In the Arbitration under the Arbitration Rules of the United Nations Commission on International Trade Law and the North American Free Trade Agreement

(Case No. UNCT/14/2)

ELI LILLY AND COMPANY

Claimant

v.

GOVERNMENT OF CANADA

Respondent

EXPERT REPORT OF PROFESSOR NORMAN V. SIEBRASSE

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I. Introduction

A. Background and Qualifications

1. I am a Professor of Law at the University of New Brunswick, in Fredericton, New Brunswick. I reside in Fredericton, New Brunswick. I teach in the areas of intellectual property law, commercial law and remedies. My academic research focuses on patent law, in particular pharmaceutical patent law, patent law remedies, and the intersection of patent law and commercial law. My academic articles are regularly cited by the Canadian courts, including the Supreme Court of Canada. Attached as Appendix A is my curriculum vitae. I occasionally consult on matters within my area of expertise. I have recently consulted for Apotex Inc, a generic pharmaceutical manufacturer, in the remedial stage of its litigation with Merck regarding the drug lovastatin.[1] I have also recently consulted for Industry Canada on the treatment of intellectual property rights in insolvency.

2. I have been asked by counsel for Eli Lilly and Company ("Lilly") to provide an overview of the requirements for obtaining a patent in Canada, to describe the law of utility in Canada both at the time Lilly's Strattera and Zyprexa patents were filed and granted, and at the time they were held to be invalid, and to describe the legal consequences of the current law of utility in Canada. I confirm that I have no other relationship to Eli Lilly and Company or any of its affiliates.

B. Overview of Patent Law in Canada

(i) Purpose of Patent Rights

3. Patent rights in Canada are wholly a creature of statute: "An inventor gets his patent according to the terms of the *Patent Act*, no more and no less."[2] The grant of a patent for an invention provides the patentee with exclusive rights over the exploitation of the invention[3] for a limited term.[4] The purpose of the patent system is to promote the public good by providing an incentive for the creation and disclosure of new inventions.[5] By giving an inventor exclusive rights to exploit the invention, the reward to the inventor is made commensurate with the social benefit of the invention. This means that patents give the inventor a strong incentive to invest in research in areas which the inventor believes will lead to commercially and socially valuable inventions.

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1 The trial decision is reported at *Merck & Co, Inc v Apotex Inc.* 2013 FC 751 (C-193). I also consulted in respect of Apotex Inc's appeal to the Federal Court of Appeal.

2 *Apotex Inc v Sanofi-Synthelabo Canada Inc,* 2008 SCC 61, ¶ 12, [2008] 3 SCR 265, 69 CPR(4th) 251 [Sanofi] (C-196); aff'g 2006 FCA 421, 59 CPR(4th) 46, aff'g 2005 FC 390, 39 CPR(4th) 202 [*Sanofi*], quoting with approval *Commissioner of Patents v Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] SCR 49, 57 (C-212).

3 *Patent Act*, RSC, 1985, c P-4, s 42 [*Patent Act* or the Act] (C-50).

4 The term of a patent is 20 years from the filing date: *Patent Act*, *ibid* s 44.

5 *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, ¶ 32, [2012] 3 SCR 625, 106 CPR(4th) 161, rev'g 2010 FCA 242 rev'g 2009 FC 638 [*Viagra*] (C-197); *Apotex Inc. v Wellcome Foundation Ltd.,* 2002 SCC 77, ¶ 37, [2002] 4 SCR 153, 21 CPR (4th) 499, var'g (2000) [2001] 1 FC 495, 10 CPR (4th) 65 (FCA) var'g (1998) 79 CPR (3d) 193, 1998 CanLII 7610 (FC) [*Wellcome / AZT*] (C-213).

4. The patent system is often described as a bargain or contract between society and the inventor. The consideration provided by the patentee is twofold: there must be a new, useful and non-obvious invention; and the patentee must give this invention to the public by adequately describing it. In return, the patentee is given a limited period of exclusive rights to the invention.[6]

(ii) Patentability Requirements

5. The first part of the patent bargain is that the patentee must have produced an invention that is new, useful, and involves an inventive step.[7]

6. The requirement that an invention be new is also referred to as a requirement of novelty, and an invention that is not new is said to be anticipated. The requirement of novelty is intended to ensure that exclusive rights are not granted for inventions which already exist. Canada has a world-wide novelty requirement, which is to say that if the invention was previously known anywhere in the world, it will not be patentable in Canada.

7. The requirement of an inventive step is now usually referred to as the requirement of non-obviousness.[8] An invention that does not meet this requirement is said to be obvious. The purpose of the non-obviousness requirement is to ensure that patents are not granted for new developments which emerge easily simply as the result of the general progress of technology.[9]

8. The requirement that an invention be useful is also referred to as the utility requirement. The utility requirement is the main focus of my report and is discussed in detail below in Section II.

(iii) Claims and Disclosure

9. The second part of the patent bargain is that the patentee must adequately describe the invention. There are two parts to this requirement: first, the patent must allow others "to ascertain with some measure of exactness the boundaries of the exclusive privilege upon which they may not trespass during the exercise of the grant"[10]; and second, it must describe the invention sufficiently that a person skilled in the relevant field could carry out the invention once the period of exclusivity has expired. In short, the patent must both define and describe the

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6 *Consolboard Inc. v MacMillan Bloedel (Saskatchewan) Limited,* [1981] 1 SCR 504, at 517, 56 CPR(2d) 145 rev'g (1979) 41 CPR(2d) 94 (FCA) rev'g (1978) 39 CPR(2d) 191 (FCTD) [*Consolboard*] (C-118); *Pioneer Hi-Bred v Canada (Commissioner of Patents),*[1989] 1 SCR 1623, at 1636 [*Pioneer Hi-Bred*] (C-198).

7 *Patent Act*, *supra* note 3, s 28.2, s 2 definition of "invention", and s 28.3, respectively.

8 The requirement was codified in 1993 in s 28.3 of the *Patent Act*, *supra* note 3, (C-50) as requiring that the subject matter of the invention must not have been "obvious." Prior to that time, it was more usual to refer to the requirement of an "inventive step." The terms "obvious" and "non-obvious" are now used almost exclusively.

9 *Graham v John Deere Co*, 383 US 1, 17 (1966) (C-199).

10 *Consolboard, supra*, note 6, at 517 (C-118); *Pioneer Hi-Bred*, *supra*, note 6, at 1636 (C-198); and similarly *Mailman v Gillette Safety Razor Co. of Canada Ltd.*,[1932] SCR 724, at 729 [*Mailman*] (C-200).

invention. These two functions are carried out by distinct parts of the patent specification, the claims and the disclosure.[11]

10. The claims define the scope of the exclusive rights granted by the patent.[12] Consequently, it is the invention as claimed which must meet the substantive patentability requirements.[13] Multiple claims are often asserted in a single patent. It is common that only some of the claims of a particular patent are challenged in litigation. It is nonetheless common to speak of "the patent" being invalid as a shorthand meaning that the key claims were held to be invalid.

11. Precision is required in drafting the claims in order to define the scope of the exclusivity, because a patent that claims too broadly will be invalid, while one which claims too narrowly will not adequately protect the invention.[14] Disclosure, on the other hand, requires a fulsome description in order to allow others to make use of the invention at the end of the term, and build on the knowledge disclosed even during the term. The two parts of the specification, the claims and the disclosure, therefore have very different functions, "delimitation of the invention, and full practical directions how to use it [which] are in their nature almost antagonistic."[15]

12. Claims originated to resolve this tension. Patents were originally granted on the basis of a general description, without claims, which served to both "describe and ascertain" the invention. This was a problem for the public, which was not given clear notice of the scope of the exclusivity. It was also a problem for the patentee, as the patent might be held invalid for claiming old subject matter if a court construed the descriptive aspects as defining the scope of the exclusivity. Claims were therefore originally introduced "for the security of the patentee, that he may not be supposed to claim more than what he can support as an invention" in his efforts to make full disclosure.[16]

13. In the pharmaceutical context, several types of claims are permissible. A patent may claim the pharmaceutical compound itself, or a process for making that compound, or both. A patent may claim individual compounds, or a broad class of related compounds, often referred to as a "genus." A particular formulation of a compound may be claimed, such as a slow release formulation consisting of a compound in combination with a slow-release coating. A particular use of a known compound may also be claimed, as for example the claim to the use of AZT for the treatment of HIV / AIDS.[17] The right to market a particular drug product may be covered by

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[11] See *Patent Rules*, SOR/96-423, s 2 definition of "description." (C-51). Prior to 1996 "the part of a specification other than the claims," was defined to be the "disclosure." The term was changed to "description" (though the definition itself was unchanged) in 1996. The term "disclosure" is still commonly used. Nothing turns on the terminology.

[12] *Patent Act*, *supra* note 3, s 27(4) (C-50).

[13] *Mailman*, *supra* note 10, at 730-31 (C-200).

[14] See *Burton Parsons Chemicals, Inc v Hewlett-Packard (Canada) Ltd,,* [1976] 1 SCR 555, at 565, 17 CPR(2d) 97 rev'g [1973] FC 405 (CA), 10 CPR(2d) 126 aff'g 7 C.P.R. (2d) 198 (FCTD) [*Burton Parsons*] (C-201).

[15] *British United Shoe Machinery Company Ld v A Fussell & Sons Ld* (1908), 25 RPC 631, at 650 (CA) (C-202).

[16] *Kay v Marshall* (1836), 2 WPC 36, 40 ER 418, 423 (C-203).

[17] See *Wellcome / AZT, supra* note 5 (C-213).

more than one type of claim, which may be found in the same patent, or in different patents. For example, a slow-release formulation of a particular drug product may be covered by a compound claim to the individual compound itself, a process claim to the method of making the compound, and a claim to the slow-release formulation.

14. It is common to refer to any patent which effectively protects market exclusivity for a product as being a patent "for" that product. So, for example, Canadian patent 2,209,735, which is at issue in this arbitration, claims the use of atomoxetine for treating attention-deficit/hyperactivity disorder ("ADHD").[18] Atomoxetine is the active pharmaceutical ingredient in the drug product sold by Lilly under the Strattera brand name. Canadian patent 2,041,113, also at issue in this arbitration, claims the compound olanzapine, as well as olanzapine for the treatment of schizophrenia, which is sold by Lilly under the Zyprexa brand name. The patent is commonly referred to as a "selection" patent, in that an earlier patent claimed a broad class of compounds (a "genus") that included olanzapine.

15. The disclosure, which is the part of the specification before the claims, includes a description of the technical background to the invention and the problem faced by the inventor, as well as a description of the invention itself and means of carrying it out.[19] In Canadian law the requirement to adequately describe the invention is normally referred to as the "disclosure" requirement, or the requirement for "sufficiency" (referring to "sufficient" disclosure). A patent that fails to sufficiently disclose the invention will be invalid.

II. Law of Utility In Canada

A. Overview

16. In the period from 2002 to approximately 2008, the substantive, evidentiary and disclosure aspects of the Canadian law of utility changed dramatically. Under prior law, utility was assessed against an objective standard, set by the Act, and the threshold for utility was low: "very little will do."[20] It is convenient to refer to this traditional standard as the "mere scintilla" test.[21] Compounds that had not been made or tested could still satisfy the utility requirement, based on a "sound prediction" of utility. While the invention had to meet the utility requirement at the time of filing of the patent application, post-filing evidence was admissible to establish utility, as it was (and remains) for other patentability requirements, such as non-obviousness. So, if a pharmaceutical was actually being used to treat a particular disease at the time of litigation, the courts would accept that as conclusive evidence that it would have been useful in treating that

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[18] The patent refers to "tomoxetine" rather than "atomoxetine." These terms are synonyms. This report will use the latter term, as it is used in the litigation.

[19] *Patent Act*, *supra* note 3, s 27(3) (C-50); *Patent Rules*, *supra* note 11, s 80 (C-51).

[20] *Otto v Linford* (1882), 46 LT (NS) 35, 41 (CA), quoted by Estey J in *Wandscheer et al. v Sicard Ltd.*, [1948] SCR 1, at 24, 8 CPR 35 aff'g [1946] Ex CR 112, (1944) 4 Fox Pat C 43, 4 CPR 5 [*Wandscheer*] (C-204 and C-42).

[21] The term "mere scintilla" is the term used by the courts post-2005 to explain the standard required by the Act, though the term was not used in the jurisprudence prior to 2005. In my academic writing, I have used the term "actual utility", to denote the standard of utility required by the Act (i.e., a "mere scintilla"). Regardless of whether "mere scintilla" or "actual utility" is used, this is meant to refer to the standard of utility and not to the evidence needed to show the standard was met.

disease at the time of filing. By the same token, there was no requirement to disclose evidence establishing the utility of the invention in the patent; the fact that the invention could be shown to be useful when challenged was enough.

17. By contrast, under the current law, the standard for utility now has two branches: the mere scintilla test and the "promise" branch. The "promise" branch is an extra-statutory requirement in addition to the utility required by the Act, in the sense that a mere scintilla of utility will not suffice if the patent is held to promise more. The promise of the patent turns on the wording of the patent in question, not on the statutory standard. Construction of the promise of the patent is now a central feature in any litigation in which utility is raised, and it typically requires expert evidence. Post-filing evidence is no longer admissible to establish utility of the invention, regardless of whether utility is assessed by reference to the mere scintilla test or the promise of the patent.[22] Where utility cannot be demonstrated at the date of filing, the patentee will only be entitled to rely on a sound prediction of utility if the evidence in support is disclosed in the patent itself. The various aspects of the current law of utility interrelate, and they may be collectively referred to as Canada's "Promise Utility Doctrine."[23]

18. Each of these changes in isolation would have made it easier to challenge a patent for lack of utility. Taken together, they are frequently fatal to validity, particularly in the pharmaceutical sector, as a potential response to one element of the doctrine is blocked by another element, magnifying the cumulative impact.

19. In summary, assessing utility by reference to the "promise" has substantively raised the standard for utility while at the same time, the elimination of the ability to rely on post-filing evidence has made it substantially more difficult to establish utility, based on any standard. Canadian courts now impose a high evidentiary burden to show that utility was demonstrated at the date of filing, making it necessary for patentees to assert that utility was "soundly predicted." However, under the current law, evidence to establish that utility was soundly predicted must be disclosed in the patent itself, notwithstanding that this requirement did not exist and could not have been anticipated at the date the patent was filed.

B. Utility at Date of Filing/Examination of Zyprexa and Strattera Patents

(i) Utility Standard

20. The fundamental characteristic of the mere scintilla branch of the utility requirement is that the standard for utility is measured objectively, against the requirement set out by the Act. The requisite standard under the Act is low. Traditionally it was said that a "slight

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22 *Wellcome / AZT, supra* note 5, ¶ 46 (C-213).

23 I have treated two aspects of the Promise Utility Doctrine in my academic writing, namely "The False Doctrine of False Promise," (2013) 29 Can IP Rev 3-56 (C-205), dealing with the substantive aspect, which I referred to as the "promise doctrine," and "Must the Factual Basis for Sound Prediction Be Disclosed in the Patent?" (2012) 28 Can IP Rev 39-80 (C-206), dealing with the disclosure aspect, which I referred to as the "factual basis" requirement, or the "*raloxifene* doctrine" (after the case establishing the disclosure requirement). Lilly has referred to as the law of utility in all of its aspects as currently applied by the courts as the "Promise Utility Doctrine", which is a convenient phrase to describe the law pertaining to utility as applied in a given case.

amount" of utility is sufficient,[24] or "very little will do,"[25] while, as noted, more recently it has become standard to say that a "mere scintilla" of utility is sufficient.[26]

21. The mere scintilla standard is illustrated by the 1948 decision of the Supreme Court of Canada in *Wandscheer v Sicard*.[27] The invention concerned a snowblower, of a now familiar design, in which the inventive feature was a rotating ejector pipe allowing the snow to be thrown in a range of directions.[28] While the *concept* of a rotating pipe was disclosed, the patentee actually used a right-angled stovepipe bend, with the result that the snow would pack up at the sharp corner and clog the pipe. The patentee did not realize that a gradual parabolic bend was needed.

22. The Supreme Court of Canada held the patent invalid for lack of utility. Tashereau J (for himself and the Chief Justice) said:

> The informations given by [the patentee] in his specifications, as to the operativeness of his rotating ejector are more than meagre. He has merely disclosed the bare idea of a chimney throwing the snow in various directions. We find no explanation as to how it will function and it is, as it has been said before "obviously suggestive of experimental or research work." As McLean J. said in *Christiani v. Rice* "The patentee is not to tell a man to make an experiment, but to tell him how to do the thing."[29]

Similarly, Rand J stated:

> On what is before us, I must hold that at best what [the patentee] presented to the public was both the idea and the task of working it out. In the language of Lindley L.J. in *Lane-Fox v. Kensington and Knightsbridge Electric Lighting Co.*.
>
> > An invention may be useful as indicating the direction in which further progress is to be expected, and yet that same invention may be useless for any other purpose; useless, that is, as an invention without further developments and improvements which have not occurred to the patentee.[30]

As the emphasized passages indicate, the purpose of the utility requirement is to ensure that patents are not granted for inventions where the award of the patent would stifle further research by competitors without having delivered a commensurate benefit. On the facts in *Wandscheer*, the patentee was asserting a patent for an invention that was not "susceptible of fulfilling its

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24 *Prentice v Dominion Rubber Co* [1928] Ex CR 196, at 199 (Ex Ct) (C-207); *Asten-Hill Ltd v Ayers Ltd*, [1939] 2 DLR 234, at 246 (Ex Ct) (C-208).

25 *Otto v Linford supra* note 20, at 41 quoted by Estey J *Wandscheer supra* note 20, at 24 (C-204).

26 See eg *Aventis Pharma Inc v Apotex Inc,* 2005 FC 1283, 43 CPR (4th) 161, ¶ 271 (C-209).

27 *Wandscheer, supra* note 20 (C-42).

28 *Ibid* at 4 (C-42). There were two patents at issue, the Wandscheer patent and the Curtis patent ("Snow Remover," Can Patent No CA 253159). The Court briefly affirmed that the Wandscheer patent was invalid for obviousness; the Court's decision, and this discussion, focuses on the Curtis patent.

29 *Ibid*, at 5 (C-42).

30 *Ibid* at 10 [emphasis added, citations omitted] (C-42).

purpose" and had never in fact been used, against a defendant, Sicard, who had developed a practical machine by independent work and ingenuity.[31]

23. In practice, because of the low standard for utility under the mere scintilla test, inventions held to lack utility were typically wholly "inoperable." For example, in one case a "Mr X," who was reluctant to divulge his true identity, claimed to have invented a "death ray," which would use a laser to kill at a distance. While this concept is not fantastical, Mr X had not constructed such a device, and on the evidence, the device he described would not have worked even if the funds had been raised to build it. The patent was consequently held invalid for lack of utility.[32] Similarly, until the laws of physics are fundamentally revised, any application for a patent for a perpetual motion machine will be rejected as lacking utility.[33]

24. To summarize, the requirement of a mere scintilla of utility set an objective standard requiring that the claimed invention be capable of some practical result, but the standard was very low – a "scintilla" or "very little" utility would do. Consequently, in practice the utility requirement would normally be applied to invalidate a patent only in the case of fanciful or inoperable inventions.

(ii) Evidence of Utility

(1) Sound Prediction

25. It is not necessary to have made or tested all structurally similar chemical compounds in a class of compounds claimed by a patent, if the utility of the untested compounds can be soundly predicted. This is known as the doctrine of sound prediction.

26. The ability to rely on a sound prediction to establish utility was explicitly recognized by the Supreme Court of Canada in *Monsanto Co. v. Commissioner of Patents*,[34] and was subsequently applied in by the Federal Court of Appeal in its 1982 decision in *Ciba-Geigy AG v Commissioner of Patents*.[35] Both cases dealt with the ability to claim a class of compounds where only a few of the compounds had been tested.

27. For example, in *Monsanto* the claim at issue was to 126 specifically listed compounds used to inhibit premature vulcanization of rubber. Only three of these substances had actually been prepared and tested. Following the general trend of the prior cases, the Patent Office had rejected the claims as being speculative without any evidence to that effect. The

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31 *Ibid* at 4, 5 (C-42).

32 *X v Commissioner of Patents* (1981), 59 CPR (2d) 7 (FCA) (C-210).

33 *Otta v Canada (Patent Commissioner)* (1979), 51 CPR (2d) 134 (PAB) aff'd 51 CPR (2d) 139 (FCA) (C-211).

34 *Monsanto Co. v Commissioner of Patents* [1979] 2 SCR 1108, 42 CPR(2d) 161 rev'g 34 CPR(2d) 1 (FCA) [*Monsanto*] (C-61), cited with approval in *Wellcome / AZT , supra* note 5, ¶ 61, (C-213) as explicitly receiving the doctrine of sound prediction into Canadian law.

35 *Ciba-Geigy AG v Commissioner of Patents.* (1982), 65 CPR(2d) 73, at 78 (FCA) [*Ciba-Geigy*] (C-44), cited in *Wellcome / AZT , supra* note 5, ¶ 63, (C-213) as being an application of the doctrine.

Supreme Court reversed, saying that "in order to succeed, such attack will have to be supported by evidence of lack of utility."[36]

28. Sound prediction often is relied on to claim a broad class of structurally similar compounds (known as a "genus") that are expected to have similar properties. If the patentee were entitled to claim only the compounds that it had actually tested, competitors would be able to take advantage of the patentee's inventive insight without infringing the patent simply by making a closely related compound that is not claimed in the patent.[37]

(2) Post-Filing Evidence

29. In Canadian patent law, utility must be assessed with respect to the invention as disclosed and claimed at the time of filing.[38] However, it is a distinct question as to whether post-filing evidence – evidence generated after the filing of the patent application – may be used to assess utility.

30. From the earliest Canadian cases until 2002, post-filing evidence was routinely used in assessing the utility of an invention.[39] The most common form of post-filing evidence used to establish utility was the commercial use of the invention. While commercial success was never required to establish utility,[40] if the invention as claimed had become a commercial success, this was considered good evidence of utility on the view that a useless invention could not be commercially successful.[41]

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[36] *Monsanto, supra* note 34, at 1122 (C-61).

[37] See *Monsanto, supra* note 34 , at 1113-4 (C-61); *Burton Parsons, supra* note 14 , at 565 (C-201).

[38] Utility is assessed as of the Canadian filing date, even if priority has been claimed to an earlier foreign application: *Aventis Pharma Inc v Apotex Inc,* 2006 FCA 64, 46 CPR(4th) 401, ¶ 30 aff'g 2005 FC 1283, 43 CPR(4th) 161, ¶ 91-96 (C-214); *Pfizer Canada Inc v Apotex Inc,* 2007 FCA 209, ¶ 153 (C-215); *Eli Lilly Canada Inc. v Novopharm Limited,* 2010 FCA 197, ¶ 82, 85 CPR(4th) 413, rev'g 2009 FC 1018, 78 C.P.R. (4th) 1 [*Olanzapine (No 1)*] (C-46).

[39] The courts did not distinguish between pre- and post-filing evidence, but it is normally possible to determine from the facts whether the evidence actually relied on was post-filing evidence.

[40] *Mullard Radio Valve Company Ltd v Philco Radio and Television Corporation of Great Britain Ltd.* (1935), 52 RPC 261, at 287 (C-216).

[41] *Wright and Corson v Brake Service Ltd*, [1925] Ex CR 127, at 131, aff'd [1926] SCR 434 (C-300); *Prentice v Dominion Rubber Co*, *supra* note 24, at 199 (C-207); *Asten-Hill Ltd v Ayers Ltd*, *supra* note 24, at 246 (Ex Ct) (C-208); *Langlois v Roy*, [1941] Ex CR 197, at 203, 1 CPR 63, at 66-67 (C-217); *Reliable Plastics Ltd v Louis Marx & Co*, [1956-60] Ex CR 257 (Ex Ct), (1958), 29 CPR 113, at 119 (C-218); *Unipak Cartons Ltd. v Crown Zellerbach Canada Ltd*, (1960) 33 CPR 1, at 9-10, 38-39, [1956-1960] Ex CR 396 (C-219); *McPhar Engineering Co of Canada v Sharpe Instruments Ltd* (1960), 35 CPR 105, at 128, 140 [*McPhar Engineering*] (C-220); *CH Boehringer Sohn v Bell-Craig Ltd*, [1962] Ex CR 201, at 204-05, 39 CPR 201, [*Boehringer*] aff'd [1963] SCR 410, 41 CPR 1 (SCC) (C-221); *Jamb Sets Ltd v Carlton*, [1964] Ex CR 377, at 387 (C-222); *Ernest Scragg & Sons Ltd v Leesona Corp* (1964), 45 CPR 1, at 89 (Ex Ct) [35] (C-223); *Omark Industries (1960) Ltd v Gouger Saw Chain Co* (1964), 45 CPR 169, at 223 (Ex Ct) (C-224); *Canadian Patent Scaffolding Co v Delzotto Enterprises Ltd*, (1978) 42 CPR(2d) 7, at 21 (FCTD) (C-225); *Gorse v Upwardor Corp* (1989), 25 CPR(3d) 166, at 183 (FCTD) (C-226); *Energy Absorption Systems Inc v Y Boissoneault & Fils Inc* (1990), 30 CPR(3d) 420, at 459 (FCTD) (C-227); *Cochlear Corp v Cosem Neurostim Ltée* (1995), 64 CPR(3d) 10, at 35 (FCTD) (C-228);

31. Another type of post-filing evidence was use of the invention by the defendant. That is, once infringement was proven, the fact that the defendant had infringed the patent, and so had used the invention, was evidence that the invention was useful.[42] Post-filing evidence was used to establish utility in chemical and pharmaceutical cases, just as for other types of inventions.[43]

32. The admissibility of post-filing evidence in establishing utility was directly challenged and affirmed by the Federal Court of Appeal in its 1982 decision *Ciba-Geigy AG v Canada (Commissioner of Patents)*,[44] which concerned an application for a patent for a process for making certain chemical compounds known as amines.

33. In *Ciba-Geigy*, the Patent Office had refused to allow the patent application because it refused to consider post-filing evidence consisting of examples of the implementation of claimed process, saying "We do not believe . . . that the applicant should be permitted to retain claims on the basis of something done after the event."[45]

34. The Court of Appeal reversed, and held that such evidence was admissible. The Court reasoned that the evidence established that the claimed process could in fact produce the amines in question. Since the laws of chemistry don't change, this is and always was true, no matter when it is actually verified; if a process works today, it must also have worked yesterday. The fact that it was not *tested* yesterday does not mean it did not *work* yesterday.[46] So, while the process was actually used to produce the amines after the filing date, it must equally have been true that the process would have worked to produce the amines prior to the filing date.

35. Consistently with this view, post-filing evidence was also admissible to establish lack of utility; so, post-filing experiments showing that some members of a class of compounds were in fact not useful, were admissible to establish lack of utility for the class as a whole.[47]

36. Further, section 38 of the *Patent Act* expressly contemplates that the Commissioner may require the applicant to provide specimens for the purpose of experimentation by the Commissioner. Such experiments are necessarily post-filing. The evident

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Bayer AG v Apotex Inc (1995), 60 CPR (3d) 58, at 90 (OCJ - GD) (C-40); *Risi Stone Ltd v Groupe Permacon Inc* (1995), 65 CPR(3d) 2, at 21 (FCTD) (C-229); *Almecon Industries Ltd v Anchortek Ltd* (2001), 17 CPR(4th) 74, at 99 (FCTD) (C-230); *Illinois Tool Works Inc v Cobra Fixations Cie / Cobra Anchors Co* (2002), 20 CPR(4th) 402, at 404 (FCTD) (C-231).

42 See *Overend v Burrow Stewart & Milne Co* (1909), 19 OLR 642, at 648 (Ont CA) (C-232) (use by defendant) quoting to the same effect *Lucas v Miller* (1885), 2 RPC 155, at 160 (C-233); *McPhar Engineering*, *ibid* , at 148 (C-220); *Boehringer*, *ibid* (C-221); *Lubrizol Corp v Imperial Oil Ltd* (1990), 33 CPR(3d) 1, at 27 (FCTD) (C-234).

43 *Boehringer*, *supra* note 41, at 204-05 (C-221); *Ernest Scragg & Sons*, *supra* note 41, at 89 (C-223); *Hoechst Pharmaceuticals of Canada Ltd v Gilbert & Co*,[1966] SCR 189, at 191, 50 CPR 26 aff'g [1965] 1 Ex CR 710, 714, 50 CPR 26 (C-301); *Ciba-Geigy*, *supra* note 35 (C-44); *Bayer AG v Apotex Inc* (1995), 60 CPR(3d) 58, at 90 (OCJ - GD) (C-40); *Lubrizol Corp v Imperial Oil Ltd ibid*, at 27 (C-234).

44 *Ciba-Geigy*, *supra* note 35, at 75 quoting the decision of the Patent Appeal Board (C-44).

45 *Ibid* at 75 (C-44), quoting the decision of the Patent Appeal Board. The examples in question were sufficient to establish the utility of the process: *ibid* at 77 (C-44).

46 *Ibid* at 78 (C-44), quoting and applying *Monsanto*, *supra* note 34, at 1116-7 (C-61).

47 *Monsanto*, *supra* note 34, at 1117 (C-61).

rationale for such experiments is the same as just described; post-filing evidence may establish that the invention was in fact useful at the time of filing.

37. In summary, while the claimed invention, not an improved version, had to meet the utility requirement at the time of filing, post-filing evidence could be introduced to establish that fact. Post-filing evidence of utility was routinely considered, and I am not aware of any cases prior to 2002 in which a court refused to consider post-filing evidence in assessing the utility of a patent. While post-filing evidence is no longer admissible to establish utility, post-filing evidence remains admissible to establish lack of utility.

(iii) Disclosure

38. Proper disclosure is considered to be "at the heart of the whole patent system"[48] As the Supreme Court of Canada has explained,

> the grant of a patent is in the nature of a bargain between the inventor on the one hand and the Crown, representing the public, on the other hand. The consideration for the grant is twofold: "first, there must be a new and useful invention, and secondly, the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired"[49]

39. So, for example, if a patent claims a new chemical compound which is difficult to synthesize, the patent must provide sufficient disclosure that a skilled person would be able to synthesize the compound at the end of the patent term. Because the patent is addressed to a person skilled in the art to which it pertains, the patent need not disclose anything which would be part of the common general knowledge of such a person.

40. While the claimed invention must be new, useful and non-obvious, it is not generally necessary to disclose what makes it so.[50] Under prior law, there was no requirement to disclose the utility of the invention in the patent application unless it would not be apparent from the subject-matter of the invention itself, and it was never necessary to provide evidence in the patent itself to prove that the invention was useful for its apparent or stated purpose.[51]

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48 *Consolboard*, *supra* note 6, at 517 (C-118).

49 *Ibid* at 517, citations omitted (C-118). The disclosure requirement is statutorily set out in subsection 27(3) of the *Patent Act, supra* note 3 (C-50).

50 *Consolboard*, *supra* note 6, at 526 (C-118).

51 *Viagra, supra* note 5, ¶ 37-38 (C-197); *Pfizer Canada Inc. v Ranbaxy Laboratories Ltd,* 2008 FCA 108, ¶ 56, 67 CPR (4th) 23 rev'g 2007 FC 91, 56 CPR (4th) 96 [*Atorvastatin*] (C-234).

C. Promise Utility Doctrine

(i) Promise of the Patent

41. The standard against which utility is assessed now has two branches. The first branch corresponds to the long standing requirement of a mere scintilla of utility, while the second branch sets an elevated standard according to the "promise of the patent":

> Where the specification does not promise a specific result, no particular level of utility is required; a "mere scintilla" of utility will suffice. However, where the specification sets out an explicit "promise", utility will be measured against that promise.[52]

That is, if the courts hold that there is a "promise" in the patent, the utility of the invention is assessed against that promise. It is only if the court finds that there is no promise that the invention is assessed against the objective standard set out in the Act, in which case "the law sets the bar low for utility."[53]

42. The central aspect of the promise doctrine is that it constitutes an elevated standard for utility, above that which is required under the Act. As the Federal Court of Appeal has explained:

> An inventor whose invention is described in a patent which would otherwise be valid can nonetheless promise more for his invention than required by the Act so as to render his patent invalid.[54]

43. While the language quoted above refers to an "explicit" promise, in practice, the courts very often find a promise in the patent, and consequently the standard for utility is very often the elevated requirement under the promise doctrine, rather than the lower standard set out in the Act. The change to the substantive utility requirement has therefore had the effect of raising the standard for utility in a large proportion of pharmaceutical patent cases.

44. This change in substantive law is abundantly clear from the marked changes in the structure of the judicial decisions analyzing the utility requirement, and the evidence adduced on this point. The Court of Appeal has emphasized that "[t]he promise of the patent is fundamental to the utility analysis," and "is to be ascertained at the outset of an analysis with respect to utility."[55] Construction of the promise of the patent is now undertaken at the outset of any utility analysis, and normally occupies its own section of the decision, with a separate

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[52] *Olanzapine (No 1)* 2010 FCA 197, *supra* note 38, ¶ 76 (C-46), reaffirmed in *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 186, ¶ 48, 114 CPR(4th) 1 rev'g 2011 FC 1486, 101 CPR(4th) 1 leave to appeal to SCC granted 30 Jan 2014 (35562) [*Plavix*] (C-47).

[53] *Mylan Pharmaceuticals ULC v AstraZeneca Canada Inc.*, 2012 FCA 109, ¶ 7, 101 CPR(4th) 275 [*Anastrozole*] (C-236).

[54] *Plavix* 2013 FCA 186, *supra* note 52, ¶ 54, emphasis added (C-47).

[55] *Olanzapine (No 1)* 2010 FCA 197, *supra* note 38, ¶ 93 (C-46).

heading. Construction of the promise under current law is a very technical exercise. Expert evidence is normally required.[56] No case prior to 2005 included this type of analysis.

45. The *Anastrozole* case illustrates the centrality of the promise doctrine to the current analysis of utility.[57] The construction of the promise took up 62 paragraphs of a 233 paragraph decision, and the evidence of three expert witnesses was considered in a close reading of the specification. The patent at issue concerned the drug anastrozole, which was used in the treatment of breast cancer. A statement in the disclosure that the invention was "useful for this purpose" was held to constitute the promise of the patent, and a key question was whether the word "this" referred to a prior statement regarding pharmacological activity, or a different prior statement relating to the treatment of breast cancer.

46. None of this debate would have occurred under the prior law. There was no dispute as to the actual utility of anastrozole, which was approved by the Health Canada for use in the treatment of breast cancer. As noted by the court, the generic competitor, Mylan "accepts that anastrozole is a potent and selective aromatase inhibitor, which has fewer undesirable side effects than AG, and is useful in the treatment of breast cancer. This is why Mylan seeks to make a generic version of this compound."[58] While these facts alone would have easily established utility prior to 2005, they are now excluded as post-filing evidence, as is discussed below.

47. The question of the promise of the patent was determinative of validity, because pre-filing evidence alone established that anastrozole had pharmacological activity, but not that it would be clinically effective to treat breast cancer. In the end, the trial judge adopted the more modest construction of the promise, and he consequently upheld the validity of the patent.

48. The construction of the promise of the patent may even vary between different panels of the same court construing the very same patent. In *Latanoprost (No 2)*[59] the patent claimed "a therapeutic composition for topical treatment of glaucoma." The question was whether the patent promised reduced irritation in chronic treatment of glaucoma. This was important because as of the time of filing the inventors had only conducted single dose studies.[60] The trial judge rejected this construction of the promise and held that the patentee had demonstrated the utility of the drug through animal and human tests that showed it reduced intraocular pressure with minimal side effects.

49. The Federal Court of Appeal reversed. The Court considered expert evidence to the effect that glaucoma is a chronic condition, and held that the promise must be construed with the nature of the disease it purports to treat. Because a skilled person would know that glaucoma

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56 *Olanzapine (No 1)* 2010 FCA 197, *supra* note 38, ¶ 80 (C-46).

57 *Astrazeneca Canada Inc. v Mylan Pharmaceuticals ULC,* 2011 FC 1023, 96 CPR(4th) 159 [*Anastrozole*], aff'd 2012 FCA 109, *Anastrozole, supra* note 53 (C-237 and C-236).

58 *Anastrozole,* 2011 FC 1023, *ibid* ¶ 149 (C-237); see similarly *Mylan Pharmaceuticals ULC v Pfizer Canada Inc,* 2011 FC 547, ¶ 233, (C-302), noting "There is no dispute that, in looking at the matter from the viewpoint of the present moment, donepezil meets that promise [of efficacy in the treatment of Alzheimer's]. The question is whether, as of the filing date, June 21, 1988, donepezil met the promise."

59 *Pfizer Canada Inc. v Apotex Inc,* 2010 FC 447, 84 CPR(4th) 1 (C-303), rev'd *Apotex Inc. v Pfizer Canada Inc.,* 2011 FCA 236, 95 CPR(4th) 193 [*Latanoprost (No 2)*] (C-99).

60 *Latanoprost (No 2)* 2011 FCA 236, *ibid* ¶ 31(C-99).

is a chronic condition that required chronic treatment, "treatment" was construed as "chronic treatment" due to the chronic nature of the disease.[61] This conclusion was notwithstanding that there was no mention of chronic treatment in the patent itself. Because the Court held that utility for chronic treatment had not been established as of the filing date, the patent was held to be invalid. Again, this is notwithstanding that latanoprost had actually been approved by Health Canada for chronic treatment of glaucoma prior to the time of trial.[62]

50. This holding by the Court of Appeal is particularly striking because in *Latanoprost (No 1)*,[63] separate litigation involving a different generic pharmaceutical company, the same patent had been litigated before the same trial judge who had considered expert evidence from the same witnesses and had construed the promise in exactly the same way as in *Latanoprost (No 2)*.[64] However, in *Latanoprost (No 1)*, a differently constituted panel of the Court of Appeal had affirmed the trial judge's construal of the promise, and consequently affirmed the validity of the same patent.[65] Two different appellate panels therefore reached different conclusions on the construction of the promise, notwithstanding that this was an issue of law relating to the same patent. The difference in result between the two cases is a striking illustration of the vagaries of the exercise of construing of the promise.

51. In another recent decision concerning esomeprazole, a drug which works as a proton pump inhibitor to control gastric reflux and related maladies, the Federal Court considered three different putative promises, two of which each had two distinct extensions, or sub-promises, for a total of five different promises for which evidence was separately assessed.[66] In particular, the promise that the drug was useful as use as a proton pump inhibitor was met, but the promise of an improved therapeutic profile over previous drugs (including two sub-promises) was not.[67] The result was that the patent was held to be invalid on the sole basis that it lacked

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[61] *Latanoprost (No 2)* 2011 FCA 236, *ibid* ¶ 24, 27 (C-99).

[62] See XALATAN, Product Monograph, DIN: 02231493, Notice of Compliance issued 1997-06-17; Product Monograph and NOC information available from Health Canada (C-238).

[63] *Pfizer Canada Inc. v Pharmascience Inc,* 2009 FC 1294, 81 CPR(4th) 423 aff'd 2011 FCA 102, 92 CPR(4th) 301 [*Latanoprost (No 1)*] (C-49 and C-98, respectively).

[64] Compare *Latanoprost (No 1)* 2009 FC 1294, *ibid* ¶ 141-48 (C-49) with *Latanoprost (No 2)* 2010 FC 447, *supra* note 59, ¶ 170-75 (C-). That the patent was challenged twice by different parties is a consequence of the Canadian patent linkage system under which a finding of invalidity is binding only on the parties, and does not affect the validity of the patent *in rem*.

[65] *Latanoprost (No 1)* 2011 FCA 102, *supra* note 63, ¶ 32-35 (C-98).

[66] The three main promises were (1) use as a proton pump inhibitor; (2) stability against racemization; and (3) improved therapeutic profile: *Astrazeneca Canada Inc v Apotex inc,* 2014 FC 638, ¶ 133 [*NEXIUM*] (C-48). The extension to the second considered chemical and enzyme-mediated racemization (*ibid*, ¶ 103 (C-48)), and the third promise included improved pharmacokinetic and metabolic properties, and a putative extension to a lower degree of interindividual variation (*ibid*, ¶ 104 (C-48)).

[67] *Ibid at* ¶ 215-17 (C-48). The promise of stability against racemization was treated as not being determinative in light of the failure of the promise of improved therapeutic profile, but for completeness, the court held that the promise of chemical-mediated racemization was satisfied, and the promise of stability against enzyme-mediated racemization was also satisfied, though on the basis of information not disclosed in the patent, while the promise of improved pharmacokinetic and metabolic properties was not satisfied: *ibid* at ¶ 215-17 (C-48).

utility.[68] Consequently, the invalidity of the patent turned entirely on the interpretation of the word "will" in the following passage from the disclosure:

> It is desirable to obtain compounds with improved pharmacokinetic and metabolic properties which will give an improved therapeutic profile such as a lower degree of interindividual variation. The present invention provides such compounds. . . [69]

52. As discussed above,[70] it is the claims, not the disclosure, that define the invention. Claims originated to resolve the tension between defining and disclosing the invention. The need for precision in defining the invention was allocated to the claims, to allow the inventor to provide a fulsome disclosure of the invention to the public without fear that some stray phrase would lead to invalidity. The promise doctrine erases this line because utility is assessed against what is said in the disclosure, rather than by using an objective standard to assess the utility of the invention as claimed.

53. Construction of the promise is an arbitrary and hair-splitting exercise because the statutory function of the disclosure is to disclose the invention, not to define it. It is the role of the claims to define the invention. Patentees have always been aware of the need for precision in claim drafting, but the whole purpose of claims is to isolate the definition of the invention, exactly so that patent drafters need not hesitate to provide a fulsome disclosure. The effect of the promise doctrine is to take words which were intended to disclose the invention, and use them for the "antagonistic" purpose of defining the invention. The arbitrary and hair-splitting nature of the exercise of construing the promise is an inevitable consequence of interpreting the disclosure for a purpose for which it was never intended.

(ii) Post-Filing Evidence

54. In its 2002 decision in *Wellcome / AZT* the Supreme Court of Canada held that post-filing evidence is no longer admissible to establish utility.[71] Since then, lower courts have consistently followed *Wellcome / AZT* in refusing to admit post-filing evidence to establish utility. This means that the fact that a pharmaceutical is actually being used to treat a particular disease at the time of litigation is no longer considered to be admissible evidence that it is useful. As a result, many pharmaceuticals that were known to be useful in fact by the time of litigation, in that they were widely used to treat a disease, have been held to lack utility.

55. The rejection of post-filing evidence is unique to evidence *establishing* utility. Post-filing evidence continues to be admissible and regularly used to establish non-obviousness.[72] Post-filing evidence also remains admissible to establish *lack* of utility.[73] If the

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68 *Ibid* at ¶ 165, 195, 214 (C-48).

69 *Ibid at* ¶ 3 (C-48), quoting the specification, and saying "The validity of the `653 patent ultimately turns on its proper interpretation, as informed by [the quoted statement]."

70 See above § 1.B.(iii) Claims and Disclosure.

71 *Wellcome / AZT*, *supra* note 5, ¶ 46, 78-85 (C-213).

72 In particular, commercial use of the invention after it has been patented and put on the market is an important and commonly invoked consideration in establishing non-obviousness, on the view that if there was money to be made from the invention, it must not have been obvious, or it would have been done earlier. See eg *The King v Uhlemann Optical Co*, [1952] 1 SCR 143, at 152-53 aff'g 11 CPR 26, at

validity of a patent is challenged in litigation, post-filing experiments carried out by the defendant showing that the invention is not useful are admissible to show the patent is invalid.

56. The change in the law eliminating the ability to rely on post-filing evidence of utility has had a dramatic impact on the ability to prove that a pharmaceutical invention satisfies the utility requirement.

57. Because patents for pharmaceuticals are invariably filed long before marketing authorization is obtained, commercial use can no longer be used to establish utility. Due to the high evidentiary burden imposed by the Canadian courts, even early stage human trials, such as may be carried out prior to patenting, are often not adequate to demonstrate utility to the satisfaction of the Canadian courts, particularly when the utility of the patent is assessed against an elevated promise of clinical efficacy, or a similar standard.

58. With post-filing evidence excluded from the analysis, utility of even those compounds which are in fact routinely used as a treatment for a disorder must often be established on the basis of sound prediction, which, as described above, was originally relied upon to establish the utility of untested members of a genus claim to a large number of compounds.[74] Establishing a sound prediction of utility based on pre-filing evidence is inherently more difficult than establishing demonstrated utility based on post-filing evidence. For example, in *Wellcome / AZT* the trial judge held that the simple fact that AZT was the primary drug in the treatment of HIV/AIDS was sufficient to establish utility.[75] The Supreme Court held that this fact was post-filing evidence and so inadmissible. The Court went to hold that the utility of AZT was established based on sound prediction, but this required a detailed scrutiny and assessment of the evidence of the testing that had been done prior to filing the patent.[76]

47-48 [1950] Ex CR 142 (C-239); *Wright & Corson v Brake Service Limited*, *supra* note 41, at 131, aff'd [1926] SCR 434 (C-300); *Eli Lilly & Co v Marzone Chemicals Ltd* (1977), 37 CPR(2d) 3, at 36 (FCTD) aff'd (1978) 37 CPR(2d) 37 (FCA) (C240); *Wessel v Energy Rentals Inc*, 2004 FC 791, ¶ 22.1, 22.3 (C-241); *Janssen-Ortho v Novopharm Ltd* 2006 FC 1234, ¶ 113.7 aff'd 2007 FCA 217, ¶ 25.7 (C-242); *Jay-Lor International Inc v Penta Farm Systems Ltd.* 2007 FC 358, ¶ 91.2, 91.5 (C-243). Note that, strictly the date for assessing validity varies with the issue. Obviousness and novelty (anticipation) are both assessed at the claim date: *Patent Act*, *supra* note 3, ss 28.2, 28.3 (C-50). Sufficiency is assessed as of the date of publication of the patent, which is 18 months from the earlier of the Canadian filing date, or the earliest claimed priority date, unless the applicant requests on earlier publication date: *Novartis Pharmaceuticals Canada Inc v Teva Canada Ltd,* 2013 FC 283, ¶ 188 [*zoledronate*] (C-244); *Pfizer Canada Inc. v Novopharm Ltd.* 2009 FC 638, ¶108 (C-245); *Patent Act*, *supra* note 3, s 10 (C-50).

[73] *Wellcome / AZT*, *supra* note 5,, ¶ 56, 76 (C-213).

[74] The doctrine of sound prediction was originally developed when a few compounds of a class had been tested, but many remained untested, even at the time the patent was attacked. Until *Wellcome / AZT* it had been generally understood to apply only in such circumstances, to allow a class containing untested members to be validly claimed: see *Apotex Inc. v Wellcome Foundation Ltd.*, [2001] 1 FC 495 at ¶ 53 [*Wellcome / AZT* FCA] (C-117). Prior to *Wellcome / AZT*, it had not been necessary to rely on sound prediction in respect of compounds which were known to be useful in fact.

[75] *Apotex Inc. v Wellcome Foundation Ltd*. (1998), 79 CPR (3d) 193, 226, 1998 CanLII 7610. [*Wellcome / AZT* FC] (C-116).

[76] See *Wellcome / AZT*, *supra* note 5, ¶ 73-75 (C-213), summarizing the trial judge's analysis of the facts.

59. It should be noted that the evidence needed to demonstrate utility will depend on the how the promise of the patent is construed. For example, if the patent is construed as promising only pharmacological activity, such as inhibition of the aromatisation of the steroid ring in *Anastrazole*, utility may be demonstrated on the basis of *in vitro* tests conducted prior to the filing date.[77] If the promised utility is construed to be use in humans, then human trials will normally be required to demonstrate utility.[78] Due to the high evidentiary standard applied by the Canadian courts in consequence of the promise of the patent, human trials conducted prior to filing do not necessarily suffice to demonstrate utility. Even though the results of the trials are positive, the courts will generally scrutinize the methodology and results of the trials to determine whether utility is demonstrated.[79] Even positive and statistically significant results may not suffice to "demonstrate" a promised utility of efficacy in humans.[80]

60. The evidentiary standard to demonstrate utility therefore seems to be higher in the context of pharmaceuticals than for other inventions. In the pharmaceutical context, if the patent is construed as promising utility in treating humans, it appears that such utility cannot be demonstrated except by human testing. However, in the mechanical context, it has been recognized that a sufficiently precise model could suffice to demonstrate utility even in the absence of actual testing.[81]

(iii) Enhanced Disclosure Requirement for Sound Prediction

61. As just discussed, the doctrine of sound prediction requires detailed scrutiny of the pre-filing evidence. Moreover, the Federal Courts have further constrained a patentee's ability to show utility through sound prediction, as an enhanced disclosure requirement has been imposed which further limits even the pre-filing evidence which is admissible in establishing utility. This enhanced disclosure requirement is retroactive in the sense that it applies to patents that were filed and granted before the requirement became law.

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77 *Anastrazole,* 2011 FC 1023, *supra* note 57, ¶ 167 (C-237).

78 In *Wellcome / AZT*, *supra* note 5, (C-213), the human trial of AZT for treating HIV/AIDS had not been conducted at the time of filing of the patent. The Supreme Court held that such utility had been soundly predicted based on pre-filing evidence, including *in vitro* tests. The Supreme Court also held that demonstrated utility could not be established on the basis of post-filing evidence. However, the Court never explained why the pre-filing evidence did not suffice to establish demonstrated utility. The implication is that demonstrated utility of pharmaceuticals requires testing in humans. See also *Mylan Pharmaceuticals ULC v Pfizer Canada Inc,* 2011 FC 547, ¶ 237 aff'd 2012 FCA 103 (1,338,808 / donepezil / ARICEPT) (C-); *Purdue Pharma v Pharmascience Inc.,* 2009 FC 726, ¶ 101 (2,098,738 / oxycodone) (C-246).

79 See eg *Apotex Inc. v Sanofi-Aventis,* 2011 FC 1486, ¶ 339-49 (C-247) rev'd on other grounds *Plavix,* 2013 FCA 186, *supra* note 52 (C-47); *Eli Lilly Canada Inc. v Novopharm Limited,* 2011 FC 1288, 100 CPR(4th) 269, aff'd 2012 FCA 232, [*Olanzapine (No 2)*] (C-146); *Novopharm Limited v Eli Lilly and Company,* 2010 FC 915, 87 CPR(4th) 310 (C-160) aff'd sub nom *Eli Lilly & Co v Teva Canada Ltd,* 2011 FCA 220, 94 CPR(4th) 95 [*Atomoxetine*] (C-163); *Latanoprost (No 2)* 2011 FCA 236, *supra* note 59 (C-99); *Eli Lilly Canada Inc. v Apotex Inc.*, 2008 FC 142, 63 CPR (4th) 406, aff'd 2009 FCA 97, 78 CPR(4th) 388, [*Raloxifene*] (C-115 and C-119).

80 *Atomoxetine* 2010 FC 915, *ibid,* aff'd 2011 FCA 220, *ibid* (C-160 and C-163).

81 *Eurocopter v Bell Helicopter Textron Canada Limitée* , 2013 FCA 219, ¶ 147-8, (C-304) aff'g 2012 FC 113, 100 CPR(4th) 87 [*Eurocopter*] (C-120).

62. This heightened disclosure requirement is said to be based on the test for sound prediction set out by the Supreme Court of Canada in *Wellcome / AZT*, in which the court summarized the law of sound prediction as requiring a three part test:

a. there must be a factual basis for the prediction;

b. there must be a sound line of reasoning;

c. there must be proper disclosure.[82]

63. Under current law, the third branch of the test for sound prediction has been interpreted by the lower courts as imposing an additional disclosure obligation as part of the utility requirement:

> [I]t is beyond debate in Canada that where a patentee asserts that the utility of its invention has been demonstrated, it need not assert its supporting evidence in the patent.
>
> In a case involving a claimed sound prediction of utility, it is equally beyond debate that an additional disclosure obligation arises [which] is met by disclosing *in the patent* both the factual data on which the prediction is based and the line of reasoning followed to enable the prediction to be made.[83]

64. This requirement was established by the *Raloxifene* case, in which the invention at issue was for the use of the compound raloxifene in the treatment of osteoporosis.[84] Raloxifene was in fact approved and sold for that purpose, but after the decision in *Welcome / AZT*, that fact was not admissible to establish utility due to the exclusion of post-filing evidence. The patentee therefore sought to show that utility had been soundly predicted based on the pre-filing evidence.

65. The trial judge held that the patentee did in fact have a factual basis and a line of reasoning that together established a sound prediction of utility based on pre-filing evidence alone.[85] However, that was not enough. A key element of the factual basis for the prediction was the so-called "Hong Kong study," which had been completed prior to the Canadian filing date.[86] The Hong Kong study, however, was not disclosed in the patent itself, and for that reason alone the key claims of the patent were held to be invalid.[87] The Court of Appeal affirmed, saying, "In

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82 *Wellcome / AZT*, *supra* note 5,¶ 70 (C-213).

83 *Atomoxetine* 2010 FC 915, *supra* note 79, ¶ 116-17 (original emphasis) aff'd 2011 FCA 220, ¶ 46-47 (C-160 and C-163).

84 *Raloxifene* 2008 FC 142, aff'd 2009 FCA 97, *supra* note 79 (C-115 and C-119). For a detailed discussion of the emergence of this requirement, see Siebrasse, "Factual Basis," *supra* note 23, at 44-46 (C-206).

85 *Raloxifene* 2008 FC 142, *supra* note 79, ¶ 156, 162 (C-115).

86 *Ibid* at ¶ 120 (C-115).

87 *Ibid* at ¶ 163-78 (C-115). The requirement that the factual basis for the sound prediction be disclosed in the patent itself was determinative of the result, as the claims in question were infringed and other validity attacks were rejected: *ibid* at ¶ 183, 187 (C-115).

sound prediction cases there is a heightened obligation to disclose the underlying facts and the line of reasoning for inventions that comprise the prediction."[88]

66. This requirement to disclose evidence of patentability in the patent itself is unique to utility based on sound prediction. Evidence of utility need not be disclosed in the patent if utility can be established based on demonstrated utility.[89] Consequently, under current law, as the Federal Court noted in *Anastrozole*, "[t]he disclosure requirements for sound prediction are more onerous than for demonstrated utility."[90] For this reason, the requirement to disclose the factual basis for sound prediction in the patent is referred to by the courts as an "additional," "heightened," or "enhanced" disclosure requirement.[91]

67. While the heightened disclosure requirements have made the distinction between demonstrated utility and sound prediction crucial, the distinction is conceptually arbitrary and unclear in practice. There is only one utility requirement under the *Act*,[92] and the concept of "sound prediction" is nothing more than an acknowledgment that utility need not be established by actual testing. Traditionally, there was never a bright light between sound prediction and demonstrated utility, because exactly the same evidence used to demonstrate utility could be, and normally was, used to establish sound prediction.[93] The distinction did not have to be precise, because it had no practical implications.

68. Under current law, whether the patentee can demonstrate utility as of the filing date or must rely on a sound prediction of utility often turns on the construction of the promise of the patent. For example, if an elevated promise of use in humans or clinical effectiveness in humans is construed based on the statements in the patent disclosure, a high evidentiary standard will be applied in order to demonstrate utility, since the patentee will need to demonstrate – without relying on post-filing evidence – that the invention is effective in the treatment of humans. The practical effect, then, is that the patentee will likely need to rely on a sound prediction of utility, based solely on evidence that is disclosed in the patent itself given the doctrine of sound prediction's enhanced disclosure requirement.

69. The arbitrariness of the heightened disclosure requirement under sound prediction is illustrated by the *Rosiglitazone* case, where a crucial question was whether the patent promised that the claimed compound "will be useful" or only that "it was expected to be useful."[94] The trial judge held that the promised utility was that the claimed compounds were of "potential use"

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88 *Raloxifene*, 2009 FCA 97, *supra* note 79, ¶ 14 (C-119).

89 *Atomoxetine* 2010 FC 915, *supra* note 79, ¶ 116-17, quoted in text above (C-160).

90 *Anastrozole* 2011 FC 1023, *supra* note 57, ¶ 188 (C-237).

91 See eg *Viagra,* 2012 SCC 60, *supra* note 5, ¶ 37, 43 ("heightened," "enhanced") (C-197); *Raloxifene,* 2009 FCA 97, *supra* note 79, ¶ 14 ("heightened") (C-119); *NEXIUM,* 2014 FC 638, *supra* note 66, ¶ 151-52, ¶ 155, 159-60 ("enhanced") (C-48); *Plavix, supra* note 52, Gauthier J (concurring) ¶ 132 ("heightened") (C-47); *Atomoxetine,* 2010 FC 915, *supra* note 79, ¶ 117 ("additional"), ¶ 121 ("heightened") (C-160); *Sanofi-Aventis Canada Inc v Apotex Inc,* 2009 FC 676 ¶ 216, 77 CPR(4th) 99, aff'd 2011 FCA 300, 97 CPR(4th) ("heightened") (C-248).

92 *Patent Act, supra* note 3, s 2, definition of "invention" (C-50).

93 The demonstrated utility of the compounds actually tested was (and remains), a primary factual basis for predicting the utility of untested compounds.

94 *GlaxoSmithKline Inc. v Pharmascience Inc.,* 2011 FC 239, ¶ 107 [*Rosiglitazone*] (C-249).

in treating diabetes.[95] Relying on evidence that was not disclosed in the patent,[96] he held that this "potential" for use in treating diabetes had been demonstrated.[97]

70. Given that potential use for treating diabetes was demonstrated, it would seem to follow that use for treating diabetes could have been soundly predicted, as the two are alternative ways of expressing the same concept. However, if the trial judge had evaluated the utility on the basis of sound prediction, the same evidence used to demonstrate utility would not have been admissible, since it was not disclosed in the patent.

(iv) Origin of the Promise Utility Doctrine

71. The Promise Utility Doctrine is a surprising and unexpected development in Canadian patent law. Patent law in Canada is entirely statutory, and yet there have been no changes to the *Patent Act* relating to the law of utility. The changes to the law that have been applied to invalidate numerous pharmaceutical patents post-2005 are wholly extra-statutory and judge-made.

72. The substantive requirement that utility be assessed by reference to the "promise of the patent," was adopted at the trial level beginning in 2005 and affirmed by the Court of Appeal in 2008. The change had no basis in prior case law or the Act.[98] The sole pre-2005 Canadian authority cited for the promise doctrine is the 1981 decision of the Supreme Court in *Consolboard*. However, *Consolboard* did not establish the promise doctrine in Canadian law, nor can it reasonably be interpreted as acknowledging the existence of that doctrine in prior law.

73. *Consolboard* itself had nothing to do with the promise doctrine. The central issue in the case was whether there was a heightened disclosure requirement for utility, which would require the utility of the invention to be disclosed in the patent itself. The Supreme Court held that there was no such heightened disclosure requirement.[99] *Consolboard* was often cited in the 25 years from the time it was decided until 2005, but never in support of the exercise by which the court construes a "promise," against which utility is assessed. [100] Given the importance of the

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95 *Ibid* at ¶ 94(c), 98(b) (C-249).

96 The patent claims a broad genus of compounds, as well as a number of individual compounds. Rosiglitazone itself was claimed in Claim 41. The patent did disclose a representative efficacy test, Canadian Patent 1,328,452, at 80, but the particular tested compound was not rosiglitazone: *ibid* ¶ 112 (C-249).

97 *Rosiglitazone,* 2011 FC 239, *ibid* ¶ 115 (C-249).

98 The original Federal Court cases were *Bristol-Myers Squibb Co v Apotex Inc,* 2005 FC 1348 (C-190), *Pfizer Canada Inc v Apotex Inc,* 2005 FC 1205 (C-250) and *Aventis Pharma Inc v Apotex Inc,* 2005 FC 1283 (C-209). The first Court of Appeal decision affirming the promise of the patent analysis was *Atorvastatin* 2008 FCA 108, *supra* note 51 (C-234).

99 *Consolboard*, *supra* note 6, at 525 (C-118).

100 It was cited primarily with respect to the disclosure requirement, which was the central issue in the case. It is also often cited for the correct approach to claim construction, as well as some ancillary issues. This is illustrated by the subsequent Supreme Court of Canada decisions citing *Consolboard*: *Viagra,* 2012 SCC 60, *supra* note 5, ¶ 40 (disclosure) (C-197); *Monsanto Canada Inc v Schmeiser,* 2004 SCC 34, ¶ 18 (claim construction) (C-251); *Harvard College v Canada (Commissioner of Patents),* 2002 SCC 76, ¶ 59 (claim construction) (C-252); *Wellcome / AZT*, *supra* note 5 ¶ 92 (claim construction) (C-213); *Housen v Nikolaisen,* 2002 SCC 33, ¶ 12 (deference to findings of fact) (C-253); *Free World Trust*

promise of the patent in current law, if *Consolboard* really was authority for this doctrine, it surely would have been invoked earlier.

74. The particular statement from *Consolboard* cited as authority for the promise doctrine is that an invention is useful if it will do "what the specification promises that it will do."[101] While this phrase does use the word "promise," it must be read in context. As just noted, the question at issue in *Consolboard* was whether it was necessary for the patentee to disclose the utility in the specification. The Supreme Court held that it was not, explaining as follows:

> In my respectful opinion the Federal Court of Appeal erred also in holding that s. 36(1) requires distinct indication of the real utility of the invention in question. There is a helpful discussion in *Halsbury's Laws of England*, (3rd ed.), vol. 29, at p. 59, on the meaning of "not useful" in patent law. It means "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do." There is no suggestion here that the invention will not give the result promised. The discussion in *Halsbury's Laws of England*, *ibid*., continues:
>
> > .. the practical usefulness of the invention does not matter, nor does its commercial utility, unless the specification promises commercial utility, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested.
>
> and concludes:
>
> > . . it is sufficient utility to support a patent that the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice.
>
> Canadian law is to the same effect.[102]

The thrust of this discussion is to say that there is no requirement to disclose the utility of the invention in the patent itself, and more broadly, to establish a relatively low standard for utility. In particular, the statement that "it is sufficient utility to support a patent that the invention . . . affords the public a useful choice," is inconsistent with the promise doctrine, under which

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v Électro Santé Inc, 2000 SCC 66, ¶ 26 (anticipation), ¶ 52 (claim construction) (C-189); *Whirlpool Corp v Camco Inc,* 2000 SCC 67, ¶ 42 (disclosure), ¶ 49(g) (claim construction) (C-254); *Pioneer Hi-Bred Ltd v Canada (Commissioner of Patents), supra* note 6, (claim construction) (C-198). This general pattern is also true of lower court decisions.

101 *Consolboard*, *supra* note 6, at 525 (C-118).

102 *Consolboard*, *ibid* (C-118). The Court also quoted (*ibid* at 526 (C-118)) *Unifloc Reagents, Ltd v Newstead Colliery, Ltd* (1943), 60 RPC 165 at 184 (Ch) (C-255) for the proposition that "If when used in accordance with the directions contained in the specification the promised results are obtained, the invention is useful in the sense in which that term is used in patent law." On the facts, the question in *Unifloc* was purely one of operability; the decision implicates neither the promise of the patent doctrine, nor comparative utility.

affording a useful choice – that is, an invention which has utility – does not suffice if more is promised.

75. It is important to recognize that the mere use of the word "promise" by the Court when discussing utility does not mean that the case is an application of the promise branch of the Promise Utility Doctrine. To the contrary, "promise" in the context of *Consolboard* refers simply to the alleged or stated utility of the invention. The Court made no attempt to "construe" the "promise of the patent."

76. As discussed above, the key feature of the promise branch of current Canadian Promise Utility Doctrine is that it constitutes an elevated standard for utility, which is higher than that required by the Act. A patent for an invention that has the utility required by the Act will nonetheless be held invalid if the patent is construed as promising more.[103]

77. Application of the promise branch is evident if the court states that it is applying a higher utility standard in light of the promised utility, or if the promised utility is higher than that applied on similar facts in other cases. The distinction between utility based on the mere scintilla standard and the promise of the patent is also evident when the patent has multiple promises. The mere scintilla test will be satisfied so long as the invention actually satisfies one of the disclosed uses, but the patent will be invalid under the promise of the patent unless all of the "promised" uses are satisfied.[104] None of these apply to *Consolboard*, or to any prior Canadian case.

78. Before 2005, the phrase "promise of the patent" and similar phrases, such as the purpose "intended by the patentee" were often used simply to refer to the utility of the invention. In discussing the utility requirement, it is necessary to refer to the putative utility somehow. Rather than describing the particular utility ascribed to the invention in question, the courts routinely refer to the "intended" or "promised" utility as a shorthand way of referring to the use of the invention which was often disclosed in the patent itself. Prior to 2005, there was no case in which the court construed the promise of the patent in a manner similar to the exercise undertaken today, nor was there a case that distinguished between two branches of the utility requirement based on the presence or absence of a promise.

79. The reference to "promised" or "intended" utility originated as a rejection of a requirement, found in some of the early English cases, that utility is established only by commercial acceptance.[105] The difficulty is commercial acceptance of an invention is determined

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103 *Plavix,* 2013 FCA 186, *supra* note 52, ¶ 54 (C-47).

104 For example, in *NEXIUM,* 2014 FC 638, *supra* note 66 (C-48), discussed above, § 2.C.(i) Promise of the Patent, the patent was construed as having three promises (¶ 133), of which only one was satisfied (¶165, 195, 214), and the patent was held invalid. Compare this with the well established US rule under which "Proof of one of the disclosed utilities suffices to meet the statutory utility requirement": *Standard Oil Co (Indiana) v Montedison SpA*, 664 F 2d 356, 375 (3rd Cir 1981) (C-256); and see similarly *Conner v Joris*, 241 F 2d 944, 947 (CCPA 1957) (C-257); *In re Gottlieb*, 328 F 2d 1016, 1019 (CCPA 1964) (C-258).

105 See the Annotation by the editor to the Exchequer Court decision in *Wandscheer v Sicard Ltd* (1944), 4 Fox Pat C 43 at 45-46 (C-259). For cases suggesting a requirement of commercial acceptance, see *Morgan v Seaward* (1836), 1 WPC 187 (Exch Ct) (C-260) and *Cornish v Keene* (1835), 1 WPC 512 (C-261); The leading cases rejecting commercial acceptance as test for utility are *Lane Fox v Kensington and Knightsbridge Electric Lighting Co Ltd* (1892), 9 RPC 413 (CA) (C-262) and *Fawcett v Homan*

by many factors other than the technical merits of the invention. A new red dye may be perfectly effective at dying fabric red, and yet fail to gain commercial acceptance because that shade of red is not in fashion that year.[106] The statement that the invention is useful if it does "what the specification promises it will do" established that the red dye need not be the height of this year's fashion in order to have patentable utility; it need only be effective in dying the fabric red.

80. In *Consolboard*, the Court was using the promise language in this innocuous fashion. The Court contrasted a patent that worked as "promised" with one that would not work at all.

81. Nor was (or is) there any basis for the promise doctrine in the Canadian *Patent Act*. In Canadian law, a patent is a statutory right; the Commissioner of Patents has "*no* discretion to refuse a patent . . . if the statutory criteria are met."[107]

82. Moreover, section 53(1) of the Canadian *Patent Act* provides that a patent is invalid if it contains representations which are wilfully misleading. Section 53(1) has never been cited by the courts as the statutory basis for the promise doctrine, and indeed in *Olanzapine (No 1)* an attack based on section 53(1) was rejected, even though the patent was ultimately held invalid for failure to satisfy the promise of the patent on the basis of the same statements that were held not to implicate section 53.[108]

83. In summary, *Consolboard* had nothing to do with the promise doctrine, and there was no statutory or jurisprudential basis for that doctrine in Canadian law at the time *Consolboard* was decided. Consequently, *Consolboard* neither established nor acknowledged the promise doctrine in Canadian law.

84. The changes in the law regarding post-filing evidence and the enhanced disclosure requirement for utility based on sound prediction both had their origin in the 2002 Supreme Court of Canada decision in *Wellcome / AZT*, although it would be some time before these concepts were linked with the promise of the patent and applied together to constrain a patentee's ability to show utility of his invention.

85. In *Wellcome / AZT*, the Federal Court of Appeal, in the course of holding the patent to be valid, had held that evidence of actual utility subsequent to a patent's priority date may be introduced to establish that the invention satisfies the utility requirement.[109] On appeal,

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(1896), 13 RPC 398 (CA) (C-263). An early Canadian case to the same effect is *Prentice v Dominion Rubber Co*, *supra* note 24, at 199-200 (C-207).

[106] See *Badische Anilin und Soda Fabrik AG v Levinstein* (1887), LR 12 App Cas 710, 715, 719 (HL) (C-264).

[107] *Harvard College v Commissioner of Patents,* 2002 SCC 76 at ¶ 11 (Binnie J), accord ¶ 119 (majority) (C-); see also Harold G Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed (Toronto: Carswell, 1969) at 5 (C-265).

[108] *Eli Lilly Canada Inc. v Novopharm Limited,* 2009 FC 1018, ¶ 150-53, rev'd on other grounds 2010 FCA 197 [*Olanzapine (No 1)*] (C-145 and C-46). See also *Bauer Hockey Corp v Easton Sports Canada Inc,* 2010 FC 361, ¶ 323-36 aff'd 2011 FCA 83, distinguishing between s 53 and the promise of the patent (C-266).

[109] *Wellcome / AZT* FCA, [2001] 1 FC 495, *supra* note 74, ¶ 52 (C-117).

the SCC held that "post-patent proof" was not admissible to establish the utility of the invention.[110] Since that time the Canadian courts, following *Wellcome / AZT*, have consistently refused to admit post-filing evidence to establish utility.

86. The heightened disclosure requirement for utility based on sound prediction was introduced by the trial courts in 2008 and confirmed by the Court of Appeal in 2009, based on their new interpretation of the third part of the test for sound prediction set out by the Supreme Court in *Wellcome / AZT*, namely that "there must be proper disclosure."[111]

87. The requirement of proper disclosure was not an issue between the parties in *Wellcome / AZT*,[112] but the Federal Courts interpreted the Supreme Court's brief *obiter dicta* remarks as imposing a heightened disclosure requirement, applicable only to sound prediction, which requires that the evidence supporting the sound prediction, as well as the reasoning behind the prediction, must be disclosed in the patent itself.

88. There are no sound prediction cases prior to 2008 in which evidence from outside the patent was excluded from consideration, and indeed, there is not even any suggestion to that effect. On the contrary, the prior cases simply considered sound prediction on the basis of the totality of the evidence, and evidence from outside the patent was routinely considered. Indeed, all the leading cases prior to 2008, including *Wellcome / AZT* itself, actively considered evidence from outside the patent itself as part of the factual basis for sound prediction.

III. Law of Utility Applied to Invalidate the Patents at Issue

89. The application of the Promise Utility Doctrine to the patents at issue in this complaint resulted in invalidation of the patents. It is clear that the two patents at issue would have been valid under Canadian law when the patents were filed and granted.

(i) Zyprexa

90. The main claims at issue in the "Zyprexa" or "olanzapine" patent, Canadian Patent 2,041,113, are to the compound olanzapine and olanzapine for the treatment of schizophrenia.[113]

91. The olanzapine patent was invalidated in patent infringement litigation between Lilly and Novopharm. In Olanzapine *(No 1)*[114] the trial judge, O'Reilly J, had held the olanzapine patent was not a valid selection patent.[115] The Court of Appeal vacated this decision

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110 *Wellcome / AZT*, *supra* note 5, ¶ 46; and see also *ibid* ¶ 56 (C-213).

111 *Raloxifene,* 2008 FC 142, aff'd 2009 FCA 97, *supra* note 79 (C-115 and C-119).

112 *Wellcome / AZT*, *supra* note 5, ¶ 70 (C-213).

113 Canadian Patent 2,041,113 (C-62), Claims 3, 6; other claims at issue were to various pharmaceutical formulations of olanzapine: see *Olanzapine (No 1)* 2009 FC 1018, *supra* note 108, ¶ 46 (C-145), summarizing the claims at issue. Olanzapine is sold by Lilly under the brand name ZYPREXA.

114 *Olanzapine (No 1)*, 2010 FCA 197, *supra* note 38, rev'g 2009 FC 1018 *supra* note 108 (C-46 and C-145).

115 *Olanzapine (No 1)* 2009 FC 1018, *supra* note 108, ¶ 154. A "selection patent" refers to a patent which claims a specific compound from a previously known large class of compounds (C-145).

on the basis that the requirements for a selection patent are the same as for any other patent, and it was therefore an error of law to hold a patent invalid as not meeting the conditions for a selection patent.[116] The Court of Appeal in *Olanzapine (No 1)* held that the patent met the non-obviousness requirement, but remanded the case to the trial judge for a determination of the issues of utility and sufficiency. On remand, in *Olanzapine (No 2)*,[117] O'Reilly J held that the requirement of sufficiency was met,[118] but he held the patent invalid on the sole basis of lack of utility.[119]

92. O'Reilly J noted that "Olanzapine is regarded as a relatively safe, and often effective, medicine for treating schizophrenia. Olanzapine is widely prescribed and is a commercial success."[120] It is therefore clear that the patent would have been held to be useful under prior law, under which evidence of commercial use of the patented product was routinely accepted as establishing utility. However, because of the rule against post-filing evidence, this fact was not considered in establishing utility. The question, instead, was whether utility could be established as of the filing date.[121]

93. It is worth emphasizing that O'Reilly J also held that pre-filing evidence alone would have been sufficient to demonstrate the utility required by the Act:

> If the utility of the invention in the '113 patent relates merely to a compound with potential antipsychotic properties that might have relatively low EPS liability, that utility had been demonstrated by the tests conducted prior to the filing date.[122]

94. However, he held that the promise of the patent required utility to be assessed against an elevated standard:

> However, I cannot accept that the `113's promise was so small. As stated above, based on the wording of the `113 patent and the evidence, I find that the promise of the patent is that olanzapine treats schizophrenia patients in the clinic in a markedly superior fashion with a better side-effects profile than other known antipsychotics.[123]

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116 *Olanzapine (No 1)* 2010 FCA 197, *supra* note 38, ¶ 4, 27, 33 (C-46).

117 *Eli Lilly Canada Inc v Novopharm Limited,* 2011 FC 1288, aff'd 2012 FCA 232 [*Olanzapine (No 2)*] (C-146 and C-147). The Court of Appeal decision was a two paragraph decision delivered from the bench affirming the decision under appeal. All the relevant reasons are therefore found in the decision of the trial judge.

118 *Olanzapine (No 2),* 2011 FC 1288, *ibid* ¶ 272 (C-146).

119 *Olanzapine (No 2),* 2011 FC 1288, *ibid* ¶ 273 (C-146).

120 *Olanzapine (No 1),* 2009 FC 1018, *supra* note 108, ¶ 1 (C-145).

121 *Olanzapine (No 1),* 2010 FCA 197, *supra* note 38, ¶ 81 (C-46); *Olanzapine (No 2),* 2011 FC 1288, *supra* note 117, ¶ 126, 265 (C-146).

122 *Olanzapine (No 2),* 2011 FC 1288, *supra* note 117, ¶ 209 (C-146).

123 *Ibid*; see also *ibid* at ¶ 120, 124, 228 (C-146).

95. Under the Promise Utility Doctrine, the utility of the patent was measured against this promise. O'Reilly J held that the evidence available as of the filing date was insufficient to demonstrate utility based on this heightened promise.[124]

96. O'Reilly J also held that sound prediction of utility could not be established because of the heightened utility required by the promise of the patent. He held that pre-filing information could support the inference that olanzapine would be useful as an antipsychotic, but that evidence could not establish that it was markedly superior to other known antipsychotics.[125] As he stated:

> The main problem, however, with Lilly's submissions on sound prediction is that they are based on a reading-down of the promise of the '113 patent to the same utility that had been relied on for the '687 patent.[126]

97. The '687 patent claimed a broad genus of compounds, which encompassed olanzapine. Because all the compounds of the '687 patent satisfied the utility requirement of the Act, by virtue of their use as antipsychotics; it follows that olanzapine, as a member of that class, must also have satisfied the utility requirement established by the Act. It is therefore clear that olanzapine would have been held to have utility under the utility standard required by the Act, but for the elevated standard established by the promise doctrine.

98. In summary, the olanzapine patent would have been valid under prior law, and was invalid under the Promise Utility Doctrine because of the exclusion of post-filing evidence and the heightened utility requirement established by the promise of the patent.

(ii) Strattera

99. Canadian Patent 2,209,735 (the "Strattera" or "atomoxetine" patent) claims atomoxetine for the treatment of attention deficit hyperactivity disorder (ADHD).[127]

100. The atomoxetine patent was invalidated in a declaratory action brought by Novopharm against Lilly.[128] The patent was attacked on the basis of obviousness, incomplete disclosure concerning the selection of atomoxetine from an earlier genus patent, anticipation, and lack of utility.[129] The trial judge held that the patent was not obvious,[130] not anticipated[131] and

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124 *Ibid* at ¶ 213 (C-146).

125 *Ibid* at ¶ 218 (C-146).

126 *Ibid* at ¶ 228 (C-146).

127 *Atomoxetine,* 2010 FC 915, *supra* note 79, ¶ 32. Atomoxetine is sold by Eli Lilly under the brand name STRATTERA. Atomoxetine was at one time known as "tomoxetine," and it is referred to by that name in the patent. The terms are synonymous.

128 *Atomoxetine,* 2010 FC 915, aff'd 2011 FCA 220, *supra* note 79 (C-160). A declaratory action under s 60(1) of the *Patent Act, supra* note 3 (C-50), allows an interested party to bring an action to have patent declared invalid. It is generally brought by a party who is contemplating some action which it fears may infringe the patent in question.

129 *Atomoxetine,* 2010 FC 915, *supra* note 79, ¶ 3 (C-160).

130 *Ibid* at ¶ 77 (C-160).

131 *Ibid* at ¶ 87 (C-160).

that it was not a "bad" patent selection patent.[132] These holdings were not challenged on appeal. The sole basis for invalidity, which was affirmed on appeal, was lack of utility.

101. Atomoxetine was approved for treatment of ADHD in both the US and Canada many years prior to trial.[133] It is therefore clear that it would have been held to be useful under prior law, under which evidence of actual use of a patented product was routinely accepted as establishing utility. However, because of the rule against post-filing evidence, that fact was not considered in establishing utility.

102. The trial judge, Barnes J, held that the patent must be assessed against the promise of the patent,[134] and he construed the patent as promising that atomoxetine was "clinically useful" to "effectively treat humans with ADHD. . . . in the longer term."[135] It is evident that the trial judge considered this promised utility to be higher than the "scintilla" of utility necessary to establish utility under the Act.[136] Barnes J held that the evidence was not sufficient to demonstrate the promised utility of clinical effectiveness.[137] Under the mere scintilla standard, the patent would have been held to have utility, because utility would have been measured by the "scintilla" required under the Act, rather than by the construed promise of clinical utility.

103. Barnes J then turned to the question of whether the same evidence might suffice to establish a sound prediction of clinical effectiveness. He held that sound prediction could not be established because the relevant evidence was not disclosed in the patent and was therefore not admissible to establish sound prediction.[138] It is clear that under prior law the patent would not have been held to lack utility on this basis, because the evidence in question would have been admissible. Indeed, this same clinical evidence was considered in this case in the context of demonstrated utility,[139] and was excluded only for the purpose of sound prediction due to the heightened disclosure obligation.

104. In summary, the atomoxetine patent would have been valid under the prior law. The invalidity of the patent turned on three novel rules of Canadian law, namely the heightened standard for utility under the promise doctrine; the exclusion of post-filing evidence; and the requirement that evidence of sound prediction must be disclosed in the patent.

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132 *Ibid* at ¶ 88 (C-160).

133 *Ibid* at ¶ 21, noting "regulatory approval was obtained in the United States on November 26, 2002 and in Canada on December 24, 2004." (C-160)

134 *Ibid* at ¶ 93, 112 (C-160). The trial judge at ¶ 93 cited *Olanzapine (No 1)* 2010 FCA 197, *supra* note 38, ¶ 76, (C-46) quoted at para 42 above. Thus it was clear that he was using "promise" to mean the elevated promise set out in the specification, and not merely as meaning utility.

135 *Atomoxetine,* 2010 FC 915, *supra* note 79, ¶ 93, 112 (C-160).

136 *Ibid* at ¶ 93, 112 (C-160).

137 *Ibid* at ¶ 113 (C-160).

138 *Ibid* at ¶ 120 (C-160), referring in particular to the so-called "MGH Study."

139 *Ibid* at ¶ 94-113 (C-160), discussing the MGH Study at length; while the trial judge ultimately held that the MGH Study did not suffice to establish demonstrated utility, it was clearly considered to be admissible evidence.

IV. Legal Consequences of the Current Law of Utility in Canada

105. The changes to the substantive, evidentiary and disclosure requirements of the law of utility are significant. Individually, each has the effect of making it easier to challenge a patent for lack of utility than under prior law, and there have been no offsetting changes making it more difficult to attack utility. Moreover, the various aspects of the law of utility interact to magnify the effect of the individual changes, such that there has been a sea change in the Canadian law of utility.

106. The elevated standard for utility imposed by the promise of the patent, and the rule against post-filing evidence, both independently make it harder to establish utility, the former by raising the bar, the latter by restricting the available evidence. The two aspects of the law also interact. It might be possible to establish an elevated level of utility, such as clinical effectiveness, using post-filing evidence, and it might also be possible to establish a lesser degree of utility, such as aromatase inhibition, using only pre-filing evidence, but it may be impossible to prove clinical effectiveness based only on pre-filing evidence.

107. This problem may be extreme, depending on how the promise of the patent is construed. If the court finds that the patent promises effectiveness in chronic treatment, this means that long-term studies will be necessary to establish utility. But it is effectively impossible to carry out long-term studies prior to filing, because it is very difficult to maintain confidentiality in large or long term clinical trials on human patients. This means that the trials necessary to show utility would render the patent invalid for lack of novelty, since the trials themselves would be prior art. For that reason, among others, patent applications are normally filed after *in vitro* experiments, *in vivo* animal trials, or small-scale human trials.

108. Related problems arise in any case where the patent is construed to promise clinical effectiveness, even if the patent is not held to promise long-term efficacy. Under current law, the *in vitro* or *in vivo* experiments, or small-scale human trials on which a patent application is based, are typically subject to a searching scrutiny for methodological and statistical rigor. This type of scrutiny would not have been necessary under prior law, since the fact that the compound was commercially used was sufficient to establish utility. Any promise of effective use in humans will be difficult to establish based on pre-filing evidence. The small-scale human trials on which patent applications are normally based are inherently statistically weak, because statistically strong results, by the very nature of statistics, require large-scale or long term trials. The patentee is in a Catch-22: small-scale trials are inherently incapable of demonstrating utility to a high degree of statistical certainty necessary to establish clinical effectiveness, and yet the large-scale trials necessary for strong statistical results cannot be undertaken before the patent application is filed or the patent will fail for lack of novelty or anticipation.

109. Because the elevated standard for utility and the prohibition of post-filing evidence make it more difficult to establish demonstrated utility, utility based on sound prediction has become far more important than under prior law. In particular, under prior law, demonstrated utility could easily be established for any commercially valuable product by the simple fact that the product was actually being used to treat a disorder.

110. While sound prediction has become much more important than under prior law, the changes to the law under the Promise Utility Doctrine have also made it more difficult to establish utility based on sound prediction. In the first place, the promise of the patent and the rule against post-filing evidence both apply equally to sound prediction, thereby making sound prediction more difficult to establish for the same reasons that demonstrated utility is now more difficult to establish.

111. In addition, the disclosure requirement that is applicable only to sound prediction further restricts the evidence available to establish utility. The rule limits the admissible information not just to pre-filing evidence, but to pre-filing evidence which is actually disclosed in the patent. Intuitively, it would seem that if there is almost sufficient evidence to actually demonstrate utility, then it should be simple to establish utility based on the putatively more relaxed standard of sound prediction. However, if the patentee has evidence which is almost sufficient to demonstrate utility and which would in fact suffice to establish sound prediction, the patent will nonetheless be held invalid if that evidence is not disclosed in the patent itself.

112. In practice, the Promise Utility Doctrine has a greater impact in the pharmaceutical field and in other fields of invention. This is because demonstrating utility of pharmaceuticals according to the higher standard imposed by the promise of the patent requires clinical trials, and, as just noted, in practice pharmaceuticals must be patented before extensive clinical trials are undertaken. Other types of inventions, such as mechanical inventions, can be extensively tested in secrecy prior to filing.

113. While the exclusion of post-filing evidence applies in principle to any type of invention, post-filing evidence is more important in the context of pharmaceutical inventions, because extensive testing cannot be done until after the filing date for the practical reasons described above.

114. In addition, the combination of the elevated standard and the restriction to pre-filing evidence means that the doctrine of sound prediction is, in practice, applied almost exclusively in the chemical and pharmaceutical fields.[140]

115. In conclusion, under the Promise Utility Doctrine, as compared with prior law, the standard for establishing utility has been elevated, the evidence admissible to establish utility has been restricted, and the disclosure requirements have been heightened. These changes, individually and cumulatively, have made it easier to challenge a patent for lack of utility than under prior law. None of these changes could have been anticipated. Canadian patent drafters would not have been alert to any of the problematic aspects of the Promise Utility Doctrine until 2002 at the earliest, and the new requirements were not applied to revoke patent protection until

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[140] I am aware of only one case, *Eurocopter*, *supra* note 81, (C-120 and C-304) in which the doctrine of sound prediction was applied outside of that field. In *Eurocopter* it was held that the utility of one of the claims of the patent at issue had neither been demonstrated nor soundly predicted. However, the claim that was invalidated was for an embodiment which was not in commercial production, and which was never built or tested. I am not aware of any cases outside the chemical or pharmaceutical field in which the validity of the commercially valuable embodiment of the invention was assessed on the basis of sound prediction. In contrast, in the pharmaceutical field, the utility of the commercially successful product must often be established on the basis of sound prediction.

2005. This means the patents that are being invalidated in litigation today on the basis of the Promise Utility Doctrine were drafted without knowledge of the Promise Utility Doctrine's requirements.

* * *

Done at Fredericton, NB on 29 Sept 2014.

[Signed]

Norman V. Siebrasse

Attachment A

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EMPLOYMENT

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University Research Professor, University of New Brunswick, July 2002 – June 2005
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Supreme Court of Canada, Law Clerk to Madam Justice Beverley McLachlin, 1991-1992
Schlumberger Oil Field Services, Field Engineer Trainee, October 1985 - April 1986
Bell Northern Research, Hardware Design Engineer, May 1983 - March 1985

EDUCATION

LL.M. 1993, The University of Chicago Law School
LL.B. 1991, Queen's University, Faculty of Law
B.Sc.(Eng. Physics) 1982, Queen's University, Faculty of Engineering
Philosophy/ Physics (part time), 1987-88, Queen's University, Faculty of Arts and Science
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BLOGGING

Primary Blog

Siebrasse, Sufficient Description: blog on current Canadian cases in patent law – Jan 2011 - present

Guest Blogging

IPKat (European Intellectual Property Law): guest blogger Jan - Jun 2012

- Friday fantasies (Introducing me)
- Double Recovery in Transnational Patent Litigation
- Misleading Affidavits
- "Obvious to try" is obviously not obvious
- A hint of a suggestion of a possibility of confusion
- A Sweet Decision on Obviousness
- Is overlooking a fact an error of principle?
- A new battleground of innovative and generic drug manufacturers?
- It is not always reasonable to pursue all reasonable points
- Same sentence, different meaning
- "[T]he issue of principle . . . is that there is no issue of principle."
- Zeus denies fire to Prometheus
- Comity and ex turpi causa: Servier v Apotex [2012] EWCA Civ 593
- What one hand gives, the other takes away? A deeper look at Myriad Monday,
- Lilly, Regeneron and a puzzling point: can you help?
- The wrong tool for the wrong job: time to keep the US courts away from patentable

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SELECTED CONFERENCES, SEMINARS & PRESENTATIONS

Public Citizen & American University Washington College of Law, "Secondary Use Pharmaceutical Patents: Litigation and Trade Policy Briefing," 5 June 2014, Washington DC
PatCon 4: The Annual Patent Conference, "Compensation and Deterrence in Monetary Patent Remedies," 4-5 April, 2014, San Diego, CA
Second Annual University of Toronto Patent Colloquium, Panelist, "Views from the Top," 22 November 2013, Toronto
IPIC Webinar, US Supreme Court Decision *Association for Molecular Pathology v Myriad Genetics*, Panelist, 9 July 2013
International Economic Forum of the Americas, Conference of Montreal, 2013, Panelist,

"Innovation: The Importance of Intellectual Property Protection," 12 June 2013, Montreal

United Nations Ad Hoc Open-ended Informal Working Group to Study Issues Relating to the Conservation and Sustainable Use of Marine Biological Diversity Beyond Areas of National Jurisdiction (ABNJ Working Group), General Assembly Workshop on Marine Genetic Resources, Presentation on Panel 5, Intellectual Property Rights Issues, 2 -3 May 2013, New York

Patent Trolls, Canadian Bar Association, New Brunswick Branch, Continuing Legal Education, Saint John, NB, 25 April 2013

9th Shanghai International IP Forum, Keynote speaker, "The Capitalization and Commercialization of Intellectual Property Rights," Shanghai, China, 9 November 2012

Business Method Patents and Patent Trolls, Consumer and Commercial Law Workshop, Halifax, NS, November 2012

Current Issues in Construction of a Patent, Panelist, 11 October 2012, Vancouver, Intellectual Property Institute of Canada, Annual General Meeting

Presentation to Standing Committee on Industry, Science and Technology of the House of Commons regarding the Intellectual Property Regime in Canada, October 4, 2012.

Comparative Intellectual Property Law Symposium – Utility Requirements: Converging and Diverging Approaches, 4 April 2012, Ottawa, Panel Moderator, "Canada and the World" (AIPLA / IPIC / AIPPI / FICPI accredited)

Comparative Multidisciplinary Approaches to Intellectual Property Law, 23-25 May 2012, Ottawa, Presenter, "Evidentiary Problems of Multidisciplinarity in Litigation" (SSHRC funded)

Osgoode Professional Development Critical Case Update, 2 Feb 2012, "Business Methods and Patentable Subject Matter: Canada (A.G) v. Amazon.com, Inc., Fed CA," panelist (telephone seminar)

UNCITRAL Working Group VI: Security Interests, 15th Session, 27 April - 1 May 2009, New York; 16 th session, 2-6 November 2009, Vienna; 17 th session, 8-12 February 2010, New York, as member of Independent Film and Television Alliance delegation

Workshop on Marine Biodiversity Beyond National Jurisdiction, 28 March 2008, Ottawa, held by the Department of Foreign Affairs and International Trade

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Leveraging Knowledge Assets, presented at the Canadian Bar Association Intellectual Property Section Breakfast Meeting, 29 June, 2005

Farmers' Privilege and the Patenting of Higher Life Forms, presented at the Genome Canada GE^{3}LS Symposium 2004, 13-15 March 2005, Toronto

The Implications of the Experimental Use Defence to Patent Infringement on Basic Research: A Comparative Perspective, presented at the Innogen Conference on the Evolution of the Life Science Industries, 23-25 February 2005, Edinburgh, Scotland

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TEACHING RESPONSIBILITIES

Competition and Trade Regulation, 2014
Intellectual Property Law, 1995-96 – present
Remedies, 2007 - present
Secured Transactions, 2003 – present
Commercial Law, 1997-98 – present
Real Estate Transactions, 1993-94 – 2001
Advanced Intellectual Property Law, 2000
Critical Approaches to Law, 1997-98 – 1998-1999
Legal Method, 1995-96, 1996-97
Municipal and Planning Law, 1993-94, 1994-95

PROFESSIONAL AND SCHOLARLY ACTIVITIES

Canadian Business Law Journal, Editorial Advisory Board Member – Sept 2014 - Present.
IPIC (Intellectual Property Institute of Canada), Biotechnology Patents Committee 2011 - Present
IPIC Patent Legislation Committee 2012 - Present
IPIC Information, Communication & Technology Committee, 2014
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