

**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)

AMICUS CURIAE SUBMISSIONS

**BY THE
CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION**

Jonathan Stainsby
Daniel Hynes
Aitken Klee LLP
181 Bay Street, Suite 3350
Toronto, Ontario
Canada, M5J 2T3
Tel: (647) 317-6868
Fax: (613) 695-5854
E-mail: jstainsby@aitkenklee.com
E-mail: dhynes@aitkenklee.com

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CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

1. The Canadian Generic Pharmaceutical Association ('CGPA') appreciates the opportunity to provide these submissions in connection with the arbitration between Eli Lilly and Company ('Lilly') and Canada. The CGPA's motivation and basis for seeking to file an *amicus* brief on this arbitration, as well as the significant public interest in the outcome of this arbitration, are set out in the CGPA's application for leave to file these submissions and will not be re-iterated here.

Preliminary Issue

2. Investor-state arbitrations under NAFTA are not intended as 'blanket protection' for investors against the mere disappointment arising from rejected complaints before national courts or from dealing with national authorities.¹ The Tribunal should be mindful that Lilly's arguments, as they relate to Canadian patent law, have been fully canvassed and adjudicated by Canadian Courts, the very courts charged with interpreting and applying domestic Canadian patent law.

3. As detailed below, the olanzapine patent was the subject of a six (6) day hearing before the Honourable Mr. Justice Hughes of the Federal Court under the *Patented Medicines (Notice of Compliance) Regulations* ('NOC Regulations'), a full trial (44 days) before the Honourable Mr. Justice O'Reilly in the Federal Court (on impeachment and infringement issues), an appeal to the Federal Court of Appeal, a rehearing before Justice O'Reilly, a second appeal to the Federal Court of Appeal, and an oral hearing of an application for leave to appeal to the Supreme Court of Canada.²

¹ *Robert Azinian et al v United Mexican States*, ICSID Case No. ARB(AF)/97/2, Final Award, November 1, 1999, at ¶¶83 and 84 (CGPA-034), cited with approval in *Marvin Feldman v Mexico*, ICSID Case No ARB(AF)/99/1, Final Award, (16 December 2002), at ¶111 and ¶112 (CGPA-026).

² This resulted from the fact that under Canadian law and procedure, patentees are able to avail themselves of what is referred to as 'dual' litigation; even should a patentee be unsuccessful under the *NOC Regulations*, a full trial on issues of patent validity and infringement remains open to it. Lilly exploited this anomalous procedure to the full by

4. The trial of the olanzapine impeachment/infringement action commenced only seventeen (17) months after the application under the *NOC Regulations* had been dismissed. Lilly was unsuccessful, and appealed ('Olanzapine Appeal #1'), which resulted in a rehearing before Justice O'Reilly, where Lilly was again unsuccessful. A second appeal followed ('Olanzapine Appeal #2'), which was dismissed from the bench by the Federal Court of Appeal.

5. An application for leave to appeal to the Supreme Court of Canada then followed. Significantly, the record on that application for leave to appeal introduced this very arbitration to the public for the very first time. This arbitration had been commenced on November 7, 2012, the day before the deadline for filing the application for leave to appeal from the decision in Olanzapine Appeal #2, the second appellate decision to uphold the invalidation of the olanzapine patent (the application for leave to appeal was filed on November 8, 2012).

6. It is important to note that, in the midst of all these hearings, Lilly, through the same counsel representing it on this arbitration, specifically argued that, in respect of the very issues subject to the arbitration, the courts 'did nothing more than follow established principles of patent law.'³ Lilly made this statement in written argument filed with the Court in Olanzapine Appeal #1 which involved the very same issues it was appealing in Olanzapine Appeal #2 (as the judgment in Olanzapine Appeal #2⁴ was extremely brief and raised no substantive issues of patent law, in essence Lilly was appealing from the judgment in Olanzapine Appeal #1).

7. Despite having stated that the judgment in Olanzapine Appeal #1 did not change the law, Lilly nonetheless sought to convince the Supreme Court of Canada (and now seeks to convince this Tribunal) that there was merit to its position that the Federal Court of Appeal's decision in Olanzapine Appeal #1 represented a departure from existing jurisprudence and followed a line of newly minted authority that altered the jurisprudential landscape by deviating and departing from what had gone before. The Supreme Court dismissed Lilly's application for leave to appeal on May 16, 2013, three (3) days after hearing oral argument.⁵

commencing an action for patent infringement the day after it learned that its application under the *NOC Regulations* had been dismissed.

³ Lilly Responding Memorandum of Fact and Law in SCC 33870, October 26, 2010, ¶2 (R-034).

⁴ The judgment in Olanzapine Appeal #2 arose from Lilly's appeal from the second judgment of Justice O'Reilly, who had followed the directions set forth in the judgment in Olanzapine Appeal #1 and invalidated the olanzapine patent a second time. Accordingly, Lilly's application for leave to appeal from Olanzapine Appeal #2 – and the arguments it makes on this arbitration – are directed to the reasons for decision in Olanzapine Appeal #1. Lilly's earlier position on that judgment is quoted above (CGPA-018, CGPA-020).

⁵ It is rare for the Supreme Court of Canada to have an oral hearing on the merits of a leave application. Again, this illustrates that Lilly had the full benefit of the Canadian legal system.

8. Thus, where it suited Lilly's purposes, Lilly defended the Federal Court of Appeal's judgment in Olanzapine Appeal #1; now that that gambit has not worked, Lilly attacks that very same judgment as representing or instantiating an important shift in Canadian patent jurisprudence.

9. In view of this, it appears that this arbitration was initially brought in an effort to convince the Supreme Court of Canada that Lilly's application for leave to appeal from the Federal Court of Appeal's judgment in Olanzapine Appeal #1 had merit. In a highly unusual move, in addition to putting its Notice of Arbitration before the Supreme Court, Lilly supported its application for leave to appeal with affidavits from two prominent (and then recently retired) jurists from the UK (Lord Justice Jacob of the Court of Appeal of England and Wales) and the US (Judge Paul Michel of the US Court of Appeal for the Federal Circuit).

10. Lilly's position on this arbitration is very clearly opportunistic, rather than reasoned and considered. It is directly contrary to the position Lilly took before the Supreme Court of Canada in 2010 and inconsistent with the realities of Canadian patent jurisprudence and the development of Canadian patent law over the past decades.

11. It was widely anticipated that when its application for leave to appeal was dismissed, Lilly would abandon this arbitration. Lilly has not done so. Indeed, in June 2013, Lilly expanded the scope of this arbitration by adding its complaint regarding the invalidation of the 735 patent to the use of atomoxetine to treat attention deficit hyperactivity disorder ('ADHD').

12. Lilly also enjoyed the full benefit of the Canadian legal system in defending the 735 patent, beginning with a full trial (17 days) before the Honourable Mr. Justice Barnes, who found the 735 patent invalid in 2011. Lilly appealed this decision to the Federal Court of Appeal, which dismissed the appeal. Lilly then sought leave to appeal to the Supreme Court of Canada (application for leave dismissed).

13. While the CGPA accepts that the Supreme Court's refusal to grant leave to appeal is of no true precedential value, it must nonetheless be appreciated that the *Supreme Court Act* provides that leave to appeal may be granted where:

...the Supreme Court is of the opinion that any question involved therein is, by reason of its public importance or the importance of any issue of law or any issue of mixed law and fact involved in that question, one that ought to be decided by the Supreme Court or is, for any other reason, of such a nature or significance as to warrant decision by it...⁶

⁶ *Supreme Court Act*, RSC 1985, c S-26, section 40(1) (CGPA-042).

It is well-recognized that the Supreme Court accepts appeals that involve ‘issues of public importance’ on a national scale.⁷

14. In dismissing Lilly’s applications for leave to appeal in both olanzapine and atomoxetine, the Supreme Court of Canada would have formed the view that neither raised an issue of ‘public importance’ or ‘national importance’ or an ‘important issue’ of law or mixed law and fact. This belies Lilly’s assertions that the decisions that invalidated its two patents reflected an important change in Canadian patent law.

15. It is important to note that the generic pharmaceutical industry is occasionally disappointed with court decisions as they relate to patent law and related damages law. However, the CGPA and its members understand the need for a balanced approach to Canadian patent law that can only be obtained by having domestic Canadian courts that are consistently involved in patent law make substantive determinations about Canadian patent law. The CGPA is very concerned that Canadian patent law not be the subject of ‘super appellate’ review, which would disrupt the natural development of Canadian domestic patent law and lead to a loss of the fundamental balance that presently exists in this area.

16. Lilly enjoyed the full and extensive protection of the Canadian legal system. The two matters took up at least 73 days of court time and were considered by some 20 different judges. A large number of counsel were engaged by Lilly in the defence of its two patents. Despite having received the benefit of this protection and disappointed with the results, Lilly has turned to this Tribunal for a more favourable decision. Lilly seeks to obtain a different disposition by disrupting the fine balance that Canadian courts have established in patent law.

⁷ John Sopinka and Mark A. Gelowitz, *Conduct of an Appeal*, 3rd ed (Toronto: LexisNexis, 2012) at 315, 316 (CGPA-048). The late Honourable Justice John Sopinka was a well-respected member of the Supreme Court of Canada who published the first edition of this text in 1993. In it, he explained that the Supreme Court of Canada’s role was not merely to correct errors made by the Courts below but to grant leave only to appeals that had ‘public importance’ as ‘[o]n a fundamental level, whether or not the Court of Appeal was ‘wrong’ has little if anything to do with whether the case is one of public importance.’ Justice Sopinka also listed factors that militate toward the Supreme Court of Canada finding an issue of public importance and granting a leave application:

a novel constitutional issue, the interpretation or application of a significant federal statute of general application, the interpretation or application of a provincial statute with corresponding similar legislation in other provinces, an issue for which there are conflicting decisions in the provincial appellate courts, or an issue that requires revisit by the Supreme Court on an important question of law [...] [t]he Court is considerably less likely to grant leave to appeal in cases which are primarily factual in nature, or in which the result generated will be of interest primarily to the parties themselves and not of general application.

17. The CGPA does not dispute this Tribunal's jurisdiction to preside over this arbitration; the CGPA does, however, urge this Tribunal to dispose of this arbitration without commenting upon any substantive principles of Canadian patent law.

Submissions

1. Perspective

18. The CGPA respectfully submits that were this Tribunal to release a decision opining on substantive Canadian patent law issues, such a decision would run the very real risk of upsetting (or promoting or encouraging Canadian Courts to upset) existing and longstanding Canadian jurisprudence, jurisprudence that promotes the fundamental balance established in Canadian patent law, often referred to as the 'bargain theory' (explained further below).

19. Further, a decision in this matter that touches on substantive patent law issues risks creating uncertainty and unpredictability in the eyes of the Canadian public, including for generic pharmaceutical manufacturers that rely on consistency and predictability in Canadian patent law.

20. The centrality of the bargain theory to Canadian patent law is well illustrated in the following statement made by the Supreme Court of Canada nearly 15 years ago:

A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the *quid pro quo* for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*. Monopolies are associated in the public mind with higher prices. The public should not be expected to pay an elevated price in exchange for speculation, or for the statement of "any mere scientific principle or abstract theorem" (s. 27(3)), or for the "discovery" of things that already exist, or are obvious. ***The patent monopoly should be purchased with the hard coinage of new, ingenious, useful and unobvious disclosures.***⁸ [emphasis added]

⁸ *Apotex Inc. v Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 at ¶37 ('AZT') (CGPA-006); see also *Brenner v. Manson*, 383 U.S. 519 (1966) at 535-536 (CGPA-008) where the United States Supreme Court held a similar view of the American patent system:

[w]e [do not] mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. ***But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.*** [emphasis added]

21. This understanding continues to inform Canadian patent law. In 2012, the Supreme Court of Canada approved the last-cited passage and noted that:

The patent system is based on a “bargain”, or *quid pro quo*: the inventor is granted exclusive rights in a new and useful invention for a limited period *in exchange for disclosure of the invention so that society can benefit from this knowledge*. This is the basic policy rationale underlying the *Act*. The patent bargain encourages innovation and advances science and technology.⁹ [emphasis added]

22. In these submissions, the CGPA relies on the Supreme Court’s elucidation of the patent bargain, and the ‘hard coinage’ analogy, as animating patentability requirements in Canada: while patents bestow intangible rights in the form of intellectual property, the bargain underlying the grant of a monopoly is real. In order to draw ingenious, useful and unobvious disclosures into the public domain, for the benefit of society at large, a patentee is given a monopoly for the limited period of 20 years. That is the patent bargain and it is balanced.

23. The patents at issue – those for olanzapine and atomoxetine – granted second monopolies on previously monopolized compounds.

- a. The olanzapine patent was a selection patent, claiming a member of a previously disclosed genus of compounds. Accordingly, Lilly had to show that olanzapine, the compound that had been selected, possessed unexpected, substantial and peculiar advantages over the members of the prior genus class of compounds. These advantages were the asserted utility of olanzapine.
- b. The atomoxetine patent claimed a new use for a known compound – atomoxetine was known and its potential use as an antidepressant had previously been studied by Lilly. It had been the subject of earlier Lilly patents. As the 735 patent claimed a new use (treatment of ADHD), that was the utility and the compound had to meet that utility – either by demonstration or sound prediction of the utility stated in the patent.

24. In each, Lilly had already patented the underlying subject matter, the compound, claimed in each of these two patents. For Lilly to secure a second patent and a second monopoly over olanzapine, it was necessary that Lilly assert and rely upon unexpected, substantial and peculiar advantages, advantages over and above the compounds of the genus. In its judgment on rehearing of the olanzapine trial, the Federal Court relied on the requirements for a selection patent and found that Lilly did not have a sound and articulable line of reasoning or *prima facie* reasonable inference from available evidence. Therefore, there was insufficient support for the

⁹ *Teva Canada Limited v Pfizer Canada Inc.*, 2012 SCC 60 at ¶32 (‘*Teva Sildenafil SCC*’) (CGPA-037).

promises Lilly made in the patent regarding the asserted advantages and the patent was held invalid.¹⁰

25. The atomoxetine patent claimed a new use for atomoxetine. The Federal Court found that this new use (treatment of ADHD) had not been demonstrated. Accordingly, Lilly could only have predicted the utility of atomoxetine for this new use as at the filing date of the 735 patent. However, the Court held that Lilly could not rely on a prediction of utility as the basis for the prediction (a short clinical study) had not been disclosed in the 735 patent (though it could have been).

a. Promise

26. The so-called ‘promise doctrine,’ as described by Lilly, does not exist. The jurisprudence clearly establishes that the word ‘promise’ itself is only a shorthand reference to what the patentee has chosen to say that the claimed invention will do – what the utility of the claimed invention is.¹¹ The term ‘promise doctrine’ is no more than a construct employed by Lilly to support the arguments made on this arbitration (arguments previously made unsuccessfully before the Canadian Courts, including the Supreme Court of Canada).

27. Patents involve a bargain. The monopoly they bestow is not an entitlement that one receives for simply sending reams of paper to the Patent Office. Hard coinage must be paid. There is no requirement that anyone should apply for a patent, but once an application is made, the requirements that demarcate and delineate patent validity must be met. The terms of the bargain and the nature of the required coinage are described in the *Patent Act*, as applied and interpreted in judge-made law. Neither the terms of the bargain nor the requirements of the *Act* can be simply wished away.

¹⁰ *Apotex Inc. v Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 26 at ¶¶8-11 (*‘Sanofi SCC’*) (CGPA-005); *Eli Lilly Canada Inc. v Novopharm Ltd.*, 2011 FC 1288 at ¶267, 268 (CGPA-019).

¹¹ The term ‘promise doctrine’ did not appear in any Canadian patent jurisprudence prior to 2014 and its meaning is different than as used by Lilly in this arbitration. It first appeared in the Federal Court of Appeal’s decision in *Pfizer Canada Inc. v. Apotex Inc.*, 2014 FCA 250 at ¶65, 66 (*‘Celecoxib FCA’*) (CGPA-032). Consistent with the propositions advanced in these submissions, *Celecoxib FCA* states that ‘[t]he promise doctrine represents an exception to the above minimum statutory requirements. Though an inventor need not describe any particular utility for the invention, an inventor who explicitly promises a specific result will be held to that promise when called upon to prove utility. That the invention may well have satisfied the scintilla threshold is of no assistance in establishing utility where a promise, if it be made, cannot be met.’ The only other references to the term are in the Federal Court’s decisions in *Eli Lilly Canada Inc. v Mylan Pharmaceuticals ULC*, 2015 FC 17 at ¶88 (CGPA-016); *Gilead Sciences Inc. v. Idenix Pharmaceuticals Inc.*, 2015 FC 1156 at ¶227 (CGPA-021); and *Eli Lilly Canada Inc. v. Hospira Healthcare Corporation*, 2016 FC 47 at ¶40 (CGPA-015), each of which merely cites to *Celecoxib FCA*, and none of which provides any further elucidation of the term.

28. Holding patentees to the promises made in their patents has long been a central element of Canadian patent law, dating at least to *New Process Screw* in 1933.¹² It is an aspect of utility – does the claimed invention do what the inventor has chosen to say it will do, or is the prediction that it will do that a sound one? In the case of validity challenges to patents such as those for olanzapine and atomoxetine, an analysis of the utility is inevitable and necessary, as the promise of utility was the very basis for the grant of the patent.

29. The decisions complained of did no more than apply long-standing principles of Canadian patent law; the decisions do not represent a change or departure from prior jurisprudence. As noted, in 2010 Lilly agreed with this proposition as the correct understanding of the Federal Court of Appeal's judgment in Olanzapine Appeal #1.¹³ Nor was the jurisprudence changed by the decision by the Supreme Court of Canada in *AZT* and/or the subsequent decisions that Lilly points to.

30. There is no arbitrariness or uncertainty in these decisions; Lilly challenges them only because it was unsuccessful and has exhausted all available routes of appeal under the Canadian judicial system.

A false dichotomy: ‘scintilla’ and ‘promise’ branches of utility

31. In the event that this Tribunal chooses to delve into the intricacies of Canadian patent law, it must be appreciated that Lilly’s arguments present a highly artificial and simplistic overview of Canadian patent law.

32. The concept of the ‘promise’ arises directly from the *Patent Act* (sections 2 (an invention must be ‘useful’) and section 27(3)) and has been cited in the jurisprudence for decades.¹⁴ Section 27(3) of the Patent Act mandates that an applicant for a patent ‘shall in the specification ... correctly and fully describe the invention and its operation or use as contemplated by the inventor.’¹⁵

33. The argument that there are now two ‘branches of utility’, the ‘mere scintilla’ branch and the ‘promise’ branch¹⁶ is incorrect. This distinction arises only in specific

¹² *New Process Screw Corp. v PL Robertson Mfg Co. Ltd.*, (1961), 39 CPR 31 (Ex Ct) (‘*New Process Screw*’) (CGPA-028). In fact, although the concept was made explicit in *New Process Screw*, it was a part of Canadian law from the very beginning.

¹³ See ¶6, *supra*.

¹⁴ *Patent Act*, ss. 2 and 34 (now 27(3)) (CGPA-041). See *Wandscheer v Sicard Ltd.*, [1948] S.C.R. 1 at 5, 15 and 24 (CGPA-039); *Consolboard Inc. v MacMillan Bloedel (Sask.) Limited*, at 525-6 (CGPA-010); *Teva Sildenafil SCC* at ¶38; *AZT* at ¶62 (CGPA-037); *Monsanto Co. v. Commissioner of Patents*, [1979] 2 S.C.R. 1 108 (‘*Monsanto*’) at 1116-7 (CGPA-027); *New Process Screw*, *supra*, at p. 45-6 (CGPA-028); *Amfac Foods Inc. v Irving Pulp & Paper Ltd.* (1986), 12 C.P.R. (3d) 193 (FCA) at 197 (CGPA-001); *Celecoxib FCA*, *supra*, at ¶66 (CGPA-032).

¹⁵ *Patent Act*, s. 27(3) (CGPA-041).

¹⁶ Lilly’s Memorial at ¶60.

circumstances, such as where the would-be patentee seeks a second monopoly on a previously patented or a previously known compound, as described above.

34. What Lilly describes as the promise branch of utility has been part of the hard coinage of utility for decades.¹⁷ Its application is dependent upon what the patentee itself chooses to disclose (*i.e.*, what it says) in its patent: where the patentee voluntarily and explicitly states that the invention has a particular effect, the patentee will be held to that promise; where the patentee has not chosen to make any such statement, the skilled reader will find the utility of the claimed invention based on the patent document as a whole (in which case the utility may be a so-called ‘scintilla’). What is required in each case will be a function of the context, the nature of the patent, what the patentee has chosen to say in the patent and the particularities of the discipline to which the patent relates. Again, in certain situations, such as those at play in the litigation underlying the subject matter of this arbitration, the patentee is compelled to state what the invention does to differentiate it from its prior patents – compelled to disclose the utility and the nature of the prediction relied upon.

35. Further, the Federal Court of Appeal has expressly addressed this dynamic between scintilla and promise:

Though an inventor need not describe any particular utility for the invention, an inventor who explicitly promises a specific result will be held to that promise when called upon to prove utility. **That the invention may well have satisfied the scintilla threshold is of no assistance in establishing utility where a promise, if it be made, cannot be met.**¹⁸ [emphasis added]

36. Lilly asserts that the utility requirement in Canadian law sets an extremely low threshold for patentability.¹⁹ This is an oversimplification. There is no ‘one size fits all’ concept of utility, no one understanding of the required utility will suffice for all patents and all situations. The utility requirements are directly connected to the nature of the patent, the statements the patentee has chosen to make in the patent and the ‘particularities of the discipline to which [the patent] relates.’²⁰

37. In Canada, patents must ‘correctly and fully describe the invention and its operation or use as contemplated by the inventor.’²¹ Anything less is insufficient and fatal to the validity of the patent.²² If a patentee chooses to state in the disclosure of

¹⁷ *AZT*, *supra*, at ¶37 (CGPA-037).

¹⁸ *Celecoxib FCA*, *supra* (CGPA-032), citing *Sanofi-Aventis v Apotex Inc.* 2013 FCA 186 at ¶¶48-9 and 54 (‘*Plavix FCA*’) (CGPA-035); see also *Plavix FCA* at ¶51 (CGPA-035) where the Court addresses selection patents.

¹⁹ *Lilly Memorial* at ¶45.

²⁰ *AZT*, *supra*, at ¶71 (CGPA-037).

²¹ *Patent Act*, s. 27(3) (CGPA-041).

²² *Teva Sildenafil SCC* at ¶¶31-35 (CGPA-037).

his patent what the invention will do (*i.e.*, to articulate a so-called ‘promise’), then the patentee will be held to that promise.²³ Accordingly, a so-called ‘promise’ is nothing more than a statement in the patent explaining what the inventor says the invention will do. However, for second or follow-on patents, patents asserting a second monopoly over a previously patented invention (as both of the compounds claimed in the patents at issue in fact were), this disclosure must be made.

38. In particular, a second patent that covers a previously patented compound, including a compound that falls within a previously patented genus or class of compounds (however large that genus or class may have been), can be granted and upheld as valid only in well-defined situations. This applies to the 113 and the 735 patents; each is a second patent on a previously claimed compound, a fact that Lilly downplays, and even attempts to wholly ignore.

39. One circumstance where a second patent monopoly can be sought is where the subject matter of the second patent is identified as possessing unexpected, substantial and peculiar advantages that set it apart from the broader subject matter of the first patent (*i.e.*, the genus). In such circumstances, the second patent is referred to as a ‘*selection patent*.²⁴ This is the nature of the 113 patent for olanzapine.

40. In a second circumstance, the later patent claiming the same compound can be upheld as valid but only if it discloses a *new use* for that old compound. Such a second patent is referred to as a ‘*secondary use patent*’ or a ‘*new use patent*.²⁵ This is the character of the 735 patent for atomoxetine.

41. For selection patents the unexpected, substantial and peculiar advantages must be clearly (or, to quote the *Act*, ‘correctly and fully’) disclosed in the patent.²⁶ For secondary use patents the new use, too, must be correctly and fully disclosed.²⁷

42. Thus, each of the olanzapine and atomoxetine patents needed to meet obligations that went beyond the disclosure of a so-called ‘scintilla of utility.’ In both cases, at the time of filing its patent application, Lilly, as the applicant, needed to have been able to demonstrate or soundly predict the advantages associated with the compound that it had selected (olanzapine) or the new use for the old compound (atomoxetine).²⁸

²³ *Plavix FCA*, *supra*, at ¶¶48-49 (CGPA-035); *Pfizer Canada Inc. v Canada (Minister of Health)*, 2008 FCA 108 at ¶53 (CGPA-033); *Consolboard Inc. v MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504 at 525, 526 (CGPA-010).

²⁴ *Sanofi SCC*, *supra*, at ¶¶10 and 11 (CGPA-005).

²⁵ *Novopharm Limited v Eli Lilly and Company et al.*, 2011 FCA 220 (‘Atomoxetine FCA’) (CGPA-020).

²⁶ *Sanofi SCC*, *supra*, at ¶114 (CGPA-005); *Patent Act*, s. 27(3) (CGPA-041).

²⁷ *Patent Act*, section 27(3) (CGPA-041).

²⁸ *Sanofi SCC*, *supra* (CGPA-005).

43. To this extent, then, Lilly was required to make ‘promises.’ In the olanzapine patent, Lilly had to disclose unexpected, substantial and peculiar advantages for olanzapine, advantages that Lilly had demonstrated or was able to soundly predict at the time the patent was filed. In the atomoxetine patent, Lilly had, at the time of filing, to disclose that it had demonstrated or was able to soundly predict the utility of atomoxetine in the treatment of ADHD. These ‘promises’ were no more than the disclosure of the utility that Lilly relied upon in seeking its patent monopolies. Disclosure was required because of the nature of the two patents, the validity of which rested and relied upon Lilly making the very promises of which it now complains; simply put, in each case the asserted utility was the gravamen of the invention.

44. However, Lilly had not demonstrated and could not soundly predict the utility in either case, despite having had every opportunity to do so. This led to the Courts invalidating both patents.

45. Canadian law was very lenient with regard to the issuance of the 113 and 735 patents. For the 113, Lilly had clearly not demonstrated the advantages of the olanzapine compound (indeed, Lilly prosecuted the application leading to the 113 patent as a selection patent). For the 735, Lilly had clearly not demonstrated that atomoxetine was useful in treating ADHD. Despite not having shown either compound to have the claimed characteristics, and thus not *knowing* that either compound had those characteristics, Lilly was able to and did rely upon the concept of sound prediction in obtaining both patents. This was very much to Lilly’s benefit and potential advantage, as described in *Celecoxib FCA*.²⁹ Both patents were issued by the Canadian Intellectual Property Office even though Lilly had not provided or referred to evidence that established or ‘demonstrated’ the utility of either purported invention.

46. Lilly led evidence at trial before the Federal Court that Lilly had in fact met the threshold for utility required under the doctrine of sound prediction: Lilly had the opportunity to lead witnesses, and to present its theory of the case. The facts were disputed. Ultimately, the Court arrived at findings of fact that were contrary to Lilly’s assertions. Lilly now impugns the law, when in fact it merely is disappointed with the Federal Court’s findings of fact made under the rubric of the doctrine of sound prediction. Lilly sets up a straw man arguing that Canada’s long-established utility standard is flawed in an effort to avoid the fact that Lilly simply did not have a sound legal basis for having obtained its secondary patents in the first place.

47. But for the doctrine of sound prediction, neither patent would have issued. Importantly, the doctrine of sound prediction benefits patent applicants by allowing

²⁹ *Celecoxib FCA*, *supra*, at ¶65, 66 (CGPA-032).

them to offer only post-dated consideration or ‘hard coinage.’ In exchange, the law requires that applicants provide disclosure in the patent of the factual basis and sound line of reasoning supporting the prediction. That is, patent monopolies can be secured for inventions which patent applicants have not yet demonstrated will work, but only if the applicants disclose a sound prediction that their inventions will work. As noted by the Federal Court of Appeal:

Indeed, if disclosure in the patent of the factual basis of the prediction of utility was not required for sound prediction, it would be difficult to see what Lilly could be said to have given to the public, in exchange for the grant of the monopoly, that it did not already have. When utility is based on sound prediction, disclosure of its factual foundation goes to the essence of the bargain with the public underlying patentability.³⁰

48. In the case of selection patents and secondary use patents, such as the 113 for olanzapine and the 735 for atomoxetine, disclosure of the special advantage or new use must be made, otherwise the prior patent or other disclosure will in both cases anticipate the follow-on patent or render it obvious. That disclosure is regarded at law as a promise.³¹

49. This is not only logical, it is also fully consistent with the precepts of patent law as a whole. In most circumstances, a patentee cannot obtain further monopoly protection for an invention on which it has already enjoyed monopoly protection. Only one patent is awarded for each invention.³²

50. By satisfying the requirements of sound prediction, patentees are relieved from having to wait for the conclusion of years-long clinical trials or experiments before having a basis to strike a bargain with the Canadian public and the patent office to secure an issued patent and enjoy the resulting monopoly.

51. While sound prediction benefits patent applicants, they do run the risk of obtaining patents that are vulnerable to invalidity attacks if there was not a proper basis, sound line of reasoning or proper disclosure of the applicants’ sound predictions.³³ This is precisely what happened with the patents for olanzapine and atomoxetine.

52. As the advantages and the new use were predictions, Lilly had to disclose the factual basis and line of reasoning supporting each. That was the hard coinage that Lilly had to pay for the grant of the second monopolies. Ultimately, when its patents

³⁰ *Atomoxetine FCA* at ¶51 (CGPA-020).

³¹ *Plavix FCA*, *supra*, at ¶51 (CGPA-035).

³² See *Whirlpool Corp v Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 at ¶37 (CGPA-040).

³³ *AZT*, *supra* (CGPA-037).

were challenged, Lilly's predictions were shown to have been unsupported and unsound and, accordingly, Lilly's patents were invalidated by the Federal Court.

53. The concepts that Lilly says are new, unfair and arbitrary are none of these things. The so-called 'promise of the patent' and the 'heightened' disclosure requirement in sound prediction are not new. These concepts are intended to hold patentees to account for statements made in patents – in language of the inventors' own choosing – regarding what the inventors choose to say their inventions will do.

54. Moreover, Lilly's complaint only arises because it sought *extended* patent monopolies. When it was shown through litigation that Lilly's statements exceeded what Lilly was able to predict, the patents were properly found invalid, as the patent bargain had not been met.³⁴

55. Lilly suggests that there is a distinction to be made between developments in the common law and the creation of entirely new grounds for patent revocation.³⁵ However, Lilly's patents for olanzapine and atomoxetine were not invalidated on the basis of any new ground of revocation. They were invalidated because they failed to satisfy longstanding requirements of patentability.

56. The Courts, including the Supreme Court of Canada, have endorsed the notion that judge-made law has a role to play in clarifying what is otherwise a purely statutory area of law. The *Patent Act* does not exclude 'judge-made' doctrine, which is an essential component of patent law, in Canada and around the world. The Supreme Court of Canada observed in *Sanofi SCC*, even as it clarified the statutory nature of patent law in Canada and proceedings under the *NOC Regulations*, that there is a role for 'judge-made' doctrine in clarifying the *Patent Act*:

The most recent reference to the law of patents being wholly statutory are the words of Lord Walker in *Synthon B.V. v SmithKline Beecham plc*, [2006] 1 All E.R. 685, [2005] UKHL 59, at paras. 57-58:

The law of patents is wholly statutory, and has a surprisingly long history... . **In the interpretation and application of patent statutes judge-made doctrine has over the years done much to clarify the abstract generalities of the statutes and to secure uniformity in their application.**³⁶ [emphasis added]

57. Accordingly, the proposition that the concepts of the 'promise' and the disclosure requirement for sound prediction are not found in the *Act* is entirely

³⁴ See *Eli Lilly Canada v Novopharm Limited*, 2009 FC 1018 (CGPA-017), rev'd in part 2010 FCA 197 (CGPA-018), *Eli Lilly Canada v Novopharm Limited*, 2011 FC 1288 (CGPA-019), aff'd 2012 FCA 232 ('olanzapine') (CGPA-020); *Novopharm Ltd. v Eli Lilly and Co.*, 2010 FC 915 (CGPA-029), aff'd 2011 FCA 220 ('atomoxetine') (CGPA-020).

³⁵ Lilly's Memorial at ¶230.

³⁶ *Sanofi SCC*, *supra*, at ¶12 (CGPA-005).

without import or effect. Many patent law concepts are developed through judge-made doctrine, including, for example, the patentee-friendly concept of sound prediction, itself. Indeed, the concept of ‘purposive construction’ of a patent, which might be considered the cornerstone of patent law in Canada,³⁷ is judge-made doctrine.³⁸ Similarly, the tests for anticipation and obviousness are judge-made doctrine clarifying how scant statutory provisions in the Canadian *Patent Act* should be applied to individual patents.³⁹ The concept of ‘utility’ finds its sole statutory expression in the definition of ‘invention’ in s. 2 of the *Act* (‘new and useful’). Judge-made doctrine has indeed clarified many of the abstract generalities of the statute.

58. It is an oversimplification to assert that the fundamental function of the patent system is solely to encourage innovation.⁴⁰ This is a one-sided view of the policy objectives underlying the *Patent Act*. Patent protection is clearly one purpose of patent law but it is only one purpose, and is itself balanced by the patent bargain and the hard coinage referred to by the Supreme Court of Canada.⁴¹ It is an equally important goal of patent law to coax otherwise private and undisclosed research into the public domain – that is the other side of the bargain in this context.

59. The purpose of patent law with respect to pharmaceuticals is even more nuanced. The Federal Court of Appeal made this clear (in litigation involving Lilly):

[...] Parliament, through the delegated authority of the Governor-in-Council, has considered the question whether a remedy should be available to second persons [i.e. generic manufacturers] in the circumstances alleged by the statements of claim and the extent of that remedy. **It did so in an attempt to strike a balance between the need for patent protection on the one hand and the timely entry of lower priced drugs on the market, on the other.**⁴² [emphasis added]

60. So, while adequate (but not excessive) patent protection is one aim of patent law, in the arena of pharmaceutical patents so, too, is timely access to lower priced

³⁷ Purposive construction is the approach of interpreting a patent based only on the meaning a person of ordinary skill in the art (i.e. a reasonable person test) would find by relying on only the content within the four corners of the patent.

³⁸ *Whirlpool SCC*, *supra*, at ¶39-40 (CGPA-040).

³⁹ *Sanofi SCC*, *supra*, at ¶30-37 (anticipation) and at ¶67-71 (obviousness) (CGPA-005).

⁴⁰ Lilly’s Memorial at ¶30.

⁴¹ See *Bristol Myers Squibb Co. v Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533 (CGPA-009).

⁴² *Apotex Inc. v Eli Lilly Canada Inc.*, 2011 FCA 358 at ¶18 (CGPA-002), leave to appeal dismissed [2012] S.C.C.A. No. 78 (CGPA-003), citing *Apotex Inc. v Merck & Co. Inc.*, (2009), 76 C.P.R. (4th) 1 at ¶¶45 to 61 (CGPA-004); *Bristol Myers Squibb Co. v Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533 at ¶¶6 to 12, 45, 46 and 50 (CGPA-009); *AstraZeneca Canada Inc. v Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560 at ¶¶12 to 23 (CGPA-007).

drugs. Lilly overlooks this component of the balance in Canadian patent law pertaining to pharmaceutical inventions.

Post-filing evidence / after-the-fact validation

61. The Supreme Court of Canada has cautioned against allowing the use of post-filing evidence to justify unsound predictions made at the time of filing patent applications. In *AZT*, the Supreme Court of Canada expressly rejected the theory of after-the-fact validation, overturning the Federal Court of Appeal on this point:

In my view, with respect, Glaxo/Wellcome's proposition is consistent neither with the Act (which does not postpone the requirement of utility to the vagaries of when such proof might actually be demanded) nor with patent policy (which does not encourage the stockpiling of useless or misleading patent disclosures). Were the law to be otherwise, major pharmaceutical corporations could (subject to cost considerations) patent whole stables of chemical compounds for all sorts of desirable but unrealized purposes in a shot-gun approach hoping that, as in a lottery, a certain percentage of compounds will serendipitously turn out to be useful for the purposes claimed. Such a patent system would reward deep pockets and the ingenuity of patent agents rather than the ingenuity of true inventors.⁴³

62. There is no support for Lilly's argument that it is the so-called 'promise doctrine' that precludes a patentee from proving utility with post-filing evidence. As framed, Lilly's argument suggests that there might previously have been the ability to rely on post-filing evidence, which is categorically incorrect. The Canadian law of utility has always required the patentee to have shown utility as at the time of filing; whether a scintilla or in making out the elements of a sound prediction, a patent bargain could not be properly struck if the patent applicant did not have proof or a sound prediction *at the time of filing* that the invention would work as claimed.

63. Permitting reliance on post-filing evidence would stifle innovation as would-be patentees scrambled to file patent applications for any nascent idea, without regard to whether the would-be patentees had a realistic expectation that what was being claimed would work for the intended purpose. Real innovators – those who paid the hard coinage of investment in research and development – would be precluded from benefiting from their work by those who merely make paper inventions with no substantial intellectual or empirical effort.

64. The prohibition on patenting mere speculation is intended to preserve and promote the delicate balance that underpins the patent bargain. If the factual basis and line of reasoning for a prediction is not disclosed in the patent, the patentee will have

⁴³ *AZT* at ¶80, see also ¶37 (CGPA-037).

given nothing in exchange for the monopoly (no ‘hard coinage’), and the patentee’s side of the bargain would be unmet.⁴⁴

b. The proper role of sound prediction in the context of drug development

65. The doctrine of sound prediction is certain, well defined and well understood. While expressed in *AZT*, it was an element of Canadian law before *AZT*.⁴⁵

66. For nearly 15 years, *AZT* has provided a clear and consistent standard by which the validity of patents based on prediction has been assessed. *AZT* reaffirmed the principle that a patent can validly claim a utility that has not yet been demonstrated, but instead is based on prediction. However, *AZT* made it clear that the prediction must be sound and the patent must disclose the factual basis and line of reasoning for the prediction. A patent based on unsupported speculation, or one that fails to meet the disclosure requirements, will be held invalid.⁴⁶

67. In *AZT*, the Supreme Court was careful to note that it is necessary that patents disclose solid, accurate and meaningful teachings. Solid, accurate and meaningful teachings are, of course, the antithesis of speculation.⁴⁷

68. Generic pharmaceutical manufacturers must comply with the requirements of the *NOC Regulations* in order to make lower-cost generic versions of marketed drugs available to the Canadian public. The *NOC Regulations* require a generic manufacturer to serve a Notice of Allegation containing a detailed statement of the legal and factual basis for any allegation of patent invalidity. Accordingly, a clear and consistent standard by which to evaluate the validity of patents is essential to the ability of generic pharmaceutical manufacturers to select appropriate drugs for genericization. The principles expressed in *AZT* are the basis upon which CGPA members assess the validity of many pharmaceutical patents, including those that include assertions of anticipated therapeutic utility.

69. It is not uncommon for patents covering pharmaceuticals to be based on predicted therapeutic utility. Drug development typically includes a preclinical phase, which may include testing in animal models. If the preclinical study results are promising, the drug moves to the clinical phase in which it is tested in humans. An inventor need not await the results of clinical trials demonstrating therapeutic efficacy in humans before filing a patent application. Patent applications for drugs are

⁴⁴ *Atomoxetine FCA*, *supra*, at ¶51 (CGPA-020).

⁴⁵ See *AZT*, *supra*, at ¶61 (CGPA-037), acknowledging that the doctrine of sound prediction had been ‘explicitly received’ into Canadian law in 1979 with the Supreme Court of Canada’s *Monsanto* decision, *supra* (CGPA-027).

⁴⁶ *AZT* at ¶¶70 and 83 (CGPA-037).

⁴⁷ *AZT* at ¶¶69 and 83 (CGPA-037).

routinely filed on the basis of pre-clinical *in vitro* and *in vivo* animal studies. In such a case, therapeutic efficacy in humans is necessarily based on prediction.

70. *AZT* holds that a patent based on prediction can be validly obtained, so long as the prediction is sound (at the time of patent filing) and the factual basis and line of reasoning for the prediction are disclosed in the patent.⁴⁸ If, for example, a patent discloses positive pre-clinical test results in an animal model which can be extrapolated to soundly predict therapeutic efficacy in humans, the patent will not be held invalid for lack of utility (barring evidence of inutility in fact).

71. Sound prediction benefits patentees by permitting the early granting of patents, in circumstances where the utility of the invention has not yet been demonstrated, on the basis of a prediction that the invention will in fact have the stated utility.

72. As noted by the Federal Court of Appeal, if the factual basis and line of reasoning for a prediction is not disclosed in the patent, the patentee will have given nothing in exchange for the monopoly (no ‘hard coinage’), and the patentee’s side of the bargain would be unmet.⁴⁹

c. Canada’s doctrine of sound prediction is in line with treaty obligations

73. The ‘promise of the patent’ and the disclosure requirement in sound prediction are fully compatible with Canada’s existing treaty obligations (TRIPS, NAFTA, etc.). The concept of the promise of a patent is not a newly created ‘doctrine,’ nor do the *AZT* disclosure requirements place Canadian law out-of-step with other jurisdictions.⁵⁰

74. It is neither necessary nor helpful to insist that concepts and principles from other jurisdictions be incorporated into Canadian law. The patent laws of the US, the UK, the European Union (which follows the European Patent Convention) and Japan, to name but a few, differ in significant respects from Canadian patent law.⁵¹ Recent

⁴⁸ *AZT*, *supra*, at ¶70 (CGPA-037).

⁴⁹ *Atomoxetine FCA*, *supra* (CGPA-020).

⁵⁰ See, e.g., Gold, R., and Shortt, M., ‘*The Promise of the Patent in Canada and Around the World*’, 30 CIPR 36 (CGPA-047) and Vaver, D., ‘*Is Canada’s Patent Law Out of Step?*’, Reworked Remarks for University of Toronto 2nd Patent Law Colloquium, November 22, 2013, at 2 (CGPA-049).

⁵¹ The UK employs the ‘worth a try’ test for obviousness, while Canadian courts do not (*Pfizer v. Apotex*, 2009 FCA 8 at 28-9 (CGPA-031)); the US permits reliance on post-filing proof, but Canada does not (*Janssen-Ortho Inc. v Novopharm Limited*, 2006 FC 1234 at ¶113(8) (CGPA-023), aff’d 2007 FCA 217 (CGPA-024), leave denied [2007] SCCA No. 442 (CGPA-025), *In re Zenitz* (1964), 52 CCPA 746 at ¶2 (CGPA-022)); selection patents are no longer part of UK law (*Dr. Reddy’s Laboratories v Eli Lilly & Company Ltd.*, 2008 EWHC 2345 at ¶¶95-109 (CGPA-011), aff’d [2009] EWCA 1362 at ~35-40 (CGPA-012)); methods

efforts to arrive at a uniform global law were abandoned when the goal was seen to be unattainable.⁵² International treaties do not compel or even promote harmonization, but, rather, provide that the laws of the signatory states will differ (expressly so as regards ‘utility’ and ‘industrial applicability’).⁵³ The concept of ‘harmonization’ raises important and related threshold questions involving matters of patent policy. Canadian Parliament alone has the responsibility and authority to make policy decisions respecting the content of Canadian statutory law.

75. The Supreme Court of Canada has expressly acknowledged that legislative reforms in 1993 that led to the promulgation of the *NOC Regulations* were made to bring Canadian patent law in line with TRIPs and NAFTA:

In a reversal of policy, Parliament in 1993 repealed the compulsory licence provisions of the Patent Act by what became known as Bill C-91 (S.C. 1993, c. 2) and extinguished all compulsory licences issued on or after December 20, 1991. In part, these changes flowed from international obligations accepted by Canada under the Agreement on Trade-Related Aspects of Intellectual Property Rights, 1869 U.N.T.S. 299 (“TRIPS”). More immediately, perhaps, it was thought that Canada’s compulsory licensing system would be declared incompatible with Canada’s obligations under the North American Free Trade Agreement, Can. T.S. 1994 No. 2, in particular art. 1709(10), signed at the end of 1992.

However, having agreed to respect the 20-year monopoly granted by patents, Parliament wished to facilitate the entry of competition immediately thereafter. It acted to eliminate the usual regulatory lag of two years or more after expiry of a patent for the generic manufacturer to do the work necessary to obtain a NOC. Parliament did so by introducing an exemption from the owner’s patent rights under which the generic manufacturers could work the patented invention within the 20-year period (“the early working exception”) to the extent necessary

of medical treatment are not patentable in Canada, but are in the USA (*Visx Inc. v Nidek Co.*, (1997), 77 C.P.R. (3d) 532 at ¶6 ([CGPA-038](#)) and *Tennessee Eastman Co. v Commissioner of Patents*, [1974] S.C.R. 111 at 117-9 ([CGPA-036](#))); the differences in utility and construction are discussed in Gold and Shortt, *supra*, generally, and at 60-2, 66, 71 and 74 ([CGPA-047](#)).

⁵² World Intellectual Property Organization, Draft Substantive Patent Law Treaty online: http://www.wipo.int/patentlaw/en/draft_splt.htm.

⁵³ *Marrakesh Agreement Establishing the World Trade Organization*, Annex IC, 15 April 1994, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (TRIPs), Article 1 and 27(1) ([CGPA-045](#)); *North American Free Trade Agreement*, 32 I.L.M. 289 and 605, Article 1709 ([CGPA-043](#)). *Patent Cooperation Treaty*, June 19, 1970, 28 U.S.T. as amended, (‘PCT’) Articles 5, 27(5) and (6) ([CGPA-044](#)). Articles 27(5) and (6) provide that nothing in the PCT shall be construed as limiting the Contracting States’ freedom to prescribe the substantive conditions of patentability, a provision that has been recognized by the Federal Courts - see, e.g., *Atomoxetine FCA*, *supra*, at ¶¶48-50 ([CGPA-020](#)) and *Eli Lilly Canada Inc. v Apotex Inc.*, 2009 FCA 97 at ¶19 ([CGPA-014](#)).

to obtain a NOC at the time the patent(s) expired (s. 55.2(1)) and to “stockpile” generic product towards the end of the 20-year period to await lawful market entry (s. 55.2(2)). In order to prevent abuse of the “early working” and “stockpiling” exceptions to patent protection, the government enacted the *NOC Regulations* that are at issue in this appeal.

The patent owner’s remedies under the *NOC Regulations* are in addition to all of the usual remedies for patent infringement under the Patent Act.⁵⁴

76. To the extent that international harmonization is possible at all with respect to national aspects of patent law, concerns regarding harmonization were considered by Canada’s Parliament in 1993 and, had their efforts failed, one would have expected such failure to be addressed at that time by Canada’s counterparts during these multi-lateral negotiations. Canada became a member to the TRIPS and the NAFTA treaties, which suggests Canada’s trading partners accepted Canada’s efforts toward harmonization as sufficient for membership. Contrary to Lilly’s assertions, Canadian jurisprudence regarding utility as it relates to sound prediction, selection patents, and secondary use patents has not changed that.

2. Potential impact

77. Lilly’s proposal would radically alter the direction of Canadian patent law by tilting the balance between patent protection and timely access to generic medicine heavily toward increased patent protection. The potential legislative or jurisprudential changes that might follow a NAFTA Tribunal finding in favour of Lilly would create uncertainty for generic pharmaceutical manufacturers whose business revolves around assessing and, where appropriate, challenging the validity of patents on pharmaceutical products.

78. Importantly, the Canadian public depends on the steady supply of safe generic drugs to offset the mounting costs associated with prescription medications. The availability of generic drugs in Canada has a very significant effect on drug expenditures in Canada by not only public provincial drug plans and private drug insurance plans, but also by members of the Canadian public not covered by either public or private drug plans.

Conclusion

79. The Canadian patent system is carefully balanced between providing ample patent protection to properly and carefully encourage innovation and providing the

⁵⁴ *Bristol-Myers Squibb Co. v Canada (Attorney General)*, [2005] 1 SCR 533 at ¶¶10-12 (CGPA-009).

Canadian public with useful disclosures in issued patents. In the pharmaceutical sector, the balance is similarly struck between proper protection of patent rights and ensuring timely access to generic medicines.

80. The approach to this issue expressed on this arbitration is not new: patentees who grow accustomed to undisturbed monopolies will do what is necessary to prolong that protection. That is why a patent system must be balanced in the first place. The patent bargain struck with the Canadian public must be paid by the patentee with the hard coinage of novelty, inventiveness and utility. Canadian patentees can obtain the benefit of patent protection for true selection inventions and from secondary use patents, *provided only that they disclose and have demonstrated or can soundly predict*, in the first case, unexpected, substantial and peculiar advantages and, in the second case, a new use.

81. To obtain these follow-on patents, the patentee must *disclose* and explain the difference between what it claims in the second patent and what it previously claimed in the first patent. The CGPA submits that Lilly's attempts to do this with olanzapine and atomoxetine failed, and rightly so.

82. The decisions that are the focus of this arbitration are not a departure from prior jurisprudence. The CGPA agrees that they do no more than 'follow established principles of patent law and the jurisprudence' of the Federal Courts.⁵⁵ Should this Tribunal decide to substantively address Canadian patent law in this arbitration, the CGPA submits this Tribunal should arrive at a similar assessment of Canadian patent law.

All of which is respectfully submitted by the Canadian Generic Pharmaceutical Association, this 12th day of February, 2016, by counsel for the Canadian Generic Pharmaceutical Association:

[signed]

Jonathan Stainsby
Daniel Hynes
Aitken Klee LLP
181 Bay Street, Suite 3350
Toronto, Ontario, Canada, M5J 2T3
Tel: (647) 317-6868
Fax: (613) 695-5854
E-mail: jstainsby@aitkenklee.com
E-mail: dhynes@aitkenklee.com

⁵⁵ Lilly Responding Memorandum of Fact and Law in SCC 33870, October 26, 2010, ¶2 (R-034).