S.C.C. File No. 35562

IN THE SUPREME COURT OF CANADA
(ON APPEAL FROM THE FEDERAL COURT OF APPEAL)

B E T W E E N:

APOTEX INC. and APOTEX PHARMACHEM INC.

Appellants

- and -

SANOFI-AVENTIS and BRISTOL-MYERS SQUIBB SANOFI PHARMACEUTICALS HOLDING PARTNERSHIP

Respondents

- and -

FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE, CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES, CENTRE FOR INTELLECTUAL PROPERTY POLICY, INTERNATIONAL ASSOCIATION FOR THE PROTECTION OF INTELLECTUAL PROPERTY ("AIPPI"), BIOTECANADA AND CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

Interveners

FACTUM OF THE INTERVENER CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES

(Pursuant to Rules 42 and 59 of the *Rules of the Supreme Court of Canada*)

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PART I – OVERVIEW

1. The present appeal invites this Court to consider the concept of "promise" in the context of what it means for an invention to be "useful" under s. 2 of the *Patent Act*.[1]

2. Ascertaining the "promise of the patent" has become inextricably linked with the utility analysis (i.e., demonstration or sound prediction) and the distinct issue of inventorship. Consideration of any one of these concepts cannot be carried out in isolation.

3. The majority of Canada's Research-Based Pharmaceutical Companies ("**Rx&D**") members either own, or are licensed to use, pharmaceutical patents for new and improved therapies, and are the parties most impacted by the issues posed to the Court on this appeal.[2]

4. In recent years, Canadian jurisprudence in relation to utility and "promise" has been transformed into a "hopeless tangle of contradictory approaches"[3] that has particularly impacted the validity of pharmaceutical patents.[4] Patent disclosures are being dissected into heightened "promises" of utility that bear no relation to the principles of purposive construction and this Court's repeatedly stated judicial anxiety to protect genuinely useful inventions[5].

5. Patents for inventions that are "useful" in fact and enthusiastically received by the public and the healthcare community are frequently held to be "useless" for the purpose of patent law and, as a result, invalid. The application of the "promise doctrine" along with the heightened disclosure requirements (of including data and a sound line of reasoning in the patent application), have resulted in an inequitable bargain for patentees who disclose useful inventions but are deprived of their patentability. This approach is a departure from Canada's international treaty obligations[6] and "sounds a highly discordant note"[7] with the patent laws of Canada's major trading partners. This cannot be what Parliament intended.

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[1] *Patent Act*, RSC 1985, c P-4, s 2 [*Patent Act*].
[2] N Siebrasse, "The False Doctrine of False Promise" (2013) 29:3 CIPR 33 at 33-34 (the author determined that 18 of the 20 cases turning on promise of the patent since 2005 involved pharmaceutical patents); Application for Leave to Appeal of Apotex Inc. *et al*., Affidavit of Ryan Baulke, Exhibit "A" attaches a list of 43 pending pharmaceutical patent cases in which patent validity depends, in part, on a determination of "promised utility".
[3] Notice of Application for Leave to Appeal of Apotex Inc *et al*, dated September 30, 2013 at 14.
[4] See *supra* note 2.
[5] *Consolboard Inc v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504, 122 DLR (3d) 203 at 521 [*Consolboard*].
[6] *Paris Convention for the Protection of Industrial Property; Patent Cooperation Treaty*, 19 June 1970, TIAS 8733; 28 UST 7645; 9 ILM 978 (1970) (entered into force 24 January 1978) [*PCT*]; *Patent Act, supra* note 1 at ss. 28.1 and 28.4; *TRIPS infra* note 7; *NAFTA infra* note 7; *Commissioner of Patents v President and Fellows of Harvard*

6. Rx&D asks this Court to reaffirm the statutory basis of patentability and hold that the utility requirement is satisfied if, upon challenge, the patentee can establish that the utility of the claimed invention was demonstrable as of the filing date. In this regard, post-filing evidence of utility should always be admissible as *prima facie* evidence that the invention was capable of industrial application[8] as of the filing date. Reaffirming this concept of utility should bring an end to the exhaustive, pedantic, overly grammatical and often irreconcilable expert testimony over the length and breadth of a patent's "promise" and restore a significant measure of fairness and predictability. Such a reaffirmation would preclude attacks based on inutility without corresponding evidence that the invention is devoid of utility.

7. On the other hand, to accept the Appellants' approach to "promise" and the accompanying utility analysis will perpetuate the unjust and anomalous result that a patent challenger may successfully defeat a useful patent for lacking "promised" utility. Ironically, this then clears the way for the challenger to market a generic medicine for the same utility "promised" in the patent. The time has come for this Court to clarify the concepts of "promise" and utility and to restore a reasonably predictable standard for assessing the utility of patented inventions.

8. The discovery of new therapies is a global endeavour – it is expensive, competitive, time-consuming, and complex. The innovative pharmaceutical industry depends on patents in order to earn the research and investment dollars necessary to fund the high-risk enterprise of bringing new therapies to market. Achieving fairness and predictability within the Canadian patent system in a manner that is harmonized with Canada's international treaty obligations on the key conditions of patentability (i.e., new, useful, unobvious) is vital for Rx&D's members as part of the global community dedicated to bringing the best innovative medicines and vaccines to Canadians in a timely and appropriate manner.

College, [2002] 4 SCR 45 at 12-13 (dissenting opinion of McLachlin CJ, Major, Binnie and Arbour JJ) [*Harvard Mouse*].

[7] *Ibid Harvard Mouse* at 3.

[8] *North American Free Trade Agreement*, Can TS 1994 No 2, 32 ILM 289 (entered into force 1 January 1994) Art 1709(1) [*NAFTA*]; *North American Free Trade Agreement Implementation Act*, SC 1993, c 44, s 3; *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UN TS 299, 33 ILM 1197 (entered into force 1 January 1996) Art 27 and footnote 5 [*TRIPS*].

PART II – QUESTIONS IN ISSUE

9. Rx&D submits that the "promised" utility of a patented invention should be assessed as follows:

(a) The utility of an invention, as promised, must be demonstrable (i.e., capable of industrial application) under s. 2 of the *Patent Act*, as of the filing date.

(b) Post-filing evidence of utility should always be admissible as *prima facie* evidence that the usefulness of the invention was demonstrable at the filing date.

(c) Utility should not be assessed in light of a "promise" unless one is explicitly stated in a patent claim, or necessary to support an inventive step. A scintilla of utility should suffice in all other cases.

(d) Disclosure of the invention and its operation or use as contemplated by the inventor, as required by s. 27 of the *Patent Act*, should not be elevated to the level of "promised utility". The legal requirements of utility and sufficiency under ss. 2 and 27 of the *Patent Act*, respectively, should be kept separate. The validity analysis, including the issue of utility, should proceed on a claim-by-claim basis.

(e) If the utility condition for patentability can be satisfied as proposed above, then the debate on the "promise of the patent" and sound prediction will be simplified in a manner that restores fairness and predictability to the notional bargain between the patentee and the public.

PART III – ARGUMENT

The problem with promise

10. There is one law of utility founded in s. 2 of the *Patent Act*. This provision requires that an "invention" be "new" and "useful". Being "useful" is a "condition precedent" to establishing an invention under the Act.[9]

11. The "utility" requirement was enacted to ensure that patents would only be granted for useful inventions i.e., subject-matter that is capable of industrial application:

[9] *Consolboard*, *supra* note 5 at 527.

> "…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."[10]

12. While it was once rare for patented inventions to be invalidated for lack of utility, allegations of inutility have taken centre stage in many validity challenges in recent years, particularly in the case of pharmaceutical patents.[11] The utility requirement in the *Patent Act* itself, however, has remained unchanged for decades.[12]

13. Patents for pharmaceutical compounds that are: (i) approved by Health Canada; (ii) listed and paid for by Canadian public and private drug plans; and (iii) prescribed by Canadian medical professionals to Canadian patients, are now frequently held to be "useless" for the purpose of patent law. Paradoxically, the challengers of these patents can then proceed to market a competing generic medicine for the same utility that was held to be lacking for the purposes of patent law. This recent trend is due to an overzealous construction of the "promise" that improperly conflates the s. 2 utility requirement with the s. 27(3) disclosure requirements.

14. As stated by this Court, a patentee is *not* required to explain how an invention works, as "[p]ractical readers merely want to know that it does work and how to work it".[13] Utility is not a disclosure requirement.[14] Yet, the jurisprudence is now replete with analyses not about whether the invention has the utility claimed, but whether the "promised" utility was demonstrated or predictable by the filing date in a manner that is fully disclosed in the patent itself.

15. In the pharmaceutical field, new medicines rarely progress through to human clinical trials prior to the filing of a patent application. Thus, the debate, often a battle of experts, between the patentee and the challenger when invalidity is asserted has become a matter of determining the breadth of the "promise".

16. In most cases, the patentee must argue that the "promise" should be narrowly construed to be coextensive with what demonstration or sound prediction was available at the time of filing. The challenger argues that the "promise" should be interpreted in a broad way beyond what was demonstrated or soundly predictable so as to defeat the patent. Ironically, a

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[10] *Teva Canada Ltd v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 SCR 625 at 38 [*Viagra*]; *Apotex Inc v Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 SCR 153 at 53 [*AZT*]; *Consolboard, supra* note 4 at 525.
[11] See note 2 *supra*.
[12] *Harvard Mouse*, *supra* note 6 at 3.
[13] *AZT*, *supra* note 10 at 70.
[14] *Consolboard, supra* note 5 at 526.

challenger's success clears the way to use and profit from the invention for the very utility set out in the patent.

17. Construing the "promise" in the manner proposed by the Appellant is fundamentally inconsistent with purposive construction. The words of the patent disclosure cannot be read and understood acontextually from the claims.[15] "[E]xcessive literalism" and "meticulous verbal analysis" is precisely what purposive construction is intended to avoid.[16]

18. Moreover, the Appellant's approach to "promise" triggers heightened and uncertain disclosure requirements that force reliance on the doctrine of sound prediction which has proven to be an unwieldy instrument for establishing utility. What is predicted to an inventive mind at the date of filing will be less apparent to the skilled, but unimaginative, technician (POSITA). Requiring that a sound prediction be disclosed in the patent to the satisfaction of the POSITA puts the patentability of an invention at the mercy of a non-inventive third party. This cannot have been intended by Parliament to be a prerequisite for patentability.

19. For example, Canadian Patent No. 1,339,132 ("the '132 Patent") for latanoprost, a glaucoma treatment, is a recent casualty of the conflation of promise and heightened disclosure requirements imposed by the doctrine of sound prediction whereby two panels of the Federal Court of Appeal delivered conflicting decisions on the scope of the patent promise.[17] This case illustrates how contradictory approaches applied to the law of promise and utility become determinative of patent validity.

20. In the context of a Section 6 application under the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"), Justice Heneghan of the Federal Court found the '132 Patent valid in the face of challenges based on several grounds, including lack of utility and lack of sound prediction.[18] This decision was upheld by the Federal Court of Appeal.

21. In a subsequent challenge under the *Regulations* by a different generic manufacturer, Justice Heneghan again upheld the validity of the patent on the basis that utility was demonstrated. The Federal Court of Appeal, however, reversed the decision by construing the

[15] Reply Factum of the Appellants Apotex Inc *et al* (August 5, 2014), at 26-35.
[16] *Free World Trust v Électro Santé Inc*, 2000 SCC 66, [2000] 2 SCR 1024 at 44 [*Free World*]; *Whirlpool Corp v Camco Inc*, 2000 SCC 67, [2000] 2 SCR 1067 at 44-45.
[17] *Pharmascience Inc v Pfizer Canada Inc, et al*, 2011 FCA 102, 92 CPR (4th) 301 at 32-37; *Apotex Inc v Pfizer Canada Inc, et al*, 2011 FCA 236, 95 CPR (4th) 193 at 21-55 [*Latanoprost FCA*].
[18] *Pfizer Canada Inc, et al and Apotex Inc, et al*, 2010 FC 447, 84 CPR (4th) 1.

patent to include a "promise" that latanoprost worked in *chronic* treatment of glaucoma. This promise was implied by the Court of Appeal from the chronic nature of the disease state itself:

> "…this claimed utility, correctly construed, means that chronic use of Latanoprost will (reduce interocular pressure without causing substantial ocular irritation): glaucoma is a chronic disease, the management of which requires chronic treatment."[19]

22. The Federal Court of Appeal then held that the data disclosed in the '132 Patent was insufficient to demonstrate or soundly predict the chronic use of latanoprost on a long-term basis as of the Canadian filing date, notwithstanding that post-filing clinical trials confirmed the claimed utility.[20] A similar "promise" construction based on chronic disease state was applied to invalidate a patent for the drug atomoxetine, despite the fact that it is approved to be a useful drug for the treatment of attention deficit hyperactivity disorder (ADHD).[21]

23. Latanoprost and atomoxetine both illustrate how construing heightened and implicit "promises" push otherwise demonstrably useful inventions into the realm of sound prediction. Having then failed to run sufficient studies in humans to establish chronic use at the time of filing, patents for useful pharmaceutical inventions were invalidated for failing to disclose a sufficient factual basis and sound line or reasoning to support the heightened and implicit promise of chronic use.

24. Legitimate inventors of novel therapies are severely prejudiced under the current Canadian regime. Since clinical trials take several years to conduct, the inventor is left to rely on the sound prediction doctrine. However, the inventor cannot know the extent of further experimentation required to obtain data which would be free of criticism by the POSITA for failing to form the basis of a sound prediction.

25. Moreover, while carrying out further work before filing a Canadian application to reach some apparently necessary, yet unspecified endpoint, the statutory novelty bar is running against the inventor in Canada. If the Canadian patent application is different from the international application, the inventor will be deprived of the benefit of the international priority date.[22] The inventor may not be in a position to meet the current Canadian utility requirements prior to a

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[19] *Latanoprost FCA, supra* note 13 at 13 and 28.
[20] *Ibid* at 21-55.
[21] *Eli Lilly and Company v Teva Canada Limited*, 2011 FCA 220, 94 CPR (4th) 95 at 18-43, 46-51 [*Atomoxetine FCA*].
[22] *Patent Act, supra* note 1 at s 28.1.

novelty destroying disclosure, such as the conduct of clinical trials, or in the limit case, when the first international patent application is published, and lose his/her patent entitlement in Canada.

26. Accepting the approach for establishing utility proposed by Rx&D (i.e., utility must have been demonstrable as of the patent filing date) would avoid the interminable, exhaustive, and ultimately unpredictable determination of the length and breadth of a patent's "promise" and restore a significant measure of fairness and predictability. While conducting the validity analysis, including the issue of utility, on a claim-by-claim basis is intended in the language of the *Patent Act*, the concept of "promise of the patent" ignores the reality that patent applications are prosecuted and issued by examining the claims individually.

A solution: "demonstrable" utility as of the filing date

27. The utility requirement should be satisfied if, upon challenge, the patentee can establish that as of the filing date the claimed invention could have been proven to be useful in fact.

28. There is a well-established history of accepting post-filing evidence of patent utility in Canadian law, including evidence that the impugned invention satisfied an unmet need and was well-accepted by the public:[23]

> "Further, '[e]vidence as to utility may be found in the reception of the invention by the public. Enthusiastic reception by those to whom it is directed will tend to indicate that the invention is useful".[24]

29. Such evidence concerning the public's reception of the invention would not be available until after the filing date of the patent, at the earliest, lest the patent be invalid for anticipation.

30. This approach is consistent with section 38 of the *Patent Act* which provides that the Commissioner of Patents, presumably in cases of doubt as to whether the invention meets the represented utility, is statutorily empowered to call for samples of the composition of matter (e.g. a medicine) and conduct appropriate experiments.[25] It would be anomalous if the Commissioner of Patents is statutorily entitled to accept post-filing evidence of utility to grant a patent, but the courts are required to ignore it when faced with a judicial challenge to an issued patent.

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[23] *Wright v Brake Service Limited* [1925] Ex CR 127 at 6-7; *Cochlear Corp v Cosem Neurostim Ltee* [1995] 102 FTR 81, 64 CPR (3d) 10 at 41-41; Stephen J & T Andrew Currier, *Canadian Patent Law* (Markham: LexisNexis, 2012) at §7:12.
[24] *Viagra, supra* note 10 at 41.
[25] *Patent Act*, *supra* note 1 at s 38; *Apotex Inc. v. Wellcome Foundation Ltd*., [2001] 1 FC 495, 10 CPR (4th) 65 at 50-52, 93, rev'd by *AZT supra* note 10 [*AZT FCA*].

31. This approach is also consistent with the prospective notion of "contemplation" found in s. 27(3) of the *Patent Act* which requires that the inventor describe the invention and its operation or use as "contemplated"[26] by the inventor and not as "demonstrated" or "soundly predicted" by the inventor.

32. Nevertheless, a number of lower courts have rejected post-filing evidence of utility by interpreting this Court's 2002 decision in *AZT* as standing for the rigid proposition that such evidence can never be considered unless explicitly contained within the patent. With respect, this is not what Parliament intended.

33. In *AZT*, this Court held that utility must have been demonstrated or soundly predicted as of the filing date as a condition precedent to the existence of invention.[27] Lower courts have added to this principle by requiring that a factual basis and line of reasoning supporting the sound prediction must be disclosed in the patent.[28]

34. The requirement that utility must exist as of the filing date should not preclude the relevance of post-filing evidence. Rather, post-filing evidence that an invention is useful in fact is *prima facie* evidence that the same invention was also useful at the time of filing.

35. The U.S. system is of particular interest since its statute mirrors the language of s. 2 of the *Patent Act* and similarly provides that an invention must be "new and useful" as a condition precedent to patentability.[29] In the U.S., post-filing evidence "…can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification. (i.e., demonstrated utility)".[30]

The future of sound prediction

36. How will the admissibility of post-filing evidence impact the doctrine of sound prediction? Establishing that an invention was demonstrable at the time of filing will largely obviate the need for the sound prediction test. Sound prediction may still have a place, however,

[26] *Ibid Patent Act* at s 27(3).
[27] *AZT*, *supra* note 10 at 78-79.
[28] See for e.g., *Eli Lilly Inc v Apotex Inc*, 2008 FC 142, 63 CPR (4th) 406 at 153-178 aff'd 2009 FCA 97, 78 CPR (4th) 388 at 11-19; *Atomoxetine FCA*, *supra* note 17 at 47; *Latanoprost FCA*, *supra* note 13 at 43-44.
[29] 35 USC 101; *Harvard Mouse*, *supra* note 6 at 3.
[30] *In re Brana*, 51 F 3d 1560 at 1567 footnote 19; J Erstling, "Usefulness Varies by Country" (2012) 3:1 Cybaris, An Intellectual Property Review.

in instances where the utility of the invention has not, or cannot, be demonstrated at the time of patent challenge.

37. The doctrine of sound prediction, as conceived by this Court, appears to have been aimed at preventing the patenting of "mere speculation", "research projects" or a "lucky guess". At the same time, the doctrine was intended to promote the early disclosure of new and useful inventions, even though their utility had not been verified by tests (which the Court in *AZT* acknowledged may take many years in the case of pharmaceutical products).[31]

38. As subsequently applied and interpreted by the lower courts over the years, however, experience has shown that the sound prediction test has proven far too blunt an instrument to achieve the intended aim without extensive collateral damage. Rather, it has operated far more frequently to disentitle inventors of patents for legitimately useful inventions. The current application of the "promise" and sound prediction doctrines is problematic because it treats useful inventions as "useless" and overshoots the aim of preventing the patenting of "mere speculation".

Conflation of utility and inventorship

39. The popular perception of the lower courts is that *AZT* changed the utility requirement. In fact, what the Court did in *AZT* was change the definition of "invention" by requiring that an "invention" have been demonstrated or soundly predicted as of the filing date.

40. To avoid patents based on "mere speculation", U.S. jurisprudence adopted an approach that requires an inventor to have conception and a "good faith" belief before inventorship can be satisfied. This means that the invention must have been reduced to practice, which could include a written description, all of which is established by corroborating evidence of the inventor (e.g. lab book entries).[32] This is a separate condition of patentability distinct from the satisfaction of the utility requirement.

41. Such an approach, which considers evidence of the inventor's conception and good faith belief, recognizes the quality of inventorship that is a prerequisite to having an "invention" and avoids the patenting of "mere speculation".

[31] *AZT*, *supra* note 10 at 66.
[32] *Burroughs Wellcome Co v Barr Laboratories, Inc*, 40 F 3d 1223 (CA) at 1228; *AZT FCA*, *supra* note 25 at 30-33.

Conclusion

42. Rx&D submits that "there is a high economic cost attached to uncertainty and it is the proper policy of patent law to keep it to a minimum."[33] Elusive "promises" and heightened disclosure requirements offend the bargain theory and should not form part of the utility analysis in Canada. Evidence that the invention is useful in fact, is consistent with the *Patent Act* and policy and restores the fairness and reasonable predictability that are sorely lacking from the utility inquiry, as presently interpreted in Canada. The law of utility must remain grounded in s. 2 of the *Patent Act* and be interpreted in light of the principles of predictability and fairness.

43. The bargain underpinning the patent system should not be made hollow once society has obtained disclosure and reaped the fruits of a useful invention.

PART IV - SUBMISSIONS ON COSTS

44. Rx&D does not seek costs and agrees to pay any additional disbursements occasioned to the appellants and respondents by its intervention.

PART V – ORDER SOUGHT

45. Rx&D respectfully requests the following additional relief:

(a) an order granting Rx&D leave to make oral submissions for no more than 10 minutes; and

(b) such further and other relief as this Court may deem just.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 16th day of September, 2014.

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[33] *Free World, supra* note 16 at 42.

PART VI - TABLE OF AUTHORITIES

Case	Para. Ref.
Patent Act, RSC 1985, c P-4.	1, 5, 9, 10, 12, 25, 26, 30, 31, 35, 42
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