises of utility serves important policy objectives at the heart of the Canadian patent system, and is reflected in other patent systems around the world, including the United States.[172] As Mr. Dimock explains, "[t]his 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."[173] Enforcing promises of utility also discourages speculative patenting, since patents that are overbroad – that is, monopolizing more than the patentee can fairly be said to have invented – may be invalidated on this basis.[174] The promise standard also promotes accuracy and discourages overstatement in patent disclosures, which is of paramount importance in a system aimed at securing public benefit from improvement in the state of knowledge.[175]

3) Courts interpret patents using settled principles of patent construction to determine if there is a promise

101. Claimant alleges that the manner in which Canadian courts interpret patents to determine whether there is a promise is subjective, arbitrary, and unpredictable and

[170] Claimant's Memorial, para. 229.

[171] Dimock Report, para. 55.

[172] Holbrook Report, paras. 13, 40, 56, and 58.

[173] Dimock Report, para. 219.

[174] *Gold and Shortt*, p. 40, (**R-050**).

[175] Stephen J. Perry and T Andrew Currier, *Canadian Patent Law*, Markham, Ont: LexisNexis, 2012, p. 141 (**R-308**).

proceeds in a manner that departs from the approach to patent interpretation used before 2005.[176] Each of these allegations is false. As Mr. Dimock describes, construing the promise of a patent "is not a "subjective" and "arbitrary" process but a fair interpretation of the patent in accordance with the long established "purposive" and "informed" approach to patent construction".[177]

102. The same rules apply to construing a promise in the patent as to any aspect of patent construction.[178] These principles are fair, balanced, and straightforward, and have been part of Canadian patent law since before Claimant filed its patents for atomoxetine and olanzapine. First, the patent must be read as a whole. This means that the court must have regard to both the claims and the description in the patent specification. Second, the patent is read from the perspective of a skilled reader (or person of ordinary skill in the art ("POSITA"), equipped with the common general knowledge in the relevant field. Third, the court will receive expert evidence from the parties on how a skilled reader would have understood the patent.[179]

103. Applying these principles, if the court determines that a skilled reader would have understood the patent to contain a promise, then that is the promise to which the patent will be held. This was the case for claimant's patents for the use of atomoxetine and olanzapine. As Mr. Dimock explains, the courts in those cases applied settled principles of patent construction to determine that the patent contained a promise, and found promises based on the express words of the patent, read as a whole, in light of the expert evidence adduced by the parties.[180] Claimant argues that Canadian courts now

[176] Claimant's Memorial, paras. 57, 61, 62, and 64.

[177] Dimock Report, para. 85.

[178] Dimock Report, paras. 85-87; *See* also *Gold and Shortt*, p. 42 (**R-050**) (writing that "interpreting the promise of the patent is an aspect of construing the patent, and thus courts are to approach promises by employing purposive construction.").

[179] Dimock Report, para. 85.

[180] Dimock Report, para. 87. Claimant complains that the trial judge in the atomoxetine proceedings identified an additional *implicit* promise of long-term effectiveness. However, as found by the Court of Appeal, the trial judge was not construing the patent as promising more than its explicit promise that it will treat ADHD. Rather, he was simply interpreting what "treatment" means in this particular context

regard the promise as fundamental to the utility analysis, and solicit expert testimony on whether there is a promise in a manner unheard of before 2005.[181] This is incorrect. As Ron Dimock explains:

> this "new" approach identified by Professor Siebrasse is strikingly similar to the description of the "old" approach described by Dr. Fox in 1969:
>
> > The plea of non-utility based on a failure to produce the promised results of a specification is similar to, and cannot always be separated from, the plea of false representation, or failure of consideration as it is sometimes called. It necessarily involves 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. If the ordinary workman would so read the specification as promising a certain result, and that result is performed by following the specification, the specification is sufficient and the patent cannot be held void on the ground of inutility.[182]

104. Nor is the receipt of expert evidence on matters of patent construction a new development in Canadian law, as Claimant submits.[183] Since the court must interpret the patent from the perspective of a skilled reader, such evidence enables the court to do so in a knowledgeable way.[184] As Mr. Dimock explains, expert evidence has been received on questions of patent construction for decades. While he notes that the use of expert evidence in patent trials has increased over the course of his career, this "phenomenon is

applying rules of construction of patents that are standard in Canadian law. *Atomoxetine FCA*, para. 21 (**R-028**); Dimock Report, para. 195

[181] Claimant's Memorial, para. 62.

[182] Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969), p. 153 (**R-163**).

[183] Claimant's Memorial, para. 62.

[184] Dimock Report, para. 90.

by no means unique to the issue of construing the promise of a patent" and is driven by the litigation strategy of the parties.[185]

105. Claimant contends that construing the promise of the patent is inherently subjective, arbitrary, and unpredictable because promises may be found where the patentee did not intend to make one and because different judges may arrive at different conclusions as to the promise of a patent. In truth, when Canadian judges interpret patents, they do not do so "subjectively", but apply the settled rules of interpretation discussed, hear all of the evidence adduced, and determine how a skilled reader would have understood the patent.[186] The fact that this process could reasonably lead different judges to different conclusions does not make the enterprise subjective, arbitrary, and unpredictable. Claimant's arguments could be levelled at the judicial interpretation of any document, be it a patent, a contract, or a title deed. They are the inherent challenges of interpretation.

106. Claimant argues that Canadian courts impermissibly look beyond the claims to identify the promise of the patent, leading to uncertainty over whether the court will find a promise.[187] However, as Mr. Dimock explains, it has long been known that the patent must be construed as a whole (including both the description and the claims) and that reference may therefore be made to the descriptive portion of the patent in construing its promise.[188] This is evident from the case law[189] and was noted by Canadian patent practitioner William Hayhurst in a 1994 publication:

> To avoid problems of false suggestion and inutility, the patent agent should be chary of promising results in the descriptive portion where

[185] Dimock Report, paras. 90-91.

[186] Dimock Report, paras. 83-84 and 87.

[187] Claimant's Memorial, paras. 57, 65.

[188] Dimock Report, para. 88.

[189] *See* for example *Rodi & Wienenberger A.G. v. Metalliflex Limited*, (1959) 32 CPR 102 ("*Metalliflex 1959*") (**R-008**).

> those results may not be achieved by things that arguably fall within the claims.[190]

107. In other words, it is the pen of the patent applicant that makes the promise. The courts simply adjudicate whether that promise is supported by the evidence at the time the patent was filed.

4) The utility of the invention must be established at the filing date, and cannot be retroactively proved with post-filing evidence

108. Claimant accepts that the utility of an invention must be established at the filing date, and that this rule has not changed between the filing and invalidation of Claimant's patents.[191] There are two ways in which the utility of an invention can be established by the filing date: demonstration and sound prediction. [192]

109. Demonstration of utility can be achieved if a patentee's invention is actually built or practiced by the filing date, and the utility promised by the patent is realized.[193] However, this model of full development of the claimed invention at the filing date posed particular difficulties for some fields of technology, such as chemical or pharmaceutical inventions. In chemistry, failure to claim a broad range of compounds – far exceeding those actually made and tested – could make it easy for a monopoly over the claimed compounds to be circumvented by making a slight variation. In the pharmaceutical field, research time-lines are very long and applicants run the risk of their invention being found anticipated or obvious, by the time they are sure that the proposed invention will work as described.

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[190] 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 (our emphasis) **(R-201)**; *See* also W.L. Hayhurst, "Disclosure Drafting" (1971), 28 PTIC Bull (7th) 64, pp. 73-74 **(R-164)** (writing that "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."); W.L. Hayhurst, Q.C., "Survey of Canadian Law – Industrial Property: Part I" (1983), 15 Ottawa L. Rev. 38, pp. 68-69 (emphasis added) **(R-199)**.

[191] Claimant's Memorial, para. 52; Siebrasse Report, para. 16.

[192] Dimock Report, para. 92.

[193] Dimock Report, para. 95.

110. Recognizing these difficulties, the Supreme Court of Canada in the 1979 *Monsanto* case adopted a second, more flexible test for establishing utility at the filing date: sound prediction.[194] This more permissive rule allows a patentee to claim an invention even where he has not actually demonstrated utility. However, the patentee cannot claim beyond the limits of a "sound" prediction. There must be sufficient preliminary research to support the prediction. This is what distinguishes a sound prediction from a mere speculation, or an educated guess.

111. A prediction will be sound, and therefore establish utility, if the patent discloses a factual basis and a line of reasoning that a skilled reader would regard as adequately supporting the prediction of the utility promised by the invention.[195] Sound prediction has worked to the advantage of pharmaceutical companies. As Mr. Dimock explains:

> Sound prediction is a rather useful doctrine for patent applicants such as pharmaceutical companies as it permits patents to be granted and upheld even where the invention has not been demonstrated at the filing date across the full scope of the claimed invention.[196]

112. While Claimant accepts that the rule has always been that utility must either be demonstrated or soundly prediction as at the filing date, Claimant argues that utility at the filing date could be proved with post-filing evidence until the Supreme Court of Canada's 2002 ruling in *AZT*.[197] This complaint has nothing to do with the meaning of utility under the *Patent Act* or NAFTA Article 1709(1), but relates to the date at which utility must be established, and the timing of evidence that can be relied upon to establish it. Moreover, Claimant's allegation demonstrates that its issue is not with the two court decision that the "measures" in this matter, but rather with settled Supreme

[194] Dimock Report, paras. 99-101, 161. Initially, the doctrine of sound prediction was applied only in the chemical arts, which were regarded as highly predictable. However, over time the application of doctrine was expanded, including to pharmaceuticals, though they were regarded as a less predictable art.

[195] Dimock Report, paras. 99-100.

[196] Dimock Report, para. 100.

[197] Claimant's Memorial, paras. 52, 70.

Court of Canada doctrine that is entirely independent of the question of whether patentees are held to the level of utility promised in the patent.

113. Claimant's account is, in any event, incorrect. The Supreme Court of Canada's ruling in *AZT* did not change the law on post-filing evidence of utility.[198] As Mr. Dimock notes:

> 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).[199]

114. Applicants are only entitled to a patent if they have actually made an invention having the utility described in the patent as at the filing date.[200] An invention has been made where it has been reduced to a "definite and practical shape."[201] The Supreme Court of Canada explained this concept in a 1930 case, *Christiani v. Rice*, endorsing the principle that "it is not enough for a man to say that an idea floated through his brain; he must have reduced it to a definite and practical shape before he can be said to have invented a process."[202] Since one necessary element of an invention is its utility, this is part of what an inventor must have reduced to a "definite and practical shape" before he can be said to have invented anything.[203] If patentees could retroactively validate speculative guesses of utility, then there would be nothing to distinguish a "sound prediction" at the filing date from a mere idea that floated through the brain.

[198] Dimock Report, para. 110.

[199] Dimock Report, para. 102.

[200] Dimock Report, para. 93.

[201] Dimock Report, para. 93.

[202] *Christiani v. Rice*, [1930] SCR 443, para. 31(**R-185**); *See* also *Wandscheer et al. v. Sicard Ltd.*, [1948] SCR 1, p. 4 (**R-181**).

[203] Dimock Report, para. 94.

115. Claimant argues that post-filing evidence was, until 2002, routinely used by the courts in assessing the utility of an invention.[204] This is incorrect. Claimant fails to recognize a crucial distinction between the use of post-filing evidence to establish utility at the filing date as opposed to the *operability* (or utility-in-fact) of the invention.[205] Operability refers to whether the alleged invention is eventually proved to work in fact. This is distinct from establishing utility at the filing date, which considers whether the patentee had sufficient basis to lay claim to an "invention" or was merely speculating. As Mr. Dimock observes, in all but one of the cases relied upon by Professor Siebrasse to suggest that Canadian courts previously accepted post-filing evidence of utility, "such "post-filing" evidence was provided to rebut allegations of invalidity, in that the invention was obvious or it was not operable."[206] In other words, in those cases, the issue was not whether the applicant had actually invented something at the time of filing.[207]

116. The only case relied upon by Professor Siebrasse, and the only case of which Mr. Dimock is aware, that can be construed as relying on post-filing evidence in support of demonstrating or soundly predicting utility at the time of filing is *Ciba-Geigy AG v Canada (Commissioner of Patents)*.[208] In that case, the Federal Court of Appeal reversed the Patent Office's rejection of a patent application. The Patent Office had refused to consider post-filing evidence in support of a sound prediction.

117. Claimant casts *Ciba-Geigy* as specifically affirming after-the-fact validation of predictions of utility with post-filing evidence.[209] This over-reads *Ciba-Geigy*, and

[204] Claimant's Memorial, para. 53; Siebrasse Report, para. 30.

[205] Dimock Report, para. 105.

[206] Dimock Report, para. 105 (emphasis added).

[207] Dimock Report, para. 105.

[208] Dimock Report, para. 106; *Ciba-Geigy AG v. Canada (Commissioner of Patents)*, (1982), 65 CPR (2d) 73 (FCA) (**R-190**). In *Ciba-Geigy*, the Patent office refused to consider post-filing evidence in the context of an objection to the soundness of predicted utility, and rejected the patent application. The decision of the Patent Office was subsequently overturned by the Federal Court of Appeal.

[209] Claimant's Memorial, para. 53.

ignores the Supreme Court of Canada's subsequent comments on that case. First, the Federal Court of Appeal in *Ciba-Geigy* found it probable that sufficient testing had been done at the filing date to support a sound prediction. Thus, as Mr. Dimock observes, "there was no need to consider post-filing evidence in *Ciba-Geigy*."[210] This was specifically observed by the Supreme Court of Canada in *AZT* in its discussion of *Ciba-Geigy*, which dismissed any notion that *Ciba-Geigy* was authority for "after-the-fact" validation".[211]

118. Second, reading *Ciba-Geigy* as permitting patents to be filed on pure guesses justified by after-the-fact testing (which is how Claimant reads the case) is completely at odds with the *Patent Act* and its purpose. As Justice Binnie wrote for the Supreme Court of Canada in *AZT*:

> …
>
> ["after-the-fact" validation] 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 policy (which does not encourage the stockpiling of useless or misleading patent disclosures).
>
> …
>
> 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.[212]

119. The Supreme Court of Canada's comments on *Ciba-Geigy* in *AZT* were not a reversal of Canadian law but, as Mr. Dimock explains, "confirmation of a well-

[210] Dimock Report, para. 109.

[211] Dimock Report, para. 112.

[212] *AZT*, para. 80 (**R-004**).

established rule."[213] For this reason, the Canadian Patent Office has also always required that an applicant be in a position to establish the utility of its claimed invention at the time a patent application is filed.[214] Indeed, the 1990 version of MOPOP stated, under the heading "Utility essential to invention", that "[a]n 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."[215] The Patent Office would not accept post-filing evidence of utility, regardless of whether an applicant relied on demonstration or sound prediction of utility.[216]

120. If post-filing evidence of utility were permitted, inventions could be nothing more than bare speculation, with a statutory monopoly in hand as insurance in the event that the idea ultimately proved to be useful. As Mr. Dimock explains, reliance on post-filing evidence to establish utility at the time of filing "can be described as a "file now, pay later" approach" that runs counter to the principles underlying the patent bargain.[217]

5) Canadian courts fairly adjudicate whether utility has been established based on the evidence put before them by the parties

121. Claimant argues that Canadian courts subject patents to "heightened scrutiny" when assessing the evidence on whether the promise of the patent has been met.[218] Claimant argues that it is "arbitrary and unpredictable" for judges to "second guess" the evidence put forward by patentees to support the utility of the invention because there is no way to know in advance how much evidence will be required to demonstrate or soundly predict utility.[219] Once again, these allegations do not relate to the meaning of utility under the *Patent Act* or NAFTA Article 1709(1). They relate to the courts' appreciation of evidence put before them by the parties on the issue of utility.

[213] Dimock Report, para. 110.

[214] Gillen Statement, paras. 33-34.

[215] "Manual of Patent Office Practise", Consumer and Corporate Affairs Canada, Patent Office (1990) 18.20.02 (**R-309**).

[216] Gillen Statement, paras. 38, 41.

[217] Dimock Report, para. 108.

[218] Claimant's Memorial, para. 57.

[219] Claimant's Memorial, para. 265.

122. In any event, these allegations are baseless and misconceive the role of the court. Patents are presumed valid until evidence showing invalidity is introduced.[220] When a patent is challenged, evidence may be introduced that the utility of the patent was not established, whether by demonstration or sound prediction at the filing date. The role of the court is to determine, on a balance of probabilities, whether the patent is invalid.[221] The court does not control the substance of the evidence put before it by the parties (those decisions rest entirely in the hands of the litigants). The court's statutory duty is to fairly decide the issues of validity before it based on all of the evidence. There is nothing arbitrary about this essential function of the court.

123. Nor is the level of evidence required to demonstrate or soundly predict the promised utility of the invention "arbitrary and unpredictable." The challenger will have to show, on a balance of probabilities, that the utility of the disclosed invention was neither demonstrated nor soundly predicted at the time of filing.[222] While the evidence and reasoning required to support a sound prediction will vary with the context, as Mr. Dimock notes, the key principle is that there must be "a sufficient factual basis and line of reasoning so that a skilled reader would recognize the prediction as a sound one."[223]

124. Claimant further alleges that court scrutiny of evidence of utility has become so heightened that the utility requirement in Canada can no longer be met in the pharmaceutical context in the absence of clinical trials.[224] This is false. As Mr. Dimock explains, "[n]umerous pharmaceutical patents have been upheld in the absence of clinical trials, including on the basis of sound prediction."[225] Indeed, the Supreme Court

[220] Dimock Report, para. 29.

[221] Dimock Report, para. 29.

[222] Dimock Report, para. 29.

[223] Dimock Report, para. 100.

[224] Claimant's Memorial, para. 66.

[225] Dimock Report, para. 100.

of Canada in *AZT* found that *in vitro* tests were sufficient to support a sound prediction of utility for the use of a pharmaceutical compound to treat HIV in humans.[226]

6) Where utility is merely predicted at the filing date, the patent must disclose a sound basis for the prediction

125. Claimant alleges that when it filed its patents, Canadian law did not require it to disclose the basis for a sound prediction of utility in the patent, and that this requirement was introduced by the Federal Court in 2008 based on an interpretation of the Supreme Court of Canada's 2002 decision in *AZT*.[227] Claimant's narrative – which relates to rules regarding disclosure, which are not at all governed by NAFTA Chapter Seventeen – is incorrect. It has been recognized in Canadian law since at least the 1970s that a sound prediction of utility must be adequately supported by information contained in the patent disclosure. This requirement did not change between the filing and invalidation of Claimant's patents.[228]

126. Where a patentee relies upon a sound prediction to establish the utility of the invention, the patent must disclose the factual basis and a line of reasoning that support the prediction. The information disclosed must be sufficient that a skilled reader, who is equipped with the common general knowledge in the field, would recognize the prediction as sound.[229] This disclosure requirement for sound prediction was correctly identified and applied by Justice Barnes to Claimant's patent for atomoxetine, and had no bearing on the invalidation proceedings concerning the olanzapine patent.[230]

127. The nature of disclosure required for sound prediction flows from settled principles of disclosure. Whether an invention is "correctly and fully described" under the *Patent Act* depends on whether a skilled reader in the relevant field could understand

[226] *AZT* (**R-004**).

[227] Claimant's Memorial, para. 73.

[228] Dimock Report, paras. 50, 138, and 222.

[229] Dimock Report, para. 100.

[230] Dimock Report, para. 222; Claimant does not allege the disclosure requirement for sound prediction had any bearing on the invalidity of its patent for the use of olanzapine. Claimant's Memorial, para. 111.

and operate the invention. In general, there is no obligation to disclose the utility of the invention in the patent. However, it is necessary to disclose utility in certain contexts. For example, for both new use and selection patents, the promised utility is at the core of the invention and must be disclosed.[231] In the context of sound prediction, proper disclosure requires that the patent disclose enough information so that a person skilled in the art, and equipped with the common general knowledge, could recognize that its utility was "soundly predicted," and not bare speculation.[232] Without this, there may be nothing in the disclosure to separate a sound prediction (and therefore a legitimate invention) from a mere idea that occurred to the patentee. This is evident in the case of Claimant's patent for the use of atomoxetine, where the patent simply predicted a new use for a known compound without providing the skilled reader with any factual basis in the disclosure to indicate that the prediction was sound.

128. Claimant alleges that the sound prediction disclosure requirement applied by Justice Barnes did not exist when it applied for its patent for atomoxetine.[233] This is false. The need to disclose the basis for a sound prediction in the patent has been recognized in Canadian patent law since at least the 1970s, as demonstrated in the jurisprudence and legal literature canvassed in the expert report of Mr. Dimock.[234] For example, in his 1970 patent tutorials, Mr. Hayhurst wrote:

[231] Dimock Report, paras. 116-123.

[232] Dimock Report, para. 222.

[233] Claimant's Memorial, para. 137. Claimant indeed presses its point further, and suggests that Justice Barnes effectively acknowledged that the requirement was new and unfair to Lilly. Claimant's Memorial, para. 138. This is a misstatement of the record. Justice Barnes noted Lilly's argument, without any suggestion that he endorsed it. *Atomoxetine FC*, para. 121 **(R-027)** (stating "Lilly argues that the validity of the '735 Patent is now being assessed against the backdrop of a more rigorous disclosure obligation than may have been apparent at the time of its filing in 1996. Lilly also questions what public policy or statutory purpose is served by imposing a heightened disclosure obligation in cases of a sound prediction of utility — provided, of course, that what is disclosed is sufficient to understand and to work the invention. [Footnote Omitted] 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.")

[234] Dimock Report, paras. 123, 135, and 149-152; W.L. Hayhurst, Q.C., "Annual Survey of Canadian Law – Industrial Property" (1979), 11 *Ottawa L. Rev*. 391, p. 427. (emphasis added) **(R-198)** (writing that "The public is adequately protected by two other principles… and secondly, that the claim is invalid, for

> Not only must you instruct those skilled in the art. You must also provide a disclosure which justifies the claims you are making. Here emphasis shifts from the adequacy of the disclosure to the validity of the claims…[y]ou must include sufficient examples to justify a sound prediction that everything falling within the scope of the claims will have the promised utility.[235]

129. The question of whether the patent specification sufficiently supported a sound prediction was squarely at issue in the 1979 *Monsanto* case, in which the Supreme Court of Canada received the doctrine of sound prediction into Canadian law.[236] The primary issue in *Monsanto* was whether a patent claim for 126 different compounds was adequately supported by the disclosure in the patent specification of just three examples of claimed compounds that had been prepared at the filing date.[237] The patent examiner rejected the claim, and the Patent Appeal Board affirmed that it was "not satisfied that three specific examples are adequate support for the breadth of the claim."[238] It did so despite expert affidavits submitted by Monsanto from persons skilled in the art affirming that they could soundly predict the utility of all the claimed compounds based on the three examples disclosed.[239] The Federal Court of Appeal affirmed.

130. The Supreme Court of Canada reversed all of the courts below. However, this was not because the Court rejected the principle that adequate support for a sound prediction must be provided in the specification. Indeed, the Court's decision was premised on the fact that there had been disclosure of three working examples. The

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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."); 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) **(R-201)** (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.").

[235] W.L. Hayhurst, "Disclosure Drafting" (1971), 28 PTIC Bull (7th) 64, pp. 77, 78. (emphasis added) (**R-164**).

[236] Dimock Report, para. 126.

[237] Dimock Report, para. 127.

[238] *Monsanto Co. v. Commissioner of Patents (The Board)*, (1977), 34 CPR (2d), p. 14 (**R-197**).

[239] Dimock Report, para. 131.

Court could not accept the Board's unexplained rejection of the expert evidence of persons skilled in the art adduced by Monsanto that the claimed utility of the invention could be soundly predicted on the basis of the three examples disclosed. The Court concluded that the Board should have allowed the claims because it "does not appear … that the Board really found that the claims in issue did not involve a sound prediction."[240] The Supreme Court's ruling in *Monsanto* was described by Mr. Hayhurst in a 1983 article in the following terms:

> 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. [241]

131. As Mr. Dimock explains, the Supreme Court in *Monsanto* emphasized that a sound prediction must not go beyond the consideration provided by the disclosure, quoting the following principle from the English case of *Olin Mathieson*:

> Where, then, is the line to be drawn between a claim which goes beyond the consideration and one which equiparates with it? In my judgment this line was drawn properly by Sir Lionel when he very helpfully stated in the words quoted above that it depended upon whether or not it was possible to make a sound prediction. If it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so. Of course, in so doing he takes the risk that a defendant may be able to show that his prediction is unsound or that some bodies falling within the words he has used have no utility or are old or obvious or that some promise he has made in his specification is false in a material respect; but if, when attacked, he survives this risk successfully, then his

[240] *Monsanto 1979*, para. 17 **(R-023)**.

[241] W.L. Hayhurst, Q.C., "Survey of Canadian Law – Industrial Property: Part I" (1983), 15 Ottawa L. Rev. 38, p. 69. (emphasis added) **(R-199)**; *See* also Adrian Zahl, "Covetous Patent Claims" (2004) 21 CIPR 141, p. 147 **(R-310)** (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. In the absence of evidence that a sound prediction *cannot* be made, the commissioner is required by law to grant a patent." (emphasis added).

> claim does not go beyond the consideration given by his disclosure, his claim is fairly based on such disclosure in these respects, and is valid.[242]

132. When the Supreme Court of Canada next addressed the issue of sound prediction, in its 2002 decision in *AZT*, it reaffirmed that a sound prediction must be adequately supported by the disclosure.[243] The Court noted that it had explicitly received the doctrine of sound prediction into Canadian law in *Monsanto*. It then restated the components of the doctrine. Justice Binnie wrote for the Court that: (1) there must be a factual basis for the sound prediction, (2) the inventor must have 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.[244] On the facts before it, the Court observed that there was no issue concerning disclosure because the underlying facts and line of reasoning were in fact disclosed in the specification.[245]

133. Claimant's contention that, in the leading cases on sound prediction before 2008, the courts relied on evidence that was not disclosed in the patent, is unsupported and inaccurate.[246] In both pre-2008 cases where the Supreme Court of Canada applied the doctrine of sound prediction, *Monsanto* and *AZT*, the Court found that the information contained in the patent disclosure itself was adequate to support the sound prediction. In *Monsanto*, the expert affidavits simply established what a skilled reader could predict from the factual basis of the patent disclosure, which contained three examples.[247] In *AZT*, Justice Binnie made clear that "both the underlying facts (the test data) and the line of reasoning (the chain terminator effect) were in fact disclosed."[248] In contrast,

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[242] *Monsanto 1979*, para. 13 (emphasis added) (**R-023**).

[243] Adrian Zahl, "Covetous Patent Claims" (2004) 21 CIPR 141, p. 158 (emphasis added) (**R-310**) (writing that "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.").

[244] *AZT*, para. 70 (**R-004**); Dimock Report, para 124.

[245] Dimock Report, para. 125; *AZT*, para. 70 (**R-004**).

[246] Claimant's Memorial, paras. 52, 57.

[247] Dimock Report, para. 132.

[248] *AZT*, para. 70 (**R-004**).

Claimant's patent for the use of atomoxetine did not disclose *any* factual basis or line of reasoning to support the prediction of utility on which it relied. Claimant relied solely on the MGH study to support its sound prediction, and that study was nowhere referenced in the patent.[249]

134. Claimant is further incorrect in alleging that when it filed its patents, the Patent Office did not require that any basis to support a prediction of utility be disclosed in the patent.[250] In the 1990s, examiners' assessment of whether the basis of a sound prediction of utility had been sufficiently disclosed was made against the language included by the applicant in the patent specification itself. As Mr. Gillen explains, examiners would not accept predictions of utility that were completely unsubstantiated in the patent application.[251]

D. There Is No "Systemic Discrimination" Against Pharmaceutical Patents

135. Claimant alleges that Canada's utility doctrine discriminates *de facto* against pharmaceuticals as a field of technology.[252] Claimant's allegation is based upon a selective and misleading analysis of patent litigation outcomes.

136. Claimant itself admits that there is no *de jure* discrimination against pharmaceutical inventions, in that Canadian patent utility requirements apply to inventions in all technical fields.[253] As Mr. Dimock explains, "[n]othing in the *Patent Act* or in the case law indicates that there is any discrimination. The law of utility is the same for all inventions whether they be pharmaceutical or some other subject matter."[254]

[249] *See* above, Part II.A.1.

[250] Wilson Report, para. 30.

[251] Gillen Statement, para. 43.

[252] Claimant's Memorial, para. 213

[253] Claimant's Memorial, para. 214

[254] Dimock Report, para. 158.

137. Yet Claimant's argument of *de facto* discrimination is also groundless. Patents in non-pharmaceutical fields have been held to their promises.[255] Moreover, Canadian utility law is inherently permissive to pharmaceutical patent-holders in that it allows patents to be successfully upheld on the basis of merely predicted, rather than fully demonstrated invention. This has allowed pharmaceutical companies to successfully seek patents and to defend their validity despite not having demonstrated utility across the full scope of their claims.[256] This makes Claimant's allegations regarding the allegedly discriminatory impact of sound prediction particularly perverse.[257]

1) The pharmaceutical sector is uniquely litigious

138. Claimant attempts to make out its case in reliance on statistics that suggest that pharmaceutical patent holders have been uniquely targeted by Canada's utility doctrine.[258] Claimant's analysis is significantly distorted by crucial omissions. Specifically, it ignores the fact that patent litigation in the pharmaceutical sector has surged in this same period, not because of any change in the law of utility, but because developments in the patent regime that *strengthened* intellectual property protection for pharmaceuticals. Specifically, incentives and opportunities to litigate were increased by the abolition of compulsory licensing and the introduction of *PM(NOC)* proceedings, both in 1993.

139. The pre-1993 compulsory licence regime enabled generic manufacturers to enter the market by paying a nominal royalty of only four to five per cent to the patent holder. Once a licence was obtained, the patent holder could not prevent the generic company from entering the market or seek further compensation by asserting its patent rights

[255] Dimock Report, para. 159.

[256] Dimock Report, paras. 160-161.

[257] Claimant's Memorial, para. 224

[258] Claimant's Memorial, paras. 291.

through infringement proceedings. As such, neither side had an incentive to litigate over pharmaceutical patent validity.[259]

140. In the same year that compulsory licensing ended (1993), the introduction of *PM(NOC)* proceedings further strengthened the rights of pharmaceutical patent holders and increased the opportunity for pharmaceutical litigation by granting pharmaceutical patent holders unique pre-emptive rights to block market entrants.[260] As discussed above, *PM(NOC)* proceedings are unique to the pharmaceutical field. Any pharmaceutical manufacturer wishing to enter the market in Canada must obtain an NOC from the Minister of Health. A pharmaceutical patent-holder can block the issuance of a competitor's NOC by Health Canada pending determination of its allegations of infringement.[261] The generic company may in turn allege that the patent is invalid, including for inutility. The Federal Court will consider and address these issues in determining whether the Minister of Health should be restrained from issuing an NOC.[262]

141. Crucially, *PM(NOC)* rulings relate only to the issue of whether the Minister should be restrained from issuing an NOC and *do not* constitute final determinations on issues of patent validity, including patent utility. Even if the generic company is successful on the basis that the patent asserted against it does not meet the utility requirement, the patent remains valid and can be asserted against the generic company or any other party through normal patent infringement remedies before the courts. In other words, the *PM(NOC)* proceeding is an additional line of defence beyond normal patent remedies for pharmaceutical patent holders.[263]

[259] Dimock Report, para. 39.

[260] Dimock Report, para. 45.

[261] Dimock Report, paras. 43, 154.

[262] Dimock Report, para. 44.

[263] Dimock Report, para. 156; Brisebois Statement, para. 31.

2) Overall rates of invalidation have not increased

142. Claimant's reliance on the rise in the absolute number of pharmaceutical patent challenges on the basis of "utility" in the 2005-2014 period fails to account for both the abolition of compulsory licensing and the introduction of *PM(NOC)* proceedings. The *PM(NOC)* process was only introduced in 1993 but already accounted for 65% of all pharmaceutical patent litigation between 1980-2004.[264] This percentage increased to 83% for 2005-2014.[265] In this context – which Claimant fails to acknowledge – it is unsurprising that absolute numbers of court rulings on all grounds, including utility, are higher in the pharmaceutical than in other sectors, and in comparison with the pre-*PM (NOC)* period.

143. Claimant is also unfounded in alleging disproportionately negative litigation outcomes based on application of the "utility" criteria in the 2005-2014 period alone. Notwithstanding the introduction of the *PM(NOC)* process, overall rates of success in pharmaceutical patent challenges remained consistent between 1980-2004 and 2005-2014. In 1980-2004, 48% of patent validity challenges in this sector were successful. In 2005-2014, the rate was 50%.[266]

144. Further, utility was not the most frequent basis for challenge to pharmaceutical patents in the 2005-2014 period.[267] Challenges based upon obviousness far outnumber those based upon utility, while the number of novelty-based challenges was virtually identical.[268] Moreover, only one-third of all challenges on the basis of utility were successful, reflecting outcomes on other grounds.[269]

[264] Brisebois Statement, para. 32.

[265] Brisebois Statement, para. 32.

[266] Brisebois Statement, para. 34.

[267] Brisebois Statement, para. 35.

[268] Brisebois Statement, para. 35.

[269] Brisebois Statement, para. 36.

145. Finally, the overwhelming majority of successful pharmaceutical challenges related to secondary patents.[270] As patent scholars have noted, secondary patents are much more likely to be challenged, and are more likely to be found invalid than primary patents in Europe and the United States.[271]

3) Only three, not twenty-three, pharmaceutical patents were true invalidations

146. Claimant's statistics further mislead because they include patents suffering from multiple flaws, not limited to failure to fulfil the utility criteria, and count as "invalidations" cases which did not reach that result.

147. Claimant references a total of twenty-three alleged "invalidations" of pharmaceutical patents in the 2005-2014 period based upon utility, but fails to mention that eleven of these also were successfully challenged on other grounds. In other words, had the utility issue not been raised, the patent would have in any event failed a validity challenge. Overall, only twelve out of sixty-eight patent challenges in the 2005-2014 period involving allegations of lack of utility were successful on the basis of utility alone.[272]

148. Claimant's statistics are further skewed in that, as described above, they include *PM(NOC)* determinations, which are not true "invalidations" but rather decisions to

[270] Brisebois Statement, para. 42. Secondary patents are those where an applicant seeks to extend an already-existing patent monopoly by claiming such things as new uses of patented compounds, selections from already-patented genus, or improvements on existing pharmaceutical formulations.

[271] Brisebois Statement, para. 46; *See* also European Commission (2009) Pharmaceutical Sector Inquiry: Final Report (**R-243)**; and Hemphill, C. Scott and Sampat, Bhaven N., When Do Generics Challenge Drug Patents?, 1 September 2011. Columbia Law and Economics Working Paper No. 379; Journal of Empirical Legal Studies, 2011; 5th Annual Conference on Empirical Legal Studies Paper; Columbia Law and Economics Working Paper No. 379. Online: SSRN: http://ssrn.com/abstract=1640512 (**R-245**); Claimant also suggests that rates of invalidation on grounds of "utility" are much lower in the United States or in Mexico: Claimant's Memorial, para. 222. This statement is misleading in that, as Professor Holbrook notes, issues that might in Canada be raised under the heading of "utility" in the United States may instead be raised under the related issues of "enablement" or "written description" (Holbrook Report, paras. 41-45 and 56-61). Moreover, as Ms. Lindner notes, overall rates of patent litigation in Mexico are very low, given institutional limitations (Lindner Report, paras. 85-86).

[272] Brisebois Statement, para. 37.

allow a NOC to be issued, the effect of which can thereafter be challenged through infringement proceedings under the *Patent Act*.[273] If *PM(NOC)* proceedings are removed from the analysis (as they must be in order to provide an accurate assessment), *only three* pharmaceutical patents were actually invalidated on the sole basis of lack of utility in the 2005-2014 period, two of which are the patents at issue in this proceeding.[274] This also means that over the past thirty-five years, only three pharmaceutical patent claims have been invalidated in Canada on the sole basis of utility, compared with two in other sectors during this same period. [275]

149. Claimant's statistics-based allegations of *de facto* discriminatory effect on the pharmaceutical sector as a result of Canada's utility doctrine are not made out.

E. Claimant's Own Patenting Behaviour Illustrates Why Rules to Prevent Speculative Patenting Are Needed

150. Claimant argues that Canada's utility rules "serve no legitimate policy objective." [276] This sweeping statement is unacceptable on multiple levels, not least of which because it wilfully ignores the issue of speculative patent filing done on the basis of little or no supporting research. Claimant's own patent filing behaviour actually suggests the importance of Canada's rules.[277]

151. Industry Canada's analysis of Claimant's patent filing behaviour during the 1990s reveals that its patents for olanzapine and atomoxetine at issue in this proceeding formed part of an overall pattern in which Claimant adopted a scattershot approach to patent filings, claiming dozens of new uses of known and previously-patented

[273] Dimock Report, para. 44.

[274] Brisebois Statement, para. 40.

[275] In the pharmaceutical sector only 17% of cases involved invalidation on the basis of utility alone, while 14% of cases were found in the non-pharmaceutical sector to be invalid on the basis of utility alone.

[276] Armitage Statement, para. 13.

[277] Armitage Statement, para. 13.

compounds on the basis of little apparent evidence, only to abandon the vast majority of these applications.[278]

152. As Dr. Brisebois of Industry Canada confirms, Claimant filed a total of ninety-six separate patents for various new uses of atomoxetine, olanzapine and raloxifene between 1990 and 2004.[279] Dr. Brisebois included the third compound in his review because Claimant's patent for a use of raloxifene was successfully challenged on the basis of lack of utility before the Canadian courts, about which Claimant also complains in its Memorial.[280]

153. Between 1992 and 2004, Claimant filed patent applications claiming twelve alleged new uses of atomoxetine in the treatment of psoriasis, stuttering, incontinence, hot flashes, anxiety, learning disabilities, tic disorders, cognitive failure, oppositional defiant disorder, conduct disorder, pervasive development disorder, and ADHD.[281]

154. Close inspection of the patent specifications for these filings revealed that roughly half of Claimant's applications contained no reference to experimental data.[282] Moreover, of the seven patent applications actually referencing experimental data, three referenced only a single case study.[283] While the reference to data might suggest that these were more "secure" applications, in fact, all three were abandoned during prosecution.[284] To the extent that three were granted, in all but one case – the patent for the use of atomoxetine to treat ADHD – Claimant failed to pay the maintenance fees, [285] allowing the patent to lapse before its full term had expired. As patent maintenance fees

[278] Brisebois Statement, paras 47-68.

[279] Brisebois Statement, para. 50.

[280] Claimant's Memorial, para. 74.

[281] Brisebois Statement, para. 52.

[282] Brisebois Statement, para. 62.

[283] Brisebois Statement, para. 62.

[284] Brisebois Statement, para. 62.

[285] Brisebois Statement, para. 63.

are *de minimis*, Claimant's abandonment was an acknowledgement that these uses allegedly "invented" and claimed in the patent were unsustainable.

155. A similar pattern emerges when considering Claimant's patent filings for olanzapine. Between 1995-1998, Claimant filed sixteen separate patents based upon its alleged "invention" of the following new uses for the drug for the treatment of: excessive aggression, fungal dermatitis, bipolar disorder, sexual dysfunction, insomnia, anaesthetic agent, nicotine withdrawal, tic disorder, anorexia, depression, autism and mental retardation, pain, migraines, dyskinesia, addictive substance withdrawal, and Alzheimer's disease.[286] These patents were all filed in the period when Claimant's longstanding monopoly on olanzapine, as part of a larger genus, was about to expire.[287]

156. Again, roughly a third of these applications (five out of sixteen) contained no reference at all to relevant experimental data.[288] Of the eleven that did, in nine of eleven cases this was limited to bare reference to a clinical study in which the claimed use of olanzapine had allegedly been demonstrated.[289]

157. Reference to clinical trials implied that Claimant had collected a significant amount of clinical data relevant to the asserted uses, prior to the filing date of the patent applications at issue. However, in a separate disclosure relating to its brand-name olanzapine product "Zyprexa", Claimant provided what it asserted to be a complete list of all clinical trials conducted on olanzapine. Several of the uses for which Claimant referenced clinical trials in its patent filings were not referenced in that document,

[286] Brisebois Statement, para. 53.

[287] Claimant's patent for the selection of olanzapine from the previously-patented genus, at issue in this proceeding, was in addition to these sixteen. Claimant's "selection" patent for olanzapine did not claim a "new use", as that use had already been claimed in the prior genus patent: rather, it was based on olanzapine having substantially more effectiveness and fewer side-effects in anti-psychotic treatment than other members of its class.

[288] Brisebois Statement, para. 57.

[289] Brisebois Statement, para. 57.

notably: dyskinesia, tic disorders, autism, mental retardation, excessive aggression, insomnia, migraine pain, and addictive substance withdrawal.[290]

158. Moreover, in 1994-1995, Claimant had directed or was aware of a clinical study whose secondary objective was to evaluate the effectiveness of olanzapine as a treatment for Alzheimer's disease. The results were negative.[291] Despite Claimant's awareness of these negative results, it proceeded to file a patent application alleging the discovery of the use of olanzapine to treat Alzheimer's disease, asserting that the new use had been confirmed by clinical trials.[292]

159. The promising clinical results asserted in the nine patent applications should have provided strong incentive to Claimant to pursue the related patent applications. Instead, Claimant abandoned eight of these nine patent applications during prosecution, *i.e.* before the patent had even been granted.[293] The one patent issued from nine applications, granted on the basis that a claimed therapeutic use had been "demonstrated", was allowed by Claimant to lapse for failure to pay the maintenance fee. In other words, again, despite its representation that it had discovered a "new use" for olanzapine in the patent based upon clinical studies, Claimant itself recognized that the patent was worthless.

160. The pattern is even more marked in the case of raloxifene. Claimant filed no fewer than sixty-eight separate secondary patent applications for the compound between 1993 and 2001, for uses ranging from osteoporosis, to high cholesterol, to breast disorders, to acne, to obsessive-compulsive disorders.[294] Of these, over half contained no reference to relevant experimental data.[295] Claimant went on to abandon ninety-nine

[290] Eli Lilly, "Trials of Zypreza" (LY170053), online: www.lillytrials.com/results/Zyprexa.pdf (**R-217**).

[291] Brisebois Statement, para. 59.

[292] Patent Specification CA 2,219,902 (**R-273**).

[293] Brisebois Statement, para. 60.

[294] Brisebois Statement, para. 55 and Annex E.

[295] Brisebois Statement, para. 65.

percent of these patent applications, mostly during prosecution or, if the patent was granted, for failure to pay maintenance fees.[296]

161. Ultimately, out of ninety-six patent applications filed on the basis of its alleged "invention" of new uses for these three compounds, filed in the period from 1990 to 2004, Claimant abandoned ninety-four in total, maintaining only two of the six patents it ultimately was granted.[297] In relation to general patent filing averages, this represented an extraordinarily high percentage of "dead" patent filings. It was also substantially higher than the percentage of dead applications in the same field by all other applicants in Canada.[298]

162. Several observations flow from the above. First, when filing its patent applications in the 1990s and 2000s, in roughly half of the cases Claimant made some reference to relevant experimental data supporting the asserted utility. This behaviour contradicts its assertion that in this period there was no requirement to file data in support of an asserted utility. Claimant clearly was not influenced by what it characterised as a "change" in Canadian patent rules on disclosure in the Supreme Court's 2002 *AZT* decision. Before that decision was issued, Claimant was likely as not to put supporting data in its specification. After that decision was issued, it still filed patents lacking any supporting data. [299]

163. Second, the extremely high abandonment rate in Claimant's patent application filings suggests that these patent applications were filed extremely early in the research process, when the alleged new use was at best speculation, and certainly less than a "sound prediction." This would be consistent with the Federal Court findings regarding

[296] Brisebois Statement, para. 65.

[297] Brisebois Statement, para. 67.

[298] Brisebois Statement, para. 66.

[299] Indeed, Claimant filed at least two patents for a "new" therapeutic use for atomoxetine after the *AZT* decision of 2002 (which it alleges "changed" the rules concerning evidence required in patent applications), again with no supporting data in the specification: Patent Specification CA 2,532,349 **(R-311)**; Patent Specification CA 2,536,161 **(R-312)**.

the olanzapine and atomoxetine patents at issue in this proceeding. The patent application filings making no reference to data at all could, in this context, have been filed on the basis of pure speculation. Claimant's patent filing behaviour is even more striking when compared to the patenting behaviour of other applicants, given its proportionately high number of "dead" applications.

164. Regardless of its intentions, Claimant's behaviour had the effect of creating a "thicket" of patent applications that ultimately proved of low quality and were abandoned. This would have had the effect of dissuading rather than promoting innovation in this area, undermining a fundamental purpose of the *Patent Act*.[300] It is precisely such behaviour which Canada's rules against speculative patenting seek to address.

F. Health Canada Approval of Zyprexa and Strattera Has Nothing to Do with the Validity of Claimant's Patents

165. Claimant critiques the Federal Court invalidation of its patents for atomoxetine and olanzapine by citing later Health Canada approval for its drug products employing these compounds, suggesting that through this it had fulfilled the requirement of "utility" under the *Patent Act*.[301] Claimant also aggrandizes the value of studies it disclosed in its patent applications (or, in the case of atomoxetine, had performed as of the time of filing, but not disclosed in its application) by suggesting that they were important to this subsequent Health Canada approval.[302]

166. The first of these allegations is a red herring. Approval of a drug by Health Canada has no bearing on whether a patent fulfilled the "utility" requirement in the *Patent Act*. Health Canada's approval in the New Drug Submission process relied on

[300] Brisebois Statement, para. 68.

[301] Claimant's Memorial, paras. 92 and 125.

[302] *See* Armitage Statement, paras. 16 and 22; Nobles Statement, para. 21; Stringer Statement, para. 16; Postlethwait Statement, para. 29. Beyond the fact that through such statements Claimant seeks to relitigate issues already addressed in the relevant trials, none of these four witnesses is a scientist, and none of these four witnesses were involved in any of the relevant studies which they suggest "established" the utility of the patents at the time of filing.

studies and data that did not even exist at the time the patent was filed.[303] Canadian law does not grant patents for almost-inventions, even if the applicant's speculation at the time of filing is later confirmed.[304]

167. The second of Claimant's arguments is factually incorrect. Ms. Barton examined Health Canada New Drug Submission approval files for Claimant's two drug products to verify Claimant's suggestion that studies disclosed in the patent specification for olanzapine, or the MGH study Claimant had available but not disclosed for atomoxetine, had been "relied upon" by Health Canada when approving the relevant drugs for approval. Ms. Barton determined that the studies referenced in Claimant's olanzapine patent specification were not included in the new drug submission for Claimant's Zyprexa product.[305] In the case of atomoxetine Ms. Barton observed that Claimant had not submitted the MGH study to Health Canada as a relevant clinical trial. At best, Claimant referred in its submission to an article disclosing the study, among its additional literature references. Health Canada does not rely upon such references in granting its approval. In both cases, therefore, studies upon which Claimant relied to justify its "invention" of a use of atomoxetine, or of the relative effectiveness of olanzapine, and on which basis it filed its patents, played no role in Health Canada's approval process.

168. Health Canada new drug approval depends on the voluminous information actually submitted to it in the course of a New Drug Submission ("NDS") under the *Food and Drug Regulations*. The aim of the NDS process is to establish against a rigorous standard that the drug meets Health Canada requirements relating to safety, efficacy, and quality. Ms Barton further confirmed that given their partial and preliminary nature, the studies disclosed by Claimant in its olanzapine patent application (and, in the case of atomoxetine, conducted as of that time but not disclosed) would

[303] Barton Statement, para. 22 and FF.

[304] Dimock Report, para. 111.

[305] Barton Statement, para. 44 and FF.

likely have made marginal or no contribution to satisfying Health Canada criteria subsequent necessary for new drug market authorization in Canada.[306]

169. In summary, Claimant cannot rely on subsequent Health Canada approval on the basis of later and different studies to retroactively validate the insufficient basis upon which it filed its patents in the first place. Ms. Barton's evidence further confirms that Claimant's touting of its preliminary research as material to Health Canada's later, much more comprehensive process, is without merit.

G. United States "Enablement" and "Written Description" Doctrines Are Similar to Canada's Utility Doctrine, and United States Patent Law Has Evolved Since NAFTA

170. Claimant has alleged that the utility requirement in the United States is a simple, binary requirement - unless it is unbelievable on its face or wholly inoperative, it is useful.[307] Furthermore, according to Claimant, post-filing evidence is generally accepted to establish utility in the United States, whereas in Canada, since 2002, it has

[306] Barton Statement, para. 49. As Kimby Barton notes, the MGH study relating to atomoxetine was a small preliminary proof-of-concept study involving 22 adults, whose objective was to establish the tolerability of the compound, indicative of a preliminary study of a drug whose efficacy has not yet been established. By contrast, Health Canada's approval for Claimant's atomoxetine-based drug relied on 9 pediatric studies involving a total of 2189 children / adolescents, and 2 adult studies with 536 adult subjects in total, as well as patient exposure and safety data obtained from an 18-month post-marketing period in the United States, covering about 2,000,000 exposures. *See* Barton Statement, para. 29.

The olanzapine patent specification referred only to an open study of the compound in 8 patients, as well as preliminary results from three ongoing clinical trials. This is far inferior to the extensive clinical trials, involving hundreds if not thousands of clinical results, required for a new drug approval in Canada. For toxicity, the olanzapine specification referred to a single dog toxicity study of another substance that led to cholesterol increases, comparing it to olanzapine, asserting that olanzapine did not lead to cholesterol increases. This would not be sufficient for Health Canada non-clinical trials, which typically rely on a battery of tests to establish toxicity, carcinogenicity, genotoxicity, and mutagenicity of drug products prior to market approval. Otherwise, the olanzapine specification provides high-level chemical and manufacturing information that again would be insufficient to obtain drug approval. *See* Barton Statement, para. 44 and FF.

[307] Claimant's Memorial, paras. 146 and 147. *See* also Claimant's Merges Report, paras. 5 and 17. Claimant also alleges at para. 150 of its Memorial that a study has revealed that between 1989 to 1996, only 5 cases out of 200 in the U.S. included an allegation of inutility, and only one of these five utility challenges was successful. As Professor Holbrook states in footnote 8 of his expert report, Claimant's conclusion is misleading. The study includes both the predictable and unpredictable arts, when it is ordinarily only an issue in the unpredictable arts. Claimant's conclusion also avoids referring to invalidations based on enablement and written description, despite the considerable overlap with utility. When these are included, challenges were successful 36.1% of the time.

been rejected.[308] Claimant further alleges that utility has remained a stable, *de minimis*, standard in the United States since NAFTA came into force.[309] In contrast, Claimant alleges that the utility standard in Canada has been heightened dramatically post-NAFTA.[310]

171. Claimant's portrayal of United States law is inaccurate and misleading. As Professor Holbrook explains in his expert report, the utility standard presents a substantial hurdle for patentees in the chemical and biological arts (the "unpredictable arts") given the inherent unpredictability of chemical compounds.[311] Proving whether an invention will "work" is not a simple yes or no question in this context. It is for this reason that patent applications in the unpredictable arts are often supported by test results.[312] Furthermore, in the case of chemical compounds, United States courts have interpreted "specific, substantial and credible" utility to mean that a patent cannot be granted for something vague or hypothetical – the invention must provide a real-world and specific use that is credible to the person having ordinary skill in the art ("PHOSITA").[313] In this way, it acts as a tool for United States courts to ensure that patentees do not block off broad areas of research with no benefit to the public.[314] Further, contrary to what the Claimant asserts, the general rule in the United States is that utility must demonstrated as of the filing date.[315] In short, Claimant's depiction of the United States utility standard is simplistic, inaccurate, and ignores the complexities of the standard in the context of the unpredictable arts.

[308] Claimant's Memorial, paras. 53, 70-71, and 157; Claimant's Merges Report, paras. 5 and 19.

[309] Claimant's Memorial, paras. 7, 8, 36, 42, 145, and 211-212. *See* also Merges Report, paras. 5, 6, and 7.

[310] Claimant's Memorial, paras. 7 and 8, 36, 56, 57, 211, and 212. *See* also Merges Report, paras. 8 and 35.

[311] Holbrook Report, paras. 18, 24-25, 26, and 29.

[312] Holbrook Report, paras. 24-25 and 33.

[313] Holbrook Report, paras. 21-31.

[314] Holbrook Report, para. 18, citing *Brenner*.

[315] Holbrook Report, paras. 17 and 34.

172. The utility requirement in the U.S. cannot be accurately assessed in isolation from the rest of United States patent law. Professor Holbrook explains not only the overlap between the United States law of "utility" and "enablement" and "written description" (they often rise and fall together in the courts), but the similar role they play to the law of utility in Canada.[316] These disclosure requirements have been used by United States courts to limit claim scope and prevent speculative patenting.[317] Sufficient proof of enablement means ensuring that PHOSITA does not need to perform "undue experimentation" to employ the full scope of the invention.[318] In the context of written description, by demanding the specification demonstrate that the inventor be "in possession" of the invention, U.S. courts want proof that the inventor possesses the full scope of the claims at the date of filing.[319] Again, in the context of the unpredictable arts, these requirements are a considerable challenge for patentees to meet.[320] Claimant has focused almost exclusively on the United States utility standard, whereas an accurate comparison of U.S. and Canadian patent law requires the systems to be analysed as a whole.

173. Professor Holbrook also reveals that contrary to what Claimant alleges, the United States patent system has evolved substantially over the past 20 years, mainly through the interpretive power of the courts.[321] The utility standard was been relaxed after NAFTA came into force, but then was raised in 2005.[322] Post-NAFTA, the enablement requirement has been "ratcheted up"[323], while the written description requirement emerged after the entry into force of NAFTA as a result of Claimant's own

[316] Holbrook Report, paras. 41-55 (on enablement) and 56-61 (on written description).

[317] Holbrook Report, paras. 41, 47, 48, 56, 58, and 60.

[318] Holbrook Report, para 44.

[319] Holbrook Report, para 57.

[320] Holbrook Report, paras. 44, 58, and 59.

[321] Holbrook Report, paras. 62-75.

[322] Holbrook Report, para. 66.

[323] Holbrook Report, para. 67.

efforts.[324] Other requirements in United States patent law, including "obviousness" have been tightened post-NAFTA.[325] In some cases, the evolution of United States patent law has led to widespread uncertainty for patentees.[326] Like Canadian law, United States law has evolved since NAFTA came into force, undermining any suggestion by the Claimant that the Parties enshrined a particular standard in NAFTA.

174. As in Canada, it is the courts, and not the United States Patent and Trade Office, that retain full power to determine the validity of any patent grant.[327] The Manual of Patent Examining Procedure (MPEP) and the decisions of examiners are not determinative of the law, and as Professor Holbrook explains, any sophisticated patentee would know that an interpretation of the law provided by the United States Patent and Trade Mark Office is not final.[328]

H. Mexican Patent Law Does Not Apply the Same Criteria and Has Continued to Evolve Since NAFTA

175. Claimant argues that since NAFTA entered into force, Mexico too has shared a common understanding and practice regarding utility.[329] It suggests that Mexico, like the United States, has remained fixed in its interpretation and application of this standard.[330] Claimant points to the fact that there has been no litigation challenging its equivalent olanzapine and atomoxetine patents in Mexico, as further proof that Mexican law (unlike Canada's) is consistent with international law.[331] According to Claimant, only Canada has failed to respect the "common" NAFTA approach "enshrined" in Chapter Seventeen.

[324] Holbrook Report, para. 68.

[325] Holbrook Report, paras. 72-74.

[326] Holbrook Report, para. 63.

[327] Holbrook Report, paras. 77 and 79.

[328] Holbrook Report, para. 76.

[329] Claimant's Memorial, para. 7.

[330] Claimant's Memorial, paras. 7-8.

[331] Claimant's Memorial, paras. 113 and 141.

176. As with Claimant's arguments regarding United States patent law, Claimant's perspective on Mexican law is methodologically flawed, self-serving and inaccurate. The Mexican patent system addresses utility issues in its own distinct manner. As Ms. Heidi Lindner explains in her expert report, Mexican patent law has not remained static since NAFTA.[332] Instead, it was substantially reformed in 2010, notably to limit the practise of presenting patent applications to secure a filing date without having first completed the necessary research and development to support the claims made in the application.[333] To the extent Claimant's patents were not litigated in Mexico this reflects institutional challenges within the Mexican system and not the intrinsic validity of Claimant's patents under Mexican law.[334]

177. In her expert report, Ms. Lindner explains that Mexican patent law did not undergo substantive harmonization with patent laws of Canada or the United States, in connection with the coming into force of NAFTA and that NAFTA reforms instead addressed procedural issues.[335] Otherwise, Mexico had and retains a distinct concept of "industrial applicability", one of the two optional approaches set out in NAFTA Article 1709(1),[336] a criterion which the World Intellectual Property Organization has noted is distinct from possible approaches applying the 'utility' criteria.[337]

178. Her explanation also confirms that Claimant has understated the role this requirement plays in Mexican patent law. Industrial applicability, as a substantive requirement, must be satisfied,[338] and in the case of inventions such as pharmaceuticals, inventions, requires adequate disclosure in the patent specification for the asserted use to

[332] Lindner Report, para. 11.

[333] Lindner Report, paras. 32, 35, and 53.

[334] Lindner Report, paras. 85 and 86.

[335] Lindner Report, paras. 19 and 25.

[336] Lindner Report, para. 20.

[337] Gervais Report, paras. 31 and 39FF.

[338] Lindner Report, paras. 12 and 42.

be credible.[339] In any event, as she explains, it is misleading to analyse 'industrial applicability' in isolation: the Mexican system address issues such as speculative claims of industrial applicability and over-claiming through a range of conceptual tools. As Ms Lindner concludes, "Whether examiners object to patent applications because the claims in the patent applications are overly broad and speculative, or lack clarity or adequate support (such as experimental evidence), an attentive analysis of the examiners' objections shows that these objections are in fact tied to the industrial application requirement."[340]

179. Ms. Lindner further explains that Mexico has undertaken several substantive modifications to its basic patent law since 1994.[341] Notably in 2010, Mexico introduced legislative amendments to strengthen the industrial applicability criterion and to clarify the disclosure requirement to limit the practice of speculative patenting practise of filing patents prematurely.[342] Claimant's experts, Fabian Ramon Salazar and Gilda Gonzalez Carmona spent much time in their witness statement trying to downplay the impact of these reforms.[343] As Ms. Lindner points out, they were prompted by policy concerns analogous to those expressed in Canada, and resulted in reinforced ability of examiner to discipline speculative patent filings.[344] There is no suggestion in any of the relevant discussions that Mexican legislators were prevented from strengthening the Mexican application of "industrial applicability" as a result of NAFTA Chapter Seventeen.

180. Ms Lindner also points out that no conclusions may be drawn from the absence of any challenge to Claimant's atomoxetine and olanzapine patents in Mexico.[345] The structure of the Mexican judicial system makes it burdensome to challenge a patent

[339] Lindner Report, paras. 42- 44.

[340] Lindner Report, para. 62.

[341] Lindner Report, para. 27.

[342] Lindner Report, paras. 31, 32, 35, and 37.

[343] Salazar Statement, paras. 29 and 31-33; Gonzalez Statement, paras. 22-23

[344] Lindner Report, paras. 30, 35, 49 and 51-52.

[345] Lindner Report, para. 89.

before Mexican tribunals.[346] As a result, many patents that are intrinsically flawed go unchallenged.[347] In fact, having reviewed Claimant's two patent specifications in light of the actual requirements of Mexican law, Ms. Lindner concludes there would be good grounds for refusing the grant of the patents on grounds of lack of industrial applicability.[348] In the circumstances, there is no guarantee that, if challenged, the patents would survive Mexican court scrutiny, which renders Claimant's entire analysis of Mexican law irrelevant and of no value to its claims.

I. Substantive International Patent Law Is Not Harmonized

181. Claimant invites this Tribunal to conclude that the utility requirement in patent law is "substantially harmonized" across jurisdictions[349] and that it is "widely understood" to be an "undemanding" criteria.[350] This is simply untrue. Claimant's assertions suggest a degree of international consensus on substantive patent law that simply does not exist.

182. As Professor Gervais explains in his report, the international community has tried to harmonize substantive patentability requirements for the past 30 years, without success. International patent law treaties up to the 1980s – notably, the Paris Convention and PCT – made no attempt to adopt a binding definition of substantive terms, and expressly affirmed the independence of each national patent system.[351]

183. The first harmonization attempt was made in 1983 by WIPO members (which included the NAFTA Parties) in the context of the so-called "draft Treaty

[346] Lindner Report, paras. 84, 86-87.

[347] Lindner Report, para. 83.

[348] Lindner Report, paras. 100 and 108.

[349] Armitage Statement, para. 7.

[350] Claimant's Memorial, para. 38.

[351] Article 27(5) *PCT* reads: "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". Article 4bis of the Paris Convention reads: "Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not".

Supplementing the Paris Convention as far as Patents are concerned", also known as the "Basic Proposal". The Basic Proposal suggested for the first time definitions of the terms "novel" and "involve an inventive step". However, it did not include definitions for "utility" or "industrial applicability"; rather, it expressly left WIPO members with the choice of applying either notion at their election.[352] WIPO Members discussed the terms of the Basic Proposal at a conference in The Hague in 1991. The Members could not reach consensus on its terms and, as a result, the Basic Proposal discussions ended.[353]

184. As a result, WIPO Members decided to abandon the efforts towards harmonization of *substantive* requirements and instead pursued potential harmonization of *procedural* requirements, such as filing date requirements, electronic filing and standardized forms.[354] These discussions led to the adoption of the Patent Law Treaty ("PLT") in 2000 which expressly focusses on procedural rather than substantive patent law issues. Notably, the PLT does not include provisions on patentability requirements.[355]

185. In parallel to the Basic Proposal negotiations in the early 1990s, WTO members, including the NAFTA Parties, were discussing the terms of the proposed TRIPS Agreement. In light of the failed attempt to harmonize patentability requirements in the Basic Proposal, 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

[352] Gervais Report, para. 18.

[353] Gervais Report, para. 19.

[354] *See* World Intellectual Property Organization (WIPO), "History", online: http://www.wipo.int/patent-law/en/plt.htm (**R-215**).

[355] Patent Law Treaty, Article 2(2) of the PLT reads: "Nothing in this Treaty or the Regulations is intended to be construed as prescribing anything that would limit the freedom of a Contracting Party to prescribe such requirements of the applicable substantive law relating to patents as it desires". WIPO states in this regard: "[t]he PLT is expressly directed toward harmonization of procedures, and not to harmonization of substantive law": WIPO, "Study on the Interface between the SPLT, The PLT and the PCT, 24 September 2001, online: http://www.wipo.int/edocs/mdocs/scp/en/scp_6/scp_6_5.pdf, para.13 (**R-313**).

agreement.[356] Definitions of patentability requirements were instead left to each Member, allowing ample room for national variations and approaches.[357] This flexibility was expressly recognized in Article 1(1) of TRIPS:

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

186. The flexibility left to the WTO Members by TRIPS is not contentious – indeed, Claimant's own legal counsel recognized in a peer-reviewed article that "the TRIPs Agreement is not intended to be a harmonization agreement, meaning that countries are not required to create identical regimes."[358]

187. At about the same time as the TRIPS negotiations, the NAFTA negotiations began.[359] The text of NAFTA Chapter 17 is based on a draft of the TRIPS Agreement (the so-called "Dunkel Draft").[360] As a result, NAFTA Parties essentially replicated TRIPS Article 27.1 in NAFTA Article 1709(1):

NAFTA Article 1709(1)	**TRIPS Article 27.1**
Subject to paragraphs 2 and 3, each Party shall make patents available for any inventions, whether products or processes,	Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes,

[356] Gervais Report, para. 25.

[357] Gervais Report, para. 25.

[358] 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 (our emphasis) (**R-314**).

[359] The TRIPS was negotiated as part of the Uruguay Round, which lasted from 1986 to 1994 (WTO Legal Texts, online: http://www.wto.org/english/docs_e/legal_e/legal_e.htm (**R-315**), while the negotiations of NAFTA took place from 1990 to 1993 (North American Free Trade Agreement, About NAFTA, online: http://www.naftanow.org/about/default_en.asp) (**R-316**).

[360] Gervais Report, para. 56. Claimant acknowledges this fact: Claimant's Statement of Claim, para. 42 and Claimant's Memorial, FN 399. *See* also *Canada – Patent Protection of Pharmaceutical Products*, *Doc* WT/DS114/R, 17 March 2000, paras. 4.6 (**R-317**): "The provisions of Chapter Seventeen were largely based on, and in many instances were a verbatim reproduction of, the provisions of the then draft TRIPS Agreement." World Trade Organization, Canada- Patent Protection of Pharmaceutical Products, online: http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf.

in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For purposes of this Article, a Party may deem the terms "inventive step" and "capable of industrial application" to be synonymous with the terms "non-obvious" and "useful", respectively.	in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[FN 5] … [FN 5]: For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

188. Neither TRIPS nor NAFTA required a common terminology for the "utility" requirement. Instead, reflecting continuing differences of substantive law, Parties were allowed to select "utility" or "capable of industrial application" which were "deemed" equivalent for the purpose of both TRIPS and NAFTA.

189. In November 2000, 6 years after NAFTA was concluded, WIPO Members again sought to agree on definitions of the patentability requirements, this time including utility, with the goal of concluding a "Substantive Patent Law Treaty" ("SPLT"). [361] WIPO would have hardly undertaken this task if the TRIPS and NAFTA language had *already* achieved substantive harmonization. To the contrary, recognizing the lack of substantive harmonization to date, WIPO observed that a "number of issues in respect of national and regional patent law have neither been addressed by the TRIPS Agreement, nor by any other worldwide international treaty on patent law." These "unaddressed" issues included the definition of novelty, of inventive step, and of industrial applicability/utility.[362]

[361] Two authors noted in the context of a discussion on the Substantive Patent Law Treaty that: "[i]deally, member states *would agree to adopt identical rules concerning what constitutes a* novel and *useful invention…and what information must be revealed by the patent disclosure*" (our emphasis): Jerome H. Reichman and Rochelle Cooper Dreyfuss, "Harmonization without consensus: critical reflections on drafting a substantive patent law treaty", Duke Law Journal, 2007 vol 57:85, p.6 (**R-218**).

[362] WIPO, *Suggestions for the Further Development of the International Patent Law*, document SCP/4/2, 25 September 2000, online: http://www.wipo.int/edocs/mdocs/scp/en/scp_4/scp_4_2.pdf, paras. 7 and 9 (**R-221**).

190. WIPO acknowledged at the outset of the SPLT negotiations that the two notions mentioned in NAFTA Article 1709(1) namely, "utility" and "capable of industrial application", "do not have exactly the same meaning."[363] Following a request made in 2000 by WIPO for comments from Members on the "utility" criteria, the Delegation of the United States "emphasized the importance of achieving true harmonization on this term."[364] WIPO therefore proposed several potential solutions to "achieve harmonization". Among others, WIPO suggested 3 alternative definitions of "utility", proposed to subsume the "utility" requirement under the provision addressing "patentable subject matter", and otherwise suggested to remove the definition altogether.[365] Despite such efforts, WIPO Members failed to reach agreement on any approach".[366]

191. To resolve this impasse, the United States and European Union proposed that WIPO prepare a study on the "industrial applicability" and "utility" criteria.[367] WIPO published its report in March 2003, entitled "'Industrial Applicability' and 'Utility' Requirements: Commonalities and Differences" (the "Report").[368] As Professor Gervais explains, the Report is relevant for two main reasons.

192. First, the Report confirmed that the notions of "industrial applicability" and "utility" as of 2003 continued to be applied differently across jurisdictions. In this

[363] Gervais Report, para. 31.

[364] Gervais Report, para. 32.

[365] Gervais Report, para. 34FF.

[366] Gervais Report, para. 36.

[367] Gervais Report, para. 37.

[368] 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 (**R-230**).

regard, the Report concluded that: "[t]he scope of the term "industrial applicability" differs from one country to another and so does the term "utility."[369]

193. Second, the Report included, among several different approaches to "utility" by WIPO Members, the "promise" notion used in Canadian law. WIPO made no suggestion that this formulation violated or was in any way inconsistent with TRIPS, NAFTA or with any other international instrument. Instead, it was presented as one of the interpretations of "utility" to be included in the overall harmonization process. As Professor Gervais notes, "a country whose laws reflect the state of the law on promises as described in the WIPO summary in this context means that it is in line with international norms and practices."[370]

194. Professor Gervais notes that since 2003, there has been no further progress. In May 2004, the United States, Japan and the European Union Patent office made a joint proposal to WIPO (the "Joint Proposal") to try to advance harmonization discussions on a limited number of issues that might have a chance of achieving short-term agreement, including prior art, grace periods, novelty and non-obviousness/inventive step. Utility was intentionally left out of the Joint Proposal.[371] As Professor Gervais explains:

> There are thus several noteworthy aspects to this Joint Proposal. First, it is an acknowledgement by three of the most important players in international trade and intellectual property matters, including the United States, that the issue of possible patent law harmonization is extremely complex. *Second, utility and industrial applicability are* ***not*** *included in the list of issues suggested to be ripe for possible international harmonization or even discussion in the SPLT context*, rather, that requirements was seen as best left to the discretion and interpretation of Member States themselves.

[369] 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, para. 53 (**R-230**).

[370] *Ibid*., paras. 41 and 46: "the essential principle is that the invention should allow the addressee to achieve the effects or results promised by the patentee".

[371] Gervais Report, para. 44.

> In other words, WIPO Member States who issued this proposal believed that fruitful discussions were possible on novelty (and non-obviousness / inventive step) but utility did not make the cut. If utility, industrial applicability or both had been an easy target for negotiators and an easy "win" for WIPO and the negotiators, it would have been on the list or at the very least been mentioned as such.[372]

195. The Joint Proposal failed to gain traction and, therefore, negotiations towards a Substantive Patent Law Treaty were abandoned by 2006.[373]

196. The "utility" requirement continues to evade international consensus to this day. In July 2011, officials from Denmark, France, Germany, Japan, the United Kingdom, the United States, and the European Patent Office met in Tegernsee, Germany to re-launch a dialogue on harmonizing substantive patent law. Issues like first-to-file, grace period, prior user rights, scope of prior art, definition of novelty and non-obviousness/inventive step, and publication of patent applications at 18 months were identified. Once again, "utility" was left off the table as unripe for discussion.[374]

197. A recent study jointly prepared by WIPO, WTO and WHO further emphasizes this point. In their study, which concerned access to medical technologies and innovation, the "three international intergovernmental organizations that manage intellectual property instruments and/or have a normative role in the area"[375] stated as follows:

> Even though the same essential patentability criteria are found in the vast majority of countries, there is no agreed international understanding about the definition and interpretation of these criteria. This creates some

[372] Gervais Report, paras. 46 and 47.

[373] As one author explains the failure of the SPLT in the following terms: "If we set aside global harmonization aside for a moment, we could ask: is there some best practice Canada should be in step with? The short answer is: no. There is no common consensus beyond some core issues on what a universally acceptable patent law should look like. That's why the attempts at WIPO to establish a substantive Patent Law Treaty failed. One country's best practice turns out to be another's worst": David Vaver, "Is Canada's Patent Law Out of Step", Reworked Remarks for University of Toronto 2nd Patent Law Colloquium, 22 November 2013, p. 3 **(R-318)**.

[374] Gervais Report, para. 53.

[375] Gervais Report, para. 50.

> policy space regarding their establishment under the applicable national law. Accordingly, patent offices and courts interpret and apply national patentability requirements on a case-by-case basis within the applicable legal framework. [376]

198. It further expressly confirmed that "new use" and "second medical use" patents (*i.e.* the nature of Claimant's patent over atomoxetine) are not addressed by TRIPS and that national patent laws differ on this point:

> In certain cases, a previously known substance, used for a certain purpose, may later be found effective in the treatment of a disease, and a patent application may be filed claiming the "first medical use" (also called "secondary use" or "new use") of the known product. If the first or earlier use was already medical in nature, such claims are labeled "second medical indication". The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) does not expressly address this question. National patent laws differ on this point. Some patent laws specifically rule out the patenting of first or secondary medical indications [….] Some jurisdictions allow patents on a known medical substance for use in a new method of treatment if that use is not known […]
>
> Countries apply different approaches […] and various definitions and practices exist in the granting of patents to pharmaceutical inventions (*e.g.* for claimed inventions relating to second medical use, dosage regimes etc.).[377]

199. Given all of this context, Claimant's suggestion that the criterion of "utility" has been harmonized at the international level is without foundation.

J. The Patent Cooperation Treaty Addresses Only Procedural Issues

200. Claimant suggests that the Patent Cooperation Treaty ("PCT") provides a definition of "industrial applicability" which can be used as the basis for interpreting the

[376] WTO, WIPO and WHO, *Promoting Access to Medical Technologies and Innovation*, Intersections between public health, intellectual property and trade (2013) online: http://wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf , p. 57 (our emphasis) (**R-220**).

[377] WTO, WIPO and WHO, *Promoting Access to Medical Technologies and Innovation*, Intersections between public health, intellectual property and trade (2013) online: http://wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf, p. 128 and 131 (our emphasis) (**R-220**).

meaning of that patentability criterion, as applied under the domestic laws of the NAFTA Parties.[378] Claimant also suggests that the PCT's "form and contents" requirements restrict Canada's ability to require specific disclosure in nationally filed patent applications.[379] In suggesting that the PCT somehow imposes these substantive obligations, Claimant misrepresents both the nature and terms of the treaty. As Claimant itself notes, is a "procedural" treaty.[380] The Treaty's primary objectives are to create a more efficient filing procedure for applicants seeking multi-jurisdictional patent protection, and to enable the sharing of technical information relating to patents worldwide.[381]

201. As explained by Mr. Reed, the PCT allows an applicant to file a single application under the Treaty that, assuming it complies with PCT "form and contents" requirements, will be eligible for preliminary international review by PCT searching and examining authorities and for consideration by national Patent Offices.[382] Under the Treaty, applicants also have the benefit of additional time in which to make decisions about whether or where to file for patent protection, and additional information through the PCT's generation of a prior art search and a preliminary and non-binding written opinion on the apparent patentability of an invention claimed in an international application.[383]

[378] Claimant's Memorial, paras. 204-206.

[379] Claimant's Memorial, para. 280 (arguing that Claimant expected that "Canada would adhere to its treaty obligations (and domestic legislation) and not impose additional disclosure obligations beyond those contained in the PCT."); and Erstling Report, paras. 29-31.

[380] Claimant's Memorial, para. 202. The PCT is classified by WIPO as a "Global Protection" treaty, meant to "simplify and reduce the cost of making individual applications or filings," rather than a "Substantive IP Protection" treaty or a "Classification" treaty." (*See* Gervais Report, para. 78).

[381] *See Patent Cooperation Treaty*, World Intellectual Property Organization (1970), Preamble (**R-037**); and *Summary and Advantages of the Patent Cooperation Treaty* in Records of the Washington Diplomatic Conference on the PCT (1970), pp. 746-747, paras. 4-13 (**R-039**).

[382] Reed Report, para. 15 and FF.

[383] Reed Report, paras. 19, 20.

202. Contrary to Claimant's characterization, these procedural benefits do not make the PCT relevant to determining either the meaning or scope of substantive patentability requirements in NAFTA.[384] Indeed, PCT Article 27(5) expressly gives complete discretion to Contracting States to determine both the substantive patentability criteria applicable under their national laws, and whether an invention claimed in an application filed under the PCT meets those substantive patentability criteria so as to warrant the grant of a patent.[385]

203. Consistent with this, compliance with PCTs "form and contents" requirements regarding the description and claims in an application filed under the treaty does not mean compliance with the substantive patentability criteria of PCT Contracting States.[386] To comply with "form and contents" requirements under the PCT, an applicant must provide certain elements or categories of information (*i.e.* a request, description, claim or claims, drawing(s), and an abstract), in a specified format in the application for that application to be admissible to the PCT and to national Patent Offices.[387] The PCT's directions as to the substance of the "form and contents" of an application are broad and

[384] Reed Report, para 28.

[385] *PCT* Article 27(5) **(R-037)** ("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. In particular, any provision in this Treaty and the Regulations concerning the definition of prior art is exclusively for the purposes of the international procedure and, consequently, any Contracting State is free to apply, when determining the patentability of an invention claimed in an international application, the criteria of its national law in respect of prior art and other conditions of patentability not constituting requirements as to the form and contents of applications.").

[386] Reed Report, para. 44.

[387] Reed Report, paras. 33, 36 (citing PCT Article 3(2) **(R-037)**. As the Notes on Article 27(1), *Records of the Washington Diplomatic Conference on the PCT*, (1970), p. 35 **(R-039)**, read, "The requirements relating to form and contents are principally provided for in Articles 3 (The International Application), 4 (The Request), 5 (The Description), 6 (The Claims), 7 (The Drawings), and 8 (Claiming Priority), and the Rules pertaining to these Articles (mainly Rules 3 to 13). The words "form or contents" are used merely to emphasize something that could go without saying, namely, that requirements of substantive patent law (criteria of patentability, etc.) are not meant*."* (our emphasis) *See* also *PCT Applicant's Guide (International Phase)*, World Intellectual Property Organization (WIPO) International Bureau (July 24, 2014), s. 5.010 **(R-042)**. In asking "[w]hat are the elements of an international application?" the *Guide* explains that "Any international application must contain the following elements: request, description, claim or claims, one or more drawings (where drawings are necessary for the understanding of the invention), and abstract."

un-restrictive (*i.e.* "[the] claims shall be fully supported by the description").[388] None of the required categories of information are defined, and further guidance provided in the PCT Regulations is equally high-level[389] If an international application complies "on its face" with these requirements, something typically verified by non-technical clerks, the application will benefit from an international filing date under the PCT and thereafter be eligible for consideration by national Patent Offices.[390]

204. While the ability to file and rely on a single PCT application is procedurally useful for multi-jurisdictional filings, the content of that application must be consistent with the requirements of domestic substantive patent law. As a recent joint study prepared by WIPO, the WTO, and WHO explains:

> [d]espite […] regional and international cooperation, national patent laws and practices differ, leading to potentially diverging outcomes. Where patent applications are filed for the same invention in different national or regional patent offices, they are processed separately according to the applicable national law or regional law, and such processing may have diverging outcomes. For example, when a PCT application relating to a certain pharmaceutical compound reaches the national phase in the PCT contracting states, different substantive patentability requirements may apply under the patent law of each country.[391]

205. It is well – known that applicants seeking patent protection through the PCT, must not only ensure that international applications filed under the Treaty comply with

[388] Reed Report, para. 33, *See PCT* Articles 5 (The Description) and 6 (The Claims) (**R-037**).

[389] Reed Report, para. 35-37. *See* for example, *PCT Regulations*, Rule 5.1(a)(vi) (**R-040**).

[390] *PCT* Article 11(1)(iii) (**R-037**). Gillen Statement, para. 57, citing *Patent Cooperation Treaty Applicant's Guide (International Phase)*, World Intellectual Property Organization (WIPO) International Bureau (July 24, 2014), Chapter 6 – Processing of the International Application by the Receiving Office, s. 6.001 (**R-042**). Unlike "form and contents", the evaluation of the actual content of the description and claim(s) of an application is conducted by national Patent Office examiners during the national phase, on the basis of the domestic patentability requirements of each jurisdiction where an applicant files for patent protection (Gillen Statement, para. 55). *See also* Notes on Article 11(1), *Records of the Washington Diplomatic Conference on the PCT*, (1970), p. 21-22 (**R-039**).

[391] WTO, WIPO and WHO, *Promoting Access to Medical Technologies and Innovation*, Intersections between public health, intellectual property and trade (2013) online: http://wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf, pp. 128 and 131 (our emphasis) (**R-220**).

the broad "form and contents" of the PCT, but also with the requirements of the substantive patent laws of all jurisdictions in which they may file.[392]

206. A second advantage under the PCT is that it provides applicants a preliminary prior art search and written opinion as to whether an invention they claim in PCT application could potentially be patentable. This prevents applicants from having to incur the costs of filing patent applications in multiple jurisdictions for an invention which may be unpatentable on its face.[393]

207. The preliminary search and examination and resulting written opinion on patentability, is generated on the basis of broad, general definitions of "novelty," "inventive step" and "industrial applicability" contained in the PCT and expressly used only for the purposes of the "preliminary and non-binding" assessment of patentability.[394] Neither the outcome of the preliminary search and examination nor the patentability definitions in the Treaty are binding on Contracting States, who retain full discretion over whether or not to grant a patent for an invention claimed in an international application. The PCT explains that "[a]ny Contracting State may apply additional or different criteria for the purpose of deciding whether, in that State, the claimed invention is patentable or not," and that the preliminary opinion on patentability "shall not contain any statement on the question whether the claimed invention is or seems to be patentable or unpatentable according to any national law."[395]

208. Given this context, Claimant's suggestions that the PCT somehow provides a definition of "industrial applicability" relevant to interpreting the meaning of that

[392] Reed Report, paras. 44-45.

[393] Reed Report, para. 20 and FF.

[394] *PCT*, Article 33(1) (**R-037**) reads that "[t]he objective of the international preliminary examination is to formulate a preliminary and non-binding opinion on the questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), and to be industrially applicable." *See* also Gervais Report, para. 74.

[395] *PCT*, Articles 33(5) and 35(2), respectively (**R-037**). Michael Gillen confirms that from a Patent Office perspective, the results of the preliminary opinion on patentability are "strictly advisory in nature [and …] national Patent Offices are not required to defer to them."(Gillen Statement, para. 60).

patentability criterion as applied under the domestic laws of the NAFTA Parties, and that PCT "form and contents" requirements somehow limit Canada's ability to impose specific utility-related disclosure requirements, are unsustainable.

III. JURISDICTION

209. Claimant makes the unqualified statement that this dispute is within the jurisdiction of this Tribunal.[396] While Canada is not seeking dismissal of the claim on the basis of lack of jurisdiction, there are issues arising from Claimant's arguments which go to the limits of the Tribunal's competence.

210. The Tribunal's jurisdiction is limited to determining whether Canada has violated an obligation set out in NAFTA Chapter Eleven (in this case, Article 1105(1) (Minimum Standard of Treatment) and/or Article 1110 (Expropriation)).[397] The Tribunal lacks jurisdiction to rule on alleged breaches of any other international treaty obligations of Canada, specifically, the TRIPS or the PCT. As the Tribunal in *Grand River* noted in self-reference: "[it] is a Tribunal of limited jurisdiction; it has no mandate to decide claims based on treaties other than NAFTA."[398] Thus, to the extent that Claimant is asking for a determination that Canada has violated TRIPS and/or PCT whether or not it

[396] Claimant's Memorial, para. 161.

[397] *See* NAFTA Articles 1116(1) and 1117(1) (limiting claims to whether a 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)…").

[398] *Grand River Enterprises Six Nations, Ltd. et al v. United States of America,* (UNCITRAL) Award, 12 January 2011, ("*Grand River Award*"), para. 71 **(RL-010)**. *See* also *Methanex Corporation v. United States of America*, UNCITRAL, Final Award of the Tribunal on Jurisdiction and Merits, 3 August 2005, Part II, Chap. B, ("*Methanex Final Award on Jurisdiction*"), p. 2, para. 5 **(RL-011)** ("[it] does not construe Article 1131 NAFTA as creating any jurisdiction to decide on alleged violations of the GATT" and the Tribunal "disclaim[ed] any power to decide Methanex's allegations that the USA has violated provisions of the GATT."); *Bayview Irrigation District et al v. United Mexican States*, ICSID Case No. ARB(AF)/0501, Award, 19 June 2007, ("*Bayview Award*"), para. 121 (**RL-012**), (stating that a NAFTA Chapter Eleven Tribunal had no jurisdiction to make a finding that Mexico had breached another treaty: "[I]f the interests of USA nationals were thought to be prejudiced by any action alleged to amount to a violation of the [1944 Water Treaty], that is an issue which could be taken up by the United States government under the dispute resolution procedures in the [1944 Water Treaty].").

is tied to establishing a breach of NAFTA Article 1105 and/or 1110, this would be beyond the competence of the Tribunal. [399]

IV. MINIMUM STANDARD OF TREATMENT

A. Summary of Canada's Position on NAFTA Article 1105(1)

211. Claimant alleges that Canada breached NAFTA Article 1105(1) because the judgments of the Federal Court finding Claimant's patents for atomoxetine and olanzapine invalid under the *Patent Act* were (1) "arbitrary, unjust and idiosyncratic," (2) a violation of its "legitimate expectations," and (3) "discriminatory".[400]

212. Claimant not only misstates and misapplies the legal standard applicable under NAFTA Article 1105(1), a standard which Canada has not even come close to violating, but it also fails to demonstrate that Canada breached the more onerous test Claimant advocates.

213. First, Article 1105(1) requires the NAFTA Parties to accord to investors and their investments the customary international law minimum standard of treatment of aliens. That standard, as has been overwhelmingly affirmed in NAFTA jurisprudence since 2001, protects investors against measures which "weighed against the given factual context, amount to a gross denial of justice or manifest arbitrariness falling below acceptable international standards."[401] In the context of this dispute, which deals

[399] There is also a constraint on the Tribunal's jurisdiction with respect to Chapter Seventeen in that the Tribunal may only consider whether the revocation of the Claimant's patents was "consistent" with Chapter Seventeen. *See* Article 1110(7) ("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)."). Final word on whether Canada has committed a violation of Chapter Seventeen rests with a tribunal formed under the dispute resolution provisions set out in NAFTA Chapter Twenty, which can only be initiated by the NAFTA Parties. *See* NAFTA Article 2004 (Recourse to Dispute Settlement Procedures).

[400] Claimant's Memorial, paras. 251-291.

[401] *International Thunderbird Gaming Corporation v. United Mexican States*, (UNCITRAL) Arbitral Award, 26 January 2006, ("*Thunderbird Award*"), para. 194 (**RL-003**).

exclusively with two Federal Court rulings, denial of justice is the only basis of liability in international law for the judgments of domestic courts interpreting domestic law.

214. There has been no such denial of justice or any other arbitrary or unfair conduct by the Federal Court, Federal Court of Appeal and the Supreme Court of Canada. Claimant was afforded full opportunity to plead its case in both the atomoxetine and olanzapine patent litigations. In deciding that Claimant's two patents were invalid under the *Patent Act*, the Court considered extensive factual and expert evidence put forward in a full adversarial process. The Federal Court reached rational decisions based upon such evidence and issued reasoned judgments relying on long-standing precedent and principles of Canadian patent law. The courts acted in full compliance with their statutorily-directed, specialized jurisdiction and the judgments were upheld on appeal.

215. This NAFTA Tribunal cannot act as yet another court of appeal. International law provides no basis to second-guess the reasoning of the Canadian courts on questions of Canadian law in the absence of a denial of justice. Claimant uses inflammatory language such as "arbitrary," "illogical and absurd" and "discriminatory" to describe the Federal Court's interpretation of Canadian law. These are mere labels which cannot mask the lack of legal foundation of Claimant's position.

216. Second, having no credible basis to show that Canada has violated the customary minimum standard of treatment, Claimant seeks to alter that standard by arguing that Canada's judiciary violated its "legitimate expectations" of how the *Patent Act* would be interpreted and thereby violated customary international law. Even if Canada were to be judged on that fundamentally inapposite legal test, there would still be no violation of Article 1105(1).

217. Claimant has failed to establish that Article 1105(1) protects against the violation of an investor's "legitimate expectations." Claimant provides no evidence of substantial state practice and *opinio juris* to support its contention that this doctrine is now a rule of custom. Other NAFTA tribunals have already rejected the same line of argument the

Claimant proffers here, including reliance on arbitral awards interpreting autonomous "fair and equitable treatment" treaty provisions. Mere failure to meet an investor's legitimate expectations does not violate the minimum standard of treatment in customary international law.

218. But the status of the "legitimate expectations" theory in international law is irrelevant to this dispute in any event. It is a doctrine which is fundamentally inapplicable with respect to judgments rendered by domestic courts acting in their *bona fide* adjudicative function of domestic statutory interpretation. To assert otherwise would circumvent the customary international law rule with respect to international tribunal's review of domestic court decisions in the context of denial of justice. It would also radically expand the theory of "legitimate expectations" beyond situations where the State, through its executive, legislative and/or bureaucratic branches, repudiate clear and explicit representations made to a foreign investor to induce the investment. Claimant has not identified a single instance of an international tribunal finding a violation of an investor's "legitimate expectations" based solely on the outcome of a domestic court's interpretation or application of domestic law.

219. Claimant's submissions on "legitimate expectations" are not only legally defective but are bereft of factual support as well. Claimant was fully aware that, under Canadian law, patents are only presumptively valid and are always subject to future review by the Federal Court for actual compliance with the *Patent Act*. Clamant could not have had a "legitimate expectation" that latently defective patents would be enforced when challenged, nor could Claimant have the expectation that a court would necessarily agree with its own subjective interpretation of Canadian law or accept all of its factual and expert evidence in favour of enforcing the patents.

B. Article 1105(1) Accords the Minimum Standard of Treatment of Aliens as Established by Customary International Law

1) The threshold for a violation of the minimum standard of treatment is high and requires a finding of egregious or manifestly unfair behaviour

220. 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.

221. 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, which 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).[402]

222. The FTC Note of Interpretation represents the definitive meaning to be given to Article 1105(1) and is binding on all arbitration tribunals constituted under NAFTA Chapter Eleven.[403] 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

[402] NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter Eleven Provisions, s. 2 (July 31, 2001), ("*FTC Notes of Interpretation*") **(RL-009)**.

[403] 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."

in a particular provision of NAFTA is possible."[404] Since the FTC Note of Interpretation, NAFTA tribunals have consistently recognized its binding effect.[405] Claimant acknowledges that the Note is binding on this Tribunal.[406]

223. The tribunal in *S.D. Myers v. Canada* noted that a NAFTA tribunal "does not have an open-ended mandate to second-guess government decision-making" and elaborated on the international minimum standard as follows:

> The Tribunal considers that a breach of Article 1105 occurs only when it is shown 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. That 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. [407]

224. The tribunal in *Waste Management v. Mexico* reviewed previous NAFTA Chapter Eleven awards in *S.D. Myers v. Canada*, *Mondev v. United States*, *ADF v. United States*, and *Loewen v. United States*, and their analysis of the minimum standard of treatment under customary international law, and concluded that for there to be a breach of Article 1105, the impugned conduct must have been "arbitrary, grossly unfair,

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[404] *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**).

[405] *ADF Award*, paras. 175-178 (**RL-005**); *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. 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**); *Thunderbird Award*, paras. 192-193 (**RL-003**); *Glamis Gold, Ltd. v. United States of America*, (UNCITRAL) Award, 8 June 2009, ("*Glamis Award*"), para. 599 (**RL-006**); *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, 18 September 2009 ("*Cargill Award*") paras. 267-268 (**RL-015**); *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**); *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**). *See also*, *Methanex Final Award on Jurisdiction*, p. 9, para. 20 (**RL-011**); *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**).

[406] Claimant's Memorial, para. 253, FN. 453.

[407] *S.D. Myers, Inc. v. Government of Canada*, (UNCITRAL), Partial Award, ("*S.D. Myers Partial Award*"), paras. 261, 263 (**RL-076**).

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[…]"[408]

225. The tribunals in both *Glamis Gold v. United States* and *Cargill v. Mexico* confirmed again that a measure must be of serious gravity to breach the threshold protected by Article 1105. Echoing the same standard applied by the *Glamis* tribunal,[409] the *Cargill* tribunal wrote:

> 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. [410]

226. The *Mobil and Murphy v. Canada* tribunal also undertook a detailed examination of past NAFTA Chapter Eleven jurisprudence and confirmed yet again that Article 1105(1) only requires what is reflected in customary international law on the treatment of aliens and endorsed the standard described in *Waste Management II*, *International*

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[408] *Waste Management II Award*, para. 98 **(RL-014)** ("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. "). *See S.D. Myers Partial Award,* para. 263 **(RL-076)**; *Mondev Award*, para. 127 **(RL-004)**; *ADF Award*, para. 184 **(RL-005)**; *Loewen Award*, paras. 132-134 **(RL-013).**

[409] The Tribunal in *Glamis* wrote: "[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." *Glamis Award*, para. 627 **(RL-006)**.

[410] *Cargill Award*, para. 296 **(RL-015)**.

Thunderbird, *Glamis* and *Cargill* – that is, the impugned measures must amount to "egregious behaviour" that is "grossly unfair" or "offends judicial propriety."[411]

227. Canada does not disagree with Claimant' submission that the content of the international minimum standard may evolve over time with the development of customary international law.[412] However, it is clear from the post-FTC Note of Interpretation NAFTA jurisprudence described above (most of which is ignored by Claimant in its Memorial) that a violation of Article 1105(1) will not be found unless there is evidence of serious malfeasance, manifestly arbitrary behaviour or denial of justice by the respondent NAFTA Party.[413]

228. The FTC Note of Interpretation also confirmed that even if a NAFTA Party has violated another provision of the NAFTA or a separate international agreement, this

[411] *Mobil Decision on Liability*, paras. 138-153 (**RL-007**). *See* paras. 152-153 (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 have noted above, at a level which protects against egregious behavior."). *See* also, *Apotex Award*, para. 9.47 (**RL-016**) (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**).

[412] Claimant's Memorial, para. 255. As Canada stated in its Article 1128 submission in the *ADF* case: "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." para. 179 (*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 (**RL-077**)).

[413] *See* Patrick Dumberry, "The Fair and Equitable Treatment Standard", Netherlands: Kluwer Law, 2013, p. 262 (**R-320**) (past NAFTA tribunals "have emphasized 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."), cited with approval in *Apotex Award*, para. 9.47 (**RL-016**). Claimant's reliance on *Merrill & Ring Forestry LP v. Canada* adds nothing to the question of what standard of treatment is owed to investors under the minimum standard of treatment under customary international law. *See* Claimant's Memorial, para. 255. The *Merrill & Ring* Tribunal did not articulate a coherent view of what would be required to violate Article 1105(1) generally, nor did it address the specific issue in this dispute – challenging the interpretation of domestic law by a domestic court.

does not establish that there has also been a breach of Article 1105(1).[414] This binding direction confirms what is clear in international law anyway: a mere breach of a separate treaty obligation does not necessarily mean that the measure was so unfair as to fall below the minimum standard of treatment in international law.[415]

229. Thus, even if it were true (it is not) that Canada, through the judgments of its Federal Courts, failed to comply with obligations in NAFTA Chapter Seventeen, TRIPS or the PCT, this would not mean that Canada has also breached Article 1105(1). Rather, Claimant would still have to convince the Tribunal that Canada breached the minimum standard of treatment in customary international law described above and, specifically, prove a denial of justice.

2) Denial of justice is the only basis upon which the judgments of a domestic court interpreting domestic law may be found in violation of the customary international law minimum standard of treatment

230. The minimum standard of treatment of aliens in customary international law protects foreign investors against denial of justice by the domestic courts of a host State. Given that Claimant's Article 1105 claim is entirely based on judgments of the Canadian Federal Courts interpreting Canadian law and adjudicating on the evidence presented by the disputing parties (a fact that fundamentally distinguishes this case from virtually all of the inapposite international jurisprudence Claimant relies on for support), the rules related to denial of justice are vital to the disposition of this dispute.[416]

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[414] *FTC Notes of Interpretation*, para. 3 **(RL-009)** ("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)").

[415] *See* for example, *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.

[416] Canada agrees with Claimant that a State is responsible in international law for the conduct of its organs, including the judiciary. *See* Claimant's Memorial, para. 177 *citing* Article 4(1) of the Draft Articles on State Responsibility. But Claimant misses the point: the question is what types of acts by the judiciary engage international liability. As set out in this Counter Memorial, there must be a denial of justice in order for a State to be liable at international law for a domestic court's final ruling on the interpretation of domestic law.

231. It is well-settled, and has been affirmed in a long line of NAFTA and other international awards and academic texts, that judgments of national courts interpreting domestic law cannot be challenged as a violation of international law in the absence of a denial of justice – for example, refusal to entertain a suit or serious failure to adequately administer justice or if there has been a "clear and malicious misapplication of the law."[417] There must be a very serious failure in the administration of justice before a State can be found in violation of international law for the domestic law decisions of its domestic courts.[418] This rule stems from the 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.[419] Professor Douglas aptly summarizes the customary international rule: "Denial of justice is the sole form of

[417] *Robert Azinian, Kenneth Davitian & Ellen Baca v. United Mexican States*, ICSID Case No. ARB(AF)/97/2, Award, 1 November 1999, ("*Azinian Award*"), paras. 102-103 **(RL-002)**.

[418] Jan Paulsson, *Denial of Justice in International Law*, (Cambridge: 2005), p. 98 **(R-321)** ("Denial of justice is always procedural. There may be extreme cases where the proof of the failed process is that the substance of a decision is so egregiously wrong that no honest or competent court could possibly have given it. Such cases would sanction the state's failure to provide a decent system of justice. They do not constitute an international appellate review of national law."). It is for this reason that exhaustion of local remedies is a precondition to claiming a denial of justice – unless it would be demonstrably futile to exhaust all mechanisms to appeal an unjust ruling by a lower court, a State cannot be held liable for the failing of its system of justice if the system has not been given the full opportunity to correct the defects which are complained of. *See* 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)**.

[419] J.L. Brierly, *The Law of Nations* (Oxford: 1963), p. 287 **(R-324)** ("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 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…"); Zachary Douglas, "International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed," International and Comparative Law Quarterly (ICLQ), p. 11 **(R-323)** ("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.").

international delictual responsibility towards foreign nationals for acts or omissions within an adjudicative procedure for which the State is responsible."[420]

232. Even if the decisions of Canada's Federal Courts were viewed as "incorrect" either in their interpretation of the concept of utility in the *Patent Act* or in their conclusions on the factual evidence presented during the litigations, States do not incur liability in international law for erroneous decisions or misapplications of national law.[421] As Professor (now Judge of the International Court of Justice) Greenwood wrote, "error on the part of the national court is not enough, what is required is 'manifest injustice' or 'gross unfairness.'"[422] This has also been the consistent position of the three NAFTA Parties.[423]

[420] Zachary Douglas, "International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed," International and Comparative Law Quarterly (ICLQ), p. 34 **(R-323)**. *See* also *id.*, p. 29 **(R-323)** ("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.").

[421] 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)**; J.L. Brierly, *The Law of Nations* (Oxford: 1963), pp. 286-287 **(R-324)** (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."); A.V. Freeman, *The International Responsibility of States for Denial of Justice* (Longmans: 1970) p. 319 **(R-326)** ("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."); 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 **(R-322)** ("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."); Jan Paulsson, *Denial of Justice in International Law*, (Cambridge: 2005), pp. 73-81 **(R-321)**; Zachary Douglas, "International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed," International and Comparative Law Quarterly (ICLQ) **(R-323)**.

[422] *Loewen Group and Another v. United States of America*, Second Opinion of Christopher Greenwood Q.C, 16 August 2001, para. 94 **(RL-018)**. *See* for example, *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) **(RL-019)**. ("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"); *Barcelona Traction, Light and Power Company Limited (Belgium v. Spain),* Judgement of 5 February 1970, Separate Opinion of Judge Tanaka, p. 158 **(RL-020)** (Issues of municipal law "do not belong to the realm of international

233. Accordingly, liability under Article 1105(1) cannot be found based on whether Canadian courts made an error in interpreting domestic law or substitute its own preferred interpretation of Canadian law unless "it is impossible for a third party to recognize how an impartial judge could have reached the result in question."[424]

234. This rule has been consistently applied by NAFTA tribunals.

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.").

[423] *See* for example, *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. 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)** ("International tribunals defer to the acts of municipal courts not only because the courts are recognized as being expert in matters of a State's domestic law, but also because of the judiciary's role in the organization of the State."); *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)** ("The United States agrees with Mexico that customary international law recognizes distinctions between acts of the judiciary and acts of other organs of the state and accords great deference to judicial acts…all evidence of State practice that is before this Tribunal demonstrates that the rules of customary international law in this respect are well-established: […] a denial of justice claim is an extreme charge that cannot be met by a showing of error – even an error with extreme consequences – by the municipal court, but instead requires a showing of bad faith or flagrant and inexcusable disregard of law.")

[424] Rudolf Dolzer and Christoph Schreuer, *Principles of International Law*, (Oxford: Oxford University Press), 2008, p. 165-166 **(R-327)** ("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."). *See* also Campbell Mclachlan, Laurence Shore & Matthew Weiniger, "International Investment Arbitration: Substantive Principles", (Oxford Univeristy Press 2007), p. 229 **(R-328)** ("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."); *Loewen Group and Another v. United States of America*, Opinion of Christopher Greenwood Q.C, 26 March 2001, para. 64 **(RL-025)** ("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 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.*") (our emphasis).

235. The decision in *Mondev v. United States* is particularly relevant to this dispute because the judgments of United States domestic courts were squarely at issue.[425] In *Mondev*, the Canadian claimant was an investor in a commercial real estate development project in Boston whose lawsuits against the City of Boston and the Boston Redevelopment Authority ("BRA") were dismissed by the Supreme Judicial Court of Massachusetts ("SJC").[426] The claimant argued that by finding that the BRA immune from intentional tort liability and by overturning a jury verdict in favour of the claimant against the City of Boston, the SJC had engaged in a "significant and serious departure" from its previous jurisprudence on principles of contract law and state immunity and had rendered a judgment that "was arbitrary and profoundly unjust."[427]

236. The *Mondev* tribunal set out the basis upon which a NAFTA Chapter Eleven tribunal may review judgments of domestic courts pursuant to Article 1105:

> 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.[428]

237. Applying this standard, the *Mondev* tribunal expressed doubt that the SJC had actually "made new law" in its judgments, but stated "*even if it had done so its decision*

[425] *Mondev Award* (**RL-004**). The claimant argued that various other actions by the City and BRA violated Articles 1102, 1105, and 1110 but those were determined by the tribunal to be outside the tribunal's jurisdiction *rationae temporis* because they took place before NAFTA came into force. *See id.*, paras. 37-40 and 56-92.

[426] *Mondev Award* (**RL-004**). Leave to appeal to the United States Supreme Court was denied.

[427] *Mondev Award*, para. 131 (**RL-004**).

[428] *Mondev Award*, para. 127 (emphasis added) (**RL-004**).

would have fallen within the limits of common law adjudication. There is nothing here to shock or surprise even a delicate judicial sensibility."[429] The tribunal emphasized that the interpretation of domestic contract and tort law by the Massachusetts courts "fell well within the interstitial scope of law-making exercised by courts such as those of the United States" and warned against turning NAFTA tribunals "into courts of appeal, which is not their role."[430]

238. In other words, the *Mondev* tribunal recognized that domestic courts are to be afforded substantial deference and that NAFTA tribunals cannot "second-guess the reasoned decisions of the highest courts of a State."[431] *Mondev* also confirmed that even if a domestic court was to elaborate a new interpretation of the law (as Claimant alleges in this case), this is not unexpected in a common law jurisdiction and, in the absence of a denial of justice, there would still be no violation of Article 1105(1).

239. In *Azinian v. Mexico*, the claimants alleged that its landfill and waste management concession contract had been wrongly terminated by city officials, thereby violating NAFTA Articles 1105 and 1110.[432] The termination had been reviewed by Mexican courts and judgments rendered in favour of the city on the basis that the termination of the contract was valid under Mexican law. The tribunal dismissed the suggestion that the judgments of the Mexican courts could be called into question under NAFTA Chapter Eleven without a flagrant misapplication of the law, affirming that a claimant cannot "seek international review of the national court decisions as though the international jurisdiction seized has plenary appellate jurisdiction" and found that there was no evidence that the Mexican courts had engaged in a "pretence of form to achieve an internationally unlawful end."[433] *Azinian* confirms that even a wrong decision or

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

[430] *Mondev Award*, paras. 136-137 (emphasis added) (**RL-004**).

[431] *Mondev Award*, para. 126 (**RL-004**).

[432] *Azinian Award*, para. 75 (**RL-002**).

[433] *Azinian Award*, para. 99 (**RL-002**). *See* also *ADF Group Inc. v. United States of America*, ICSID Case No. ARB(AF)/00/1, Award, 9 January 2003, ("*ADF Award*"), para. 190 (**RL-005**) (endorsing the position of the *Azinian* Tribunal and stating that a NAFTA Tribunal "does not sit as a court with appellate

interpretation of Mexican law by the Mexican courts is not enough to violate international law – there must be a denial of justice or "malicious misapplication of the law."[434]

240. In *Loewen*, the tribunal affirmed that it is "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."[435] But the tribunal was equally firm in stating that "a NAFTA claim cannot be converted into an appeal against the decisions of municipal courts."[436]

241. The claimant in *Waste Management II* unsuccessfully argued that Mexico had expropriated its waste disposal concession investment in violation of NAFTA Article 1110 and denied it the minimum standard of treatment under Article 1105(1). In addition to allegations against local, state and federal government officials, the claimant based its claims on the failure of Mexican courts to provide adequate relief to protect its investment. The tribunal refused to second-guess the reasoning of the Mexican courts:

> Turning to the actual reasons given by the federal courts, the Tribunal would observe that it is not a further court of 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. […] [H]owever these cases might have been decided in different legal systems, the Tribunal does not discern in the decisions of the federal courts any denial of justice as that concept has been explained by NAFTA tribunals, notably in the Azinian, Mondev, ADF and Loewen cases. The Mexican court decisions were not, either ex facie or on closer examination, evidently arbitrary, unjust or

jurisdiction with respect to the United States measures" and whether they have legal validity under United States domestic law).

[434] *Azinian Award*, paras. 102-103 **(RL-002)**.

[435] *Loewen Award*, para. 123 **(RL-013)**.

[436] *Loewen Award*, para. 134 **(RL-013)**. The Canadian claimant in that case alleged that the state courts in Mississippi had failed to afford it due process and a fair hearing during a trial arising out of its investment in the funeral home business. Ultimately, despite finding serious defects in the administration of justice, the tribunal stopped short of declaring the United States in violation of Article 1105(1) because the claimant had not exhausted all avenues of appeal to correct those defects.

> idiosyncratic. There is no trace of discrimination on account of the foreign ownership of Acaverde, and no evident failure of due process.[437]

242. The tribunal in *International Thunderbird* also affirmed that "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…"[438]

243. Finally, after describing the rules regarding denial of justice in international law, the tribunal in *Grand River* made the following observation:

> Such questions about the permissible reach of state regulation over Indian peoples and lands under U.S. law were raised in connection with the Claimant's argument of a reasonable expectation that the [Master Settlement Agreement] and related measures would not apply to them, an argument the Tribunal addressed above. 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.[439]

244. Many other investment treaty tribunals have affirmed the same. For example, in *GEA Group v. Ukraine*, the claimant challenged various decisions of the Ukrainian courts as having violated its legitimate expectations and delivered "grossly improper" judgments with respect to the enforcement of an ICC arbitration award and bankruptcy proceedings.[440] The *GEA* tribunal, endorsing the reasoning of *Mondev* with respect to domestic court rulings, found nothing improper in the Ukrainian courts' procedural or

[437] *Waste Management II Award*, paras. 129-130 **(RL-014)**.

[438] *Thunderbird Award*, para. 120 **(RL-003)**. The claim in *Thunderbird* involved the claimant's investment in gaming facilities in Mexico which were illegal under Mexican law. The tribunal confirmed that judicial rulings of the Mexican courts on issues of Mexican law are not reviewable under NAFTA Chapter Eleven.

[439] *Grand River Award*, para. 234 (our emphasis) **(RL-010)**. The tribunal described the standards relevant for finding a denial of justice at paras. 222-225.

[440] *See GEA Group Aktiengesellschaft v. Ukraine*, ICSID Case No. ARB/08/16, Award, 31 March 2011, ("*GEA Group Award*"), para. 310 **(RL-026)**.

substantive decisions – the courts simply disagreed with the claimant's arguments and rejected them in accordance with Ukrainian law. [441]

245. In summary, customary international law is decisive on the core issue presented to this Tribunal: unless the Claimant can prove that it suffered a denial of justice at the hands of the Federal Court, there is no legal claim under Article 1105(1).

C. The Canadian Federal Courts Did Not Engage in Any Egregious, or Grossly Unfair Conduct That Could Amount to a Breach of the Customary Minimum Standard of Treatment

246. Claimant conspicuously avoids any discussion of the customary rules regarding denial of justice even though that is precisely the gravamen of its case. Claimant avoids such language because it would be outrageous to allege that it had suffered from lack of due process, procedural irregularities, political interference, lack of impartiality, pretence of form or bad faith or anything else which could offend judicial propriety. Nevertheless, Claimant affixes the hallmark labels of "arbitrariness" and "discrimination" to the Federal Court judgments which found its patents for atomoxetine and olanzapine inconsistent with the requirements of the *Patent Act*. Canada will address both of these allegations in turn.

1) The judgments were not arbitrary

247. Claimant argues that the interpretation of utility by the Federal Court and the outcome of the olanzapine and atomoxetine patent litigations are "arbitrary, unjust and idiosyncratic" because (1) it is inherently unpredictable to identify the promise of the patent, (2) the patent holder must submit "heightened" evidence to support its patent,

[441] *GEA Group* Award, paras. 306-324 (**RL-026**). *See* also *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*"), 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) (**RL-028**). *See* also *Barcelona Traction, Light and Power Company Limited (Belgium v. Spain),* Judgement of 5 February 1970, Separate Opinion of Judge Tanaka, p. 158 (**RL-020**): "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.")

and (3) the law requires that evidence of sound prediction of utility must be disclosed in the patent application itself. [442]

248. Claimant both misunderstands the concept of "arbitrariness" in international law and misrepresents the interpretation and application of utility under Canadian law.

249. Arbitrariness in international law means that "prejudice, preference or bias is substituted for the rule of law."[443] In order to be arbitrary, a measure must have no legitimate purpose, not be based on legal standards or must have intentionally ignored due process and proper procedure.[444] 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.

250. The concept of arbitrariness was succinctly described by the International Court of Justice in the *Elettronica Sicula SpA (ELSI) United States v. Italy* case. [445] The ICJ observed that conduct which is unlawful in domestic law is not necessarily arbitrary and that even conduct which may be considered arbitrary by domestic law will not necessarily breach international law. [446] The ICJ continued:

> Arbitrariness is not so much something opposed to a rule of law, as something opposed to the rule of law…it is willful disregard of due

[442] Claimant's Memorial, paras. 261-271.

[443] *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 **(RL-030)** (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). The *LG&E* Tribunal did not find Argentina's measures to be arbitrary because they "were the result of reasoned judgment rather than simple disregard of the rule of law." *LG&E Liability*, para. 162 **(RL-030)**.

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

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

[446] *ELSI Judgment*, p. 74, para. 124 **(RL-031)**.

> process of law, an act which shocks, or at least surprises a sense of judicial propriety.[447]

251. The ICJ's observation in *ELSI* was endorsed by the *Mondev* and *Loewen* tribunals in the context of a NAFTA Chapter Eleven claim challenging the outcome of a judicial proceeding,[448] just as Claimant does here. Furthermore, as the *Thunderbird, Cargill*, and *Glamis* tribunals emphasized, there must be manifest arbitrariness in order to breach the customary international law minimum standard of treatment of aliens.[449] As set out above, arbitrariness in the context of judicial decisions must be viewed through the lens of denial of justice.

252. Claimant invents its own definition when it argues that a State acts arbitrarily when a new law is "unclear and the investor cannot reasonably plan for and comply with it."[450] This is an overly simplistic statement and irrelevant to the current dispute. It is simplistic because, even if a new law is drafted in a way that is "unclear," there will still be no violation of Article 1105 unless it is applied by government authorities in a way that can be described as "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."[451] Merely being "unclear" cannot constitute a basis of liability under customary international law, especially in the context of domestic court judgments on domestic law where relief is

[447] *ELSI Judgment*, p. 76, para. 128 (emphasis added) **(RL-031)**.

[448] *Mondev Award*, para. 127 **(RL-004)**; *Loewen Award*, para. 131 **(RL-013)**. *See* also *Alex Genin et al v. Republic of Estonia*, ICSID Case No. ARB/99/2, Award 25 June 2001, ("*Genin*"), para. 371 **(RL-032)** (approving the *ELSI* description of arbitrary).

[449] *Glamis Award*, paras. 625-626 **(RL-006)**; *Cargill Award*, para. 245 **(RL-015)**; *Thunderbird Award*, para. 194 **(RL-003)** ("[T]he Tribunal views acts that would give rise to a breach of the minimum standard of treatment prescribed by the NAFTA and customary international law as those that, weight against the given factual context, amount to a gross denial of justice or *manifest arbitrariness* falling below international standards."), para. 197 ("[T]he Tribunal cannot find sufficient evidence on the record establishing that the SEGOB proceedings were arbitrary or unfair, *let alone so manifestly arbitrary or unfair as to violate the minimum standard of treatment*.") Claimant also cites and emphasises the *Thunderbird* tribunal's position that arbitrariness must be "manifest" in order to fall below the minimum standard of treatment. *See* Claimant's Memorial, para. 261, FN. 473.

[450] Claimant's Memorial, para. 261.

[451] *Cargill Award*, para. 293 **(RL-015)**.

only available on the basis of denial of justice. It is also irrelevant to the current dispute because there is no "new law" at issue – the *Patent Act* has not changed. As described above, and in the expert opinion of Mr. Dimock, the patent law rules that are the focus of Claimant's dissatisfaction were established in Canadian law long before the atomoxetine and olanzapine patents were filed. [452]

253. It is for this reason that Claimant's reliance on *Occidental v. Ecuador (VAT Dispute)* arbitration falls flat. [453] Not only is the *Occidental* award not relevant for the purpose of interpreting NAFTA Article 1105(1),[454] the facts of that case are completely different. In *Occidental*, the challenged actions were those of Ecuador's administrative tax authorities, not the interpretation of Ecuadorian law by the highest levels of its domestic courts. The tribunal concluded that the Ecuadorian tax authorities had acted arbitrarily with respect to whether the claimant was entitled to VAT rebates or not because its various bureaucratic decisions on the issue turned out to be "manifestly wrong," tax authorities provided answers that were "wholly unsatisfactory and thoroughly vague" and failed to reconcile inconsistent and confusing practices and regulations.[455] *Occidental* is of no value in the context of this dispute.

254. Claimant's argument that Canada's "promise doctrine" is arbitrary also lacks any basis in fact.

255. First, Claimant says that it is "inherently unpredictable" to identify the promises contained in a patent application because doing so is "subjective."[456] This is fatuous. If

[452] Dimock Report, para. 218.

[453] Claimant's Memorial, para. 261, citing *Occidental Exploration and Production Co. v. Republic of Ecuador*, UNCITRAL/LCIA Case No. UN 3467, Award, 1 July 2004, ("*Occidental Award*") **(RL-033)**.

[454] The *Occidental* Tribunal specifically distinguished the autonomous fair and equitable treaty standard it was bound to apply as distinct from the customary international law minimum standard of treatment applicable in the NAFTA. *Occidental Award*, para. 192 **(RL-033)**. As discussed below, NAFTA tribunals have been unwilling to put weight on investment treaty awards which do not specifically apply customary international law when determining the standard of treatment required under NAFTA Article 1105(1).

[455] *Occidental*, paras. 163, 184 **(RL-033)**.

[456] Claimant's Memorial, para. 263.

the patent asserts that it will have a particular utility, the patent will be held to that assertion. It is the patentee, as the drafter of the patent, which controls what promises are made. When the Court is called upon to interpret the patent, it does not do so "subjectively" but rather applies the ordinary and settled rules of construction. Contrary to Professor Siebrasse's view, it is a long-standing principle of interpretation that the patent specification is construed as a whole (*i.e.* both disclosure and claims) and in the eyes and mind of persons skilled in the art. [457] As Mr. Dimock explains, this is not a "subjective" process, rather, "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." [458] This is not "arbitrary," it is what judges are called upon to do every day, be it interpreting statutes, contracts or patents. Claimant is in essence arguing that the Federal Court is not capable of carrying out its core function of hearing arguments from both sides, assessing facts, considering testimony and making a decision based on the evidence presented and in light of applicable legal rules.

256. What Claimant really has issue with are the factual determinations by the Court about the wording of Claimant's olanzapine and atomoxetine patent applications, not the rules of patent construction. Claimant insists (as it did at trial) that it only promised that olanzapine was "useful as an anti-psychotic" and that atomoxetine was to "[treat] humans with ADHD." The Federal Court disagreed and concluded that, based on the evidence and testimony presented during lengthy trials, Claimant promised more in its patent applications.[459] Claimant cannot label these decisions "arbitrary, unjust and idiosyncratic" merely because the judges had a different reading of a document.[460]

[457] Dimock Report, para. 85.

[458] Dimock Report, para. 85.

[459] Claimant's Memorial, para. 263, FN. 478.

[460] Claimant's reference to the outcome of two other patent cases involving the glaucoma drug latanoprost is irrelevant to this dispute. *See* Claimant's Memorial, paras. 64, 263. Those litigations did not involve the Claimant and the patents are completely unrelated to those at issue in this arbitration.

257. Second, Claimant alleges that a heightened evidentiary burden is arbitrary because it allows judges to "second-guess the scientific evidence" and complains that "patent applicants have no way of knowing at the time of drafting how much (and what type of) evidence a judge will require to demonstrate or soundly predict a patent's utility."[461] Again, this does not correspond to reality. Patents do not have to be proven valid by a "heightened evidentiary" burden. Rather, granted patents benefit from a presumption of validity. If a challenger adduces evidence of invalidity, then the ordinary balance of probabilities test applies.[462]

258. Furthermore, a judge does not "second-guess" or arbitrarily concoct how much scientific evidence he or she feels like requiring in order to rule a patent valid or not. He or she looks at the evidence that the parties present to the Court, often with the assistance of expert testimony, and adjudicates whether, at the time of filing the patent, the utility of the invention had been demonstrated or soundly predicted. If a mere prediction of utility was relied upon, the judge will assess, based on expert evidence put forward by the parties, whether the skilled reader would have recognized the prediction as sound. Whether this will require clinical trials or not entirely depends on the specific patent at issue and its claimed utility. As Mr. Dimock notes, numerous pharmaceutical patents have been upheld in the absence of clinical trials.[463] This is not arbitrariness – this is the essence of the adjudicative role of a court. Claimant's criticism of the Court's evidentiary assessment of the clinical trials in the atomoxetine and olanzapine litigation is nothing more than Claimant asking this Tribunal to second-guess the Federal Court's factual determinations. [464]

259. Third, Claimant complains that it is arbitrary that evidence in support of the promised utility must have been disclosed in the patent application itself. [465] This

[461] Claimant's Memorial, paras. 265-268.

[462] Dimock Report, para. 29.

[463] Dimock Report, para. 100.

[464] Claimant's Memorial, paras. 265, 267.

[465] Claimant's Memorial, paras. 269-270.

critique also has nothing to do with arbitrariness. Where a patentee is relying on a mere prediction of utility to justify the grant of a patent, enough information must be disclosed so that the skilled reader can recognize that prediction as sound (and thus, in keeping with the legal test on which the patent's validity depends). Otherwise, there would be no way for the skilled reader to distinguish a patent for which utility was soundly predicted from one that patented a wild-guess or a spontaneous idea. As Mr. Dimock explains, the requirement to disclose the basis for predictions of utility has been part of Canadian law since the 1970s.[466] The Claimant's subjective preference for a system which allows post-filing evidence does not make the existing rules in Canadian patent law arbitrary.

260. Claimant's complaint about the interpretation of the *Patent Act* by the Federal Courts and the outcomes of the atomoxetine and olanzapine litigations are simply critiques, not evidence of arbitrariness.

2) The judgments were not discriminatory

261. Claimant argues that the interpretation of the utility requirement in the *Patent Act* by the Canadian Federal Courts is discriminatory. Claimant alleges that because the "promise doctrine" mostly impacts pharmaceutical patents and most pharmaceutical patent holders in Canada are foreign, it necessarily follows that there is discrimination on the basis of nationality and/or technology in violation of the minimum standard of treatment in customary international law. [467]

262. This argument is illogical. First of all, NAFTA Article 1105 protects against unjustifiable discriminatory treatment in court proceedings founded on the investor's foreign nationality, not mere differential treatment.[468] In order to challenge the judgment

[466] Dimock Report, para. 50.

[467] Claimant's Memorial, para. 291.

[468] As the tribunal in *Methanex* pointed out, in the absence of a treaty rule to the contrary, customary international law allows States to differentiate in its treatment of nationals and aliens. *Methanex Final Award on Jurisdiction*, para. 25 **(RL-011)**. This position was endorsed by the Tribunal in *Grand River Award*, paras. 208-209 **(RL-010)** ("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,

of a domestic court, the Claimant would have to demonstrate that "it was the victim of discrimination on account of its nationality…"[469] As the *Loewen* tribunal explained, "it is the responsibility of the courts of a State to ensure that litigation is free from discrimination against a foreign litigant and that the foreign litigant should not become the victim of sectional or local prejudice."[470] The tribunal in *Waste Management II* applied the same rule and found "no trace of discrimination on account of the foreign ownership" of the claimant's investment. [471]

263. Second, it is a *non sequitur* to argue that because Canadian patent law adopts a particular approach to utility and because two of its patents were invalidated that Claimant and other foreign brand-name pharmaceutical investors are subject to discrimination. All drug patent applicants, Canadian and foreign alike, are held to the same standard of the promised utility of their patents: that the invention be demonstrated, or at least soundly predicted, as of the time of filing, and that the basis for an invention be properly disclosed. The rule applies equally to any patent in whatever industry. Even if it were true that more pharmaceutical patents have been invalidated than in other industries is symptomatic of the litigiousness of the pharmaceutical industry, not the discriminatory effect of Canadian law. [472]

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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.").

[469] *Loewen Group and Another v. United States of America*, Opinion of Christopher Greenwood Q.C, 26 March 2001, para. 64 **(RL-025)**.

[470] *Loewen Award*, para. 123 **(RL-013)**. The *Loewen* tribunal found that there was local favouritism against the Canadian claimant. *See Loewen Award*, paras. 135-136 **(RL-013)**. *See* also *Lemire Decision on Jurisdiction and Liability*, para. 261 **(RL-029)** ("To amount to discrimination, a case must be treated differently from similar cases without justification, a measure must be "discriminatory and expose[s] the claimant to sectional or racial prejudice"; or a measure must "target[ed] Claimant's investments specifically as foreign investments.") (Internal citations omitted); *Alex Genin et al v. Republic of Estonia*, ICSID Case No. ARB/99/2, Award 25 June 2001, ("*Genin Award*"), paras. 363-370 **(RL-032)** (confirming that discrimination in international law means targeting an investor because of its foreign status).

[471] *Waste Management II*, para. 130 **(RL-014)**.

[472] *See* Part D above.

264. Claimant's protest regarding discrimination does not withstand scrutiny. Claimant argues that the principle beneficiaries of this approach are generic drug makers.[473] But among generic companies operating in Canada, half of the top 18 (based on sales) are not Canadian-owned .[474] Claimant also says that foreign brand-name drug makers are being discriminated against as a result of the Federal Courts interpretation of the law, but Canadian innovator companies including biopharmaceutical companies, are subject to the same rules as Claimant.[475] Finally, as set out in Part D above and described in Dr. Brisebois statement, Claimant's statistics regarding patent invalidation in the pharmaceutical industry are misleading: in reality, there have been only three invalidations based solely on utility, two of which are the subject of this arbitration. It is impossible to draw the sweeping conclusion at "discrimination" the Claimant advocates.

D. Claimant Has Not Established That "Legitimate Expectations" Are Protected by the Minimum Standard of Treatment under Customary International Law, or That It Had Any Legitimate Expectations to Begin With

265. Claimant also argues that its "legitimate expectations" were breached by the Canadian federal judiciary when it ruled that the atomoxetine and olanzapine patents were invalid under the *Patent Act*.[476] Claimant says that the doctrine of "legitimate expectations" is a rule of customary international law and asserts that Canada is liable under Article 1105 because (1) it reasonably expected the Federal Court to adopt a definition of utility that would have resulted in the validation of its patents, and (2) it expected Canada to conform to the PCT.

[473] Claimant's Memorial, para. 291.

[474] Claimant's Memorial, para. 291. Of the eighteen generic drug companies operating in Canada (based on sales), nine are Canadian-owned (Apotex, Pharmascience, Sanis Health Inc (Shoppers Drug Mart), Pro Doc (Jean Coutu), AA Pharma Inc., Riva, Jamp Pharma, Mint Pharma and Sterimax) and nine are foreign-owned (Teva, Actavis, Mylan, Ranbaxy, Sivem (Mckesson), Hospira, Taro Pharma, Aptalis and Pharma Partners (Fresnius Kabi).

[475] *See* Claimant's Memorial, para. 291, fn. 539.

[476] Claimant's Memorial, paras. 272-289.

266. Claimant's arguments are defective on multiple levels. First, Claimant has failed to prove that the theory of "legitimate expectations" has become a rule of customary international law that is protected by NAFTA Article 1105(1). Second, regardless of its status generally in international law, it is a doctrine which fundamentally cannot be applied to judgments of the domestic judiciary acting in an adjudicative function of domestic statutory interpretation. Third, even if the theory of legitimate expectations is now a rule of custom protected under Article 1105(1), and even if it were applicable to the judiciary, Claimant could not have reasonably had the expectations claimed. Rules regarding utility are long-standing in Canadian law and the grant of a patent is always contingent on future confirmation by the courts for compliance with Canadian law. Claimant could not have had a "legitimate expectation" of how a court would rule in the future in light of the law, facts, evidence and other considerations presented before the court at the time of challenge. To assert otherwise would give every disappointed litigant an automatic remedy in international law against any adverse domestic ruling that it "expected" to win.

1) Claimant has failed to prove that "legitimate expectations" is a rule of customary international law protected by NAFTA Article 1105(1)

a) Claimant has the burden of proving the existence of a rule of customary international law

267. It is axiomatic that in order to prove the existence of a rule of customary international law, two requirements must be met: substantial state practice and an understanding that such practice is required by law (*opinio juris sive necessitatis*).[477]

[477] United Nations, *Statute of the International Court of Justice*, 18 April 1946, Article. 38(1)(b) ("*ICJ Statute*") **(RL-034)** (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."); *North Sea Continental Shelf Cases (Federal Republic of Germany v. Denmark; Federal Republic of Germany v. The Netherlands)*, Judgment [1969] ICJ, p. 43 (**RL-035**) (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"); *Case Concerning the Continental Shelf*, (*Libyan Arab Jamahiriyah v. Malta*) [1985] ICJ Rep., p. 29, para. 27 **(RL-036)** ("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…"); *Case of Nicaragua v. United States (Merits)*,

268. It is also unassailable that the burden of proving the existence of a rule of customary international law rests on the party that alleges it. The International Court of Justice wrote that "the Party which relies on a custom of this kind must prove that this custom is established in such a manner that it has become binding on the other party."[478] The *Cargill* tribunal confirmed that "where a custom is not clear, or is disputed, then it is for the party asserting the custom to establish the content of that custom."[479] Other NAFTA tribunals have affirmed the same.[480]

ICJ Rep. 14 (1986), p. 108, para. 207 **(RL-037)** ("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 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."); *United Parcel Service of America Inc. v. Canada*, Award on Jurisdiction (UNCITRAL) 22 November 2002, ("*UPS Jurisdiction Award*"), para. 84 **(RL-038)**; *Glamis Award*, paras. 602-603 **(RL-006)**.

[478] *Case Concerning Rights of Nationals of the United States of America in Morocco* (*France v. United States*), [1952] ICJ Rep. 176, p. 200 **(RL-039)** (quoting Asylum (*Colom. v. Peru*), 1950 ICJ 266).

[479] *Cargill Award*, para. 271 **(RL-015)**. The Cargill tribunal continued: "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." *Cargill Award*, para. 273 **(RL-015)**.

[480] *ADF Award*, paras. 183-184 **(RL-005)** ("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 […] any general requirement to accord "fair and equitable treatment" and "full protection and security" must be disciplined by being based upon State practice and juridical or arbitral caselaw or other sources of customary or general international law."); *UPS Jurisdiction Award*, para. 84 **(RL-038)** ("[R]elevant practice and the related understandings must still be assembled in support of a claimed rule of customary international law."); *Glamis Award*, paras. 601-603 **(RL-006)** ("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"); *Mobil Decision on Liability* **(RL-007)**; *Apotex Award* **(RL-016)**. *See* also Nguyen, Quoc Dinh, Dallier & Pellet, *Droit International Public*, 6th ed., (LGDJ 1999), p. 330 **(R-329)** (burden on 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."); Ian Brownlie, "Principles of Public International Law", Seventh Edition, 2008, p. 12 **(R-330)** ("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.").

b) Claimant fails to submit evidence of state practice and opinio juris

269. Claimant has submitted no evidence of state practice or *opinio juris* to support its assertion that the minimum standard of treatment of aliens in customary international law now includes a protection of an investor's "legitimate expectations." Claimant fails to demonstrate the practice of the three NAFTA Parties, let alone evidence of practice by any of the other 193 members of the United Nations sufficient to show that an investor's expectations are protected by customary international law.

270. Instead, Claimant relies almost exclusively on non-NAFTA arbitration awards interpreting autonomous "fair and equitable treatment" provisions in investment treaties and which do not require, as does NAFTA Article 1105(1), the application of the customary international law minimum standard of treatment of aliens. This same flawed approach to proving custom and the same arguments regarding legitimate expectations have been made and rejected before by the *Cargill*, *Glamis* and *Mobil* tribunals.[481] This Tribunal should do the same.

271. First, as a threshold evidentiary issue, arbitral awards cannot *create* customary international law – only states can create custom.[482] As Professor Lauterpacht wrote, "[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."[483] The

[481] Claimant in this case repeats most of the same arguments the claimant in *Mobil* made with respect to legitimate expectations. *See Mobil Decision on Liability*, paras. 111-113, 127-130 (**RL-007**). As described below, the tribunal did not endorse the Claimant's position.

[482] As noted in Statute of the Court, International Court of Justice, *ICJ Statute*, Article 38(1)(d) (**RL-034**), judicial decisions are a "subsidiary means for the determination of rules of law."

[483] Sir Hersch Lauterpacht, *The Development of International Law by the International Court*, (London: Stevens, 1958), pp. 20-21 (**R-331**). *See* also Mohamed Shahabuddeen, *Precedent in the World Court* (Cambridge University Press, 1996), pp. 71-72 (**R-332**) ("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.").

Glamis tribunal endorsed the position of the United States on this point: "Arbitral awards, Respondent rightly notes, do not constitute State practice and thus cannot create or prove customary international law."[484] While arbitral awards may contain valuable analysis of State practice and *opinio juris* in relation to a particular rule of custom, and can be considered accordingly,[485] they cannot by themselves substitute for actual evidence of state practice and *opinio juris* as the ICJ confirmed in *Diallou.*[486] Accordingly, Claimant cannot point to arbitral awards endorsing its theory of legitimate expectations as evidence of customary international law unless the awards themselves have examined evidence of state practice and *opinio juris*.

272. Second, the non-NAFTA arbitral decisions upon which Claimant relies to support its "legitimate expectations" argument were mostly interpreting autonomous stand-alone Fair and Equitable Treatment ("FET") clauses that were not specifically conditioned on the minimum standard of treatment of aliens under customary international law. Such awards are not relevant in the context of NAFTA Article 1105(1). The *Cargill* tribunal noted that such awards are only relevant "if the fair and equitable treatment clause of the BIT in question was viewed by the Tribunal as involving, like Article 1105, an incorporation of the customary international law

[484] *Glamis Award*, para. 605 **(RL-006)**. The *Cargill* tribunal also noted that "the awards of international Tribunals do not create customary international law but rather, at most, reflect customary international law." *Cargill Award*, para. 277 **(RL-015)**.

[485] The *Cargill* 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." *Cargill Award*, para. 277 **(RL-015)**. The *Glamis* 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." *Glamis Award*, para. 611 **(RL-006)**.

[486] *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 **(RL-041)**. In that case, the ICJ held 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. The ICJ found that the claimant had failed to prove the alleged rule of custom.

standard rather than autonomous treaty language."[487] As Professors Dolzer and Schreuer have written, "in the context of NAFTA, the three state parties decided that the standards of "fair and equitable treatment" and "full protection and security" must be understood to require host states to observe customary international law and *not more demanding autonomous treaty-based standards.*"[488]

273. A close reading of the awards relied on by Claimant shows that none of them, including *Biwater Gauff, Azurix, CMS, LG&E, Occidental, TECMED* and *Duke Energy*, examined actual state practice and *opinio juris* to establish that protection of an investor's legitimate expectations is now a rule of customary international law.[489] In fact, most of those tribunals expressly noted there was no need for them to do so because the applicable fair and equitable treatment provision was not limited to the customary

[487] *Cargill Award*, para. 278 **(RL-015)**. The *Cargill* tribunal said 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." *Cargill Award*, para. 276 **(RL-015)**. The tribunal also considered the number of treaties which contain a provision that requires fair and equitable treatment but noted that States are beginning to renegotiate that provision. According to the tribunal, "[i]n such a fluid situation, the Tribunal does not believe it prudent to accord significant weight to even widespread adoption of such clauses." *Cargill Award*, para. 276 **(RL-015)**.

[488] Dolzer and Schreuer, *Principles of International Investment Law* (Oxford: Oxford University Press, 2008), p. 16 (emphasis added) **(R-327)**. *See* also, p. 126: "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."

[489] *Biwater Gauff (Tanzania) Ltd. v. United Republic of Tanzania*, ICSID ARB/05/22, Award, 24 July 2008, ("*Biwater Gauff Award*"), para. 586 **(RL-043)**; *Azurix v. Argentine Republic*, ICSID ARB/01/12, Award, 14 July 2006, ("*Azurix Award*"), paras. 361, 363 **(RL-044)**; *Occidental Award*, paras. 180, 192 **(RL-033)**; *CMS Gas Transmission Co. v. Argentine Republic*, ICSID ARB/01/8, Award, 12 May 2005, ("*CMS Award*"), para. 284 **(RL-047)**; *LG&E Liability*, para. 122 **(RL-030)**; *Duke Energy Electroquil Partners & Electroquil S.A. v. Republic of Ecuador*, ICSID ARB/04/19, Award, 18 August 2008, ("*Duke Energy Award*"), paras. 333-337 **(RL-048)**. *Occidental* is similarly unhelpful. In that case, the Tribunal noted that the question of whether the FET standard in the treaty was more demanding than the minimum standard of treatment under customary international law did not arise, so it had no need to undertake the analysis of state practice and *opinio juris* that Article 1105 requires. *Occidental Final Award*, para. 192 **(RL-033)** ("The question whether there could be a Treaty standard more demanding than a customary international law standard that has been painfully discussed in the context of NAFTA and other free trade agreements does not therefore arise in this case.") There was no reference to the minimum standard of treatment under customary international law in Article II (3)(a) of the US-Ecuador BIT, which was at issue in that case.

international law minimum standard of treatment of aliens.[490] This is why NAFTA tribunals like *Glamis, Cargill* and *Mobil* declined to endorse *TECMED* in the NAFTA context with respect to legitimate expectations. [491]

274. The FTC Note of Interpretation is clear: Article 1105 "[does] not require treatment in addition to or beyond that which is required by the customary international law minimum standard of treatment of aliens." [492] Thus, without real evidence of state practice and *opinio juris* to show that the protection of legitimate expectations is now a rule of customary international law, the Claimant's assertion that it is must fail.[493]

[490] The *TECMED* tribunal stated that the FET standard in the applicable BIT was "autonomous" and did not undertake any examination of customary international law. *Technicas Medioambientales Tecmed, S.V. v. United Mexican States*, ICSID ARB(AF)/00/2, Award, 29 May 2003, ("*TECMED Award*"), paras. 155-156 **(RL-049)**. *See* also *Biwater Gauff Award*, paras. 591, 595 **(RL-043)** (noting there was no reference to the minimum standard of treatment under customary international law and concluded that the BIT's "autonomous standard" left it open to the Tribunal to determine the precise scope based on whether the Tribunal felt the conduct "is fair and equitable or unfair and inequitable."). None of the cases cited by the *Biwater Gauff* tribunal undertook an analysis of customary international law either. *See* for example *Saluka Investments B.V. v. Czech Republic*, UNCITRAL, Partial Award, 17 March 2006, ("*Saluka Partial Award*"), para. 294 **(RL-050)** ("[T]his Tribunal has to limit itself to the interpretation of the "fair and equitable treatment" standard as embodied in Article 3.1 of the Treaty. That Article omits any express reference to the customary minimum standard. The interpretation of Article 3.1 does not therefore share the difficulty that may arise under treaties (such as the NAFTA) which expressly tie the "fair and equitable" treatment standard to the customary minimum standard. Avoidance of these difficulties may even be regarded as the very purpose of the lack of a reference to an international standard in the Treaty. This clearly points to the autonomous character of a "fair and equitable treatment" standard such as the one laid down in Article 3.1 of the Treaty.").

[491] *Glamis Award*, para. 610 **(RL-006)**; *Cargill Award*, paras. 280, 286 **(RL-015)**; *Mobil Decision on Liability*, paras. 113, 148-151 **(RL-007)**.

[492] *FTC Notes of Interpretation*, para. 2 **(RL-009)**. *See Mondev Award*, para. 122 **(RL-004)** ("The FTC interpretation makes it clear that in Article 1105(1) the terms "fair and equitable treatment" and "full protection and security" are, in the view of the NAFTA Parties, references to existing elements of the customary international law standard and are not intended to add novel elements to that standard.). *See* also *UPS Jurisdiction Award*, para. 97 **(RL-038)** ("[W]e agree in any event that the obligation to accord fair and equitable treatment is not in addition to or beyond the minimum standard."); *Loewen Award*, para. 128 **(RL-013)** ("'fair and equitable treatment' and 'full protection and security' are not free-standing obligations. They constitute obligations only to the extent that they are recognized by customary international law."); *Glamis Award*, para. 609 **(RL-006)** ("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.").

[493] The Article 1105 claims in *UPS, ADF, Glamis,* and *Apotex* all failed in part on the ground that the Investor had not fulfilled its burden to establish state practice and *opinio juris*. *UPS Jurisdiction Award*, para. 86 **(RL-038)** ("…UPS has not attempted to establish that that state practice reflects an understanding

c) Mere failure to fulfil an investor's "expectations" does not breach the minimum standard of treatment protected in Article 1105(1)

275. Previous NAFTA tribunals have already expressed the view that mere failure to meet an investor's expectations does not breach Article 1105(1). While the unjustified repudiation of specific representations made to the investor in order to induce an investor can be a factor in assessing whether the minimum standard of treatment has been breached, the open-ended insurance policy against regulatory change Claimant advocates has not be endorsed.

276. The *Waste Management II* tribunal said that the breach of representations made by the host State to the investor and which were reasonably relied on by the investor may be "relevant" as to whether the NAFTA party acted in a way that was "grossly unfair, unjust or idiosyncratic" or exhibited "a complete lack of transparency and candour in an administrative process."[494] Similarly, the *Thunderbird* tribunal considered expectations of the investor as part of the "context" of the measure but found that the impugned actions would still have to rise to a level that amounted to a "gross denial of justice or manifest arbitrariness falling below acceptable international standards."[495] The *Glamis* tribunal considered it possible that the repudiation of specific assurances or commitments to the investor to induce an investment could be a factor in deciding whether a measure is sufficiently egregious so as to fall below the minimum standard of treatment but took "no position on the type or nature of repudiations measures that would be necessary to violate international obligations."[496]

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of the existence of a generally owed international legal obligation"); *ADF Award*, para. 183 (deciding that claimant had not proven that customary international law includes an "a general and autonomous requirement…to accord fair and equitable treatment and full protection and security to foreign investments" simply by pointing to bilateral investment treaties which contain such provisions); *Glamis Award*, para. 627 (**RL-006**) ("The Tribunal holds that Claimant has not met its burden of proving that something other than the fundamentals of the *Neer* standard apply today"); *Apotex Award* (**RL-016**).

[494] *Waste Management II*, para. 98 (**RL-014**).

[495] *Thunderbird Award*, paras. 147, 194 (**RL-003**).

[496] *Glamis Award*, paras. 620, 627 (**RL-006**). In fact, the *Glamis* tribunal decided that a legal opinion issued by the United States Department of the Interior (known as the "M-opinion") which eventually led

277. The *Mobil* tribunal concluded that the repudiation by a State of its "clear and explicit representations" made to induce an investment and which were objectively and reasonably relied upon by the investor is a "relevant factor" in determining whether there has been a breach of Article 1105, but only when it amounts to "egregious behaviour."[497] The *Mobil* tribunal stated:

> [Article 1105] does not require a State to maintain a stable legal and business environment for investments, if this is intended to suggest that the rules governing an investment are not permitted to change, whether to a significant or modest extent. Article 1105 may protect an investor from changes that give rise to an unstable legal and business environment but only if those changes may be characterized as arbitrary or grossly unfair or discriminatory, other otherwise inconsistent with the customary international law standard. In a complex international and domestic environment, there is nothing in Article 1105 to prevent a public authority from changing the regulatory environment to take account of new policies and needs, even if some of those changes may have far-reaching consequences and effects, and even if they impose significant additional burdens on an investor. Article 1105 is not, and was never intended to amount to, a guarantee against regulatory change, or to reflect a requirement that an investor is entitled to expect no material changes to the regulatory framework within which an investment is made. Governments change, policies change and rules change. These are facts of life with which investors and all legal and natural persons have to live with.[498]

278. Canada's position has always been that mere failure to fulfil "expectations," however characterized, does not automatically fall below the customary international law standard of treatment required by NAFTA Article 1105.[499] The United States has taken the same view on several occasions that "states may amend or modify their regulations to achieve legitimate public welfare objectives and will not incur liability

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to the rejection of the claimant's mining project did not breach customary international law even though it was a dramatic change to the legal interpretation of long-standing rules upon which Claimant had relied to make its investment. *See id.*, paras. 136-147, and 758-772. *See* also *Mobil Decision on Liability*, para. 147 (**RL-007**).

[497] *Mobil Decision on Liability*, paras. 152-153 (**RL-007**).

[498] *Mobil Decision on Liability*, para. 153 (emphasis added) (**RL-007**).

[499] *See Mobil Decision on Liability*, paras. 133-134 (**RL-007**) quoting Canada's position.

under customary international law merely because such changes interfere with an investor's "expectations" about the state of regulation in a particular sector." [500]

279. Claimant, on the other hand, does not even believe it necessary that Canada make specific representations or promises to it before its "legitimate expectations" can arise and be guaranteed under NAFTA Article 1105 because that is too "narrow" a standard and "not found in customary international law."[501] Claimant disputes the findings of the *Mobil* and *Glamis* tribunals, both of which have the opposite position as what Claimant argues here.[502]

280. This is an illogical and revisionist statement. It is illogical because the theory of legitimate expectations has not been proven to be a rule of customary international law in the first place, so disputing one element of a rule which is not actually a rule does nothing to assist Claimant. It is revisionist because the requirement that an investor's legitimate expectations must be based on specific promises or representations to the investor is by no means a "narrow standard" – it is *the* standard. The *Mobil* and *Glamis* tribunals were not the only NAFTA tribunals to make this conclusion: *Metalclad*, *Waste Management II, International Thunderbird* and *Grand River* all considered it essential evidence as to whether the respondent NAFTA Party had made specific assurances to the investor that were later repudiated.[503]

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[500] *Mesa Power Group LLC v. Government of Canada*, Submission of the United States of America, 25 July 2014, para. 8 **(RL-051)**. The United States has expressed the same position in non-NAFTA arbitrations. *See* for example, *TECO Guatemala Holdings LLC v. Republic of Guatemala*, ICSID Case No. ARB/10/23, 23 November 2012, para. 6 **(RL-052)**. This is consistent with what the United States argued in the *Glamis Award* arbitration, arguments which the tribunal in that case accepted. *See Glamis Award*, paras. 575-582, 618-622 **(RL-006)**.

[501] Claimant's Memorial, para. 284.

[502] *Mobil Decision on Liability*, para. 152 **(RL-007)** (there must be "(i) clear and explicit representations made by or attributable to the NAFTA host State in order to induce the investment, and (ii) were by reference to an objective standard, reasonably relied on by the investor, and (iii) were subsequently repudiated by the NAFTA host state" in order to be "relevant" in assessing whether the impugned behavior was "arbitrary, grossly unfair, unjust or idiosyncratic."); *Glamis Award*, paras. 620, 621 **(RL-006)**.

[503] *Metalclad Corporation v. The United Mexican States*, ICSID Case No. ARB(AF)/97/1, Award, 30 August 2000, ("Metalclad Award"), para. 89 **(RL-053)** ("Metalclad was entitled to rely on the

281. Even non-NAFTA arbitral tribunals interpreting autonomous fair and equitable treatment provisions have insisted on more rigorous criteria than what Claimant advocates. For example, the tribunal in *EDF v. Romania* stated:

> The idea that legitimate expectations, and therefore FET, imply the stability of the legal and business framework, may not be correct if stated in an overly-broad and unqualified formulation. The FET might then mean the virtual freezing of the legal regulation of economic activities, in contrast with the State's normal regulatory power and the evolutionary character of economic life. Except where specific promises or representations are made by the State to the investor, the latter may not rely on a bilateral investment treaty as a kind of insurance policy against the risk of any changes in the host State's legal and economic framework. Such expectation would neither be legitimate nor reasonable.[504]

282. Accordingly, legitimate expectations must, first, be based on objective rather than subjective, expectations of the investor.[505] Second, there must have been a specific assurance or promise by the State to induce the investment which was relied on by the

representations of federal officials and to believe that it was entitled to continue its construction of the landfill. In following the advice of these officials, and filing the municipal permit application on November 15, 1994, Metalclad was merely acting prudently and in the full expectation that the permit will be granted."); *Waste Management II*, para. 98 **(RL-014)** ("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."); *Thunderbird Award*, paras. 146-148 **(RL-003)** (concept of legitimate expectations involves reliance on the specific assurances provided by government officials but concluding that the Mexican SEGOB did not generate such expectations through its *Oficio* relating to gambling machines). *See* also *Grand River Award*, para. 141 **(RL-010)** ("Ordinarily, reasonable or legitimate expectations of the kind protected by NAFTA are those that arise through targeted representations or assurances made explicitly or implicitly by a state party.").

[504] *EDF Award*, para. 217 (emphasis added) **(RL-008)**. *See* also *id.* para. 218 **(RL-008)** (citing *Parkerings-Compagniet AS v. Republic of Lithuania*, ICSID ARB/05/8, Award, 11 September 2007, para. 332 **(RL-040)**: "It is each State's undeniable right and privilege to exercise its sovereign legislative power. A State has the right to enact, modify or cancel a law at its own discretion. Save for the existence of an agreement, in the form of a stabilization clause or otherwise, there is nothing objectionable about the amendment brought to the regulatory framework existing at the time an investor made its investment."),

[505] *Mobil Decision on Liability*, para. 152 **(RL-007)**; *EDF Award*, para. 219 **(RL-008)** ("Legitimate expectations cannot be solely the subjective expectations of the investor. They must be examined as the expectations at the time the investment is made, as they may be deduced from all the circumstances of the case, due regard being paid to the host State's power to regulate its economic life in the public interest."); *Glamis Award*, para. 627 **(RL-006)** ("Creation by the state of objective expectations in order to induce investment…").

investor.[506] Third, the relevant expectations must be those existing at the time the investor decided to make the investment.[507] Finally, to assess the reasonableness of an investor's expectations, "all circumstances, including not only the facts surrounding the investment, but also the political, socioeconomic, cultural and historical conditions prevailing in the host State" need to be taken into account.[508]

283. In summary, while NAFTA tribunals have considered the repudiation of legitimate expectations of foreign investors by officials of the executive or legislative branch of government, assuming they reasonably existed at the time the investment was made and were based on specific representations to induce the investment, as relevant in determining whether the measure in question was egregious enough to breach customary international law, no NAFTA tribunal has found that the mere failure to fulfil an investigator's expectations constituted in and of itself a breach of the minimum standard of treatment under Article 1105(1). Something more is required.

[506] *Mobil Decision on Liability*, para. 152 **(RL-007)**; *Glamis Award*, para. 620 **(RL-006)** ("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."); *Waste Management II*, para. 98 **(RL-014)** (noting the relevance of a "breach of representations made by the host State which were reasonably relied on by the claimant."); *EDF Award*, para. 217 **(RL-008)** ("Except where specific promises or representations are made by the State to the investor, the latter may not rely on a bilateral investment treaty as a kind of insurance policy against the risk of any changes in the host State's legal and economic framework. Such expectation would be neither legitimate or reasonable.")

[507] *Bayindir Insaat Turizm Ticaret Ve Sanayi A.Ş. v. Islamic Republic of Pakistan*, ICSID ARB/03/29, Award, 27 August 2009 ("*Bayindir Award*"), paras. 190-191 **(RL-054)** ("Several awards have stressed that the expectations to be taken into account are those existing at the time when the investor made the decision to invest. There is no reason not to follow this view here."); *Duke Energy Electroquil Partners & Electroquil S.A. v. Republic of Ecuador*, ICSID ARB/04/19, Award, 18 August 2008, ("*Duke Energy Award*"), para. 340 **(RL-048)**.

[508] *Duke Energy Award*, para. 340 **(RL-048)**, cited with approval in *Bayindir Award*, para. 192 **(RL-054)**. *See* also *Saluka Partial Award*, para. 304 **(RL-050)** ("This Tribunal would observe, however, that while it subscribes to the general thrust of 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*.").

2) The theory of "legitimate expectations" does not apply to the adjudicative role of the judiciary

284. The debate regarding the current status of the "legitimate expectations" theory in international law is ultimately irrelevant in the context of the current dispute.

285. The doctrine of legitimate expectations as advocated by Claimant is fundamentally inapplicable with respect to the rulings of domestic courts acting in their *bona fide* role of interpreting and applying domestic law. As described above, it is well-settled that the judgments of domestic courts interpreting domestic law can only be considered in violation of customary international law if there has been a denial of justice. There is no authority to suggest that this rule can be circumvented by arguing that an investor's legitimate expectations were breached because a domestic court set out a new interpretation of a domestic law, regardless of how significant that new interpretation might be or interpreted the evidence in a way Claimant did not expect.[509]

286. Indeed, not a single arbitral award cited by Claimant applying the doctrine of legitimate expectations deals exclusively with the judgments of domestic courts exercising their adjudicative role of interpreting and applying domestic law. All of the precedents relied upon by Claimant focus on measures taken by the respondent State's executive, legislative or bureaucratic branches, not solely its judiciary.[510] None endorse or even lends support to Claimant's position.

287. To the contrary, the tribunal in *Jan de Nul v. Egypt* rejected the claimant's argument that Egyptian court rulings be assessed in the broader context of the fair and equitable treatment provision in the applicable treaty, including the protection of its legitimate expectations.[511] The tribunal affirmed that when a judgment of a domestic

[509] To the contrary, as the *Mondev* Tribunal explained, even if Supreme Judicial Court of Massachusetts had "made new law" in its judgments, this would fall "well within the interstitial scope of law-making exercised by courts such as those of the United States." *Mondev Award*, para. 137 (**RL-004**).

[510] *See* for example *TECMED* (deals with citations of Mexican environmental authorities); *Occidental* (tax authorities); *Duke Energy* (which involved, *inter alia*, a state owned entity and customs).

[511] *Jan de Nul Award*, paras. 176-178 and 191 (**RL-028**). The fair and equitable provision in the Egypt-Belgium treaty did not contain a reference to the minimum standard of treatment of aliens in customary

court is the object of the complaint, "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."[512]

288. International law simply does not recognize the doctrine of legitimate expectations as applying to judgments of domestic courts, not only because of the special adjudicative of the judiciary and the great deference afforded to domestic courts in interpreting and applying domestic law, but because judges do not – and cannot – make promises or representations to a foreign investor. Courts interpret and apply the law as it exists and in light of the evidence presented. No investor, domestic or foreign, can have the reasonable expectation that it will always prevail in litigation or that a court's interpretation of the law will never evolve. It is the very essence of the judicial process to develop principles of law through incremental decisions based on the facts, parties and rules presented before them, especially in a jurisdiction like Canada where judicial decision-making is inherently evolutionary.

289. It would be an unprecedented and radical expansion of the theory of legitimate expectations if the long-standing customary rules regarding denial of justice were cast aside and an obligation was imposed on a State's domestic courts to ensure that their interpretation of domestic law and adjudication of evidence presented to them do not violate the expectations of foreign investors.

3) Canada did not frustrate Claimant's "legitimate expectations"

290. Even if it were true that the doctrine of legitimate expectations is now a stand-alone rule of customary international law, and even if it were theoretically possible to apply the doctrine to domestic court rulings in the absence of a denial of justice, Claimant would still fail in its attempt to hold Canada liable under NAFTA Article

international law, making the tribunal's reasoning that denial of justice is the only remedy against a domestic court ruling all the more compelling.

[512] *Jan de Nul Award*, para. 191 **(RL-028)**. The *Jan de Nul* tribunal went on to endorse the views of *Loewen* and *Mondev* tribunals with respect to denial of justice and concluded that the Egyptian courts had not breached those rules. *Id.*, paras. 192-193 **(RL-028)**.

1105(1). The Federal Court did nothing to violate any expectation Claimant could reasonably have held.

291. Claimant says that it "could not have reasonably expected that Canada would promulgate the unique promise utility doctrine, which has no basis in Canada's statutory patent law…"[513] As a basis for such allegations, Claimant relies on witness statements from its employees who testify that they did not know of any reason why their patents would be invalid for lack of utility. [514]

292. The expert opinion of Mr. Dimock and Part C above establish that there is no merit to such allegations. The "promise of the patent" is merely an articulation of the long-standing utility requirement in Canadian law that the patent must do what the patent says that the invention will do. This is completely consistent with the Supreme Court of Canada's reasoning in *Consolboard* (and prior case law and academic literature). [515] This is not a "heightened" or "new" requirement: patent applicants are free to define what their invention will do, Canadian patent law merely requires that the patent actually do what is claimed. These are long-standing rules of Canadian patent law which, when applied to Claimant's patents for atomoxetine and olanzapine in light of the facts and expert testimony, revealed that they were latently defective as at the time of filing. Claimant's subjective view of how it would like the law to be interpreted is not a "legitimate expectation" – it is a mere viewpoint with which the Federal Court, the Federal Court of Appeal, and the Supreme Court of Canada disagree.

293. As for the recollections of Claimant's employees, (Messrs. Stringer, Armitage, Postlethwaith and Ms. Nobles), none of them offer evidence that they had any real understanding of Canadian patent law at the time and none of them even testified in support of the atomoxetine and olanzapine patents before the Federal Court – their

[513] Claimant's Memorial, para. 279.

[514] Stringer Statement, para. 25; Armitage Statement, para. 8, 12, and 16; Noble Statement, para. 23; Poitlethewait Statement, paras. 22, 29.

[515] Dimock Report, para. 56.

testimony would have had no value in determining whether the patents were valid under the *Patent Act* or not, and their testimony has no value in this arbitration either.

294. More to the point is that Canada made no promise or assurance to the Claimant with respect to its patents. As described at Part B above, the grant of a patent by the Patent Office is only presumptively valid and always subject to final determination by the Federal Court based on the evidence presented to the court. It is for this reason Claimant's argument regarding a patent being a "bundle of legally enforceable rights" which it relied on to make further investment decisions is deficient.[516] The grant of a patent monopoly is not unconditional – it requires the patentee to uphold the patent bargain by proving, if challenged before the Federal Court at any time within those twenty years of exclusivity, that it actually had sufficient evidence at the time the patent was filed to prove it was not engaged in mere speculation.

295. Claimant also says it could not have expected that Canada would have developed a utility doctrine in violation of NAFTA Chapter Seventeen. [517] As set out in detail below, there is no violation of NAFTA Chapter Seventeen. But even if there was, this would still not establish a violation of the minimum standard of treatment in customary international law – the FTC Note of Interpretation makes it clear that a breach of another provision of NAFTA does not equate to a breach of Article 1105(1).[518] Furthermore, it cannot be a reasonable expectation of any investor that the courts will not evolve in its interpretation of the law. The evolution of the court's interpretation of patent law is neither unusual nor undesirable.[519] As the *Mondev* tribunal explained, judicial "law-

[516] Claimant's Memorial, paras. 286-287.

[517] Claimant's Memorial, para. 279.

[518] *FTC Notes of Interpretation*, s. 2(3) (July 31, 2001) (**RL-009**).

[519] Indeed, as Professor Holbrook's expert opinion on United States patent law demonstrates, Claimant and other investors in the United States are well-accustomed to evolutionary, sometimes radical, changes in the patent law regime as U.S. Federal Courts are faced with new circumstances. Holbrook Report, paras. 62-75.

making" in this fashion is reasonable and, in the absence of a denial of justice, cannot be challenged under Article 1105. [520]

296. Claimant also says it expected that its PCT application for atomoxetine would be sufficient to meet Canada's requirements relating to the disclosure of utility. Claimant also argues that it did not expect Canada, a PCT contracting state, to impose "additional and retroactive disclosure" requirements beyond those provided for in the PCT. [521]

297. These are frivolous assertions. First, Claimant cannot ground its "legitimate expectations" in the PCT when it did not even file both patents at issue in this proceeding under that treaty – its olanzapine patent was not a PCT application but was filed directly with the Patent Office. Second, Claimant cannot have had a "legitimate expectation" that Canada would not "impose additional disclosure obligations beyond those contained" in the PCT,[522] when the PCT is strictly a procedural treaty which expressly provides that it does not prescribe substantive patent law obligations.[523] Third, Claimant could not have had expected that mere compliance with the PCT's bare "form and contents" requirements would mean its patent automatically complied with Canada's substantive disclosure requirements.[524] No patentee could have such an expectation in any jurisdiction, let alone Canada – the PCT only sets out general requirements regarding the categories of information and the format that must be

[520] *Mondev Award*, paras. 133, 136-137 (**RL-004**).

[521] Claimant's Memorial, para. 28.

[522] Claimant's Memorial, para. 280.

[523] *PCT,* 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**). Indeed, the courts in Canada have already considered this issue with regards to Canada's utility-related disclosure requirement and have disagreed with Claimant's argument. In *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97, para. 19 (**R-354**), the court found that "The appellant further argues that requiring the complete disclosure of the factual basis underlying the sound prediction is inconsistent with the Patent Cooperation Treaty, 1970, 28 U.F.T. 7647 (Treaty). 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."

[524] Claimant's Memorial, para. 280.

included in a PCT patent application.[525] It is well-known by users of the PCT system that applications filed under the PCT must, in addition to fulfilling "form and contents" requirements, always fulfil the substantive patentability criteria relevant to jurisdictions in which they might seek patent protection.[526] Claimant's self-serving view of the PCT is not a proper interpretation of that instrument.

298. Claimant knew (or should have known if it had read the case-law and treatises referred to in Mr. Dimock's expert report) what Canadian patent law required in order for its patents to be valid. There were extensive warnings in the jurisprudence and literature that promises in the patent had to be met, that utility had to be established at the filing date, and the basis for mere predictions of utility had to be disclosed in the patent.[527] Claimant knew (or should have known) that the legal requirements could make it difficult to defend the validity of its patent if it were challenged in the future. It also knew (or should have known) that the legal meaning of patentability standards is constantly being clarified and elaborated through court decisions. In any legal system (especially in a common law jurisdiction), this can produce an evolution in the law as broad legal terms are applied in new and different factual contexts over time. Indeed, Claimant's own annual public report filings contain warning statements that "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.*"[528]

[525] Reed Report, para. 33 and Gillen Report, para. 56, both citing *PCT* Article 3 (**R-037**).

[526] Reed Report, paras 44-45. See *WIPO PCT Applicant's Guide*, at paras 5.094 to 5.095 ('The Description'). http://www.wipo.int/pct/en/appguide/text.jsp?page=ip05.html#_5.094 (**R-042**).With regards to the content of the description in a PCT application, the *Applicant's Guide* explicitly warns applicants that "The details required for the disclosure of the invention so that it can be carried out by a person skilled in the art depend on the practice of national Offices. It is therefore recommended that due account be taken of national practice (for instance in Japan and the United States of America) where the description is drafted. The need to amend the description during the national phase (*see* para. 5.111 below) may thus be avoided." (emphasis added)

[527] Dimock Report, paras. 147-152.

[528] *See* for example, Eli Lilly Annual Report, Fiscal Year 1999 (**R-303**)("Patents, Trademarks and Other Intellectual Property Rights. Intellectual property protection is, in the aggregate, material to our ability to successfully commercialize our life sciences innovations. We own, have applied for, or are licensed under, a substantial number of patents, both in the United States and in other countries, relating to products,

299. In light of the circumstances of this dispute, the only legitimate expectation Claimant could have had is that it would receive a fair hearing from the Federal Court in the case of a challenge to its patents. That is exactly what it got.

V. EXPROPRIATION

A. Summary of Canada's Position on NAFTA Article 1110

300. Claimant alleges that the court decisions determining that its patents were invalid amounted to an expropriation because "no special rules attach to claims of expropriation based on judicial measures."[529] This assertion drastically oversimplifies the expropriation analysis. Claimant's position overlooks the unique and essential role played by domestic courts in declaring entitlements under domestic property law, which are in fact the starting point of the analysis under the international law of expropriation.

301. The first step in the expropriation analysis is to determine whether there was a property interest capable of expropriation. NAFTA Article 1110(1) protects investments against expropriation, and the definition of "investment" under NAFTA encompasses a range of property interests, including "real estate or other property, tangible or intangible". While NAFTA protects these categories of property interests, the legal source of these entitlements is domestic law. Nothing in NAFTA determines whether an asserted property right actually exists at domestic law, or the nature and scope of such rights.

302. Therefore, at the outset of the expropriation analysis, it is necessary to look to domestic law to determine whether there was in fact a property interest capable of expropriation that is protected by NAFTA Article 1110(1). The body of domestic law that must be considered includes domestic court rulings on the validity of asserted

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product uses, formulations, and manufacturing processes. 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. Moreover, patents relating to particular products, uses, formulations, or processes do not preclude other manufacturers from employing alternative processes or from successfully marketing alternative products that might successfully compete with our patented products.") (emphasis added).

[529] Claimant's Memorial, para. 179.

property rights under domestic law. If there is no valid property right at domestic law, then there is nothing that can be "taken" within the meaning of the international law of expropriation. The only context in which a domestic court ruling on the validity of an asserted property right could amount to an expropriation is if there has been a denial of justice. In these circumstances, the court has failed to meet international minimum standards for adjudication of domestic rights.

303. Claimant overlooks all of this because it does not like where the analysis leads. Claimant's patents were not property interests capable of expropriation under NAFTA Article 1110(1) because they were not valid domestic property interests at all. This was finally resolved by the Canadian court decisions declaring Claimant's patents invalid *ab initio*. Claimant does not, and cannot, allege that the courts in those decisions committed a denial of justice. Claimant received robust due process, extensive appellate review, and thoroughly reasoned judgments. The prospect of such invalidation was expressly stated in the *Patent Act* as a condition on the initial patent grant. Claimant's NAFTA Article 1110(1) Claim cannot get past the first step in the analysis.

304. Claimant puts forward a rule under which domestic court determinations of rights at domestic law can be transformed into expropriations if they breach some other, undefined rule of international law. This proposal has no basis in the international law of expropriation. The requirements of NAFTA Article 1110(1), including the need to identify a domestic property interest capable of expropriation at the outset, cannot be circumvented simply by pointing to some other, independent rule of international law. Claimant's proposal would confer a plenary jurisdiction on international investment tribunals, not only to act as courts of appeal over the property law decisions of domestic courts, but also to rule on alleged breaches of innumerable international treaties.

305. An additional independent barrier to Claimant's argument is found in Article 1110(7), which provides that the revocation of an intellectual property right cannot engage NAFTA Article 1110 if it is consistent with NAFTA Chapter Seventeen. Canada is plainly in compliance with Chapter Seventeen. Claimant's allegation that "capable of

industrial application" has a unique and fixed meaning stands in stark contrast with the absence of harmonization of these terms in international law. This is evident from the text of NAFTA Article 1709(1) itself and confirmed by the divergent practice of the Parties post NAFTA. In fact, Claimant's seeks to load into these undefined terms an array of specific content that would serve its own interests. Claimant's tangential arguments on Article 1709(7), 1709(8) and 1709(1) are equally without merit.

306. Even if this Tribunal were to conclude that Claimant's invalid patents were capable of expropriation and that the court decisions at issue were inconsistent with Chapter Seventeen, such that NAFTA Article 1110 applies, there was still no expropriation, whether direct or indirect. Claimant cannot parse out two invalid patents from its overall enterprise in Canada, and has shown no substantial deprivation. Further, the character of the measures at issue – *bona fide* judicial determinations of rights at domestic law – strongly weights against a finding of indirect expropriation.

B. NAFTA Article 1110(1) Incorporates Customary International Law Rules on Expropriation

307. NAFTA Article 1110(1) provides:

> 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.

308. NAFTA does not define "expropriation," but NAFTA Tribunals have interpreted Article 1110(1) as incorporating customary international law rules.[530] For there to be an

[530] *Glamis Award*, para. 354 (**RL-006**) (holding that "inclusion in Article 1110 of the term "expropriation" incorporates by reference the customary international law regarding that subject"); *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 (**RL-074**) ("The key terms in Article 1110 –"nationalization,"

expropriation, there must be a "taking" of fundamental ownership rights that causes a substantial deprivation of the economic value of an investment.[531]

309. NAFTA tribunals have generally applied a three-step analysis to determine whether a Party's measures have breached the standards of Article 1110(1). First, the Tribunal must identify the investment that is capable of being expropriated. Second, the Tribunal must determine whether that investment has been expropriated. Third, if an expropriation is found, then the tribunal will determine whether it was lawful under the sub-paragraphs of Article 1110(1).[532]

C. Claimant's Expropriation Claim Fails Because an Invalid Patent Is Not a Property Interest Capable of Expropriation

1) Domestic law determines the property interests protected by NAFTA Article 1110(1)

310. The first step in the expropriation analysis is to determine the existence, nature, and scope of the property rights alleged to have been taken. Claimant entirely ignores this critical threshold question.[533]

"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."). *See* also the positions of the NAFTA Parties on this issue: *Mondev Second Submission of Canada*, paras. 64-5 (**RL-021**) (defining "expropriation" in Article 1110 with reference to international law); *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 (**RL-055**) (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."); *Methanex Corporation v. The United States of America*, UNCITRAL, Mexico Fourth Submission per Article 1128, 30 January 2004, para. 13 (**RL-042**) ("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.").

[531] *Pope & Talbot v. Government of Canada*, (UNCITRAL) Interim Award, 26 June 2000, ("*Pope and Talbot Interim Award*"), para. 102 (**RL-056**) ("…under international law, expropriation requires a 'substantial deprivation[']"); *Grand River Award*, para.148 (**RL-010**) ("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…"); *Glamis Award,* para. 357 (**RL-006**).

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

[533] Claimant's Memorial, paras. 170-173.

311. NAFTA Article 1110(1) protects investments against expropriation. "Investment" in turn is defined in NAFTA Article 1139 as including a broad list of property interests. Among these is "real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes".[534] Claimant alleges that its patents for the use of atomoxetine and olanzapine fall within this category.[535] While it is not in dispute that intellectual property rights may qualify as investments under NAFTA, nothing in NAFTA answers whether an investor actually holds a property interest, including an intellectual property right, protected by NAFTA Article 1110(1), or the nature and scope of that right. In other words, there must be validly "acquired" "property" in order for there to be an investment capable of expropriation.

312. Thus, under NAFTA as under general public international law, when faced with a claim of expropriation, an international tribunal must first undertake a necessary *renvoi* to domestic law to determine the existence, nature, and scope of the property interests that the claimant alleges were taken.[536] As McLachlan writes:

> The property rights that are the subject of protection under the international law of expropriation are created by the host State law. Thus, it is for the host State to define the nature and extent of property rights that a foreign investor can acquire.[537]

[534] NAFTA, Article 1139(g) (emphasis added).

[535] Claimant's Memorial, para. 163.

[536] Monique Sasson, *Substantive Law in Investment Treaty Arbitration The Unsettled Relationship Between International and Municipal Law*, Wolter Kluwers 2010, pp. 81-82 **(R-333)** (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"); Andrew Newcombe, *Law and Practise of Investment Treaties, Standards of Treatment*, February 2009, para. 7.19 **(R-334)** (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*)."

[537] Campbell Mclachlan, Laurence Shore & Matthew Weiniger, "International Investment Arbitration: Substantive Principles", (Oxford University Press 2007), para. 8.65 **(R-328)**; Sonarajah, The International Law on Foreign Investment, Third Edition, p. 383, FN 67 **(R-335)**. ("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.")

313. If there is no property right at domestic law, then there is nothing that can be taken.[538] Similarly, any conditions and limitations inherent to an asserted property right may bear on whether there has been a taking of that property. [539] For example, property in land could be subject to an easement, or an interest in an estate could be defeasible or contingent on certain events.

314. International arbitral tribunals have affirmed this principle. The tribunal in *Emmis v. Hungary* observed that to "determine whether an investor/claimant holds property or asserts capable of constituting an investment it is necessary in the first place to refer to host State law. Public international law does not create property rights."[540] Similarly, in *EnCana v. Ecuador*, the majority held that "for there to have been an expropriation of an investment or return … the rights affected must exist under the law which creates them, in this case, the law of Ecuador."[541]

315. The necessary *renvoi* to domestic law has been specifically recognized in the context of intellectual property rights. As Douglas writes, the existence of international intellectual property treaties "does not absolve a tribunal from the task of applying the

[538] *Azinian Award* (**RL-002**).

[539] *Bayindir Award*, para. 458 (**RL-054**) (stating that "the fact that Bayindir was expelled is obviously not enough. As rightly pointed out by the Respondent, if the expulsion was lawful under the Contract, then there would be no taking of or interference with Bayindir's rights".); *International Fisheries Company (U.S.A.) v. United Mexican States*, July 1931, p. 699 (**RL-059**) (stating that "there is no ground for an international claim if the annulment of the contract has been made in accordance with its express terms.").

[540] *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, paras. 161-162 (**RL-060**).

[541] *EnCana Corporation v. Republic of Ecuador*, (UNCITRAL) Award, 3 February 2006, ("*Encana Award*"), para. 184 (**RL-061**); *See* also *George W. Cook (USA) v. United Mexican States*, Award, 3 June 1927, p. 215 (**RL-062**), *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.").

municipal law of the host state to resolve any dispute about the existence of intellectual property rights as part of a covered investment."[542]

2) Absent a denial of justice, international tribunals must accept domestic court determinations that a property right does not exist under domestic law

316. The body of domestic law defining the existence, nature, and scope of property rights protected by NAFTA Article 1110 includes domestic court decisions.[543] Claimant's position entirely overlooks the role of domestic courts in defining individuals' entitlements under domestic law.

317. Tribunals have recognized the need to defer to domestic court determinations of legal entitlements under domestic law.[544] When a domestic court determines that the claimed domestic property right was invalid, the expropriation analysis simply cannot get off the ground, because there is no property interest that can be taken. As Newcombe explains, in the context of contractual rights:

[542] 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 **(R-337)** (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…").

[543] Zachary Douglas, "Nothing if Not Critical for Investment Treaty Arbitration: Occidental, Eureko and Methanex", (2006) 22 Arbitration International, Issue 1, p. 45 **(R-338)** (writing that "International law does not apply to the question of what entitlements the investor actually has deriving from a contract subject to municipal law and the municipal courts.").

[544] *Affaires Du Chemin De Fer Panevezys-Saldutiskis Railway* Cases, PCIJ series A/B. No. 76 (1939), p. 18 **(RL-066)** (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."); *Mr. Franck Charles Arif v. Republic of Moldova*, ICSID Case No. ARB/11/23, Award, 8 April 2013,("*Arif Award*"), para. 417 **(RL-063)** (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."); *Liman Award*, para. 430 **(RL-027)** (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.); *Encana Award*, paras. 200, FN 138 **(R-061)**.

> Where the investment in question is a contract governed by host state 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. The investor will either have to show that the judicial determination of the contract rights amounted to a denial of justice or that the law in question cancelling or nullifying the contract was itself expropriatory.[545]

318. As this passage suggests, there is an exception to the principle that a domestic court's determination of rights cannot amount to an expropriation. As Canada established above, customary international law requires deference to domestic court rulings on issues of domestic law. However, if the court decision is reached through a denial of justice, then the determination of domestic rights need not be deferred to in the expropriation analysis, as the process for determining rights at domestic law has fallen below the fundamental international minimum standard for the judicial process.

319. Claimant contends that there is no requirement for a denial of justice for a domestic court determination of domestic rights to amount to an expropriation.[546] This is incorrect. As explained by Professor (now Judge of the International Court of Justice) Greenwood, expert witness for the United States in the *Loewen* case:

> 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."[547]

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[545] Andrew Newcombe, *Law and Practice of Investment Treaties, Standards of Treatment*, February 2009, para. 7.19 **(R-334)**; *See* also Martins Paparinskis, *The International Minimum Standard and Fair and Equitable Treatment*, (Oxford University Press, 2013), p. 208 **(R-340)** (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 from denial of justice").

[546] Claimant's Memorial, para. 182.

[547] *Loewen Group and Another v. United States of America*, Opinion of Christopher Greenwood Q.C, 26 March 2001, pa. 10 (**RL-025**); *see* also *Mondev Award*, para. 75 (**RL-004**) (holding that "the only arguable basis of claim under NAFTA concerns the conduct of the United States courts in dismissing LPA's claims. Moreover it is clear that Article 1105(1) provides the only basis for a challenge to that conduct under NAFTA.").

320. The Tribunal in *Loewen* agreed with Professor Greenwood, holding that the judicial measure in question could not amount to an expropriation in the absence of a denial of justice:

> Claimant's reliance on Article 1110 adds nothing to the claim based on Article 1105. In the circumstances of this case, a claim alleging an appropriation in violation of Article 1110 can succeed only if *Loewen* establishes a denial of justice under Article 1105.[548]

321. The same principle was applied in *Azinian v. United States of America*.[549] In that case, the Mexican courts upheld a municipality's decision to annul a contract with the claimant, finding *inter alia* that the contract was invalid. The Tribunal held that there could be no breach of NAFTA Article 1110 unless the domestic court's determination that the contract was invalid under domestic law was reached through a denial of justice. The tribunal identified four types of denial of justice: refusal to entertain suit, subjecting a suit to undue delay, administering justice in a seriously inadequate way, or clearly and maliciously misapply the law such that there is a pretence of form to mask an internationally unlawful end.[550] Without showing such impropriety in the judicial process, then the Mexican court determination that the contract was invalid had to be deferred to, and there was simply no property interest that could be expropriated. The *Azinian* tribunal explained:

> 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.

[548] Loewen Award, para. 141 (**RL-025**).

[549] *Azinian Award* (**RL-002**).

[550] *Azinian Award*, para. 103 (**RL-002**).

> More is required; the Claimants must show either a denial of justice, or a pretence of form to achieve an internationally unlawful end.
>
> But the Claimants have raised no complaints against the Mexican courts; they do not allege a denial of justice. Without exception, they have directed their many complaints against the Ayuntamiento of Naucalpan. The Arbitral Tribunal finds that this circumstance is fatal to the claim, and makes it unnecessary to consider issues relating to performance of the Concession Contract. For if there is no complaint against a determination by a competent court that a contract governed by Mexican law was invalid under Mexican law, there is by definition no contract to be expropriated.[551]

322. In deciding that there could be no expropriation in the case before it, the *Azinian* tribunal understood that the Mexican court's determination of these rights *under Mexican law* could only be questioned from an international law perspective if there were serious irregularities in the judicial process, amounting to a denial of justice. The Tribunal canvassed the different forms of denial of justice in detail, and found none applicable on the facts before it.[552]

323. The same principle has more recently been applied by international investment tribunals under other bilateral investment treaties.

324. In *Arif v. Moldova*, the tribunal held that the declaration of Moldovan courts that the claimant's asserted contractual rights were invalid under Moldovan law could not amount to an expropriation.[553] The Tribunal emphasized that there was no justification

[551] *Azinian Award*, paras. 99-100 **(RL-002)**; *See* also Andrew Newcombe, *Law and Practise of Investment Treaties, Standards of Treatment*, February 2009, para. 7.19 **(R-334)** (explaining that as "the investor did not claim that the Mexican courts had committed a denial of justice or that the Mexican law governing public service concessions under which the concession was held invalid was itself expropriatory, there simply was no breach of Mexico's investment guarantees.").

[552] *Azinian Award*, paras. 102-103("emphasis added") **(RL-002)** (explaining that denial of justice "could be pleaded if the relevant courts refuse to entertain a suit, if they subject it to undue delay, or if they administer justice in a seriously inadequate way" or if there was a "clear and malicious misapplication of the law" akin to a ""pretence of form" to mask a violation of international law.").

[553] *Arif Award*, para. 420 **(RL-063)** (holding that "The Tribunal has already accepted the invalidity of these rights as declared by the Moldovan judicial system as a result of the legitimate application of Moldovan law and has found that this invalidity cannot be interpreted as an expropriation of the investor's rights, *i.e.*, the Tribunal has found that there is no possible expropriation of invalid rights.").

for revisiting the decision of the Moldovan courts, as the claimant had not established that the courts committed a denial of justice in the determination of rights at domestic law:

> As established above, these agreements have been declared invalid under Moldovan law by the whole of the Moldovan judicial system, including the Supreme Court. The Tribunal is not persuaded that there has been collusion between the courts and the investor's competitors in the proceedings before the Moldovan courts over these agreements or that the Moldovan courts have acted in denial of justice in any way (see Section VI.B.2). Moreover, there is no evidence in the record that persuades the Tribunal to conclude that the Moldovan judiciary has not applied Moldovan law legitimately and in good faith in the proceedings commenced by Claimant's competitors.
>
> Le Bridge has had a fair opportunity to defend its position under Moldovan law before the Moldovan courts. This Tribunal is not a court of appeal of last resort. There is no compelling reason that would justify a new legal analysis by this Tribunal regarding the invalidity of these agreements which has already been repeatedly, consistently and irrevocably decided by the whole of the Moldovan judicial system.[554]

325. In *Liman Caspian v. Kazakhstan*, the Tribunal held that court decisions determining that Claimant was not the rightful holder of shares under Kazakh law was not expropriatory. The Tribunal held that these domestic court determinations "have to be accepted from the perspective of international law" as the Tribunal had found that the Kazakh court decisions were not "arbitrary, grossly unfair, unjust, idiosyncratic, discriminatory or lacking due process, even if they might have been incorrect as a matter of Kazakh law".[555]

3) Claimant's patents were invalid, hence there is no expropriation

326. Applying the above in the present case, Claimant's expropriation claim is inherently defective, as the property interests alleged to have been taken were not valid property interests under domestic law. The only property interests that Claimant alleges

[554] *Arif Award*, paras. 415-416 (**RL-063**).

[555] *Liman Award*, para. 431 (**RL-027**).

was expropriated are its patents for particular uses of olanzapine and atomoxetine.[556] However, as discussed, the existence, nature, and scope of the property interest asserted by Claimant must be answered by domestic Canadian law.

327. Claimant's patents were invalid under the statute that governs their creation (the *Patent Act*) and were therefore not property interests capable of being taken. The Canadian judicial system, including appellate courts, determined that in fact Claimant never had a valid patent right in domestic Canadian law. Both patents were declared invalid *ab initio*.[557]

328. Just like in cases such as *Azinian*, *Arif*, and *Liman Caspian*, the declaration of Canadian courts asserted domestic law rights are invalid cannot amount to an expropriation in the absence of a denial of justice. Claimant does not, and could not, allege that a denial of justice occurred in the determination that its patent rights were invalid. As described above, Claimant received full due process, extensive appellate review, and the courts issued thoroughly reasoned judgments determining that Claimant's asserted patent rights were not valid under Canadian law.[558]

329. The invalidation of Claimant's patents occurred in a manner consistent with the express conditions on the initial patent grant. Canada's *Patent Act* leaves no doubt that rights conferred by a patent are subject to the limitations set out in the *Patent Act*, and particularly the condition that granted patents are subject to subsequent review and invalidation *ab initio* by the Federal Court.[559] Notably, s. 42 of the *Patent Act* states that the right of exclusivity conferred by a patent it "subject to this Act" and "subject to

[556] Claimant's Memorial, para. 239.

[557] *See Apotex Inc. v. Pfizer Ireland Pharmaceuticals*, 2012 FC 1339, para. 27 (**R-153**) (holding that a "declaration of invalidity is a declaration that a patent is, and has been void all along (*i.e. ab initio*)"); Statement of Claim, para. 75; Dimock Report, para. 28.

[558] Dimock Report, para. 224.

[559] Dimock Report, para. 28.

adjudication" before any court of competent jurisdiction.[560] Section 60(1) makes clear that the Federal Court is a competent court to declare a patent invalid, and specifies that any interested person may initiate proceedings seeking a declaration of invalidity.[561] Section 62 provides that if such a declaration is made, the patent will "be held to have been void and of no effect".[562]

330. In these circumstances, there is no basis on which an international tribunal can overrule the determinations of Canadian courts about Claimant's rights under Canadian patent law.

D. Claimant's Proposed Judicial Expropriation Rule Would Turn Investment Tribunals into Supranational Courts of Appeal

1) Claimant is attempting an end-run around the requirements of the international law of expropriation

331. Claimant suggests that a domestic court ruling that rights are invalid at domestic law can be transformed into a breach of NAFTA Article 1110(1) if it breaches some other, undefined rule of international law.[563] Here, Claimant points to alleged violations of the NAFTA Chapter Seventeen and Article 1105, but on the basis of the rule it puts forward, it could equally have alleged violations of any international treaty. The potential triggers for Claimant's "judicial expropriation" rule are as numerous as the sources of rules of international law. Claimant's proposal would confer on international

[560] *Patent Act*, s. 42 **(R-001)** (providing that "Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.") (our emphasis).

[561] *Patent Act*, s. 60(1) **(R-001)** (providing that "A patent or any claim in a patent may be declared invalid or void by the Federal Court at the instance of the Attorney General of Canada or at the instance of any interested person.").

[562] *Patent Act*, s. 62 **(R-001)** (stating that "A certificate of a judgment voiding in whole or in part any patent shall, at the request of any person filing it to make it of record in the Patent Office, be entered on the margin of the enrolment of the patent in the Patent Office, and the patent or such part thereof as is so voided shall thereupon be and be held to have been void and of no effect, unless the judgment is reversed on appeal as provided in section 63.").

[563] Claimant's Memorial, paras. 180, 242.

investment tribunals an at-large jurisdiction to serve as courts of appeal in domestic property law matters, and to rule on alleged inconsistencies with any international treaty that could plausibly be linked with the substance of a domestic court ruling (regardless of whether that external treaty contemplates its own, State-to-State dispute settlement mechanism).

332. Claimant's proposal does not reflect the international law of expropriation but rather confuses distinct international legal obligations. The law of expropriation has its own requirements that must be made out, the first of which is what legal entitlements an investor has under domestic law that could be the subject of expropriation. Domestic court decisions are part of the mechanism for determining whether such rights exist. A claimant cannot circumvent an adverse determination of its rights at domestic law simply by pointing to an alleged inconsistency with some other, independent international obligation owed between States. Such interstate obligations do not change the existence, nature, or scope of an investor's legal entitlements under domestic law. As Douglas explains:

> Foreign nationals do not have a general right to reparation for damage caused when States to [sic] do not comply with their international obligations to other States. The obligations to accord various minimum standards of treatment to foreign nationals in general international law and investment treaties do not operationalize such a general right.[564]

333. Canada denies that the domestic court decisions at issue are inconsistent with any international obligation. However, the point here is that such obligations are not relevant to determining what Claimant's legal entitlements were under domestic law. The only rule of customary international law that relates to the acceptability of domestic court determinations of domestic rights is the rule against denial of justice.

[564] Zachary Douglas, "International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed," International and Comparative Law Quarterly (ICLQ), 3 September 2014, pp. 34 **(R-323)** ("International delictual responsibility towards foreign nationals is not the same as international responsibility towards States for the violation of the treaty establishing the international norm.").

334. The indeterminate nature of Claimant's proposed rule is self-evident. There are innumerable international treaty obligations with subject matter that could conceivably overlap with domestic property law disputes. If a domestic court's adjudication of property rights can be transformed into an expropriation by alleged inconsistency with any of these other international law obligations, then NAFTA Chapter Eleven tribunals will be transformed both into tribunals with plenary jurisdiction over all international treaties and supranational courts of appeal in domestic property law issues.

2) Claimant mischaracterizes the doctrine and arbitral jurisprudence on expropriation by judicial measures

335. In support of its theory, Claimant invokes a speech by International Court of Justice President Eduardo Jiménez Aréchaga and the manner in which the NAFTA tribunal in *Azinian* relied on that speech.[565] Claimant suggests that Judge Aréchaga endorsed the proposition that "no special rules attach to claims of expropriation based on judicial measures"[566] and that "one way an expropriatory judicial measure may be distinguished from a non-compensable exercise of judicial authority is if the measure is "clearly incompatible with a rule of international law."[567] In fact, Judge Aréchaga made no such conclusion. Judge Aréchaga's speech was on the topic of State responsibility generally, and set out the now uncontroversial proposition that a State is responsible for the actions of the judiciary. The speech had nothing to do with the primary rule of international law against expropriation, or how judicial action may breach it. Similarly, the *Azinian* tribunal invoked Judge Aréchaga's speech for this bare proposition of State responsibility for the judiciary, and went on to find no expropriation because the claimant had not proved a denial of justice by the Mexican courts.[568]

336. Claimant further attempts to support its theory by alleging that the tribunal in *Saipem v. Bangladesh* found a judicial expropriation simply because the court decision

[565] Claimant's Memorial, paras. 178-179.

[566] Claimant's Memorial, para. 179.

[567] Claimant's Memorial, para. 179.

[568] *Azinian Award*, para. 98 (**RL-002**).

in question was inconsistent with the New York Convention. This is a distorted account of the tribunal's decision. First, the tribunal in *Saipem* found that the conduct of the Bangladeshi courts amounted to an abuse of right[569] and the Bangladesh court decisions frustrated "if not the wording at least the spirit" of the New York Convention."[570] Second, *Saipem* turned on unique facts readily distinguishable from the present case. In *Saipem*, the claimant challenged the decision of a Bangladesh court to refuse enforcement of an ICC Arbitral Award on the basis that the Award was a nullity, having been issued by an ICC Tribunal whose authority had been revoked by the Bangladesh courts. In other words, the asserted right at issue in *Saipem* was an international arbitral award, not a right purely derived from domestic law.

337. The *Saipem* tribunal found a judicial expropriation based on its findings of extreme impropriety in the conduct of the Bangladeshi courts, amounting to an abuse of right.[571] Specifically, the tribunal made the following findings about the treatment received by the claimant before the Bangladesh courts:

- The Bangladesh courts "abused their supervisory jurisdiction over the arbitration process";[572]

[569] *Saipem* Award, para. 159 **(RL-064)**.

[570] *Saipem S.p.A v. The People's Republic of Bangladesh*, ICSID Case No. ARB/05/7, Award, 30 June 2009, ("*Saipem Award*"), para. 167 **(RL-064)**. The *Saipem* Tribunal's reference to the New York Convention has been controversial in the investment arbitration literature. *See* for example, Martins Paparinskis, *The International Minimum Standard and Fair and Equitable Treatment*, Oxford Monographs in International Law, 31 January 2013, p. 208 **(R-340)** (writing that the "ease with which the Tribunal examined compliance with the New York Convention might also suggest a conflation of primary and secondary rules and assumption of (unlimited) jurisdiction over all primary obligations addressed by the judicial organ in the administration of justice."); *See* also Zachary Douglas, "International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed," International and Comparative Law Quarterly (ICLQ), p. 32 **(R-323)** (explaining that a national court decision inconsistent with the New York Convention could give rise to State responsibility vis-à-vis other States, but not vis-à-vis foreign nationals).

[571] *Saipem Award*, para. 160 **(RL-064)**.

[572] *Saipem Award*, para. 159 **(RL-064)**.

- The Bangladesh court decision "can only be viewed as a grossly unfair ruling" based on an "ill-founded finding of misconduct" that "lacks any justification";[573]

- The Bangladesh courts used their jurisdiction to revoke arbitrators for misconduct for reasons wholly unrelated with such misconduct.[574]

- The Bangladesh courts "simply took as granted what Petrogangla [the Bangladesh state owned enterprise] falsely presented";[575]

338. Given the true focus of *Saipem*, it is unsurprising that subsequent commentary and jurisprudence has emphasized that the case was really about egregious judicial conduct,[576] effectively tantamount to a denial of justice.[577] There are two reasons that the *Saipem* tribunal may have been reluctant to make a finding of denial of justice. First, the claimant declined to plead denial of justice on the basis that the governing bilateral investment treaty did not confer jurisdiction on the Tribunal for such a claim.[578] Second, it was undisputed that the claimant had not exercised its rights of appeal in the key domestic proceedings at issue.[579] Normally, this would be a bar to a denial of justice

[573] *Saipem Award*, paras. 155, and 183 (**RL-064**).

[574] *Saipem Award*, paras. 155, 159 (**RL-064**).

[575] *Saipem Award*, paras. 155, 157 (**RL-064**).

[576] *GEA Award*, para. 234 (**RL-026**) (emphasis added) (explaining that the *Saipem* Tribunal "concluded that, based on the circumstances of that case, the non-enforcement of the ICC Award amounted to an expropriation due to the particularly egregious nature of the acts of the Bangladeshi courts."). *See* also *Swisslion Doo Skopje v The Former Yugoslav Republic of Macedonia*, ICSID Case No. ARB/09/16, Award, 6 July 2012 ("*Swisslion Doo Award*"), para. 313, FN 377 **(RL-065)** (emphasizing that the holding in *Saipem* "the tribunal found that that the courts decided the case on facts and points of law that had not been in dispute between the parties, the courts' intervention was "abusive", "grossly unfair", and that they "exercised their supervisory jurisdiction for an end which was different from that for which it was instituted and this violated the internationally accepted principle of prohibition of abuse of rights.").

[577] *See* Mavluda Sattorova, *Denial of Justice Disguised? Investment Arbitration and the Protection of Foreign Investors form Judicial Misconduct*, ICLQ 2012, p. 12 **(R-339)** (arguing that *Saipem* was "clearly about a denial of justice.").

[578] *Saipem Award*, para. 121 **(RL-064)** The claimant in *Saipem* submitted that "the BIT does not confer to your Tribunal jurisdiction over a claim based on denial of justice, and restricts your jurisdiction to a claim for expropriation. This is why we did not bring a claim on the ground of denial of justice before you."

[579] *Saipem Award*, para. 174 **(RL-064)**.

claim, which requires "judicial finality," meaning that the entire judicial system has been given the opportunity to pronounce on a dispute.[580]

339. To the extent that *Saipem* can be read as supporting a principle that judicial determination of domestic rights can amount to an expropriation in the absence of a denial of justice, this does not reflect the content of the international law of expropriation. As Paparinskis writes, such a reading of *Saipem*:

> …goes against the grain of established approaches regarding mistreatment of aliens and investors by courts: 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 from denial of justice.[581]

340. Furthermore, no international investment tribunal has followed the alleged rule that Claimant reads into *Saipem*. Where judicial expropriation has been alleged, tribunals have not had regard to whether the judicial decision breached some other rule of international law. In *Arif v. Moldova*, the tribunal found that court decisions invalidating contracts did not constitute an expropriation, despite finding that court conduct breached a Fair and Equitable Treatment obligation under the governing bilateral investment treaty.[582] The Fair and Equitable Treatment breach was not even mentioned as relevant to the court's expropriation analysis. Similarly, in *GEA v. Ukraine*, which concerned the refusal of a Ukrainian court to enforce an ICC Award, the

[580] *Swisslion Doo Award*, para. 313, FN 377 **(RL-065)** (explaining that in finding that judicial expropriation did not necessarily presuppose denial of justice, the *Saipem* Tribunal was "evidently concerned about imposing a requirement to exhaust all local remedies before judicial action could be challenged."); Mavluda Sattorova, *Denial of Justice Disguised? Investment Arbitration and the Protection of Foreign Investors form Judicial Misconduct*, ICLQ 2012, p. 7 **(R-339)** (arguing that "one is left to speculate as to whether labeling a denial of justice as 'a judicial expropriation' served the sole purpose of justifying the inapplicability of the local remedies rule in the case before the Tribunal.").

[581] Martins Paparinskis, *The International Minimum Standard and Fair and Equitable Treatment*, (Oxford University Press, 2013), p. 208 **(R-340)**. Paparinskis further argues that *Saipem* "provides an insufficiently rigorous distinction between denial of justice and other obligations under international law" and that it is "unclear how *Saipem* can be reconciled with the law of denial of justice and how 'judicial expropriation' can be distinguished from denial of justice".

[582] *Arif Award*, para. 547 **(RL-063)**.

Tribunal's expropriation analysis made no reference to whether the court decision was in accordance with the New York Convention.[583]

341. The other cases relied upon by Claimant to support its theory that a judicial determination that domestic property right does not exist can amount to an expropriation in the absence of a denial of justice do not actually support this proposition. *Biwater Gauff v. Tanzania* did not relate to the conduct of the judiciary. Rather, the Tribunal in that case stated that denial of justice need not be established before a *breach of contract by a State party*, in that case the executive branch, can amount to an expropriation.[584] Similarly, in *ATA v. Jordan* it was new legislation that extinguished a previously acknowledged right to arbitration under Jordanian law that was at issue.[585] The Jordanian courts were simply the organ of state that gave effect to the expropriatory legislation.

342. Other cases cited by Claimant are situations where the judiciary interfered with a property right acknowledged to exist, rather cases where the judiciary was adjudicating on the very existence of the rights in question at domestic law, as is the case here. In *Oil Field of Texas v. Iran*, the arbitral tribunal found that an Iranian judicial order preventing the return of property to the claimant amounted to a judicial expropriation.[586] There was no issue in that case as to whether the claimant owned the property concerned.[587]

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[583] *GEA Group Award*, para. 230 (**RL-026**); *See* also *Frontier Petroleum Services Ltd. v. The Czech Republic*, (UNCITRAL), Final Award, 12 November 2010 (**RL-067**) (not raising a claim of expropriation where the Czech courts refused to enforce an arbitral award).

[584] *Biwater Gauff Award*, para. 458 (**RL-043**).

[585] *ATA Construction, Industrial and Trading Company v. The Hashemite Kingdom of Jordan*, ICSID Case No. ARB/08/02, Award, para. 126 (**RL-068**).

[586] *Oil Field of Texas, Inc. v. The Government of the Islamic Republic of Iran, National Iranian Oil Company*, 12 Iran USCTR 308, Award No. 258-43-1, 8 October 1986, paras. 41-43 (**RL-069**).

[587] *See* also *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. 155, 159, and 707 (**RL-070**) (holding that compensation paid for the compulsory acquisition of shares that the claimant was acknowledged to own under Kazakh law was "manifestly and grossly inadequate" when roughly $3,000 compensation was ordered for a 60% stake in a company that was sold less than a year later for $350 million). Subsequent tribunals have observed that the *Rumeli* tribunal's finding was based on "collusion

343. Moreover, as Greenwood observes, *Oil Field of Texas* was actually a denial of justice case, as the claimant could not access the Iranian courts to challenge the decision of the Iranian court.[588] Similarly, Mouri writes that in reaching its conclusion, the tribunal in *Oil Field of Texas* "seems to have been substantially influenced by the assumption that there was a denial of justice through lack of due process of law".[589]

E. NAFTA Article 1110(7) Further Bars a Finding of Expropriation in This Case

1) NAFTA Article 1110 does not apply because the measures are consistent with Chapter Seventeen

344. NAFTA Article 1110(7) confirms that Article 1110 does not even apply in this case. As Claimant concedes, the invalidation of an intellectual property right cannot engage NAFTA Article 1110 if it is consistent with NAFTA Chapter Seventeen.[590] NAFTA Article 1110(7) states:

> 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).

between the State and the claimants' competitor, which collusion was then effected through court proceedings." *See Swisslion Doo Award*, para. 313, FN 377 **(RL-065)**.

[588] 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. 65 **(R-322** (writing that "It is clear, therefore, that the Tribunal considered that, if there had been a means by which the Claimant could have challenged the decision of the Islamic court within the Iranian judicial system, the decision of the Islamic court would not have amounted to a violation of international law."); *See* also *The Loewen Group Inc. and Raymond Loewen v. United States of America*, ICSID ARB(AF)/98/3, Counter-Memorial of the United States of America, 30 March 2001, p.182, FN99 **(RL-078)** (noting that the finding of expropriation in *Oil Field of Texas* was in the context of the Iranian court ordering "without a hearing, respondent to cease payments for and retain equipment belonging to claimant.").

[589] Allahyar Mouri, *The International Law of Expropriation as Reflected in the Work of the Iran-U.S. Claims Tribunal* (Norwell, NA: Nijhoff Publishers, 1994), p. 251 **(R-342)**.

[590] Claimant's Memorial, para. 184.

345. The purpose of this provision is not, as Claimant contends, to illustrate the line between compensable and non-compensable expropriations under international law.[591] Rather, Article 1110(7) clarifies that an expropriation claim cannot even be brought in the context of intellectual property rights barring inconsistency with Chapter Seventeen. The NAFTA Parties were concerned about the potential for abusive expropriation claims in the context of intellectual property, and therefore provided in Article 1110(7) an additional safe guard against such claims and their potential impact on their domestic intellectual property regimes. [592] As the text of Article 1110(7) makes clear, this additional hurdle applies to measures taken by any branch of government.[593]

346. Claimant argues that the invalidation of its patents infringe NAFTA Chapter Seventeen in four ways, namely: (i) the "utility" requirement as applied by the Canadian courts is inconsistent with its meaning under NAFTA Article 1709(1); (ii) Canada's promise doctrine discriminates against pharmaceutical inventions contrary to NAFTA Article 1709(7); (iii) Canada revoked Claimant's patent based on a legal ground that did not exist when they were granted, thereby infringing NAFTA 1709(8); and (iv) that Canada failed to provide adequate and affective protection and enforcement of intellectual rights as mandated by NAFTA Article 1701(1).[594]

347. None of these arguments withstand scrutiny. NAFTA Article 1110 does not apply in this case because the invalidation of Claimant's patents was wholly consistent with NAFTA Chapter Seventeen.

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[591] Claimant's Memorial, para. 183.

[592] M. Kinnear, A. Bjorklund and J. Hannaford, *Investment Disputes under NAFTA: An Annotated Guide to NAFTA Chapter 11* (Kluwer: 2006), p. 1110-57 **(R-343)** ("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.").

[593] NAFTA Article 1110(7) makes reference to the "issuance of compulsory licenses" which would typically be an executive branch function. Similarly, the "revocation, limitation or creation" of intellectual property rights could be achieved through executive, legislative, or judicial action.

[594] Claimant's Memorial, para. 186.

2) The Measures are Consistent with NAFTA Article 1709(1)

348. Article 1709(1) states:

> Subject to paragraphs 2 and 3, each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For the purposes of this Article, a Party may deem the terms "inventive step" and "capable of industrial application" to be synonymous with the terms "non-obvious" and "useful", respectively.

349. Section 2 of the *Patent Act* states:

> "invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

350. Canada is plainly in compliance with Article 1709(1) because, as is required by that provision, section 2 of the *Patent Act* states explicitly that patents are available for inventions in Canada provided they are "useful". If Canada were to remove the condition of usefulness from the *Patent Act*, then there could be a question of non-compliance with NAFTA Article 1709(1). But that is not the case: Article 1709(1) and section 2 of the *Patent Act* are perfectly aligned with respect to the requirement that a patent be made available for an invention that is "useful". The analysis need not go any further.

351. Nevertheless, Claimant argues that "capable of industrial application" and "utility" have a common "internationally-accepted meaning" that is "well understood in the patent context" as requiring that an invention has "the capacity to be put to a specific use in industry."[595] Because the "promise utility doctrine" as applied to the measures at

[595] Claimant's Memorial, paras. 5, 17, and 192.

issue allegedly placed "additional hurdles" than this "low threshold", Claimant argues that the measures were inconsistent with NAFTA Article 1709(1).[596]

352. Claimant's argument is without any merit. 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. This would amount to the imposition of a special meaning on the term, which Claimant has entirely failed to prove.

a) Claimant has failed to establish any special meaning for the terms "utility "and "capable of industrial application"

353. NAFTA Chapter Seventeen contains no definition of any of the terms "invention", "new" "result from an inventive step", "capable of industrial application", "non-obvious" or "useful". Despite this, Claimant argues that "utility" and "capable of industrial application" have a "shared" ordinary meaning that is "straightforward", namely "the capacity to be put to a specific use in industry."[597] Claimant alleges that this "definition" is the outcome of an analysis of the ordinary meaning, context and the subsequent practice of the parties under the Vienna Convention on the Law of Treaties ("VCLT").

354. In reality, Claimant is advocating a highly specific and self-serving definition of the terms "capable of industrial application" and "utility", contrary to the ordinary measures of the terms – that is, a "special meaning" under Article 31(4) of the VCLT.

355. Claimant's explicit definition of "capacity to be put to a specific use in industry" – to which it (conveniently) ascribes a very low threshold – is already a highly specific technical meaning. Claimant would bear the burden of proving even this definition, and has failed to do so. But in any event, Claimant goes far beyond this, loading the term

[596] Claimant's Memorial, para. 207 and ff.

[597] Claimant's Memorial, paras. 191 and 192.

"utility" with an array of specific content. According to Claimant, as a result of the use of the term "utility" in NAFTA:

> 1) assertions of utility set out in the patent shall have no weight, even where such assertions go to the core of the invention;
>
> 2) normal principles of patent construction do not apply with regard to such assertions of utility;
>
> 3) evidence produced years after filing must be taken into account when considering whether an applicant had a valid basis to claim a particular utility at the time that it filed its patent;
>
> 4) such evidence must be taken at face value and not subject to court scrutiny on the basis of expert testimony; and
>
> 5) disclosure of the basis of a predicted utility cannot be required in patent specifications.[598]

356. All of these specific rules are, according to Claimant, imposed upon Canada through the simple and undefined reference to "utility" or in the alternative "industrial applicability" in Chapter Seventeen of NAFTA. Yet, Claimant has failed to "establish" that the Parties "intended" this special meaning, as required under VCLT Article 31(4): "[a] special meaning shall be given to a term *if it is established that the parties so intended*."

357. Claimant has entirely failed to establish such broad and radical special meaning on the part of the Parties to NAFTA. There is no evidence that the NAFTA Parties wanted to give to the terms "utility" or "capable of industrial application" Claimant's fixed and unique interpretation, nor *a fortiori* any intention that would deprive them of policy flexibility required to implement the patent bargain domestically.

[598] These criticisms are addressed in section II.C.

b) Claimant's "ordinary meaning" interpretation fails

358. Consideration of the terms "utility" and "industrial applicability" under the "ordinary meaning" analysis set out in Article 31 VCLT confirms that these are not one-sided technical terms, let alone the highly specific definition Claimant posits: they instead bear a range of meanings, reflecting their diverse usages in various national patent law systems.

359. Claimant relies on dictionary definitions to support a bare definition of the terms "capable of industrial application" as meaning "capacity to be put to a specific use in the industry", which it then also ascribes to "utility" as well.[599] Setting aside the fact that Claimant in fact goes on to ascribe a range of rules to the term, this in any event is not a "good faith" interpretation in the context of Chapter Seventeen, and in light of its object and purpose, as required by the VCLT. As the Tribunal in *Aguas del Tunari* observed: "[t]he meaning of a word or phrase is not solely a matter of dictionaries and linguistics… the word "meaning" itself has at least sixteen dictionary meanings."[600]

360. "Ordinary meaning" in the treaty context does not refer to a generic, layperson's understanding, but to what a person reasonably informed on the subject matter of the treaty would make of the terms used.[601] The terms "capable of industrial application" and "utility" included in Article 1709 of NAFTA must therefore be interpreted in the particular context of the subject matter of Chapter Seventeen, *i.e.* intellectual property law. Claimant itself acknowledges that "capable of industrial application" and "utility" are terms of art in the intellectual property context.[602]

[599] Claimant's Memorial, para. 193FF.

[600] *Aguas del Tunari, S.A. v. Republic of Bolivia*, ICSID Case No. ARB/02/3, Decision on Respondent's Objections to Jurisdiction, 21 October 2005, para. 91 (**RL-071**).

[601] Olivier Dörr and Kirsten Schmalenbach, *Vienna Convention on the Law of Treaties*, *A commentary*, Springer, New York, 2012, p. 542 (**R-344**); Richard Gardiner, *Treaty Interpretation*, Oxford University Press, UK, 2011, pp. 166 and 174 (**R-345**).

[602] Claimant's Memorial, para. 191.

361. The term "utility" can therefore reasonably be informed by the various national definitions recognized by WIPO, including Canada's.

362. In the international context, relevant international organizations and States have recognized that neither "utility" not "industrial applicability" are harmonized terms, and instead bear a range of distinct technical meanings in various national patent law systems.[603] The United States acknowledged this fact 6 years after the entry into force of NAFTA by requesting "true harmonization on this item" and proposed that WIPO conduct a study on the various applications of utility and industrial applicability internationally.[604] WIPO confirmed, in 2003, not only that the two words did not mean the same thing, but that the same terms ("utility" and "capable of industrial application") were interpreted and applied in diverse ways around the world.[605] As Professor Gervais confirms, this was true in the 1990s when TRIPS and NAFTA were being negotiated.[606] It is still true today.

363. In this context, there are no grounds for selecting any one country's "technical" definition of utility or elements thereof over that of any other country. Claimant certainly has no basis for imposing the domestic U.S. definition of "utility" on Canada through reference to this bare, undefined term in NAFTA. Indeed, the basic unreasonableness of Claimant's argument was epitomized by the comment of Claimant's United States law expert Professor Merges, who in his Report stated: "The entire approach of the Canadian court is inconsistent with basic principles of U.S. utility law".[607] In so stating, Professor Merges was ignoring the warning of the U.S. Supreme Court, which as Professor Gervais notes, expressly acknowledges the strict territoriality

[603] Gervais Report, para. 54.

[604] Gervais Report, para. 32.

[605] 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, para. 53 (**R-230**).

[606] Gervais Report, paras. 27 and 53.

[607] Merges Statement, para. 43

of patent term interpretation.[608] As the U.S. Supreme Court explained in *Microsoft Corp. v. AT&T Corp*. in 2007:

> The presumption that United States law governs domestically but does not rule the world applies with particular force in patent law. The traditional understanding that our patent law "operate[s] only domestically and d[oes] not extend to foreign activities," Fisch & Allen ['The Application of Domestic Patent Law to Exported Software: 35 U. S. C. §271(f)', 25 U. Pa. J. Int'l Econ. L. 557 (2004)] 559, is embedded in the Patent Act itself, which provides that a patent confers exclusive rights in an invention within the United States. 35 U. S. C. § 154(a)(1) (patentee's rights over invention apply to manufacture, use, or sale "throughout the United States" and to importation "into the United States"). […] Thus, the United States accurately conveyed in this case [in an amicus curiae brief filed by the US government]: "Foreign conduct is [generally] the domain of foreign law," and in the area here involved, in particular, foreign law "may embody different policy judgments about the relative rights of inventors, competitors, and the public in patented inventions".[609]

364. As Professor Gervais explains, it is "well understood" in international property law that bare reference to the technical patent law terms of "utility" or "industrial applicability" (in themselves only stated as deemed alternatives "for the purposes of" Article 1709(1)), was not meant to refer to any one specific national definition, or *a fortiori* to highly specific definition Claimant seeks to impose.[610]

c) The context, object and purpose of NAFTA Chapter Seventeen reinforces the analysis

365. Consideration of the terms "utility" and "industrial applicability" in the context of the treaty, notably Chapter Seventeen, reinforces the Parties' intention to leave these terms to be applied in a flexible and principled manner, in accordance with national law.

366. The absence of substantive harmonization between the Parties is embedded in the basic terms of NAFTA Article 1709(1) itself: NAFTA Article 1709(1) (like TRIPS)

[608] Gervais Report, para. 61.

[609] *Microsoft Corp. V. At&T Corp.*, 550 U.S. 437, pp. 454-455(2007) **(R-355)**.

[610] Gervais Report, para. 58.

expressly provides Parties with the choice of applying "industrial applicability" or "utility", at the Parties' election. Professor Gervais notes:

> If there had been even a tendency to consider industrial applicability as the norm, industrial applicability alone would be mentioned in Article 27.1 TRIPS (or NAFTA Article 1709(1)) and there would be no reference to the fact that States may "deem" industrial applicability and utility as equivalent for the purposes of the treaty. The NAFTA negotiators and WTO members insisted on keeping both, as they did for inventive step and non-obviousness, pointing to their desire to maintain flexibility.[611]

367. The absence of definitions of these terms again provides important context. Again, as Professor Gervais confirms:

> 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.[612]

368. Chapter Seventeen otherwise begins at Article 1701 by listing and affirming a series of existing international treaties to which the Parties shall, at a minimum, give effect. None of these treaties regulate substantive patent law. Indeed, as the list excludes the PCT, the Parties do not even undertake to harmonize *formal* requirements of patent filing, an issue addressed under the latter treaty. To the contrary, the one treaty in Article 1701 addressing patent law issues, the Paris Convention, establishes the basic "principle of independence of patents", according to which the patent bargain may be applied differently by countries.[613]

369. The specific terms of NAFTA Chapter Seventeen do nothing to regulate domestic court powers of patent interpretation. Chapter Seventeen in its specific

[611] Gervais Report, para. 57.

[612] Gervais Report, para. 58.

[613] Gervais Report, para. 61.

provisions instead focuses on ensuring the availability of domestic courts, and the empowerment of such courts to resolve domestic intellectual property disputes.

370. NAFTA Article 1714(2) requires that the enforcement procedures be fair and equitable, not unnecessarily complicated or costly, and do not entail unreasonable time-limits or unwarranted delays. NAFTA Article 1715(1) sets out certain basic procedural requirements, such as the right to written notice, legal representation, to present argument and evidence. NAFTA Article 1714(3) contemplates that domestic courts will arrive at decisions on the merits of particular cases, and specifies three requirements of due process that must be satisfied in such proceedings. Decisions on the merits shall "preferably" be in writing and state the reasons on which they are based, be available to the parties without undue delay, and be based only on evidence on which the parties were offered the opportunity to be heard.[614]

371. Of particular significance, NAFTA Chapter Seventeen contemplates that resolving errors in the adjudication and enforcement of intellectual property rights must be resolved within the framework of the domestic legal system. Considerable latitude is accorded to domestic legal systems in determining the scope and rigour of appellate review. NAFTA Article 1714(4) requires that judicial decisions at first instance are subject to review within the domestic system at least on the legal aspects of the case.[615] Notably, this mandated review process does not specify the standard of review that domestic courts must apply on appeal (correctness or a more deferential standard). Nor does it require for there to be any review of the factual findings reached by the court of first instance.

372. Overall, the context of Chapter Seventeen again points to Parties being left to administer their national patent schemes, in particular through the impartial oversight of domestic courts. Any reading of "utility" that would bind the hands of national courts

[614] NAFTA, Article 1714(3).

[615] NAFTA, Article 1714(4).

with regard to the application of substantive patent criteria conflicts with the context provided by the other provisions of the Chapter.

373. Instruments adopted in connection with NAFTA also forms part of the "context" according to VCLT.[616] In this regard, Canada, Mexico and the United States all adopted implementing legislation to ensure that their domestic legal orders aligned with the obligations they were undertaking under the NAFTA. Fixing the definition of "utility", in the manner Claimant suggests, including related severe strictures on court's statutory role in interpreting and applying the *Patent Act,* would certainly have required domestic statutory change. Yet no such change occurred, nor was even suggested, in Canada or the other Parties.

374. Claimant's over-reading of "utility" also finds no support in the "object and purpose" of the NAFTA. With respect to intellectual property, NAFTA Article 102 (d) expressly states that "the objectives of this Agreement are to… Provide adequate and effective protection and enforcement of intellectually property rights in each Party's Territory." Canada fully lives up to this object and purpose in the patent domain by maintaining a world-class system of patent registration and sophisticated, specialised courts before which parties may seek to defend and enforce their patent rights. Beyond this, NAFTA's "object and purpose" was not to harmonize patentability requirements, nor restrictions on the manner in which domestic courts may apply such requirements. The "object and purpose" of NAFTA is certainly not to shield from invalidation patents that fail to comply with the substantive requirements of the *Patent Act*.

d) Subsequent practice in the application of the treaty

375. Claimant argues that the practice of the Parties has been "consistent" since NAFTA. Specifically, Claimant alleges that "throughout the 1990s and into the early 2000s, in all three jurisdictions an invention qualified as industrially applicable or useful if it was operable and could be made or used in any industrial activity. According to

[616] United Nations, *Vienna Convention on the Law of Treaties*, 23 May 1969, Article 31(2)(a) (**RL-072**).

Claimant, this confirms that "utility" is a "uniform standard" that requires only that "an invention is capable of a specific use in industry."[617]

376. Both the laws in place as of the signing of NAFTA and the subsequent practice of the Parties in the application of Chapter Seventeen contradict Claimant's interpretation. As Mr. Dimock confirms, Canada's patent law already incorporated rules of promise, requirements that the invention (including its utility) be "made" as of the filing date, and requirements of disclosure of the basis of predictions of utility, among other requirements, as at the time NAFTA was signed, belying Claimant's inaccurate and self-serving account. Beyond this, the expert reports of Mr. Dimock, Professor Holbrook and Ms. Lindner demonstrate that: Canada the United States and Mexico have continued to apply the patentability requirements of NAFTA in different ways, and in combination with different overall requirements, in accordance with their domestic policy objectives. This subsequent practice is fundamentally at odds with Claimant's implausible notion of a fixed standard "enshrined" in the NAFTA text.[618]

377. None of the three NAFTA Parties have acted as though Chapter Seventeen prevented them for considering, in a flexible and principled manner, how requirements of "utility" or "industrial applicability" should be applied in the context of specific cases. Nor have the three NAFTA Parties taken the position that their domestic patent law cannot evolve as courts interpret and apply such criteria.

e) The PCT is of no assistance to Claimant

378. Claimant argues that the PCT is a "relevant" rule of international law for the purpose of interpreting the "utility" requirement in NAFTA Chapter Seventeen.[619] Specifically, Claimant argues that the definition of "industrial applicability" in PCT

[617] Claimant's Memorial, para. 196.

[618] Gervais Report, para. 63 and FF.

[619] Claimant's Memorial, para. 202.

Article 33(4) informs the content of NAFTA Article 1709(1).[620] This argument has no merit both because the PCT is not a relevant rule of international law and because it does not actually define the utility requirement substantially.

379. In order to determine the "relevance" of an international law treaty under VCLT Article 31(3)(c), regards must be given to its object and purpose.[621] The purposes of the PCT and of NAFTA are intrinsically different.[622] Whereas NAFTA include substantive rules, the PCT, as Claimant itself notes, is a "procedural" treaty [623] which explicitly gives sole discretion over substantive patent laws to Contracting States. It is difficult to understand the relevance of the PCT in interpreting the meaning of a specific patentability requirement found in NAFTA when the text of the PCT itself provides that it is not relevant in this regard. In fact, the PCT is not even on the list of treaties that Parties committed to upholding under NAFTA Chapter Seventeen.[624]

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.[625] The PCT explicitly warns applicants that the preliminary opinion on patentability generated does "not contain any statement on the

[620] Claimant's Memorial, para. 203. The *PCT* defines "industrially applicable" in Article 33(4) as follows: "For the purposes of the preliminary international examination, a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry […]". (*PCT*, Article 33(4) **(R-037)**).

[621] *The Mox Plant Case*, *(Ireland v United Kingdom)* (ITLOS) Judgment, 3 December 2001, para. 51 (**RL-073**).

[622] Gervais Report, para. 78.

[623] Claimant's Memorial, para. 202.

[624] *See* NAFTA Article 1701(2). The treaties listed in that provision are the *Geneva Convention for the Protection of Producers of Phonographs Against Unauthorized Duplication of their Phonograms* (1971), the *Berne Convention for the Protection of Literary and Artistic Works* (1971), *the Paris Convention for the Protection of Industrial Property* (1967), and *the International Convention for the Protection of New Varieties of Plants* (1978 or 1991).

[625] *PCT*, Articles 33(1) and 33(5) (**R-037**). *See* also Gervais Report, para. 74.

question whether the claimed invention is or seems to be patentable or unpatentable according to any national law,"[626] and that "[a]ny Contracting State may apply additional or different criteria for the purpose of deciding whether, in that State, the claimed invention is patentable or not."[627] Dr. Gillen confirms that from a Patent Office perspective, the results of the preliminary opinion on patentability are "strictly advisory in nature and […] national Patent Offices are not required to defer to them."[628]

381. Furthermore, the notion of "utility," found in TRIPS and NAFTA, is not defined in the text of PCT.[629] Claimant has no basis for arguing that the PCT's definition of "industrial applicability" is relevant, let alone consistent with, the "capable of industrial application" and "utility" criteria in NAFTA Article 1709(1) , which are in any event undefined.

382. If the Parties agreed to include a definition of "industrial applicability" in the PCT, it is precisely because they were well aware that it did not strip them of any discretion in applying the substantive patentability requirements they desire at the national level. Indeed, the success of the PCT is likely "due to the fact that it did not interfere with the well-established principle that IP rights are territorial in scope […]; [t]hus, countries did not see in this treaty any threat to its sovereignty, and this explains the large number of PCT members." [630] In contrast, as Professor Gervais explains in his expert report, all later attempts at substantive harmonization have failed.

3) The measures are consistent with NAFTA Article 1709(7)

383. Article 1709(7) provides that subject to stated exclusions from patentability, patents are to be "available and patent rights enjoyable without discrimination as to the

[626] *PCT*, Article 35(2) (**R-037**).

[627] *PCT*, Article 33(5) (**R-037**).

[628] Gillen Statement, para. 60.

[629] Gervais Report, paras.76-77.

[630] Juan Lapenne, "Patent Cooperation Treaty (*PCT*)" 92 J. Pat & Trademark Off. Soc'y 192 2010, p. 26 (**R-346**).

field of technology, the territory of the Party where the invention was made and whether the products are imported or locally produced."

384. Canada is plainly in compliance with this provision. As Ron Dimock confirms, the rules of patentability in Canada, including those applied in connection with the "utility" criteria, are applied without distinction as to field of technology.[631] This is obvious from the *Patent Act*, which contains no limitations on the availability of a patent due to the field of technology. Canadian patent law takes into account that in the field of pharmaceutical and other "uncertain" arts a party need not come forward with a fully-realized invention (as was long required for mechanical inventions), but may instead file a successful application on the sole basis of a "prediction" so long as that prediction has some basis in fact and an associated line of reasoning.[632]

385. Claimant nevertheless argues that "in practice", Canada's "promise utility doctrine has had adverse effects exclusively within the pharmaceutical sector" such that it constitutes a *de* facto discrimination. [633] As established above, this claim is ill-founded.[634]

386. As Dr. Brisebois' statement describes, to the extent the absolute number of pharmaceutical patent challenges have increased in Canada in recent years, including on the basis of utility, this simply reflects the increase in pharmaceutical patent rights since NAFTA. Such increased protections for the pharmaceutical industry had the side-effect of transforming circumstances from one which pharmaceutical patents had rarely been the subject of litigation, to one in which pharmaceutical disputes have come to dominate the patent bar.

[631] Dimock Report, paras. 158-161.

[632] Dimock Report, para. 100.

[633] Claimant's Memorial, para. 214.

[634] Part II.D above.

387. Nor is the "utility" requirement typically applied to invalidate patents in pharmaceutical cases. As Dr. Brisebois describes, in the large majority of cases in which a pharmaceutical patent has been challenged on the basis of utility, the patent has been found to meet the utility criterion. [635]

388. Claimant's statistics are defective in other respects as well: they include patents successfully challenged because they suffered from multiple flaws, not limited to utility. Further, Claimant counted among the "invalidations" cases of unsuccessful *PM(NOC)* challenges which do not actually invalidate the patent and allow the patentee to sue the alleged infringing party in Federal Court. Most telling, only three pharmaceutical patents were truly invalidated on the sole basis of utility in Canada over the past 35 years, two of which are the patents at issue in this proceeding. [636] In the same period, two non-pharmaceutical patents had claims invalidated on the sole basis of lack of utility. Claimant manufactures evidence of "discrimination" where none exists. There is no issue of compliance with Article 1709(7).

4) The measures are consistent with NAFTA Article 1709(8)

389. Article 1709(8)(a) provides that a Party may revoke a patent only when "grounds exist that would have justified a refusal to grant a patent." Claimant argues that this provision precluded the Canadian courts from invalidating its patents under what it terms the "promise utility doctrine", alleging that this "doctrine" did not exist at the time those patents were filed.[637]

390. Canada has complied fully with Article 1709(8)(a), the ordinary meaning of which is easy to understand: if the patent should not have been granted in the first place, then it may be justifiably invalidated. The purpose of the provision is to ensure that patents are not invalidated for reasons extrinsic to the NAFTA Parties patent law. The invalidation of Claimant's atomoxetine and olanzapine patents was precisely because the

[635] Brisebois Report, para. 36.

[636] See Part II.D.3 above.

[637] Claimant's Memorial, para. 228.

Federal Court determined, on the basis of the evidence, that grounds existed that would have justified refusing the patent grant in the first place.

391. Like all patents examined by the Patent Office, Claimant's patent applications were evaluated for *prima facie* compliance with the *Patent Act* criteria of novelty, non-obviousness, and utility, based on the information provided by the patentee. But the *Patent Act* could not be more clear: the grant of a patent is always subject to review by the Federal Court for a final determination of whether the patent should have been granted.

392. In the case of atomoxetine, the Patent Office would have "assumed" that the claimed utility of the invention was "demonstrated" based upon the assertive language of the specification. But the Claimant failed to prove this to the Federal Court when its patent was challenged because the actual study it relied upon - the MGH Study - proved to be partial and inconclusive. [638] Thus, the court invalidated the patent because "grounds existed" that (had the Patent Office had full information), "would have justified a refusal to grant the patent" in the first place.

393. The same applies for olanzapine, where the Federal Court determined, on the basis of extensive expert evidence, that studies relied upon by Claimant in fact provided no basis to demonstrate or even to soundly predict any relatively better utility for the compound, compared with its already-patented genus. [639]

394. Claimant's argument that the promise doctrine is "an entirely new requirement that the Patent Office could not have used in an initial refusal to grant the patent". [640] As Mr. Dimock notes: "Claimant's patents were invalidated on the basis of longstanding rules that have not changed since Claimant filed its patent, and that were the subject of

[638] Part II.A.1 above.

[639] Part II.A.2 above.

[640] Claimant's Memorial, para. 231.

review and discussion in Canadian legal literature at the time Claimant's patents were filed."

395. In any event, any attempt at reading Article 1709(8) as preventing Canadian courts from any evolution or classification in interpreting the *Patent Act*, would be inconsistent with the basic functioning of the Canadian patent system – and, for that matter, of the United States. Retroactivity of interpretive decision-making is a standard feature of patent systems worldwide.[641] As stated in a recent article concerning the US system :

> The Federal Circuit Court of Appeals, the appellate court tasked with deciding patent appeals, has frequently startled the patent law community with apparently run-of-the-mill rulings that substantially alter the value of previously issued patents. These decisions often change how lower courts must construe patent claims that have already been written, evaluate the propriety of behavior during patent prosecution that has already occurred, determine the validity of patents that have already issued, or assess the infringement by products that have already been sold.[642]

396. Courts regularly review application of the statutes they apply in an effort to ensure that the underlying object and purpose of the statute is upheld. In the context of a complex domain such as patent law, this can include development of new interpretive frameworks in light of issues arising with new classes of patents. Such frameworks

[641] *See* for instance Daniel R. Cahoy, "Changing the rules in the middle of the game: how the prospective application of judicial decisions related to intellectual property can promote economic efficiency", American Business Law Journal Fall 2003 **(R-347)**; Arti K. Rai, "Patent validity across the executive branch: ex ante foundations for policy development, 1244 Duke Law Journal, Vol. 61:1237 **(R-123)**.

[642] David L. Schwartz, "Retroactivity at the Federal Circuit", 89 IND. L.J. 1548 (2014) **(R-107)**. The author gives several examples of precise legal principles pertinent for intellectual property law which were radically modified by court decisions. For instance: "*Valmont Industries* represented an enormous shift in the law. Until 1993, educated patent lawyers may have preferred means-plus-function claim language because it was viewed as broader than regular claim language. After 1993, means-plus-function claim language was nearly always narrower than standard claim language. Means-plus-function claim language became disfavored, and the number of issued patents using means-plus-function language dropped from nearly fifty percent in the early 1990s to under ten percent in 2010". "Another significant change occurred with respect to the law of joint Infringement". "Beauregard is significant because it shows that sometimes a Federal Circuit decision positively affects issued patents. Putting aside the prospective effects of the Beauregard decision, the decision also had retroactive effects. The decisions change the rules for existing patents…"

must necessarily be developed after the patent is granted, and once the patent is up for review before the courts. Professor Gervais notes:

> Evolution in the interpretation and application of patentability criteria, particular as novel issues arise, are part and parcel of any system. When those decisions clarify how patent criteria should apply in particular circumstances, this can have an impact on the validity of previously-issued patents. 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.[643]

397. As Mr. Dimock demonstrates, the enforcement of promised utility, the requirement that utility be demonstrated or soundly predicted as of the filing date, and the need to disclose the basis for sound prediction, were all doctrines present in Canadian patent law at the time that it filed its patents. But even if such doctrine had been introduced and applied after Claimant's patents were filed, the decisions would remain consistent with Article 1709(8). Under Claimant's reading, *any* legal developments since the signature of NAFTA would amount to violations of NAFTA Article 1709(8). Nothing in the subsequent practice of the Parties suggests that they have ever felt so constrained.

398. To the contrary, courts have continued to play their role in the domestic patent systems of the United States and Canada in interpreting and applying the law. As Professor Holbrook notes, patent law developments in the United States, including but not limited to new interpretations of "utility" and related criteria, have regularly, and sometime surprisingly, called into question the validity of thousands of prior patent grants, accorded under interpretations of United States patent law that the United States court deemed were incorrect.

399. Imposing the kind of re-ordering of the functioning of the Parties' domestic legal systems and their ability to interpret legislative requirements, as suggested by Claimant's interpretation, would have sparked enormous debate, and required extensive

[643] Gervais Report, para. 69.

and controversial legislative change. As one author has opined, Claimant's radical over-reading of the plain and ordinary meaning of 1709(8) would in effect mean that "all the patent laws or judicial decisions in the United States, Canada and elsewhere since the 1990s that have tightened patent eligibility standards to obtain better quality patents were illegal."[644] Nothing in Article 1709(8) imposes this absurd result.

5) The measures are consistent with NAFTA Article 1701(1)

400. Finally, Claimant argues that the "utility" requirement as applied in the matters at issue constitutes "a failure per se" to "provide adequate and effective protection of intellectual property rights" under NAFTA Article 1701(1).[645]

401. The plain and ordinary meaning of this undertaking, in the entire context of Chapter Seventeen, is that the Parties will 1) ensure domestic legal protection for the intellectual property rights referenced in the Chapter and 2) ensure that such rights are supported by an adequate enforcement mechanism, notably via full and fair procedure before domestic courts.

402. Article 1709(1) cannot, by any reasonable measure, provide any basis for imposing specific interpretations or applications of substantive patent law on any of the Parties, or *a fortiori* imposing an obligation of result with respect to a particular patent. To the extent that such rules are not expressly set out elsewhere in Chapter Seventeen (and they are not), this bare statement of principle cannot reasonably be employed to impose on Canada, and on the Parties, a series of strictures at odds with the reasonable functioning of the Parties' respective legal systems.

[644] Jerome H. Reichman, *Compliance of Canada's Utility Doctrine with International Minimum Standards of Patent Protection*, remarks published in the 2014 issue of the *Proceedings of the 108th Annual meeting of the American Society of International Law*, p. 2 (**R-348**).

[645] Claimant's Memorial, para. 232.

F. Even if NAFTA Article 1110 Applies, There Was No Expropriation in This Case

403. As discussed, Claimant's expropriation claim is defective from the start. A judicial determination that a property interest did not exist means there is no property to expropriate. In any event, NAFTA Article 1110 also does not apply because the measures at issue are fully consistent with NAFTA Chapter Seventeen, again because that Chapter does not allow second-guessing of domestic court decisions.

404. However, even if Claimant gets past these threshold barriers, it has still failed to establish that the measures amount either to a direct or an indirect expropriation.

1) There was no direct expropriation

405. Claimant alleges that the invalidation of its patents bear the hallmarks of both a direct and an indirect expropriation.[646] Claimant is confused with respect to both legal concepts. Direct expropriation requires that "the government measures in question result in a state sanctioned compulsory transfer of property from the foreigner to either the government or a state-mandated third party."[647] Claimant relies on authorities that do not support to proposition that there can be a direct expropriation in the absence of transfer of title. Claimant cites passages from *Metalclad* and *Fireman's Fund* that did not define direct expropriation, but referred to expropriation generally (both direct and indirect).[648] Even in the arbitral award on which Claimant places the greatest reliance, *Saipem v. Bangladesh*, the Tribunal rejected the argument that there was a direct expropriation.[649]

406. In the present case, the test for direct expropriation is not satisfied. The court decision invalidating Claimant's patent did not result in the transfer of property of rights

[646] Claimant's Memorial, para. 239.

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

[648] Claimant's Memorial, paras. 170-171.

[649] *Saipem Award*, para. 129 (**RL-064**) (holding that "the acctions of the Bangladeshi courts do not constitute an instance of direct expropriation, but rather of "measures having similar effects").

to the State or to any other party. Rather, there was a determination that no valid property rights existed.

2) There was no indirect expropriation

407. Claimant argues that all that is required to establish an indirect expropriation is a substantial deprivation of its investment.[650] This is incorrect. Determining whether a measure constitutes an indirect expropriation requires a contextual inquiry that goes beyond purely the effects of a measure.[651] Recent Canadian and United States investment treaties set out interpretive annexes[652] intended to assist tribunals by explaining further what States mean and have always meant by the term "indirect expropriation".[653] As such, while the NAFTA does not contain the same annex, the

[650] Claimant's Memorial, paras. 174-175.

[651] *S.D. Myers*, Partial Award, paras. 281, 285 **(RL-076)** (holding that "international law makes it appropriate for tribunals to examine the purpose and effect of government measures."); Newcombe, para. 7.7 **(R-334)** (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."); Kinnear, at 1110 15-17 **(R-343)** (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]").

[652] *See* for example, *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)**.

[653] As stated by the former Chief of the NAFTA Arbitration Division in the Office of the Legal Adviser for the United States Department of State, the clarifications on the meaning of the expropriation provisions in recent investment agreements of the United States "do not change the nature of the substantive obligations that existed under the United States' prior agreements; instead, they merely elucidate, for the benefit of tribunals charged with interpreting the treaty, the Parties' intent in agreeing to those obligations." 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), pp. 5-6 **(R-356)**.

factors laid out in these recent interpretative texts provide useful guidance to assess whether there has been an indirect expropriation in this case. These Annexes provide that:

> a. Indirect expropriation results from a measure or series of measures of a Party that have an effect equivalent to direct expropriation without formal transfer of title or outright seizure;
>
> b. The determination of whether a measure or series of measures of a Party constitutes an indirect expropriation requires a case-by-case, fact based inquiry that considers, among other factors:
>
> > i. the economic impact of the measure or series of measures, although the sole fact that a measure or series of measures of a Party has an adverse effect on the economic value of an investment does not establish that an indirect expropriation has occurred,
> >
> > ii. the extent to which the measure or series of measures interferes with distinct, reasonable investment-backed expectations, and
> >
> > iii. the character of the measure or series of measures;
>
> c. Except in rare circumstances, such as when a measure or series of measures is so severe in the light of its purpose that it cannot be reasonably viewed as having been adopted and applied in good faith, non-discriminatory measures of a Party that are designed and applied to protect legitimate public welfare objectives, such as health, safety and the environment, do not constitute indirect expropriation.

408. Applying the three factors for determining whether there has been an indirect expropriation set out in sub-section (b) of these Annexes, it is apparent that Claimant has not established an indirect expropriation.

a) The economic impact of the measures does not amount to a substantial deprivation of Claimant's investment in Canada

409. An expropriation requires a "taking" of fundamental ownership rights that cases a substantial deprivation of the economic value of an investment.[654] Claimant contends that it is beyond dispute that Canada's invalidation of its patents deprived these investments of substantially all value.[655] This is incorrect.

410. In assessing whether there has been a substantial deprivation, the investor's enterprise must be considered as a whole.[656] Tribunals have resisted attempts by claimants to parse their investment into sub-investments in an effort to show a substantial deprivation. Notably, NAFTA tribunals have declined to find an indirect expropriation where investors' complaint is purely that profits in a particular line of business have been diminished and other lines of business remained available.[657]

411. Applying these principles in this case, it is apparent that Claimant has not suffered a substantial deprivation. Claimant's atomoxetine and olanzapine products form just one part of Claimant's overall enterprise in Canada, which continues to grow and enjoys substantial profits in numerous lines of business. Nor did the measures

[654] *Pope and Talbot Interim Award*, para. 102 **(RL-056)**: ("[…] under international law, expropriation requires a 'substantial deprivation['"]); *Merrill & Ring Forestry L.P. v. Government of Canada (UNCITRAL) Award*, 31 March 2010, ("*Merrill & Ring Award*"), para. 145 (**RL-075**): ("The standard of substantial deprivation identified in *Pope & Talbot*, and followed by many other decisions, both in the context of NAFTA and other investment protection agreements, is the appropriate measure of the requisite degree of interference."); *Grand River* Award, para. 148 **(RL-010)**; *Glamis Award,* para. 357 (**RL-006**).

[655] Claimant's Memorial, para. 173, FN 334.

[656] *Grand River Award*, para. 148 (**RL-010**) ("NAFTA Tribunals have regularly construed Article 1110 to require a complete or very substantial deprivation of owners' rights in the totality of the investment, and have rejected expropriation claims where (as here) a claimant remained in possession of an ongoing business."); *See* also *Merrill & Ring Award*, para. 144 (**RL-075**) (holding that "the business of the investor has to be considered as a whole and not necessarily with respect to an individual or separate aspect…").

[657] *Marvin Feldman v. Mexico*, ICSID Case No. ARB(AF)/99/1, Award, 16 December 2002, para. 152 ("*Feldman Award*") **(RL-058)** (finding no expropriation where the claimant remained in possession and able to conduct other lines of business); *Pope and Talbot Interim Award*, para. 101 **(RL-056)** (declining to find an indirect expropriation because, while the investor alleged that the measure reduced the profitability of the its softwood lumber exports to the United States, the investor was still able to export substantial volumes of exports at considerable profit).

prevent Claimant from continuing to produce and sell its atomoxetine and olanzapine based products. It still holds a valid *NOC* permitting it to sell these products.[658] It continues to do so at considerable profit.

b) The measures did not interfere with Claimant's distinct, reasonable investment-backed expectations

412. NAFTA tribunals have also considered claimants' distinct investment-backed expectations as a relevant factor in determining whether there has been an indirect expropriation.[659] Claimant alleges that the invalidation of its patents deprived it of reasonably-to-be expected economic benefit.[660] Claimant's allegation has no merit. As discussed above, Claimant could not reasonably have expected that its patents would not be invalidated, given the longstanding patent law principles that led to their invalidation, and the express terms of the original patent grant.[661]

c) The character of the measures is not consistent with a finding of indirect expropriation

413. Even where a claimant has shown a substantial deprivation, tribunals must also consider the character of the measure to determine whether it can amount to an indirect expropriation demanding State compensation.[662] Here, the character of the measures heavily weighs against a finding of indirect expropriation.

414. Claimant contends that "no special rules attach to claims of expropriation based on judicial measures."[663] This sweeping statement is antithetical to the rules in customary international law regarding denial of justice and expropriation, already

[658] Barton Statement, paras. 31 and 51.

[659] *Glamis Award*, para. 356, FN 704 (**RL-006**).

[660] Claimant's Memorial, para. 239.

[661] *See* Part IV.D.3

[662] *TECMED Award*, paras. 115, 122 (**RL-049**); *Feldman Award*, para. 103 (**RL-058**); *S.D. Myers First Partial Award*, para. 281 (**RL-017**); *Archer Daniels Award*, para. 250 (**RL-074**); *Methanex Final Award on Jurisdiction*, Part IV, Chapter D, p. 4, para. 7 (**RL-011**).

[663] Claimant's Memorial, para. 179.

discussed. Moreover, the whole notion of judicial expropriation is entirely unsettled even in domestic legal systems, let alone in customary international law. The United States Supreme Court recently split evenly on whether Takings Clause under the United States Constitution can ever apply to judicial action. [664] The decision was highly controversial, with many commentators contending that the whole concept of judicial takings is unsound both as a matter of law and policy.[665] Courts serve a vital public function in resolving disputes over property and other rights, in cases initiated not by the State but by private litigants. If every judicial decision with respect to property rights could amount to an expropriation, the judicial system would be paralyzed.

415. Here, the invalidation of Claimant's patents was a legitimate and good faith exercise of the judicial authority of the State. The Canadian courts that found Claimant's patents to be invalid were discharging the essential public function of resolving disputes between private parties. There is no suggestion that the courts failed to act in good faith. Their decisions aimed to fairly resolve a dispute initiated by private parties in a manner consistent with both the letter and spirit of Canada's *Patent Act*, which in turn aims at the public policy objective of encouraging innovation and disclosure of inventions. Claimant benefited from extensive due process, including robust avenues of appeal.

416. All of the considerations relevant to whether there has been an indirect expropriation strongly indicate that there was no such expropriation in this case.

VI. CONCLUSION

417. Claimant's NAFTA claim wrongly casts this Tribunal as a court of appeal from decisions of Canada's Federal Court, which found its two patents invalid in that they failed to comply with basic requirements of patentability set out in Canada's *Patent Act*.

[664] *Stop the Beach Renourishment, Inc. v. Florida Department of Environmental Protection et al*., 560 U.S., (2010) **(R-046)**.

[665] John D. Echeverria; *Stop the Beach Renourishment: Why the Judiciary is Different* in Vermont Law Review, Vol. 35:475 **(R-341)**.

The two decisions at issue were reasoned, procedurally just, within the Federal Court's statutory jurisdiction, based upon thorough review of fact and expert evidence, and made in accordance with Canadian law. Nothing in these court decisions comes close to a violation of either Article 1105(1) or Article 1110 of NAFTA.

418. In order to provide a basis for its claims regarding Canadian patent law and Canadian court's application and interpretation of this law, Claimant has made many inaccurate statements regarding Canadian court interpretations, and trends in patent invalidation on the basis of utility. Overall, this claim is nothing more than an attempt by the Claimant to employ NAFTA Chapter Eleven as a vehicle to air its grievances concerning the evolution and policy orientations of Canadian patent law, which it sees as not sufficiently aligned with its own interests. Yet the *Patent Act* exists not to serve Claimant, but rather the public interest. The *Patent Act* does so by rewarding innovation when it has been achieved, and where that innovation has adequately been disclosed to the public.

419. Claimant through its misapplication of NAFTA seeks in effect to substitute Canadian patent policy and requirements, for an alternative, detailed set of rules of its own making. Claimant's rules would promote the granting of patent monopolies on the basis of speculation, in a manner dissuading innovation, and with the public receiving only misleading and incomplete disclosure in return. These are not the rules set out by Canada's legislature in the *Patent Act*. These are not rules endorsed by Canada's courts. These are not rules established in international law. Nor are they required by NAFTA Chapter Eleven, the only basis for this Tribunal's jurisdiction.

420. The Tribunal in the exercise of its limited investment law jurisdiction cannot impose a substantive patent law harmonization that relevant international actors have failed to achieve.

VII. REQUEST FOR RELIEF

421. 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.

January 27, 2015

Respectfully submitted

[signed]

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