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

REJOINDER MEMORIAL

December 8, 2015

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REJOINDER MEMORIAL

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I. INTRODUCTION

A. Preliminary Statement

1. In the introduction to its Reply, Claimant suggests that Canada's Counter-Memorial is based on a number of fallacies. Each one of Claimant's specious arguments is rebutted below. Ultimately, however, there is only one fallacy that matters – the one offered by Claimant to suggest that a NAFTA Chapter Eleven tribunal is some sort of *über*-tribunal empowered to sit in judgment of the Supreme Court of Canada's interpretation of Canadian law, to rule on Canada's obligations under all of the international treaties that it has signed, and to promulgate substantive international obligations relating to patent law. In making these arguments, Claimant has fundamentally misconceived both the obligations under Chapter Eleven and the limited jurisdiction that the NAFTA Parties agreed to bestow on NAFTA Chapter Eleven tribunals. Once Claimant's self-serving rhetoric is disregarded, it is clear that there is no legal basis in NAFTA that can support Claimant's allegations in this dispute.

2. In essence, this claim amounts to nothing more than yet another attempt by Claimant to change the interpretation given to the *Patent Act* by the Canadian courts in accordance with their constitutional role. This is made all the more apparent by the redefined focus of Claimant's claim. Claimant initially purported to challenge the specific judicial invalidations of its patents for olanzapine and atomoxetine. Canada rebutted these claims in its Counter-Memorial, showing that the Canadian court decisions in question applied long-established Canadian law and that Claimant was afforded due process during the proceedings. There is no room for debate: Claimant was not denied justice by the Canadian judicial system.

3. In its Reply, Claimant admitted that in invalidating the two patents in question, the Canadian courts correctly applied clear, existing, and binding Canadian law and that it was afforded due process in those proceedings. In fact, Claimant now claims that it never alleged otherwise. Claimant purports to clarify that it is not alleging that either

Canada's *Patent Act* or the specific court decisions invalidating its patents breach Canada's NAFTA obligations. Rather, it now says that it is challenging the very interpretations of Canada's *Patent Act* by Canadian courts over the last dozen years, mostly in cases wholly unrelated to Claimant's patents.

4. Claimant's challenge amounts to no less than an assertion that the Canadian courts, including the Supreme Court of Canada, have misunderstood and misapplied Canada's *Patent Act* and decades of their own case law. Absent a denial of justice, an arbitral tribunal may not involve itself in the question of whether a State's judiciary has correctly interpreted applicable domestic legislation. Canada is a parliamentary democracy, and if the courts have misunderstood one of Parliament's laws, there is a remedy – the law can be amended to correct that misinterpretation and ensure the courts appropriately understand Parliament's intent. However, regardless of whether Parliament does so, it is not the role of a Chapter Eleven tribunal to interfere in the interpretation of domestic law by domestic courts.

5. Undeterred by this fact, and in the face of its failure to convince Canadian courts to interpret Canadian law to its liking, Claimant has turned to this Tribunal alleging a violation of international law. These arguments face three additional insurmountable hurdles. First, such a challenge fails to recognize that the jurisdiction of this Tribunal is time-limited. NAFTA Articles 1116(2) and 1117(2) make clear that the Tribunal cannot reach back into the past to hear claims that should have been brought more than three years ago. In redefining the measure that allegedly breached NAFTA as the judicial doctrine itself, rather than the specific atomoxetine and olanzapine proceedings, Claimant has taken its claim beyond the Tribunal's jurisdiction *rationae temporis*. The judicial doctrine that Claimant now says is the focus of its NAFTA claim was applied to Claimant in another proceeding that ended when the Supreme Court of Canada denied leave to appeal in October 2009, more than three years before Claimant initiated this NAFTA arbitration in September 2013. As such, Claimant's reformulated claim is time-barred.

6. Second, NAFTA Chapter Eleven contains no specific obligations with respect to the content of patent law. As a result, Claimant is forced to suggest that the Tribunal import obligations with respect to patents from other chapters of NAFTA and other international treaties. Yet, such an attempt ignores the limited subject matter mandate of this Tribunal. For example, Claimant spends a significant amount of time discussing the *Patent Cooperation Treaty* ("PCT") and alleging that Canada is in breach of its obligations thereunder. Claimant's arguments are devoid of merit; but more importantly, a Chapter Eleven tribunal has no authority to interpret the PCT, let alone find a breach of its provisions. Under Article 59 of the PCT, any disputes about either "the interpretation or application of this Treaty or the Regulations" are to be brought before the International Court of Justice. Claimant's assertion that this Tribunal can find a breach of Chapter Eleven if it finds a breach of some other international obligation tears at the fabric of the entire system of international adjudication which gives power to specific bodies to resolve specific types of disputes. Chapter Eleven tribunals are not courts of general international jurisdiction.

7. Third, even if the Tribunal could consider claims with respect to alleged breaches beyond Chapter Eleven (and it cannot), Canada is in perfect compliance with its obligations under NAFTA and other international treaties. In particular, under Canada's *Patent Act*, patents are available for inventions that are "useful," provided that other patentability criteria are also met. Canadian courts appropriately interpret and apply the *Patent Act* as they have always done – in accordance with long-standing case law and doctrine, and in light of the evidence and arguments presented to them. Claimant's efforts to show otherwise are based upon a distorted and inaccurate recitation of Canadian patent laws and policy. The Tribunal cannot, as Claimant urges, disregard the core purpose of the patent bargain in the context of the patents that Claimant sought. Patents reward and encourage innovation in exchange for disclosure that advances the state of the art. They are not designed to reward secrecy, subterfuge, and speculation – even when it turns out that the speculative guess was a good one. The core question for patent law is: at what point is a State willing to recognize that innovation has been

achieved and reward the inventor with the extraordinary benefit of a patent? For each and every patent sought, Canada applies the same patentability criteria in order to answer this question.

8. Neither Chapter Seventeen of NAFTA nor any other international treaty imposes any restrictions upon how the parties define or implement their respective patentability criteria. Indeed, there has never been an international treaty in which States have accepted specific restrictions on what substantive conditions they can require an inventor to meet in order to be awarded the benefit of a patent. This is not to say that there have been no efforts to negotiate such a treaty. There have been. They have all failed. It is not the role of this Tribunal to declare what the international rules should be with respect to the substantive conditions of patentability when all efforts to negotiate such rules have failed.

9. Ultimately, Claimant's case can be reduced to an effort to shift the blame for its own failings onto the Canadian judiciary. However, the Canadian courts did nothing other than assess whether Claimant had actually, at the time it filed for its patents, invented something that could be used for what Claimant promised it could be used for. This is exactly what Canadian law has required for decades. Claimant can blame its patent agents, its lawyers or whomever at the company decided to run the risk of filing applications for what they should have known were deficient patent applications. However, Claimant cannot lay the blame at the feet of Canada's courts.

10. This Rejoinder is organized into three main parts. In **Part II**, Canada reiterates several crucial facts that Claimant continues to either ignore or misrepresent. For instance, contrary to what Claimant alleges, Canadian law provides effective protection for patent rights where the patentee upholds its end of the patent bargain by having invented and disclosed something that meets Canada's patentability criteria. Claimant seems determined to have the Tribunal overlook this fact. It should not do so. In this case, after enjoying years of monopoly rights, Claimant claimed that it had invented new uses for raloxifene and atomoxetine (already known and patented compounds) and that it

had identified olanzapine as being a particularly effective compound from a previously patented genus. In fact, it did not claim that it had invented just a single new use for these known compounds. To the contrary, during this period, Claimant proclaimed the "invention" of nearly 100 different uses and advantages for these three compounds. At the time it made these claims in its patent applications, it had demonstrated nothing. These alleged uses and advantages were nothing more than guesses. Unsurprisingly, of all the numerous applications it filed, only three were ultimately pursued by Claimant. The others were abandoned. In this particular context, the fact that Claimant could not meet the requirements to prove the patentability of even its three remaining alleged inventions in a court of law, before a judge considering all the evidence, is unsurprising. Claimant simply did not uphold its end of the patent bargain, and as a result, its patents were found to be invalid.

11. In **Part III**, Canada explains how Claimant's recast claim is outside of the Tribunal's jurisdiction *rationae temporis*. Claimant now challenges as a breach of NAFTA what it alleges are three separate and novel interpretations of Canada's *Patent Act* that occurred in 2002, 2005 and 2008. All three interpretations that it now challenges were applied to Claimant with respect to its patent for raloxifene by the Federal Court in 2008. This decision was upheld by the Federal Court of Appeal, and the Supreme Court of Canada denied leave to appeal in October 2009. As a result of these decisions, a generic drug manufacturer was allowed to enter the market and compete with Claimant. This triggered the limitations clock found in NAFTA Articles 1116(2) and 1117(2), which provide that any claim must be submitted to arbitration within three years of the time from which Claimant knew or should have known of both the measures in question and that some harm or loss arose from such measures. Claimant did not submit its claim until 2013. Thus, any attempt by Claimant to argue that the law itself violates NAFTA is time – barred. Claimant cannot avoid this fact by constructing a claim that merely does not seek damages for the raloxifene decision. The limitations rule in Articles 1116 and 1117 does not depend on what Claimant pleads; it depends on the relevant facts.

12. In **Part IV**, Canada explains that, even if this Tribunal were to decide that it has jurisdiction to consider Claimant's allegations in the context of how the challenged Canadian law was applied to its specific patents for atomoxetine and olanzapine, Claimant has failed to prove that Canada breached its obligations under either Article 1110 or Article 1105.

13. Article 1110 is simply not engaged by the judicial invalidation of Claimant's patents. The Canadian courts' invalidations of Claimant's patents are not takings of property – they are determinations that no property right ever existed. Moreover, Article 1110 would in any event be inapplicable in this case because its application is barred by Article 1110(7). Canada's measures are fully consistent with its obligations under Chapter Seventeen of NAFTA. In particular, the judicial interpretations that Claimant alleges breach Chapter Seventeen are long-standing in Canadian law and nothing that the NAFTA Parties agreed in Chapter Seventeen, or in any other treaty, renders the application of such principles a violation of Canada's international obligations. For each of these reasons, the Tribunal should refuse to further consider Claimant's allegations of a breach of Article 1110. However, purely for the sake of providing the Tribunal with a complete response to Claimant's meritless allegations, in Part IV Canada also shows that the application to Claimant's patents of the judicial interpretations of the *Patent Act* that Claimant challenges did not amount to either a direct or an indirect expropriation.

14. The judicial measures in question are also consistent with Canada's obligations in Article 1105 of NAFTA. Claimant has failed to meet its burden of proving the existence of the alleged rules of customary international law that these judicial acts have supposedly breached. With respect to the treatment of investments by courts, customary international law only protects against judicial conduct that amounts to a denial of justice. Claimant admits that there was no denial of justice in this case, and it has failed to prove the applicability of any other rules of customary international law. Further, Claimant's allegations of a breach of Article 1105 are based on inaccurate characterizations of the relevant facts. Contrary to what Claimant alleges, neither the Canadian law Claimant challenges nor the application of that law to Claimant was

arbitrary, discriminatory or inconsistent with how Canadian law has been applied for decades.

15. In sum, while it may be clothed in the language of NAFTA Chapter Eleven, this claim is nothing more than an attempt to usurp the sovereignty of States to determine their own conditions of patentability, to override the sovereignty of domestic courts to interpret their own laws, and to invade the jurisdiction of the international tribunals empowered by States to interpret other international treaties. Indeed, it is an unprecedented attempt to indict Canadian courts and their interpretation of Canadian law. This claim is outside of the Tribunal's jurisdiction and is based on misunderstandings, misconceptions and misrepresentations of both the relevant law and facts. This claim should be definitively rejected and Canada should be awarded its costs by the Tribunal for all of the reasons previously outlined by Canada in its Counter-Memorial and discussed further below.

B. Evidence Submitted in Support of Canada's Rejoinder

16. In support of this Rejoinder, Canada has submitted, in addition to documentary exhibits and relevant legal authorities, the following witness and expert evidence:

- *Second Witness Statement of Dr. Marcel Brisebois*: Dr. Brisebois is currently a Senior Patent Examiner with the Canadian Patent Office. From December 2013 to March 2015 he was a Senior Analyst in Industry Canada's Strategic Policy Sector. Dr. Brisebois has submitted a second witness statement to assist the Tribunal in further understanding the inherent biases and errors in the statistical analysis presented by Claimant with respect to the application of Canada's *Patent Act* in Canadian courts. In particular, Dr. Brisebois details the fundamental errors that are contained in the data set that Claimant provided to Dr. Levin—errors that render Dr. Levin's conclusions unreliable—and highlights salient analyses that Claimant failed to have Dr. Levin undertake.

- *Second Witness Statement of Dr. Michael Gillen*: Dr. Gillen held various positions at the Patent Office from 1988 to 2014, including Chair of the Patent Appeal Board (from 2003-2006), and Chief of the Biotechnology Division (from 2006-2014). Dr. Gillen has filed a second witness statement to correct a number of misstatements and misunderstandings in the witness statement of Mr. Wilson with respect to the practices of the Patent Office, particularly as they relate to new use and selection patents in the pharmaceutical context. He has also clarified the relevance of the *Manual of Patent Office Practice* ("MOPOP") and revealed, once again, that Claimant has placed improper emphasis on this guide.

- *Second Expert Report of Mr. Ronald Dimock*: Mr. Dimock is Partner at Dimock Stratton LLP in Toronto and has held that role since 1994. He has practiced patent law since 1976. He is widely regarded as one of the preeminent experts in Canadian patent law and has a broad and varied practice in the Canadian courts. He is neither solely an academic (like Professor Siebrasse) nor solely the representative of brand name pharmaceutical companies (like Mr. Reddon). He has submitted a second report to further clarify for the Tribunal several aspects of how the *Patent Act* is, and has been, applied by the Canadian courts. In particular, he corrects the inaccurate account of the law of utility and the practice of Canadian courts given by Professor Siebrasse and Mr. Reddon. He also explains that the focus on utility in Canadian jurisprudence is due in part to the fact that patentees emphasize promises of utility to meet other patentability requirements, such as non-obviousness.

- *Second Expert Report of Professor Timothy Holbrook:* Professor Holbrook is currently Professor of Law at Emory University School of Law in Atlanta. He has submitted a second expert report to correct certain claims made in the second reports of Professor Merges and Mr. Kunin. In particular, he concludes that Professor Merges and Mr. Kunin have misunderstood how the United States' law on utility deals with selection and new use patents, and how the utility requirement

has greater relevance in the chemical and pharmaceutical context. He also explains and clarifies the significant nature of the changes that United States' patent law has undergone in recent years.

- *Second Expert Report of Ms. Heidi Lindner*: Ms. Lindner is currently the Director of the patent litigation department at Arochi & Lindner, a leading intellectual property firm in Mexico. She has submitted a second expert report to respond to the reports submitted by Mr. Salazar and Ms. Gonzalez. Ms. Lindner concludes that Claimant's experts' interpretation of the Mexican legislation and legislative history is mistaken and that, in particular, they have underestimated the significance of the changes to Mexican patent law in recent years. As a result, she concludes that Mr. Salazar and Ms. Gonzalez have not accurately described the industrial applicability requirement in Mexican law.

- *Second Report of Mr. David Reed*: Mr. Reed is a former United States patent agent for Proctor and Gamble with almost two decades of experience in filing applications under the PCT. In his second report, Mr. Reed concludes that Claimant's expert, Mr. Erstling, has overstated the meaning of the term "form and contents" in the PCT. Because of this misunderstanding, Mr. Erstling wrongly concludes that the PCT restricts what a State can require in the international patent application. As Mr. Reed explains, the PCT does not prohibit Canada from imposing the substantive conditions of patentability that it desires, and nor does it restrict Canada from requiring that certain disclosures related to those substantive criteria be included in the patent application.

- *Second Expert Report of Dr. Daniel Gervais*: Dr. Gervais is currently Professor at Vanderbilt University Law School in Nashville and the Director of the Vanderbilt Intellectual Property Program. He was recently elected President-Elect (and *ex officio* member of the Executive Committee) of the International Association for the Advancement of Teaching and Research in Intellectual Property. He has filed a second report to correct several errors and misunderstandings in the report of

Claimant's expert, Mr. Thomas. He concludes that Mr. Thomas is implicitly arguing that there are harmonized patentability criteria in international law, despite Mr. Thomas' claims to the contrary. Dr. Gervais further concludes that any such claims are baseless and definitively disproved by numerous treaties and the analysis and commentary of the World Intellectual Property Organization ("WIPO").

II. BACKGROUND

17. In its Counter-Memorial, Canada fully set out the relevant facts necessary to respond to and correct the numerous misunderstandings and misconceptions contained in Claimant's Memorial. When considered along with the appropriate legal standards, those facts make clear that there is no basis to support Claimant's assertion that Canada's *Patent Act*, as it has been interpreted by Canada's courts in line with their constitutionally role, is in violation of Canada's obligations under NAFTA Articles 1105 and 1110. Canada will not repeat itself in this submission. However, in the Background section of this Rejoinder, Canada will briefly highlight several key facts which Claimant seems desperate to ignore or continues to misrepresent.

18. In particular, contrary to what Claimant alleges, Canadian law strikes a careful balance between inventors and the public by requiring that certain patentability criteria be satisfied prior to a patent being granted. The reality, which Claimant ignores, is that this patent bargain must still be satisfied in the context of secondary patents, such as Claimant's "selection patent" for olanzapine and its "new use" patent for atomoxetine. It also ignores the responsibility of the Canadian courts to ultimately determine whether the patent bargain has been upheld. This background is crucial for the Tribunal to understand how and why the *Patent Act* has been interpreted in the way that it has been by Canadian courts and why those interpretations are perfectly consistent with Canada's obligations under NAFTA. It is also crucial for understanding why, after years of monopoly with respect to raloxifene, atomoxetine and olanzapine, it was increasingly difficult for Claimant to uphold its end of the patent bargain when it sought secondary

patents with respect to these compounds in the 1990s. In this context, it is no surprise that the Canadian courts found Claimant's patents invalid.

A. Canadian Law Provides Protection for Patent Rights Where Such Protection Is Warranted

1. *The Patent Bargain Reflected in Canada's Patent Act Involves a Careful Balance of Benefits and Obligations*

19. In its Memorial and Reply, Claimant presents a vision of patents as property that transcends and exists independently from the domestic legal order. Claimant is incorrect. A patent is a purely domestic legal construct. It has no inherent attributes. Instead, it exists only as a matter of the law that created it. As such, it only has the validity and life that its source law gives to it. Patents do not exist at common law in Canada.[1] Instead, Canada's Parliament legislated to create the patent system through the first federal *Patent Act* in 1869.[2]

20. The *Patent Act* represents the desire of Canada's Parliament to craft a fair "patent bargain" through which an inventor is given a time-limited monopoly in exchange for innovation and the disclosure of an invention that improves the general state of knowledge.[3] This bargain is maintained through a series of requirements – including, but certainly not limited to, the utility of the invention – and lies at the heart of a system designed to achieve a careful balance between competing interests. In order to incentivize innovation, the public foregoes the advantages of a competitive market for the patented subject matter for a limited period of time. However, the public is only willing to incur the higher costs associated with a monopoly (and reward the patentee

[1] Dimock First Report, para. 13.

[2] *An Act respecting Patents of Invention, C.S.C. 1869* (**R-415**). The *Patent Act* was subsequently amended several times, including in 1989 when compulsory licences were abolished.

[3] *See* Respondent's Counter-Memorial ("Resp. CM"), para. 84; Dimock First Report, para. 14.

with extraordinary economic benefits) in exchange for the inventor's discovery and disclosure of an actual invention.[4]

21. Claimant attempts to isolate the utility criterion for patentability and consider it in a vacuum, independent from all other aspects of the patent bargain.[5] This approach is misleading because it ignores the fact that the patentability requirements work together as checks and balances to ensure that the patent bargain is upheld.[6] The *Patent Act* defines an invention as follows:

> "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.[7]

22. The *Patent Act* further requires that:

> The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains…[8]

23. Thus, Canada's *Patent Act* requires (consistent with NAFTA Article 1709(1)) that an invention be new, useful, and non-obvious in order to be patentable.[9] An invention is new if it has not been made available to the public anywhere in the world by someone other than the inventor prior to the date that the patent application is filed or

[4] *See* Dimock First Report, para. 14; *Apotex Inc. v. Wellcome Foundation Ltd*., [2002] 4 SCR 153 ("*AZT*"), paras. 37, 45 (**R-004**).

[5] *See, e.g.*, Cl. Reply, paras. 89, 157, fn 212 ("But contrary to Canada's assertion, that submission had nothing to do with the *utility requirement* and was made in the entirely separate context of the non-obviousness requirement. Indeed, whether a selection compound demonstrates an advantage over other compounds in its genus has no bearing on the utility requirement, the sole ground for invalidation here.").

[6] Dimock Second Report, para. 18.

[7] *Patent Act*, RSC 1985, c P-4, ("*Patent Act*") s. 2 (emphasis added) (**R-001**).

[8] *Patent Act*, s. 28.3 (emphasis added) (**R-001**).

[9] *See Patent Act*, ss. 2, 28.2, 28.3 (**R-001**); Resp. CM., para. 84; Dimock First Report, para. 14; Dimock Second Report, para. 12.

priority is claimed, whichever is earlier.[10] An invention is useful if it does what the patent promises it will do.[11] If the patent makes no promises, then a mere scintilla of utility suffices.[12] An invention is non-obvious if it possesses some inventive ingenuity over the state of the art to which it pertains.[13] Obviousness is assessed by considering the differences between the state of the art and the invention's inventive concept from the perspective of the person of ordinary skill in the art ("POSITA").[14] If the differences between the state of the art and the inventive concept "constitute steps which would have been obvious to the [POSITA]," the "invention" is obvious and does not qualify for patent protection.[15]

24. The *Patent Act* sets out two further core patentability criteria. First, the invention must cover patentable subject-matter.[16] Canada has excluded certain subject-matter from patentability for public policy reasons, including higher life forms, methods of medical treatment and methods employing professional skills.[17] Until 1987, patents were also unavailable for foods or medicines.[18] Second, inventions must be sufficiently disclosed.[19] This core criterion has long been recognized in Canada as the "consideration

[10] Dimock First Report, para. 15. If it is the inventor itself, which has disclosed the invention to the public anywhere in the world, then under s. 28.2(1)(a), the invention will be considered new as long as the disclosure occurred less than one year prior to the claim date. *See also Patent Act*, s. 28.2 (**R-001**).

[11] Dimock Second Report, para. 38; Dimock First Report, para. 58; *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] SCR 504, 1981 CarswellNat 582 ("*Consolboard*"), paras. 36-37 (**R-011**). Canada discussed at length the promise doctrine's longstanding existence in Canada in its Counter-Memorial: s*ee* Resp. CM., paras. 88-100.

[12] Dimock Second Report, para. 9; Dimock First Report, para. 58.

[13] *Patent Act*, s. 28.3 (**R-001**); Dimock First Report, para. 17.

[14] *Apotex v. Sanofi-Synthelabo Canada*, 2008 SCC 61, para. 67 (**C-196**).

[15] *Ibid.*

[16] *See Patent Act*, ss. 2, 27(8), 28.3 (**R-001**), Dimock First Report, para. 18.

[17] *See Patent Act*, ss. 2, 27(8) (**R-001**); Dimock First Report, para. 18; *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 SCR 45, para. 35 (**R-146**); *Lawson v. Commissioner of Patents*, (1970), 62 CPR 101 (Ex Ct), p. 103 (**R-147**); *Tennessee Eastman Co. v. Canada (Commissioner of Patents)*, [1974], SCR 111, para. 20 (**R-148**).

[18] Prior to 1987, as a matter of policy, a pharmaceutical compound could only be claimed "in connection with the process by which it was made." After 1987, the compound and any derivatives could also be claimed: Dimock First Report, para. 35.

the public receives for the grant of monopoly rights to the inventor."[20] It lies at the core of the patent bargain.[21]

25. To ensure that patents are not granted for mere speculation, each of the above criteria must be met at the time an applicant files for its patent.[22] In Claimant's view, the patent bargain is satisfied if an "invention" provides any practical benefit at any point in time after the patent is granted.[23] Claimant's view overlooks the fact that Parliament did not intend to create a "file first, invent later" system.[24] The bargain is for invention, not speculation. It has always been imperative in Canadian law that there actually be an invention as of the filing date to merit the monopoly rights of a patent.[25] Otherwise, monopoly rights based on nothing more than speculation will block others from pursuing promising lines of research, effectively chilling innovation.[26] The public is not willing to accord a monopoly in exchange for merely an idea (even if it is a good one) or a guess (even if it later turns out to be correct).[27]

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[19] *Patent Act*, s. 27(3) (**R-001**).

[20] Dimock First Report, para. 19; *Teva Canada v. Pfizer Canada Inc.*, [2012] 3 SCR 625, paras. 32-35, citing *Tubes, Ltd v. Perfecta Seamless Steel Tube Co.* (1902), 20 RPC 77, pp. 95-96 (**R-006**).

[21] *See also* Resp. CM., paras. 7, 84.

[22] *See Patent Act*, ss. 28.1, 28.3 (**R-001**); *AZT*, para. 52 (**R-004**); Dimock First Report, paras. 15-17; Dimock Second Report, paras. 107, 109.

[23] *See, e.g.*, Cl. Reply, para. 344 ("Canada maintains that the doctrine 'ensures that the public receives its end of the patent bargain … where a particular promised utility [*i.e.*, an effective treatment for the claimed condition] is the only consideration that the public receives in exchange for the monopoly that it confers.' Yet Canada has not alleged that Zyprexa, Strattera, or any of the other patented drugs affected by the promise utility doctrine actually failed as treatments.") (emphasis added).

[24] Canada introduced a "first-to-file" system in 1989. Under this system, priority is afforded to the first inventor to file its patent application. Prior to 1989, Canada had a "first-to-invent" system, which afforded priority to the first inventor to invent the patented subject-matter. *See* Dimock Second Report, paras. 108. The new first –to-file system does not do away with the requirement that the applicant must actually have invalid something. Therefore, as Mr. Dimock aptly explains, "The system is therefore best described as a 'first (inventor) to file' system." Dimock Second Report, para. 109.

[25] *See* Resp. CM., paras. 119-120.

[26] *See* Dimock First Report, paras. 111-112; *AZT*, paras. 66, 80, 84 (**R-004**).

[27] Dimock First Report, para. 93; Dimock Second Report, para. 94.

26. The *Patent Act*'s requirements for patentability are the same for all inventions, from mechanical inventions to chemical compounds to new uses of existing compounds.[28] Indeed, Canada has always granted patents for a broad range of inventions across industrial sectors.[29]

27. Yet, as will be seen below, whether a particular patent meets each patentability requirement will depend on the nature of the invention, the state of the art, and the way in which the invention has been described and claimed by the patentee. This is particularly important context when secondary patents, such as the raloxifene, atomoxetine and olanzapine patents at issue in this case, are concerned.

2. *Secondary Patents Must Satisfy the Patent Bargain and Meet All Patentability Criteria*

28. Canada's *Patent Act* recognizes that an invention encompasses new uses of, or improvements to, existing inventions.[30] In its Counter-Memorial, Canada introduced a distinction between what it called "primary" and "secondary" patents.[31] While these are not terms of art, and are sometimes referred to in a variety of ways (including, for example, "originating" versus "follow-on," "subsequent" or "second generation" patents), they provide a useful moniker for the types of patents at issue in this case.

[28] *See* Resp. CM., para. 136; Dimock First Report, paras. 158-159.

[29] Since the earliest days of patent granting in Canada, patents have been granted for inventions ranging from the mechanical sector (*e.g.* Canadian Patent 125, "A Machine for Punching Horse Shoes," 1869 (**R-416**)) to the pharmaceutical sector (*e.g.* Canadian Patent 23378, "Composition of Drugs for the Cure of Piles," 1886 (**R-417**); Canadian Patent 29329, "Means by the Use of Vaporous Cristals of Ammonium Chloride for Carrying Other Drugs to the Respiratory and Other Passages of the Body," 1888 (**R-418**)) to the chemical sector (*e.g.* Canadian Patent 125530, "Method of Obtaining Nitrogen and Making Compounds therefrom," 1910 (**R-419**)). In more recent years, patents have also been granted for software and computer-related inventions (*e.g.* Canadian Patent 2467883, "Signature Matching Methods and Apparatus for Performing Network Diagnostics," 2013 (**R-420**)).

[30] Patent Act, s.2 (**R-001**).

[31] *See, e.g.*, Resp. CM., paras. 97, 145, fn 270; Brisebois First Statement, paras. 41-46.

29. As Dr. Brisebois explains, a "primary" patent is a patent "directed to a new, previously-unknown base compound or composition, and its potential use."[32] In contrast, a "secondary" patent is a patent directed to:

> modified forms of that base compound, or to a new medical use of a known drug, to new combinations of known drugs, to particular formulations, dosage regiments and processes, or other secondary modifications to an already well-known drug [such as] selection patents… since they involve a member of an already patented class of compounds.[33]

30. As technology advances, a narrowing gap between the state of the art and new developments can change the nature of the inventions for which patents are sought, and increase the incidence of secondary patents. This trend has been particularly prevalent in the pharmaceutical sector.[34] Ongoing efforts to improve existing drugs are common, and fueling the drive to patent these improvements are so-called linkage regimes (like the *Patented Medicine (Notice of Compliance)* ("PM(NOC") regulations in Canada)[35] which require generic drug manufacturers to challenge patents before the generic company is permitted to enter the market.[36] Because secondary patents can create an additional barrier to market entry for generics, brand name drug companies often seek many secondary patents in respect of a single drug.[37] Indeed, in the last two decades the

[32] Brisebois First Statement, para. 41.

[33] Brisebois First Statement, para. 41.

[34] *See* Resp. CM., para. 145; Brisebois First Statement, paras. 41-46. *See also* European Commission (2009) Pharmaceutical Sector Inquiry: Final Report, para. 497 (**R-243 amended**); 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, vol. 8, issue 4 ("Hemphill, "When Do Generics Challenge Drug Patents?") (**R-245**).

[35] *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, s. 7 (**R-031**); Dimock First Report, paras. 41-45.

[36] *See* Bouchard et al., "Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals," *Northwestern Journal of Technoglogy and Intellectual Property*, vol. 8, issue 2 (Spring 2010) ("Bouchard, "Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals") (**R-421**).

[37] *See, e.g.*, European Commission (2009) Pharmaceutical Sector Inquiry: Final Report, paras. 476-506, 523-527 (**R-243 amended**); Similar trends have been observed in other jurisdictions. A. Kapczynski, C.

number of patents per medicinal ingredient listed on Health Canada's Patent Register (the list of patents a generic manufacturer must address to obtain regulatory approval) has steadily increased.[38]

31. The availability of secondary patents is important for encouraging further innovation. However, the patent bargain must still be upheld for such patents and all patentability requirements must be met. Secondary patents typically advance the state of the art incrementally, often by applying known techniques to known compounds.[39] As such, the gap between the prior art and the claimed invention in such patents is often smaller than when a new compound has been invented. This can raise issues with respect to novelty and obviousness. In order to avoid such issues, patentees will frequently make specific promises regarding unexpected and substantial advantages over the prior art.[40]

32. For example, a "selection" patent is a type of secondary patent granted for a smaller subset of an already known and patented genus of compounds.[41] The invention that warrants a monopoly under these circumstances is the discovery of an unexpected and substantial advantage of the selection over the genus.[42] A patentee seeking a selection patent must therefore promise that the selection provides such an unexpected

Park, and B. Sampat, "Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of 'Secondary' Pharmaceutical Patents," *PLOS One*, vol. 7, Issue 12 (December 2012), p. 1 **(R-422)**.

[38] *See, e.g.*, Bouchard, "Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals, pp. 176-177, 181-182, 192 **(R-421)** (showing 3,850 patents granted for 95 drugs between 1977 and 2008, producing an average of 40 patents per drug); A. Kapczynski, C. Park, and B. Sampat, "Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of 'Secondary' Pharmaceutical Patents," *PLOS One*, vol. 7, Issue 12 (December 2012), p. 1 **(R-422)**; *Hatch-Waxman Act* "Changing Patterns of Pharmaceutical Innovation," National Institute for Health Care Management Research and Educational Foundation, May 2002, ("*Hatch-Waxman Act* "Changing Patterns of Pharmaceutical Innovation"") pp. 16-18 **(R-423)**; European Commission (2009) Pharmaceutical Sector Inquiry: Final Report, Ch. C.2.1 (showing that the "ratio of primary to secondary patents (and their applications) is 1:7," para. 489) **(R-243 amended)**.

[39] *See e.g.* Bouchard, "Empirical Analysis of Drug-Approval-Drug Patenting Linkage for High Value Pharmaceuticals," p. 220 **(R-421)**.

[40] Dimock Second Report, paras. 12-25.

[41] *See, e.g.*, Resp. CM., para. 97.

[42] Dimock Second Report, para. 22; Gillen Second Statement, para. 10.

and substantial advantage to meet the novelty and non-obviousness requirements.[43] Similarly, a patentee seeking a "new use" patent will promise that a known compound can be used in a way that is new and unexpected.[44] Without a new or better utility for the known compound, there is simply no invention worthy of a patent in such cases.

33. In its Reply, Claimant suggests that it should be able to rely on promises of specific utility for the purposes of overcoming obviousness and novelty challenges, but that it should not be held to such statements in the context of a utility challenge.[45] As Mr. Dimock notes, this practice of "reading up the invention" "to enhance the inventive concept of the claimed invention, widening or heightening the gap between the prior art and the invention, for purposes of defending an attack of obviousness" is becoming routine.[46] Indeed, this practice can be seen in many of the cases counted in Claimant's statistics in an attempt to show the allegedly discriminatory application of the promise utility doctrine to pharmaceutical patents.[47] This practice is misguided.

34. In making this myopic argument, Claimant overlooks the fact that the requirements for patent validity are better viewed as a "seamless garment of the law" than as separate watertight compartments.[48] As Mr. Dimock notes, "the tactic of 'reading up the invention' for obviousness and 'reading it down' for the purposes of utility has

[43] Dimock Second Report, paras. 12-14, 20-22; Gillen Second Statement, para. 13.

[44] Dimock Second Report, paras. 12-14, 22; Gillen Second Statement, para. 13.

[45] Cl. Reply, para. 89, fn 423 ("…that submission had nothing to do with the *utility requirement* and was made in the entirely separate context of the non-obviousness requirement. Indeed, whether a selection compound demonstrates an advantage over other compounds in its genus has no bearing on the utility requirement …"); Siebrasse Second Report, paras. 48-50.

[46] Dimock Second Report, paras. 15-17. As Mr. Dimock points out, Claimant's expert Mr. Reddon has himself engaged in this strategy on behalf of his clients.

[47] *See e.g.*, *Astrazeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638 (aff'd 2015 FCA 158, leave application pending), para. 265 **(C-48)**; *Eli Lilly v. Novopharm*, 2009 FC 235, paras. 92-100 **(C-452)**; *Alcon Canada Inc. v. Cobalt Pharmaceuticals Co.*, 2014 FC 149 ("*Olopatadine*"), para. 56-63 **(C-353)**.

[48] *See, e.g.*, *Purdue Pharma v. Pharmascience Inc.*, 2009 FC 726, paras. 51-52 **(R-246)**; *Sanofi-Aventis Canada Inc. v. Ratiopharm Inc.*, 2010 FC 230, paras. 5, 51 **(C-465)**. This is not a uniquely Canadian principle: *see* Gervais Second Report, para. 7; Holbrook Second Report, para. 5; Lindner Second Report, para. 20.

generally been rejected by the courts."[49] This rejection is unsurprising, as such an approach effectively does away with the patent bargain with respect to "new use" and "selection" patents.

35. Indeed, if Claimant's arguments were accepted, this would be the result. Claimant argues that selection patents, for example, automatically meet the "mere scintilla" standard of utility because they have the same utility as the previously patented genus.[50] This amounts to an assertion that a selection can be patented as long as it is new and non-obvious; the utility criterion is rendered irrelevant. Such an approach plainly contradicts the requirements of the *Patent Act*, and undermines the patent bargain. Such practice is not, and has never been, permitted by the Canadian courts. Canadian law holds the patentee to its promises of utility.[51] Otherwise, the public is shortchanged in the exchange for a grant of market exclusivity.

36. The infringement action in which the validity of Claimant's patent over olanzapine was at issue offers an example of the application of this principle. Claimant argued that, "[a]lthough a number of advantages are disclosed in the Patent, they are not the utility of the Patent," and that "the advantages are relevant to obviousness and have no bearing on whether olanzapine meets the utility requirements."[52] The Federal Court of Appeal held that the advantages cited by Claimant rendered its invention non-obvious,[53] but did not accept its position that the advantages were relevant only to

[49] Dimock Second Report, para. 18. *See also Hoffmann-La Roche Ltd. v. Apotex Inc.*, 2011 FC 875, para. 22 **(R-357)**; *Olopatadine*, paras. 59-63 **(C-353)**; *Allergan Inc. v. Canada (Minister of Health)*, 2014 FC 566, para. 24 **(R-358)**.

[50] Claimant's Memorial ("Cl. Mem."), para. 98; Cl. Reply, paras.89, fn 423.

[51] Dimock Second Report, para. 150.

[52] *Eli Lilly Canada Inc., et.al. v. Novopharm Limited*, Memorandum of Fact and Law of the Appellants, Court File No. A-454-09, ("*Eli Lilly v. Novopharm, Memorandum of the Appellants*") paras. 42, 82 **(R-424)**.

[53] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197, ("*Olanzapine FCA I*"), paras. 63-64 **(R-015)** ("In the context of a selection patent, the inventive step is olanzapine, coupled with its advantages, over the compounds of the '687 Patent.").

obviousness.[54] Since Claimant had argued that the advantages formed part of the inventive concept to ensure that its selection patent was not found obvious with respect to the existing genus, it could not then rely on a different conception of the invention for the purposes of the other patentability requirements, including utility.[55] It is the Canadian courts' consideration of these promises - which Claimant itself made - that Claimant now decries.

3. *The Patent Applicant, the Patent Office and the Courts Each Play a Role in Ensuring that the Patent Bargain Is Met*

37. Many actors in the patent system play different roles in upholding the patent bargain, including, in particular, the patent applicant, the Patent Office and the courts. In its submissions, Claimant ignores the role of the applicant in shaping its patent, misunderstands the role of the Patent Office, and conveniently ignores the fact that it is the litigants (including Claimant itself) which shape the litigation before the courts, not the other way around.

a) The Applicant Determines the Scope of the Monopoly that It Seeks

38. Claimant agrees in its submissions that in seeking a patent, an applicant bears the burden of demonstrating that its invention meets all of the requirements of the *Patent Act*.[56] After all, it is the pen of the applicant, often guided by the expert advice of a patent agent and patent lawyers, that controls the contours of its invention.[57] However, Claimant does not accept the consequences of this burden: a patent applicant will be held to its own words. As noted by the House of Lords in its decision in *Kirin-Amgen*, which has been cited with approval by Canadian courts:

> The conventions of word meaning and syntax enable us to express our meanings with great accuracy and subtlety and the skilled man will

[54] *Olanzapine FCA I*, para. 90 (**R-015**).

[55] Resp. CM., paras. 54-61.

[56] *See, e.g.*, Cl. Reply, para. 24 ("This scientific research was more than sufficient to support Lilly's patents, both in Canada and around the world.").

[57] *See* Resp. CM., paras. 106-107.

> ordinarily assume that the patentee has chosen his language accordingly. As a number of judges have pointed out, the specification is a unilateral document in the words of the patentee's own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document *inter rusticos* for which broad allowances must be made.[58]

39. As discussed above, applicants will often make specific promises of utility when drafting their patent applications, particularly when there is a concern that the claimed invention could be considered anticipated (i.e., not new) or obvious, as is often the case in the context of secondary patents. As Mr. Dimock points out:

> The motivation to specify a statement of utility in the patent arises where the invention relates to an incremental advance over the prior art (for example, either because it relates to previously known compounds or concerns a well-developed field of technology that may be "crowded" with patents).[59]

40. A patentee may need to make a promise of utility to be able to say it invented anything at all.[60] For example, in its application for the '113 patent for olanzapine (a selection patent), Claimant highlighted its discovery of a "compound which possesses surprising and unexpected properties by comparison with flumezapine and other related compounds."[61] Specifically, Claimant represented that "the compound of the invention shows marked superiority, and a better side effects profile than prior known antipsychotic agents, and has a highly advantageous activity level."[62] These promises of substantial advantage were not inadvertent. Claimant needed to describe olanzapine's unexpected and substantial advantages to satisfy the novelty and non-obviousness requirements of the *Patent Act* because the compound and its use were previously

[58] *Kirin-Amgen Inc and others v. Hoechst Marion Roussel Limited and others*, [2004] UKHL 46, para. 34 (**R-425**). *See also Pfizer Canada Inc. v. Canada (Minister of Health)*, 2005 FC 1725, para. 28 (**R-454**); *Stonehouse v. Batco Manufacturing*, 2004 FC 1767, para. 71 (**R-455**).

[59] Dimock Second Report, para. 14.

[60] Dimock Second Report, paras. 12-25.

[61] Patent Specification CA 2,041,113, ("'113 Patent"), p. 3 (**R-030**).

[62] '113 Patent, p. 6 (**R-030**).

claimed in Claimant's '687 genus patent. However, making such promises also had consequences for the utility of Claimant's patent. Specifically, claiming these unexpected and substantial advantages in the patent meant that Claimant bore the burden of proving that it had demonstrated or soundly predicted them at the time of filing. It was with respect to this condition that Claimant ultimately failed.

b) The Patent Office Determines Whether the Patentability Requirements of the Patent Act Are Met Based On the Record Before It

41. In its Counter-Memorial, Canada set out the role of the Patent Office in assessing patent applications and upholding the requirements of the *Patent Act*.[63] In response, Claimant has created a straw man, accusing Canada of "diminish[ing] and impugn[ing] the work of examiners," and characterizing Patent Office examinations as "cursory, non-substantive reviews."[64] These characterizations are not found in Canada's submissions.

42. It is undisputed that the Patent Office is acutely aware of the patent bargain and the special manner in which it is upheld in the context of new use and selection patents. Canadian patent examiners understand that the utility of a new use or selection patent is necessarily enhanced relative to the "primary" patent to which it relates.[65] Otherwise, "the applicant gives nothing in return for the patent monopoly sought for the alleged invention."[66]As Dr. Gillen describes:

> Examiners working in [the biotechnology and chemistry sectors] (including pharmaceuticals) typically spend more time assessing utility for new use and selection patents than for new compound and genus patents. This is because the new use, or newly identified advantages of the selection over the genus, forms the basis for the invention.[67]

[63] Resp. CM., paras. 67-76. *See also* Dimock First Report, paras. 20-26; Gillen First Statement, paras. 11-16.

[64] *See, e.g.*, Cl. Reply, paras. 29-34.

[65] *See* Gillen Second Statement, para. 13.

[66] Gillen Second Statement, para. 13.

[67] Gillen Second Statement, para. 10.

43. However, the fact is that examiners still apply certain presumptions in favour of the patentee, with the system recognizing that it is ultimately the Canadian courts that may be called upon to determine whether the patent bargain is met and the patent properly granted. Canada's purpose of identifying the systemic limitations of the Patent Office[68] was not to diminish the importance and substantive nature of patent examiners' review of applications. Rather, by contrasting the fundamentally different design of Patent Office review with litigation before the courts, Canada was demonstrating that it is not unexpected – and certainly not arbitrary – that a court might reach a different conclusion with respect to a patent than did the Patent Office. The court makes a decision based on a more extensive record and an adversarial proceeding.[69] This is by no means a commentary on the effectiveness and competence of patent examiners; it is an observation with respect to the system's design and intended purpose.

c) The Courts Ultimately Determine a Patent's Validity Based on the Evidence and Argument Presented by Litigants

44. As discussed in Canada's Counter-Memorial, the task of adjudicating whether the patent bargain has been respected falls to the Canadian courts.[70] This can happen in two types of proceedings in Canada: a proceeding under the PM(NOC) regulations or an impeachment or infringement action.[71]

45. As mentioned above, Canada's linkage regime, the PM(NOC) regulations, requires a generic pharmaceutical company to challenge the validity of a patent prior to being allowed to enter the market. Accordingly, the PM(NOC) regulations provide pharmaceutical patent holders with an additional mechanism to assert their patent rights

[68] Resp. CM., paras. 70-72; Gillen First Statement, paras. 11-16.

[69] *See* Gillen First Statement, para. 15 ("Courts have the benefit of often substantial competing expert and fact evidence on technical issues relevant to a patent's validity, generated in an adversarial context… It would be inefficient for such extensive resources to be used by the Patent Office during its examination of patent applications. If the Patent Office subjected every single patent application to that sort of extensive review, the entire system would grind to a halt."); *See also* Resp. CM., para. 71.

[70] Resp. CM., paras. 77-80.

[71] Dimock First Report, paras. 41-45.

which is not available to the holders of other types of patents.[72] In a PM(NOC) proceeding, the Federal Court determines whether the allegations of patent invalidity made by a generic manufacturer seeking to enter the market are justified, and renders a decision. A PM(NOC) proceeding is more summary in nature than an infringement or impeachment action, and does not involve live testimony from experts.[73] Further, a decision in a PM(NOC) proceeding is not determinative of actual patent validity, and is not binding as between the patentee and other generic companies.[74] As a result, even after a finding at the PM(NOC) stage against the validity of a patent, a patentee can still seek to protect its monopoly through infringement actions.[75]

46. A final and binding determination with respect to the validity of the patent is made by the Federal Court of Canada in the context of impeachment or infringement actions under the *Patent Act*.[76] In such actions, parties adduce extensive evidence, including *viva voce* testimony from experts, to support their arguments with respect to how a person skilled in the art would understand the patent, the scope of the prior art (particularly in relation to claims of obviousness and lack of novelty), whether the invention was useful in light of the promises in the patent, and whether there was an actual invention at the time the claim was made. These trials can last for many weeks and require the trial judge to make determinations on the construction of the patent, the credibility of witnesses and the reliability of testimony and other evidence.

47. While this has all been fully explained in Canada's Counter-Memorial and need not be repeated in detail here,[77] one point does deserve further emphasis: in an

[72] Dimock First Report, paras. 41-45.

[73] *See* Bouchard, "Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals," p 180 (**R-421**).

[74] *PM(NOC) Regulations*, s. 7 (**R-031**); Dimock First Report, para. 43. The United States has a similar provision in the *Hatch-Waxman Act* "Changing Patterns of Pharmaceutical Innovation," p. 17 (**R-423**); Bouchard, "Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals." pp. 176-177 (**R-421**).

[75] *See* Dimock Second Report, paras. 142-143.

[76] *Patent Act*, ss. 55, 60 (**R-001**).

[77] Canada described the role of the courts in adjudicating patent rights: Resp. CM., paras. 77-80.

adversarial court system, parties drive litigation and patent litigation is no exception. The manner in which a patent's validity is challenged and defended has a profound effect on the manner in which the patent's validity will be decided. Indeed, the grounds on which a patent is challenged and the evidence the parties choose to lead will greatly impact the outcome of the litigation.[78] The parties' decisions in these respects are necessarily grounded in the way the challenged patent is drafted and supported.

48. Claimant accuses the Canadian courts of "scouring" a patent for promises, as though they engage in a rogue investigation completely divorced from the evidence and arguments before them.[79] But as Mr. Dimock points out, the "scouring" language seems to be unique to Claimant's submissions in this proceeding.[80] Courts do not "scour" a patent for promises; parties and their patent lawyers do.[81]

49. For example, in the proceeding during which the validity of Claimant's olanzapine patent was at issue, the generic challenger argued, *inter alia*, that Claimant's olanzapine patent was invalid because it was obvious, because the subject matter of certain of its claims was not "patentably distinct over the subject-matter of the claims of the [genus] patent" (a double-patenting argument),[82] and because it lacked utility.

50. In response, Claimant identified the discovery of olanzapine's numerous advantages over its genus as set out in the patent's disclosure as the "inventive step" of the invention for the purposes of overcoming the generic's obviousness claim.[83] As the

[78] Canada described the role of the courts in adjudicating patent rights: Resp. CM., paras. 77-80.

[79] *See* Cl. Reply, paras. 73, 79, 174, 177, 178.

[80] Dimock Second Report, para. 74.

[81] Dimock Second Report, para. 75 ("The courts are not 'scouring the patents for promises', as both Professor Siebrasse and Mr. Reddon seemingly independently state. Rather it is the parties in pharmaceutical litigation – and not the courts – that are now placing promises made in the patents front and centre before the courts.").

[82] *Eli Lilly Canada Inc., et.al. v. Novopharm Limited*, Amended Statement of Defence and Counterclaim, Court File No. T-1048-07, paras. 12, 13, 14 ("*Eli Lilly Amended Statement of Defence and Counterclaim*") (**R-426**).

[83] *See, e.g., Eli Lilly v. Novopharm, Memorandum of the Appellants*, paras. 26-27, 40(a), 66, 73 (**R-424**).

Federal Court of Appeal emphasized, "the selection patent must promise an advantage in the sense that, if the advantage is not promised, the patentee will not be able to rely on the advantage to support the patent's validity."[84] As such, it was not the Court that "scoured" Claimant's patent to identify statements of advantage, it was Claimant itself that did so in order to overcome the challenge to the patent's obviousness. In so doing, Claimant exposed itself to the weakness of its arguments in support of how it fulfilled the utility criterion. Claimant's argument that the novelty and non-obviousness requirements "are entirely separate patent requirements from … utility"[85] is precisely the argument Canadian courts have rejected in the name of fairness.[86]

B. Claimant's Invalid Raloxifene, Atomoxetine and Olanzapine Patents Were Speculative Secondary Patents

51. Claimant's Reply continues to gloss over the fact that it had already enjoyed a long history of patent protection with respect to raloxifene, atomoxetine and olanzapine when the Canadian courts were called upon to determine the validity of certain secondary patents that Claimant held with respect to these compounds. Claimant's submissions imply that it was denied the benefits of its research and development with respect to these pharmaceutical compounds. This is inaccurate and misleading. The fact is that Claimant had enjoyed monopolies relating to these compounds for years before it filed applications for the patents at issue in these proceedings.

52. With respect to raloxifene, Claimant was granted Canadian Patent No. 1,090,795 in 1980 for a genus group of compounds, including raloxifene, on the basis of such compounds being useful as antifertility agents.[87] With respect to atomoxetine, Claimant

[84] *Olanzapine FCA I*, para. 78 (**R-015**).

[85] *See, e.g.*, Cl. Reply, para. 89.

[86] *See* Dimock Second Report, para. 18. *See also Hoffmann-La Roche Ltd. v. Apotex Inc.*, 2011 FC 875, para. 22 (**R-357**) ("As Apotex argued, where advantages form part of the stated invention, it would be unfair to allow the patent holder to rely on those advantages to show that the invention as unobvious and, at the same time, dismiss those advantages as being irrelevant to utility. A patent holder cannot read up the invention for obviousness and read it down for utility.").

[87] Patent Specification 1,090,795 ("'795 Patent"), p. 2 (**R-270**).

was granted Canadian Patent No. 1,181,430 in 1985 for atomoxetine being "particularly effective" as an antidepressant.[88] Finally, with respect to olanzapine, Claimant was granted Canadian Patent No. 1,075,687 in 1980 for a genus group of compounds, including olanzapine, on the basis of such compounds being useful in the treatment of mild anxiety and certain kinds of psychotic conditions, such as schizophrenia and acute mania.[89]

53. Accordingly, contrary to what Claimant implies, by the mid-1990s Claimant had enjoyed monopoly rights with respect to raloxifene, atomoxetine and olanzapine for at least 10 years. As the patents in question were filed prior to the 1989 revisions to Canada's *Patent Act*, they had a life span of 17 years from the date they were issued.[90] Thus, by the mid-1990s as these patents were nearing the end of their lives, Claimant was searching for another way to extend their monopoly over different aspects of these compounds.

54. What followed was a "scattershot"[91] approach to patent filings that resulted in the submission speculative patent applications. Between 1992 and 2004, Claimant filed a total of 96 patent applications asserting "new uses" with respect to raloxifene (68 applications),[92] atomoxetine (12 applications)[93] and olanzapine (16 applications).[94] Unlike its earlier patent applications with respect to these compounds, which contained detailed disclosures and relied upon experimental data,[95] this newer generation of patent

[88] *See* Patent Specification CA 1,181,430 ("'430 Patent"), p. 1 **(R-269)**.

[89] '687 Patent, p. 20 **(R-292)**.

[90] *Patent Act*, s. 45(1) **(R-001)**.

[91] Brisebois First Statement, para. 68.

[92] *Id*., para. 50.

[93] *Id*., para. 50.

[94] *Id*., para. 50.

[95] With respect to its patent concerning raloxifene, *See* Patent '795, pp. 68-72 **(R-270)**. With respect to its patent concerning atomoxetine, '430 Patent, pp. 14-17 **(R-269)**. With respect to its patent concerning olanzapine, *see* '687 Patent, p. 21 **(R-292)**.

applications was largely unsupported,[96] and relied instead upon more extensive language implying that the new use had been "demonstrated".[97] Ultimately, Claimant abandoned virtually all of these applications for "new use" patents, either during prosecution or following the patent grant for failure to pay the maintenance fees.[98]

55. This practice makes it clear that Claimant was seeking to obtain patent protections at an earlier point in the inventive process than it had previously, that is, before its guesses and speculations had actually become inventions. The three patents related to raloxifene, atomoxetine and olanzapine that were eventually challenged successfully in the Federal Court were part of this same speculative practice.

56. With respect to raloxifene, Claimant filed Canadian Application No. 2,101,356 (the "'356 Patent") in July 1993 and the patent was granted in November 1998. The '356 Patent disclosure stated that the compound was useful in the prevention and treatment of osteoporosis by inhibiting bone loss. The disclosure outlined experiments that were undertaken on laboratory animals which suggested the compound's efficacy.[99]

57. With respect to atomoxetine, Claimant filed Canadian Patent Application No. 2,209,735 (the "'735 Patent") in January 1996 and it was granted in October 2002. The application for the '735 Patent was a PCT application for a new use patent. The disclosure stated that atomoxetine provides a method for treating attention-deficit/hyperactivity disorder (ADHD) but did not disclose experimental data to support such an assertion.[100]

[96] Claimant made reference to experimental data in 30 of 68 applications for new uses of raloxifene, 11 of 16 applications for new uses of olanzapine, and 7 of 12 applications for new uses of atomoxetine. Brisebois First Statement, fn 18.

[97] Brisebois First Statement, para. 62. *See also* Gillen First Statement, para. 49.

[98] Brisebois First Statement, para. 65.

[99] Patent Specification CA 2,101,356, pp. 7-8 **(R-429)**.

[100] *See* '735 Patent, pp. 8-9 **(R-026)**.

58. Finally, with respect to olanzapine, Claimant filed Canadian Patent Application No. 2,041,113 (the "'113 Patent") in 1991 for olanzapine and it was granted in July 1998. This was a selection patent, which was premised upon the statement that olanzapine "possesses surprising and unexpected properties," and delivered "surprising and excellent results" in clinical trials for treating a wide range of central nervous system disorders, including schizophrenia.[101] However, the disclosure included comparisons with only two compounds of the original genus in support of its claims of "surprising," "unexpected" and "excellent" advantages over the already patented genus.

59. In short, these patents generally relied upon bare assertions of utility that intimated that it had been demonstrated, but included limited or no reference to experimental data to support the promised utility.

60. Claimant itself acknowledges that its drafting practices were inconsistent in this regard with its earlier practices.[102] Claimant denies, however, that its patent applications became less detailed because it was engaged in speculative patenting.[103] Instead, Claimant says that the change was due to the enactment of the PCT and the need for patentees to simply comply with its "form and contents" requirements.[104] This narrative is inconsistent with undisputed facts.

61. First, neither the '356 Patent (raloxifene) nor the '113 Patent (olanzapine) were PCT applications. Accordingly, the PCT could not possibly be relevant to why Claimant drafted those patents the way that it did. Second, as Dr. Brisebois explained, roughly half of the patent applications filed by Claimant for new uses of the raloxifene, atomoxetine and olanzapine compounds in the 1990 to 2004 period did in fact contain reference to relevant experimental data supporting the asserted new use.[105] As such,

[101] *See* '113 Patent, pp. 3-4 **(R-030)**.

[102] Armitage Statement, para. 11.

[103] Cl. Reply, para. 14.

[104] Cl. Reply, para. 189.

[105] Brisebois First Statement, para. 18.

Claimant's approach to its patent filings was simply inconsistent, suggesting that it included the supporting data in its patent applications when it had it, but omitted data when it did not. Contrary to what Claimant alleges, these changes in drafting approach were unrelated to the PCT.

62. In 2004, 2005 and 2007, Claimant commenced PM(NOC) proceedings to prevent generic manufacturers from entering the market for atomoxetine, raloxifene, and olanzapine, respectively. The relevant facts of the atomoxetine and olanzapine proceedings and their outcomes have been detailed at length in Canada's Counter-Memorial and need not be repeated here.[106] The facts of the raloxifene matter will be detailed below in the jurisdiction section. In short, in each case, the Canadian courts found that Claimant had failed to uphold its end of the patent bargain, and failed to properly disclose a useful invention.

III. CLAIMANT'S CHALLENGE TO THE CANADIAN LAW ON UTILITY IS OUTSIDE THE TRIBUNAL'S JURISDICTION *RATIONAE TEMPORIS*

A. Overview

63. Claimant's Reply contained a surprising reformulation of the measures it is challenging as violations of NAFTA Chapter Eleven. In its previous submissions, the measures that were the target of Claimant's complaint were the specific Canadian court decisions that invalidated its patents for olanzapine and atomoxetine.[107] In essence, Claimant was challenging the *application* of Canada's law to its patents. Canada's Counter-Memorial definitively established why the two court decisions in question were consistent with long-standing Canadian law and did not amount to a denial of justice under international law.[108] In its Reply, Claimant expressly admits that it has no grounds to allege a denial of justice.[109] However, in an attempt to salvage its claim, Claimant has

[106] Resp. CM, paras. 22-38 (atomoxetine), 39-64 (olanzapine).

[107] Cl. Reply, para. 22; Cl. Mem., paras. 12, 14, 163, 184, 238, 239-243; Section IV(A); IV(B).

[108] Resp. CM., paras. 82-134.

[109] Cl. Reply, para. 17, fn 433.

now recast its complaint to focus not on the way in which Canadian law was applied in the two court proceedings, but instead on the law itself, that is, the judicial interpretation of the word "useful" in Canada's *Patent Act* between 2002 and 2008. Claimant's tactical switch has a serious consequence for this arbitration: its recast claim is outside the jurisdiction *rationae temporis* of the Tribunal pursuant to NAFTA Articles 1116(2) and 1117(2).

64. In the 2008 PM(NOC) proceeding of *Eli Lilly v. Apotex* that Claimant itself initiated with respect to its raloxifene patent,[110] Claimant litigated before the Federal Court the very same interpretations of Canada's *Patent Act* that it now alleges are the measures which violate NAFTA Chapter Eleven.[111] The Federal Court ruled against Claimant on February 5, 2008 by concluding that Apotex's allegations of inutility were justified with respect to the raloxifene patent. The Federal Court of Appeal upheld the decision, and the Supreme Court of Canada denied leave to appeal on October 22, 2009.[112] As a result, Apotex was permitted to enter the market and take away a portion of Claimant's previously-monopolized market with respect to raloxifene.

65. Under NAFTA Articles 1116(2) and 1117(2), if Claimant believed that the judicial doctrine applied to it by the Canadian courts in the raloxifene proceeding – the same doctrine which was later applied in the atomoxetine and olanzapine proceedings – was contrary to Canada's obligations in NAFTA Chapter Eleven, it was required to bring that claim against Canada within three years. In other words, Claimant had until October 22, 2012 – three years from the day Claimant exhausted all appeals and the raloxifene judgment became final – to launch a Chapter Eleven arbitration with respect to this claim against Canada. Claimant failed to do so, filing its Notice of Arbitration on September 12, 2013, nearly four years after it first acquired knowledge of the alleged

[110] *Eli Lilly Canada Inc. v. Apotex Inc. et al*, 2008 FC 142, ("*Raloxifene FC*") (**R-200**).

[111] *Raloxifene FC* (**R-200**); *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97 ("*Raloxifene FCA*") (**R-354**); *Eli Lilly Canada Inc. and Eli Lilly and Company Limited v. Apotex Inc. and Minister of Health*, 2009 CanLII 57517 (SCC) ("*Raloxifene SCC*") (**R-430**).

[112] *Raloxifene FCA* (**R-354**); *Raloxifene SCC* (**R-430**).

breach and suffered loss or damage.[113] Claimant's reformulated attack on judicial interpretations that are over a decade old is time-barred and, thus, outside the jurisdiction of this Tribunal.

B. Articles 1116(2) and 1117(2) Establish a Strict Three-Year Time Limit to Submit a Claim to Arbitration

66. The consent of the NAFTA Parties to arbitrate disputes with investors is not unlimited or without conditions. Article 1122(1) stipulates that a NAFTA Party's consent to arbitrate is conditioned on compliance with the procedures established in NAFTA Chapter Eleven.[114] Failure to meet those conditions vitiates consent and renders a tribunal without jurisdiction.[115]

67. Adherence to the time limits for filing a claim that are set out in Articles 1116(2) and 1117(2) is one of the pre-conditions to Canada's consent. Article 1116(2) states:

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

[113] NAFTA Article 1137(1) ("Time when a claim is submitted to arbitration) states: "1. A claim is submitted to arbitration under this Section when […] (c) the notice of arbitration given under the UNCITRAL Arbitration Rules is received by the disputing Party." The *Feldman* tribunal concluded that the time bar clock is stopped at the filing of the NOA, not the NOI. *See Marvin Feldman v. Mexico*, ICSID Case No. ARB(AF)/99/1, Interim Decision on Preliminary Jurisdiction Issues, 6 December 2000, para. 44 **(RL-115)**.

[114] NAFTA Article 1122 (Consent to Arbitration) states: "Each Party consents to the submission of a claim to arbitration in accordance with the procedures set out in this Agreement."

[115] *Methanex Corporation v. United States of America*, UNCITRAL, Partial Award, 7 August 2002, para. 120 **(RL-088)**. ("In order to establish the necessary consent to arbitration, it is sufficient to show (i) that Chapter 11 applies in the first place, i.e. that the requirements of Article 1101 are met, and (ii) that a claim has been brought by a claimant investor in accordance with Articles 1116 and 1117 (and that all pre-conditions and formalities required under Articles 1118-1121 are satisfied). Where these requirements are met by a claimant, Article 1122 is satisfied; and the NAFTA Party's consent to arbitration is established."); *Apotex Holdings Inc., Apotex Inc. v. United States of America*, ICSID Case No.ARB(AF)/12/1, Award, 25 August 2014, para. 335 ("*Apotex Award*") **(RL-016)** (concluding that the tribunal had no jurisdiction *rationae temporis* over measures that fell outside NAFTA Chapter Eleven's three-year limitations period); *Bilcon of Delaware Inc. v. Government of Canada*, PCA/UNCITRAL, Award (17 March 2015), ("*Bilcon Award*"), paras. 266-282, 742 **(CL-166)** (finding that events that occurred outside the three-year limitations period were beyond the tribunal's jurisdiction).

68. Similarly, Article 1117(2) provides:

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

69. As Professor Reisman succinctly explained in an expert report in a previous NAFTA dispute:

> It takes great effort to misunderstand Article 1116(2). It establishes that the challenge of the compatibility of the measure must be made within three years of first acquiring (i) knowledge of the measure and (ii) that the measure carries economic cost for those subject to it. If the challenge is not made within those three years, it is time-barred.[116]

70. Several NAFTA Chapter Eleven tribunals have declined jurisdiction over claims of alleged breaches that fell outside the three-year time limit. A detailed consideration of the NAFTA Chapter Eleven limitations period is set out in *Grand River Enterprises Six Nations Ltd. v. United States*.[117] In that case, the claimant commenced a NAFTA Chapter Eleven arbitration on March 12, 2004, alleging NAFTA violations arising from a 1998 tobacco litigation Master Settlement Agreement (MSA) and subsequent state actions taken pursuant to the MSA.[118] The United States challenged the tribunal's jurisdiction over the claim on the ground that it was time barred by Article 1116(2). The *Grand River* tribunal agreed with the United States finding that claims based on the MSA and subsequent measures taken pursuant to the MSA were untimely.[119] In its

[116] W. Michael Reisman, Opinion with Respect to the Effect of NAFTA Article 1116(2) on Merrill & Ring's Claim, April 22, 2008, para. 28, ("Reisman Expert Opinion") **(R-431)**.

[117] *Grand River Enterprises Six Nations, Ltd., et al. v. United States of America*, UNCITRAL, Decision on Objections to Jurisdiction, 20 July 2006 ("*Grand River Decision on Objections to Jurisdiction*"), para. 38 **(RL-090)**.

[118] *Grand River Decision on Objections to Jurisdiction*, para. 24 **(RL-090)**.

[119] *Grand River Decision on Objections to Jurisdiction*, paras. 103-104 **(RL-090)**. The only claim it reserved for consideration on the merits was one based on separate and distinct legislation adopted by individual states after March 12, 2001 (i.e., within the applicable three-year limitation period).

award, the tribunal confirmed that NAFTA imposes a strict three-year limitations period on NAFTA Chapter Eleven claims.[120]

71. More recent NAFTA tribunals have also ruled particular claims outside their jurisdiction *rationae temporis* because the claimant had first acquired knowledge of the alleged breach and that it had suffered a loss more than three years prior to filing a notice of arbitration. In *Apotex v. United States* the tribunal agreed with the United States that the claimant's allegation that a decision by the United States Food and Drug Administration that prevented Apotex from bringing one of its drugs to market was time-barred because it was taken more than three years before the Notice of Arbitration was filed.[121] Similarly, the *Bilcon v. Canada* tribunal found that various decisions and actions by government officials relating to the claimant's investment in a quarry could not be the basis of a NAFTA claim because they fell outside of the three-year limitations period set out in Articles 1116 and 1117.[122] Each of these tribunals recognized that the trigger for the limitations period for an alleged breach starts from the moment the claimant *first* acquires knowledge of the breach and knowledge that it has suffered some type of cognizable loss or damage.

C. The Time Limit in NAFTA Articles 1116(2) and 1117(2) Begins to Run from the First Date a Claimant Acquires Knowledge of the Alleged Breach and a Loss

72. The use of the word "first" is critical to the ordinary meaning of Articles 1116(2) and 1117(2) because it identifies the precise moment at which the three-year time

[120] *Grand River Decision on Objections to Jurisdiction*, para. 29 (**RL-090**). *See also Marvin Feldman v. Mexico*, ICSID Case No. ARB(AF)/99/1, Award, 16 December 2002, ("*Feldman Award*"), para. 63 (**RL-058**). The *Grand River* tribunal characterized "actual knowledge" of the breach and of loss or damage as "foremost a question of fact," whereas constructive knowledge could be imputed to an investor if it can be shown that the investor would have known that fact had it exercised reasonable care or diligence. *See Grand River Decision on Objections to Jurisdiction*, paras. 54, 58-59 (**RL-090**).

[121] *Apotex Award*, paras. 314-335 (**RL-016**) (finding that the FDA's 11 April 2006 decision could not be the basis for a NAFTA claim because it occurred more than three-years prior to when Apotex filed its Notice of Arbitration (4 June 2009)).

[122] *Bilcon Award*, paras. 258-282 (**CL-166**).

limitation begins to run. The word "first" means "earliest in occurrence, existence."[123] The inclusion of "first" to modify the phrase "acquired knowledge" was a deliberate drafting choice of the NAFTA Parties intended to mark the beginning of the time when knowledge of breach and a loss existed, and not the middle or end of a continuous event or series of events. In other words, once the investor first acquires knowledge of the alleged breach and that it has suffered damage, the limitations period for filing a claim commences and will end at the three-year mark regardless of whether the impugned measure continues thereafter.

73. All three NAFTA Parties have made it clear on numerous occasions that this is the proper interpretation of Articles 1116(2) and 1117(2). For example, in its NAFTA Article 1128 non-disputing Party submission to the tribunal in *Merrill & Ring v. Canada*, the United States wrote:

> An investor *first* acquires knowledge of an alleged breach and loss at a particular moment in time: under Article 1116(2), that knowledge is acquired on a particular 'date'. Such knowledge cannot *first* be acquired on multiple dates, nor can such knowledge *first* be acquired on a recurring basis...
>
> [O]nce an investor first acquires knowledge of breach and loss, subsequent transgressions by the state arising from a continuing course of conduct do not renew the limitations period under Article 1116(2).[124]

74. Mexico concurred "in its entirety" with the United States Article 1128 submission in *Merrill & Ring*.[125] In other words, the two non-disputing NAFTA Parties endorsed precisely what Canada had argued in that case, that is, an allegation that an

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

[124] *Merrill & Ring Forestry L.P. v. Canada*, UNCITRAL, 1128 Submission of the United States, 14 July 2008, ("*Merrill & Ring Submission of the United States*"), para. 5 **(RL-091)**; As Professor Reisman has explained, "an investor does not and logically cannot 'first acquire' knowledge of the allegedly incompatible measure that constitutes the challenged 'breach' *repeatedly*." Reisman Expert Opinion, para. 29 (emphasis in original) **(R-431)**.

[125] *See Merrill & Ring Forestry L.P. v. Canada*, UNCITRAL, 1128 Submission of Mexico, 2 April 2009 ("*Merrill & Ring Submission of Mexico*"), para. 5 **(RL-092)**.

alleged breach of NAFTA Chapter Eleven is continuing does not stop the time-bar clock.[126]

75. The United States reiterated exactly the same position in its recent Article 1128 submissions to the tribunal in *Bilcon v. Canada*,[127] *Detroit International Bridge Company v. Canada*,[128] and *Mercer v. Canada*.[129] Mexico's concurring view that "the three-year limitations period cannot be extended by an allegation that the alleged violation has continued" reflects its own long-standing position[130] and is the same position consistently taken by Canada with respect to Articles 1116(2) and 1117(2).[131] The clear and consistent position of the United States, Mexico and Canada on this issue constitutes a "subsequent agreement between the parties regarding the interpretation of

[126] *Merrill & Ring Forestry L.P. v. Government of Canada*, UNCITRAL, Rejoinder Memorial, 27 March 2009, ("*Merrill & Ring Rejoinder Memorial*"), para. 36 **(RL-093)**.

[127] *William Ralph Clayton,William Richard Clayton, Douglas Clayton, Daniel Clayton, and Bilcon Of Delaware Inc. v. Government of Canada*, UNICTRAL, Submission of the United States of America, 19 April 2013, para. 12 **(RL-094)**. In the footnote following this paragraph, the United States noted: "The United States' views on the interpretation of NAFTA Articles 1116(2) and 1117(2) are reflected in the attached non-disputing Party submission of July 14, 2008 in the NAFTA Chapter Eleven case *Merrill & Ring Forestry, L.P. v. Canada*."

[128] *Detroit International Bridge Co. v. Canada*, NAFTA/UNCITRAL, (PCA Case No. 2012-25) Submission of the United States of America, 14 February 2014, ("*DIBC Submission of the United States*"), para. 3 **(RL-095)**.

[129] *Mercer International Inc. v. Government of Canada*, ICSID Case No. ARB(AF)/12/(3), Submission of the United States of America, 8 May 2015, ("*Mercer Submission of the United States*"), paras. 4-6 **(RL-097)**.

[130] *Detroit International Bridge Co. v. Canada*, NAFTA/UNCITRAL, (PCA Case No. 2012-25), Submission of Mexico Pursuant to Article 1128 of NAFTA, 14 February 2014, para. 21 **(RL-096)**; *Merrill & Ring Submission of Mexico* **(RL-092)**; *Marvin Feldman v. Mexico*, ICSID Case No. ARB(AF)/99/1, Respondent's Counter-Memorial on Preliminary Questions, 8 September 2000, paras. 189, 199 **(RL-098)**.

[131] *Bilcon of Delaware Inc. v. Government of Canada*, PCA/UNCITRAL, Rejoinder, 21 March 2013, paras. 54-60 **(RL-099)**; *Merrill & Ring Rejoinder Memorial*, paras. 24-51 **(RL-093)**; *Detroit International Bridge Co. v. Canada*, NAFTA/UNCITRAL (PCA Case No. 2012-25), Canada's Memorial on Jurisdiction and Admissibility, 15 June 2013, paras. 206-214 **(RL-100)**; *Detroit International Bridge Co. v. Canada*, NAFTA/UNCITRAL (PCA Case No. 2012-25), Canada's Reply Memorial on Jurisdiction and Admissibility, 6 December 2013, paras. 153-156 **(RL-101)**; *Detroit International Bridge Co. v. Canada*, NAFTA/UNCITRAL (PCA Case No. 2012-25), Canada's Reply to NAFTA Article 1128 Submissions, 3 March 2014, ("*DIBC Canada's Reply to NAFTA Article 1128 Submissions*"), paras. 26-33 **(RL-102)**.

the treaty" and/or "subsequent practice" which "shall be taken into account" when interpreting NAFTA.[132]

76. In accordance with this authoritative interpretation, the fact that a measure may have a continuing effect on an investor, or that it may be applied more than once to that same investor over a period of time, is irrelevant for the purposes of Articles 1116(2) and 1117(2). Similarly, the fact that a claimant may not know "the extent of quantification of the loss or damage"[133] or that "the amount or extent may not become known until some future time"[134] does not matter. The sole relevant question is when the claimant first acquired knowledge of the breach and some loss.

77. Tribunals interpreting these provisions have agreed with the NAFTA Parties' shared views. The *Feldman v. Mexico* tribunal described NAFTA Chapter Eleven's "clear-cut" three-year limitations period as "a clear and rigid limitation defense, which, as such, is not subject to any suspension…, prolongation or other qualification."[135] Similarly, the Tribunal in *Grand River* rejected the idea that subsequent acts allowed the Claimant to evade the three-year deadline to file a claim, explaining:

> [T]his analysis seems to render the limitations provisions ineffective in any situation involving a series of similar and related actions by a respondent state, since a claimant would be free to base its claim on the most recent transgression, even if it had knowledge of earlier breaches and injuries.[136]

[132] United Nations, *Vienna Convention on the Law of Treaties*, 23 May 1969, Article 31(3)(a)(b) **(RL-072)** ("There shall be taken into account…(a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions.").

[133] *Mondev International Ltd. v. The United States of America* (ICSID Case No. ARB(AF)/99/2) Award, 11 October 2002, para. 87 ("*Mondev Award*") **(RL-004)**.

[134] *Grand River Decision on Objections to Jurisdiction*, paras. 77-78 **(RL-090)**.

[135] *Feldman Award*, para. 63 (emphasis added and citation omitted) **(RL-058)**; *See also Grand River Decision on Objections to Jurisdiction*, para. 29 **(RL-090)**.

[136] *Grand River Decision on Objections to Jurisdiction*, para. 81 **(RL-090)**. *See also Merrill & Ring Submission of the United States*, para. 7 **(RL-091)**.

78. The only NAFTA tribunal which suggested that the continued application or effect of an impugned measure extends the limitations period until the measure is revoked is *UPS v. Canada*.[137] In that case, the claimant unsuccessfully challenged various aspects of Canada's customs laws and access to the Canadian postal infrastructure.[138] The measures at issue were first implemented by Canada three years before the NAFTA claim was made, but UPS argued that Canada's conduct was ongoing and constituted a new violation of NAFTA each day.[139] The *UPS* tribunal, in a single paragraph and without analysis or reference to any case law or other material, agreed with that position.[140]

79. All three NAFTA Parties agree that the *UPS* tribunal was incorrect on this issue.[141] The *UPS* tribunal did not address the fact that, whatever principles on continuing breaches may or may not exist in general international law, they cannot supersede the *lex specialis* specifically imposed by the NAFTA Parties in the treaty.[142] The *UPS* tribunal's interpretation fails to give the word "first" meaning and, thus, runs afoul of the principle of interpretation of *effet utile*.[143] As the United States wrote in its submission in *Merrill and Ring*:

> Under the *UPS* tribunal's reading of Article 1116(2), for any continuing course of conduct the term 'first acquired' would in effect mean 'last acquired,' given that the limitations period would fail to renew only

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

[138] *UPS Merits Award*, paras. 11-13 **(RL-103)**.

[139] *Id.*, paras. 22-24 **(RL-103)**.

[140] *UPS Merits Award*, para. 28 **(RL-103)**.

[141] *DIBC Canada's Reply to NAFTA Article 1128 Submissions*, paras. 26-33 **(RL-102)**; *Merrill & Ring Submission of the United States*, 14 July 2008, paras. 5, 10. **(RL-091)**; *See also Merrill & Ring Submission of Mexico* **(RL-092)**.

[142] The *UPS* Tribunal characterized its finding that limitations periods are renewed by continuing courses of conduct as "true generally in the law". Whether or not this is accurate, such a general principle cannot override the specific requirements of Articles 1116(2) and 1117(2) which specifically govern the operation of the limitations periods for claims brought under NAFTA Chapter Eleven.

[143] The doctrine of *effet utile* is also known as the doctrine of effectiveness, *See e.g*. Lord McNair, *The Law of Treaties* (Oxford: Clarendon Press, 1961) (reprinted 2003), pp. 383-392 **(R-433)**.

> after an investor acquired knowledge of the state's *final* transgression in a series of similar and related actions. Accordingly, the specific use of the term 'first acquired' under Article 1116(2) is contrary to the *UPS* tribunal's finding that a continuing course of conduct renews the NAFTA Chapter Eleven limitations period.[144]

80. No other NAFTA tribunal has endorsed the *UPS* tribunal's idea that a continuing breach tolls the three-year limitations period. In short, the fact that a measure may be applied to a claimant in a way that has a continuing effect, or that it may be applied many times after original adoption, is irrelevant to whether an action is timely brought under Articles 1116(2) and 1117(2). Interpreting the time limitation in Articles 1116(2) and 1117(2) to begin running anew from each date on which an investor knows of a new application of the measure to a particular investment or to another one of its investments would read the requirement of "first" out of Articles 1116 and 1117.

D. Claimant Failed to Submit Its Claims Challenging the Canadian Law of Utility Within the Prescribed Three-Year Time Limit

1. *Claimant Is Now Challenging the Judicial Interpretation of Canada's Patent Act*

81. Prior to its Reply, Claimant appeared to challenge the particular judicial invalidations of its olanzapine and atomoxetine patents, while simultaneously referring to more nebulous "measures" for which it failed to provide particulars.[145] For example, Claimant's Notice of Arbitration ("NOA") cited the "common law promise doctrine as applied to the Strattera and Zyprexa patents and Canada's failure to rectify the promise doctrine" as the relevant "measures."[146]

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[144] *Merrill & Ring Submission of the United States*, para. 10 (emphasis in original) **(RL-091)**. This submission was supported by Mexico; *See Merrill & Ring Submission of Mexico*, p. 5 **(RL-092)**.

[145] Claimant's previous position was that the law, as the courts had interpreted it, had been wrongly applied to its patents. Claimant's argument in regards to the promise utility doctrine itself was its alleged unpredictability. Cl. Mem., paras. 8, 19, 57, 61, 64, 65, 258, 262, 263, 264.

[146] NOA dated September 12, 2013, designated as the Statement of Claim, para. 81.

82. Canada raised the inconsistency and ambiguity of Claimant's challenge in its Statement of Defence,[147] explaining that:

> Claimant fails to provide any particulars of this allegation [the failure to rectify the allegedly judge-made law], nor demonstrate how this alleged measure (if any) resulted in any damages to its investments. Canada reserves the right to respond to this allegation, including to raise jurisdictional objections, as appropriate, should Claimant pursue claims in respect of this alleged measure in any future submissions.[148]

83. In its Memorial, Claimant repeatedly referred to "Canada's measures in respect of the Zyprexa and Strattera patents"[149] and to "the Federal Courts' application of the promise utility doctrine" in the specific proceedings which invalidated its patents.[150] In all of these submissions, while the precise claim was ambiguous, Claimant consistently tied its argument to the court decisions invalidating its patents for atomoxetine and olanzapine.

84. As a result, Canada understood Claimant to be challenging solely the judicial invalidations of its two specific patents. Accordingly, Canada set out in its Counter-Memorial details as to the fairness of the proceedings and the opportunity Claimant had to present its case. In so doing, Canada definitively established that Claimant did not suffer a denial of justice with respect to the invalidation of its atomoxetine and olanzapine patents.

85. It was only at the document production stage, after Canada filed its Counter-Memorial, that Claimant began to reorient its claims. For example, in its objections to Canada's document requests, Claimant alleged that the "measure" it was actually challenging in these NAFTA proceedings was as follows:

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[147] Statement of Defence ("*SOD*") 30 June 2014, paras. 80-81.

[148] *SOD*, para. 80 (emphasis added).

[149] Cl. Mem., para. 13.

[150] Cl. Mem., para. 218 (emphasis added).

> The measure at issue in this proceeding is Canada's development of a new utility doctrine (the promise utility doctrine), and its retroactive application of that doctrine to invalidate Claimant's '113 and '735 Patents. Both of those patents were invalidated by the Federal Court on a single ground: inutility.[151]

86. In response, Canada immediately objected to this reorientation, noting:

> Claimant mischaracterizes the measures at issue. In order to establish jurisdiction in this matter, Claimant stated the measures to be the invalidation of two of its patents by the Federal Court. Having asked the Tribunal to assert jurisdiction on the basis of these two specific measures, Claimant cannot now recast the measure as "Canada's development of a new utility doctrine." This goes beyond the Tribunal's jurisdiction, extending to an undefined time period and cases involving unspecified patents that did not form any part of Claimant's investment.[152]

87. Despite Canada's objection, in its Reply, Claimant definitively moved away from its previous claims with respect to the specific court decisions invalidating its atomoxetine and olanzapine patents. Indeed, Claimant now agrees that it received a fair process in the Canadian courts, and that the courts properly applied Canadian law to its atomoxetine and olanzapine patents.[153] Claimant now challenges three aspects of Canadian law that allegedly emerged in judicial decisions rendered between 2002 and 2008.[154]

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

[152] Procedural Order No. 2, Annex B (emphasis added) (**R-434**).

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

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

88. First, it alleges that in the 2002 *AZT* decision, the Supreme Court of Canada revolutionized Canadian law by establishing a "heightened evidentiary burden," which disallowed post-filing evidence of utility (the "post-filing evidence rule").[155]

89. Second, it alleges that in the mid-2000s there was a "radical shift in Canadian law" that prompted the courts to "scour" the patent disclosure in search of a "promise" (the "promise of the patent" doctrine).[156] This "elevated standard," says Claimant, is contrary to the practice of the courts at the time it filed for its patents. At that time, Claimant asserts that a patentee needed only demonstrate a "mere scintilla" of utility, regardless of what it said in its patent.[157]

90. Third, Claimant alleges that in 2008, in a case involving itself and its patent for raloxifene, the Federal Court created an "additional disclosure rule" that requires the basis for a sound prediction of utility to be disclosed in the patent (the "sound prediction disclosure rule").[158] Claimant's expert Mr. Reddon goes so far as to describe this requirement as the "*Raloxifene* rule".[159]

91. As explained below, this shift in focus regarding the measures Claimant alleges breach NAFTA brings the claim outside the Tribunal's *rationae temporis* jurisdiction.

2. *Claimant First Acquired Knowledge of the Challenged Judicial Interpretations in the 2008 PM(NOC) Proceedings Related to its Raloxifene Patent*

92. As described above, Claimant held a patent for raloxifene (the '356 Patent), which was set to expire in July 2013.[160] Another pharmaceutical company, Apotex, sought to market a generic version of the raloxifene product before that date, and

[155] *See* Cl. Reply, paras. 92, 93.

[156] Cl. Reply, para. 73.

[157] Cl. Reply, para. 72.

[158] Cl. Reply, paras. 48, 104.

[159] Reddon First Report, para. 11.

[160] *Raloxifene FC*, para. 1 (**R-200**); '356 Patent (**R-429**).

accordingly requested that the Minister of Health issue it a Notice of Compliance (NOC). As a precondition to receiving an NOC, Apotex served its Notice of Allegation on Claimant on June 16, 2005.[161] In it, Apotex alleged that Claimant's patent was invalid on a number of grounds, including lack of soundly predicted utility.[162]

93. Claimant applied to the Federal Court on August 5, 2005 for an order prohibiting the Minister of Health from issuing an NOC to Apotex.[163] Following a PM(NOC) proceeding in which 19 expert witnesses submitted affidavit evidence,[164] the Federal Court dismissed Claimant's application. The Court found that Claimant had not demonstrated or soundly predicted utility as of the filing date, and, as a result, Apotex's allegations were justified.[165]

94. All three aspects of Canadian patent law that Claimant now challenges in this arbitration as a violation of Canada's obligations under Chapter Eleven were applied to Claimant in the raloxifene case.

a) The "Promise of the Patent" Doctrine Was Applied in the Raloxifene Proceedings

95. The Federal Court in the raloxifene case held Claimant's patent to the level of utility promised in the patent disclosure. This is the promise of the patent rule that Claimant alleges was "invented" by the Federal Court in 2005.

96. The Court canvassed the factual circumstances of the case to determine whether Claimant had made an invention that was properly disclosed and claimed.[166] The Court looked first to the patent's claims,[167] but noting that "one must both advance the state of

[161] *Raloxifene FC*, para. 3 **(R-200)**.

[162] *Id.*, para. 3 **(R-200)**.

[163] *Id.*, para. 3 **(R-200)**.

[164] *Id.*, para. 5 **(R-200)**.

[165] *Id.*, para. 163 **(R-200)**.

[166] *Id*, para. 75 **(R-200)**.

[167] *Id.*, para. 76 **(R-200)**.

the art and disclose that advance in order to gain the patent monopoly,"[168] the Court also assessed the disclosure made in Claimant's patent. Based on its analysis of the patent as a whole, the Court determined that Claimant's patent made several specific promises.[169] The Court noted that these promises were what the patentee disclosed to the public in exchange for securing its monopoly, and that the patentee would be held to these promises as a result. Consequently, the Court proceeded to evaluate whether Claimant had demonstrated or soundly predicted this promised utility as of the filing date

b) The Post-Filing Evidence Rule Was Applied in the Raloxifene Proceedings

97. The Court in the raloxifene case also applied the "heightened evidentiary burden" that Claimant alleges was developed by the Supreme Court in the 2002 *AZT* case to bar the use of post-filing evidence to show utility.

98. As part of the proceedings in the raloxifene case, both Claimant and Apotex submitted a significant amount of expert evidence to demonstrate what was known about raloxifene at the priority date.[170] Unsurprisingly, the parties' experts disagreed as to what was known, and the Court was left to determine which evidence it found most compelling.[171] Claimant argued that only Dr. Black, one of the patent's named inventors, had sufficient studies to lead him, and him alone, to predict with confidence raloxifene's effectiveness in fulfilling the patent's promise.[172] For its part, Apotex argued that the

[168] *Id.*, para. 74 **(R-200)**.

[169] *Id.*, para. 78 **(R-200)**: "Page 3 makes a promise: The current invention provides methods of inhibiting the loss of bone without the associated adverse effects of estrogen therapy, and thus serves as an effective and acceptable treatment for osteoporosis. …At pages 6 and 7 the promise of the invention is made, namely that this group of compounds inhibits bone loss but does not elicit significant estrogen responses in primary sex tissues. At page 11, we are told that the most preferred compound is raloxifene particularly as a hydrochloride salt" (emphasis added).

[170] *See Id.*, paras. 5-10, 6-7 and 8-9 **(R-200)**. Claimant filed evidence from 10 witnesses, 8 of whom were asserted to be experts, and one of whom was a named inventor on the patent. All but three were cross-examined by Apotex. For its part, Apotex filed evidence from 10 witnesses, 9 of whom were asserted to be experts. Claimant cross-examined all 9 experts.

[171] *See, e.g., Id.*, paras. 82 – 124 **(R-200)**. *See also Raloxifene FC*, para. 26 **(R-200)** ("Where the experts disagree, it is incumbent on the trial judge to make a binding determination.").

[172] *Id.*, para. 154 **(R-200)**.

general state of the art was sufficient to lead any person skilled in the art to predict with confidence the same conclusions stated in the patent.[173]

99. The Court framed the utility issue in the following manner:

> *Sound Prediction*: Was there a proper basis as of the priority date or the Canadian filing date for Black *et al.* to make a sound prediction as to what is claimed in the patent?[174]

100. In the Court's assessment of the existence of a sound prediction as of the patent's priority or Canadian filing date, it did not consider any evidence that post-dated the Canadian filing date of July 27, 1993. Indeed, the latest dated document considered by the Court as evidence was a study reported in a Hong Kong abstract on March 29, 1993.[175] The Court agreed with Claimant that this study was "sufficient to turn that *prediction* into a *sound* prediction."[176]

c) The Sound Prediction Disclosure Rule Was Applied in the Raloxifene Proceedings

101. The Court also applied the third aspect of Canadian law disputed by Claimant, the "sound prediction disclosure rule," in the raloxifene proceedings. Specifically, the Federal Court applied the three-part framework for sound prediction, asking whether there was: (i) a sound basis for prediction, (ii) an articulable and sound line of reasoning to infer the result, and (iii) proper disclosure.[177] The Court held that in light of the Hong Kong study described in the 1993 abstract, Claimant could have satisfied the first two branches of the sound prediction framework.

102. However, under the third branch, the Court did not permit Claimant to rely on the Hong Kong Study to establish a sound prediction of utility because the study was not

[173] *Id.*, para. 153 **(R-200)**.

[174] *Id.* para. 126 (emphasis added) **(R-200)**.

[175] *See Raloxifene FC*, para. 120 **(R-200)**.

[176] *Id.*, paras. 156-157 **(R-200)**.

[177] *Id.*, para. 160 **(R-200)**.

disclosed in the patent application.[178] The Court recalled the essential principle that had been restated in *AZT:* "the disclosure must be in the patent, not elsewhere."[179] As noted, Claimant alleges that this was the first time that such a rule had ever been applied and even labels it the "*Raloxifene* rule."[180]

103. Claimant argued before the Federal Court (just as it does now before this Tribunal) that it was not required under the PCT to set out any more than the minimum disclosure in its patent.[181] The PCT's "form and content" requirements, Claimant argued, limit the necessity of a patentee to make disclosure.[182] In essence, it made exactly the same argument in the Canadian courts in 2008 that it is making before this Tribunal more than three years later. The Federal Court disagreed with Claimant, stating that "procedural matters, form and content, to the extent that content is not otherwise governed by substantive conditions of patentability, are to be compliant with general PCT provisions. National law prevails where 'substantive' legislation and jurisprudence affect content."[183]

3. *Claimant Incurred a Loss as a Result of the Challenged Judicial Interpretations in 2009, More than Three Years Before Submitting This Claim to Arbitration*

104. Claimant appealed the Federal Court's decision in the *raloxifene* case to the Federal Court of Appeal on the grounds that the Federal Court erred by requiring the basis of the sound prediction to be disclosed in the patent. The Federal Court of Appeal affirmed the trial court's decision on March 25, 2009.[184] In doing so, it held that "where the claimed invention had not yet actually been reduced to practice, the patent must

[178] *Id.*, paras. 162-163 **(R-200)**.

[179] *Id.*, para. 164 **(R-200)**.

[180] Reddon Report, para. 11.

[181] *Raloxifene FC*, para. 164 **(R-200)**.

[182] *Id.*, para. 169 **(R-200)**.

[183] *Id.*, para. 164 **(R-200)**.

[184] *Raloxifene FCA* **(R-354)**.

provide a disclosure such that a person skilled in the art, given that disclosure, could have as the inventors did, soundly predicted that the invention would work once reduced to practice."[185] It recognized that "disclosure is the *quid pro quo* for valuable proprietary rights to exclusivity."[186] The Federal Court of Appeal was equally clear in rejecting Claimant's arguments about the PCT, stating that:

> [The PCT] 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.[187]

105. On March 30, 2009, the Minister of Health issued an NOC to Apotex.[188] As a result, Apotex was allowed to enter the market with its generic raloxifene product. Accordingly, on this date, Claimant suffered a loss as a result of the exact interpretations of Canadian law that it is challenging as a breach of NAFTA in this arbitration.

106. Claimant sought leave to appeal the decision to the Supreme Court of Canada but the Supreme Court denied on October 22, 2009.[189]

107. The fact that the raloxifene decision was rendered in the context of a PM(NOC) proceeding, and not of an impeachment or an infringement proceeding, is irrelevant. There is no dispute that a PM(NOC) proceeding does not invalidate a patent. As such, even after Apotex was allowed to enter the market under an NOC issued by the Minister of Health in March 2009, Claimant still held a valid patent in Canadian law with respect to raloxifene. Nevertheless, the specific judicial doctrine which Claimant now alleges is a violation of NAFTA was undoubtedly applied to the Claimant in this proceeding. Further, there can be no dispute that Apotex's entrance into the market caused Claimant

[185] *Id.*, para. 18 **(R-354)**.

[186] *Raloxifene FC*, para. 71, citing *AZT*, para. 37 **(R-200)**.

[187] *Raloxifene FCA*, para. 19 **(R-354)**.

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

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

loss. In this regard, it is telling that in its statistical analyses, Claimant expressly equates PM(NOC) decisions with decisions on patent validity.[190] As explained above, under NAFTA, all that is required for the limitations period to begin to run is that a claimant suffers a cognizable "loss" as a result of the alleged breach. The extent of that loss need not be specifically quantified in order for the limitations period to commence.

108. Similarly, the fact that the measure was applied and the loss was suffered with respect to Claimant's raloxifene patent, rather than its patents over atomoxetine and olanzapine is also irrelevant. NAFTA Articles 1116(2) and 1117(2) make clear that the limitations period begins to run from the "first" moment that that the "investor" has knowledge of the alleged NAFTA breach and loss. As succinctly explained by the United States in its Article 1128 submission in *Merrill & Ring*, "knowledge cannot *first* be acquired on multiple dates, nor can such knowledge *first* be acquired on a recurring basis."[191]

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

[190] *See* Levin Report, Appendix C, stating "The chart that follows shows all patent validity cases heard in the Federal Court of Canada and decided between January 1, 1980 and August 10, 2015." The list includes both PM(NOC) cases (*e.g. Aventis Pharma Inc. v. Apotex*, 2006 FCA 64, listed at Levin Report, Appendix C, p. 10) and infringement/impeachment actions (*e.g. Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2011 FCA 300, listed at Levin Report, Appendix C, p. 14). Both of these proceedings relate to the same patent. As Canada will discuss in greater detail below, this double-counting is one of the many flaws afflicting Claimant's data set.

[191] *Merrill & Ring Submission of the United States*, para. 5 (emphasis in original) **(RL-091)**; *DIBC Submission of the United States*, para. 5 **(RL-095)**; *Mercer Submission of the United States*, para. 4 **(RL-097)**; As Professor Reisman has explained, "an investor does not and logically cannot 'first acquire' knowledge of the allegedly incompatible measure that constitutes the challenged 'breach' *repeatedly*." Reisman Expert Opinion, para. 29 (emphasis in original) **(R-431)**.

110. In sum, Claimant first acquired knowledge of all relevant aspects of what it calls Canada's "promise utility doctrine" and a loss as a result of that doctrine no later than October 22, 2009 when the Supreme Court of Canada denied it leave to appeal the raloxifene decision. However, Claimant did not submit this claim to arbitration until September 12, 2013 – nearly four years after that date. As such, Claimant failed to satisfy the preconditions to Canada's consent to arbitrate articulated in Articles 1116(2) and 1117(2). Its challenge to the interpretations of the *Patent Act* rendered by the Canadian Courts between 2002 and 2008 are, therefore, beyond the jurisdiction of the Tribunal.

111. As a result, the only claim that is available to Claimant is that it was denied justice by the specific court proceedings that invalidated its atomoxetine and olanzapine patents. Indeed, Canada has consistently stated since its Statement of Defence that any other claim would be beyond the Tribunal's jurisdiction. As Canada has already proven in its Counter-Memorial, and as Claimant conceded in its Reply,[192] there was no denial of justice, Claimant's case must be dismissed in its entirety.

112. However, even if this Tribunal were to find that Claimant's reoriented claim is not time-barred, both Canada's law and its application to Claimant's patents by Canadian courts were consistent with Canada's obligations under Articles 1110 and 1105 of NAFTA. As Canada will show below, Claimant's allegations are meritless and should be dismissed.

IV. CANADA'S LAW ON UTILITY AND ITS APPLICATION TO CLAIMANT'S PATENTS ARE NOT AN UNLAWFUL EXPROPRIATION IN BREACH OF ARTICLE 1110

A. Overview

113. Claimant alleges that the interpretations of the term "useful" in the *Patent Act* by the Canadian courts over the last decade resulted in the unlawful expropriation of two of its patents. Such a claim, if allowed, would have far-ranging implications that no

[192] *See* Cl. Reply, para. 17.

NAFTA Party agreed to. It would subject the decisions of domestic courts concerning the existence of property rights at domestic law to reconsideration by investor-State tribunals. It would also force a degree of intellectual property law harmonization that neither the NAFTA Parties, nor other States that are party to substantive intellectual property treaties such as TRIPS, ever conceived possible when those treaties were signed. The serious implications for the entire system of investment treaty arbitration are obvious. On Claimant's view of Article 1110, whenever a court in a NAFTA Party invalidates an investor's patent, the investor will have a supra-national right of appeal to determine whether the domestic court correctly applied the highly specific patentability criteria that Claimant reads into NAFTA Chapter Seventeen. This Tribunal should decline Claimant's invitation to drastically transform both the international investment and intellectual property regimes in this way.

114. In the following sections, Canada demonstrates the multiple flaws in Claimant's position on Article 1110. First, Claimant ignores the function of the courts in determining whether a property right exists at domestic law. The determinations that Claimant's patents were invalid are not measures capable of constituting expropriations for a simple reason – they are measures determining that property never existed, not measures taking that property. Second, Claimant cannot overcome Article 1110(7), which is a further, independent hurdle to establishing an expropriation in this case. Canada's measures were consistent with its obligations under Chapter Seventeen; hence, Article 1110 does not apply. For both of these reasons, the Tribunal should refuse to further consider the merits of Claimant's Article 1110 claim.

115. In any case, for the sake of providing a complete response to Claimant's meritless allegations, Canada's judicial measures do not constitute an unlawful expropriation. Claimant has invented a theory of judicial expropriation that has no grounding in international law, which has long recognized that domestic court determinations of rights only attract liability at international law when there is a denial of justice. Moreover, even if denial of justice were not the only available cause of action

to challenge a judicial measure, the conduct challenged here does not meet the conditions necessary to be considered an unlawful direct or indirect expropriation.

B. A Judicial Determination That a Patent Is Invalid Does Not Engage the Obligations Under Article 1110

116. Canada explained in its Counter-Memorial that the first step in an expropriation analysis under Article 1110 is to determine whether Claimant holds valid property rights capable of being taken.[193] Claimant agrees that it is the host State law that creates the property rights protected by the international law of expropriation.[194] Thus, it agrees that whether such a property right exists under domestic law is the critical starting point of the analysis. However, Claimant refuses to accept the consequence of that basic premise.

117. Claimant argues that the fact that patent rights are subject to adjudication by the courts shows that they are no different than any other property right, "title to which may be challenged in later litigation."[195] This analogy is inapt. In a title challenge, there is no question that the property exists – the issue before the courts in that instance is who has the right to the title or possession of that property. This is not the case when patent validity is adjudicated. Under Canadian law, if the court determines that a patent right is invalid, it determines that the property in question never existed in accordance with section 60 of the *Patent Act*.[196] As Mr. Dimock explains:

> Validity, which is at issue in most patent cases, is not a question of title but a question of the very existence of the rights. To my knowledge, this is very different than most other forms of property where the existence of the property is not an issue.[197]

118. Invalidity findings by the courts are, thus, different from other circumstances in which patent rights are acknowledged to exist, but are taken away. For example, under

[193] *See* Resp. CM., para. 310.

[194] Cl. Reply, para. 229.

[195] *See* Reddon Report, para. 28; Cl. Reply, paras. 232-233.

[196] *See* Dimock Second Report, para. 139.

[197] Dimock Second Report, para. 135 (emphasis added).

the *Patent Act*, if a patentee abuses its patent rights, its existing patent can be cancelled or nullified.[198] In such a circumstance, there is no dispute that the property existed. Judicial invalidation of a patent is completely different. Indeed, Canadian courts have warned against confusing instances where a patent is taken away with instances of judicial invalidation.[199] Accordingly, the Canadian courts' determination that Claimant's atomoxetine and olanzapine patents were invalid means that Claimant did not have a property right in Canada that was capable of expropriation.[200]

119. Claimant's assertion that Canada's argument that no valid patent right ever existed amounts to an "untimely jurisdictional objection" demonstrates a fundamental misunderstanding of Canada's position.[201] Canada does not dispute that intellectual property rights may qualify as investments under NAFTA[202] or that judicial acts are attributable to Canada as a matter of international law. But these are only part of the inquiry for the purposes of Article 1110.[203] As one author explains:

> Once it has been determined that a particular type of interest in property attracts international law protection, the issue becomes whether the interest exists; the classification of a right as protected under international law is different from the substantive regime of the right.[204]

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[198] *Patent Act*, ss. 60, 65, 66 (**R-001**). Section 66 of the *Patent Act* provides that where exclusive rights are abused, the Commissioner of Patents may "order the patent to be revoked" if compulsory licensing is inadequate to remedy an abuse of patent rights. Similarly, section 60 of the *Competition Act* empowers the Federal Court to revoke a patent if the exclusive rights and privileges of the patent are used in restraint of trade and other remedies prove inadequate, *Competition Act*, RSC 1985, c C-34, s. 60 (**R-154**).

[199] *Belanger Inc. v. Keglonada Investments Ltd.*, 1986 CarswellNat 605, 8 CPR (3d) 557 (FC), para. 11 (**R-435**) ("It is to be noted that revocation by the Commissioner is not a finding of invalidity *ab initio* of a patent, but a penalty for abuse of the exclusive rights granted by the patent. The issue of initial validity would remain to be determined in this action which presumably would proceed to determine the issue of damages, if any, suffered before the effective date of the Commissioner's ruling.").

[200] Resp. CM, paras. 310-315.

[201] Cl. Reply, para. 230.

[202] Resp. CM., para. 311.

[203] *See, e.g.*, *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. 147 (**RL-013**).

[204] Monique Sasson, *Substantive Law in Investment Treaty Arbitration The Unsettled Relationship Between International and Municipal Law*, Wolter Kluwers 2010, p. 67 (**R-333 Amended**).

120. Only where judicial proceedings are so flawed that they constitute a denial of justice can a domestic court's determination of whether an asserted right exists at domestic law constitute an expropriation.[205] None of the arguments made by Claimant in its Reply should lead the Tribunal to a different conclusion.

121. Claimant argues that it is only necessary to show a denial of justice for misapplication of national law by the courts to generate international responsibility, whereas misapplication of international law subjects the courts to the same scrutiny as any other organ of state.[206] What Claimant ignores is that the first step of the expropriation analysis is squarely a question of national law: was there a valid property right under national law that was capable of being taken?

122. Viewed in this light, it is precisely the standard articulated by Paulsson in his treatise, in the very passage relied upon by Claimant, that applies in this case:

> [t]o the extent that national courts disregard or misapply national law, their errors do not generate international responsibility unless they have misconducted themselves in some egregious manner which scholars have often referred to as technical or procedural denial of justice.[207]

123. Canada's courts determined that, as a matter of Canadian national law, Claimant did not hold a valid property interest, and Claimant concedes that there was no denial of justice in reaching this conclusion.[208] This determination cannot be interfered with by an international tribunal.

124. As Canada explained in its Counter-Memorial, cases like *Azinian v. United States*, *Loewen v. United States*, *Arif v. Moldova*, and *Liman Caspian v. Kazakhstan* all

[205] Resp. CM, para. 318.

[206] Cl. Reply, para. 245.

[207] Cl Reply, para. 245, quoting Jan Paulsson, *Denial of Justice in International Law* (2010), p. 5 (**CL-147**).

[208] *See* Cl. Reply, paras. 17, 334, fn 433.

illustrate this point.[209] Claimant attempts to distinguish these cases on the basis that the claimants there did not allege "illegality" on the part of the courts beyond denial of justice. According to Claimant, the cases "simply did not address the theory of expropriation at issue here."[210] It is unsurprising that those cases did not address a theory of expropriation that Claimant has invented in this arbitration. In these cases, the tribunals proceeded on the well-established principle that, in the absence of a denial of justice, there is no basis for an international tribunal to interfere with a domestic court's determination of what rights exist at domestic law. Far from being a factor that can be used to distinguish these cases, the fact that the tribunals in these disputes did not apply Claimant's theory shows that it does not exist at international law.

125. In fact, Claimant has failed to point to any case in which a domestic court's determination that an asserted property right was never valid at domestic law has been found to be a judicial expropriation. Instead, Claimant relies upon cases in which the courts interfered with or extinguished rights that were acknowledged to be valid at domestic law.[211] In *Saipem v. Bangladesh*, the existence of the underlying property rights (residual contractual rights crystallised in an ICC award) was not at issue.[212]

[209] Resp. CM., paras. 319-325; *Robert Azinian, Kenneth Davitian & Ellen Baca v. United Mexican States*, ICSID Case No. ARB(AF)/97/2, Award, 1 November 1999, paras. 99-100 (*"Azinian Award"*) (**RL-002**) (concluding that for an international tribunal to review a domestic court finding a contract invalid "the Claimants must show either a denial of justice, or a pretence of form to achieve an internationally unlawful end … 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"); *Loewen Award*, para. 141 (**RL-013**) ("In the circumstances of this case, a claim alleging an appropriation in violation of Article 1110 can succeed only if Loewen established a denial of justice under 1105."); *Mr. Franck Charles Arif v. Republic of Moldova*, ICSID Case No. ARB/11/23, Award, 8 April 2013, ("*Arif Award*"), paras. 415-416 (**RL-063**) ("…these agreements have been declared invalid under Moldovan law by the whole Moldovan judicial system … The Tribunal is not persuaded that … the Moldovan courts have acted in denial of justice in any way."); *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, para. 431 ("*Liman Excerpts of Award*") (**RL-027**) (finding that domestic court determinations had "to be accepted from the perspective of international law," having found the 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.").

[210] Cl Reply, para. 252.

[211] Cl. Reply, paras. 246-249, fn 492.

[212] *Saipem S.p.A v. The People's Republic of Bangladesh*, ICSID Case No. ARB/05/7, Award, 30 June 2009, paras. 128-129, 202 ("*Saipem Award*") (**RL-064**).

While the Bangladeshi courts declared the ICC Award "a nullity," it was not contested that the underlying contractual rights existed. Similarly, in *ATA v. Jordan*, the tribunal found a treaty breach on the basis of a court decision triggering retroactive application of new legislation that "extinguished a valid right to arbitration".[213] The tribunal expressly noted that there "has never been any allegation in this case by either party that the Arbitration Agreement at issue was *per se* 'null and void, inoperative or incapable of being performed.'"[214] In *Oil Field of Texas*, there was no dispute as to whether the claimant had a valid title in the property taken by the court.[215] In *Sistem Muhendislik v. Kyrgyz Republic*, the tribunal expressly held that the claimant's asserted property interests were valid under domestic law, in part because a "failure to perform a contractual obligation may breach the contract but does not render the contract void *ab initio*."[216]

126. Beyond the fact that these cases concerned rights acknowledged to be valid at domestic law, they are also distinguishable because they involved serious procedural irregularities on the part of the State. In its Counter-Memorial, Canada detailed these circumstances in *Saipem*[217] and *Oil Field of Texas*[218]. Similarly, in *Sistem*

[213] *ATA Construction, Industrial and Trading Company v. The Hashemite Kingdom of Jordan*, ICSID Case No. ARB/08/02, Award, ("*ATA Award*"), para. 126 **(RL-068)** (emphasis added).

[214] *Id.*, para. 128 **(RL-068)**.

[215] *See* Resp. CM., para. 342; *Oil Field of Texas, Inc. v. Iran*, 12 Iran-U.S. C.T.R. 308, 318 (1986), ("*Oil Field of Texas*"), paras. 41, 43 **(CL-59)** ("NIOC has retained possession of the three existing blowout preventers leased pursuant to the Lease Agreement despite the fact that the Claimant demanded their return if rent was not paid on them … NIOC confirmed that this Court order prevented NIOC not only from making payments, but also from returning the equipment to Oil Field … The interference with the use of the three blowout preventers as caused by the Ahwaz Court order amounts to a taking of this equipment.") (emphasis in original removed).

[216] *Sistem Muhendislik Insaat Sanayi Ve Ticaret A.S. v. Kyrgyz Republic*, ICSID Case No. ARB(AF)/06/1, Award (9 September 2009), ("*Sistem Award*"), paras. 69-73 **(CL-146)**. In this case, there was no dispute as to actual title and ownership of the hotel in question – it had even been confirmed in an agreement between the respondent Kyrgyz Republic and the claimant's home state Turkey. This award, just as the others relied on by Claimant, is of zero value for Claimant's claim before this Tribunal.

[217] Resp. CM, paras. 336-338. Notably, the *Saipem* tribunal found that the conduct of the Bangladeshi courts amounted to an abuse of right and that the decision "can only be viewed as a grossly unfair ruling" that "lacks any justification". *See also Saipem Award* **(RL-064)**.

[218] Resp. CM, para. 343. The tribunal in *Oil Field of Texas* expressly noted "the Claimant's impossibility to challenge the Court order in Iran". *Oil Field of Texas*, paras. 43 **(CL-59)**. *Saipem Award* **(RL-064)**.

Muhendislik,[219] the claimant lost control of its property following an armed seizure of the hotel in which it was alleged that the State had colluded.[220]

127. Furthermore, contrary to what Claimant argues,[221] the fact that judicial invalidations fall within the ambit of the broad term "revocation," which is used in Article 1110(7), does not signal an intention by the NAFTA Parties to displace the rule that judicial determinations regarding the existence of property rights are not capable of being expropriations in the absence of a denial of justice. Article 1110(7) uses broad language encompassing a wide range of State actions with respect to intellectual property rights beyond invalidation by courts. The more reasonable inference with respect to the use of very broad terms in Article 1110(7) is that the NAFTA Parties were exercising an abundance of caution (what is colloquially called a "belt and suspenders" approach) in casting the protective shield of Article 1110(7) as broadly as possible.

128. Claimant's attempt to reach a different conclusion by drawing an analogy to the reasoning of the tribunal in *Waste Management v. Mexico* is a non-sequitur.[222] The tribunal in *Waste Management* was considering whether the term "measure tantamount to expropriation" had any meaning independent of "expropriation" under Article 1110(1). Looking to Article 1110(8), the tribunal concluded that it did. Article 1110(8) clarified that certain measures shall not be considered a "measure tantamount to expropriation." The tribunal reasoned that, because the measures described in Article 1110(8) would not amount to expropriation in any event, the legal scope of the term "measures tantamount to expropriation" had to be broader; otherwise, Article 1110(8) as a whole would serve no purpose.[223]

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[219] *Sistem Award*, paras. 97, 128 (**CL-146**).

[220] *Ibid.*

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

[222] Cl. Reply, paras. 257-258.

[223] *Waste Management, Inc. v. Mexico*, NAFTA/ICSID(AF) No. 00/3, Award, 30 April 2004, para. 144 (**CL-65**). It should be noted that most NAFTA tribunals have not reached the same conclusion as the *Waste Management II* tribunal regarding the scope of the term "measure tantamount to expropriation." *See*

129. The context of Article 1110(7) is completely different. Unlike Article 1110(8), as construed by the *Waste Management* tribunal, Article 1110(7) still has meaning even if judicial invalidations are not in any case subject to Article 1110. For example, the term "revocation" in Article 1110(7) captures other measures that could constitute expropriations, including confiscations by the executive branch and extinguishment of rights by the legislature. The most that can be said about the word "revocation" in Article 1110(7) is that its broad language covers more measures than it needs to, since some covered measures would not in any case be expropriations. This does not make Article 1110(7) as a whole or the term "revocation" unnecessary or ineffective.

130. Claimant further strains to argue that the negotiation and outcome of the Comprehensive Economic and Trade Agreement (CETA) with the European Union somehow undermines Canada's position on the proper interpretation of Article 1110 in this case.[224] The comparisons that Claimant attempts to draw say nothing about the scope of Article 1110.[225] More telling is Claimant's deceptive omission of a clarifying

Pope & Talbot v. Government of Canada, (UNCITRAL) Interim Award, 26 June 2000, para. 104 **(RL-056)** ("'Tantamount' means nothing more than equivalent. Something that is equivalent to something else cannot logically encompass more."); *S.D. Myers, Inc. v. Government of Canada*, Partial Award, 13 November 2000 ("*S.D. Myers Partial Award*"), para. 286 **(RL-076)** ("the drafters of the NAFTA intended the word 'tantamount' to embrace the concept of so-called 'creeping expropriation', rather than to expand the internationally accepted scope of the term expropriation."); *Feldman Award*, para. 100 **(RL-058)** ("The Tribunal deems the scope of both expressions to be functionally equivalent.").

[224] Cl. Reply, fn 515.

[225] As a preliminary matter, Claimant's comparison to CETA is inappropriate, as CETA involves different parties, has not entered into force, and is still subject to legal scrub. Health Canada Website, Canadian Department of Foreign Affairs, Trade, and Development, *CETA Final Text* (excerpts), p. 25 **(C-387)**.

Even if a comparison is pursued, Claimant's argument fails. Claimant cites a Canadian proposal advanced during negotiations for CETA Article X.11 (Expropriation): "For greater certainty, this Article does not apply to a decision by a court, administrative tribunal, or other governmental intellectual property authority, limiting or creating an intellectual property right, except where the decision amounts to a denial of justice or an abuse of right." European Commission, Trade Policy Committee, EU Canada FTA Negotiations: Investment Chapter, Trade B2/CBA/cg/Ares 1151153 (7 April 2014), p. 13 **(C-386)**. This "for greater certainty" proposal does not imply that Canada ever considered that judicial invalidations of intellectual property rights would otherwise be subject to the CETA expropriation article, or that they are subject to NAFTA Article 1110.

Claimant attempts a further baseless inference about NAFTA Article 1110(7) from the text of CETA Article X.11.6, which states: "For greater certainty, the revocation, limitation or creation of intellectual property rights to the extent that these measures are consistent with TRIPS and Chapter X (Intellectual Property) of this Agreement, do not constitute expropriation. Moreover, a determination that these actions

declaration in CETA recalling the Parties' understanding that the role of investor-State tribunals is not to second guess domestic court determinations on the validity and existence of intellectual property rights within the expropriation analysis. That Joint Declaration states:

> Mindful that investor state dispute settlement tribunals are … not an appeal mechanism for the decisions of domestic courts, the Parties recall that the domestic courts of each Party are responsible for the determination of the existence and validity of intellectual property rights.[226]

131. This understanding is entirely consistent with Canada's position in this arbitration that a domestic court's determination that a patent is invalid cannot constitute an expropriation under Article 1110.

C. Article 1110(7) Also Bars the Application of Article 1110 in this Case

132. In its Reply, Claimant misinterprets Canada's position on Article 1110(7). Canada's primary position is that the invalidation of Claimant's patents by the Canadian courts cannot constitute expropriations at customary international law. Accordingly, Article 1110(7) does not even apply in this case. In the alternative, if the Tribunal finds that the judicial invalidations could be expropriations, then Article 1110(7) applies and imposes an additional barrier to finding an expropriation. In short, consistency with Chapter Seventeen of NAFTA is a complete defence to any assertion of a violation of

are inconsistent with the TRIPS Agreement or Chapter X (Intellectual Property) of this Agreement does not establish that there has been an expropriation." The first sentence resembles NAFTA Article 1110(7). Claimant suggests that the absence of an equivalent to the second sentence in NAFTA Article 1110(7) implies a difference in scope between the two articles. This is false. The second sentence merely clarifies that it is impermissible to draw from the first sentence the logical fallacy that Claimant is trying to force onto Article 1110(7). The first sentence of CETA Article X.11.6 provides that consistency with the CETA Intellectual Property Chapter and TRIPS means that there can be no expropriation. From this, it is impermissible to conclude that a breach of the CETA Intellectual Property Chapter or TRIPS means that there has been an expropriation, as Claimant erroneously reasons in the context of NAFTA 1110(7).

[226] Health Canada Website, Canadian Department of Foreign Affairs, Trade, and Development, *CETA Final Text* (excerpts), p. 24 (emphasis added) (**C-387**). The absence of this clarifying language from NAFTA Article 1110 does not imply any difference in scope. The CETA declaration simply "recalls" the CETA Parties existing understanding of the role of domestic court decisions under the international law of expropriation. It is in the manner of a "for greater certainty" provision.

Article 1110. Claimant alleges that Canada is in breach of its obligations under Articles 1701(1), 1709(1), 1709(7) and 1709(8). These allegations are meritless. As shown below, Canada's law is consistent with all of its obligations in Chapter Seventeen.

1. *Canada's Law Is Consistent With Article 1701(1)*

133. Article 1701(1) provides:

> Each Party shall provide in its territory to the nationals of another Party adequate and effective protection and enforcement of intellectual property rights, while ensuring that measures to enforce intellectual property rights do not themselves become barriers to legitimate trade.

134. Claimant argues that Canada's promise utility doctrine violates Article 1701(1) because it "destroyed the level of protection" afforded to its atomoxetine and olanzapine patents, and "prevent[ed it] from enforcing its patents."[227] Such a claim fundamentally misunderstands the procedural nature of the obligation in Article 1701(1). Moreover, it ignores the overwhelming evidence that Canada's laws provide effective protection of intellectual property rights.

135. As Canada explained in its Counter-Memorial, Article 1701(1) is a general statement of principle that requires the Parties to ensure (i) that legal protection is available for the intellectual property rights described in Chapter Seventeen, and (ii) that such rights are supported by an adequate enforcement mechanism, namely a full and fair procedure before their domestic courts.[228] Article 1701(2) clarifies that "[i]n order to provide adequate and effective protection and enforcement of intellectual property rights, each Party shall, at a minimum, give effect to this Chapter."

136. Canada's law creates a system for patent protection that gives effect to the provisions of Chapter Seventeen as required by Article 1701(1). The *Patent Act* sets out the substantive description of that protection and the rights of holders of intellectual

[227] *See* Cl. Reply, para. 306.

[228] Resp. CM., para. 401.

property, and Canada's courts are available to enforce those rights. The protections contained in the *Patent Act* and the recourse for patentees to full and fair procedures before the courts satisfy Article 1701(1).

137. Claimant argues that Canada's laws make it "far more difficult for pharmaceutical innovators to obtain and enforce patent rights in Canada."[229] It points to the invalidation of its two patents as evidence that Canada's entire system is ineffective. Such a sweeping conclusion is absurd. The Canadian patent system effectively confers and enforces intellectual property protection for patents that uphold the patent bargain. The number of pharmaceutical patents granted in Canada has steadily risen since 1980, including since 2005 when Claimant alleges the promise utility doctrine made it more difficult to obtain patents.[230] Between 1980 and 2013, Canada granted a total of 25,760 pharmaceutical patents.[231] During the same period, Canadian courts decided validity challenges with respect to pharmaceutical patents in 134 cases,[232] including both PM(NOC) proceedings and impeachment or infringement actions.[233] Of those decided challenges, half found the patent valid.[234] In other words, invalidity findings were made with respect to 0.003% of all of pharmaceutical patents granted in Canada. Canada is in full compliance with its obligations under Article 1701(1).

[229] Cl. Mem., para. 234. *See also* Cl. Reply, para. 306.

[230] In 2005, 686 patents were granted. 844 were granted in 2006; 1,091 in 2007; 1,349 in 2008; 1,524 in 2009; 1,583 in 2010; 1,996 in 2011; 1,943 in 2012; and 2,041 in 2013. This is compared to the 538 patents granted in 1980: WIPO Database, Patent Grants by Technology – Pharmaceutical, Total Count by Filing Office – Canada (1980 – 2013) **(R-436)**.

[231] *Ibid*.

[232] Brisebois Second Statement, Annex F.

[233] *Ibid*.

[234] *See* Brisebois Second Statement, Annex F. The proportion of successful validity challenges for pharmaceutical patents in Canada is no different from the proportion of successful patent validity challenges in the United States: Mark A. Lemley and Carl Shapiro, *The Journal of Economic Perspectives, Probabilistic Patents*, Vol 19. No. 2 (American Economic Association, 2005), p. 76 **(R-437)** (writing that "roughly half of all litigated patents are found to be invalid, including some of great commercial significance.").

2. *Canada's Law Is Consistent With Article 1709(1)*

138. Article 1709(1) provides:

> 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 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.

139. Claimant argues that Canada has breached Article 1709(1) because Claimant's patents were invalidated even though they met the utility standard that Claimant contends the NAFTA Parties are obliged to apply. Claimant argues that the terms "capable of industrial application" and "useful" in Article 1709(1) create a specific "baseline" standard for patentability, and that the so-called "Promise Utility Doctrine" is inconsistent with that "baseline."[235] As Canada sets out below, Claimant's arguments are misguided. A proper analysis of Article 1709(1) under Articles 31 and 32 of the *Vienna Convention on the Law of Treaties* ("VCLT") reveals that the term "useful" in Article 1709(1) does not have the specific, and extremely restrictive meaning that Claimant contends. Rather, it is a broader concept that allows the parties considerable flexibility to determine the specific standard of utility to be applied.

a) Claimant's Analysis of the Meaning of Article 1709(1) Is Flawed

140. Claimant makes four fundamental errors in its analysis of the meaning of Article 1709(1). First, Claimant argues that the words "shall make patents available" in Article 1709(1) impose "an obligation to grant and maintain patents as long as the three enumerated criteria [novelty, non-obviousness, and usefulness] are met."[236] Claimant's position overstates the obligation in Article 1709(1). The obligation to "make patents available" is not the same as an obligation to "grant and maintain patents." Article

[235] Cl. Reply, para. 55.

[236] Cl. Mem., para. 189.

1709(1) sets out a general nomenclature of three considerations that each Party must apply in making patents available. It does not state that these are the only requirements that a NAFTA Party may apply in deciding whether to grant a patent. Every NAFTA Party imposes additional requirements that are integral to the patent bargain. If they are not met, the patent will not be granted. For example, the United States requires compliance with a "written description" requirement,[237] and Mexico requires compliance with a "sufficient description" requirement.[238] On Claimant's reading of Article 1709(1), both the United States and Mexico would be, and would always have been, in breach of Article 1709(1). This cannot be correct.

141. Second, Claimant asks the Tribunal to consider utility in isolation, abstracted from the patent bargain as a whole. It alleges that Canada breaches NAFTA Article 1709(1) because the alleged "promise utility doctrine" is outside of the meaning of "useful" in Article 1709(1).[239] Claimant's formalistic approach is at odds with the well-accepted tenet of patent law that it does not make sense to consider the meaning of one single patentability criterion in isolation from the other criteria of patentability.[240]

142. Claimant's approach inappropriately places domestic law labels over substance. Each NAFTA Party has functionally similar requirements to the alleged "promise utility doctrine" in Canada, though they sometimes apply different domestic law labels, such as "enablement" in the United States.[241] The label attached to a measure in domestic law cannot be a legitimate basis to distinguish compliance from non-compliance with NAFTA Chapter Seventeen.

[237] Holbrook Second Report, para. 7.

[238] Lindner Second Report, paras. 18-20 ("While the description and the disclosure of the invention are not themselves substantive application requirements, they are closely linked to the industrial applicability requirement and necessary to establish the existence and purpose of the invention.").

[239] Cl. Mem., para. 189; Cl. Reply, para. 260.

[240] Dimock Second Report, para. 53; Gervais Second Report, para. 7; Holbrook Second Report, para. 5; Lindner Second Report, para. 22.

[241] Holbrook First Report paras. 9, 13-61; Holbrook Second Report, paras. 25-33.

143. Claimant's approach also completely ignores the interaction between different patentability requirements. As explained above in section II(A), the patentee may need to promise a particular utility in its patent in order to satisfy other patentability requirements, such as novelty or non-obviousness.[242] This is particularly acute in the context of selection patents (such as Claimant's patent for olanzapine) and new use patents (such as Claimant's patent for atomoxetine).[243] Claimant's singular focus on the utility label completely ignores this dynamic. Given these interactions, it is impossible to consider the patentability requirements in isolation from each other.

144. Third, while recognizing in its Reply that NAFTA did not harmonize substantive patentability requirements,[244] Claimant contends that the utility requirement referenced in Article 1709(1) did establish a "baseline" level of protection.[245] However, as Professor Gervais explains, "Claimant's baseline argument is essentially a harmonization argument in disguise."[246]

145. The term baseline connotes a minimally constraining obligation that allows a degree of flexibility for the Party that bears the obligation.[247] However, the meaning that Claimant ascribes to the utility requirement under Article 1709(1) is maximally constraining on the NAFTA Parties and leaves them no flexibility whatsoever.[248] Claimant argues that "useful" in Article 1709(1) is a "low threshold" that means "the capacity or ability to be put to a specific or practical use in industry."[249] It is apparent

[242] Dimock Second Report, paras. 12-25.

[243] Dimock Second Report, paras. 21-22.

[244] Cl. Reply, para. 15.

[245] Cl. Reply, para. 19.

[246] Gervais Second Report, para. 4.

[247] The *Oxford English Dictionary* defines "baseline" as: "A minimum or starting point used for comparisons or development of thought." Oxford English Dictionary, The Definitive Record of the English Language, online: http://www.oed.com/view/Entry/281154?redirectedFrom=baseline **(R-438).**

[248] Gervais Second Report, para. 6 ("Claimant's argument is dangerously close to saying that the U.S. definition of utility is the baseline standard established in Chapter Seventeen … in my opinion it is difficult to conceive of a utility standard lower than the current U.S. standard.").

[249] Cl. Reply, para. 260.

from Claimant's interpretation of utility in Article 1709(1) that a Party could not possibly demand anything more than the "mere scintilla" test that Claimant says is compatible with its proposed "baseline."[250] For all practical purposes, Claimant's "baseline" standard is a harmonized standard that inappropriately elevates the domestic law of one NAFTA Party (the United States) to a binding international standard.[251] Moreover, it is a harmonized standard that completely reads out the utility condition for certain types of secondary patents, such as selection patents, in which the invention builds upon an earlier invention that already delivered a scintilla of utility.[252] Under Claimant's approach, new use and selection patents would automatically meet the utility requirement because of the earlier invention's utility. This completely undermines the very foundation of patent law and voids the patent bargain. Such an interpretation of Article 1709(1) is unreasonable.

146. Fourth, Claimant's interpretation of Article 1709(1) confuses the meaning of "useful" in Article 1709(1) with how the standard is implemented by the NAFTA Parties. There is a difference between the standard of utility required (i.e. the threshold of utility required, such as a scintilla or a promise) and rules that relate to how that standard is implemented (i.e. when utility has to be established, what evidence can be relied upon to establish utility, and the extent to which utility has to be disclosed).[253]

[250] Cl. Reply, paras. 45, 260, fn 571.

[251] Susy Frankel, *Test Tubes for Global Intellectual Property Issues: Small Market Economies*, Cambridge Univ. Press, 2015, p. 65 **(R-439)** (the current President of the International Association for the Advancement of Teaching and Research in Intellectual Property, noting that "No one national law, however, can govern the meaning of a term in an international agreement. Such dominance of one national law is the antithesis of VCLT interpretation because it effectively postulates that one party's preferred negotiating text (which likely reflected their law) at the time has the same meaning as the end agreement.").

[252] Cl. Mem., para. 86; Siebrasse First Report, para. 50 ("Under the prior law, the olanzapine (Zyprexa) patent would necessarily have been considered to have utility, precisely because it was a selection patent; a selection from a genus of useful compounds must itself be useful.").

[253] Gervais Second Report, paras. 22, 23, 25. In the TRIPS context, see *India - Patent Protection For Pharmaceutical And Agricultural Chemical Products*, document WT/DS50/AB/R, 19 December 1997, para. 59 **(R-403)** ("…as a Member, India is 'free to determine the appropriate method of implementing' its obligations under the TRIPS Agreement within the context of its own legal system."); *China – Measures Affecting The Protection And Enforcement Of Intellectual Property Rights*, WTO document WT/DS362/R, January 26, 2009, para. 7.601 **(R-404)** ("The panel notes that it is the standard in the treaty

Throughout its pleadings, Claimant alleges that the "promise utility doctrine" as a whole is inconsistent with the utility standard in Article 1709(1).[254] But on Claimant's own account, only one of the elements of the "promise utility doctrine" actually concerns the standard of utility itself – the promise threshold.[255] The other elements only go to the implementation of that standard.

147. In particular, Claimant's allegations that Canada has breached Article 1709(1) because courts "exclude all post-filing evidence" and require that "only evidence in the patent itself can support a 'sound prediction'"[256] do not concern the threshold of utility at all, but relate to how utility can be established. Even Professor Siebrasse agrees that it is important to distinguish the issue of the appropriate threshold of utility from the evidence required to show that the standard was met.[257] Further, as Claimant itself acknowledges, the NAFTA Parties have flexibility in deciding how to implement the obligations of NAFTA Chapter Seventeen.[258] Accordingly, even if NAFTA Article 1709(1) required the NAFTA Parties to impose the specific "low threshold" utility standard Claimant alleges (it does not), it has nothing to say about how the NAFTA

obligation that varies as applied to different fact situations, and not necessarily the means by which Members choose to implement that standard.").

[254] Cl. Mem., para. 209; Cl. Reply, paras. 260, 267.

[255] Cl. Reply, para. 73 ("For decades, the mere scintilla standard was applied … but in the mid-2000s, Canada's Federal Courts began to impose an elevated standard under which utility is assessed against the 'promise of the patent.'"); Cl. Reply, para. 91 ("The second element of the promise utility doctrine is a heightened evidentiary standard."); Cl. Reply, para. 104 ("The third element of the promise utility doctrine is an additional disclosure rule…").

[256] Cl. Mem., para. 209; Cl. Reply, paras. 6, 70.

[257] Siebrasse First Report, fn 21 ("In my academic writing, I have used the term 'actual utility', to denote the standard of utility required by the Act (i.e., a 'mere scintilla'). Regardless of whether 'mere scintilla' or 'actual utility' is used, this is meant to refer to the standard of utility and not to the evidence needed to show the standard was met.") (emphasis added); Siebrasse First Report, para. 19 ("the elimination of the ability to rely on post-filing evidence has made it substantially more difficult to establish utility, based on any standard.") (emphasis added). Claimant has also, in pleadings before Canadian courts, drawn a distinction between the threshold of utility and the standard of proof requiremed to meet that threshold. *Eli Lilly and Company v. Teva Canada Limited*, Memorandum of Fact and Law of the Appellant, Court File No. A-387-10, 28 February 2011, para. 19 **(R-458)**.

[258] Cl. Reply, para. 271 ("Canada confuses the latitude that Chapter 17 gives to parties in *implementing* obligations under NAFTA with the interpretation of the obligation itself. That NAFTA parties have leeway in choosing how to implement a treaty obligation does not mean that parties may alter what the obligation is (or interpret an obligation out of existence.").

Parties are permitted to implement the requirement, particularly with regard to issues of evidence and disclosure.[259]

148. For all of these reasons, Claimant's interpretation of Article 1709(1) must be rejected. A proper VCLT analysis considers the following points: (1) the ordinary meaning of the terms "useful" and "capable of industrial application" as understood in the patent law field in the NAFTA Parties; (2) the context of Article 1709(1); (3) the subsequent practice of the NAFTA Parties; (4) other relevant rules of international law; and (5) to the extent necessary to eliminate ambiguity, any relevant supplemental means of interpretation.

149. Such an analysis reveals that Article 1709(1) leaves to each NAFTA Party the flexibility to define and implement the specific legal standard under each of the enumerated criteria of novelty, non-obviousness or inventiveness, and utility or industrial applicability. It does not adopt any one particular meaning for any of the terms. Indeed, there is no evidence that the NAFTA parties intended to constrain themselves in Article 1709(1) to any particular definitions, and certainly not the highly specific and restrictive meaning that Claimant advocates.

b) The Ordinary Meaning of Article 1709(1) Makes Clear that the NAFTA Parties Have the Flexibility to Set and Implement the Utility Requirement

150. As Canada explained in its Counter-Memorial, Claimant is wrong to suggest that an "ordinary meaning" analysis simply refers to a generic, layperson's understanding as reflected in standard dictionary definition.[260] To the contrary, the ordinary meaning is that given to a term by a person reasonably informed on the subject matter of the treaty.[261] As Claimant itself acknowledges, in a "technical field such as patent law, specialized legal definitions are especially relevant to any assessment of a treaty's

[259] Gervais Second Report, paras. 21-25.

[260] Resp. CM., para. 360.

[261] 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, ("Gardiner"), pp. 166 and 174 (**R-345 amended**).

ordinary meaning"[262] and Article 1709(1) "makes sense only if one starts from the premise that the NAFTA parties intended the terms 'capable of industrial application' and 'useful' to have their special technical meaning."[263] Canada agrees. Standard dictionary definitions are not germane to interpreting Article 1709(1).[264]

(1) The NAFTA Parties Had Different Thresholds for Utility Prior To NAFTA

151. To understand the ordinary meaning of "capable of industrial application" and "useful" in patent law, it is necessary to look to domestic law because there is no internationally accepted definition of these terms.[265] Patent law is territorial in nature, and patentability requirements are defined and implemented under the domestic law of each patent-granting national jurisdiction.[266] A review of the specialized sources on the legal meaning of these terms in each of the domestic patent law regimes of the NAFTA Parties, such as jurisprudence and legal scholarship, reveals the NAFTA Parties' different approaches to the concepts of usefulness and industrial applicability when NAFTA was signed.[267] These differences have been fully detailed in the expert reports

[262] Cl. Mem., para. 194. *See also* Gardiner, p. 164 (**R-345 amended**) ("Nevertheless, courts and tribunals often make an attempt at finding a meaning for a term by use of a dictionary or, particularly in technical areas, specialist books that define the term in issue." (emphasis added)).

[263] Cl. Reply, para. 280; *See also* Cl. Reply, para. 279 ("In any case, whether the term 'capable of industrial application' is given its ordinary meaning within the patent law context or ascribed a 'special meaning' as a term of art in patent law, the result is the same.").

[264] Even if standard dictionary definitions were an appropriate reference point for the ordinary meaning of "useful" in the intellectual property context, they do not lead to the narrow meaning that Claimant suggests. The *Oxford English Dictionary* definition of useful cited by Claimant suggests that even in its ordinary meaning, whether something is useful may be a highly contextual consideration that could require an object to serve a particular function or have a particular degree of functionality. The definition states "capable of being put to good use; suitable for use; advantageous, profitable, beneficial." (Emphasis added). Whether a particular use is a *good* use or a thing is suitable, advantageous, profitable, or beneficial is a question of judgment that could vary based on the context. *Oxford English Dictionary*, The Definitive Record of the English Language, online: http://www.oed.com/view/Entry/281154?redirectedFrom=baseline (**R-438**).

[265] Gervais First Report, paras. 39-40, 57-58; Gervais Second Report, paras. 29, 41, 47.

[266] Gervais First Report, paras. 60-62; Gervais Second Report, paras. 13-14.

[267] Claimant puts forward a single definition of useful in *Black's Law Dictionary* as determinative of the meaning of "useful" in the patent law context. The weight that can be placed on this source must be highly qualified. First, a general legal dictionary definition is far from a specialized source in the patent law context. It offers only a single, high level interpretation of useful in the intellectual property context. More

before the Tribunal and need not be repeated here. The main points will simply be highlighted below.

152. As Canada explained in its Counter-Memorial, the meaning of "useful" in Canadian patent law has long been understood as a contextual consideration that asks the question, "useful for what?" [268] If the patent contains a promise as to the usefulness of the invention, then the invention will only be considered useful if it meets that promise. If a patent does not contain a promise of usefulness, then a "mere scintilla" of utility will suffice. This utility standard was well known in Canadian patent law when NAFTA was drafted. As explained in the expert reports of Mr. Dimock, the promise standard has been recognized by Canadian courts, legal scholars, and patent practitioners for over 60 years.[269] Mr. Dimock sets out a list of historical authorities in his second expert report,[270] but to take just one example, in 1960, Canadian patent lawyer Donald Hill wrote:

> One standard for measuring utility is of course that provided by the patentee himself; if certain results are promised specifically, or may reasonably inferred from the specification, and these are not yielded by practice of the invention, the patent will fail. In the absence of specific promises, however, the courts do not seem to be overly anxious to strike down a patent on the ground of lack of utility so long as some measure of usefulness can be obtained.[271]

153. Claimant's arguments in its Reply that this standard did not exist in Canada until after 2005 are wrong and are fully refuted in the second expert report of Mr. Dimock.[272]

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specialized sources dealing with patent law would be more authoritative. Second, the *Black's Law Dictionary* diction is based exclusively on United States sources. At most, it reflects a high level interpretation of the patent law meaning of useful in just one of the NAFTA parties. Third, the examples given alongside the definition of "useful" in *Black's Law Dictionary* suggest a more nuanced meaning that that Claimant ascribes to it. One example given notes that a machine is useful in the patent law sense when it achieves "its" purpose and that the word cannot be given a "practical and not a speculative meaning." *Black's Law Dictionary* (9th ed. 2009) (Excerpts), "Useful" (**CL-71**).

[268] Dimock First Report, para. 158; Dimock Second Report, para. 9.

[269] Dimock First Report, para. 49; Dimock Second Report, para. 26.

[270] Dimock Second Report, Annex B.

[271] Donald Hill, "Claim Inutility" (1960), 35 CPR 185, p. 186 (**R-160**).

[272] Dimock Second Expert Report, paras. 26-86.

In fact, its position in this arbitration is contradicted by its own practice outside of this proceeding. First, Claimant itself has recognized in its pleadings in Canada's domestic courts that the promise standard has existed in Canada since at least the Supreme Court of Canada's *Consolboard*[273] decision in 1981.[274] It could hardly do otherwise. As recognized by leading Canadian patent lawyer and scholar, William Hayhurst, by 1983 it was "trite law that, as long as that which is disclosed has some practical utility the quantum of utility may be slight unless the specification promises more."[275]

154. Second, had there been a major shift in Canadian law, then Claimant should have a significant number of documents reflecting comments and advice on the allegedly new requirements. There should be internal memoranda, legal opinions, emails, meeting notes, and other written evidence of discussions. After all, according to Claimant, the changes to Canadian law were both revolutionary and struck at the heart of its business model. At the document production stage, Canada sought all documents that described, provided views or contained discussion on the compliance or expected compliance of Claimant's patent applications for olanzapine and atomoxetine, including advice from legal counsel.[276] The date range for the requests cited above spanned from 1992 to the

[273] *Consolboard* (**R-011**).

[274] *Eli Lilly Canada v. Apotex*, Lilly's Memorandum of Fact and Law, Court File No. T-1599-13, 14 May 2015, paras. 88-89 (**R-440**) ("The SCC has interpreted inutility to mean 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.' [Citation to *Consolboard*] Thus, as in all inutility allegations, the first step is to determine the promise of the patent. 'The promise of the patent is the standard against which the utility of the invention described in the patent is measured.'") In the Court proceedings that led to the invalidation of its olanzapine patent, Claimant invited the Court to rely upon the very historical authorities for the law of utility that it now alleges are irrelevant. In the olanzapine proceedings, Claimant asked the Federal Court to adopt Dr. Fox's 1969 treatise *Canadian Patent Law and Practice* for the "important distinction between the promised results of a patent and any statement of advantages made in a patent." *Eli Lilly Canada Inc. v. Novapharm Limited*, Memorandum of Fact and Law of the Plaintiffs, Court File No. T-1048-07, January 4, 2011, para. 58 (**R-462**). But now in this NAFTA challenge, Claimant's expert Professor Siebrasse dismisses *the very same passage* of Dr. Fox's treatise as irrelevant because it is based only on "old English 'false promise' doctrine, which as noted, did not form part of Canadian law …" Siebrasse Second Report, para. 40. Claimant cannot invite Canadian courts to apply Dr. Fox's 1960 articulation of the promise standard, and then accuse the courts of breaching NAFTA Article 1709(1) when the very same standard is applied.

[275] W.L. Hayhurst, Q.C., "Survey of Canadian Law – Industrial Property: Part I" (1983), 15 Ottawa L. Rev. 38, pp. 38-130, ("Hayhurst, Survey of Canadian Law"), pp. 68-69 (emphasis added) (**R-199**).

[276] *See* Procedural Order No. 2, Annex B, Requests 4 and 5 (**R-434**).

present.[277] Per the Tribunal's Order, the Claimant was obliged to produce, or assert privilege over, any relevant documents.

155. Claimant did not produce or log on its privilege log any responsive documents. Not a single document. No emails. No legal opinions. No meeting notes. Apparently, Claimant did not ever discuss or receive any written advice on what it now says was a fundamental change of one of the core concepts in Canadian law that allegedly caused it hundreds of millions of dollars of damages. This is not credible. As Claimant's own expert Andrew Reddon explains, he regularly provided advice to his clients on developments in patent law.[278] The lack of documents is proof that Claimant's allegations of significant changes in Canadian law are merely an artifice for the purposes of this arbitration.

156. Finally, even leaving aside the contrived nature of Claimant's position, Claimant's and Professor Siebrasse's attempts to quibble with the Supreme Court of Canada's statement of the law of utility in *Consolboard* and those of the distinguished scholars Canada has identified are irrelevant.[279] They amount to nothing more than a statement that Canada's highest court and these legal scholars were wrong. Whether or not one agrees that the Supreme Court should have endorsed the promise standard in that case, the fact is that the Court did endorse that standard.[280] It was the highest authority on the meaning of utility in Canadian law when NAFTA was drafted.[281]

157. There is no reason to think that when the drafters of NAFTA made reference to "useful" in Article 1709(1), they decided to ignore the pronouncement of the highest court of one of the three NAFTA Parties on the meaning of that term or the scholarship of Canada's preeminent patent law specialists examining the Canadian law of utility.

[277] *Ibid*.

[278] Reddon Report, para. 10.

[279] Cl. Reply, paras. 81-82; Siebrasse Second Report, paras. 23-26, 40.

[280] Dimock Second Report, para. 45.

[281] Dimock Second Report, para. 26.

Further, there is no evidence to show that Canada intended to replace its existing domestic law with a completely new and different standard of utility that would overturn decades of Canadian case law and academic commentary.

158. Nor is there any reason to think that the drafters were not aware that the standard in Canada differed from that in the other NAFTA Parties in certain respects. For example, while NAFTA was being negotiated, judicial interpretation of the United States' utility requirement included a substantiality component.[282] This did not form a part of either Canadian or Mexican law.[283] In Mexico, there was no utility standard at all; rather, the standard was industrial applicability. The Mexican law of industrial applicability contained none of the promise language found in Canadian law, or of substantial utility found in American law.[284]

(2) The NAFTA Parties Implemented Their Utility Standards in Different Ways When NAFTA Was Signed

159. As discussed above, the meaning of "useful" or "capable of industrial application" in Article 1709(1) must be distinguished from questions of the implementation of these standards.[285] Implementation issues, such as what evidence can be admitted to establish utility or how utility must be disclosed, are not governed by NAFTA Article 1709(1) at all. Thus, the Tribunal need not consider this issue further. Nevertheless, the fact is that the way in which the NAFTA parties understood how they were permitted to implement patentability requirements in their domestic laws when NAFTA was signed shows that Article 1709(1) does not restrict the NAFTA Parties in the way Claimant alleges.

[282] In *Brenner v. Manson*, 383 US 519 (1966) ("*Brenner*"), p. 534 **(R-053)**, the United States Supreme Court established a test for determining whether a patent should be issued, stating that the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility."

[283] Lindner First and Second Reports; Dimock First and Second Reports.

[284] Lindner First Report, paras. 20-21; Lindner Second Report.

[285] *See* Section IV(C)(2)(a), para. 138.

160. In Canada**,** the various rules concerning the implementation of the utility requirement that Claimant now challenges were well-established when NAFTA was concluded. First, where a particular level of utility was promised, the promise would be construed based on settled principles of patent construction. Contrary to what Claimant argues in its Reply, Canadian courts have not begun, since 2005, "scouring" patents for promises of utility.[286] As Mr. Dimock explains in his expert reports, Canadian courts have long understood that the invention, including its utility, is to be construed on the basis of the patent as a whole.[287] As Mr. Dimock further explains, if there has been any greater emphasis placed on promise in recent jurisprudence, it is at least partially a result of the tactics of pharmaceutical patent litigation counsel, who are emphasizing statements of comparative advantage or heightened utility to overcome issues related to obviousness challenges.[288] In other words, the development and elaboration of the law is being driven by litigants themselves responding to new technological and economic realities. This is the way the law has developed for centuries. It is no different with respect to patent law.

161. Second, contrary to what Claimant alleges, post-filing evidence of utility was not admissible to show that utility had been established at the filing date when NAFTA was signed.[289] This rule was not created by the Supreme Court of Canada's 2002 decision, *AZT*.[290] In fact, from the early part of the 20th century, jurisprudence developed providing that for someone to have "made" an invention, the invention – including its

[286] Cl. Reply, paras. 73, 79, 174, 177, 178.

[287] Dimock First Report, para. 68 (citing Harold G. Fox, *Canadian Patent Law and Practice, 4th Ed.* (Toronto: Carswell, 1969), p. 153 (**R-163**): "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 particular result is promised."); Dimock Second Report, paras. 83-84. *See also* Hayhurst, Survey of Canadian Law, pp. 68-69 (**R-199**) ("Also it is trite law that, as long as that which is disclosed has some practical utility the quantum of utility may be slight unless the specification promises more. For this reason, the patent agent should be chary of making promises and of reciting objects *in the specification* …") (emphasis added).

[288] Dimock Second Report, paras. 75, 77-78.

[289] Dimock First Report, para. 221; Dimock Second Report, paras. 88-89.

[290] Cl. Reply, para. 93.

utility – must have been reduced to a definite and practical shape.[291] To receive a patent, it was not enough "for a man to say that an idea floated through his brain."[292] As described in the 1990 edition of MOPOP: "An invention, such as that relating to a new substance, may not be said to be invented until such date as the utility for it is known."[293] Post-filing evidence obviously cannot establish that a patentee had made an invention at the filing date.[294] Both when NAFTA was drafted and today, a patentee in Canada could not "file now and invent later."[295]

162. Third, Canada's law has long required that the basis for a sound prediction be disclosed in the patent itself. Contrary to what Claimant asserts, the rule predates Claimant's patents and was not "created" by Canadian courts in 2008 in a case involving Claimant's patent for raloxifene.[296] As Mr. Dimock explains, the doctrine of sound prediction was recognized as part of Canadian law by the Supreme Court of Canada in its 1979 *Monsanto*[297] decision.[298] Claimant would prefer to read *Monsanto* as rejecting any requirement to disclose the basis for a sound prediction of utility in the patent. This is false.[299] As explained in a 1983 law review article by patent lawyer William Hayhurst:

> The Supreme Court of Canada [in *Monsanto*] [had] regard to the applicant's evidence of undoubted experts that the disclosure of the three

[291] Dimock First Report, para. 93; Dimock Second Report, para. 94.

[292] *Wandscheer et al. v. Sicard Ltd*., [1948] SCR 1, p. 4 (**R-181**), quoting *Permutit Co. v. Borrowman*, (1926) 43 RPC 356 at 359.

[293] Manual of Patent Office Practice, Consumer and Corporate Affairs Canada, Patent Office (1990), s. 18.20.02 (**R-309**).

[294] Dimock Second Report, para. 89.

[295] Dimock First Report, para. 112; Dimock Second Report, para. 89. *See also* Gillen Second Statement, paras. 18-22.

[296] Cl. Reply, para. 104.

[297] *Monsanto Co. v. Commissioner of Patents* [1979] 2 SCR 1108 (**R-023**).

[298] Dimock First Report, para. 126; Dimock Second Report, para. 131.

[299] Dimock First Report, paras. 126-127; Dimock Second Report, paras. 121-125, 131.

> compounds provided a sound basis for predicting the promised utility of the others.[300]

163. The Patent Office has long recognized that a failure to disclose the basis of a sound prediction is grounds for rejecting a patent application.[301] For example, as Dr. Gillen explains, in a decision rendered in 1995, the "Commissioner upheld [an] Examiner's rejection of two of the claims because no basis for a sound prediction had been disclosed."[302]

164. Moreover, Claimant's own patent applications were specifically subjected to Office Actions on the basis of this rule. In October 2003, five years before Claimant alleges the rule was "created," Claimant received an objection from a Canadian Patent Examiner with respect to one of its patent applications for the use of atomoxetine stating that the "description fails to provide a sound line of reasoning for the utility claims" and that the "factual support described does not lead to the conclusion that the subject matter of these claims would have the predicted utility."[303] In October 2004, Claimant received another Office Action raising precisely the same issue with respect to one of its patents for the use of olanzapine.[304] It is completely disingenuous for Claimant to argue that it

[300] Hayhurst, Survey of Canadian Law, p. 69 **(R-199)**. *See also* Adrian Zahl, "Covetous Patent Claims" (2004) 21 CIPR 141, p. 147 **(R-310)** (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). Carol Hitchman, "The History of the Doctrine of Sound Prediction" (2012), 27 CIPR 343, p. 350 **(R-336)** (Using the contract concept of patents, the Court noted that if the claim does not go "beyond the consideration given by his disclosure, his claim is fairly based". Thus, the need for proper disclosure was raised in the *Monsanto* case.")

[301] *See* Commissioner's Decision 1206, relating to Application No. 529,362, December 11, 1995 ("Commissioner's Decision") **(R-381)**.

[302] Gillen Second Statement, para. 16; Commissioner's Decision, pp. 9-10 **(R-381)**.

[303] CIPO Office Action, Application No. 2,304,657, 23 October 2003, p. 1 **(R-443)**.

[304] CIPO Office Action, Application No. 2,248,873, 7 October 2004, p. 5 **(R-444)** ("The description fails to provide a sound line of reasoning for the utility of olanzapine for treating inflammation. The factual support described does not lead to the conclusion that the subject matter of these claims would have the predicted utility. *Apotex Inc. v. Wellcome Foundation Ltd*, 2002 SCC 77.

had never heard of what it labels the "*Raloxifene* rule" prior to 2008, when it had been specifically subjected to that rule years earlier.[305]

165. As with the issue of the threshold for utility, it is inconceivable that the NAFTA Parties were ignorant of how one of them implemented its utility standard. It is also inconceivable that they were unaware of the various methods of implementation in the United States and Mexico, and how those methods both resembled and differed from Canada's.

166. In the United States the manner in which the utility standard was implemented diverged from the highly specific, restrictive meaning that Claimant attempts to give the term. A review of the case law prior to 1995 reveals a consistent pattern of examiners rejecting applications for failure to provide convincing data to support the utility requirement for patentability under the relevant legislation.[306] As Professor Holbrook explains, while these requirements were legally grounded in separate provisions of the United States Code dealing with enablement and written description, they are inextricably linked to the utility requirement in United States law.[307] Specifically in the pharmaceutical context, when NAFTA was negotiated, the United States was applying the longstanding *Brenner v. Manson* standard to refuse pharmaceutical patent applications where patentees failed to provide adequate proof that the asserted utility had a substantial use that was not merely hypothetical.[308] Nor did American courts generally accept post-filing evidence to demonstrate that the utility of an invention had been

[305] Cl. Reply, para. 113; Reddon Report, para. 11.

[306] Timothy R. Howe, "Patentability of Pioneering Pharmaceuticals: What's the Use?", 32 San Diego L. Rev. 819 (1995), p. 826 **(R-445)**.

[307] Holbrook Second Report, paras. 5, 25.

[308] The U.S. Supreme Court's seminal *Brenner* decision in 1965 affirmed that to be patentable, an invention in the chemical arts had to have a real-world use. *Brenner*, para. 529 **(R-053)**. Holbrook First Report, para. 64.

established at the filing.[309] Utility had to be established at the time that a patent application was filed, not after the fact.[310]

167. In Mexico prior to NAFTA, establishing that an invention was capable of industrial applicability was relatively simple because patentable inventions were essentially limited to mechanical apparatus—the invention either worked as intended or it did not work.[311] By the time NAFTA entered into force, Mexico had included pharmaceutical and chemical products as patentable subject matter.[312] Since the industrial applicability of such inventions is not necessarily self-evident, Mexico required a sufficient description of the invention.[313] This last requirement became necessary to provide patent examiners with sufficient information, at the time of filing, to conclude that an invention is capable of industrial applicability.[314] However, Mexico lacked many of the specific rules regarding the implementation of its standard that existed in both Canada and the United States.

168. The above practice of the NAFTA Parties shows that at the time NAFTA was signed, each NAFTA Party applied a threshold of utility, and associated rules relating to the proof and disclosure of utility, in accordance solely with their own domestic laws. There was no harmonized or agreed standard or method of implementation between them. There is no evidence to suggest that the NAFTA Parties intended to impose restrictions on the implementation of their utility standards which would have required substantial changes to each of their domestic laws. The ordinary meaning of the term "useful" in Article 1709(1) must therefore correspond with the concept of utility as it

[309] Holbrook Second Report, paras. 34-44.

[310] Holbrook First Report, para. 32; Holbrook Second Report, para. 44.

[311] Lindner Second Report, paras. 7, 25, fn 24.

[312] Lindner Second Report, para. 8.

[313] Failure to satisfy any of these requirements could result in the patent not being granted or being invalidated if challenged on one of these grounds; Lindner Second Report, paras. 19-20.

[314] Lindner Second Report, para. 18-22; *See also*, Lindner First Report, para. 52 ("If an applicant produces information showing that the applicant had not completed the invention process, including establishing that the invention was capable of industrial application, before the filing date, the patent should be held invalid.")

existed individually in each of the NAFTA Parties' law. Viewed in this light, it is evident that Canada's law is consistent with Article 1709(1).

c) The Context of Article 1709(1) Confirms that the NAFTA Parties Did Not Adopt a Restrictive Definition of Utility in Article 1709(1)

169. The consistency of Canada's law with Article 1709(1) is also established by considering the context of the language. In particular, Claimant's suggestion that the NAFTA Parties agreed to a highly specific, restrictive meaning for "useful" in Article 1709(1) is untenable in light of the overall scope of obligations in Chapter Seventeen. If the NAFTA Parties had wanted such a specific and restrictive meaning, they could have included a precise definition of "capable of industrial application" or "useful" in the NAFTA Intellectual Property Chapter. They did not.

170. In fact, Article 1709(1) does not even require the NAFTA Parties to have the same basic patentability requirements. The Parties are expressly provided the option of using either the criterion of "useful" or "capable of industrial application." Contrary to Claimant's assertion, these terms are not synonymous. The distinct nature of these concepts was well-known at the time NAFTA was drafted.[315]

171. The meaning of "useful" in Article 1709(1) must also be placed in the context of the other patentability requirements to which the article refers. Nothing in Chapter Seventeen suggests that the drafters intended a more restrictive standard for utility than for novelty or non-obviousness.[316] Claimant has not addressed the other patentability requirements whatsoever and has adduced no evidence to suggest that NAFTA imposed a uniform and restrictive meaning on either obviousness or novelty.

172. Moreover, on other core elements of the patent bargain, such as sufficiency of disclosure, Chapter Seventeen imposes absolutely no disciplines. Claimant does not and cannot contest this. It makes little sense to suggest that the NAFTA Parties decided to

[315] Gervais First Report, para. 57; Gervais Second Report, paras. 19-20.

[316] Gervais Second Report, paras. 7-11.

bind themselves to highly specific patentability requirements with respect to utility while at the same time leaving other patentability requirements completely to their own discretion.

173. It makes even less sense given that, as Canada has noted above, the various criteria are overlapping.[317] For example, Canadian law locates the disclosure requirement for sound prediction under the heading of "utility" but the requirement is closely related to proper disclosure of the invention.[318] It is nonsensical to suggest that Canada's disclosure requirement for sound prediction breaches Article 1709(1) but that such breach could be remedied simply by imposing the exact same requirement under the heading of "sufficient disclosure" instead. The labels that a NAFTA Party attaches to its patentability requirements in domestic law cannot make the difference between whether that rule is in compliance or in breach of NAFTA Chapter Seventeen.

174. Similarly, Chapter Seventeen imposes no obligations with respect to the overbreadth doctrine in patent law. Professor Siebrasse recognizes that overbreadth is a longstanding doctrine in Canadian patent law that was part of Canadian law when NAFTA entered into force.[319] However, he argues that it is "quite distinct" from the utility requirement.[320] This is incorrect. As Mr. Dimock explains, a claim may be held overbroad if it encompasses subject matter that does not have the utility promised by the invention.[321] Canadian courts have applied the overbreadth doctrine in this sense for decades.[322] As the Federal Court in *Alcon Canada Inc. v Cobalt Pharmaceuticals Co.* explained, an "allegation of overbreadth is simply another way of articulating the utility

[317] Gervais Second Report, para. 6; Holbrook Second Report, paras. 26, 49.

[318] Dimock First Report, paras. 125-126.

[319] Siebrasse Second Report, para. 38.

[320] Siebrasse Second Report, para. 37.

[321] Dimock Second Report, paras. 56-57.

[322] Dimock Second Report, para. 69; *Hoechst Pharmaceuticals of Canada Limited et al. v. Gilbert & Company et al.*, (1964), Fox Pat C 28 (Ex Ct) **(R-195)**; *Amfac Foods Inc. v. Irving Pulp & Paper, Ltd.*, (1986), 12 CPR (3d) 193 (FCA) **(R-168)**; *Unilever PLC. v. Procter & Gamble Inc.*, (1995), 61 CPR (3d) 499 (FCA) **(R-172)**; *Apotex Inc. v. Wellcome Found. Ltd.*, (1998) 79 CPR (3d) 193 **(C-116)**.

argument, but from the perspective of claims drafting rather than from the perspective of the demonstration or sound prediction of utility."[323] Again, it makes no sense to suggest that Canada's promise rule falls afoul of the meaning of utility in Article 1709(1) if Canada could permissibly apply what is effectively a similar requirement under the heading of "overbreadth."

d) Subsequent Practice Confirms that the NAFTA Parties Did Not Adopt a Restrictive Definition of Utility in Article 1709(1)

175. The subsequent practice of the NAFTA Parties also undermines Claimant's view that the word "useful" in Article 1709(1) imposes a highly specific, restrictive obligation on the NAFTA Parties. In particular, Claimant has adduced no evidence to show that Mexico, Canada, and the United States changed their respective practices when NAFTA came into force to bring their legislation into line with the alleged single restrictive standard adopted in Article 1709(1). In fact, to the contrary, the NAFTA Parties have behaved in a manner that makes it clear that Article 1709(1) allows broad discretion in how it is applied.[324]

176. As Professor Holbrook explains, changes in United States law post-NAFTA relating to subject matter and written description have dramatically altered the state of United States patent law, making it more difficult to obtain and protect innovations through patent protection.[325] For example, United States courts adopted an entirely new written description requirement after the entry into force of NAFTA.[326] This requirement was promulgated in the *Ariad* case, ironically at the behest of Claimant.[327] The written description requirement is closely linked to disclosure aspects of the utility requirement

[323] *Olopatadine*, para. 225 (**C-353**); Dimock Second Report, para. 61.

[324] *See, e.g.*, Holbrook Second Report, para. 5; Lindner Second Report, para. 9.

[325] Holbrook Second Report, paras. 45-48.

[326] Holbrook Second Report, para. 27-30, 31; *Regents of the University of California v. Eli Lilly & Co*., 119 F.3d 1559, 1566-69 (Fed. Cir. 1997) (**R-101**); *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co*., 598 F.3d 1336, (Fed. Cir. 2010) (**R-099**).

[327] Holbrook Second Report, paras. 30, 47, fn. 47.

as its primary purpose is to combat speculative, overly broad claims that cover subject matter not actually invented by the patent applicant.[328]

177. Further, contrary to Claimant's assertions,[329] the standard of industrial applicability has also significantly evolved in Mexico since NAFTA entered into force. Notably, legislative amendments were introduced in 2010 to palliate abuses of the patent system, in particular with respect to industrial applicability.[330] Claimant attempts to qualify the 2010 amendments as unnecessary, minor and redundant.[331] As Ms. Lindner explains, this is false. The 2010 legislative reforms significantly raised the threshold of utility required under Mexico's industrial applicability standard, and amended the definition of industrial applicability to emphasize that a patent can only be granted when the invention is able to solve a specific problem in a practical manner,[332] or when it can be used or produced for the purposes specified in the application.[333]

e) Relevant Rules of International Law Confirm that the NAFTA Parties Did Not Adopt a Restrictive Definition of Utility in Article 1709(1)

178. Consideration of "relevant rule[s] of international law applicable in the relations between the parties" pursuant to Article 31(3)(c) of the VCLT confirms that the NAFTA Parties did not adopt a restrictive definition of utility advocated by the Claimant.[334]

179. The TRIPS Agreement is a relevant rule of international law because it is a major intellectual property treaty, negotiated almost concurrently with NAFTA, containing almost identical language to that of NAFTA, which binds all three NAFTA Parties.[335]

[328] Holbrook First Report, para. 58; Holbrook Second Report, paras. 25-33.

[329] Cl. Reply, paras. 163-164.

[330] Lindner First Report, para. 28; Lindner Second Report, paras. 12-22.

[331] *See* Cl. Reply, para. 163; Gonzalez Second Report, paras. 21-23; Salazar Second Report, para. 17.

[332] Lindner Second Report, paras. 14, 17.

[333] Lindner Second Report, para. 14.

[334] *Vienna Convention on the Law of Treaties*, Art. 31(3)(c) **(CL-66)**.

[335] Resp. CM, para. 187; Gervais First Report, para. 56; Gervais Second Report, para. 19.

180. Claimant asserted the relevance of TRIPS to the interpretation of Article 1709(1) in its Memorial.[336] However, in its Reply,[337] Claimant now claims that TRIPS is "not of primary relevance to the interpretation of NAFTA obligations".[338] Claimant's retreat is understandable. It is undisputed that TRIPS does not prescribe specific substantive conditions of patentability. As Professor Gervais outlines in his report, various WTO Appellate Body and dispute-settlement panels have all confirmed that the TRIPS leaves it to WTO Member States to define and implement the various criteria prescribed by TRIPS into their national laws.[339]

181. In contrast to TRIPS, and despite Claimant's continued insistence to the contrary, the PCT is not a "relevant rule of international law" for the purposes of interpreting Article 1709(1). The PCT is recognized by WIPO as a merely procedural treaty.[340] Claimant bases its argument on the relevance of the PCT solely on the definitions section of the treaty, specifically the definition of "capable of industrial application."[341] However, the definition of "capable of industrial application" included in the PCT is deliberately broad, and was intended only for the preliminary and non-binding assessment portion of the PCT international phase.[342] As explained by Mr. Reed, Article 27 of the PCT, read as a whole, makes clear that the PCT has nothing to say about the substantive patentability criteria applied by Contracting States.[343]

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[336] Cl. Mem., para. 204.

[337] Cl. Reply, para. 283.

[338] Cl. Reply, fn 82.

[339] Gervais Second Report, para. 21.

[340] *See* WIPO, "WIPO-Administered Treaties", online, http://www.wipo.int/treaties/en/ **(R-255)**, listing the PCT under the "Global Protection System" group of treaties, which "ensures that one international registration or filing will have effect in any of the relevant signatory States. The services provided by WIPO under these treaties simplify and reduce the cost of making individual applications or filings in all the countries in which protection is sought for a given IP right." This is to be contrasted with the "IP Protection" group of treaties, which "define internationally agreed basic standards of intellectual property (IP) protection in each country."

[341] Cl. Reply, para. 276.

[342] Resp. CM., para. 380; Gervais First Report, para. 74.

[343] Reed Second Report, paras. 8, 12.

f) Supplementary Means of Interpretation Confirm that the NAFTA Parties Did Not Adopt a Restrictive Definition of Utility in Article 1709(1)

182. To the extent that the Tribunal considers them at all relevant, supplementary means of interpretation pursuant to Article 32 of the VCLT also support Canada's position that Article 1709(1) does not impose a restrictive definition of utility on the NAFTA Parties. Various reports from WIPO and regional initiatives on the meaning of "utility" are appropriate supplementary means for the Tribunal to confirm the meaning of Article 1709(1).

183. As Professor Gervais explains in his report, in 2001 the Standing Committee on the Law of Patents ("SCP") undertook a global survey of the meaning of "utility" in various jurisdictions and found that (1) the "promise of the patent" approach was recognized internationally; (2) both "utility" and "industrial applicability" vary significantly by jurisdiction; (3) national courts determine whether the standard is met; (4) "utility" and "industrial applicability" are not synonymous; and (5) "there is a wide range of differences among SCP members concerning the interpretation and practice relating to the 'industrial applicability/utility' requirement".[344] These findings show that there is no internationally agreed upon approach to utility. Certainly if NAFTA had mandated such a unified approach in Article 1709(1), it would have been of significant note. It is not even mentioned.

184. The failure of the *Substantive Patent Law Treaty* ("SPLT") negotiations further confirms Canada's interpretation of Article 1709(1). Contrary to what Mr. Thomas argues on Claimant's behalf, Professor Gervais explains that the relative silence on the issue of utility during the SPLT negotiations does not mean that there was international consensus on its substantive meaning.[345] The contemporaneous documents created during the SPLT negotiations show that, despite Mr. Thomas' purported recollection of events that happened more than a decade ago, there was no consensus, practice varied by

[344] Gervais Second Report, paras. 45-48.

[345] Gervais Second Report, paras. 34-38.

jurisdiction, and the NAFTA parties and other WTO Member States avoided ascribing a substantive definition of "utility" altogether.[346]

185. In fact, Mr. Thomas' position is fundamentally inconsistent with Claimant's own theory in this case. *AZT* the case cited by Claimant as marking a "sea change" in Canadian patent law was decided by the Supreme Court of Canada in 2002.[347] As Professor Gervais notes, if *AZT* was such a dramatic departure from international standards, "it is strange that this was not discussed or noted in the SPLT negotiation documents" where, according to Mr. Thomas, all the parties agreed as to the substantive scope of utility.[348] If the SPLT negotiations are of any use to the VCLT analysis, it is only to confirm that substantive patent law is not, and never was, harmonized. If there had been even an agreed-upon baseline of "utility," it would have been noted in the negotiations.

3. *Canada's Law Is Consistent With Article 1709(7)*

186. Article 1709(7) provides:

> Subject to paragraphs 2 and 3, patents shall be available and patent rights enjoyable without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced.

187. As set out in Canada's Counter-Memorial, Article 1709(7) requires the Parties to make patents available and patent rights enjoyable, without discrimination as to the field

[346] *See* Gervais Second Report, paras. 39-48; WTO, WIPO and WHO, "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade" (2013), **(R-220)**; WIPO, "The Practical Application Of Industrial Applicability/Utility Requirements Under National And Regional Laws", April 2001 **(R-407)**; WIPO, Report of the Standing Committee on the Law of Patents, Fifth Session, Doc. No. SCP/5/6, 27 November 2001 **(R-224)**; WIPO, Draft Substantive Patent Law Treaty, Standing Committee on the Law of Patents, Fifth Session, Doc. No. SCP/5/2, 4 April 2001 **(R-223)**.

[347] Gervais Second Report, para. 37.

[348] Gervais Second Report, para. 37.

of technology.[349] Claimant has agreed that Canada's patent law plainly does not discriminate on its face against pharmaceutical patents.[350]

188. However, Claimant argues that pharmaceutical patents are subject to *de facto* discrimination in Canada.[351] As proof, it claims that there is a statistically significant difference in utility-based invalidity rates between the pharmaceutical and non-pharmaceutical sectors after 2005.[352] Relying on the analysis of Dr. Levin, who submitted a report for the first time along with Claimant's Reply, Claimant concludes that "the discriminatory pattern of utility rulings since 2005" can be explained only by "the dramatic change in Canada's utility standard."[353] Claimant's evidence of *de facto* discrimination is flawed in three fundamental ways: (1) it is devoid of context; (2) it suffers from serious methodological flaws; and (3) it omits important inquiries.

189. Claimant ignores at least three salient contextual factors in an attempt to bolster its claim that a change in the law of utility in 2005 caused a disproportionate impact on pharmaceutical patents.

190. First, the data points analysed for the purposes of this exercise are already a small subset of all patents issued. Specifically, the universe of cases identified includes not only those patents whose validity was challenged, but those patents whose validity was ruled upon by the courts. As noted above, between 1980 and 2013, Canada granted 25,760 pharmaceutical patents,[354] and only 134 validity challenges were decided.[355] Those patents whose validity has not been challenged must be kept in mind in understanding the way in which Canada's patent system applies to pharmaceuticals.

[349] Resp. CM., para. 383.

[350] Resp. CM., para. 384; Cl. Mem., para. 214.

[351] Cl. Reply, paras. 195-198, 291-300.

[352] Cl. Reply, paras. 195, 298.

[353] Cl. Reply, para. 300.

[354] WIPO Database, Patent Grants by Technology – Pharmaceuticals, Total Count by Filing Office – Canada (1980-2013) (**R-436**).

[355] Brisebois Second Statement, Annex F.

Moreover, even within the limited universe identified by Claimant, the fact is that many of the cases on which Claimant relies do not even turn on an application of the "promise utility doctrine" it articulates.[356]

191. Second, of those pharmaceutical patents challenged between 2005 and 2014, 78% were secondary patents.[357] As explained above, many secondary patents seek a monopoly for a smaller step forward in the state of the art than primary patents. Such small steps are more difficult to defend against attacks on novelty, non-obviousness and utility. As Canada pointed out in its Counter-Memorial, secondary patents are (i) more frequently challenged and (ii) more frequently successfully challenged than "primary" patents.[358] This trend, which is particularly prevalent in the pharmaceutical sector, has been observed not only in Canada, but also in the United States and in Europe.[359]

192. Third, there was an increase in overall pharmaceutical patent litigation around 2005.[360] Claimant attributes this increase exclusively to a change in the law of utility. However, Claimant asserts a causal link with evidence, at most, of correlation. Indeed, Claimant ignores the fact that the "spike" in utility-based invalidity findings that it attributes to a change in the law of utility in 2005 was symptomatic of a larger trend of increased litigation on all validity grounds, and a proportional increase in invalidations on all grounds at the same time.[361]

[356] *See, e.g., Abbott v. Ratiopharm*, 2005 FC 1095 (**C-441**); *Abbott Laboratories v. Canada (Minister of Health)*, 2005 FC 1332 (aff'd 2007 FCA 153) (**C-113**); *Merck v. Apotex*, 2005 FC 755 (**C-354**).

[357] Brisebois First Statement, para. 43, Figure 6.

[358] *See* Resp. CM., para. 145; Brisebois First Statement, paras. 41-46.

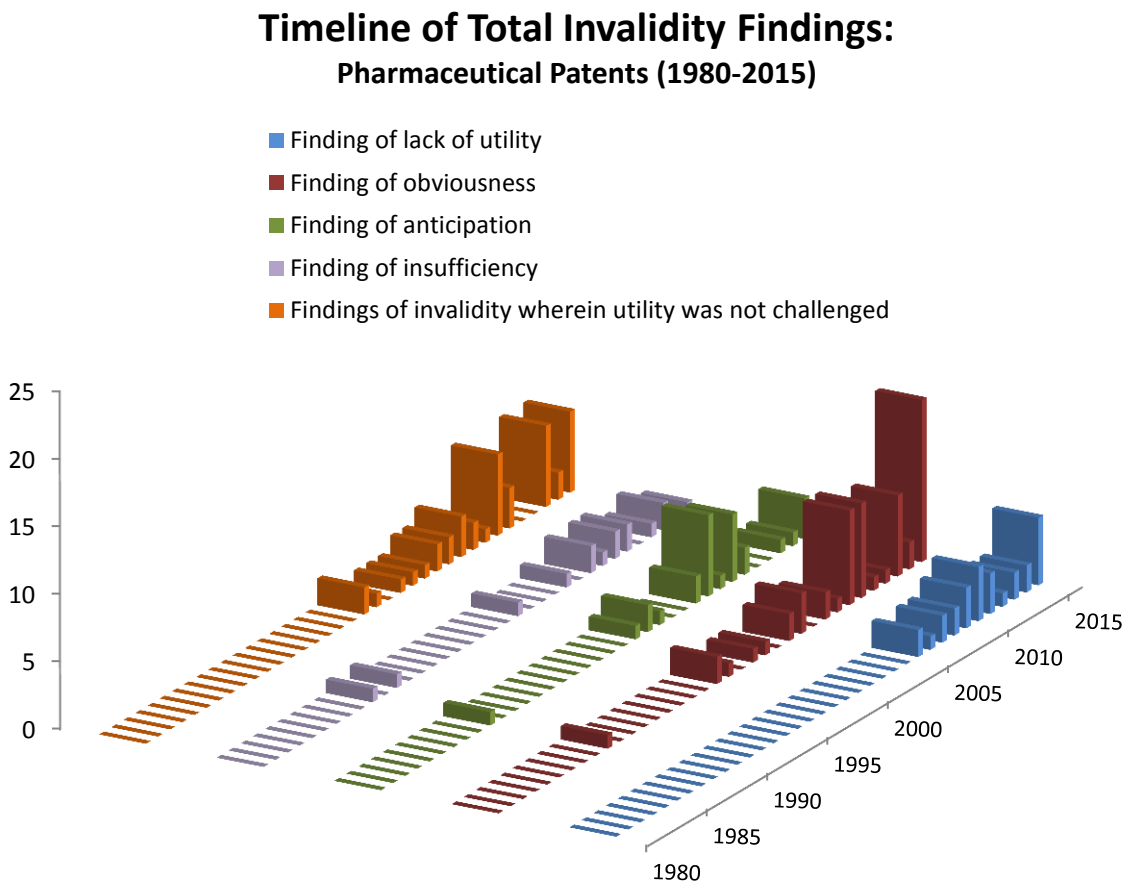
[359] *See, e.g.*, Hemphill, When Do Generics Challenge Drug Patents?, pp. 613-649 (**R-245**); European Commission (2009) Pharmaceutical Sector Inquiry: Final Report, p. 221 (**R-243 amended**).

[360] *See* Brisebois Second Statement, para. 41, Figure 1.

[361] Brisebois Second Statement, paras. 41- 42, Figures 1 and 2.

193. As shown in Figure 1 below, invalidity findings in cases in which utility was not challenged at all (orange bars) began to peak even earlier than findings of invalidity on the basis of utility (blue bars):[362]

Figure 1[363]

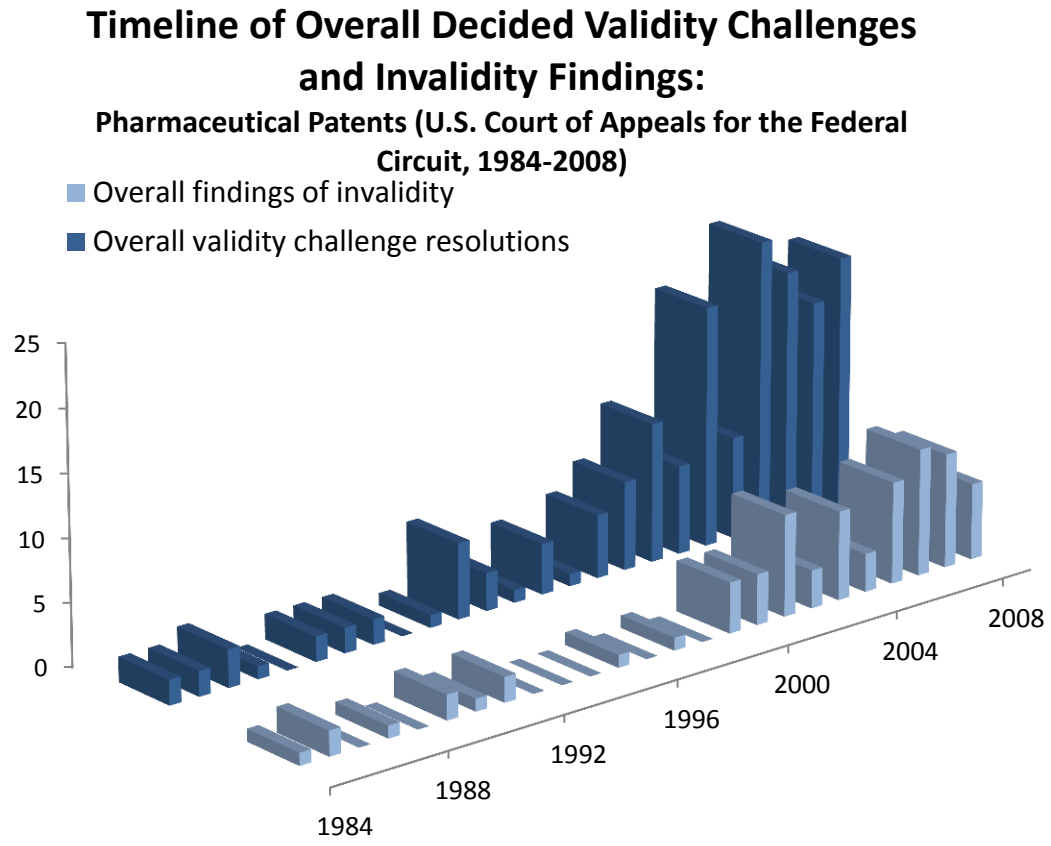


194. Further, as Figure 2 below shows, this overall trend mirrors what occurred in the United States where there was no alleged change in the law of utility:

[362] Brisebois Second Statement, paras. 42-43.

[363] Brisebois Second Statement, para. 42, Figure 2.

Figure 2[364]



195. Claimant's statistical data also suffers from three primary methodological flaws that render its conclusions unreliable. The small populations at issue mean that these methodological flaws are particularly critical. As Dr. Brisebois shows, one case mistakenly categorized fundamentally changes the statistical conclusion from "significant" to "not significant."[365]

196. First, Claimant's data set suffers from classification errors that, when corrected, reverse Claimant's conclusion that since 2005, pharmaceutical patents have had a statistically significant higher rate of invalidation on the basis of utility than non-

[364] Brisebois Second Statement, para. 46, Figure 4.

[365] Brisebois Second Statement, paras. 4,12.

pharmaceutical patents.[366] As Dr. Brisebois shows, there is in fact no statistical evidence of a difference in utility-based invalidation rates between pharmaceutical and non-pharmaceutical patents.[367]

197. Second, Claimant's results are skewed because they include PM(NOC) proceedings. As explained in Canada's Counter-Memorial, in 1993 Canada introduced the PM(NOC) regulations to replace the compulsory licence system for pharmaceutical patents.[368] Contrary to what Claimant argues, one of the primary effects of the new regulations was to increase litigation over pharmaceutical patents. Under the compulsory licence regime, there was no incentive to litigate pharmaceutical patents because the Commissioner of Patents was permitted to issue a licence as of right to a generic manufacturer under any patent covering a pharmaceutical product, without involving the patentee.[369] In contrast, the PM(NOC) regulations require a generic manufacturer to put the patentee on notice when it wishes to enter the market, and permit the patentee to seek the courts' assistance in prohibiting the Minister of Health from allowing the generic manufacturer to enter the market. Simply by commencing a PM(NOC) proceeding, the patentee gains the benefit of a 24-month stay during which the generic competitor cannot be approved to sell its product while the legal proceeding is resolved. This stay is triggered regardless of the merits of the patentee's case.[370] Armed with a new tool for patent protection, which offered significant and unique benefits, pharmaceutical patentees increasingly sought assistance from the courts to assert their patent rights.[371]

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[366] Brisebois Second Statement, paras. 5-13.

[367] Brisebois Second Statement, para. 13.

[368] *See* Resp. CM., paras. 45, 138-141; Dimock First Report, paras. 41-45.

[369] Dimock First Report, para. 38.

[370] *PM(NOC) Regulations*, s. 7 **(R-031)**; Dimock First Report, para. 43. The United States has a similar provision in the *Hatch-Waxman Act* "Changing Patterns of Pharmaceutical Innovation", p. 17 **(R-423)**; Bouchard, "Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals", pp. 176-177 **(R-421)**.

[371] Honourable John Manley, Canadian Minister of Industry, Speaking Notes for Address to the Standing Committee on Industry, Review of Bill C-91 (17 February 1997), pp. 3-4 **(C-39)**. The issue of increased litigation under the PM(NOC) regulations remained an issue of interest for the Committee in its review of

198. Indeed, it is uncontroverted that the large majority of pharmaceutical patent litigation in Canada is undertaken under these regulations,[372] and that PM(NOC) proceedings are "far more prevalent than any other type of patent proceeding in the last two decades."[373] Notably, because PM(NOC) proceedings are only available with respect to pharmaceutical patents, pharmaceutical companies are the unique beneficiaries of this statutory provision. As such, including these cases in a comparison between pharmaceutical and non-pharmaceutical sectors introduces a substantial and "impermissible and inappropriate differentiation factor between populations."[374]

199. Third, Claimant's data set is unreliable because it includes both double-counting and under-counting.[375] Including PM(NOC) results leads to double-counting because the same patent may be challenged multiple times in the PM(NOC) regime by different generic manufacturers, and then again in an impeachment/infringement proceeding.[376]

200. At the same time, counting court decisions, rather than patents for which court decisions are rendered, leads to under-counting because a single court decision can dispose of validity challenges to more than one patent. Claimant's methodology allows

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the 1993 amendments: *See* Parliament of Canada, Review of Section 14 of the Patent Act Amendment 1992 (Chapter 2, Statutes of Canada, 1993): *Fifth Report of the Standing Committee on Industry*, April 1997 , online: http://www.parl.gc.ca/content/hoc/archives/committee/352/indu/reports/05_1997-04/rec-e.html, at Recommendation 4 (**R-446**), ("The Committee has heard from many witnesses regarding the Notice of Compliance (NOC) regulations. We believe that these regulations are the heart of the debate and we have attempted to address the contention regarding them. In a specific round-table, the Committee heard testimony from legal counsel from both the generics and the brand name industries. Options were discussed and the merits of each model were debated. The Committee heard testimony from both sides suggesting that the system, in its present form, is problematic and has resulted in excessive litigation.") (emphasis added).

[372] *See* Brisebois First Statement, para. 32.

[373] Dimock Second Report, para. 144. *See also* Reddon Report, para. 24.

[374] Brisebois Second Statement, para. 21.

[375] *Id.*, paras. 23-24, 14-15.

[376] For example, the allegation of lack of utility against Canadian patent 1,341,206 was found to be justified in *Aventis Pharma Inc. v. Apotex*, 2006 FCA 64 **(C-214)** (a PM(NOC) proceeding). It was later invalidated on the same grounds in *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2011 FCA 300 **(C-510)**. Canadian patent 2,139,653 is another example of "double counting" by Claimant: *see AstraZeneca v. Apotex*, 2010 FC 714 **(C-468)** (PM(NOC) case) and *Astrazeneca Canada Inc. v. Apotex Inc.* 2015 FCA 158 (**R-399)** (infringement/impeachment case). *See also* Brisebois Second Statement, paras. 23-24.

for selective classification when a decision makes opposite findings on the same ground for different patents.[377] Perhaps unsurprisingly, each and every time a court found one patent valid on utility but another invalid, Claimant has classified this as a finding of invalidity. Correcting for these methodological errors, Dr. Brisebois again confirms that there is no statistically significant difference in utility-based invalidation rates between the pharmaceutical and non-pharmaceutical sectors.[378]

201. Finally, Claimant's evidence omits important inquiries and analyses. For example, the promise utility doctrine Claimant defines as its measure comprises three distinct elements allegedly developed in 2002, 2005 and 2008.[379] However, Claimant looks only at the purported impact of the doctrine after 2005.[380] This is unsurprising, given that, as Dr. Brisebois has shown, there is no statistical evidence of a difference in utility-based invalidation rates for pharmaceutical patents before and after either 2002 or 2008.[381] Moreover, if there was in fact a "dramatic change in Canada's utility standard" in 2005,[382] one might expect Claimant to have demonstrated that there was a statistically significant difference in invalidity findings for pharmaceutical patents on the basis of utility in the periods before and after 2005. However, this analysis is conspicuously absent from Claimant's "rigorous statistical analysis."[383] Running that analysis shows

[377] For example, Canadian patents 1,333,895 and 1,338,937 were both challenged in the same case on the basis of utility: *Novartis Pharmaceuticals Canada Inc. v. Teva Canada Ltd.*, 2013 FC 283 (aff'd 2013 FCA 244) (**C-244**). The allegations of lack of utility were found justified for one, but not for the other. Claimant counted this case as "patent found *invalid* on utility grounds", when it could equally have been treated as the opposite: *see* Levin Report, Appendix C, p. 18. The same is true of *Lundbeck Canada Inc. v. Ratiopharm Inc.*, 2009 FC 1102 ("*Lundbeck*") (**C-371**); *see* Levin Report, Appendix C, p. 15. *See also* Brisebois Second Statement, para. 15.

[378] Brisebois Second Statement, para. 26.

[379] Cl. Reply, para. 70, and, more generally, at Section II.A ("The Promise Utility Doctrine Is Made Up of Three Component Parts, All New, Which Interact to Impose an Elevated and Additional Utility Requirement Without Precedent in Canadian Law Until the 2000s").

[380] *See, e.g.*, Cl. Reply, para. 298.

[381] Brisebois Second Statement, paras. 35-39.

[382] Cl. Reply, para. 300.

[383] Cl. Reply, para. 300.

that there is no statistical evidence of a difference in utility-based invalidation rates for pharmaceutical patents before and after 2005 either.[384]

202. Similarly, as Dr. Brisebois explains, if the rate of utility-based invalidations increased for pharmaceutical patents after 2005 because of a change in the law, and the rate of invalidations on all other grounds remained relatively stable (as Claimant argues),[385] one would expect to see a statistically significant increase in overall invalidation rates for pharmaceutical patents.[386] This is again not the case.[387]

203. In sum, there is no evidence of any *de facto* discrimination against pharmaceutical patents in Canada. The interpretation given to Canada's *Patent Act* by the courts is fully consistent with Canada's obligations under Article 1709(7).

4. *Canada's Law Is Consistent With Article 1709(8)*

204. Article 1709(8) provides:

> A Party may revoke a patent only when:
>
> > (a) grounds exist that would have justified a refusal to grant the patent; or
> >
> > (b) the grant of a compulsory license has not remedied the lack of exploitation of the patent.

205. Claimant argues that Canada breached Article 1709(8) through the creation of a "fundamentally new patentability requirement, and its retroactive application."[388] Claimant is wrong both on the law and on the facts. Article 1709(8) does not constrain the role of the courts in interpreting and elaborating broad patentability criteria set out in

[384] Brisebois Second Statement, paras. 33-34.

[385] *See* Cl. Reply, para. 197.

[386] This is because a finding of invalidity on any ground is sufficient to invalidate the entire patent: Brisebois Second Statement, para. 28.

[387] Brisebois Second Statement, paras. 28-32.

[388] Cl. Reply, para. 305.

the legislation of the NAFTA Parties. It does not prevent significant, substantial, or even dramatic evolution in the law. But even if it did, Claimant is wrong that any such change occurred. As Canada explained above, and as further detailed in the reports of Mr. Dimock, Claimant's patents were invalidated on the basis of patent rules that existed when its patents were filed and would have justified a refusal to grant its patents.[389]

206. By its ordinary meaning, Article 1709(8)(a) provides that if a patent should not have been granted in the first place, it may be revoked. It excludes the possibility of revocation on arbitrary grounds that do not form part of a Party's patent law and could not have justified a refusal to grant a patent. In contrast, it permits courts to invalidate patents on the basis that they did not meet basic patentability criteria, such as utility, and should never have been granted. This is what happened to Claimant's patents for the use of olanzapine and atomoxetine.

207. Evolution in jurisprudence on a particular patentability requirement between the grant and revocation of a patent does not amount to a breach of Article 1709(8). Such evolution is inherent and necessary in any patent system. Indeed, Claimant concedes that Article 1709(8) does not prevent evolution in the standards applied to determine patent validity.[390] It also accepts that those evolving standards govern patents throughout their patent term,[391] meaning that today's judicial interpretations bear on the validity of patents granted in the past.

208. However, Claimant attempts to significantly limit the permissible degree of evolution in jurisprudence under Article 1709(8). Claimant argues that "subtle changes" and "slight tightening" of patentability standards by the Courts are allowed, while more substantial interpretive developments are not.[392] This limited flexibility is not what the

[389] Dimock First Report, paras. 224, 162-196. *See also* Resp. CM, paras. 81-134.

[390] Cl. Reply, para. 304.

[391] Cl. Reply, para. 304.

[392] Cl. Reply, para. 305.

NAFTA Parties agreed to in Article 1709(8) and is at odds both with the interpretive context of Article 1709(8) and the subsequent practice of the NAFTA Parties.

209. Nothing in the interpretive context of Article 1709(8) indicates that the NAFTA Parties intended to constrain the power of the courts to interpret the broad patentability standards contained in their patent legislation. To the contrary, NAFTA Chapter Seventeen places the courts at the centre of the adjudication of intellectual property rights.[393] There is nothing to suggest that the Parties intended to restrict the traditional role of the courts in adjudicating patent law disputes and elaborating patent law jurisprudence. Indeed, as long as patent law regimes have existed in the NAFTA Parties, the courts have been responsible for giving meaning to broadly-drafted statutory standards in specific situations. As technological evolution changes the nature of inventions, courts are called upon to develop and interpret the applicable patent law principles in dramatically new contexts. This inevitably produces change and evolution in the jurisprudence.

210. The subsequent practice of the NAFTA Parties similarly indicates that even court interpretations that significantly alter past jurisprudence do not breach Article 1709(8). As Canada explained in its Counter-Memorial, there have been dramatic changes in American and Mexican patent law since NAFTA entered into force, and those changes, particularly in the United States have been retrospectively applied to patents, sometimes resulting in the invalidation of thousands of patents.[394] Contrary to what Professor Merges suggests, the changes that have occurred in US law are not "subtle," "gradual," or "marginal."[395] For example, as Professor Holbrook explains, "the Supreme Court decision in *Alice v. CLS Bank* represents a dramatic sea change in the law of patentable subject matter that has invalidated thousands of patents."[396] Similarly, the new written description doctrine promulgated by the Federal Circuit in *Ariad* "stands alone in the

[393] Resp. CM., paras. 369-372.

[394] Resp. CM, paras. 395-399.

[395] *See, e.g.*, Merges Second Report, paras. 1, 51

[396] Holbrook Second Report, paras. 45-46.

world and has had a dramatic impact in biotechnology and software cases."[397] Post-NAFTA changes were also made to the interpretation of the obviousness requirement, making the test more rigorous.[398] Such changes show that the NAFTA Parties do not believe that Article 1709(8) prevents the invalidation of patents based on law as it stands when the challenge was made, as opposed to when the patent was granted.

211. In sum, Article 1709(8) was in no way intended to curtail the development of the patent law of the NAFTA Parties. Even if Claimant were right that the alleged "promise utility doctrine" amounted to a "dramatic change" in the law of utility in Canada (it did not),[399] this would not breach Article 1709(8). The invalidation of Claimant`s patents over atomoxetine and olanzapine by the Canadian courts was wholly consistent with Canada`s obligations in Article 1709(8).

D. There Has Been No Unlawful Direct or Indirect Expropriation of Claimant's Patents

212. For all of the reasons above, the Tribunal need not undertake any further analysis of the consistency of the challenged measures with Article 1110. Article 1110 simply does not apply in this case. Nevertheless, for the sake of providing a complete response to Claimant's meritless allegations, Canada shows below that Claimant has still failed to prove that Canada has violated its obligation under Article 1110(1) of NAFTA. In its Reply, Claimant continues to misconstrue the applicable legal test for expropriation when the measure is that of a court exercising its adjudicative function. When the correct standards are applied, it is clear that the decisions in question here did not amount to an unlawful direct or indirect expropriation.

[397] Holbrook Second Report, para. 45.

[398] Holbrook First Report, paras. 73-75; *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 92007) (**R-130**). *See also* Gervais Second Report, paras. 10-11.

[399] *See, e.g.*, Cl. Reply, paras. 69, 334, 364

1. *Claimant's Legal Theory On Judicial Expropriation Is Incorrect*

213. As Canada explained in its Counter-Memorial, when a challenge is made to the conduct of a court, it is necessary to look at the function that was being exercised by that court to determine whether and on what grounds the acts can trigger liability under international law.[400] In this case, the Canadian courts were adjudicating the existence of Claimant's property rights in accordance with domestic law. It is well-accepted in international law that only significant flaws rising to the level of a denial of justice are protected against in these circumstances.[401]

214. As Canada explained in its Counter Memorial, Article 1110 reflects the customary international law of expropriation.[402] Claimant has not established that the customary international law of expropriation protects against adverse judicial decisions on the validity of property rights at domestic law.[403] In fact, the customary international law of expropriation has, for centuries, concerned only executive, legislative, military and police actions.[404] Claimant has not cited any example of a purely "judicial taking" in the absence of a denial of justice, let alone provided this Tribunal with a single example

[400] *See* Resp. CM, para. 230, fn 416. *See also Liman Excerpts of Award*, para. 268 **(RL-027)** ("…one will have to take into account the different functions held by administrative organs and judicial organs of a state and the resulting differences in their discretion when applying the law and in the appeals against their decisions.").

[401] *See* Resp. CM., paras. 316-328. *See also Azinian Award*, para. 99 **(RL-002)**; *Loewen Award*, para. 141 **(RL-013)**; *Loewen Group and Another v. United States of America*, Opinion of Christopher Greenwood Q.C., 26 March 2001, ("*Loewen, Opinion of Christopher Greenwood*"), para. 10 **(RL-025)**; *Arif Award*, paras. 415-417 **(RL-063)**.

[402] Resp. CM, para. 308, fn 530.

[403] Claimant points to a handful of arbitral awards, but arbitral award do not constitute evidence of either state practice or *opinio juris*. *See* Resp. CM., para. 267, fn 477. In any case, those decisions all involved either the taking of property that was recognized to be valid, egregious misconduct by the State, or both. *See* Resp. CM., para. 117.

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

in history of where a judicial determination that a domestic law property right was invalid constituted an expropriation at international law. Indeed, Claimant has not even attempted to provide examples of state practice where this would be a compensable taking in any domestic legal system. The concept is unknown to Canadian law. Similarly, in the United States judicial decisions cannot "take" property within the meaning of the Fifth Amendment takings clause.[405] In the even more specific context of intellectual property rights, Claimant has failed to identify a single instance, anywhere in the world, where a State provided compensation to a patent holder after the invalidation of its patent by a domestic court. It fails to do so despite the thousands of patent invalidations around the world annually, and the high value associated with many of these patents. This case would be the first in the history of international law.

215. Completely ignoring the lack of evidence that customary international law protects against judicial expropriation, Claimant argues that a judicial determination of rights amounts to an expropriation if (i) it substantially deprives an investment of value and (ii) has the requisite "unlawful character."[406] Claimant's position is internally contradictory. It says on the one hand that there are "no special rules for claims of expropriation based on judicial measures"[407] but on the other hand puts forward its own special rule.[408]

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

[406] Cl. Reply, fn 493.

[407] Cl. Reply, para. 240.

[408] *See, e.g.*, Cl. Reply, paras. 241, 246.

216. Moreover, the theory of judicial expropriation that Claimant puts forward is untenable. It would essentially turn this Tribunal into an *über*-tribunal, responsible for reviewing the consistency of judicial determinations not just with the obligations in Chapter Eleven, but with the obligations in all other Chapters of NAFTA and in all other international treaties. There are no grounds to support such a wide exercise of jurisdiction.[409] Indeed, Claimant has failed to identify any case of judicial expropriation that did not (1) deal with the specialized context of enforcement of international arbitral awards[410] or (2) involve seriously egregious conduct on the part of the State manifested in a judicial decision.[411] Claimant cannot identify any case that remotely resembles the facts before this Tribunal, where a domestic court has discharged its ordinary function of determining what rights exist at domestic law, without any allegation of egregiously improper conduct by the State. [412]

[409] The United States holds the same view: *DIBC Submission of the United States*, para. 2 **(RL-095)** ("Articles 1116(1) and 1117(1) do not provide consent to arbitrate disputes based on alleged breaches of obligations found in other articles or chapters of the NAFTA or alleged breaches of other treaties or other international obligations."). *See also Canfor Corporation v. United States of America and Terminal Forest Products Ltd. v. United States of America*, UNCITRAL, Decision on Preliminary Question, 6 June 2006, ("*Canfor Decision on Preliminary Question*"), para. 245 **(RL-104)**; *Mondev Award*, para. 121 **(RL-004)**.

[410] *Saipem Award* **(RL-064)**; *ATA Award* **(RL-068)**.

[411] *Rumeli Telekom A.S. and Telsim Mobil Telekomunikasyon Hizmetleri A.S. v. Republic of Kazakhstan*, ICSID Case No. ARB/05/16, Award, 29 July 2008, paras. 702, 707 **(RL-070)** (The Tribunal held that "that the court process which resulted in the expropriation of Claimants' shares was brought about through improper collusion between the State, acting through the Investment Committee, and Telcom Invest." It also observed that "the constitution constitutes power in the hands of the presidency, permitting the president to … exercise significant influence over the … judiciary …"); *Sistem Award*, para. 118 **(CL-146)** (the Tribunal's finding of expropriation was pointedly "in the circumstnaces which obtained in this case", which included the armed seizure of the hotel); *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, para. 43 **(RL-069)** (noting "the Claimant's impossibility to challenge the Court order in Iran"). *See also* Resp. CM., para. 343.

[412] The case of *Swisslion v. Macedonia* also does not support Claimant's theory: *Swisslion Doo Skopje v. The Former Yugoslav Republic of Macedonia*, ICSID Case No. ARB/09/16, Award, 6 July 2012 **(RL-065)**. No judicial expropriation was found in *Swisslion*. The Tribunal's entire discussion of whether there was "illegality" that could render the decision of the Macedonian courts expropriatory concerned whether there was a denial of justice. The Tribunal noted that the question was whether the court decisions "constitute a violation of international law, and in particular whether they amount to a denial of justice." *Id.* (para. 264) (emphasis added). The Tribunal found that the Claimant's legal expert was "unable to point to any act of the judiciary that would even come close to a denial of justice at international law." *Id.* (para. 269) The Tribunal considered *Saipem* and emphasized that the court conduct at issue in that case was

217. There are numerous cases where, if Claimant's theory of judicial expropriation were correct, it should have featured prominently. It is nowhere to be found. Claimant strains to contend that *Arif v. Moldova* did not address the theory of expropriation at issue in this arbitration.[413] But the elements of Claimant's theory were all in place. Judicial measures resulted in the claimant's domestic property rights being invalidated, and the tribunal found the State's conduct to breach another rule of international law, which was the FET obligation in the governing Treaty.[414] The tribunal in that case did not find the separate breach sufficient to establish an expropriation.[415] The same is true of *GEA Group v. Ukraine*. On Claimant's theory, whether the Ukrainian court's annulment of the ICC award was consistent with the New York Convention should have been fundamental to the tribunal's expropriation analysis. It was not even mentioned.[416]

218. A Chapter Eleven tribunal does not exist to examine breaches of other international treaties, or even of other chapters of NAFTA. Rather, it exists solely to determine whether a respondent State has breached its obligations under Section A of Chapter Eleven.[417] As the *Mondev* tribunal pointed out, "Chapter Eleven arbitration does not even extend to claims concerning all breaches of NAFTA itself."[418] If there had been an intention to incorporate by reference extraneous treaty standards, "some clear indication of this would have been expected."[419] The absence of reference to such

"abusive" and "grossly unfair." *Id.* (fn 377) It did not endorse the expansive rule of judicial expropriation that Claimant advocates in this case.

[413] Cl. Reply, para. 252, fn 508.

[414] *Arif Award*, paras. 417, 556-558 (**RL-063**).

[415] *Id*. 417-421 (**RL-063**).

[416] *GEA Group Aktiengesellschaft v. Ukraine*, ICSID Case No. ARB/08/16, Award, 31 March 2011, para. 230 (**RL-026**).

[417] *Canfor Decision on Preliminary Question*, para. 245 (**RL-104**). *See also Mondev Award*, para. 121 (**RL-004**).

[418] *Mondev Award*, para. 121 (**RL-004**).

[419] *Ibid*.

extraneous treaty standards indicates the Parties' intention to exclude them from Chapter Eleven review.[420]

219. That Claimant's theory of judicial expropriation cannot be correct is also shown by the structure of Article 1110(7) itself which expressly cross-links to Chapter Seventeen. Claimant reasons that since Article 1110(7) says consistency with Chapter Seventeen means that there can be no expropriation, it must also mean that inconsistency with Chapter Seventeen proves that there has been an expropriation.[421] In essence, Claimant suggests that the existence of Article 1110(7) supports its theory of judicial expropriation. Claimant is wrong.

220. The inference that Claimant is asking the Tribunal to draw is a logical fallacy, known as the fallacy of denying the antecedent. In essence, the problem with the reasoning is that it ignores the other reasons why something may or may not have occurred. The most classic example involves the following syllogism: "If it is raining, then the streets are wet." From this, one cannot infer that if it is not raining, then the streets are not wet because there could be plenty of other reasons why the streets would be wet (e.g., someone could have washed them).

221. Applied to this case, the relevant conditional statement would be: "If a measure is consistent with Chapter 17, then it is consistent with Article 1110." From this, one cannot infer, as Claimant suggests, that because a measure is inconsistent with Chapter 17, it is inconsistent with Article 1110. There could be many other reasons why the measure is consistent with Article 1110. Claimant's interpretation perverts the logic of Article 1110(7) by transforming what was intended to be a shield for the NAFTA Parties in a sensitive area into a sword for disappointed patent litigants to wield.

[420] The United States maintains the same position: *DIBC Submission of the United States*, para. 2 **(RL-095)**

[421] Cl. Reply, paras. 255-256.

222. The Tribunal should definitively reject Claimant's argument that it is entitled to find a breach of Article 1110 on the basis of a breach of some other obligation of international law. If the correct standards in Article 1110 are applied (though as explained above, they should not be applied at all in this sentence), it is clear that the challenged measures here are consistent with Canada's obligations.

2. *Claimant's Patents Were Not Directly Expropriated*

223. In its Reply, Claimant is obviously confused with respect to the concept of direct expropriation. In support of its arguments that the invalidation of its patents amounted to a direct expropriation, it cites to passages from *Metalclad*.[422] However, *Metalclad* is of no assistance here and the passages cited by Claimant have been misleadingly stripped from their context. Direct expropriation requires a taking of property.[423] In the case at hand, there was no taking of property. Rather, there was a determination that the property in question did not exist. There is no evidence that Canada acquired something or that there was a transfer of title to some other third party as a result of these invalidations. Patents provide exclusivity in the market to patent holders. While the invalidation of Claimant's patent resulted in the loss of its exclusivity, this exclusive right was not transferred to the successful generic manufacturers who challenged the patent. Indeed, the invalidation of Claimant's patents now means that no one has exclusivity and that all are allowed to sell in the market, including Claimant.

3. *Claimant's Patents Were Not Indirectly Expropriated*

224. In its Counter-Memorial, Canada explained that an indirect expropriation occurs "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."[424] Measures have an

[422] Cl. Reply, para. 309.

[423] *Id*., paras. 405-406.

[424] *Id*., para. 407.

effect "equivalent to direct expropriation" when there is a "taking" of fundamental ownership rights that causes a substantial deprivation of the investment.[425]

225. Canada also explained how, in an analysis of indirect expropriation, three factors provide guidance on whether there has been a substantial deprivation of an investment: (1) the economic impact of the measure or series of measures; (2) the extent to which the measure or series of measures interferes with distinct, reasonable investment-backed expectations; and (3) the character of the measure or series of measures.[426] None of these factors, alone or in combination, are determinative.[427] All are merely factors that the Tribunal should consider in determining whether there has been an indirect expropriation. Further, in considering these factors, the Tribunal should be guided by the NAFTA Parties' understanding that non-discriminatory measures of a Party that are designed and applied to protect legitimate public welfare objectives cannot be considered to be indirect expropriations, except where they are so severe in light of their purpose that they cannot be reasonably viewed as having been adopted and applied in good faith.[428]

226. As Canada explained, this understanding of what can constitute an indirect expropriation is reflected in the interpretative annexes contained in recent Canadian and United States investment treaties.[429] The fact that the NAFTA Parties have not adopted a similar interpretative annex for NAFTA Chapter Eleven does not diminish their intrinsic value for this case.[430] These annexes merely explain what the NAFTA Parties mean and have always meant by the term "indirect expropriation,"[431] as affirmed by the position of

[425] *Id*. CM., para. 409.

[426] Resp. CM., para. 407.

[427] *Ibid*.

[428] *Id*., paras. 407, 413.

[429] Id., para. 407.

[430] *Ibid*.

[431] *Ibid*.

Canada's NAFTA partners in other cases.[432] They are expressly for greater certainty and "do not change the nature of the substantive obligations that existed under … prior agreements; instead, they merely elucidate, for the benefit of tribunals charged with interpreting the treaty, the Parties' intent in agreeing to those obligations."[433] The Tribunal may rely on the principles stated in these annexes to assist it in interpreting the obligations in NAFTA Article 1110.

a) The Measures Did Not Substantially Deprive Claimant of Its Investment

227. Claimant was not deprived of substantially all of the value of its atomoxetine and olanzapine patents. First, its patents were only invalidated in the last few years of the patent protection. It had years of monopoly sales before this occurred.[434] Second, the invalidation of its patents did not prevent Claimant from continuing to produce and sell its atomoxetine- and olanzapine-based drugs. In fact, Claimant continues to do so at a considerable profit.[435] Finally, Claimant's exclusive access to the market over many years also ensured an enhanced visibility of its atomoxetine and olanzapine based drugs, the effects of which it continued to enjoy after the invalidation of its patents.

b) The Measures Did Not Violate Claimant's Reasonable Investment-Backed Expectations

228. Claimant has failed to establish that Canada interfered with any reasonable investment-backed expectations about Canadian law and what it meant for the validity of the patents for atomoxetine and olanzapine that it obtained. In particular, while

[432] *See Glamis Gold, Ltd. v. United States of America*, UNCITRAL, Counter-Memorial of the United States of America, 19 September 2006, pp. 159-160 **(RL-105)**; *Methanex Corporation v. United States of America*, UNCITRAL, Amended Statement of Defence of Respondent United States of America, 5 December 2003, para. 405, fn 636 **(RL-106)**; *Grand River Enterprises v. United States of America*, UNCITRAL, Counter-Memorial of the United States of America, 22 December 2008, p. 147 **(RL-107)**.

[433] 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 **(R-353)**; Andrew Newcombe, "Canada's New Model Foreign Investment Protection Agreement" (Aug. 2004), pp. 5-6 **(R-356)**.

[434] *See, e.g.*, Strattera and Zyprexa Sales 2003-2013 (from IMS Brogan) (Confidential Exhibit) **(R-427)**. Revenue over time for Zyprexa and Strattera (Lilly's Restricted Access Exhibit) **(R-456)**.

[435] *Ibid.*

Claimant professes that it expected that the Canadian legal system would react in a certain way to its atomoxetine and olanzapine patents, it fails to show that such expectations were reasonable.

229. First, as set out in detail in Canada's Counter-Memorial and above, Canada's law on utility did not change dramatically and fundamentally as Claimant suggests.[436] Rather, the courts were consistently applying existing principles in Canadian patent law to new situations, exercising their common law adjudicative function. Claimant could not legitimately expect that the courts would not continue to clarify the law and apply it in novel situations, as all courts do. Indeed, Claimant confirmed in its Reply that it expected "from the outset" that the law governing its patents would evolve.[437] Moreover, given the state of Canadian law when Claimant made its investments, Claimant could not have reasonably expected that its patents would withstand a validity challenge in the Canadian courts. As shown above, these second generation patents do not withstand scrutiny.

230. Second, Claimant's alleged expectations resting on the standard of utility articulated in the 1990 version of MOPOP are not reasonable.[438] Claimant attributes too much weight to the up-to-date status of MOPOP at any given point in time,[439] draws tenuous conclusions with respect to patent office practice from changes to the MOPOP,[440] and selectively quotes from the 1990s versions to support its cause.[441]

[436] *See* Resp. CM., paras. 81-134; Dimock First Report, paras. 46-152; Dimock Second Report, paras. 6-131.

[437] Cl. Reply, para. 304.

[438] *See* Cl. Reply, paras. 117-146, 318.

[439] *See* Cl. Reply, paras. 143-146. As Dr. Gillen explains: "While the Patent Office endeavours to keep the MOPOP up-to-date, it would be impractical to update it with every new case decided by the courts": Gillen Second Statement, para. 23. Moreover, the fact that the MOPOP was not updated with every new case that was decided by the courts is not evidence that patent examiners did not continue to adopt their practice to further clarifications in the law: *see* Gillen Second Statement, para. 23.

[440] Dr. Gillen explains that there were several changes to the 2009 and 2010 versions of the MOPOP that clarified existing practice. For example, "there is a section added to Chapter 9 (Description) in 2010 that discusses in detail the person of ordinary skill in the art (POSITA)" but "[t]here were no changes to the POSITA analysis in the 1990s or 2000s. Patent examiners have been assessing applications through the

Claimant asserts that the standard of utility articulated in the 1990s versions of MOPOP "was a simple requirement to show that the invention was not 'totally useless,'"[442] and that the 1990 MOPOP explained that "utility, as related to inventions, means industrial value."[443] This is true, but only half true. The 1990 MOPOP also stated that the "operation or use of the invention must, of course, show the purpose for which the invention was intended"[444] and explained further that:

> The claims must be drafted to an invention having the utility disclosed. If the claims cover only things that have utility other than that disclosed or if they include inoperable and therefore useless embodiments, they are bad.[445]

231. Tellingly, Claimant also overlooks the fact that the very version of MOPOP it points to in an attempt to demonstrate a "dramatic" change in the law, articulated the *Consolboard* standard for promise utility and commented that "this was merely the reiteration of a long-accepted and extant standard."[446] The cases MOPOP cited in support were the very cases cited in the 1990s version of MOPOP Claimant purportedly relied upon in forming its expectations that Canadian law was different than it was.[447]

232. Third, Claimant's misunderstanding of Canadian law appears primarily based on its uninformed convictions. As Canada explained above, the evidence makes clear that Claimant did not request and did not receive legal advice regarding Canadian patent law

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eyes of the person of ordinary skill in the art since patents have been examined.": Gillen Second Statement, para. 32.

[441] *See* Cl. Reply, paras. 117-119.

[442] Cl. Reply, para. 117.

[443] Cl. Reply, para. 118.

[444] Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 12 (January 1990) (Excerpts), Art. 12.02.02 ("Utility must be disclosed"), p. 4 (emphasis added) **(C-54)**.

[445] *Id.*, p. 7 (emphasis added) **(C-54)**.

[446] Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 12 (December 2009), Art. 12.08.01 ("Operability"), p. 12-23 **(C-59)**. *See also* Gillen Second Statement, para. 29.

[447] Gillen Second Statement, paras. 29-30.

at the time it made its investments.[448] In this light, any claimed expectations that Claimant may or may not have had about the Canadian legal rules applicable to its patents were unfounded and unreasonable for it to hold.

233. Fourth, Claimant's actual practice in applying for patents is inconsistent with its "legitimate expectations" arguments that it did not believe it was required to disclose the basis of a sound prediction in its patent. Claimant included experimental data in some of its patent applications, but not in others.[449] If Claimant expected that there was no disclosure requirement for its patents, it would not have included any data in any of its applications.

234. Finally, despite Claimant's assertion to the contrary, it was not reasonable for it to rely on Canada's membership in the PCT as a basis for forming expectations about applicable substantive patentability requirements under Canadian law. The PCT is strictly a procedural treaty which expressly provides that it does not prescribe substantive patent law obligations.[450] As such, PCT users are well aware that they must always fulfill the substantive patentability criteria relevant to jurisdictions where they might seek patent protection.[451] Contrary to what is argued in the second report of Claimant's expert Mr. Erstling, the purpose of the PCT was not to impose restrictions on Contracting States, but rather to prescribe formalities so that applicants would not have to comply with myriad formal requirements in each jurisdiction.[452] This is confirmed by the text of the PCT itself.[453]

[448] *See* paras. 154-155 above.

[449] As noted above, Claimant made reference to experimental data in 30 of 68 applications for new uses of raloxifene, 11 of 16 applications for new uses of olanzapine, and 7 of 12 applications for new uses of atomoxetine. *See also* Brisebois First Statement, Annex E.

[450] Resp. CM., para. 297.

[451] *Ibid*.

[452] Reed Second Report, paras. 24-27.

[453] *Id*., para. 14.

235. For all of the above reasons, Claimant could not have had reasonable investment-backed expectations that it would not be open for a court to invalidate its patents.

c) The Character of Canada's Measures Weighs Heavily Against a Finding of Indirect Expropriation

236. As Canada set out in its Counter-Memorial, tribunals must also consider the character of the measure at issue in deciding whether it can amount to an indirect expropriation.[454] Here, the measures at issue are judicial adjudications of whether a patent was properly granted in accordance with Canadian law. As discussed above, and in Canada's Counter-Memorial, the adjudicative function of State organs is owed significant deference, provided the participants were not denied justice.[455] Claimant itself admits that it was not denied justice. The Canadian courts fulfilled their vital public function of resolving disputes over property and other rights in cases initiated by private litigants.[456] The outcome of the courts' proper application of Canadian law to Claimant's patents was a legitimate and good faith exercise of Canada's judicial authority.

237. With respect to Claimant's reoriented claim that the law developed by the courts over a period of several years was expropriatory, Claimant pays insufficient heed to the important policy objectives underpinning the utility doctrine in Canada. The utility doctrine is Canada's answer to speculative patenting. It is an important component of the patent bargain, whose public policy objective is to encourage innovation while ensuring the public gains actual advances in the state of the art, and that areas of research are not

[454] Resp. CM., para. 413. *See also Technicas Medioambientales Tecmed, S.V. v. United Mexican States*, ICSID ARB(AF)/00/2, Award, 29 May 2003, ("*Technicas Award*"), paras. 115, 122 (**RL-049**); *Feldman Award*, para. 103 (**RL-058**); *S.D. Myers Partial Award*, para. 281 (**RL-076**); *Archer Daniels Midland Company v. The United Mexican States*, ICSID Case No. ARB(AF)/04/05, Award, 21 November 2007, para. 250 (**RL-074**); *Methanex Corporation v. United States of America*, UNCITRAL, Final Award of the Tribunal on Jurisdiction and Merits, 3 August 2005, IV, Chap. C ("*Methanex Final Award on Jurisdiction*"), Part IV, Chapter D, p. 4, para. 7 (**RL-011**).

[455] *See Loewen Award*, para. 242 (**RL-013**); *Glamis Gold, Ltd. v. United States of America*, (UNCITRAL) Award, 8 June 2009 ("*Glamis Award*"), paras. 762, 779 (**RL-006**); *Mondev Award*, para. 126 (**RL-004**); *Azinian Award*, para. 99 (**RL-002**); *Arif Award*, paras. 398, 416, 440-441 (**RL-063**).

[456] *See* Resp. CM., paras. 414-415.

prematurely foreclosed. In the context of secondary patents, such as new use and selection patents, the utility doctrine plays a particularly salient role to ensure that inventions are not granted for mere guesses, even if those guesses are ultimately good ones. By requiring that patent applicants either demonstrate or soundly predict the utility of their inventions at the filing date, and requiring sufficient disclosure, Canadian patent law protects the public from speculative patent practices. This legitimate public welfare objective was applied in good faith to Claimant's patents. Accordingly, the nature of the measures weighs heavily against a finding of indirect expropriation.

4. *Canada's Measures Do Not Breach Any Other Rule of International Law*

238. As noted above, Claimant's theory of judicial expropriation presumes that this Tribunal is entitled to decide whether Canada has acted consistently with its obligations under other chapters of NAFTA (i.e. Chapter Seventeen) and other international treaties (i.e. the PCT). This Tribunal has no authority to make such a determinations nor does Claimant even have standing *rationae personae* to make such arguments.[457]

239. Further, Claimant's allegations of breach fail because Canada has acted consistently with its relevant international obligations. Canada has already shown above why the challenged measures are consistent with Canada's obligations under Chapter Seventeen of NAFTA.

240. Canada's patent laws, as interpreted by its courts, are also consistent with its PCT obligations. Claimant argues that the requirement in Canadian law that the basis for a sound prediction of utility be included in the patent application itself is in violation of

[457] Resp. CM, para. 210. International tribunals do not have jurisdiction to hear a dispute where the rights and obligations of a non-consenting third-party State would also have to be adjudicated. As the International Court of Justice established in the *Monetary Gold* case, a tribunal cannot have jurisdiction over a subject matter if a third-party's "legal interests would not only be affected by a decision, but would form the very subject-matter of the decision." *Monetary Gold Removed from Romber in 1943 (Italy v. France, United Kingdom of Great Britain and Norther Ireland and United States of America),* Judgment, I.C.J. Reports 1954, June 15, 1954, p. 32 **(R-457)** *See also Case Concerning East Timor (Portugal v. Australia)*, Judgment, I.C.J. Reports, June 30, 1995, p. 105 **(R-471)**. Here, Claimant is essentially asking this Tribunal to impose a legal obligation stemming from the PCT which no other PCT member state has endorsed nor could have the opportunity to comment upon.

Article 27(1) of the PCT.[458] This claim is unfounded. Claimant has seriously overstated the meaning of "form and contents" in Article 27(1) the PCT. According to Claimant, and its expert Mr. Erstling, the PCT dictates precisely the information that must be set out in an international application, and since there is no requirement to include evidence of utility in the application, requiring evidence of demonstrated or soundly predicted utility is in violation of the PCT.[459] This is wrong.

241. As Mr. Reed explains in his first and second reports, "form and contents" requirements are intended only to cover formalities. The PCT itself, in confirming the meaning of "form and contents," simply lists broad categories of information that must be included in the international application. It is true that Article 27(1) provides that no national law shall require compliance with requirements relating to the form and contents beyond what is required by the PCT. However, this restriction has to be read in context. Article 27(5) clarifies that nothing in the PCT or Regulations limits the freedom of PCT Contracting States to prescribe substantive conditions of patentability.[460] Further, Article 27(6) expressly allows each State the right to require an applicant to furnish evidence regarding those substantive patentability requirements.[461]

242. As Mr. Reed explains, contrary to what Mr. Erstling assumes, Article 27 gives a State the absolute freedom to choose its own patentability criteria and to require the applicant to furnish, in the patent application itself, whatever evidence the State believes

[458] Cl. Reply, paras. 189, 355.

[459] Cl. Reply, para. 189; Erstling Second Report, paras. 3, 6-8, 16-17.

[460] *Patent Cooperation Treaty*, 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".) *See also* Reed Second Report, paras. 7-8.

[461] *Patent Cooperation Treaty*, Article 27(6) **(R-037)** ("The national law may require that the applicant furnish evidence in respect of any substantive condition of patentability prescribed by such law."). *See also* Reed Second Report, para. 9.

is required in order to prove that such criteria have been satisfied.[462] Even Claimant seems to have been aware of the requirement to tailor PCT patent applications to meet the specific needs of individual jurisdictions. Claimant's Executive Director of International Patents, Mr. Stringer, testified in this arbitration of the need to make "jurisdiction-specific edits".[463] If Mr. Erstling were correct, such jurisdiction-specific edits would not be required.

V. CANADA'S LAW ON UTILITY AND ITS APPLICATION TO CLAIMANT'S PATENTS DO NOT BREACH ITS OBLIGATIONS UNDER ARTICLE 1105

A. Overview

243. In its Reply, Claimant continues to misstate the legal standard applicable under NAFTA Article 1105(1). In particular, Claimant continues to object to the fact that denial of justice is the only established rule of customary international law applicable to its claim. However, Claimant has offered no evidence of state practice and *opinio juris* that would establish anything to the contrary. Further, while its claim fails entirely on the law, Claimant also cannot make out its case on the facts. Canadian law has been appropriately developed and applied by the courts in line with their role in a common law system. Canadian courts have done nothing more than give effect to the patent bargain that is found in Canada's *Patent Act*. Claimant's belief that it has a better way to interpret Canadian law does not render the interpretations of the Canadian courts, including the Supreme Court of Canada, arbitrary, discriminatory, or contrary to Claimant's legitimate expectations. The measures in question here do not even come close to the type of measures that contravene the customary international law minimum standard of treatment. Claimant's Article 1105 claim is frivolous and should be dismissed.

[462] Reed First Report, paras. 9-11.

[463] Stringer First Statement, para. 6.

B. Claimant Has Not Established the Existence of a Rule of Customary International Law Other Than Denial of Justice Applicable to Judicial Adjudication

244. In its Reply, Claimant takes issue with the fact that denial of justice is the only standard under customary international law against which the Tribunal may measure the Canadian courts' adjudication of the validity of Claimant's olanzapine and atomoxetine patents. To support its untenable position, Claimant misrepresents Canada's position on the law while simultaneously failing to provide any evidence of other customary international law rules applicable in this scenario.

245. Contrary to Claimant's depiction, Canada did not argue that Article 1105(1) "is irrelevant to the conduct of its judiciary."[464] Canada agrees that a State is responsible in international law for the conduct of all of its organs, including the judiciary. What Canada clarified was that the exercise of different functions could attract different types of liability under international law.[465] Specifically, denial of justice is the only established rule of customary law applicable to an organ of the State exercising an adjudicative function, as opposed to a legislative or executive function.[466] In contrast to executive or legislative acts, adjudicative acts produce outcomes with moral and legal authority independent of the State's coercive powers. This authority is rooted in the particular form of affected party participation (submission of argument and evidence), and in the demand for heightened rationality in the process and in the result.[467]

[464] *See* Cl. Reply, para. 325.

[465] *See* Resp. CM., para. 230, fn 416.

[466] *See, e.g.*, *Mondev Award*, para. 126 **(RL-004)**. The United States and Mexico have agreed: *See The Loewen Group, Inc. and Raymond L. Loewen v. United States of America*, ICSID ARB(AF)/98/3, Response of 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, pp. 6-7 **(RL-024)**; *The Loewen Group, Inc. and Raymond L. 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)**.

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

246. Claimant's arguments amount to nothing more than a claim that their proposed interpretation of an undefined term in the *Patent Act* is more rational than that offered by the Canadian courts. Such claims to better rationality are potentially endless, and thus, international law recognizes that it is not for international tribunals to act as supranational courts of appeal.[468] As the *Mondev* tribunal noted:

> It is one thing to deal with unremedied acts of the local constabulary and another to second-guess the reasoned decisions of the highest courts of a State. Under NAFTA, parties have the option to seek local remedies. If they do so and lose on the merits, it is not the function of NAFTA tribunals to act as courts of appeal.[469]

247. Quoting from the *Azinian* decision, the *Mondev* tribunal went on to assert that a claimant is not entitled "to seek international review of the national court decisions as though the international jurisdiction seized has plenary appellate jurisdiction."[470] International law defers to domestic adjudicative processes and their outcomes, provided there is integrity of process. Through denial of justice, international law protects against systemic procedural flaws so egregious that they undermine the independent moral authority of the outcomes of adjudication.

248. Claimant cites to three cases – *Liman Caspian v. Kazakhstan*, *White Industries v. India*, and *Frontier Petroleum Services v. Czech Republic* – to support its proposition that denial of justice is "just one part of the protection afforded by the Minimum Standard of Treatment in respect of judicial measures."[471] First and foremost, arbitral decisions do not constitute evidence of customary international law.[472] Moreover,

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[468] *See, e.g.*, *Mondev Award*, paras. 126 (**RL-004**); *Azinian Award*, para. 99 (**RL-002**); *Loewen Award*, para. 51 (**RL-013**); *Arif Award*, paras. 398, 416, 440-441 (**RL-063**). *See also* Rudolf Dolzer and Christoph Schreuer, *Principles of International Law*, (Oxford University Press), 2008, pp. 165-166 (**R-327**); *Loewen Opinion of Christopher Greenwood*, para. 64 (**RL-025**).

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

[470] *Mondev Award*, para. 126 (**RL-004**); *Azinian Award*, para. 99 (**RL-002**).

[471] *See* Cl. Reply., paras. 326-327.

[472] *See* para. 259 below.

Claimant's analysis of each of these cases, and its attempt to draw parallels to this case, is unavailing.

249. For example, Claimant argues that *Liman Caspian* determined that denial of justice and fair and equitable treatment are "not synonymous with regard to acts of courts."[473] But Claimant ignores the tribunal's finding that the Energy Charter Treaty's ("ECT") fair and equitable treatment provision provides "a protection that goes beyond the minimum standard of treatment under international law."[474] The tribunal expressly contrasted this standard with NAFTA Article 1105 before indicating that: "a specific standard of fairness and equitableness above the minimum standard must be identified and applied for the application of the ECT."[475] It is, thus, not surprising that the tribunal found that the higher standard found in the ECT was not synonymous with the customary international law delict of denial of justice. However, even that tribunal, applying a standard not tied to customary international law, recognized the need to "take into account the different functions held by administrative organs and judicial organs of a state and the resulting differences in their discretion when applying the law and in the appeals against their decisions."[476]

250. Claimant also argues that the *White Industries v. India* tribunal "analyzed the acts of India's courts under three distinct aspects of the minimum standard: denial of justice, but also the protection of legitimate expectations and the requirement of transparency."[477] Claimant again ignores that the relevant provision in the India – Australia BIT is a fair and equitable treatment provision autonomous from the minimum standard of treatment contained in NAFTA Article 1105(1).[478] Moreover, Claimant

[473] Cl. Reply, para. 327; citing *Liman Excerpts of Award*, para. 268 (**RL-027**).

[474] *Liman Excerpts of Award*, para. 263 (**RL-027**).

[475] *Liman Excerpts of Award*, para. 263 (**RL-027**)..

[476] *Id.*, para. 268 (**RL-027**).

[477] Cl. Reply, para. 327.

[478] *White Industries Australia Ltd. v. India*, UNCITRAL, Award, 3 November 2011, ("*White Industries*"), para. 4.3.1, (**CL-157**), (reproducing Article 3(2) of the BIT: "Investments or investors of each contracting Party shall at all times be accorded fair and equitable treatment.")

overlooks the fact that the tribunal held that the investor had "no proper ground for [its alleged legitimate expectations] complaint" with respect to the court's actions.[479] Indeed, the tribunal dealt with the investor's complaints about its treatment by the Indian courts "substantively in connection with White's denial of justice claims"[480] and ultimately did not find a breach of the fair and equitable treatment standard at all.[481]

251. Finally, Claimant argues that the tribunal in *Frontier Petroleum Services v. Czech Republic* considered not only whether the conduct of the Czech courts "may have breached the requirements of 'procedural propriety and due process,' but also whether the Czech courts' decision was 'made in an arbitrary or discriminatory manner.'"[482] But in determining that the courts had not breached the fair and equitable treatment standard in that case, the tribunal noted that the "Claimant's requests were entertained by four levels of courts and Claimant had several opportunities to submit legal arguments on the proper interpretation and application of…Article V of the *New York Convention*."[483] In essence, the tribunal held that the claimant had not been denied justice.

252. Moreover, in each of *Liman Caspian*, *White Industries*, and *Frontier Petroleum Services*, the tribunal found that the court had not breached the fair and equitable treatment provisions of those treaties, showing that for court actions to constitute a breach, the threshold is high.[484] Further, in those cases cited by Claimant where a breach

[479] *White Industries*, para. 10.3.9 (**CL-157**).

[480] *Ibid*.

[481] *White Industries*, paras. 10.2.3, 10.3.9, 10.3.16, 10.3.19, 10.3.21 (**CL-157**).

[482] Cl. Reply, para. 327.

[483] *Frontier Petroleum Services Ltd. v. The Czech Republic*, (UNCITRAL), Final Award, 12 November 2010, ("*Frontier Petroleum Final Award*"), para. 529 (**RL-067**).

[484] For example, in *Liman Caspian*, the tribunal observed that it "has no competence to control the application of Kazakh law by the Kazakh courts," and concluded that the courts' behaviour did "not reach the threshold of judicial conduct which could be considered arbitrary, grossly unfair, unjust or idiosyncratic or involving lack of due process.": *Liman Excerpts of Award*, paras. 348-9, 366, 383 (**RL-027**). In *White Industries*, paras. 10.3.12-10.3.13, 10.3.15, 10.3.20, 10.4.5, 10.4.23 (**CL-157**), the tribunal dismissed all of the claimant's fair and equitable treatment arguments because it could not legitimately have expected that the Indian courts would "apply the New York Convention properly and in accordance with international standards," or that its Award would be timely enforced, or that there would be transparency in the court proceedings. The tribunal ultimately held that the delay experienced by the

was identified, Claimant overlooks the fact that the tribunals found that the courts were engaging in conduct that shocked a sense of judicial propriety. No element of Claimant's claim even comes close to the scenario here.

253. In an effort to distinguish NAFTA cases that are directly contrary to its position here, Claimant argues that the only reason the tribunals in *Loewen*, *Azinian*, *Waste Management*, and *Mondev* analyzed denial of justice was because it was the only relevant theory of liability on the facts of those cases.[485] However, Claimant conveniently ignores that the claimant in *Mondev* argued the very thing that Claimant argues here. As explained by the *Mondev* Tribunal:

> Claimant argued that the [Massachussetts Supreme Judicial Court ("SJC")'s] decision involved a "significant and serious departure" from its previous jurisprudence, which was exacerbated when the SJC completely failed to consider whether it should apply the rules it articulated retrospectively to Mondev's claims. In those circumstances, the SCJ's dismissal of LPA's claims 'was arbitrary and profoundly unjust.'[486]

254. The *Mondev* tribunal was "unimpressed" by Claimant's "new law" argument, finding that even if the courts had made new law, "its decision would have fallen within the limits of common law adjudication."[487] To avoid the same conclusion in this case, Claimant attempts to draw an untenable distinction between "minor and evolutionary" changes that would fall within the limits of common law adjudication, and "radical" and "dramatic" changes.[488] As is clear from the quote above, the claimant in *Mondev* also claimed a "significant and serious departure" from previous jurisprudence. The *Mondev* tribunal found that this was irrelevant. The courts' extension of existing principles to

claimant did not amount "in the tribunal's mind to 'a particularly serious shortcoming' or egregious conduct that shocks or at least surprises, a sense of judicial proprietary [*sic*]". The tribunal reaffirmed that the test for denial of justice "is a stringent one."

[485] Cl. Reply, para. 328.

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

[487] *Id.*, paras. 133-134 (**RL-004**). *See also* Resp. CM., paras. 235-238.

[488] *See* Cl. Reply, paras. 219.

new situations is the very core of common law adjudication. Merely affixing the label "radical" or "dramatic" to a specific instance of principled extension does not suffice to remove it from the limits of common law adjudication.

255. The Canadian courts' ruling on the validity of Claimant's patents is a classic case of adjudicating an adversarial proceeding in a common law jurisdiction. As such, it is subject only to the customary international law prohibiting denials of justice.[489] As Claimant agrees that it has not made out a denial of justice claim (nor could it on the facts),[490] the Tribunal need make no further inquiries.

C. Claimant Has Failed to Meet Its Obligation to Establish That Customary International Law Provides the Protections It Alleges

256. There is no dispute between the parties that customary international law protects against a denial of justice. However, to the extent that the Clamant seeks to have the Tribunal recognize other forms of conduct that the customary international law minimum standard of treatment prohibits, it bears the burden of establishing that the relevant rules exist. It has failed to do so on every count.

257. In its Reply, Claimant does not dispute that it must prove the rules of customary international law that it claims were breached. Instead, it argues that it has provided ample evidence of state practice and *opinio juris*,[491] pointing to its reference to other treaties with autonomous fair and equitable standards, on the one hand, and arbitral decisions on the other. Neither of these constitutes evidence of state practice[492] and

[489] Claimant's suggestion that Canada is advocating a rule is more protective of common law courts than civil law courts is absurd: *see* Cl. Reply, para. 332. The adjudicative function exercised in both common law and civil law systems is protected by the same rule of customary international law: denial of justice. Both systems' adjudicative processes involve the application of existing principles to new factual situations, and both systems are owed equal deference under international law.

[490] *See* Cl. Reply, paras. 17, 334, fn 433.

[491] Cl. Reply, paras. 351-354.

[492] *See*, Michael Wood, Special Rapporteur, "Second report on identification of customary international law", International law Commission, Sixty-sixth session, Geneva, 5 May-6 June and 7 July-8 August 2014, A/CN.4/672, (Michael Wood, "Second report on identification of customary international law"), paras. 40-42 **(R-449)** (identifying a non-exhaustive list of examples of what constitutes state practice, such

opinio juris.[493] A rule of customary international law is formed by widespread state practice, accompanied by an understanding that such practice is undertaken out of a sense of legal obligation.[494] As noted by the Special Rapporteur to the International Law Commission, "when a State says that something is not a rule of customary international law, that is evidence of the absence of an *opinio juris*."[495]

258. Canada, along with the other NAFTA Parties, have consistently taken the position that autonomous fair and equitable treatment provisions in other treaties do not form a rule of customary international law.[496] The content of an investment treaty negotiated between States is a matter of policy. As such, it is not evidence of *opinio juris* and is irrelevant for the purposes of determining the content of the minimum standard of treatment in Article 1105(1). As the *Mondev* tribunal noted, "Article 1105(1) refers to a standard existing under customary international law, and not to standards established by

as acts of the executive branch, including "positions expressed by States before national or international courts and tribunals (including in *amicus curiae* briefs of States)".).

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

[494] *Id.*, paras. 21-31 **(R-449)**. *See also Glamis Award*, para. 602 **(RL-006)**; *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, 18 September 2009 ("*Cargill Award*"), para. 274 **(RL-015)**.

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

[496] *The Loewen Group, Inc. and Raymond L. Loewen v. United States of America*, ICSID ARB(AF)/98/3, Second Submission of the Government of Canada Pursuant to NAFTA Article 1128, 27 June 2002, paras. 18, 26 **(RL-110)**; *The Loewen Group, Inc. and Raymond L. Loewen v. United States of America*, ICSID ARB(AF)/98/3, Response of the United States of America to the June 27 and July 2, 2002 Submissions of the Governments of Canada and Mexico Pursuant to NAFTA Article 1128, 19 July 2002, pp. 3-6, **(RL-111)**; *The Loewen Group, Inc. and Raymond L. Loewen v. United States of America*, ICSID ARB(AF)/98/3, Third Article 1128 Submission of the United Mexican States, 2 July 2002, ("*Loewen Group Third Article 1128 Submission of Mexico*"), paras. 32-40 **(RL-112)**. *Bilcon of Delaware Inc. v. Government of Canada*, PCA/UNCITRAL, Canada's Counter-Memorial, 9 December 2011, ("*Bilcon Canada's Counter-Memorial*"), paras. 313-318 **(RL-113)**; *Windstream Energy LLC v. Government of Canada*, UNCITRAL, Counter-Memorial of Canada, 20 January 2015, ("*Windstream Counter-Memorial of Canada*") paras. 372-379 **(RL-114)**; *Mercer Submission of the United States*, paras. 19-20 **(RL-097)**; *Mercer International Inc. v. Government of Canada*, ICSID Case No. ARB(AF)/12/(3), Submission of Mexico Pursuant [to] Article 1128 of NAFTA, 8 May 2015, ("*Mercer Submission of Mexico*"), paras. 18-19 **(RL-089)**.

other treaties of the three NAFTA Parties."[497] If Article 1105(1) does not refer to standards established in other treaties of the NAFTA Parties, it stands to reason that treaties concluded between non-NAFTA parties are equally irrelevant for the purposes of determining the minimum standard of treatment under Article 1105(1).

259. Claimant's reliance on arbitral decisions also falls short of what is required to meet its evidentiary burden. While arbitral decisions may elucidate existing state practice and *opinio juris*, they cannot create it.[498] Claimant's argument that previous tribunals have not required evidence of state practice and *opinio juris*, and looked simply to the reasons of arbitral awards,[499] does not do away with the requirement.[500] All three NAFTA Parties agree on these points.[501]

1. *Claimant Has Failed to Establish That Customary International Law Protects Against Arbitrary Conduct*

260. Claimant argues that customary international law protects against measures that are "unpredictable and incoherent."[502] However, it points to only a single case,[503] *Occidental v. Ecuador*, in which the tribunal did not analyze state practice or *opinio juris* with respect to a rule against arbitrary conduct. Canada has already demonstrated in its Counter-Memorial why the decision in *Occidental* is of no value in this case. Further, the comments Claimant points to in support of its definition of arbitrariness were not even made in the context of Occidental's fair and equitable treatment claim,

[497] *Mondev Award*, para. 121 (**RL-004**).

[498] Resp. CM., para. 271.

[499] *See* Cl. Reply, para. 353.

[500] Indeed, the tribunal in *Apotex* found that the claimant in that case had "not presented sufficient evidence of state practice or *opinio juris*" with respect to the rule of customary international law put forward by the claimant. *Apotex Award*, paras. 9.17-9.27 (**RL-016**).

[501] *See e.g. Bilcon Canada's Counter-Memorial*, paras. 313-318 (**RL-113**); *Windstream Counter-Memorial of Canada*, paras. 372-379 (**RL-114**); *Mercer Submission of the United States*, paras. 19-20 (**RL-097**); *Mercer Submission of Mexico*, paras. 18-19 (**RL-089**); *Loewen Group Third Article 1128 Submission of Mexico*, paras. 32-40 (**RL-112**).

[502] Cl. Reply, para. 335; Cl. Mem., paras. 258, 262.

[503] Resp. CM., para. 253.

nor were they in the context of court decisions. Rather, they were made in the context of Occidental's impairment claim, which related to the actions of Ecuador's tax authority (an administrative agency), and did not address the minimum standard of treatment under customary international law.[504] As has been recognized by numerous tribunals applying the minimum standard of treatment, customary international law does not protect against merely arbitrary, unpredictable or inconsistent treatment, even in cases where the well-reasoned and impartial decisions of a State's highest courts are not at issue.[505]

2. *Claimant Has Failed to Establish That Customary International Law Protects Against All Forms of Discrimination*

261. Claimant also alleges that Article 1105(1) prohibits treatment that discriminates between fields of technology, between brand and generic pharmaceutical companies, and on the basis of nationality.[506] Claimant is incorrect on all points. First, Claimant has failed to establish that customary international law protects against discrimination between fields of technology or between brand and generic pharmaceutical companies. It points to no state practice or *opinio juris* evidencing such a rule. Nor could it, for such a rule does not exist.

262. In support of its claim, Claimant recycles and relies on its NAFTA Chapter Seventeen argument.[507] However, the NAFTA Free Trade Commission's Notes of Interpretation which are binding on this Tribunal, are clear: "A determination that there has been a breach of another provision of the NAFTA, or of a separate international

[504] *See Occidental Exploration & Production Co. v. Ecuador*, UNCITRAL/LICA Case No. UN 3467, Final Award, 1 July 2004, paras. 159-166 **(CL-97)**.

[505] Resp. CM., para. 252; *Cargill Award*, para. 293 **(RL-015)**. *See*, more generally, Resp. CM., paras. 247-253; *Elettronica Sicula SpA (ELSI) United States v. Italy*, International Court of Justice, Judgment, 20 July 1989, p. 76, para. 128 **(RL-031)**; *Mondev Award*, para. 127 **(RL-004)**; *Loewen Award*, para. 131 **(RL-013)**; *Glamis Award*, paras. 625-626 **(RL-006)**; *International Thunderbird Gaming Corporation v. United Mexican States*, (UNCITRAL) Arbitral Award , 26 January 2006, ("*Thunderbird Award*"), para. 194 **(RL-003)**.

[506] Cl. Reply, paras. 367- 368.

[507] *See* Cl. Reply, para. 365, citing to Cl. Mem., paras. 219-222; Cl. Mem., para. 291.

agreement, does not establish that there has been a breach of Article 1105(1)."[508] Accordingly, even if there were discrimination under Chapter Seventeen (Canada has overwhelmingly demonstrated that there is not), Claimant cannot rely on an inconsistency with Chapter Seventeen to establish that there has been a breach of Article 1105(1). As the *Mondev* tribunal noted:

> Chapter 11 arbitration does not even extend to claims concerning all breaches of NAFTA itself, being limited to breaches of Section A of Chapter 11 and Articles 1503(2) and 1502(3)(a). If there had been an intention to incorporate by reference extraneous treaty standards in Article 1105 and make Chapter 11 arbitration applicable to them, some clear indication of this would have been expected.[509]

263. Second, while irrelevant here because there has been no discrimination, customary international law does not generally prohibit discrimination against foreign investments on the basis of their nationality.[510] Canada's Counter-Memorial arguments with respect to discrimination on the basis of nationality relate solely to a claim of a denial of justice, the only rule of customary international law that applies to adjudication by the courts. Under customary international law, States are obligated to provide a minimum standard of procedural fairness, which includes ensuring that foreign litigants are not denied due process in court proceedings.[511] Outside of this context, and in the absence of a treaty obligation directing otherwise, discrimination on the basis of nationality is not generally prohibited under customary international law. Claimant has failed to demonstrate otherwise.

[508] *NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter Eleven Provisions*, 31 July 2001, para. 2(3) (**RL-009**).

[509] *Mondev Award*, para. 121 (**RL-004**). *See also Canfor Decision on Preliminary Question*, para. 245 (**RL-104**).

[510] *See* Resp. CM., fn 468. *See also Grand River Enterprises Six Nations, Ltd. et al v. United States of America*, (UNCITRAL) Award, 12 January 2011, ("*Grand River Award*"), paras. 208-209 (**RL-010**); *Methanex Final Award on Jurisdiction*, para. 25 (**RL-011**).

[511] *See* Resp. CM., para. 262. *See also Loewen Award*, para. 123 (**RL-013**).

3. *Claimant Has Failed to Establish That Customary International Law Protects Its "Legitimate Expectations"*

264. Claimant continues to assert that Article 1105(1) protects its legitimate expectations.[512] Once again, Claimant points solely to prior arbitral awards in order to support its claims. It argues that doing so is appropriate, citing to *Railroad Development Corp. v. Guatemala*, because parties in international proceedings use awards in their pleadings in support of their arguments.[513] However, this fact is irrelevant. The ICJ has been clear that substantial state practice and *opinio juris* are the only manner to prove the existence of a rule of customary international law, and arbitral awards constitute neither.[514] As noted above, the International Law Commission has recognized that a State's explicit statement that a rule of customary international law does not exist is evidence of the absence of an *opinio juris*.[515] The NAFTA Parties have consistently stated that an investor's legitimate expectations do not form a rule of customary international law.[516]

265. Even on Claimant's inappropriate evidentiary standard for proving rules of customary international law, Claimant has failed to demonstrate its rule. Tellingly,

[512] *See* Cl. Reply, paras. 350-354. *Mesa Power Group LLC and Government of Canda*, UNCITRAL, Second Submission of the United States of America, 12 June 2015, para. 14 (**RL-117**); *Mesa Power Group LLC and Government of Canda*, UNCITRAL, Second Submission of Mexico Pursuant to NAFTA Article 1128, 12 June 2015, para. 10 (**RL-118**).

[513] *See* Cl. Reply, paras. 353-354, fn 715. Canada addressed Claimant's case law arguments in detail in its Counter-Memorial: *see* Resp. CM., paras. 269-289.

[514] *See* Resp. CM., para. 267, fn 477.

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

[516] *Merrill & Ring Forestry LP v. Government of Canada*, Canada's Counter-Memorial, 13 May 2008, paras. 507-509 (**RL-108**); *Mobil Investments Canada Inc. and Murphy Oil Corporation v. Government of Canada*, ICSID Case No. ARB(AF)/07/4, Canada's Rejoinder, 9 June 2010, paras. 140-142, 149 (**RL-109**); *Bilcon Canada's Counter-Memorial*, paras. 389, 391 (**RL-113**); *Windstream Counter-Memorial of Canada*, para. 405 (**RL-114**). The United States has consistently taken the same position: *see, e.g., Mesa Power Group LLC and Government of Canda*, UNCITRAL, Submission of the United States of America, 25 July 2014, para. 8 (**RL-051**); *Glamis Award*, paras. 575-582 (**RL-006**). *Mesa Power Group LLC and Government of Canda*, UNCITRAL, Second Submission of the United States of America, 12 June 2015, para. 14 (**RL-117**); *Mesa Power Group LLC and Government of Canda*, UNCITRAL, Second Submission of Mexico Pursuant to NAFTA Article 1128, 12 June 2015, para. 10 (**RL-118**).

Claimant has not cited to a single case in which its doctrine of legitimate expectations was applied to judicial proceedings.[517] Indeed, as Canada set out in its Counter-Memorial, international law simply does not recognize the doctrine of legitimate expectations in the context of domestic court judgments.[518] Nor could it. Not only does the adjudicative function exercised by the courts deserve significant deference, but courts cannot make specific representations to foreign investors.[519] If international law were to recognize an investor's expectations in the context of judicial decision-making, not only would there be no end to the investment claims brought by disappointed litigants, but it would have an inappropriate and significant chilling effect on domestic courts' ability to fulfill their core function of applying existing principles to new situations. An investor's hopes for specific litigation outcomes cannot form the basis for protection under Article 1105(1). Yet, this is exactly what Claimant seeks.[520]

[517] *See, e.g., BG Group v. Argentina*, ICSID Case No. ARB/02/1, Award, 24 December 2007, paras. 62-82, 304-310 (**CL-111**), *Total S.A. v. Argentine Republic*, ICSID Case No. ARB/04/01, Award, 27 December 2010, paras. 68-89, 99, 135-175 (**CL-106**); and *LG&E Energy Corp. v. Argentina*, ICSID Case No. ARB/02/1, Decision on Liability, 3 October 2006, paras. 54-71, 119-120, 132-139 (**CL-110**), where the measures at issue were several laws and decrees enacted by Argentina's legislative and executive branches. *See also e.g,, Technicas Award*, paras. 35-39, 152-174 (**RL-049**), where the measure at issue was the denial of a landfill operation permit by an administrative agency forming part of Mexico's executive branch; *Thunderbird Award*, paras. 137-167 (**RL-003**), where the tribunal determined that the actions of an administrative agency did not form the basis for reasonable expectations; *Grand River Award*, paras. 125-145 (**RL-010**), where the measures at issue were statutes emanating from the legislative branch of the United States and its sub-federal states, and enforcement of those statutes through the executive branch; *Frontier Petroleum Final Award*, paras. 464-468 (**RL-067**), where the only claim for which the tribunal assessed legitimate expectations was one made against Czech officials of state agencies; *Metalclad Corporation v. United Mexican States*, NAFTA/UNCITRAL, ICSID Case No. ARB(AF)/97/1, Award, 30 August 2000, paras. 74-101 (**RL-053**), where the measure at issue was the denial of a landfill construction permit by a Mexican municipality. Claimant further relies on *Fireman's Fund Insurance Company v. The United Mexican States*, ICSID Case No. ARB(AF)/02/01, Award, 17 July 2006, para. 176(k), fn. 163 (**CL-45**) to support its argument that Article 1105(1) includes legitimate expectations: Cl. Reply, fn 713. Not only were the measures at issue in that case several legislative and executive branch actions relating to financial regulation, no Article 1105 argument was made or assessed.

[518] Resp. CM., paras. 284-289.

[519] *See* Resp. CM., paras. 275-283.

[520] *See* Cl. Reply, para. 210 ("In its Memorial, Lilly established that its Zyprexa and Strattera patents were revoked under Cnaada's novel promise utility doctrine, and that if Canadian courts had applied the traditional mere scintilla utility test that existed at the time the patents were granted, the patents would have been upheld.").

D. The Threshold for Establishing a Breach of Article 1105(1) Is High

266. In addition to establishing the existence of an alleged rule of customary international law, Claimant must also demonstrate that the conduct of which it complains breached the rule by rising to the threshold required by Article 1105(1). Proving a breach of Article 1105(1) requires more than merely affixing labels to the conduct at issue. Claimant must show that, in light of all of the relevant facts, the conduct at issue falls below accepted international standards.

267. In assessing whether the conduct at issue falls below accepted international standards, a tribunal must be mindful both of the general deference afforded to domestic authorities in the conduct of their affairs,[521] and of the particular deference afforded to domestic adjudication.[522] Article 1105(1) is not an invitation to second-guess government decision-making, and it is even less tolerant of any attempt to delve into the details of domestic adjudication.[523]

E. Claimant's Arguments Rely on Mischaracterizations and Misrepresentations of Canadian Law and Court Decisions

1. *The Decisions of the Federal Courts Were Not Arbitrary*

268. Claimant levels three accusations of arbitrariness against the decisions of the Federal Courts, arguing that the promise utility doctrine: "(i) involves the inherently

[521] *See, e.g., S.D. Myers Partial Award*, paras. 261, 263 (**RL-076**); *Glamis Award*, paras. 762, 779 (**RL-006**); *Chemtura Corporation (formerly Crompton Corporation) v. Government of Canada*, UNCITRAL, Award, 2 August 2010, para. 134 ("Chemtura Award") (**RL-057**); *Apotex Award*, paras. 9.37-9.40 (**RL-016**).

[522] *See, e.g., Azinian Award*, para. 83 (**RL-002**); *Glamis Award*, para. 804 (**RL-006**).

[523] *See Loewen Award*, para. 242 (**RL-013**) ("Far from fulfilling the purposes of NAFTA, an intervention on our part would compromise them by obscuring the crucial separation between the international obligations of the State under NAFTA, of which the fair treatment of foreign investors in the judicial sphere is but one aspect, and the much broader domestic responsibilities of every nation towards litigants of whatever origin who appear before its national courts. … [T]hese latter responsibilities are for each individual state to regulate according to its own chosen appreciation of the ends of justice. As we have sought to make clear, we find nothing in NAFTA to justify the exercise by this Tribunal of an appellate function parallel to that which belongs to the courts of the host nation."). *See also Glamis Award*, paras. 762, 779 (**RL-006**); *S.D. Myers Partial Award*, paras. 261, 263 (**RL-076**); *Chemtura Award*, para. 134 (**RL-057**); *Mondev Award*, para. 126 (**RL-004**); *Azinian Award*, para. 99 (**RL-002**); *Arif Award*, paras. 398, 416, 440-441 (**RL-063**).

subjective process of construing 'promises' contained in a patent; (ii) imposes an unpredictable heightened evidentiary burden; and (iii) "arbitrarily" applies a disclosure rule for 'sound prediction' cases but not 'demonstrated' ones, thus arbitrarily, introducing two inconsistent disclosure rules for a unitary legal requirement."[524] Claimant's Reply has not added anything new to its arguments, save to criticize Canada's articulation of the rational basis for each of these purportedly "arbitrary" rules.

269. Fundamentally, Claimant is challenging the wisdom and effectiveness of the Canadian courts' application and interpretation of the *Patent Act*, and is asking the Tribunal to do the same. This is the sort of exercise Article 1105(1) does not permit.

270. Claimant has failed to show evidence that "prejudice, preference or bias [has been] substituted for the rule of law" on the facts of this case.[525] Indeed, rather than amounting to Claimant's perceived "subjective," "unpredictable" and "inconsistent" set of rules, each of the rules at issue here are in place to ensure that the patent bargain – which underpins the entire system – is upheld. That different outcomes may have been produced in the application of these rules is a not an indication of arbitrariness, but a product of the highly fact-dependent circumstances of each case, including the specific manner in which each patent was drafted and later challenged by litigants.

271. Canada set out its objections to Claimant's characterizations of each aspect of the promise utility doctrine in its Counter-Memorial,[526] but a few points bear repeating here. First, construing promises in a patent is not an "inherently subjective" exercise. Contrary to Claimant's allegations,[527] Canadian courts do not "scour" patent applications to find promises – patent litigants and their lawyers do.[528] As set out in Canada's Counter-Memorial, in assessing patent validity, Canadian courts hear carefully crafted arguments

[524] Cl. Reply, para. 324.

[525] Resp. CM., para. 249; *Joseph Charles Lemire v. Ukraine*, ICSID Case No. ARB/06/18, Decision on Jurisdiction and Liability, 14 January 2010, para. 263 **(RL-029)**.

[526] *See* Resp. CM., paras. 255-260.

[527] Cl. Reply, para. 177.

[528] Dimock Second Report, para. 75.

from both sides, consider extensive expert and other factual evidence, and make decisions based on the evidence presented.[529] To suggest that this exercise is arbitrary simply because it yielded a result against the Claimant's interests is anathema to the rule of law.

272. Claimant's attempts to cast Canadian courts' adjudication of the existence of promises in a patent as producing a "pattern of arbitrary and inconsistent results"[530] must be rejected. Claimant takes factual liberties with the cases it cites to support its argument, and ignores critical differences in the arguments made and evidence presented in each case before the courts. For example, Claimant attempts to cast different outcomes in two cases involving the glaucoma drug latanoprost as arbitrary because two panels of the Federal Court of Appeal found different promises in the same patent.[531] However, Claimant ignores the fact that the legal standard in the two cases was the same. It was the expert testimony before the two panels that was different. As Mr. Dimock explains:

> In the second proceeding – but not the first – the patent holder's own expert gave testimony that the patent promised chronic treatment. As the Court of Appeal noted in the second proceeding, the issue of chronic treatment was not at issue in the first proceeding. The court could not ignore new evidence before it from the patent holder's own expert when construing the patent's promised utility.[532]

[529] *See, e.g.*, Resp. CM., paras. 254-256.

[530] Cl. Reply, para. 177.

[531] Cl. Reply, para. 176.

[532] Dimock Second Report, para. 82; Cl. Reply, para. 176, Claimant points to two other examples of allegedly arbitrary litigation outcomes. First, it points to *Lundbeck* **(C-371)**, arguing that the court's interpretation of whether "additive" or "synergistic" was a better interpretation of the relationship between the compounds claimed in the patent at issue was arbitrary. However, Claimant completely ignores the facts of the case: in order to be inventive, the interaction between the two known compounds needed to be "synergistic", not just "additive." The parties in that case defined an "additive" effect as "1 + 1 = 2", whereas a "synergistic" effect was defined as "1 + 1 = 3" (*Lundbeck*, para. 227 **(C-371)**). Rather than playing Claimant's suggested game of arbitrary semantics, the court assessed the evidence before it through the eyes of the person skilled in the art. Second, Claimant points to *Astrazeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638 **(C-48)** (a case involving a patent of an existing compound, esamaprozole) and *AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023 **(C-237)** (a case involving a patent of a new compound, anastrazole). It argues that the courts' interpretation of "will" as different than "may" or "could" in the context of these separate patents was arbitrary. Claimant's argument is without

273. As Canada described in its Counter-Memorial, holding patentees to promises of utility serves important policy objectives that lie at the heart of the patent bargain.[533] Indeed, the rule "ensures the public receives its end of the patent bargain," particularly for new use and selection patents where a particular promised utility is the "only consideration that the public receives in exchange for the monopoly that it confers."[534]

274. Second, Canadian law does not impose an "unpredictable heightened evidentiary burden."[535] As set out in Canada's Counter-Memorial, parties adduce expert evidence to allow the court to review the patent through the eyes and mind of persons skilled in the art.[536] Courts do not "raise and lower the evidentiary bar for any given promise"[537]; they weigh the evidence before them on the balance of probabilities.[538] Litigants play a central role in this exercise, adducing evidence, and making different arguments to meet different challengers' cases. Claimant again inappropriately looks to outcomes completely devoid of their context to make its case. For example, Claimant points to two cases involving the compound ramipril in which it alleges "two judges arrived at similar conclusions about the patent's promise but reached inconsistent utility rulings, applying disparate evidentiary standards."[539] To the contrary, the judges did not apply "disparate evidentiary standards" they analyzed different evidentiary records. For example, in the first case, a PM(NOC) proceeding, the court relied heavily on the affidavit evidence of

basis. It is not arbitrary, or surprising in the least, that the court might construe different words differently in different contexts on the basis of different evidence. On every count, Claimant ignore the highly relevant and unique factual circumstances of each case in order to twist rational and reasoned differences into allegedly arbitrary conduct.

[533] Resp. CM., para. 100.

[534] Dimock First Report, para. 219. *See also* Gillen Second Report, para. 13.

[535] Cl. Reply, para. 181.

[536] Resp. CM, paras. 257-258.

[537] Cl. Reply, para. 183.

[538] Resp. CM, para. 258.

[539] Cl. Reply, para. 182.

two experts,[540] one of which was not presented to the court in the second case, an infringement/impeachment action.[541] With the benefit of *viva voce* evidence, the court in the second case made negative credibility findings against the testimony of the second expert relied on by the first court.[542] Placed in their proper context, the courts' findings are not contradictory.

275. Third, the requirement that the basis for a sound prediction be disclosed in the patent exists to prevent granting a monopoly in exchange for mere guesses. Such a requirement is not arbitrary. As discussed in Section II(A)(1) above, an invention must be "made" by the time the applicant files for a patent. The doctrine of sound prediction provides "a more flexible test" for patentees that allows them to obtain a patent without having demonstrated the utility of their inventions at the time of filing.[543] In exchange, the patentee must provide the public with sufficient information such that the person skilled in the art can make the same sound prediction. This ensures that the patent is not granted for bare speculation.[544] In a sense, the sound prediction can be viewed as the invention for which the patent is granted; disclosure of the basis for the sound prediction is the *quid pro quo* offered in exchange for the monopoly.[545]

276. Claimant cannot demonstrate that any aspect of the promise utility doctrine it articulates could be characterized as manifest arbitrariness by the courts. On the facts alone, its claim must be dismissed.

2. *The Decisions of the Federal Courts Were Not Discriminatory*

277. Claimant argues that the promise utility doctrine both discriminates against pharmaceuticals as compared to other sectors, and favours generic manufacturers (which

[540] *Sanofi-Aventis Inc. et al. v. Laboratoire Riva Inc. et al.*, 2007 FC 532, para. 50 (**C-377**).

[541] *Sanofi-Aventis Canada Inc v. Apotex Inc*, 2009 FC 676 (**C-248**).

[542] *Id*., paras. 128-131, 207-208 (**C-248**).

[543] Dimock First Report, paras. 99-100.

[544] Resp. CM., para. 127; Dimock First Report, para. 222.

[545] Dimock First Report, para. 146.

it inaccurately alleges are mostly based in Canada)[546] over foreign patent holders.[547] Claimant has no evidence of *de jure* or intentional discrimination. Instead, it argues that discrimination in this case is established *de facto* because of the differential impact that it alleges is felt by foreign pharmaceutical manufacturers. Its entire claim is premised solely on the statistical analysis that has been offered in the report of Dr. Levin.

278. However, as discussed in Section IV(C)(3) above, Claimant's statistical conclusions are unreliable because the data set it provided to Dr. Levin is riddled with errors and biases. Once these errors and biases are corrected, there is no statistical evidence of a difference between validity rates on the basis of utility between pharmaceutical and non-pharmaceutical patents.[548] Claimant has failed to demonstrate discrimination.

279. Further, even if there was statistical evidence of a difference between the impacts on different sectors, Claimant has still not established any evidence of discrimination. Differential treatment does not necessarily amount to discriminatory treatment. Discrimination can only be established by showing that the differential treatment resulted from a discriminatory bias. Establishing such a bias requires an intense examination of the facts and circumstances of the particular treatment. Claimant fails to engage in the requisite analysis and instead ignores very salient contextual facts in an attempt to draw conclusions of discrimination where none exists.

280. For example, Claimant ignores the fact that the relationship between obviousness and utility is particularly salient in the context of new use patents, selection patents, and other secondary patents, in the pharmaceutical field. As noted above, patent applicants in this area frequently assert unexpected advantages or heightened utility to overcome the obviousness requirement, while simultaneously arguing for a more restricted scope of

[546] Resp. CM, para.264 ("But among generic companies operating in Canada, half of the top 18 (base don sales) are not Canadian-owned.").

[547] Cl. Reply, para. 324.

[548] Brisebois Second Statement, paras. 2-26.

their invention for utility.[549] The fact that the courts consider the fairness of such an approach on the facts to assess the patent's compliance with all the patentability requirements is not evidence of discriminatory treatment. Nor is the fact that this approach to upholding the patent bargain may result in more inutility findings in situations where, for example, an invention is promising more than what already exists in order to qualify as an invention at all. Considered in light of all the relevant facts, Claimant's discrimination claim is baseless.

3. *The Decisions of the Federal Courts Did Not Violate Claimant's "Legitimate Expectations"*

281. Claimant argues that it "relied on Canada's long-standing, well-understood and NAFTA-consistent utility requirement ('mere scintilla')" and, having been granted patents by Canada on that basis, Claimant "could not reasonably anticipate the dramatic and fundamental changes in Canada's utility standard occasioned by the advent of the promise utility doctrine in the mid-2000s."[550] These claims are baseless. As set out in detail above and in Canada's Counter-Memorial, Canada's law on utility did not change dramatically and fundamentally as Claimant suggests.[551] Rather, the courts were extending existing principles in Canadian patent law to new situations, exercising their function of adjudication in an adversarial system. Claimant could not legitimately, and did not in fact,[552] expect that the courts would not continue to clarify the law and apply it in novel situations.

282. Moreover, as discussed in detail in Section IV(D)(3)(c) above, Claimant's expectations as alleged today were not legitimate. For example, no sophisticated commercial party could legitimately expect specific litigation outcomes.[553] It is

[549] *See* Sections II(A)(2) and II(A)(3)(c).

[550] Cl. Reply, para. 324.

[551] Resp. CM., paras. 81-134; Dimock First Report, paras. 46-152, 218; Dimock Second Report, paras. 6-131, 150.

[552] Cl. Reply, para. 304.

[553] *See* Cl. Reply, para. 210 ("In its Memorial, Lilly established that its Zyprexa and Strattera patents were revoked under Canada's novel promise utility doctrine, and that if Canadian courts had applied the

disingenuous for Claimant now to decry Canada's alleged treatment of its expectations when it sought no advice and conducted no investigation into the specific requirements of Canadian patent law when it filed its atomoxetine and olanzapine patents.

VI. REQUEST FOR RELIEF

283. For all of the above reasons, Canada respectfully asks the Tribunal to issue an Award:

- 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.

December 8, 2015

Respectfully submitted

[signed]

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On behalf of the Respondent the
Government of Canada

traditional mere scintilla utility test that existed at the time the patents were granted, the patents would have been upheld.").