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

STATEMENT OF DEFENCE

June 30, 2014

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I. PRELIMINARY STATEMENT

1. Eli Lilly and Company ("Lilly" or "Claimant") is a disappointed litigant. Having lost two patent cases before the Canadian courts, it now seeks to have this Tribunal misapply NAFTA Chapter Eleven and transform itself into a supranational court of appeal from reasoned, principled, and procedurally just domestic court decisions. Claimant argues that the domestic court decisions invalidating its patents are measures that violate NAFTA Chapter Eleven. Claimant does this on the basis of misstatements of the content of Canadian law and of Canada's international obligations. Its claim is wholly without merit and should be dismissed, with full costs to Canada.

2. Claimant sought patents in Canada in the 1990s for the pharmaceutical use of two known chemical compounds, olanzapine and atomoxetine.[1] Canada's Patent Office granted the patents on the basis of the representations made by Claimant in its applications. In accordance with Canada's *Patent Act* [2], this initial administrative grant was only presumptively valid. It remained subject to challenge, review and potential invalidation by Canada's Federal Court through private-party litigation. The two patents were challenged in court. Exercising its statutory mandate, the Federal Court determined that both were invalid.

3. Claimant filed its 1991 patent application for olanzapine despite already holding a prior patent for this compound, as part of a larger group (or "genus") of related compounds. To warrant a second monopoly, Claimant asserted that olanzapine provided marked superiority in the treatment of schizophrenia compared with other members of the

[1] Claimant marketed a formulation containing atomoxetine as an active ingredient for the treatment of Attention Deficit / Hyperactivity Disorder ("ADHD"), under the brand name "Strattera". "Strattera" is not the name of any active medical ingredient. Rather, it is a name Claimant devised and applied to its drug product for marketing purposes. Similarly, Claimant marketed a formulation containing the active ingredient olanzapine for the treatment of schizophrenia, under the brand name "Zyprexa". Again, the latter is not a scientific term, but devised by Claimant as part of a marketing strategy. Throughout this Statement of Defence, Canada shall refer to the known active ingredients Claimant sought to patent by their internationally-recognized names as designated by the World Health Organization, *i.e.*, atomoxetine and olanzapine.

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

same genus and other unrelated compounds. The trial judge reasonably and in accordance with Canadian law sought to determine whether, at the time of filing, Claimant had proved (or "demonstrated") that olanzapine had the asserted utility, or at least could soundly predict that utility based upon its then-current research. Evidence at trial revealed that Claimant had claimed the second monopoly on the basis of studies which failed to establish any particular treatment advantage of olanzapine over the already-patented class to which it belonged. Allowing patent protection on this basis would encourage speculative over-patenting. Claimant's olanzapine patent was reasonably invalidated by the Federal Court.

4. Claimant's 1996 atomoxetine patent application asserted that as at the time of filing it had invented a new use for this well-known compound. Again, the judge at trial reasonably sought to determine whether Claimant had evidence confirming this new use, as at the time of filing its patent application, or at least could soundly predict the advantageous new use at that time. Evidence at trial revealed that in fact, Claimant's application for a 20-year monopoly relied solely on a flawed and inconclusive preliminary study that it had failed to disclose in its application. Allowing patent protection in these circumstances would permit applicants to obtain and uphold patents based on speculation, and in the absence of any adequate disclosure to the public. It would also have the effect of dissuading innovation by pre-emptively fencing off areas of research in the absence of a realized invention, undermining a primary policy goal of the *Patent Act*. Claimant's atomoxetine patent was reasonably invalidated by the Federal Court.

5. In both cases, Claimant was able to appeal the initial court decisions to the Federal Court of Appeal. In both cases, the Federal Court of Appeal ultimately found no reviewable error of fact or law. In the circumstances, Claimant failed to convince the Supreme Court of Canada that leave to appeal should be granted.[3] In total, nine Canadian

[3] In the olanzapine matter, the Supreme Court of Canada exceptionally granted an oral hearing on the application for leave to appeal. Despite this, Claimant's counsel were unable to persuade the court that leave was warranted: *Eli Lilly Canada Inc., et al. v. Novopharm Limited*, 2013 CanLII 26762 (SCC)

judges from the Federal Court and Federal Court of Appeal agreed that Claimant's patents failed to fulfil Canadian standards of patentability and accordingly should be invalidated.

6. In order to make its argument that these court decisions breach Chapter Eleven of NAFTA, Claimant relies in the first place on misstatements of the content of Article 1105 of NAFTA (Minimum Standard of Treatment) and of relevant facts. Despite having received extensive due process, reasoned decisions, and full rights of appeal in respect of its two invalid patents, Claimant alleges that the court decisions at issue were "improper and discreditable"[4], in violation of the Minimum Standard of Treatment. It grounds this allegation in its disagreement with the courts' appreciation of the facts and application of the law in the two patent cases at issue. Notably, it seeks to elevate its own competing views of how Canadian law "ought" to have been applied to its patents, or its "understanding" of Canada's international intellectual property obligations, into legally-enforceable "expectations", and argues that failure to live up to these "expectations" amounts to a breach of international law.

7. Such allegations fail to engage Article 1105. Applying the Minimum Standard of Treatment of investments under Customary International Law, the Tribunal must instead determine whether the court decisions at issue violated fundamental principles of due process, rising to the level of a denial of justice. They must otherwise consider whether the decisions amounted to a malicious misapplication of the law, rising to the level of a breach of the international Minimum Standard. The court decisions at issue do not even come close to violating this rule. They were rational, principled, and offered full due process.

("*Olanzapine SCC*") **(R-002)**. *See* also *Eli Lilly and Company v*. *Teva Canada Limited*, 2011 CanLII 79177 (SCC) ("*Atomoxetine SCC*") **(R-003)**.

[4] *SOC*, para. 81.

8. Nor can Claimant's misleading account of its alleged "expectations" alter the conclusion that this Tribunal cannot act as a court of appeal. Such "expectations" neither form the basis of a violation of the Minimum Standard of Treatment, nor confer on this Tribunal jurisdiction to rule on alleged breaches of Canada's international intellectual property obligations, through Article 1105 or at all. Certainly, no specific assurance was given forming the basis of such "expectations". Claimant's alleged "expectations" were in any event unreasonable: Claimant's account is incorrect viewed in light of the content and evolution of Canadian patent law, the functioning of the Canadian patent system, and the particular circumstances of the two patent decisions at issue here.

9. Claimant's allegations also fail to engage NAFTA Article 1110 (Expropriation). Court decisions invalidating an initial patent grant do not amount to a taking of "property", either direct or indirect: rather, they amount to determinations whether or not property rights exist at all. Decisions by courts regarding the existence of a right pursuant to domestic law are not subject to review by international investment tribunals, save in the extraordinary circumstance of gross procedural misconduct amounting to a denial of justice, or where court power to make such determinations is exercised in bad faith to mask a violation of international law (*abus de droit*). No such allegations have been made here, nor would they be warranted. Therefore, Article 1110 does not apply.

10. As a further response to the claimed violation of Article 1110, NAFTA Article 1110(7) provides that where the revocation of an intellectual property right is consistent with Chapter Seventeen, Article 1110 does not apply to the measure. Court invalidation of Claimant's patents was wholly consistent with Chapter Seventeen: like the draft text of the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights[5] upon which it was based, Chapter Seventeen provides a basic framework for domestic intellectual property regimes, without dictating its specific domestic application, and provides that relevant determinations are to be subject to the

[5] Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco, on April 15 1994, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (1994) ("TRIPS") **(RL-001)**.

reviewing powers of domestic courts. The present case fits entirely within this scheme. The Article 1110(7) defence to claims of expropriation negotiated and agreed by the NAFTA Parties further confirms that Article 1110 does not apply to the court decisions at issue.

11. In this Statement of Defence, Canada will provide: (1) an overview in Canadian patent law, to provide context for Claimant's misstatements regarding Canadian law on utility; (2) a description of the specific role played by the Federal Court in applying the *Patent Act*, establishing that the court is responsible for determining the validity and existence of the intellectual property right; (3) an outline of the facts relevant to the two court proceedings, demonstrating that Claimant received full due process and reasoned and principled decisions; and (4) brief comments on Canada's international intellectual property obligations under NAFTA Chapter Seventeen, TRIPS and the Patent Cooperation Treaty ("PCT"), confirming that these have no bearing on this case. This factual background confirms and reinforces the conclusion that nothing in the two court decisions at issue in any way violates Canada's obligations under Chapter Eleven of NAFTA.

II. CANADIAN PATENT LAW

12. In its Statement of Claim[6], Claimant misleadingly suggests that since 2005 Canadian courts introduced an unexpected "promise doctrine" when judging patent validity and unfairly applied this doctrine to its atomoxetine and olanzapine patents filed in the 1990s.[7] What Claimant describes as a unitary "doctrine" in fact consists of distinct tests for patent validity under Canadian law, each of which has its own rationale in light of statutory requirements, and each of which has deep roots in Canadian patent law. The application of these tests to determine the validity of Claimant's patents was neither arbitrary nor unfair. To correct Claimant's account and provide an accurate context for considering the two court decisions at issue in this claim, in what follows, Canada briefly

[6] Notice of Arbitration dated September 12, 2013, designated as the Statement of Claim ("*SOC*").

[7] *SOC*, paras. 9 and 66.

explains certain fundamental, longstanding requirements of Canadian patent law, notably with respect to the "utility" criterion for patentability.

A. Canadian Patent Law Exists to Promote Innovation and Disclosure

13. The Canadian patent system exists to promote and to ensure public access to innovation. To achieve these goals, Canada grants a time-limited monopoly to novel, non-obvious, and useful inventions, in exchange for the disclosure of the invention to the public. Disclosure to the public is at the heart of the patent bargain, as it allows others to study and build upon existing inventions, avoid duplicative research, and properly use the invention once the monopoly expires. The offer of a time-limited monopoly is understood to encourage both innovation and disclosure of such innovation to the public. Patent systems around the world are founded on this same bargain.

14. The statutory monopoly created by the *Patent Act*, allowing the patentee to exclude others from making or using an invention, is an exception to the general policy of most States, including Canada, in favour of free competition. The statutory monopoly stakes out a particular area of innovation. It discourages other innovators from pursuing research on the same subject-matter, while typically imposing higher costs for use of the invention upon the public. Given these high social and economic costs, a patent cannot be granted or its validity confirmed lightly. As the Supreme Court of Canada has noted:

> The grant of a patent monopoly for 17 years (20 years after October 1, 1989) creates, and is intended to create, serious anti-competitive effects. Once the subject matter of the patent is fenced in by the claims, others trespass (advertently or inadvertently) on the forbidden territory at their peril. The boundary is defended by a considerable arsenal of remedies conferred by the *Patent Act*, including an accounting of the infringer's profits in an appropriate case. Patent litigation is usually protracted and costly [...] There is in the meantime a chilling effect on other researchers. They will tend to invest their talents in less litigious areas. Parliament considered this chilling effect to be a worthwhile price for the disclosure of a "new and useful" invention, bringing into the public domain information that might otherwise remain a trade secret, but there is nothing in the Act

> to suggest that Parliament was prepared to accept the chilling effect in exchange for nothing but speculation.[8]

15. There is no inherent right to a patent at Common Law. It is entirely a statutory creation that must be earned in exchange for the "hard coinage" of invention and of disclosure of the invention.

B. Patent Applicants Must Fulfil Core Criteria of Patentability

16. To confirm entitlement to a patent, the subject-matter of the proposed invention must be patentable.[9] In addition, three basic criteria for patentability must be fulfilled.[10] Notably, the subject-matter defined by a claim must be novel[11]; it must not be obvious[12] (*i.e.*, generally speaking, a person with the relevant technical expertise would not have arrived at the proposed invention without some degree of inventiveness); and the proposed invention must have utility (*i.e.* the invention must do what the applicant's patent specification says it will do).[13] Finally, there must be proper disclosure in the

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

[9] *Patent Act*, ss. 2 (definition of invention) and 27(8) (what may not be patented) **(R-001)**.

[10] These requirements flow from the statutory definition of "invention" at section 2 of the *Patent Act*, and from further definitions at sections 28.2 and 28.3 of the *Patent Act*. Section 2 of the *Patent Act* defines an invention as "any new and useful art, process, machine, manufacture or composition of matter or any new and useful improvement in any art, process, machine, manufacturer or composition of matter" **(R-001)**.

[11] *Patent Act*, s. 28.2 (subject-matter of claims must not be previously disclosed) **(R-001)**. The requirement that to be patentable the subject-matter defined by a claim must be novel is intended to ensure that patents are granted to inventions that are not already available to the public.

[12] Until amendments made in 1993, the *Patent Act* did not explicitly state that a patent had to be for something non-obvious. Rather, Canadian courts, like their counterparts in the United States and United Kingdom, deduced this requirement from the notion of inventiveness itself. Inventions implied inventive ingenuity, without which an advance was obvious. *See* David Vaver, *Intellectual Property Law: Copyright, Patents, Trade-Marks*, 2nd ed. (Toronto: Irwin Law, 2011), p. 328 **(R-005)**. Following an earlier move by the United States and United Kingdom, Canada in 1993 amended the *Patent Act* to establish the conditions under which the subject-matter defined by a claim must not, at its claim date, be obvious to a person skilled in the relevant art or science: *Patent Act*, s. 28.3 (invention must not be obvious) **(R-001)**.

[13] As the Supreme Court of Canada has stated, what "is required to meet the utility requirements in section 2 is that the invention described in the patent do what the patent says it will do, that is, the promise of the invention be fulfilled": *Teva Canada v. Pfizer Canada Inc.*, [2012] 3 SCR 625, ("*Pfizer*"), para. 38 (our emphasis) **(R-006)**.

patent of the invention and of the manner in which it may be used.[14] Through the "proper teaching" in the disclosure, a person skilled in the art obtains the technical information to make or use the invention once the monopoly has expired and to make technological improvements to the disclosed invention.[15]

C. Core Criteria Must Be Fulfilled No Later than as at the Time of Filing

17. In Canadian patent law, fulfilment of the three core criteria of patentability – novelty, non-obviousness, and utility – is judged no later than *as at the time of filing of the patent application*. This is a longstanding rule of Canadian patent law, fully consistent with the notion of the patent as a bargain or "contract" between the applicant and the public. The question is essentially: did the applicant make a patentable invention as of the filing date?

18. Claimant seeks to confuse the requirements of Canadian law in arguing that Canada unfairly and unexpectedly invalidated its patents for failure to fulfil the "utility" criterion, alleging that both compounds eventually proved to be useful in fact.[16] This argument is a red herring. As Claimant well knows, if the applicant is no more than guessing at the time it files its patent application, whether or not the applicant ultimately demonstrates its alleged invention to be "useful in fact" (years after the filing of the invention, on the basis of wholly different research) is not the relevant inquiry.

19. The policy basis for this longstanding temporal rule is both logical and principled. It guards against abuses of the patent system: an applicant cannot pre-emptively file a claim to monopoly rights, excluding others from a potential area of research, where it is merely speculating. Otherwise, nothing would prevent market

[14] Section 27(3) of the *Patent Act* **(R-001)** requires that the specification of an invention must correctly and fully describe the invention and its operation and use as contemplated by the inventor.

[15] *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 SCR 142, ("*Cadbury*"), para. 46 **(R-007)**: "A patent is a statutory monopoly which is given in exchange for a full and complete disclosure by the patentee of his or her invention. The disclosure is the essence of the bargain between the patentee, who obtained at the time a 17-year [now 20-year] monopoly on exploiting the invention, and the public, which obtains open access to all of the information necessary to practice the invention". *See* also, *Pfizer*, paras. 31-34 **(R-006).**

[16] *SOC*, paras. 26, 27, 34, 53, and 63.

participants from staking out vast areas of research, to the exclusion of others, in the absence of any real invention. This would impose the costs of the patent on the public without the "patent bargain" having been fulfilled by the patent applicant. As the Supreme Court of Canada has ruled:

> Were the law to be otherwise, major pharmaceutical corporations could (subject to cost considerations) patent whole stables of chemical compounds for all sorts of desirable but unrealized purposes in a shot-gun approach hoping that, as in a lottery, a certain percentage of compounds will serendipitously turn out to be useful for the purposes claimed. Such a patent system would reward deep pockets and the ingenuity of patent agents rather than the ingenuity of true inventors.
>
> […]
>
> In the broader context of the *Patent Act*, as well, there is good reason to reject the proposition that bare speculation, even if it afterwards turns out to be correct, is sufficient. An applicant does not merit a patent on an almost-invention, where the public receives only a promise that a hypothesis might later prove useful; this would permit, and encourage, applicants to put placeholders on intriguing ideas to wait for the science to catch up and make it so. The patentee would enjoy the property right of excluding others from making, selling, using or improving that idea without the public's having derived anything useful in return.[17]

20. Canada's desire to guard against such misuse of the patent system is entirely reasonable and consistent both with sound domestic and international goals of patenting.

D. A Patentable Invention Must Fulfil its Asserted Utility

a) The Court assesses fulfilment of the "utility" criterion against what the inventor itself asserts to be the utility of its invention

21. In Canada, a party seeking to invalidate a patent may claim that the invention lacked utility – one of the fundamental aspects of a valid patent – on the basis that at the time of filing, the applicant had not established the utility of its invention. In considering this allegation, the reviewing court will first seek to determine whether the applicant itself

[17] *AZT*, paras. 80, 84, and generally paras. 78-85 **(R-004)**.

asserted (or "promised") a particular level of utility for its invention in its patent specification.[18] This will occur, for example, where the applicant purports to have invented the use of a compound to achieve a specific result or where the applicant purports to have invented a machine said to achieve a specific technical outcome. Where the patent promises a particular level or type of utility, that promise becomes the base against which utility is judged.

22. Claimant argues that court assessment of the specific utility "promised" in the patent is a new development, created by Canadian courts only since 2005, long after its patents were granted.[19] It suggests that prior to this development, inventions in Canada simply needed to possess some *de minimis* utility, unrelated to the specific utility promised in the patent specification.[20]

23. Claimant's narrative is incorrect. As early as 1959, drawing on English precedent going back to the early 20th century, Canadian courts asserted that the invention must be useful *as specified*, endorsing a description of this as fulfilment of the "promised results" of the patent.[21] The Supreme Court of Canada endorsed this reasoning in 1981, when the Court, quoting Halsbury's Laws of England, held that an invention lacks utility when 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".[22] The

[18] In Canada, as in other patent systems, a patent specification is made up of two main elements: the description, which explains the nature of the invention, and the claims, which set the legal boundary of the applicant's invention and related 20-year monopoly. Section 27(3) of the *Patent Act* addresses the description (disclosure) and s. 27(4) the claim(s). **(R-001)**

[19] *SOC*, paras. 34 and 66.

[20] *SOC*, paras. 8, 9, 28, and 29.

[21] *Rodi & Wienenberger Aktiengesellschaft v. Metalliflex Ltd*. (1959), 32 CPR 102 (Que CA), paras. 15-17 **(R-008)** affirmed in *Metalliflex Ltd.v. Rodi & Wienenberger Aktiengesellschaft*, [1961] SCR 117 **(R-009)**. Similarly, the Exchequer Court, predecessor to the Federal Court of Canada, held in a 1961 decision that fulfillment of the utility criterion must be judged against the "promise of the patent" *i.e.* what the specification of the patent indicated that the patent would do: *New Process Screw Corp. v. PL Robertson Mfg Co. Ltd*. (1961), 39 CPR 31 (Ex Ct), para. 39 **(R-010)**.

[22] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd*., [1981] SCR 504, 1981 CarswellNat 582, ("*Consolboard*"), para. 36 (our emphasis) **(R-011)**.

Supreme Court of Canada recently reiterated the simple and fundamental notion of "utility":

> As the courts below noted, all that is required to meet the utility requirement in s. 2 is that the invention described in the patent do what the patent says it will do, that is, that the promise of the invention be fulfilled [...] Patent '446 states that the claimed compounds, including sildenafil, will be useful in treating ED. At the time the application was filed, sildenafil could assist in treating ED. This is all that is required.[23]

24. In Canada, the fall-back rule is that there is no general obligation to promise a specific utility of the invention in a patent specification.[24] Where no promise is made, the court may assume a *de minimis* or "mere scintilla" of utility is asserted, and this will be the basis against which fulfilment of the "utility" criterion of patenting will be judged.

25. In some cases, however, an applicant does promise in the specification that her invention will achieve a particular degree of utility. Patent applications may contain promises for a variety of reasons. Sometimes, a particular degree of usefulness is at the core of the invention. For example, in patents where the alleged and claimed invention is a new use for a known chemical compound, the alleged new and non-obvious "use" of the compound is the essence of the invention. This was the situation of Claimant's atomoxetine patent application. In such circumstances, fulfilment of that alleged utility becomes central to fulfilment of the "bargain" at the heart of the patent grant.

26. Another case, that of "selection patents", arises where a patent has already been granted for a broad class of compounds (or "genus"). A party may seek a second patent for a sub-species of that genus on the basis that it has discovered that the sub-species (or "selection") has a surprising and non-obvious advantage over other members of the genus.[25] This was the situation of Claimant's olanzapine patent application. In the

[23] *Pfizer*, para. 38 (our emphasis) **(R-006)**.

[24] *Consolboard*, para. 37 **(R-011)**.

[25] The conditions for a selection patent were confirmed in the 1930s in *In re I.G. Farbenindustrie A.G.'s Patents* (1930), 47 RPC 289, pp. 322-323 **(R-012)**, and recalled by the Supreme Court of Canada in *Apotex Inc*. *v*. *Sanofi-Synthelabo Canada Inc*., [2008] 3 SCR 265, ("*Sanofi-Synthelabo*"), paras. 9 and 10 **(R-013)**.

absence of that advantage, there would be no reason to grant a second patent for the sub-species compound and use thereof. That surprising advantage or specific use becomes the core of the "invention" and must be established and disclosed for patent protection to be obtained.[26] Otherwise, the patentee of an original "genus" patent would be able to "evergreen" its original patent monopoly, through subsidiary patents for sub-classes of that very same invention (essentially engendering a perpetual monopoly).[27]

b) Determining the promised utility, if any, is a highly technical exercise

27. Determining whether the patent incorporates a particular promise of utility is a highly contextual, fact-specific, and technical exercise. As the Federal Court of Appeal noted in the olanzapine matter:

> Generally, it is an exercise that requires the assistance of expert evidence […] This is because the promise should be properly defined, within the context of the patent as a whole, through the eyes of the POSITA, in relation to the science and information available at the time of filing.[28]

28. Determination of the promised utility of the patent is therefore not, as Claimant suggests, "subjective" or "arbitrary".[29] Rather, the court must determine how a person of ordinary skill in the art (the "POSITA")[30], who is the deemed reader of the patent, would

[26] As the Federal Court of Appeal stated, "In the case of selection patents, as we have seen, the novelty of the selection and its advantages (including disadvantages to be avoided) are the invention and must be described in the patent": *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 186, ("*Sanofi-Aventis*"), para. 51 (our emphasis) **(R-014)**. *See* also *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197, ("*Olanzapine FCA I*"), para. 78 **(R-015)**; *Eli Lilly Canada Inc. v. Novopharm Limited*, 2011 FC 1288, ("*Olanzapine FC II*"), paras. 85-86 **(R-016)**.

[27] *Sanofi-Synthelabo*, paras. 96-100 **(R-013)**.

[28] *Olanzapine FCA I*, para. 80 **(R-015)**.

[29] *SOC*, paras. 10, 35, 36, and 48.

[30] The legal construct of the "POSITA" exists in numerous domestic patent systems, including Canada and the United States. The POSITA is akin to the legal "reasonable person". The POSITA is an archetypal person who understands the field but is not an inventive person. If an invention is obvious to a POSITA, then it is not a patentable invention. If a POSITA would understand the patent to promise a specific outcome, this is the promise that the patent has to meet. *See Monsanto Canada Inc. v. Schmeiser*, [2004] 1 SCR 902, para. 125 **(R-017)**; *Free World Trust v. Electro Sante Inc.*, [2000] 2 SCR 1024, ("*Free World Trust*"), para. 44 **(R-018)** quoting from H.G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed. (Toronto: Carswell, 1969), p. 184 **(R-019)**.

have interpreted the words and phrases employed by the appellant in the patent specification[31], supplemented by the POSITA's common general knowledge.[32] Expert evidence at trial will establish whether the POSITA would in fact have understood the patent specification to contain a promise.

29. In determining what the POSITA would have understood, the court applies settled principles of patent construction. It is well established that construction of the patent is purposive. For example, in the context of purposive construction of a patent's claims, the Supreme Court of Canada has stated:

> [t]he key to purposive construction is […] the identification by the court, with the assistance of the skilled reader, of the particular words or phrases in the claims that describe what the inventor considered to be the "essential" elements of his invention.[33]

As the Supreme Court has further held:

> We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance [...] being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and the public.[34]

30. In the court decisions at issue, the Federal Court heard extensive expert evidence and applied these interpretive principles to construe the promised utility of Claimant's inventions, reaching a reasonable result. It was hardly unfair to hold Claimant to its promised use of atomoxetine – treatment of patients with ADHD – when that use formed the basis of its new patent claim for this known compound. Similarly, it was hardly unfair to hold Claimant to the promised use of olanzapine – comparatively superior treatment of schizophrenia – when that promise was its sole basis for distinguishing the

[31] The specification is a legal document, subject to the interpretation provisions of the federal *Interpretation Act*, RSC 1985, c I-21 **(R-020)**.

[32] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FCA 108, para. 55 **(R-021)**, citing *Consolboard*, para. 28 **(R-011)** and *Whirlpool Corp. v. Camco Inc.*, [2000] 2 SCR 1067, ("*Whirlpool*"), para. 49 **(R-022)**.

[33] *Whirlpool*, para. 45 **(R-022)**. *See* also *Free World Trust*, para. 31 **(R-018)**.

[34] *Consolboard*, para. 27 **(R-011)**.

compound from the original, already-monopolized class of compounds to which olanzapine belonged.

E. Canada Allows Utility to Be "Predicted" Rather than "Demonstrated"

31. In Canada, since at least the late 1970s, courts have progressively relaxed the rule regarding how utility can be established as at the time of filing. They have done so in favour of a rule permitting patents where the applicant bases its patent filing on a "sound prediction" of utility, where an applicant cannot demonstrate (*i.e*. definitively prove) such utility at that time. In such cases, an applicant's "sound prediction" can satisfy the utility requirement of the invention.

32. Claimant complains that its patents were invalidated through application of the doctrine of "sound prediction", suggesting that such tests were unfairly adopted it after its filings, and imposed a "higher evidentiary standard" on its application.[35] Its complaint makes little sense, because "sound prediction" amounts to a more liberal standard for satisfying the utility requirement. Rather than heightening the evidentiary standard, "sound prediction" obviates the need for actually demonstrated utility at the time of filing.

33. As in the case of "promise", this doctrine was not introduced in the mid-2000s, as Claimant alleges, but was already being applied in appropriate cases by the Supreme Court of Canada as of the 1970s. In its 1979 decision, *Monsanto Company v. Commissioner of Patents*[36], the Supreme Court of Canada decided that it was appropriate to allow an applicant to claim a patent for a broad class of chemical compounds, where the applicant had derived at least some members of that chemical class as at the time of application and confirmed their reactivity (*i.e*. could "demonstrate" the utility of these examples as of the filing date), and based upon such examples could soundly predict the reactivity of other members of that same class. The Court rejected the attempt to refuse

[35] *SOC*, paras. 10, 36, 39, and 67 ("heightened evidentiary standard").

[36] *Monsanto Company v. Commissioner of Patents*, [1979] 2 SCR 1108, ("*Montsanto*") **(R-023)**.

the claim on the basis that the applicant had "over-claimed", *i.e*. claimed beyond the scope of its true invention. The disclosure requirement had been met in that case by the disclosure of working examples, which taught the skilled reader of the patent the invention and the manner in which it could be used, and from which the other (untested) members of the claimed class could soundly be predicted.

34. In the 2002 case *AZT*[37], the Supreme Court of Canada decided to apply a "sound prediction" analysis to pharmacology. In so doing, the Supreme Court reversed the finding of the trial judge, who had considered the doctrine of sound prediction to be limited to the situation where inventors claim a number of untested compounds based on the proven utility of one or more compounds, as in *Monsanto*. The Supreme Court recognized that for certain classes of invention, it was difficult to "prove" (or "demonstrate") that one had a fully-realized invention, as at the date of application, on the basis of only early-stage research. At the same time, the court recognized the value of early disclosure of promising research and therefore sought to encourage such disclosure by more liberally interpreting the statutory conditions for patentability. The Court therefore decided that in appropriate cases patents could be sustained if, as of the time of filing, an applicant could at least soundly predict, if not fully demonstrate, the claimed utility of its invention and had disclosed the basis for that sound prediction in the patent.

35. The Court in applying the *Monsanto* doctrine in this context, articulated a three-part test to ensure the proper application of sound prediction in Canadian patent law:

> The doctrine of sound prediction has three components. Firstly, as here, there must be a factual basis for the prediction. In *Monsanto* and *Burton Parsons*, the factual basis was supplied by the tested compounds, but other factual underpinnings, depending on the nature of the invention, may suffice. Secondly, the inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis. In *Monsanto* and *Burton Parsons*, the line of reasoning was grounded in the known "architecture of chemical compounds" (*Monsanto*, at p. 1119), but other

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

> lines of reasoning, again depending on the subject matter, may be legitimate. Thirdly, there must be proper disclosure.[38]

36. Canadian courts have since followed the liberal doctrine of sound prediction articulated in *AZT*. The application of the test depends upon the state of the particular art and on what specifically the applicant has claimed in its patent. The principle of "sound prediction" has been repeatedly relied upon to uphold the validity of pharmaceutical patent claims filed on the basis of early-stage research, which otherwise would not have constituted a patentable invention. The doctrine does not necessarily require long-term or human clinical studies to establish utility: all depends on the nature of testing (the "factual basis" provided) and the applicant's line of reasoning from that factual basis, confirming a sound prediction. This doctrine is not applied exclusively to pharmaceutical inventions: it can be and has been applied to other categories of inventions to establish utility.

37. The Federal Court applied the liberal doctrine of sound prediction of utility to Claimant's patent for olanzapine, after determining on the facts that Claimant was not in a position to demonstrate the utility of its alleged invention as of the filing date. The trial judge determined in light of extensive expert evidence that the studies Claimant had in its possession as of the filing date failed to provide a basis for a sound prediction of the promised utility of the invention.

F. The Invention and its Use Must Be Properly Disclosed

38. As suggested above, disclosure of the invention and of its operation and use has always been at the heart of the "bargain" underlying Canadian patent law. Canadian courts have continued to apply this requirement for patent applications filed on the basis of a "sound prediction".

39. Claimant alleges that Canadian courts unfairly applied a "heightened" disclosure requirement to its patents, contrary to the *Patent Act*, by requiring that in cases where an

[38] *AZT*, para. 70 (our emphasis) **(R-004)**.

invention was based upon "sound prediction" of utility, the applicant disclose a factual basis for its prediction and line of reasoning in the application.[39] Again, this complaint makes little sense. By requiring such disclosure, Canadian courts are simply applying the disclosure requirement to this specific context.

40. In earlier sound prediction cases such as *Monsanto*, where working examples of inventive chemical compounds had been disclosed in the specification, that factual basis had provided sufficient disclosure of the invention of the class of chemical and of its use. From these examples, the skilled reader of the patent would know how to work and use all other members of the claimed chemical class. In *AZT*, the invention consisted of the use of a known chemical compound to treat AIDS. At the time the patent was sought, *AZT* had not been tested in humans but had been shown to be effective in treating human cells *in vitro*. In these circumstances, the disclosure therefore consisted of the test forming the factual basis for the prediction of utility in humans, and of the line of reasoning soundly predicting effectiveness in humans based on the *in vitro* result, which together allowed the POSITA to understand and to work "the invention". As the Supreme Court noted in *AZT*:

> Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practiced: […]. It is generally not necessary for an inventor to provide a theory of *why* the invention works. Practical readers merely want to know that it does work and how to work it. In this sort of case, however, the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly. Precise disclosure requirements in this regard do not arise for decision in this case because both the underlying facts (the test data) and the line of reasoning (the chain terminator effect) were in fact disclosed, and disclosure in this respect did not become an issue between the Parties. I therefore say no more about it.[40]

41. The Supreme Court therefore confirmed that the validity of patents filed in such circumstances would depend on proper disclosure. Where the prediction was in effect the

[39] *SOC*, paras. 10, 36, 39, and 67.

[40] *AZT*, para. 70 (our emphasis underlined, italics in the original) **(R-004)**.

core of the "invention", the basis for the prediction (a factual basis and sound line of reasoning) had to be established and disclosed at the time of filing of the application.

42. The Federal Court applied the same rule to Claimant's patent for the use of atomoxetine. There, Claimant failed to disclose that its "invention" was in fact merely a prediction based upon early-stage research. It therefore failed to provide the public a proper teaching regarding the nature of its invention and its operation and use. In the circumstances, it was reasonable for the court to find that Claimant had failed to uphold its side of the bargain.

G. The Federal Court When Seized of the Issue Has Responsibility to Uphold the Patent Bargain

43. At the heart of Claimant's allegations is a fundamental mischaracterization of the nature of the patent grant in Canada. It suggests that this initial grant conferred upon it an irrevocable property right and that moreover the Patent Office's practice guidelines were an authoritative source of law.[41] This is incorrect. Under Canadian law, an initial patent grant is always made subject to invalidation by the Federal Court, the ultimate arbiter of patent validity and the authoritative interpreter of *Patent Act* requirements. The nature of rights conferred by a patent grant, and any expectation that Claimant could have had when the initial patent grant was made, must be considered in light of the Federal Court's role.

a) The Patent Office makes an initial administrative grant

44. As in many jurisdictions around the world, in Canada, patents are initially granted by the Patent Office based upon an administrative review of the patent specification as filed.[42]

[41] *SOC*, paras. 8, 10, and 74.

[42] Subsection 27(1) of the *Patent Act* **(R-001)** provides that "[t]he Commissioner [of Patents] shall grant a patent for an invention to the inventor or the inventor's legal representative if an application for the patent in Canada is filed in accordance with this Act and all other requirements for issuance of a patent under this Act are met."

45. Claimant seeks to elevate this initial grant into an irrevocable certainty. Yet as Claimant is well aware, all such administrative patent grants are only presumptively valid, subject to court review.[43] Patent Office review is based upon the applicant's patent specification and an examination of available prior art. If an examiner discovers no evidence contradicting the asserted utility, the applicant's description of the invention is taken at face value, with the knowledge that such assertions must eventually withstand court scrutiny if subsequently challenged in private-party litigation.

46. In granting patents, the Patent Office seeks to reflect the current state of the law. However, neither its patent grants nor the guidelines that it employs can be regarded as the final word. The Patent Office processes thousands of patent applications annually, without the benefit of a full adversarial proceeding to determine whether the grant of a patent is warranted. It lacks statutory authority to make binding interpretive rulings on the meaning of the *Patent Act*. The Manual of Patent Office Practice ("MOPOP") has since its first 1977 version consistently stated that it is "to be considered solely as a guide, and should not be quoted as an authority. Authority must be found in the Patent Act, the Patent Regulations, and in decisions of the Courts interpreting them".[44]

47. No sophisticated patent applicant interprets MOPOP as a binding or complete statement of patent law. This is particularly the case where the provisions of the *Patent Act* are being applied to new technologies, or an application raises new or unsettled questions of interpretation and application of the *Act*.

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[43] *Patent Act*, ss. 42 and 43(2) **(R-001)**. Section 42 of the *Patent Act* provides that every patent granted under the Act shall "[…] subject to this Act, grant to the patentee […] for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction" (our emphasis). Section 43(2) provides that "After the patent is issued, it shall, in the absence of evidence to the contrary, be valid and avail the patentee and the legal representatives of the patentee for the term mentioned in Section 44 or 45, whichever is applicable" (our emphasis).

[44] "*Manual of Patent Office Practice*", Consumer and Corporate Affairs Canada, Patent Office (December 1977), Forward **(R-024)**. The same notice has appeared in every subsequent version of MOPOP. "*Manual of Patent Office Practice*", Consumer and Corporate Affairs Canada, Patent Office (August 1989, January 1990, March 1998, September 2004, February 2005, April 2006, January 2009, December 2009, November 2013, December 2013, and May 2014), Forward **(R-025)**.

b) The Federal Court confirms whether the initial grant was valid

48. The *Patent Act* provides that "A patent or any claim in a patent may be declared invalid or void by the Federal Court at the instance of the Attorney General of Canada, or at the instance of any interested person".[45] In practice, the Attorney General of Canada is not involved in such patent litigation.

49. The Federal Court is therefore required to rule on the scope and validity of patents when disputes arise between private parties, in relation to either the infringement or validity of patents granted by the Patent Office. In doing so, the Federal Court must, among other things, determine whether the patent as initially granted indeed satisfies the requirements of the *Patent Act*.

50. Unlike the initial administrative reviews by the Patent Office, which rely on the patent specification as filed and assumptions in favour of the applicant, the Federal Court will review a patent's validity in light of extensive expert and fact evidence, presented in an adversarial court process between private parties.

51. A cautious and prudent patent applicant therefore files its specification, not only with a view to passing initial Patent Office scrutiny, but also with a view to passing muster before the Federal Court, in any potential challenge to the validity of an initial patent grant.

III. THE MEASURES AT ISSUE

A. The Decisions of the Federal Court

52. The decisions of the Federal Court invalidating patents No. 2,209,735 (the "'735 Patent") (atomoxetine) and No. 2,041,113 (the "'113 Patent") (olanzapine) were taken after Claimant received full due process, and were based upon reasoned consideration of extensive fact and expert evidence, in rational application of relevant legal precedents. Claimant was allowed to appeal its case to the Federal Court of Appeal and to seek leave

[45] *Patent Act*, s. 60(1) **(R-001)**.

to appeal before the Supreme Court of Canada. In total, nine different Canadian judges in the context of these two cases found that Claimant's patents were invalid.

a) Claimant's invalid patent for atomoxetine

53. Atomoxetine was a well-known medical compound at the time Claimant filed for the '735 Patent, in 1996. Since 1979, atomoxetine had already been the subject of an existing patent for the "genus" or group of compounds to which it belonged, which were described as anti-depressants. Since 1985, atomoxetine had also been the subject of a second patent for the treatment of depression. Claimant held both patents.

54. In light of these existing patents, to seek yet another monopoly, Claimant was required to assert another new and non-obvious use for atomoxetine. Its claimed new "invention" in the '735 Patent was "the use of tomoxetine for treating attention-deficit/hyperactivity disorder in a patient in need thereof".[46] In its patent specification, Claimant employed language suggesting that it already had firmly established atomoxetine as an effective ADHD treatment, although it did not disclose any study or any working examples.[47] On the basis of Claimant's representations, the Patent Office granted the patent on October 1, 2002.

55. Following the filing of the '735 Patent, Claimant filed at least ten alternative patent applications for the use of atomoxetine for the treatment of ten other pathologies, ranging from stuttering, to anxiety disorders, to tic disorders, to hot flashes. As in the case of the '735 Patent, the majority of these other patent applications contained no relevant testing or merely anecdotal data, otherwise simply asserting the claimed utility, leaving the impression that the invention was fully realized.

[46] Patent Specification CA 2,209,735 **(R-026)**, Claim No. 1. The active ingredient was subsequently renamed "atomoxetine" to avoid confusion with another compound.

[47] For instance, Claimant stated that: "The present invention provides a method of treating attention-deficit/hyperactivity disorder […]", and that "Tomexetine is a notably safe drug, and its use in ADHD, in both adults and children, is a superior treatment for that disorder because of its improved safety. Further, tomoxetine is effective at relatively low doses […]": Patent Specification CA 2,209,735, p. 2 **(R-026)**.

56. Years after filing the '735 Patent, and based upon different and later research, Claimant on December 24, 2004 obtained Health Canada approval for the use of atomoxetine to treat ADHD.

57. In 2008, one of Claimant's competitors, Novopharm Limited, sought a declaration from the Federal Court that the '735 Patent was invalid and void, including for want of utility as of the time of filing. The trial was heard over 19 hearing days between May 11, 2010 and June 9, 2010. Testimony was received from six witnesses, including four expert witnesses.

58. After more than three months of deliberations, the trial judge issued detailed reasons. He determined, based upon the expert evidence and the language in the specification, that Claimant's patent set out "the promise that atomoxetine works to treat ADHD in some patients".[48] He noted that an invention "is only useful if it does what the inventor claims it will do".[49] On the facts, he held:

> In this case the requirement of utility would be met if, at the Canadian filing date of the '735 patent, there was sufficient evidence that atomoxetine was clinically useful in treating some patients with ADHD or, alternatively, that such efficacy could be soundly predicted. That was, after all, what the '735 Patent offered – an effective treatment for ADHD – and that was the consideration required of Lilly for the monopoly it claimed.[50]

59. Claimant suggests that it was unfair of the Federal Court to hold its invention to a "higher" standard of utility, based upon the court's construction of the promise of the patent.[51] This ignores the Court's duty to apply the law as articulated by the Supreme Court in *Consolboard*, which upheld the rule that utility is to be judged against the invention as promised in the specification. Moreover, this was a case of an invention for the new use of a known compound. The first claim of the '735 Patent stated "the use of

[48] *Novopharm Ltd. v. Eli Lilly and Co.*, 2010 FC 915, ("*Atomoxetine FC*"), para. 112 (**R-027**).

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

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

[51] *SOC*, para. 52.

tomoxetine for treating attention-deficit/hyperactivity disorder in a patient in need thereof". The Federal Court had the obligation to construe what meaning the POSITA would ascribe to the term "treatment", after considering the testimony of experts for both parties.

60. Having determined the promised utility of the patent, the trial judge went on to consider whether that utility had been demonstrated by the date of filing or (applying the more liberal test of *AZT*) was at least soundly predicted as of that date. On the basis of the evidence submitted, the trial judge found that Claimant could not demonstrate as at the time the patent was filed the asserted (or "promised") utility of the invention.[52] In particular, the trial judge accepted the expert evidence that the only study that had been conducted prior to Claimant's filing (which was not disclosed in its patent specification), the Massachusetts General Hospital ("MGH Study"), was preliminary and procedurally flawed.[53] The MGH Study failed to respect its own protocol in terms of group size (employing only half of the suggested number of patients) and provided little data (patient exposure to atomoxetine was limited to three weeks). The trial judge noted that the authors of the study themselves confirmed that the MGH Study had important limitations.[54] He concluded that the MGH Study was:

> too small in size and too short in duration to provide anything more than interesting but inconclusive data. With a patient sample of this uniformity and size, an exposure to atomoxetine of only three weeks and a degree of subjectivity in the testing, one can only conclude, as the researchers themselves stated, that the study had "limitations" and the results were promising but only preliminary.[55]

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

[53] *Atomoxetine FC*, para. 113 **(R-027)**; *Eli Lilly and Co. v. Teva Canada Limited*., 2011 FCA 220, ("*Atomotextine FCA*"), para. 37 **(R-028)** (discussing the findings of the trial judge on this point). Although the Federal Court placed no limitations on the number of witnesses who could be heard, Claimant did not call any witness with direct knowledge of the MGH Study, and even failed to call the only living inventor of the '735 Patent. The MGH Study was never submitted by Claimant as a stand-alone study in the Health Canada approval process.

[54] *Atomoxetine FC*, para. 101ff. **(R-027)**.

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

61. Moreover, the total absence of reference to the MGH Study in the '735 Patent application meant that Claimant had failed to disclose any basis for a "sound prediction" of the asserted utility that formed the substance of the invention.[56]

62. Claimant appealed the lower court decision to the Federal Court of Appeal. Claimant argued that the first judge erred by interpreting the effective "treatment" promised in the patent as treatment that will work in the long term.[57] Claimant contended that some patients only need ADHD treatments for short periods of time (for example, to improve the level of concentration while preparing for and writing examinations).[58] However, the patent specification contained nothing regarding this potential use, and the protection afforded to the patentee by the claim was not so limited. In any case, the Federal Court of Appeal determined that the trial judge found the MGH Study insufficient to demonstrate that atomoxetine was an effective treatment, regardless of the length of time for which it was taken.[59] The panel of three judges of the Federal Court of Appeal unanimously endorsed the lower court decision. There was no basis to set aside the decision of the Court below.

63. Claimant sought leave to appeal the decision to the Supreme Court of Canada, which declined to grant leave to appeal. Following its usual practise for leave to appeal decisions, the Supreme Court did not render detailed reasons.[60]

64. Claimant's equivalent United States patent for the use of atomoxetine was also invalidated at first instance, on grounds strongly parallel to those noted in Canada. In a decision dated August 12, 2010 (*i.e*. one month before the initial Federal Court of Canada decision invalidating the '735 patent), the United States District Court for the District of New Jersey (the "District Court") held Claimant's patent invalid for lack of utility, noting

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

[57] *Atomoxetine FCA*, para. 26 (**R-028**).

[58] *Atomoxetine FCA*, para. 28 (**R-028**).

[59] *Atomoxetine FCA*, para. 29 (**R-028**).

[60] *Atomoxetine SCC* (**R-003**).

that Claimant had failed to disclose any test results in its specification and that a person skilled in the art would not have been able to infer the utility of the invention based upon the specification. The Court's reasoning in this regard is instructive:

> the utility requirement prevents a party from patenting a mere research proposal or an invention that is simply an object of research […] To ensure that patents do not cover "intimations of general ideas that may or may not be workable" or just "hypothetical possibilities", the enablement/utility case law instructs that patent applicants must demonstrate utility (as well as other enablement-related requirements) at the time of filing the patent application […] there is a valid policy for requiring utility to be established at the time of filing: permitting patents to be filed prior to the establishment (through some means) of the enablement/utility cuts off future scientific research in a field "with no assurance that anything useful will be discovered in the end" […] For example, a party could conceivably file patents claiming methods of treatment for various diseases through the administration of a certain drug prior to knowing that each method of treatment works. Then, through later testing, the patent applicant could demonstrate that certain of the claimed treatments were in fact useful at the time of filing. This Court does not believe that such a shotgun approach would be permissible under § 112 of our patent laws.[61]

65. The District Court's reasoning, which had relied on earlier precedential cases by the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"), was later overturned by a Federal Circuit panel composed of only two out of three judges (as one judge died before reasons could be issued). The Federal Circuit refused to follow its own jurisprudence and to require the inventor to have in its possession some evidence on which a prediction of utility can be made at the time the application is filed. Instead, the two-member panel found the patent to be valid despite the fact that inventors had only a hypothesis of utility, without any data to support that hypothesis. Given that it was published as a non-precedential decision, in United States practise the Federal Circuit's opinion in the atomoxetine case has no binding effect, beyond the parties themselves, and does not necessarily reflect correct United States law.

[61] *Eli Lilly and Co. v. Actavis Elizabeth LLC*, 731 F. Supp. 2d 348 (DNJ 2010), p. 385 (**R-029**).

b) Claimant's invalid patent for olanzapine

66. When Claimant sought its '113 Patent in 1991, it had since 1980 owned a patent over a broad "genus" whose purported use was the treatment of mild anxiety and certain kinds of psychotic conditions, including schizophrenia (patent No. 1,075,687, or the "'687 Patent"). Olanzapine was one of the compounds included in the '687 Patent.

67. Claimant began to sell an olanzapine-based pharmaceutical product in Canada only in 1996, with one year remaining to the monopoly granted by the '687 Patent. Claimant therefore sought to extend its monopoly by seeking a further patent on olanzapine. Indeed, following the filing of its '113 Patent, Claimant filed at least 29 other Canadian patent applications relating to olanzapine, purporting to have invented at least 16 distinct new and surprising uses for the compound, ranging from sexual dysfunction to autism. The majority of these other patent applications contained no reference to actual research conducted, or contained an ambiguous reference to clinical studies that may or may not have been conducted before the filing of the corresponding patent applications. Claimant filed fourteen of these patents applications in 1996-1997, just prior to the expiry date of the '687 Patent.

68. As noted above, Canadian law allows patent holders to obtain a second patent on a selection of one or many compounds from the genus where the selected compound(s) possesses a substantive advantage over the compounds in the genus. In such cases, the "invention" is identifying the unexpected and special advantages (including disadvantages avoided) over members of the already-patented genus.

69. The '113 Patent specification accordingly stated that olanzapine "shows marked superiority, and a better side effects profile than prior known antipsychotic agents, and has a highly advantageous activity level".[62] Based upon its administrative review, the Patent Office issued the patent in July 1998.

[62] Patent Specification CA 2,041,113, p. 6 (our emphasis) **(R-030)**.

70. Claimant's competitor, Novopharm Limited ("Novopharm"), later applied pursuant to the *Food and Drug Regulations* for a Notice of Compliance ("*NOC*") from the Minister of Health to enter the Canadian market with a pharmaceutical product employing olanzapine. In response, Claimant, pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, sought from the Federal Court an order prohibiting the Minister of Health from doing so, citing the '113 Patent.[63]

71. In these proceedings, Novopharm argued among other things that the '113 Patent failed to provide sufficient disclosure of the invention in its specification, and that the level of utility promised in the patent had not been met at the time of filing. The parties filed affidavit evidence of 21 witnesses, including 17 expert witnesses, who were all cross-examined at the hearing.[64] As a result of these allegations, following established precedent, the court was prompted to construe the patent to determine the promised utility of the invention. In light of the extensive evidence filed by both parties and the language used in the patent specification, the judge construed the promised utility of the patent as "olanzapine shows marked superiority […], has a better side effects profile than "prior known" antipsychotic agents [...], and has highly advantageous activity level".[65] On the ground of sufficiency of disclosure, he found that the '113 Patent failed to provide sufficient disclosure in its specification as to the invention, if any, in selecting olanzapine from a previously disclosed group of compounds.[66] He held that there was "no data" to support Claimant's assertion that olanzapine had "surprisingly and unexpected

[63] The *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, ("*PM(NOC) Regulations*") **(R-031)** provide that when a generic company wishes to enter the Canadian market with a drug similar to one already approved for which a *NOC* has been issued by the Minister to a "first person", a generic may send a notice of allegation to this "first person" if it has listed one or more patents under the scheme of the *PM(NOC) Regulations*. The notice of allegation must allege that the patent is invalid or other similar grounds, and provide factual and legal basis for such allegations. The "first person" may then, if it chooses, institute prohibition proceedings to prohibit the Minister of Health from approving, by way of issuing and *NOC*, the application of the generic company. The Minister of Health, while named, makes no representation in such proceedings.

[64] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596, ("*Olanzapine NOC*"), paras. 3 and 4 **(R-032)**.

[65] *Olanzapine NOC*, para. 126 **(R-032)**.

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

properties" by comparison to prior art.[67] In these circumstances Claimant simply "had not paid the price, by way of a clear and explicit disclosure as to what the invention is […] that merits a further monopoly in a separate further patent".[68] In light of this conclusion on sufficiency of disclosure, the court held that it was not necessary to resolve the issue of utility.[69] Novopharm therefore received a Notice of Compliance.

72. Claimant thereafter launched a second proceeding before the Federal Court pursuant to the *Patent Act*, alleging that Novopharm's pharmaceutical product employing olanzapine infringed the '113 Patent. Again, the issues of utility and sufficiency of disclosure were raised. The trial in these proceedings was heard over 44 days and testimony was taken from 20 expert witnesses and 10 fact witnesses. The trial judge identified the issue at the outset as whether the '113 Patent was a valid selection patent.[70] He determined that to uphold the validity of the '113 Patent, he must be satisfied that olanzapine had an advantage over the compounds of the '687 Patent; that this advantage was substantial and somewhat peculiar to olanzapine; and that the patent clearly described olanzapine's substantial and special advantage.[71] Based on the evidence adduced by the parties, and after deliberating for seven months, he answered these three questions in the negative and consequently invalidated the patent.

73. Claimant appealed this decision to the Federal Court of Appeal. The Federal Court of Appeal held that the trial judge erred in finding that the conditions for a selection patent constitute an independent basis upon which to attack a patent's validity. Rather, these conditions serve to characterize the invention and inform the analysis for the grounds of validity applicable to all patents, as set out in the *Patent Act*.[72] The trial

[67] *Olanzapine NOC*, para. 154 **(R-032)**.

[68] *Olanzapine NOC*, para. 164 **(R-032).**

[69] *Olanzapine NOC*, para. 190 **(R-032)**.

[70] *Eli Lilly Canada Inc. v. Novopharm Ltd*., 2009 FC 1018, ("*Olanzapine FC I*"), para. 10 **(R-033)**.

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

[72] *Olanzapine FCA I*, para. 27 **(R-015)**.

judge also erred in failing to expressly construe the patent and determine whether it included a promise.[73] According to the Federal Court of Appeal:

> [T]he promise of the patent is to be ascertained at the outset of an analysis with respect to utility. The promise is to be construed by the trial judge within the context of the patent as a whole, through the eyes of the POSITA in relation to the science and information available at the time of filing. The promise of the patent is fundamental to the utility analysis.[74]

74. Referring solely to the patent's specification, the Federal Court of Appeal would have concluded that the promise should be construed as "olanzapine, in the treatment of schizophrenia, shows marked superiority to flumezapine and other '687 compounds, has a better side effects profile that prior known antipsychotic drugs and has a highly advantageous activity level".[75] However, considering that the trial judge had failed to provide any foundation for the construction of the patent's promise, it allowed the appeal, remitting the utility and sufficiency of disclosure grounds of alleged invalidity to the Federal Court for determination in accordance with its reasons.

75. Novopharm sought leave to appeal from this decision to the Supreme Court of Canada. Claimant opposed its request, arguing that nothing in the Federal Court of Appeal's decision raised issues of national importance. Notably, Claimant argued that in its directions with regard to utility, the Federal Court of Appeal "did nothing more than apply the settled law of this Court".[76] The Supreme Court of Canada denied leave to appeal. The matter was then sent back to the Federal Court.

76. In his second decision in this matter, the trial judge carefully followed the directions set out for him by the Court of Appeal. He began his analysis by construing the patent in order to determine whether it set out a promise. Referring to the expert

[73] *Olanzapine FCA I*, para. 98 **(R-015)**.

[74] *Olanzapine FCA I*, para. 93 **(R-015)**.

[75] *Olanzapine FCA I*, para. 99 **(R-015)**.

[76] *Novopharm Limited v. Eli Lilly and Company*, Supreme Court of Canada Case No. 33870, Memorandum of Argument of the Respondent, Application for Leave to Appeal, October 26, 2010, para. 56 (our emphasis) **(R-034)**.

evidence in this regard, he refused to accept Claimant's proposition that the advantages described in the '113 Patent, including that olanzapine showed a "marked superiority and a better side effects profile than prior known antipsychotic agents", were not part of the promise of the patent.[77] He held that this interpretation "does not line up with the plain words of the patent. Nor does it accord with the preponderance of the expert evidence about what those words conveyed to them."[78] Instead, the trial judge determined on the face of Claimant's patent specification that the promised "utility" of the invention was as follows: "Overall, therefore, in clinical situations, the compound of the invention shows marked superiority and a better side effects profile than prior known antipsychotic agents, and has a highly advantageous activity level".[79]

77. The trial judge further found that the evidence available to Claimant in 1991 did not demonstrate that olanzapine was capable of treating schizophrenia patients in the clinic in a superior fashion and with fewer side effects than other known antipsychotics.[80] Applying the permissive *AZT* standard, where utility could merely be "soundly predicted", he still found that the patent fell short:

> In sum, at the time the patent was filed in April 1991, Lilly had not found any special qualities of olanzapine that would justify a fresh monopoly. Lilly had carried out routine testing of olanzapine's properties. It had some early signals of safety and efficacy in a <u>few small studies of healthy volunteers and patients</u>. While Lilly scientists showed persistence, diligence and sound science in getting olanzapine that far, that is not necessarily enough for a patent. <u>There must be an invention. And, in the context of a selection patent, the invention is the discovery of a substantial advantage over the genus compounds</u>.[81]

[77] *Olanzapine FC II*, paras. 97, 120, and 209 **(R-016)**.

[78] *Olanzapine FC II*, para. 110 **(R-016)**.

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

[80] *Olanzapine FC II*, para. 210 **(R-016)**.

[81] *Olanzapine FC II*, para. 265 (our emphasis) **(R-016)**.

78. Claimant next unsuccessfully appealed this second trial decision to the Federal Court of Appeal. The Federal Court of Appeal noted that there was no error of law in the underlying decision, nor any reviewable error of fact.[82]

79. Claimant then sought leave to appeal the second olanzapine decision to the Supreme Court of Canada. In its submissions, inconsistent with its position on the first olanzapine appeal, Claimant suddenly claimed that the decision raised issues of national importance. After hearing the parties on the motion for leave to appeal, the Supreme Court of Canada declined to allow leave to appeal.[83]

B. A Further Unspecified Measure Alleged by Claimant

80. Claimant tangentially alleges in its Statement of Claim, as a further measure breaching NAFTA Chapter Eleven, Canada's failure to "rectify" the alleged promise doctrine.[84] Claimant fails to provide any particulars of this allegation, 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.

81. In any event, Canada cannot be sanctioned under NAFTA Chapter Eleven for failing to override the statutory responsibility of the Federal Court to interpret and apply Canadian patent law, and in lieu of such decisions substitute and impose Claimant's competing views of what Canadian patent law should provide. To the extent the court decisions themselves were not in violation of Chapter Eleven (and they were not), there is no basis for finding Canada in violation of Chapter Eleven for allegedly failing to "correct" the decisions at issue.

[82] *Eli Lilly Canada Inc. v. Novopharm Limited*, 2012 FCA 232 **(R-035)**.

[83] *Olanzapine SCC* **(R-002).**

[84] *SOC*, para. 72.

IV. NONE OF CANADA'S INTERNATIONAL INTELLECTUAL PROPERTY OBLIGATIONS IS ENGAGED

82. Claimant alleges that the two court decisions at issue breached Canada's international obligations, notably NAFTA Chapter Seventeen (and by extension the TRIPS Agreement), as well as the PCT. Its reference to these treaties is misplaced, as the Tribunal lacks jurisdiction to consider such alleged breaches. In any event, its reliance on these treaty provisions is fundamentally flawed. None has any bearing on the issues raised in the olanzapine or atomoxetine trial decisions. To the extent Claimant articulates theories or alleged "expectations" to the contrary, they are both unsupported and cannot found any breach of NAFTA Chapter Eleven.

A. The Tribunal Has No Jurisdiction Over Alleged Breaches of Canada's International Intellectual Property Obligations

83. The Tribunal's jurisdiction in this matter relates only to alleged breaches of NAFTA Chapter Eleven obligations. Chapter Eleven does not grant this Tribunal jurisdiction "at large" to rule on alleged breaches of any and all of Canada's other international obligations.

84. The Tribunal notably lacks jurisdiction to rule on alleged violations of any of TRIPS, PCT or NAFTA Chapter Seventeen. Disputes in respect of an alleged breach of TRIPS obligations may only be brought pursuant to the Dispute Settlement Understanding of the World Trade Organisation. Allegations of a breach of the PCT are, in accordance with that Treaty, to be brought before the International Court of Justice. Allegations of a breach of NAFTA Chapter Seventeen are to be brought on a State-to-State basis before a tribunal constituted pursuant to NAFTA Chapter Twenty.

85. In any event, reference to these treaties is of no assistance to Claimant. Canada provides the comments that follow to clarify the contents of these instruments, without prejudice to its primary position that Claimant's competing theories as to their contents cannot establish a breach of Chapter Eleven.

B. Canada Is in Compliance with NAFTA Chapter Seventeen

86. Chapter Seventeen outlines a basic framework for intellectual property protection, emphasizing the requirement for domestic judicial and administrative institutions to oversee and enforce such protection. Contrary to Claimant's theories, it does not provide a complete "code" for the regulation of intellectual property at the international or domestic level, freeze domestic intellectual property law in time, or dictate the outcome of particular intellectual property disputes before domestic courts.

87. Claimant's allegation that Chapter Seventeen "enshrined" a particular reading of the conditions of patentability cannot be sustained.[85] As Claimant itself notes, the language of NAFTA Article 1709(1) was drawn from the TRIPS negotiations,[86] where broad terms were used due to the lack of consensus on substantive law and the desire to maintain flexibility. Indeed, as in TRIPS, reflecting substantial differences in their respective intellectual property regimes, the NAFTA Parties were unable to agree even on common terminology for core concepts of patentability. While Article 1709(1) cites the criteria "new", "result from an inventive step", and "capable of industrial application", it immediately notes that "a Party may deem the terms 'inventive step' and 'capable of industrial application' to be synonymous with the terms 'non-obvious' and 'useful', respectively" (our emphasis).

88. NAFTA Chapter Seventeen provides no direction as to how these terms are to be interpreted and applied in particular patent cases, nor signals any intention to "freeze" their application in time. Such a reading is moreover unsupported by the subsequent practice of the Parties. Domestic patent law in all three Parties has continued to evolve, including with respect to the interpretation and application of substantive criteria of patentability, and will continue to do so.

[85] *SOC*, paras. 40 and 68.

[86] *SOC*, para. 42.

89. Claimant's further reading of specific provisions of Chapter Seventeen is fundamentally at odds with the functioning of domestic patent systems of the Parties.[87] Its strained reading of NAFTA Article 1709(8) is a case in point: nothing binds reviewing courts to apply the same assumptions and reasoning applied by the Patent Office in its original administrative review. In any case, the grounds for the initial grant and its ultimate invalidation are identical: the patent application must fulfil all statutory criteria for the grant of a patent. Its allegation of "discrimination" in violation of Article 1709(7) is equally misplaced, as Canadian patent rules apply without discrimination to inventions in all fields of technology.

90. Claimant's characterization of court decisions as a "violation" of Chapter Seventeen is particularly misguided. Domestic courts are at the heart of the dispute settlement regime contemplated by Chapter Seventeen. Through extensive and detailed provisions, notably Articles 1714 to 1717, Chapter Seventeen obliges NAFTA Parties to provide access to domestic courts in intellectual property disputes, to equip those courts with extensive reviewing powers, and to ensure that they provide basic standards of due process. The due process Claimant received before Canadian courts far exceeds what NAFTA Chapter Seventeen requires and illustrates the robustness of the Canadian system for resolving intellectual property disputes. The mere fact that Claimant is disappointed with the outcomes of two patent trials does not amount to a breach of Chapter Seventeen.

C. TRIPS Reinforces Canada's Compliance with Chapter Seventeen

91. Consideration of TRIPS simply reinforces the flaws in Claimant's strained reading of NAFTA Chapter Seventeen. As is widely acknowledged, TRIPS did not attempt to create a uniform or deeply harmonized patent regime and left ample room for national variations and approaches to substantive patent issues.

92. Emphasising this state of affairs, multilateral efforts led by the World Intellectual Property Organization ("WIPO") to further harmonize patentability

[87] *SOC*, para. 71.

requirements, both prior and subsequent to the conclusion of TRIPS, have all failed. For instance, WIPO's attempt to conclude a Substantive Patent Law Treaty in 2000, whose purpose was notably to lay down the contours of the patentability requirements, failed as a result of the wide variety of national approaches to substantive law issues. The failure of such initiatives reflects the underlying complexity of domestic intellectual property systems, including patent systems, and the challenge of harmonizing individual substantive elements between systems.

D. The Patent Cooperation Treaty Has No Bearing on this Case

93. Claimant's further allegation that Canada is in violation of the PCT is irrelevant in the context of this NAFTA Chapter Eleven claim and in light of this Tribunal's jurisdiction.[88]

94. If a dispute concerning Canada's compliance with the PCT was brought by an appropriate party and in the proper forum, Canada would vigorously defend its compliance with the PCT. The patents at issue in this case – only one of which was filed through a PCT application – were invalidated for failing to satisfy the substantive conditions of patentability under Canada's *Patent Act*. The PCT expressly does not govern either substantive conditions of patentability or the invalidation of patents. It simply facilitates the international filing of patent applications by enabling patentees to secure an international filing date and specifying the basic requirements of "form and content" that PCT patent applications must meet to be accepted and processed by national authorities. Filing in accordance with the PCT is no guarantee that a patent application will result in a successful patent grant, or that any grant of a patent will withstand judicial scrutiny. This is precisely because of the diversity of substantive patent law and its application and interpretation in jurisdictions around the world.

[88] *SOC*, para. 71.

E. Claimant's Selective Comparative Law Arguments Have No Merit

95. Claimant's reading of various international instruments suffers from a further, fundamental conceptual flaw. It is a basic principle of comparative law that legal systems function as a whole and can only legitimately be understood and compared on that basis. Ignoring this, Claimant seeks to draw comparisons based upon alleged diverging interpretations of the "utility" criterion in various legal systems, considered in isolation. Its approach fails to acknowledge that each domestic patent system has a distinct balance through which the same or similar policy objective pursued by other systems may also be achieved, albeit by different means. Indeed, the difficulty of considering individual criteria for patentability in isolation, including utility, is one factor that has thus far prevented international harmonization of substantive patent law.

96. A related issue arises in Claimant's attempt to draw conclusions from the different patent trial outcomes for its olanzapine and atomoxetine patents in different jurisdictions. Claimant suggests that Canada was the only jurisdiction in which the patents at issue were invalidated "on grounds of utility": this begs the question of whether the patents at issue were invalidated elsewhere on other grounds. It also begs the question of whether the patents at issue were identical, or contained differences in claims or description. Moreover, as is well acknowledged, differences in the manner in which a case is pleaded will have a material difference in outcome.

V. CANADA HAS NOT BREACHED CHAPTER ELEVEN OF NAFTA

A. There Is No Violation of Article 1105

97. Federal Court decisions invalidating initial patent grants for atomoxetine and olanzapine in no way violate the Customary International Law Minimum Standard of Treatment set out in NAFTA Article 1105.

a) NAFTA tribunals are not courts of appeal for disappointed domestic litigants

98. Where national court decisions are the measure at issue, a mere disagreement with the court's application of the law, appreciation of the facts or disappointment with the outcome is not a violation of Article 1105. NAFTA Chapter Eleven Tribunals have repeatedly emphasized that they are not courts of appeal.[89] "The possibility of holding a State internationally liable for judicial decisions does not […] entitle a Claimant to seek international review of the national court decisions as though the international jurisdiction seized has plenary appellate jurisdiction."[90] NAFTA was "not intended to provide foreign investors with blanket protection from this kind of [judicial] disappointment, and nothing in its terms so provides."[91] Even if a Chapter Eleven Tribunal disagrees with the decisions of a domestic court or believes that the decisions were wrong in law (which is not the case here), this does not establish a breach of the Minimum Standard of Treatment.[92]

b) The Federal Court provided ample due process and fair administration of justice

99. When considering court actions as a measure allegedly in violation of the Minimum Standard of Treatment, what is required is "something more than simple illegality or lack of authority under the domestic law of a State […]".[93] The threshold for a violation by a court of the Minimum Standard of Treatment set extremely high at Customary International Law. Conduct that violates Article 1105 must be "sufficiently

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[89] *See* for example, *Robert Azinian*, *Kenneth Davitian & Ellen Baca v. United Mexican States*, ICSID Case No. ARB(AF)/97/2, Award, 1 November 1999, ("*Azinian Award*"), para. 99, **(RL-002);** *International Thunderbird Gaming Corporation v. United Mexican States*, (UNCITRAL) Arbitral Award, 26 January 2006, ("*Thunderbird Award*"), para. 125, **(RL-003)**; *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Final Award, 11 October 2002, para. 126 **(RL-004)**.

[90] *Azinian Award*, para. 99 **(RL-002)**.

[91] *Azinian Award*, para. 83 **(RL-002)**.

[92] *Azinian Award*, paras. 97 and 99 (**RL-002**).

[93] *ADF Group Inc. v. United States of America*, ICSID Case No. ARB(AF)/00/1, Award, 9 January 2003, para. 190 **(RL-005)**.

egregious and shocking – a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons – so as to fall below accepted international standards".[94]

100. Acknowledging this high threshold, Claimant alleges that the court decisions leading to the invalidation of its patents were "improper" and "discreditable".[95] This allegation has no credibility. Claimant has been provided ample due process. There was no judicial impropriety or "seriously inadequate" administration of justice.[96] Nor were the decisions at issue in any way arbitrary, let alone "manifestly arbitrary".[97] The Federal Court decided the cases reasonably and in good faith on the basis of the evidence adduced by the Parties in an open adversarial proceeding. In both cases, as fully set out in their extensive reasons, the Federal Court applied the law and found on the basis of extensive fact and expert evidence that the patents in question were invalid. The appeals ultimately failed as the Federal Court of Appeal held that there had been no error in the application of the law and no reviewable error of fact. In this context the Supreme Court of Canada denied leave for a further appeal.

101. Claimant's further allegation that Canadian patent law applies discriminatorily to pharmaceutical patents is unsupported.[98] It is also irrelevant to a claimed breach of Article 1105, as the Minimum Standard of Treatment of investors does not impose any particular requirements in this regard. In any event, in Canada all patents are subject to the same requirements. Claimant's alleged statistics on patent invalidation are unsubstantiated, and on their face present an incomplete picture of patent invalidation rates. Notably, Claimant does not place the alleged number of pharmaceutical patent

[94] *Glamis Gold, Ltd. v. United States of America*, (UNCITRAL) Award, 8 June 2009, para. 627 **(RL-006)**.

[95] *SOC*, para. 81.

[96] *Azinian Award*, para. 102 **(RL-002)**.

[97] *Thunderbird Award*, para. 197 **(RL-003)**: A violation of Article 1105 requires a failure to provide due process (constituting an administrative denial of justice), or an alleged manifest arbitrariness in administration (constituting proof of an abuse of right).

[98] *SOC*, paras. 66 and 69.

invalidations for inutility within the context of overall patent litigation volume, or within the context of invalidation rates on other grounds. In any case, such statistics must be treated with caution as each case, including the two court decisions at issue here, is decided on its own facts.[99] There has been no discrimination shown towards the Claimant or "pretence of form to achieve an internationally unlawful end".[100]

c) Claimant cannot found a breach of Article 1105 on the basis of its alleged "expectations"

102. In citing Article 1105, Claimant has also sought to rely on its alleged legitimate expectations relating to the stability, predictability, and the consistency of Canada's legal and business framework.[101] The alleged obligation to uphold Claimant's "expectations" in this regard forms no part of the Minimum Standard of Treatment. To the extent "expectations" have been considered in connection with an alleged breach of the Minimum Standard of Treatment, Claimant cannot point to any evidence of specific assurances made to it or its reliance on such assurances to make its investment.

103. Indeed, Claimant's alleged expectations, if they indeed truly held them, were clearly unreasonable. The invalidation of its patents by the Federal Court, far from reflecting the alleged "instability" of the Canadian legal and business framework, was to the contrary consistent with the reasonable understanding of any rational actor in this sector. Claimant was well aware that initial patent grants for olanzapine and atomoxetine were only presumptively valid; that this initial grant was subject to potential court review; and that it is not unusual for initial patent grants to be overturned by the courts. It was also aware that for its patents to remain valid they would need to withstand not only the Patent Office's administrative review, but rigorous court scrutiny, in an adversarial process. Claimant's alleged reliance on the Manual of Patent Office Practice as a

[99] *SOC*, paras. 11 and 66.

[100] *Azinian Award*, para. 99 **(RL-002)**.

[101] *SOC*, paras. 81-82.

complete and binding code of Canadian patent law is flatly contradicted by the express terms of that document.

104. Claimant's alleged understanding that Canadian law would be "enshrined" to its contents as they stood in 1994[102], was also unreasonable and finds no support in international law. Nothing in Article 1105 prevents the regulatory or legal framework of a State from evolving.[103] NAFTA and other bilateral investment treaties were never meant "as a kind of insurance policy against the risk of any changes in the host State's legal and economic framework. Such expectation would be neither legitimate nor reasonable".[104] Nor are Claimant's views as to how Canadian patent law "ought to have" evolved, if it did, of any weight or relevance for purposes of the Article 1105 analysis. Claimant's related, flawed account of the content of Canadian patent law as applied to its two patents in any event misstates the longstanding origins of that law and its rational relation to fundamental patent policy.

d) A violation of NAFTA Chapter Seventeen or the PCT (even if there was one) does not constitute a violation of Article 1105

105. Claimant's suggestion that there has been a violation of Article 1105 based on an alleged violation of any of NAFTA Chapter Seventeen, TRIPS, or the PCT is also to be rejected.[105] As stated in the Free Trade Commission Note of Interpretation of 2001[106], binding upon this Tribunal, a determination that there has been a breach of another provision of NAFTA or of a separate international agreement, does not establish that

[102] *SOC*, paras. 42 and 68.

[103] *Mobil Investments Canada Inc. and Murphy Oil Corporation v. Government of Canada*, ICSID Case No. ARB(AF)/07/4, Decision on Liability and on Principles of Quantum, 22 May 2012, para. 153 **(RL-007)**.

[104] *EDF (Services) Limited v. Romania*, ICSID Case No. ARB/05/13, Award, 8 October 2009, para. 217 **(RL-008)**.

[105] *SOC*, paras. 42 and 84.

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

there has been a breach of Article 1105.[107] Indeed, Article 1105 does not confer upon this Tribunal jurisdiction to find Canada "in breach" of any such instruments.

B. NAFTA Article 1110 Does Not Apply

106. Article 1110 does not apply to the procedurally fair invalidation of a patent by a domestic court. Patent grants are invalidated each year by courts in all major jurisdictions. That this does not amount to either a direct or indirect expropriation flows both from general international law and, in this case, from the application of NAFTA Article 1110(7).

a) The procedurally fair invalidation of a patent by a court cannot amount to an expropriation

107. In all but rare circumstances, a determination by a domestic court concerning the existence of a property right, including an intellectual property right, cannot amount to an "expropriation" at international law.

108. Where a court of competent jurisdiction, applying full due process and reaching a decision pursuant to its mandate, determines that a presumed property right is legally invalid (*i.e*. that it does not exist), this does not amount to a "taking", but rather, constitutes juridical determination of the existence and scope of rights at law.

109. This rule applies in all but extraordinary circumstances, where the powers of the court have been abusively applied (*abus de droit*) or in cases of gross procedural injustice amounting to denial of justice, *i.e*. only where the court is in effect not acting in a true judicial capacity.

110. The rule was considered and applied in the very first NAFTA Chapter Eleven decision, where the tribunal considered a claim that a domestic contract had been "expropriated", after a domestic court found that contract invalid. The tribunal held as follows:

[107] The Claimant misleadingly misquotes the Note of Interpretation as stating that it does not "alone" establish a breach of Minimum Standard of Treatment. *SOC*, para. 13, FN 2.

> The possibility of holding a State internationally liable for judicial decisions does not, however, entitle a claimant to seek international review of the national court decisions as though the international jurisdiction seised (sic) has plenary appellate jurisdiction. This is not true generally, and it is not true for NAFTA. *What must be shown is that the court decision itself constitutes a violation of the treaty*. Even if the Claimants were to convince this Arbitral Tribunal that the Mexican courts were wrong with respect to the invalidity of the Concession Contract, this would not per se be conclusive as to a violation of NAFTA. More is required; the Claimants must show either a denial of justice, or a pretence of form to achieve an internationally unlawful end. […] *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*.
>
> […]
>
> A denial of justice could be pleaded if the relevant courts refuse to entertain a suit, if they subject it to undue delay, or if they administer justice in a seriously inadequate way. There is no evidence, or even argument, that any such defects can be ascribed to the Mexican proceedings in this case.
>
> There is a fourth type of denial of justice, namely the clear and malicious misapplication of the law. This type of wrong doubtless overlaps with the notion of "pretence of form" to mask a violation of international law. In the present case, not only has no such wrong-doing been pleaded, but the Arbitral Tribunal wishes to record that it views the evidence as sufficient to dispel any shadow over the *bona fides* of the Mexican judgments. Their findings cannot possibly be said to have been arbitrary, let alone malicious.[108]

111. The same reasoning applies here. A patent is a domestic statutory creation, granting a national limited-term monopoly subject to the fulfilment of certain conditions. However, the right is granted in Canada on the basis that the initial administrative grant is only presumptive and may ultimately be revoked further to court review. As patents are a statutory creation in Canada, the grounds both for the initial grant and for ultimate invalidation of that grant are identical: the patent application must, upon initial administrative and ultimate judicial review, fulfil all of the statutory conditions for the

[108] *Azinian Award*, paras. 99-103 (our emphasis underlined, italics in the original) (**RL-002**).

grant of a patent. In Canada, statutory responsibility to conduct judicial review lies primarily with the Federal Court. Where that court determines, in the exercise of its statutory mandate, applying full due process, that the patent in question fails to fulfil such criteria, the property right in effect never existed. In the circumstances, Article 1110 is not even engaged *vis-à-vis* the invalidation of a patent by a court decision.

112. In the present case, Claimant has not even alleged abusive application of the reviewing power of the court, nor any gross procedural misconduct. Nor could such allegations be articulated in good faith. The Federal Court in the two decisions at issue invalidated Claimant's patents further to careful review of an enormous factual and expert record, in light of the policy considerations underlying the *Patent Act*, and further to careful review of the relevant statutory provisions and related jurisprudence. Its decisions were principled and rational. For purposes of expropriation, the analysis effectively stops there: as investment tribunals repeatedly have held, they do not sit as courts of appeal of domestic legal determinations, either on their appreciation of the facts or on their application of the law. Just as this is true in the Article 1105 context, it is equally true in the Article 1110 context.

b) NAFTA Article 1110(7) confirms that Article 1110 does not apply

113. Given the above analysis, this Tribunal need not even consider the application of Article 1110(7) to this case. However, applying Article 1110(7), one arrives at the same result: Article 1110 does not apply to these court decisions.

114. Article 1110(7) was intended to provide, in the intellectual property context, a further "defence" for the NAFTA Parties against claims of expropriation. This reflected the prominent role of the Parties in the regulation and enforcement of intellectual property rights, and consequent risk that such State action might give rise to claims under the expropriation article. Accordingly, the NAFTA Parties provided that Article 1110 would not even *apply* to determinations in this context, so long as the measure at issue was consistent with Chapter Seventeen.

115. As set out above, NAFTA Chapter Seventeen sets out a minimum framework for intellectual property protection while leaving the Parties substantial flexibility, emphasizing the role of courts in reviewing claims in this regard. Consistent with Chapter Seventeen, Canada maintains a domestic patent regime recognizing patents that meet criteria of novelty, non-obviousness, and utility. As for disclosure requirements, these are not regulated by Chapter Seventeen. Consequently, the decisions in question are fully consistent with the provisions of Chapter Seventeen.

116. Accordingly, whether viewed in light of applicable rules of international law, or through the lens of Article 1110(7), the expropriation analysis of Article 1110 does not apply to these court decisions.

117. Given the above analysis, the specific rules of expropriation need not even be considered in connection with the impugned measures: there has been no "taking" of any property, either direct or indirect, substantial or only partial, rendering this fundamental aspect of an expropriation analysis moot. The measures at issue were moreover fully consistent with Claimant's reasonable expectations, non-discriminatory, fully legal, and consistent with rational public policy. Thus, even if the expropriation analysis applied (which it does not), Canada's alleged violation of Article 1110 would not be established.

VI. DAMAGES

118. Claimant must establish a sufficient causal link between the alleged breaches of NAFTA and the damages it claims. Claimant has not even attempted to meet its burden or establish the facts necessary to prove the damages it claims. Claimant provides no foundation for the assertion that the alleged breaches of NAFTA caused them damages of US$500 Million.

119. Canada puts Claimant to the strict proof of their entitlement to damages and the amounts of any such alleged damages suffered by Claimant.

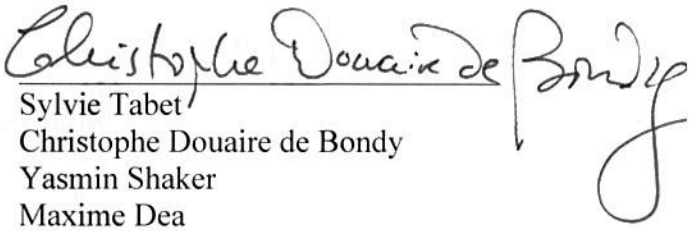
VII. REQUEST FOR RELIEF

120. For all of the above reasons, Canada respectfully asks the Arbitral Tribunal to issue an order:

- dismissing Claimant's claim in its entirety;
- awarding Canada its costs, with applicable interest, pursuant to NAFTA Article 1135(1) and Article 40 of the UNCITRAL Rules; and
- granting any other relief that may seem just.

June 30, 2014

Respectfully submitted



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On behalf of the Respondent the
Government of Canada

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

STATEMENT OF DEFENCE

June 30, 2014

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I. PRELIMINARY STATEMENT

1. Eli Lilly and Company ("Lilly" or "Claimant") is a disappointed litigant. Having lost two patent cases before the Canadian courts, it now seeks to have this Tribunal misapply NAFTA Chapter Eleven and transform itself into a supranational court of appeal from reasoned, principled, and procedurally just domestic court decisions. Claimant argues that the domestic court decisions invalidating its patents are measures that violate NAFTA Chapter Eleven. Claimant does this on the basis of misstatements of the content of Canadian law and of Canada's international obligations. Its claim is wholly without merit and should be dismissed, with full costs to Canada.

2. Claimant sought patents in Canada in the 1990s for the pharmaceutical use of two known chemical compounds, olanzapine and atomoxetine.[1] Canada's Patent Office granted the patents on the basis of the representations made by Claimant in its applications. In accordance with Canada's *Patent Act* [2], this initial administrative grant was only presumptively valid. It remained subject to challenge, review and potential invalidation by Canada's Federal Court through private-party litigation. The two patents were challenged in court. Exercising its statutory mandate, the Federal Court determined that both were invalid.

3. Claimant filed its 1991 patent application for olanzapine despite already holding a prior patent for this compound, as part of a larger group (or "genus") of related compounds. To warrant a second monopoly, Claimant asserted that olanzapine provided marked superiority in the treatment of schizophrenia compared with other members of the

[1] Claimant marketed a formulation containing atomoxetine as an active ingredient for the treatment of Attention Deficit / Hyperactivity Disorder ("ADHD"), under the brand name "Strattera". "Strattera" is not the name of any active medical ingredient. Rather, it is a name Claimant devised and applied to its drug product for marketing purposes. Similarly, Claimant marketed a formulation containing the active ingredient olanzapine for the treatment of schizophrenia, under the brand name "Zyprexa". Again, the latter is not a scientific term, but devised by Claimant as part of a marketing strategy. Throughout this Statement of Defence, Canada shall refer to the known active ingredients Claimant sought to patent by their internationally-recognized names as designated by the World Health Organization, *i.e.*, atomoxetine and olanzapine.

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

same genus and other unrelated compounds. The trial judge reasonably and in accordance with Canadian law sought to determine whether, at the time of filing, Claimant had proved (or "demonstrated") that olanzapine had the asserted utility, or at least could soundly predict that utility based upon its then-current research. Evidence at trial revealed that Claimant had claimed the second monopoly on the basis of studies which failed to establish any particular treatment advantage of olanzapine over the already-patented class to which it belonged. Allowing patent protection on this basis would encourage speculative over-patenting. Claimant's olanzapine patent was reasonably invalidated by the Federal Court.

4. Claimant's 1996 atomoxetine patent application asserted that as at the time of filing it had invented a new use for this well-known compound. Again, the judge at trial reasonably sought to determine whether Claimant had evidence confirming this new use, as at the time of filing its patent application, or at least could soundly predict the advantageous new use at that time. Evidence at trial revealed that in fact, Claimant's application for a 20-year monopoly relied solely on a flawed and inconclusive preliminary study that it had failed to disclose in its application. Allowing patent protection in these circumstances would permit applicants to obtain and uphold patents based on speculation, and in the absence of any adequate disclosure to the public. It would also have the effect of dissuading innovation by pre-emptively fencing off areas of research in the absence of a realized invention, undermining a primary policy goal of the *Patent Act*. Claimant's atomoxetine patent was reasonably invalidated by the Federal Court.

5. In both cases, Claimant was able to appeal the initial court decisions to the Federal Court of Appeal. In both cases, the Federal Court of Appeal ultimately found no reviewable error of fact or law. In the circumstances, Claimant failed to convince the Supreme Court of Canada that leave to appeal should be granted.[3] In total, nine Canadian

[3] In the olanzapine matter, the Supreme Court of Canada exceptionally granted an oral hearing on the application for leave to appeal. Despite this, Claimant's counsel were unable to persuade the court that leave was warranted: *Eli Lilly Canada Inc., et al. v. Novopharm Limited*, 2013 CanLII 26762 (SCC)

judges from the Federal Court and Federal Court of Appeal agreed that Claimant's patents failed to fulfil Canadian standards of patentability and accordingly should be invalidated.

6. In order to make its argument that these court decisions breach Chapter Eleven of NAFTA, Claimant relies in the first place on misstatements of the content of Article 1105 of NAFTA (Minimum Standard of Treatment) and of relevant facts. Despite having received extensive due process, reasoned decisions, and full rights of appeal in respect of its two invalid patents, Claimant alleges that the court decisions at issue were "improper and discreditable"[4], in violation of the Minimum Standard of Treatment. It grounds this allegation in its disagreement with the courts' appreciation of the facts and application of the law in the two patent cases at issue. Notably, it seeks to elevate its own competing views of how Canadian law "ought" to have been applied to its patents, or its "understanding" of Canada's international intellectual property obligations, into legally-enforceable "expectations", and argues that failure to live up to these "expectations" amounts to a breach of international law.

7. Such allegations fail to engage Article 1105. Applying the Minimum Standard of Treatment of investments under Customary International Law, the Tribunal must instead determine whether the court decisions at issue violated fundamental principles of due process, rising to the level of a denial of justice. They must otherwise consider whether the decisions amounted to a malicious misapplication of the law, rising to the level of a breach of the international Minimum Standard. The court decisions at issue do not even come close to violating this rule. They were rational, principled, and offered full due process.

("*Olanzapine SCC*") **(R-002)**. *See* also *Eli Lilly and Company v*. *Teva Canada Limited*, 2011 CanLII 79177 (SCC) ("*Atomoxetine SCC*") **(R-003)**.

[4] *SOC*, para. 81.

8. Nor can Claimant's misleading account of its alleged "expectations" alter the conclusion that this Tribunal cannot act as a court of appeal. Such "expectations" neither form the basis of a violation of the Minimum Standard of Treatment, nor confer on this Tribunal jurisdiction to rule on alleged breaches of Canada's international intellectual property obligations, through Article 1105 or at all. Certainly, no specific assurance was given forming the basis of such "expectations". Claimant's alleged "expectations" were in any event unreasonable: Claimant's account is incorrect viewed in light of the content and evolution of Canadian patent law, the functioning of the Canadian patent system, and the particular circumstances of the two patent decisions at issue here.

9. Claimant's allegations also fail to engage NAFTA Article 1110 (Expropriation). Court decisions invalidating an initial patent grant do not amount to a taking of "property", either direct or indirect: rather, they amount to determinations whether or not property rights exist at all. Decisions by courts regarding the existence of a right pursuant to domestic law are not subject to review by international investment tribunals, save in the extraordinary circumstance of gross procedural misconduct amounting to a denial of justice, or where court power to make such determinations is exercised in bad faith to mask a violation of international law (*abus de droit*). No such allegations have been made here, nor would they be warranted. Therefore, Article 1110 does not apply.

10. As a further response to the claimed violation of Article 1110, NAFTA Article 1110(7) provides that where the revocation of an intellectual property right is consistent with Chapter Seventeen, Article 1110 does not apply to the measure. Court invalidation of Claimant's patents was wholly consistent with Chapter Seventeen: like the draft text of the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights[5] upon which it was based, Chapter Seventeen provides a basic framework for domestic intellectual property regimes, without dictating its specific domestic application, and provides that relevant determinations are to be subject to the

[5] Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco, on April 15 1994, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (1994) ("TRIPS") **(RL-001)**.

reviewing powers of domestic courts. The present case fits entirely within this scheme. The Article 1110(7) defence to claims of expropriation negotiated and agreed by the NAFTA Parties further confirms that Article 1110 does not apply to the court decisions at issue.

11. In this Statement of Defence, Canada will provide: (1) an overview in Canadian patent law, to provide context for Claimant's misstatements regarding Canadian law on utility; (2) a description of the specific role played by the Federal Court in applying the *Patent Act*, establishing that the court is responsible for determining the validity and existence of the intellectual property right; (3) an outline of the facts relevant to the two court proceedings, demonstrating that Claimant received full due process and reasoned and principled decisions; and (4) brief comments on Canada's international intellectual property obligations under NAFTA Chapter Seventeen, TRIPS and the Patent Cooperation Treaty ("PCT"), confirming that these have no bearing on this case. This factual background confirms and reinforces the conclusion that nothing in the two court decisions at issue in any way violates Canada's obligations under Chapter Eleven of NAFTA.

II. CANADIAN PATENT LAW

12. In its Statement of Claim[6], Claimant misleadingly suggests that since 2005 Canadian courts introduced an unexpected "promise doctrine" when judging patent validity and unfairly applied this doctrine to its atomoxetine and olanzapine patents filed in the 1990s.[7] What Claimant describes as a unitary "doctrine" in fact consists of distinct tests for patent validity under Canadian law, each of which has its own rationale in light of statutory requirements, and each of which has deep roots in Canadian patent law. The application of these tests to determine the validity of Claimant's patents was neither arbitrary nor unfair. To correct Claimant's account and provide an accurate context for considering the two court decisions at issue in this claim, in what follows, Canada briefly

[6] Notice of Arbitration dated September 12, 2013, designated as the Statement of Claim ("*SOC*").

[7] *SOC*, paras. 9 and 66.

explains certain fundamental, longstanding requirements of Canadian patent law, notably with respect to the "utility" criterion for patentability.

A. Canadian Patent Law Exists to Promote Innovation and Disclosure

13. The Canadian patent system exists to promote and to ensure public access to innovation. To achieve these goals, Canada grants a time-limited monopoly to novel, non-obvious, and useful inventions, in exchange for the disclosure of the invention to the public. Disclosure to the public is at the heart of the patent bargain, as it allows others to study and build upon existing inventions, avoid duplicative research, and properly use the invention once the monopoly expires. The offer of a time-limited monopoly is understood to encourage both innovation and disclosure of such innovation to the public. Patent systems around the world are founded on this same bargain.

14. The statutory monopoly created by the *Patent Act*, allowing the patentee to exclude others from making or using an invention, is an exception to the general policy of most States, including Canada, in favour of free competition. The statutory monopoly stakes out a particular area of innovation. It discourages other innovators from pursuing research on the same subject-matter, while typically imposing higher costs for use of the invention upon the public. Given these high social and economic costs, a patent cannot be granted or its validity confirmed lightly. As the Supreme Court of Canada has noted:

> The grant of a patent monopoly for 17 years (20 years after October 1, 1989) creates, and is intended to create, serious anti-competitive effects. Once the subject matter of the patent is fenced in by the claims, others trespass (advertently or inadvertently) on the forbidden territory at their peril. The boundary is defended by a considerable arsenal of remedies conferred by the *Patent Act*, including an accounting of the infringer's profits in an appropriate case. Patent litigation is usually protracted and costly [...] There is in the meantime a chilling effect on other researchers. They will tend to invest their talents in less litigious areas. Parliament considered this chilling effect to be a worthwhile price for the disclosure of a "new and useful" invention, bringing into the public domain information that might otherwise remain a trade secret, but there is nothing in the Act

> to suggest that Parliament was prepared to accept the chilling effect in exchange for nothing but speculation.[8]

15. There is no inherent right to a patent at Common Law. It is entirely a statutory creation that must be earned in exchange for the "hard coinage" of invention and of disclosure of the invention.

B. Patent Applicants Must Fulfil Core Criteria of Patentability

16. To confirm entitlement to a patent, the subject-matter of the proposed invention must be patentable.[9] In addition, three basic criteria for patentability must be fulfilled.[10] Notably, the subject-matter defined by a claim must be novel[11]; it must not be obvious[12] (*i.e.*, generally speaking, a person with the relevant technical expertise would not have arrived at the proposed invention without some degree of inventiveness); and the proposed invention must have utility (*i.e.* the invention must do what the applicant's patent specification says it will do).[13] Finally, there must be proper disclosure in the

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

[9] *Patent Act*, ss. 2 (definition of invention) and 27(8) (what may not be patented) **(R-001)**.

[10] These requirements flow from the statutory definition of "invention" at section 2 of the *Patent Act*, and from further definitions at sections 28.2 and 28.3 of the *Patent Act*. Section 2 of the *Patent Act* defines an invention as "any new and useful art, process, machine, manufacture or composition of matter or any new and useful improvement in any art, process, machine, manufacturer or composition of matter" **(R-001)**.

[11] *Patent Act*, s. 28.2 (subject-matter of claims must not be previously disclosed) **(R-001)**. The requirement that to be patentable the subject-matter defined by a claim must be novel is intended to ensure that patents are granted to inventions that are not already available to the public.

[12] Until amendments made in 1993, the *Patent Act* did not explicitly state that a patent had to be for something non-obvious. Rather, Canadian courts, like their counterparts in the United States and United Kingdom, deduced this requirement from the notion of inventiveness itself. Inventions implied inventive ingenuity, without which an advance was obvious. *See* David Vaver, *Intellectual Property Law: Copyright, Patents, Trade-Marks*, 2nd ed. (Toronto: Irwin Law, 2011), p. 328 **(R-005)**. Following an earlier move by the United States and United Kingdom, Canada in 1993 amended the *Patent Act* to establish the conditions under which the subject-matter defined by a claim must not, at its claim date, be obvious to a person skilled in the relevant art or science: *Patent Act*, s. 28.3 (invention must not be obvious) **(R-001)**.

[13] As the Supreme Court of Canada has stated, what "is required to meet the utility requirements in section 2 is that the invention described in the patent do what the patent says it will do, that is, the promise of the invention be fulfilled": *Teva Canada v. Pfizer Canada Inc.*, [2012] 3 SCR 625, ("*Pfizer*"), para. 38 (our emphasis) **(R-006)**.

patent of the invention and of the manner in which it may be used.[14] Through the "proper teaching" in the disclosure, a person skilled in the art obtains the technical information to make or use the invention once the monopoly has expired and to make technological improvements to the disclosed invention.[15]

C. Core Criteria Must Be Fulfilled No Later than as at the Time of Filing

17. In Canadian patent law, fulfilment of the three core criteria of patentability – novelty, non-obviousness, and utility – is judged no later than *as at the time of filing of the patent application*. This is a longstanding rule of Canadian patent law, fully consistent with the notion of the patent as a bargain or "contract" between the applicant and the public. The question is essentially: did the applicant make a patentable invention as of the filing date?

18. Claimant seeks to confuse the requirements of Canadian law in arguing that Canada unfairly and unexpectedly invalidated its patents for failure to fulfil the "utility" criterion, alleging that both compounds eventually proved to be useful in fact.[16] This argument is a red herring. As Claimant well knows, if the applicant is no more than guessing at the time it files its patent application, whether or not the applicant ultimately demonstrates its alleged invention to be "useful in fact" (years after the filing of the invention, on the basis of wholly different research) is not the relevant inquiry.

19. The policy basis for this longstanding temporal rule is both logical and principled. It guards against abuses of the patent system: an applicant cannot pre-emptively file a claim to monopoly rights, excluding others from a potential area of research, where it is merely speculating. Otherwise, nothing would prevent market

[14] Section 27(3) of the *Patent Act* **(R-001)** requires that the specification of an invention must correctly and fully describe the invention and its operation and use as contemplated by the inventor.

[15] *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 SCR 142, ("*Cadbury*"), para. 46 **(R-007)**: "A patent is a statutory monopoly which is given in exchange for a full and complete disclosure by the patentee of his or her invention. The disclosure is the essence of the bargain between the patentee, who obtained at the time a 17-year [now 20-year] monopoly on exploiting the invention, and the public, which obtains open access to all of the information necessary to practice the invention". *See* also, *Pfizer*, paras. 31-34 **(R-006).**

[16] *SOC*, paras. 26, 27, 34, 53, and 63.

participants from staking out vast areas of research, to the exclusion of others, in the absence of any real invention. This would impose the costs of the patent on the public without the "patent bargain" having been fulfilled by the patent applicant. As the Supreme Court of Canada has ruled:

> Were the law to be otherwise, major pharmaceutical corporations could (subject to cost considerations) patent whole stables of chemical compounds for all sorts of desirable but unrealized purposes in a shot-gun approach hoping that, as in a lottery, a certain percentage of compounds will serendipitously turn out to be useful for the purposes claimed. Such a patent system would reward deep pockets and the ingenuity of patent agents rather than the ingenuity of true inventors.
>
> […]
>
> In the broader context of the *Patent Act*, as well, there is good reason to reject the proposition that bare speculation, even if it afterwards turns out to be correct, is sufficient. An applicant does not merit a patent on an almost-invention, where the public receives only a promise that a hypothesis might later prove useful; this would permit, and encourage, applicants to put placeholders on intriguing ideas to wait for the science to catch up and make it so. The patentee would enjoy the property right of excluding others from making, selling, using or improving that idea without the public's having derived anything useful in return.[17]

20. Canada's desire to guard against such misuse of the patent system is entirely reasonable and consistent both with sound domestic and international goals of patenting.

D. A Patentable Invention Must Fulfil its Asserted Utility

a) The Court assesses fulfilment of the "utility" criterion against what the inventor itself asserts to be the utility of its invention

21. In Canada, a party seeking to invalidate a patent may claim that the invention lacked utility – one of the fundamental aspects of a valid patent – on the basis that at the time of filing, the applicant had not established the utility of its invention. In considering this allegation, the reviewing court will first seek to determine whether the applicant itself

[17] *AZT*, paras. 80, 84, and generally paras. 78-85 **(R-004)**.

asserted (or "promised") a particular level of utility for its invention in its patent specification.[18] This will occur, for example, where the applicant purports to have invented the use of a compound to achieve a specific result or where the applicant purports to have invented a machine said to achieve a specific technical outcome. Where the patent promises a particular level or type of utility, that promise becomes the base against which utility is judged.

22. Claimant argues that court assessment of the specific utility "promised" in the patent is a new development, created by Canadian courts only since 2005, long after its patents were granted.[19] It suggests that prior to this development, inventions in Canada simply needed to possess some *de minimis* utility, unrelated to the specific utility promised in the patent specification.[20]

23. Claimant's narrative is incorrect. As early as 1959, drawing on English precedent going back to the early 20th century, Canadian courts asserted that the invention must be useful *as specified*, endorsing a description of this as fulfilment of the "promised results" of the patent.[21] The Supreme Court of Canada endorsed this reasoning in 1981, when the Court, quoting Halsbury's Laws of England, held that an invention lacks utility when 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".[22] The

[18] In Canada, as in other patent systems, a patent specification is made up of two main elements: the description, which explains the nature of the invention, and the claims, which set the legal boundary of the applicant's invention and related 20-year monopoly. Section 27(3) of the *Patent Act* addresses the description (disclosure) and s. 27(4) the claim(s). **(R-001)**

[19] *SOC*, paras. 34 and 66.

[20] *SOC*, paras. 8, 9, 28, and 29.

[21] *Rodi & Wienenberger Aktiengesellschaft v. Metalliflex Ltd*. (1959), 32 CPR 102 (Que CA), paras. 15-17 **(R-008)** affirmed in *Metalliflex Ltd.v. Rodi & Wienenberger Aktiengesellschaft*, [1961] SCR 117 **(R-009)**. Similarly, the Exchequer Court, predecessor to the Federal Court of Canada, held in a 1961 decision that fulfillment of the utility criterion must be judged against the "promise of the patent" *i.e.* what the specification of the patent indicated that the patent would do: *New Process Screw Corp. v. PL Robertson Mfg Co. Ltd*. (1961), 39 CPR 31 (Ex Ct), para. 39 **(R-010)**.

[22] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd*., [1981] SCR 504, 1981 CarswellNat 582, ("*Consolboard*"), para. 36 (our emphasis) **(R-011)**.

Supreme Court of Canada recently reiterated the simple and fundamental notion of "utility":

> As the courts below noted, all that is required to meet the utility requirement in s. 2 is that the invention described in the patent do what the patent says it will do, that is, that the promise of the invention be fulfilled [...] Patent '446 states that the claimed compounds, including sildenafil, will be useful in treating ED. At the time the application was filed, sildenafil could assist in treating ED. This is all that is required.[23]

24. In Canada, the fall-back rule is that there is no general obligation to promise a specific utility of the invention in a patent specification.[24] Where no promise is made, the court may assume a *de minimis* or "mere scintilla" of utility is asserted, and this will be the basis against which fulfilment of the "utility" criterion of patenting will be judged.

25. In some cases, however, an applicant does promise in the specification that her invention will achieve a particular degree of utility. Patent applications may contain promises for a variety of reasons. Sometimes, a particular degree of usefulness is at the core of the invention. For example, in patents where the alleged and claimed invention is a new use for a known chemical compound, the alleged new and non-obvious "use" of the compound is the essence of the invention. This was the situation of Claimant's atomoxetine patent application. In such circumstances, fulfilment of that alleged utility becomes central to fulfilment of the "bargain" at the heart of the patent grant.

26. Another case, that of "selection patents", arises where a patent has already been granted for a broad class of compounds (or "genus"). A party may seek a second patent for a sub-species of that genus on the basis that it has discovered that the sub-species (or "selection") has a surprising and non-obvious advantage over other members of the genus.[25] This was the situation of Claimant's olanzapine patent application. In the

[23] *Pfizer*, para. 38 (our emphasis) **(R-006)**.

[24] *Consolboard*, para. 37 **(R-011)**.

[25] The conditions for a selection patent were confirmed in the 1930s in *In re I.G. Farbenindustrie A.G.'s Patents* (1930), 47 RPC 289, pp. 322-323 **(R-012)**, and recalled by the Supreme Court of Canada in *Apotex Inc*. *v*. *Sanofi-Synthelabo Canada Inc*., [2008] 3 SCR 265, ("*Sanofi-Synthelabo*"), paras. 9 and 10 **(R-013)**.

absence of that advantage, there would be no reason to grant a second patent for the sub-species compound and use thereof. That surprising advantage or specific use becomes the core of the "invention" and must be established and disclosed for patent protection to be obtained.[26] Otherwise, the patentee of an original "genus" patent would be able to "evergreen" its original patent monopoly, through subsidiary patents for sub-classes of that very same invention (essentially engendering a perpetual monopoly).[27]

b) Determining the promised utility, if any, is a highly technical exercise

27. Determining whether the patent incorporates a particular promise of utility is a highly contextual, fact-specific, and technical exercise. As the Federal Court of Appeal noted in the olanzapine matter:

> Generally, it is an exercise that requires the assistance of expert evidence […] This is because the promise should be properly defined, within the context of the patent as a whole, through the eyes of the POSITA, in relation to the science and information available at the time of filing.[28]

28. Determination of the promised utility of the patent is therefore not, as Claimant suggests, "subjective" or "arbitrary".[29] Rather, the court must determine how a person of ordinary skill in the art (the "POSITA")[30], who is the deemed reader of the patent, would

[26] As the Federal Court of Appeal stated, "In the case of selection patents, as we have seen, the novelty of the selection and its advantages (including disadvantages to be avoided) are the invention and must be described in the patent": *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 186, ("*Sanofi-Aventis*"), para. 51 (our emphasis) **(R-014)**. *See* also *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197, ("*Olanzapine FCA I*"), para. 78 **(R-015)**; *Eli Lilly Canada Inc. v. Novopharm Limited*, 2011 FC 1288, ("*Olanzapine FC II*"), paras. 85-86 **(R-016)**.

[27] *Sanofi-Synthelabo*, paras. 96-100 **(R-013)**.

[28] *Olanzapine FCA I*, para. 80 **(R-015)**.

[29] *SOC*, paras. 10, 35, 36, and 48.

[30] The legal construct of the "POSITA" exists in numerous domestic patent systems, including Canada and the United States. The POSITA is akin to the legal "reasonable person". The POSITA is an archetypal person who understands the field but is not an inventive person. If an invention is obvious to a POSITA, then it is not a patentable invention. If a POSITA would understand the patent to promise a specific outcome, this is the promise that the patent has to meet. *See Monsanto Canada Inc. v. Schmeiser*, [2004] 1 SCR 902, para. 125 **(R-017)**; *Free World Trust v. Electro Sante Inc.*, [2000] 2 SCR 1024, ("*Free World Trust*"), para. 44 **(R-018)** quoting from H.G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed. (Toronto: Carswell, 1969), p. 184 **(R-019)**.

have interpreted the words and phrases employed by the appellant in the patent specification[31], supplemented by the POSITA's common general knowledge.[32] Expert evidence at trial will establish whether the POSITA would in fact have understood the patent specification to contain a promise.

29. In determining what the POSITA would have understood, the court applies settled principles of patent construction. It is well established that construction of the patent is purposive. For example, in the context of purposive construction of a patent's claims, the Supreme Court of Canada has stated:

> [t]he key to purposive construction is […] the identification by the court, with the assistance of the skilled reader, of the particular words or phrases in the claims that describe what the inventor considered to be the "essential" elements of his invention.[33]

As the Supreme Court has further held:

> We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance [...] being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and the public.[34]

30. In the court decisions at issue, the Federal Court heard extensive expert evidence and applied these interpretive principles to construe the promised utility of Claimant's inventions, reaching a reasonable result. It was hardly unfair to hold Claimant to its promised use of atomoxetine – treatment of patients with ADHD – when that use formed the basis of its new patent claim for this known compound. Similarly, it was hardly unfair to hold Claimant to the promised use of olanzapine – comparatively superior treatment of schizophrenia – when that promise was its sole basis for distinguishing the

[31] The specification is a legal document, subject to the interpretation provisions of the federal *Interpretation Act*, RSC 1985, c I-21 **(R-020)**.

[32] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FCA 108, para. 55 **(R-021)**, citing *Consolboard*, para. 28 **(R-011)** and *Whirlpool Corp. v. Camco Inc.*, [2000] 2 SCR 1067, ("*Whirlpool*"), para. 49 **(R-022)**.

[33] *Whirlpool*, para. 45 **(R-022)**. *See* also *Free World Trust*, para. 31 **(R-018)**.

[34] *Consolboard*, para. 27 **(R-011)**.

compound from the original, already-monopolized class of compounds to which olanzapine belonged.

E. Canada Allows Utility to Be "Predicted" Rather than "Demonstrated"

31. In Canada, since at least the late 1970s, courts have progressively relaxed the rule regarding how utility can be established as at the time of filing. They have done so in favour of a rule permitting patents where the applicant bases its patent filing on a "sound prediction" of utility, where an applicant cannot demonstrate (*i.e*. definitively prove) such utility at that time. In such cases, an applicant's "sound prediction" can satisfy the utility requirement of the invention.

32. Claimant complains that its patents were invalidated through application of the doctrine of "sound prediction", suggesting that such tests were unfairly adopted it after its filings, and imposed a "higher evidentiary standard" on its application.[35] Its complaint makes little sense, because "sound prediction" amounts to a more liberal standard for satisfying the utility requirement. Rather than heightening the evidentiary standard, "sound prediction" obviates the need for actually demonstrated utility at the time of filing.

33. As in the case of "promise", this doctrine was not introduced in the mid-2000s, as Claimant alleges, but was already being applied in appropriate cases by the Supreme Court of Canada as of the 1970s. In its 1979 decision, *Monsanto Company v. Commissioner of Patents*[36], the Supreme Court of Canada decided that it was appropriate to allow an applicant to claim a patent for a broad class of chemical compounds, where the applicant had derived at least some members of that chemical class as at the time of application and confirmed their reactivity (*i.e*. could "demonstrate" the utility of these examples as of the filing date), and based upon such examples could soundly predict the reactivity of other members of that same class. The Court rejected the attempt to refuse

[35] *SOC*, paras. 10, 36, 39, and 67 ("heightened evidentiary standard").

[36] *Monsanto Company v. Commissioner of Patents*, [1979] 2 SCR 1108, ("*Montsanto*") **(R-023)**.

the claim on the basis that the applicant had "over-claimed", *i.e*. claimed beyond the scope of its true invention. The disclosure requirement had been met in that case by the disclosure of working examples, which taught the skilled reader of the patent the invention and the manner in which it could be used, and from which the other (untested) members of the claimed class could soundly be predicted.

34. In the 2002 case *AZT*[37], the Supreme Court of Canada decided to apply a "sound prediction" analysis to pharmacology. In so doing, the Supreme Court reversed the finding of the trial judge, who had considered the doctrine of sound prediction to be limited to the situation where inventors claim a number of untested compounds based on the proven utility of one or more compounds, as in *Monsanto*. The Supreme Court recognized that for certain classes of invention, it was difficult to "prove" (or "demonstrate") that one had a fully-realized invention, as at the date of application, on the basis of only early-stage research. At the same time, the court recognized the value of early disclosure of promising research and therefore sought to encourage such disclosure by more liberally interpreting the statutory conditions for patentability. The Court therefore decided that in appropriate cases patents could be sustained if, as of the time of filing, an applicant could at least soundly predict, if not fully demonstrate, the claimed utility of its invention and had disclosed the basis for that sound prediction in the patent.

35. The Court in applying the *Monsanto* doctrine in this context, articulated a three-part test to ensure the proper application of sound prediction in Canadian patent law:

> The doctrine of sound prediction has three components. Firstly, as here, there must be a factual basis for the prediction. In *Monsanto* and *Burton Parsons*, the factual basis was supplied by the tested compounds, but other factual underpinnings, depending on the nature of the invention, may suffice. Secondly, the inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis. In *Monsanto* and *Burton Parsons*, the line of reasoning was grounded in the known "architecture of chemical compounds" (*Monsanto*, at p. 1119), but other

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

> lines of reasoning, again depending on the subject matter, may be legitimate. Thirdly, there must be proper disclosure.[38]

36. Canadian courts have since followed the liberal doctrine of sound prediction articulated in *AZT*. The application of the test depends upon the state of the particular art and on what specifically the applicant has claimed in its patent. The principle of "sound prediction" has been repeatedly relied upon to uphold the validity of pharmaceutical patent claims filed on the basis of early-stage research, which otherwise would not have constituted a patentable invention. The doctrine does not necessarily require long-term or human clinical studies to establish utility: all depends on the nature of testing (the "factual basis" provided) and the applicant's line of reasoning from that factual basis, confirming a sound prediction. This doctrine is not applied exclusively to pharmaceutical inventions: it can be and has been applied to other categories of inventions to establish utility.

37. The Federal Court applied the liberal doctrine of sound prediction of utility to Claimant's patent for olanzapine, after determining on the facts that Claimant was not in a position to demonstrate the utility of its alleged invention as of the filing date. The trial judge determined in light of extensive expert evidence that the studies Claimant had in its possession as of the filing date failed to provide a basis for a sound prediction of the promised utility of the invention.

F. The Invention and its Use Must Be Properly Disclosed

38. As suggested above, disclosure of the invention and of its operation and use has always been at the heart of the "bargain" underlying Canadian patent law. Canadian courts have continued to apply this requirement for patent applications filed on the basis of a "sound prediction".

39. Claimant alleges that Canadian courts unfairly applied a "heightened" disclosure requirement to its patents, contrary to the *Patent Act*, by requiring that in cases where an

[38] *AZT*, para. 70 (our emphasis) **(R-004)**.

invention was based upon "sound prediction" of utility, the applicant disclose a factual basis for its prediction and line of reasoning in the application.[39] Again, this complaint makes little sense. By requiring such disclosure, Canadian courts are simply applying the disclosure requirement to this specific context.

40. In earlier sound prediction cases such as *Monsanto*, where working examples of inventive chemical compounds had been disclosed in the specification, that factual basis had provided sufficient disclosure of the invention of the class of chemical and of its use. From these examples, the skilled reader of the patent would know how to work and use all other members of the claimed chemical class. In *AZT*, the invention consisted of the use of a known chemical compound to treat AIDS. At the time the patent was sought, *AZT* had not been tested in humans but had been shown to be effective in treating human cells *in vitro*. In these circumstances, the disclosure therefore consisted of the test forming the factual basis for the prediction of utility in humans, and of the line of reasoning soundly predicting effectiveness in humans based on the *in vitro* result, which together allowed the POSITA to understand and to work "the invention". As the Supreme Court noted in *AZT*:

> Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practiced: […]. It is generally not necessary for an inventor to provide a theory of *why* the invention works. Practical readers merely want to know that it does work and how to work it. In this sort of case, however, the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly. Precise disclosure requirements in this regard do not arise for decision in this case because both the underlying facts (the test data) and the line of reasoning (the chain terminator effect) were in fact disclosed, and disclosure in this respect did not become an issue between the Parties. I therefore say no more about it.[40]

41. The Supreme Court therefore confirmed that the validity of patents filed in such circumstances would depend on proper disclosure. Where the prediction was in effect the

[39] *SOC*, paras. 10, 36, 39, and 67.

[40] *AZT*, para. 70 (our emphasis underlined, italics in the original) **(R-004)**.

core of the "invention", the basis for the prediction (a factual basis and sound line of reasoning) had to be established and disclosed at the time of filing of the application.

42. The Federal Court applied the same rule to Claimant's patent for the use of atomoxetine. There, Claimant failed to disclose that its "invention" was in fact merely a prediction based upon early-stage research. It therefore failed to provide the public a proper teaching regarding the nature of its invention and its operation and use. In the circumstances, it was reasonable for the court to find that Claimant had failed to uphold its side of the bargain.

G. The Federal Court When Seized of the Issue Has Responsibility to Uphold the Patent Bargain

43. At the heart of Claimant's allegations is a fundamental mischaracterization of the nature of the patent grant in Canada. It suggests that this initial grant conferred upon it an irrevocable property right and that moreover the Patent Office's practice guidelines were an authoritative source of law.[41] This is incorrect. Under Canadian law, an initial patent grant is always made subject to invalidation by the Federal Court, the ultimate arbiter of patent validity and the authoritative interpreter of *Patent Act* requirements. The nature of rights conferred by a patent grant, and any expectation that Claimant could have had when the initial patent grant was made, must be considered in light of the Federal Court's role.

a) The Patent Office makes an initial administrative grant

44. As in many jurisdictions around the world, in Canada, patents are initially granted by the Patent Office based upon an administrative review of the patent specification as filed.[42]

[41] *SOC*, paras. 8, 10, and 74.

[42] Subsection 27(1) of the *Patent Act* **(R-001)** provides that "[t]he Commissioner [of Patents] shall grant a patent for an invention to the inventor or the inventor's legal representative if an application for the patent in Canada is filed in accordance with this Act and all other requirements for issuance of a patent under this Act are met."

45. Claimant seeks to elevate this initial grant into an irrevocable certainty. Yet as Claimant is well aware, all such administrative patent grants are only presumptively valid, subject to court review.[43] Patent Office review is based upon the applicant's patent specification and an examination of available prior art. If an examiner discovers no evidence contradicting the asserted utility, the applicant's description of the invention is taken at face value, with the knowledge that such assertions must eventually withstand court scrutiny if subsequently challenged in private-party litigation.

46. In granting patents, the Patent Office seeks to reflect the current state of the law. However, neither its patent grants nor the guidelines that it employs can be regarded as the final word. The Patent Office processes thousands of patent applications annually, without the benefit of a full adversarial proceeding to determine whether the grant of a patent is warranted. It lacks statutory authority to make binding interpretive rulings on the meaning of the *Patent Act*. The Manual of Patent Office Practice ("MOPOP") has since its first 1977 version consistently stated that it is "to be considered solely as a guide, and should not be quoted as an authority. Authority must be found in the Patent Act, the Patent Regulations, and in decisions of the Courts interpreting them".[44]

47. No sophisticated patent applicant interprets MOPOP as a binding or complete statement of patent law. This is particularly the case where the provisions of the *Patent Act* are being applied to new technologies, or an application raises new or unsettled questions of interpretation and application of the *Act*.

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[43] *Patent Act*, ss. 42 and 43(2) **(R-001)**. Section 42 of the *Patent Act* provides that every patent granted under the Act shall "[…] subject to this Act, grant to the patentee […] for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction" (our emphasis). Section 43(2) provides that "After the patent is issued, it shall, in the absence of evidence to the contrary, be valid and avail the patentee and the legal representatives of the patentee for the term mentioned in Section 44 or 45, whichever is applicable" (our emphasis).

[44] "*Manual of Patent Office Practice*", Consumer and Corporate Affairs Canada, Patent Office (December 1977), Forward **(R-024)**. The same notice has appeared in every subsequent version of MOPOP. "*Manual of Patent Office Practice*", Consumer and Corporate Affairs Canada, Patent Office (August 1989, January 1990, March 1998, September 2004, February 2005, April 2006, January 2009, December 2009, November 2013, December 2013, and May 2014), Forward **(R-025)**.

b) The Federal Court confirms whether the initial grant was valid

48. The *Patent Act* provides that "A patent or any claim in a patent may be declared invalid or void by the Federal Court at the instance of the Attorney General of Canada, or at the instance of any interested person".[45] In practice, the Attorney General of Canada is not involved in such patent litigation.

49. The Federal Court is therefore required to rule on the scope and validity of patents when disputes arise between private parties, in relation to either the infringement or validity of patents granted by the Patent Office. In doing so, the Federal Court must, among other things, determine whether the patent as initially granted indeed satisfies the requirements of the *Patent Act*.

50. Unlike the initial administrative reviews by the Patent Office, which rely on the patent specification as filed and assumptions in favour of the applicant, the Federal Court will review a patent's validity in light of extensive expert and fact evidence, presented in an adversarial court process between private parties.

51. A cautious and prudent patent applicant therefore files its specification, not only with a view to passing initial Patent Office scrutiny, but also with a view to passing muster before the Federal Court, in any potential challenge to the validity of an initial patent grant.

III. THE MEASURES AT ISSUE

A. The Decisions of the Federal Court

52. The decisions of the Federal Court invalidating patents No. 2,209,735 (the "'735 Patent") (atomoxetine) and No. 2,041,113 (the "'113 Patent") (olanzapine) were taken after Claimant received full due process, and were based upon reasoned consideration of extensive fact and expert evidence, in rational application of relevant legal precedents. Claimant was allowed to appeal its case to the Federal Court of Appeal and to seek leave

[45] *Patent Act*, s. 60(1) **(R-001)**.

to appeal before the Supreme Court of Canada. In total, nine different Canadian judges in the context of these two cases found that Claimant's patents were invalid.

a) Claimant's invalid patent for atomoxetine

53. Atomoxetine was a well-known medical compound at the time Claimant filed for the '735 Patent, in 1996. Since 1979, atomoxetine had already been the subject of an existing patent for the "genus" or group of compounds to which it belonged, which were described as anti-depressants. Since 1985, atomoxetine had also been the subject of a second patent for the treatment of depression. Claimant held both patents.

54. In light of these existing patents, to seek yet another monopoly, Claimant was required to assert another new and non-obvious use for atomoxetine. Its claimed new "invention" in the '735 Patent was "the use of tomoxetine for treating attention-deficit/hyperactivity disorder in a patient in need thereof".[46] In its patent specification, Claimant employed language suggesting that it already had firmly established atomoxetine as an effective ADHD treatment, although it did not disclose any study or any working examples.[47] On the basis of Claimant's representations, the Patent Office granted the patent on October 1, 2002.

55. Following the filing of the '735 Patent, Claimant filed at least ten alternative patent applications for the use of atomoxetine for the treatment of ten other pathologies, ranging from stuttering, to anxiety disorders, to tic disorders, to hot flashes. As in the case of the '735 Patent, the majority of these other patent applications contained no relevant testing or merely anecdotal data, otherwise simply asserting the claimed utility, leaving the impression that the invention was fully realized.

[46] Patent Specification CA 2,209,735 **(R-026)**, Claim No. 1. The active ingredient was subsequently renamed "atomoxetine" to avoid confusion with another compound.

[47] For instance, Claimant stated that: "The present invention provides a method of treating attention-deficit/hyperactivity disorder […]", and that "Tomexetine is a notably safe drug, and its use in ADHD, in both adults and children, is a superior treatment for that disorder because of its improved safety. Further, tomoxetine is effective at relatively low doses […]": Patent Specification CA 2,209,735, p. 2 **(R-026)**.

56. Years after filing the '735 Patent, and based upon different and later research, Claimant on December 24, 2004 obtained Health Canada approval for the use of atomoxetine to treat ADHD.

57. In 2008, one of Claimant's competitors, Novopharm Limited, sought a declaration from the Federal Court that the '735 Patent was invalid and void, including for want of utility as of the time of filing. The trial was heard over 19 hearing days between May 11, 2010 and June 9, 2010. Testimony was received from six witnesses, including four expert witnesses.

58. After more than three months of deliberations, the trial judge issued detailed reasons. He determined, based upon the expert evidence and the language in the specification, that Claimant's patent set out "the promise that atomoxetine works to treat ADHD in some patients".[48] He noted that an invention "is only useful if it does what the inventor claims it will do".[49] On the facts, he held:

> In this case the requirement of utility would be met if, at the Canadian filing date of the '735 patent, there was sufficient evidence that atomoxetine was clinically useful in treating some patients with ADHD or, alternatively, that such efficacy could be soundly predicted. That was, after all, what the '735 Patent offered – an effective treatment for ADHD – and that was the consideration required of Lilly for the monopoly it claimed.[50]

59. Claimant suggests that it was unfair of the Federal Court to hold its invention to a "higher" standard of utility, based upon the court's construction of the promise of the patent.[51] This ignores the Court's duty to apply the law as articulated by the Supreme Court in *Consolboard*, which upheld the rule that utility is to be judged against the invention as promised in the specification. Moreover, this was a case of an invention for the new use of a known compound. The first claim of the '735 Patent stated "the use of

[48] *Novopharm Ltd. v. Eli Lilly and Co.*, 2010 FC 915, ("*Atomoxetine FC*"), para. 112 (**R-027**).

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

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

[51] *SOC*, para. 52.

tomoxetine for treating attention-deficit/hyperactivity disorder in a patient in need thereof". The Federal Court had the obligation to construe what meaning the POSITA would ascribe to the term "treatment", after considering the testimony of experts for both parties.

60. Having determined the promised utility of the patent, the trial judge went on to consider whether that utility had been demonstrated by the date of filing or (applying the more liberal test of *AZT*) was at least soundly predicted as of that date. On the basis of the evidence submitted, the trial judge found that Claimant could not demonstrate as at the time the patent was filed the asserted (or "promised") utility of the invention.[52] In particular, the trial judge accepted the expert evidence that the only study that had been conducted prior to Claimant's filing (which was not disclosed in its patent specification), the Massachusetts General Hospital ("MGH Study"), was preliminary and procedurally flawed.[53] The MGH Study failed to respect its own protocol in terms of group size (employing only half of the suggested number of patients) and provided little data (patient exposure to atomoxetine was limited to three weeks). The trial judge noted that the authors of the study themselves confirmed that the MGH Study had important limitations.[54] He concluded that the MGH Study was:

> too small in size and too short in duration to provide anything more than interesting but inconclusive data. With a patient sample of this uniformity and size, an exposure to atomoxetine of only three weeks and a degree of subjectivity in the testing, one can only conclude, as the researchers themselves stated, that the study had "limitations" and the results were promising but only preliminary.[55]

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

[53] *Atomoxetine FC*, para. 113 **(R-027)**; *Eli Lilly and Co. v. Teva Canada Limited*., 2011 FCA 220, ("*Atomotextine FCA*"), para. 37 **(R-028)** (discussing the findings of the trial judge on this point). Although the Federal Court placed no limitations on the number of witnesses who could be heard, Claimant did not call any witness with direct knowledge of the MGH Study, and even failed to call the only living inventor of the '735 Patent. The MGH Study was never submitted by Claimant as a stand-alone study in the Health Canada approval process.

[54] *Atomoxetine FC*, para. 101ff. **(R-027)**.

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

61. Moreover, the total absence of reference to the MGH Study in the '735 Patent application meant that Claimant had failed to disclose any basis for a "sound prediction" of the asserted utility that formed the substance of the invention.[56]

62. Claimant appealed the lower court decision to the Federal Court of Appeal. Claimant argued that the first judge erred by interpreting the effective "treatment" promised in the patent as treatment that will work in the long term.[57] Claimant contended that some patients only need ADHD treatments for short periods of time (for example, to improve the level of concentration while preparing for and writing examinations).[58] However, the patent specification contained nothing regarding this potential use, and the protection afforded to the patentee by the claim was not so limited. In any case, the Federal Court of Appeal determined that the trial judge found the MGH Study insufficient to demonstrate that atomoxetine was an effective treatment, regardless of the length of time for which it was taken.[59] The panel of three judges of the Federal Court of Appeal unanimously endorsed the lower court decision. There was no basis to set aside the decision of the Court below.

63. Claimant sought leave to appeal the decision to the Supreme Court of Canada, which declined to grant leave to appeal. Following its usual practise for leave to appeal decisions, the Supreme Court did not render detailed reasons.[60]

64. Claimant's equivalent United States patent for the use of atomoxetine was also invalidated at first instance, on grounds strongly parallel to those noted in Canada. In a decision dated August 12, 2010 (*i.e*. one month before the initial Federal Court of Canada decision invalidating the '735 patent), the United States District Court for the District of New Jersey (the "District Court") held Claimant's patent invalid for lack of utility, noting

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

[57] *Atomoxetine FCA*, para. 26 (**R-028**).

[58] *Atomoxetine FCA*, para. 28 (**R-028**).

[59] *Atomoxetine FCA*, para. 29 (**R-028**).

[60] *Atomoxetine SCC* (**R-003**).

that Claimant had failed to disclose any test results in its specification and that a person skilled in the art would not have been able to infer the utility of the invention based upon the specification. The Court's reasoning in this regard is instructive:

> the utility requirement prevents a party from patenting a mere research proposal or an invention that is simply an object of research […] To ensure that patents do not cover "intimations of general ideas that may or may not be workable" or just "hypothetical possibilities", the enablement/utility case law instructs that patent applicants must demonstrate utility (as well as other enablement-related requirements) at the time of filing the patent application […] there is a valid policy for requiring utility to be established at the time of filing: permitting patents to be filed prior to the establishment (through some means) of the enablement/utility cuts off future scientific research in a field "with no assurance that anything useful will be discovered in the end" […] For example, a party could conceivably file patents claiming methods of treatment for various diseases through the administration of a certain drug prior to knowing that each method of treatment works. Then, through later testing, the patent applicant could demonstrate that certain of the claimed treatments were in fact useful at the time of filing. This Court does not believe that such a shotgun approach would be permissible under § 112 of our patent laws.[61]

65. The District Court's reasoning, which had relied on earlier precedential cases by the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"), was later overturned by a Federal Circuit panel composed of only two out of three judges (as one judge died before reasons could be issued). The Federal Circuit refused to follow its own jurisprudence and to require the inventor to have in its possession some evidence on which a prediction of utility can be made at the time the application is filed. Instead, the two-member panel found the patent to be valid despite the fact that inventors had only a hypothesis of utility, without any data to support that hypothesis. Given that it was published as a non-precedential decision, in United States practise the Federal Circuit's opinion in the atomoxetine case has no binding effect, beyond the parties themselves, and does not necessarily reflect correct United States law.

[61] *Eli Lilly and Co. v. Actavis Elizabeth LLC*, 731 F. Supp. 2d 348 (DNJ 2010), p. 385 (**R-029**).

b) Claimant's invalid patent for olanzapine

66. When Claimant sought its '113 Patent in 1991, it had since 1980 owned a patent over a broad "genus" whose purported use was the treatment of mild anxiety and certain kinds of psychotic conditions, including schizophrenia (patent No. 1,075,687, or the "'687 Patent"). Olanzapine was one of the compounds included in the '687 Patent.

67. Claimant began to sell an olanzapine-based pharmaceutical product in Canada only in 1996, with one year remaining to the monopoly granted by the '687 Patent. Claimant therefore sought to extend its monopoly by seeking a further patent on olanzapine. Indeed, following the filing of its '113 Patent, Claimant filed at least 29 other Canadian patent applications relating to olanzapine, purporting to have invented at least 16 distinct new and surprising uses for the compound, ranging from sexual dysfunction to autism. The majority of these other patent applications contained no reference to actual research conducted, or contained an ambiguous reference to clinical studies that may or may not have been conducted before the filing of the corresponding patent applications. Claimant filed fourteen of these patents applications in 1996-1997, just prior to the expiry date of the '687 Patent.

68. As noted above, Canadian law allows patent holders to obtain a second patent on a selection of one or many compounds from the genus where the selected compound(s) possesses a substantive advantage over the compounds in the genus. In such cases, the "invention" is identifying the unexpected and special advantages (including disadvantages avoided) over members of the already-patented genus.

69. The '113 Patent specification accordingly stated that olanzapine "shows marked superiority, and a better side effects profile than prior known antipsychotic agents, and has a highly advantageous activity level".[62] Based upon its administrative review, the Patent Office issued the patent in July 1998.

[62] Patent Specification CA 2,041,113, p. 6 (our emphasis) **(R-030)**.

70. Claimant's competitor, Novopharm Limited ("Novopharm"), later applied pursuant to the *Food and Drug Regulations* for a Notice of Compliance ("*NOC*") from the Minister of Health to enter the Canadian market with a pharmaceutical product employing olanzapine. In response, Claimant, pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, sought from the Federal Court an order prohibiting the Minister of Health from doing so, citing the '113 Patent.[63]

71. In these proceedings, Novopharm argued among other things that the '113 Patent failed to provide sufficient disclosure of the invention in its specification, and that the level of utility promised in the patent had not been met at the time of filing. The parties filed affidavit evidence of 21 witnesses, including 17 expert witnesses, who were all cross-examined at the hearing.[64] As a result of these allegations, following established precedent, the court was prompted to construe the patent to determine the promised utility of the invention. In light of the extensive evidence filed by both parties and the language used in the patent specification, the judge construed the promised utility of the patent as "olanzapine shows marked superiority […], has a better side effects profile than "prior known" antipsychotic agents [...], and has highly advantageous activity level".[65] On the ground of sufficiency of disclosure, he found that the '113 Patent failed to provide sufficient disclosure in its specification as to the invention, if any, in selecting olanzapine from a previously disclosed group of compounds.[66] He held that there was "no data" to support Claimant's assertion that olanzapine had "surprisingly and unexpected

[63] The *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, ("*PM(NOC) Regulations*") **(R-031)** provide that when a generic company wishes to enter the Canadian market with a drug similar to one already approved for which a *NOC* has been issued by the Minister to a "first person", a generic may send a notice of allegation to this "first person" if it has listed one or more patents under the scheme of the *PM(NOC) Regulations*. The notice of allegation must allege that the patent is invalid or other similar grounds, and provide factual and legal basis for such allegations. The "first person" may then, if it chooses, institute prohibition proceedings to prohibit the Minister of Health from approving, by way of issuing and *NOC*, the application of the generic company. The Minister of Health, while named, makes no representation in such proceedings.

[64] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596, ("*Olanzapine NOC*"), paras. 3 and 4 **(R-032)**.

[65] *Olanzapine NOC*, para. 126 **(R-032)**.

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

properties" by comparison to prior art.[67] In these circumstances Claimant simply "had not paid the price, by way of a clear and explicit disclosure as to what the invention is […] that merits a further monopoly in a separate further patent".[68] In light of this conclusion on sufficiency of disclosure, the court held that it was not necessary to resolve the issue of utility.[69] Novopharm therefore received a Notice of Compliance.

72. Claimant thereafter launched a second proceeding before the Federal Court pursuant to the *Patent Act*, alleging that Novopharm's pharmaceutical product employing olanzapine infringed the '113 Patent. Again, the issues of utility and sufficiency of disclosure were raised. The trial in these proceedings was heard over 44 days and testimony was taken from 20 expert witnesses and 10 fact witnesses. The trial judge identified the issue at the outset as whether the '113 Patent was a valid selection patent.[70] He determined that to uphold the validity of the '113 Patent, he must be satisfied that olanzapine had an advantage over the compounds of the '687 Patent; that this advantage was substantial and somewhat peculiar to olanzapine; and that the patent clearly described olanzapine's substantial and special advantage.[71] Based on the evidence adduced by the parties, and after deliberating for seven months, he answered these three questions in the negative and consequently invalidated the patent.

73. Claimant appealed this decision to the Federal Court of Appeal. The Federal Court of Appeal held that the trial judge erred in finding that the conditions for a selection patent constitute an independent basis upon which to attack a patent's validity. Rather, these conditions serve to characterize the invention and inform the analysis for the grounds of validity applicable to all patents, as set out in the *Patent Act*.[72] The trial

[67] *Olanzapine NOC*, para. 154 **(R-032)**.

[68] *Olanzapine NOC*, para. 164 **(R-032).**

[69] *Olanzapine NOC*, para. 190 **(R-032)**.

[70] *Eli Lilly Canada Inc. v. Novopharm Ltd*., 2009 FC 1018, ("*Olanzapine FC I*"), para. 10 **(R-033)**.

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

[72] *Olanzapine FCA I*, para. 27 **(R-015)**.

judge also erred in failing to expressly construe the patent and determine whether it included a promise.[73] According to the Federal Court of Appeal:

> [T]he promise of the patent is to be ascertained at the outset of an analysis with respect to utility. The promise is to be construed by the trial judge within the context of the patent as a whole, through the eyes of the POSITA in relation to the science and information available at the time of filing. The promise of the patent is fundamental to the utility analysis.[74]

74. Referring solely to the patent's specification, the Federal Court of Appeal would have concluded that the promise should be construed as "olanzapine, in the treatment of schizophrenia, shows marked superiority to flumezapine and other '687 compounds, has a better side effects profile that prior known antipsychotic drugs and has a highly advantageous activity level".[75] However, considering that the trial judge had failed to provide any foundation for the construction of the patent's promise, it allowed the appeal, remitting the utility and sufficiency of disclosure grounds of alleged invalidity to the Federal Court for determination in accordance with its reasons.

75. Novopharm sought leave to appeal from this decision to the Supreme Court of Canada. Claimant opposed its request, arguing that nothing in the Federal Court of Appeal's decision raised issues of national importance. Notably, Claimant argued that in its directions with regard to utility, the Federal Court of Appeal "did nothing more than apply the settled law of this Court".[76] The Supreme Court of Canada denied leave to appeal. The matter was then sent back to the Federal Court.

76. In his second decision in this matter, the trial judge carefully followed the directions set out for him by the Court of Appeal. He began his analysis by construing the patent in order to determine whether it set out a promise. Referring to the expert

[73] *Olanzapine FCA I*, para. 98 **(R-015)**.

[74] *Olanzapine FCA I*, para. 93 **(R-015)**.

[75] *Olanzapine FCA I*, para. 99 **(R-015)**.

[76] *Novopharm Limited v. Eli Lilly and Company*, Supreme Court of Canada Case No. 33870, Memorandum of Argument of the Respondent, Application for Leave to Appeal, October 26, 2010, para. 56 (our emphasis) **(R-034)**.

evidence in this regard, he refused to accept Claimant's proposition that the advantages described in the '113 Patent, including that olanzapine showed a "marked superiority and a better side effects profile than prior known antipsychotic agents", were not part of the promise of the patent.[77] He held that this interpretation "does not line up with the plain words of the patent. Nor does it accord with the preponderance of the expert evidence about what those words conveyed to them."[78] Instead, the trial judge determined on the face of Claimant's patent specification that the promised "utility" of the invention was as follows: "Overall, therefore, in clinical situations, the compound of the invention shows marked superiority and a better side effects profile than prior known antipsychotic agents, and has a highly advantageous activity level".[79]

77. The trial judge further found that the evidence available to Claimant in 1991 did not demonstrate that olanzapine was capable of treating schizophrenia patients in the clinic in a superior fashion and with fewer side effects than other known antipsychotics.[80] Applying the permissive *AZT* standard, where utility could merely be "soundly predicted", he still found that the patent fell short:

> In sum, at the time the patent was filed in April 1991, Lilly had not found any special qualities of olanzapine that would justify a fresh monopoly. Lilly had carried out routine testing of olanzapine's properties. It had some early signals of safety and efficacy in a <u>few small studies of healthy volunteers and patients</u>. While Lilly scientists showed persistence, diligence and sound science in getting olanzapine that far, that is not necessarily enough for a patent. <u>There must be an invention. And, in the context of a selection patent, the invention is the discovery of a substantial advantage over the genus compounds</u>.[81]

[77] *Olanzapine FC II*, paras. 97, 120, and 209 **(R-016)**.

[78] *Olanzapine FC II*, para. 110 **(R-016)**.

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

[80] *Olanzapine FC II*, para. 210 **(R-016)**.

[81] *Olanzapine FC II*, para. 265 (our emphasis) **(R-016)**.

78. Claimant next unsuccessfully appealed this second trial decision to the Federal Court of Appeal. The Federal Court of Appeal noted that there was no error of law in the underlying decision, nor any reviewable error of fact.[82]

79. Claimant then sought leave to appeal the second olanzapine decision to the Supreme Court of Canada. In its submissions, inconsistent with its position on the first olanzapine appeal, Claimant suddenly claimed that the decision raised issues of national importance. After hearing the parties on the motion for leave to appeal, the Supreme Court of Canada declined to allow leave to appeal.[83]

B. A Further Unspecified Measure Alleged by Claimant

80. Claimant tangentially alleges in its Statement of Claim, as a further measure breaching NAFTA Chapter Eleven, Canada's failure to "rectify" the alleged promise doctrine.[84] Claimant fails to provide any particulars of this allegation, 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.

81. In any event, Canada cannot be sanctioned under NAFTA Chapter Eleven for failing to override the statutory responsibility of the Federal Court to interpret and apply Canadian patent law, and in lieu of such decisions substitute and impose Claimant's competing views of what Canadian patent law should provide. To the extent the court decisions themselves were not in violation of Chapter Eleven (and they were not), there is no basis for finding Canada in violation of Chapter Eleven for allegedly failing to "correct" the decisions at issue.

[82] *Eli Lilly Canada Inc. v. Novopharm Limited*, 2012 FCA 232 **(R-035)**.

[83] *Olanzapine SCC* **(R-002).**

[84] *SOC*, para. 72.

IV. NONE OF CANADA'S INTERNATIONAL INTELLECTUAL PROPERTY OBLIGATIONS IS ENGAGED

82. Claimant alleges that the two court decisions at issue breached Canada's international obligations, notably NAFTA Chapter Seventeen (and by extension the TRIPS Agreement), as well as the PCT. Its reference to these treaties is misplaced, as the Tribunal lacks jurisdiction to consider such alleged breaches. In any event, its reliance on these treaty provisions is fundamentally flawed. None has any bearing on the issues raised in the olanzapine or atomoxetine trial decisions. To the extent Claimant articulates theories or alleged "expectations" to the contrary, they are both unsupported and cannot found any breach of NAFTA Chapter Eleven.

A. The Tribunal Has No Jurisdiction Over Alleged Breaches of Canada's International Intellectual Property Obligations

83. The Tribunal's jurisdiction in this matter relates only to alleged breaches of NAFTA Chapter Eleven obligations. Chapter Eleven does not grant this Tribunal jurisdiction "at large" to rule on alleged breaches of any and all of Canada's other international obligations.

84. The Tribunal notably lacks jurisdiction to rule on alleged violations of any of TRIPS, PCT or NAFTA Chapter Seventeen. Disputes in respect of an alleged breach of TRIPS obligations may only be brought pursuant to the Dispute Settlement Understanding of the World Trade Organisation. Allegations of a breach of the PCT are, in accordance with that Treaty, to be brought before the International Court of Justice. Allegations of a breach of NAFTA Chapter Seventeen are to be brought on a State-to-State basis before a tribunal constituted pursuant to NAFTA Chapter Twenty.

85. In any event, reference to these treaties is of no assistance to Claimant. Canada provides the comments that follow to clarify the contents of these instruments, without prejudice to its primary position that Claimant's competing theories as to their contents cannot establish a breach of Chapter Eleven.

B. Canada Is in Compliance with NAFTA Chapter Seventeen

86. Chapter Seventeen outlines a basic framework for intellectual property protection, emphasizing the requirement for domestic judicial and administrative institutions to oversee and enforce such protection. Contrary to Claimant's theories, it does not provide a complete "code" for the regulation of intellectual property at the international or domestic level, freeze domestic intellectual property law in time, or dictate the outcome of particular intellectual property disputes before domestic courts.

87. Claimant's allegation that Chapter Seventeen "enshrined" a particular reading of the conditions of patentability cannot be sustained.[85] As Claimant itself notes, the language of NAFTA Article 1709(1) was drawn from the TRIPS negotiations,[86] where broad terms were used due to the lack of consensus on substantive law and the desire to maintain flexibility. Indeed, as in TRIPS, reflecting substantial differences in their respective intellectual property regimes, the NAFTA Parties were unable to agree even on common terminology for core concepts of patentability. While Article 1709(1) cites the criteria "new", "result from an inventive step", and "capable of industrial application", it immediately notes that "a Party may deem the terms 'inventive step' and 'capable of industrial application' to be synonymous with the terms 'non-obvious' and 'useful', respectively" (our emphasis).

88. NAFTA Chapter Seventeen provides no direction as to how these terms are to be interpreted and applied in particular patent cases, nor signals any intention to "freeze" their application in time. Such a reading is moreover unsupported by the subsequent practice of the Parties. Domestic patent law in all three Parties has continued to evolve, including with respect to the interpretation and application of substantive criteria of patentability, and will continue to do so.

[85] *SOC*, paras. 40 and 68.

[86] *SOC*, para. 42.

89. Claimant's further reading of specific provisions of Chapter Seventeen is fundamentally at odds with the functioning of domestic patent systems of the Parties.[87] Its strained reading of NAFTA Article 1709(8) is a case in point: nothing binds reviewing courts to apply the same assumptions and reasoning applied by the Patent Office in its original administrative review. In any case, the grounds for the initial grant and its ultimate invalidation are identical: the patent application must fulfil all statutory criteria for the grant of a patent. Its allegation of "discrimination" in violation of Article 1709(7) is equally misplaced, as Canadian patent rules apply without discrimination to inventions in all fields of technology.

90. Claimant's characterization of court decisions as a "violation" of Chapter Seventeen is particularly misguided. Domestic courts are at the heart of the dispute settlement regime contemplated by Chapter Seventeen. Through extensive and detailed provisions, notably Articles 1714 to 1717, Chapter Seventeen obliges NAFTA Parties to provide access to domestic courts in intellectual property disputes, to equip those courts with extensive reviewing powers, and to ensure that they provide basic standards of due process. The due process Claimant received before Canadian courts far exceeds what NAFTA Chapter Seventeen requires and illustrates the robustness of the Canadian system for resolving intellectual property disputes. The mere fact that Claimant is disappointed with the outcomes of two patent trials does not amount to a breach of Chapter Seventeen.

C. TRIPS Reinforces Canada's Compliance with Chapter Seventeen

91. Consideration of TRIPS simply reinforces the flaws in Claimant's strained reading of NAFTA Chapter Seventeen. As is widely acknowledged, TRIPS did not attempt to create a uniform or deeply harmonized patent regime and left ample room for national variations and approaches to substantive patent issues.

92. Emphasising this state of affairs, multilateral efforts led by the World Intellectual Property Organization ("WIPO") to further harmonize patentability

[87] *SOC*, para. 71.

requirements, both prior and subsequent to the conclusion of TRIPS, have all failed. For instance, WIPO's attempt to conclude a Substantive Patent Law Treaty in 2000, whose purpose was notably to lay down the contours of the patentability requirements, failed as a result of the wide variety of national approaches to substantive law issues. The failure of such initiatives reflects the underlying complexity of domestic intellectual property systems, including patent systems, and the challenge of harmonizing individual substantive elements between systems.

D. The Patent Cooperation Treaty Has No Bearing on this Case

93. Claimant's further allegation that Canada is in violation of the PCT is irrelevant in the context of this NAFTA Chapter Eleven claim and in light of this Tribunal's jurisdiction.[88]

94. If a dispute concerning Canada's compliance with the PCT was brought by an appropriate party and in the proper forum, Canada would vigorously defend its compliance with the PCT. The patents at issue in this case – only one of which was filed through a PCT application – were invalidated for failing to satisfy the substantive conditions of patentability under Canada's *Patent Act*. The PCT expressly does not govern either substantive conditions of patentability or the invalidation of patents. It simply facilitates the international filing of patent applications by enabling patentees to secure an international filing date and specifying the basic requirements of "form and content" that PCT patent applications must meet to be accepted and processed by national authorities. Filing in accordance with the PCT is no guarantee that a patent application will result in a successful patent grant, or that any grant of a patent will withstand judicial scrutiny. This is precisely because of the diversity of substantive patent law and its application and interpretation in jurisdictions around the world.

[88] *SOC*, para. 71.

E. Claimant's Selective Comparative Law Arguments Have No Merit

95. Claimant's reading of various international instruments suffers from a further, fundamental conceptual flaw. It is a basic principle of comparative law that legal systems function as a whole and can only legitimately be understood and compared on that basis. Ignoring this, Claimant seeks to draw comparisons based upon alleged diverging interpretations of the "utility" criterion in various legal systems, considered in isolation. Its approach fails to acknowledge that each domestic patent system has a distinct balance through which the same or similar policy objective pursued by other systems may also be achieved, albeit by different means. Indeed, the difficulty of considering individual criteria for patentability in isolation, including utility, is one factor that has thus far prevented international harmonization of substantive patent law.

96. A related issue arises in Claimant's attempt to draw conclusions from the different patent trial outcomes for its olanzapine and atomoxetine patents in different jurisdictions. Claimant suggests that Canada was the only jurisdiction in which the patents at issue were invalidated "on grounds of utility": this begs the question of whether the patents at issue were invalidated elsewhere on other grounds. It also begs the question of whether the patents at issue were identical, or contained differences in claims or description. Moreover, as is well acknowledged, differences in the manner in which a case is pleaded will have a material difference in outcome.

V. CANADA HAS NOT BREACHED CHAPTER ELEVEN OF NAFTA

A. There Is No Violation of Article 1105

97. Federal Court decisions invalidating initial patent grants for atomoxetine and olanzapine in no way violate the Customary International Law Minimum Standard of Treatment set out in NAFTA Article 1105.

a) NAFTA tribunals are not courts of appeal for disappointed domestic litigants

98. Where national court decisions are the measure at issue, a mere disagreement with the court's application of the law, appreciation of the facts or disappointment with the outcome is not a violation of Article 1105. NAFTA Chapter Eleven Tribunals have repeatedly emphasized that they are not courts of appeal.[89] "The possibility of holding a State internationally liable for judicial decisions does not […] entitle a Claimant to seek international review of the national court decisions as though the international jurisdiction seized has plenary appellate jurisdiction."[90] NAFTA was "not intended to provide foreign investors with blanket protection from this kind of [judicial] disappointment, and nothing in its terms so provides."[91] Even if a Chapter Eleven Tribunal disagrees with the decisions of a domestic court or believes that the decisions were wrong in law (which is not the case here), this does not establish a breach of the Minimum Standard of Treatment.[92]

b) The Federal Court provided ample due process and fair administration of justice

99. When considering court actions as a measure allegedly in violation of the Minimum Standard of Treatment, what is required is "something more than simple illegality or lack of authority under the domestic law of a State […]".[93] The threshold for a violation by a court of the Minimum Standard of Treatment set extremely high at Customary International Law. Conduct that violates Article 1105 must be "sufficiently

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[89] *See* for example, *Robert Azinian*, *Kenneth Davitian & Ellen Baca v. United Mexican States*, ICSID Case No. ARB(AF)/97/2, Award, 1 November 1999, ("*Azinian Award*"), para. 99, **(RL-002);** *International Thunderbird Gaming Corporation v. United Mexican States*, (UNCITRAL) Arbitral Award, 26 January 2006, ("*Thunderbird Award*"), para. 125, **(RL-003)**; *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Final Award, 11 October 2002, para. 126 **(RL-004)**.

[90] *Azinian Award*, para. 99 **(RL-002)**.

[91] *Azinian Award*, para. 83 **(RL-002)**.

[92] *Azinian Award*, paras. 97 and 99 (**RL-002**).

[93] *ADF Group Inc. v. United States of America*, ICSID Case No. ARB(AF)/00/1, Award, 9 January 2003, para. 190 **(RL-005)**.

egregious and shocking – a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons – so as to fall below accepted international standards".[94]

100. Acknowledging this high threshold, Claimant alleges that the court decisions leading to the invalidation of its patents were "improper" and "discreditable".[95] This allegation has no credibility. Claimant has been provided ample due process. There was no judicial impropriety or "seriously inadequate" administration of justice.[96] Nor were the decisions at issue in any way arbitrary, let alone "manifestly arbitrary".[97] The Federal Court decided the cases reasonably and in good faith on the basis of the evidence adduced by the Parties in an open adversarial proceeding. In both cases, as fully set out in their extensive reasons, the Federal Court applied the law and found on the basis of extensive fact and expert evidence that the patents in question were invalid. The appeals ultimately failed as the Federal Court of Appeal held that there had been no error in the application of the law and no reviewable error of fact. In this context the Supreme Court of Canada denied leave for a further appeal.

101. Claimant's further allegation that Canadian patent law applies discriminatorily to pharmaceutical patents is unsupported.[98] It is also irrelevant to a claimed breach of Article 1105, as the Minimum Standard of Treatment of investors does not impose any particular requirements in this regard. In any event, in Canada all patents are subject to the same requirements. Claimant's alleged statistics on patent invalidation are unsubstantiated, and on their face present an incomplete picture of patent invalidation rates. Notably, Claimant does not place the alleged number of pharmaceutical patent

[94] *Glamis Gold, Ltd. v. United States of America*, (UNCITRAL) Award, 8 June 2009, para. 627 **(RL-006)**.

[95] *SOC*, para. 81.

[96] *Azinian Award*, para. 102 **(RL-002)**.

[97] *Thunderbird Award*, para. 197 **(RL-003)**: A violation of Article 1105 requires a failure to provide due process (constituting an administrative denial of justice), or an alleged manifest arbitrariness in administration (constituting proof of an abuse of right).

[98] *SOC*, paras. 66 and 69.

invalidations for inutility within the context of overall patent litigation volume, or within the context of invalidation rates on other grounds. In any case, such statistics must be treated with caution as each case, including the two court decisions at issue here, is decided on its own facts.[99] There has been no discrimination shown towards the Claimant or "pretence of form to achieve an internationally unlawful end".[100]

c) Claimant cannot found a breach of Article 1105 on the basis of its alleged "expectations"

102. In citing Article 1105, Claimant has also sought to rely on its alleged legitimate expectations relating to the stability, predictability, and the consistency of Canada's legal and business framework.[101] The alleged obligation to uphold Claimant's "expectations" in this regard forms no part of the Minimum Standard of Treatment. To the extent "expectations" have been considered in connection with an alleged breach of the Minimum Standard of Treatment, Claimant cannot point to any evidence of specific assurances made to it or its reliance on such assurances to make its investment.

103. Indeed, Claimant's alleged expectations, if they indeed truly held them, were clearly unreasonable. The invalidation of its patents by the Federal Court, far from reflecting the alleged "instability" of the Canadian legal and business framework, was to the contrary consistent with the reasonable understanding of any rational actor in this sector. Claimant was well aware that initial patent grants for olanzapine and atomoxetine were only presumptively valid; that this initial grant was subject to potential court review; and that it is not unusual for initial patent grants to be overturned by the courts. It was also aware that for its patents to remain valid they would need to withstand not only the Patent Office's administrative review, but rigorous court scrutiny, in an adversarial process. Claimant's alleged reliance on the Manual of Patent Office Practice as a

[99] *SOC*, paras. 11 and 66.

[100] *Azinian Award*, para. 99 **(RL-002)**.

[101] *SOC*, paras. 81-82.

complete and binding code of Canadian patent law is flatly contradicted by the express terms of that document.

104. Claimant's alleged understanding that Canadian law would be "enshrined" to its contents as they stood in 1994[102], was also unreasonable and finds no support in international law. Nothing in Article 1105 prevents the regulatory or legal framework of a State from evolving.[103] NAFTA and other bilateral investment treaties were never meant "as a kind of insurance policy against the risk of any changes in the host State's legal and economic framework. Such expectation would be neither legitimate nor reasonable".[104] Nor are Claimant's views as to how Canadian patent law "ought to have" evolved, if it did, of any weight or relevance for purposes of the Article 1105 analysis. Claimant's related, flawed account of the content of Canadian patent law as applied to its two patents in any event misstates the longstanding origins of that law and its rational relation to fundamental patent policy.

d) A violation of NAFTA Chapter Seventeen or the PCT (even if there was one) does not constitute a violation of Article 1105

105. Claimant's suggestion that there has been a violation of Article 1105 based on an alleged violation of any of NAFTA Chapter Seventeen, TRIPS, or the PCT is also to be rejected.[105] As stated in the Free Trade Commission Note of Interpretation of 2001[106], binding upon this Tribunal, a determination that there has been a breach of another provision of NAFTA or of a separate international agreement, does not establish that

[102] *SOC*, paras. 42 and 68.

[103] *Mobil Investments Canada Inc. and Murphy Oil Corporation v. Government of Canada*, ICSID Case No. ARB(AF)/07/4, Decision on Liability and on Principles of Quantum, 22 May 2012, para. 153 **(RL-007)**.

[104] *EDF (Services) Limited v. Romania*, ICSID Case No. ARB/05/13, Award, 8 October 2009, para. 217 **(RL-008)**.

[105] *SOC*, paras. 42 and 84.

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

there has been a breach of Article 1105.[107] Indeed, Article 1105 does not confer upon this Tribunal jurisdiction to find Canada "in breach" of any such instruments.

B. NAFTA Article 1110 Does Not Apply

106. Article 1110 does not apply to the procedurally fair invalidation of a patent by a domestic court. Patent grants are invalidated each year by courts in all major jurisdictions. That this does not amount to either a direct or indirect expropriation flows both from general international law and, in this case, from the application of NAFTA Article 1110(7).

a) The procedurally fair invalidation of a patent by a court cannot amount to an expropriation

107. In all but rare circumstances, a determination by a domestic court concerning the existence of a property right, including an intellectual property right, cannot amount to an "expropriation" at international law.

108. Where a court of competent jurisdiction, applying full due process and reaching a decision pursuant to its mandate, determines that a presumed property right is legally invalid (*i.e*. that it does not exist), this does not amount to a "taking", but rather, constitutes juridical determination of the existence and scope of rights at law.

109. This rule applies in all but extraordinary circumstances, where the powers of the court have been abusively applied (*abus de droit*) or in cases of gross procedural injustice amounting to denial of justice, *i.e*. only where the court is in effect not acting in a true judicial capacity.

110. The rule was considered and applied in the very first NAFTA Chapter Eleven decision, where the tribunal considered a claim that a domestic contract had been "expropriated", after a domestic court found that contract invalid. The tribunal held as follows:

[107] The Claimant misleadingly misquotes the Note of Interpretation as stating that it does not "alone" establish a breach of Minimum Standard of Treatment. *SOC*, para. 13, FN 2.

> The possibility of holding a State internationally liable for judicial decisions does not, however, entitle a claimant to seek international review of the national court decisions as though the international jurisdiction seised (sic) has plenary appellate jurisdiction. This is not true generally, and it is not true for NAFTA. *What must be shown is that the court decision itself constitutes a violation of the treaty*. Even if the Claimants were to convince this Arbitral Tribunal that the Mexican courts were wrong with respect to the invalidity of the Concession Contract, this would not per se be conclusive as to a violation of NAFTA. More is required; the Claimants must show either a denial of justice, or a pretence of form to achieve an internationally unlawful end. […] *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*.
>
> […]
>
> A denial of justice could be pleaded if the relevant courts refuse to entertain a suit, if they subject it to undue delay, or if they administer justice in a seriously inadequate way. There is no evidence, or even argument, that any such defects can be ascribed to the Mexican proceedings in this case.
>
> There is a fourth type of denial of justice, namely the clear and malicious misapplication of the law. This type of wrong doubtless overlaps with the notion of "pretence of form" to mask a violation of international law. In the present case, not only has no such wrong-doing been pleaded, but the Arbitral Tribunal wishes to record that it views the evidence as sufficient to dispel any shadow over the *bona fides* of the Mexican judgments. Their findings cannot possibly be said to have been arbitrary, let alone malicious.[108]

111. The same reasoning applies here. A patent is a domestic statutory creation, granting a national limited-term monopoly subject to the fulfilment of certain conditions. However, the right is granted in Canada on the basis that the initial administrative grant is only presumptive and may ultimately be revoked further to court review. As patents are a statutory creation in Canada, the grounds both for the initial grant and for ultimate invalidation of that grant are identical: the patent application must, upon initial administrative and ultimate judicial review, fulfil all of the statutory conditions for the

[108] *Azinian Award*, paras. 99-103 (our emphasis underlined, italics in the original) (**RL-002**).

grant of a patent. In Canada, statutory responsibility to conduct judicial review lies primarily with the Federal Court. Where that court determines, in the exercise of its statutory mandate, applying full due process, that the patent in question fails to fulfil such criteria, the property right in effect never existed. In the circumstances, Article 1110 is not even engaged *vis-à-vis* the invalidation of a patent by a court decision.

112. In the present case, Claimant has not even alleged abusive application of the reviewing power of the court, nor any gross procedural misconduct. Nor could such allegations be articulated in good faith. The Federal Court in the two decisions at issue invalidated Claimant's patents further to careful review of an enormous factual and expert record, in light of the policy considerations underlying the *Patent Act*, and further to careful review of the relevant statutory provisions and related jurisprudence. Its decisions were principled and rational. For purposes of expropriation, the analysis effectively stops there: as investment tribunals repeatedly have held, they do not sit as courts of appeal of domestic legal determinations, either on their appreciation of the facts or on their application of the law. Just as this is true in the Article 1105 context, it is equally true in the Article 1110 context.

b) NAFTA Article 1110(7) confirms that Article 1110 does not apply

113. Given the above analysis, this Tribunal need not even consider the application of Article 1110(7) to this case. However, applying Article 1110(7), one arrives at the same result: Article 1110 does not apply to these court decisions.

114. Article 1110(7) was intended to provide, in the intellectual property context, a further "defence" for the NAFTA Parties against claims of expropriation. This reflected the prominent role of the Parties in the regulation and enforcement of intellectual property rights, and consequent risk that such State action might give rise to claims under the expropriation article. Accordingly, the NAFTA Parties provided that Article 1110 would not even *apply* to determinations in this context, so long as the measure at issue was consistent with Chapter Seventeen.

115. As set out above, NAFTA Chapter Seventeen sets out a minimum framework for intellectual property protection while leaving the Parties substantial flexibility, emphasizing the role of courts in reviewing claims in this regard. Consistent with Chapter Seventeen, Canada maintains a domestic patent regime recognizing patents that meet criteria of novelty, non-obviousness, and utility. As for disclosure requirements, these are not regulated by Chapter Seventeen. Consequently, the decisions in question are fully consistent with the provisions of Chapter Seventeen.

116. Accordingly, whether viewed in light of applicable rules of international law, or through the lens of Article 1110(7), the expropriation analysis of Article 1110 does not apply to these court decisions.

117. Given the above analysis, the specific rules of expropriation need not even be considered in connection with the impugned measures: there has been no "taking" of any property, either direct or indirect, substantial or only partial, rendering this fundamental aspect of an expropriation analysis moot. The measures at issue were moreover fully consistent with Claimant's reasonable expectations, non-discriminatory, fully legal, and consistent with rational public policy. Thus, even if the expropriation analysis applied (which it does not), Canada's alleged violation of Article 1110 would not be established.

VI. DAMAGES

118. Claimant must establish a sufficient causal link between the alleged breaches of NAFTA and the damages it claims. Claimant has not even attempted to meet its burden or establish the facts necessary to prove the damages it claims. Claimant provides no foundation for the assertion that the alleged breaches of NAFTA caused them damages of US$500 Million.

119. Canada puts Claimant to the strict proof of their entitlement to damages and the amounts of any such alleged damages suffered by Claimant.

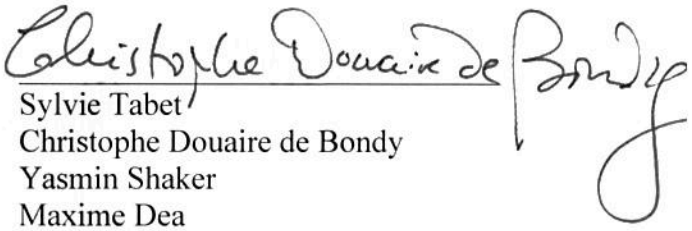
VII. REQUEST FOR RELIEF

120. For all of the above reasons, Canada respectfully asks the Arbitral Tribunal to issue an order:

- dismissing Claimant's claim in its entirety;
- awarding Canada its costs, with applicable interest, pursuant to NAFTA Article 1135(1) and Article 40 of the UNCITRAL Rules; and
- granting any other relief that may seem just.

June 30, 2014

Respectfully submitted



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