Chapter 8 Utility

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Executive Summary:

8.1. Introduction – The Need for Utility

As discussed below, to be patentable, an invention must be "useful".[1] This requirement has sometimes been described as the invention having utility (the lack thereof being "inutility") or, more simply, the invention claimed has to work or must be fairly predicted to work (a *prima facie* reasonable inference that it will work).

Proving utility is relatively simple. If you have made an embodiment of the invention, and it worked, then there is utility. If you have not yet made anything, then one must be able to conclude, from the patent application or patent, through the eyes of a skilled reader armed with the common general knowledge of the field of the invention, that it will likely work.

Where utility is not clear, the Commissioner of Patents can request a model[2] (presumably one that works). For example, a patent application for a "Death Ray" was refused[3] because the inventor could not satisfy the Commissioner of Patents, or the Federal Court of Appeal, that it would work. The patent application claimed:

- "an instrument combining the instruments of a high-potential, magnifying transmitter and a suitable source of photo-ionizing radiations",
- "a munition in the form of a ray of electrical and electromagnetic wave forms" and
- "an improvement in the methods of transmitting electrical energy to a distance through the natural media without wires"

The Patent Office found that the device was "inoperable for the purpose for which it was designed" and, therefore, not patentable.[4]

Compare this result to the work of Arthur Paul Pedrick, an eccentric former English Patent Office Examiner, whose invention entitled "Photon Push-Pull Radiation Detector For Use in Chromatically Selective Cat Flap Control And 1000 Megaton Earth-Orbital Peace-Keeping Bomb" was considered "useful" enough to be granted UK Patent No. GB 1,426,698 in 1976. The detector distinguished between Mr. Pedrick's ginger, Mr. Pedrick's ginger cat, and the neighbour's black cat to decide whether to trigger an

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1 *Patent Act*, R.S.C. 1985, c. P-4, s. 2.

2 *Patent Act,* s. 38(1) which provides:

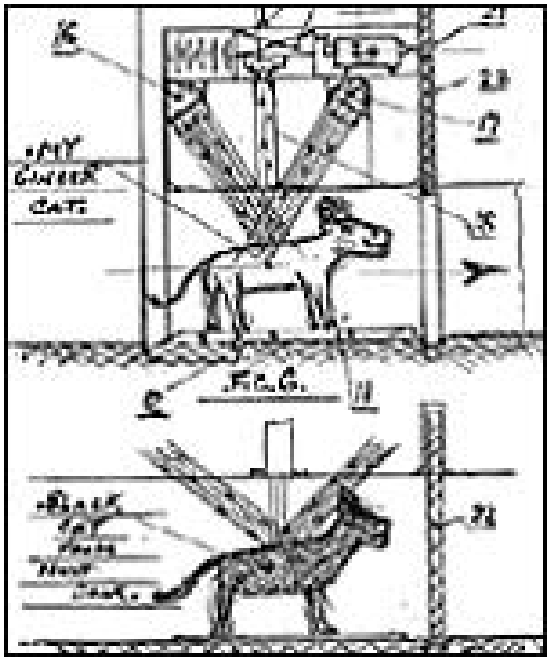
> "In all cases in which an invention admits of representation by model, the applicant, if required by the Commissioner, shall furnish a model of convenient size exhibiting its several parts in due proportion, and when an invention is a composition of matter, the applicant, if required by the Commissioner, shall furnish specimens of the ingredients, and of the composition, sufficient in quantity for the purpose of experiment."

See *X* v. *Commissioner of Patents* (1981) 59 C.P.R. (2d) 7 (F.C.A. per Thurlow C.J.) at pp. 10-11.

3 *X v. Commissioner of Patents*, (1981), 59 C.P.R. (2d) 7 (F.C.A. per Thurlow C.J.)

4 *X v. Commissioner of Patents*, (1981), 59 C.P.R. (2d) 7 (F.C.A. per Thurlow C.J.) at pp. 9-10.

orbiting nuclear bomb.



Generally speaking, an invention has "utility" if:

- It gives a benefit to the public,[5] or a useful choice;[6]
- It is useful in achieving a particular purpose.
- It provides a better or cheaper article;[7]
- It is advantageous under certain circumstances. [8]
- It works.[9]

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5 NTD: authority?

6 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] S.C.R. 504 (S.C.C. per Dickson J.) at p. 525 quoting from *Halsbury's Laws of England*, (3rd ed.), vol. 29, at p. 59.

7 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] S.C.R. 504 (S.C.C. per Dickson J.) at p. 525 quoting from *Halsbury's Laws of England*, (3rd ed.), vol. 29, at p. 59.

8 NTD: authority?

9 NTD: authority?

But why would anyone care about an invention that lacks utility?[10]

1. A claim may include embodiments that lack utility in that they do not work, thereby rendering that claim, and any claim from which it depends, invalid. [See Chapter NTD below] An invalid patent cannot be infringed.

2. A claim may encompass useful embodiments, but also include inoperative or speculative embodiments that lack a legitimate prediction of utility, are overreaching and hence, invalid.[11] [See Chapter NTD below] Whatever useful embodiments that were included in a broad, invalid claim, that are not otherwise included in a narrower (or independent) valid claim, would be unprotected and freely available to the public.

8.2. The Legislative Basis - Section 2 – a patentable invention must be "useful"

A patent for an invention that lacks utility is vulnerable to attack and invalidation.

Section 2 – which addresses utility – provides that an "invention", by definition, is "useful" [12]:

> ""invention" means any new and **useful** art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter;" [emphasis added]

Section 2 of the *Patent Act* makes no mention of such utility needing to be disclosed in the patent itself.[13]

Although section 27(3)(a) of the *Patent Act* requires the specification to "correctly and fully describe the invention and its operation or use as contemplated by the inventor", this does not impose upon a patentee an obligation of establishing the utility of the invention,[14] nor to distinctly indicate the real utility of the invention[15] nor, in the disclosure or claims, to describe in what way the invention is useful.[16] None of the requirements of s. 27(3) include the demonstration or prediction of an invention's

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10 NTD: Quote from Dr. Fox?

11 NTD: Helicopter landing gear case

12 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 144. ["the esomeprazole impeachment trial"]

13 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 144. ["the esomeprazole impeachment trial"]

14 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] S.C.R. 504 (S.C.C. per Dickson J.) at p. 521.

15 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] S.C.R. 504 (S.C.C. per Dickson J.) at p. 525.

16 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] S.C.R. 504 (S.C.C. per Dickson J.) at p. 526.

utility.[17] Section 27(3)(a) is a disclosure requirement, independent of the requirement of section 2 that an invention be useful.[18] Utility and disclosure should be treated separately in the jurisprudence as well.[19]

Section 27(3) provides that "[t]he specification of an invention must" disclose several things. There is no statutory basis for combining s. 2 and s 27(3) to create a disclosure requirement for utility.[20] Read together, there is no statutory basis for a requirement to disclose either the factual basis or the sound line of reasoning required to support a sound prediction of utility.[21] This reading of the *Patent Act* was affirmed by a unanimous decision from the Supreme Court of Canada in 2012.[22]

> "…all that is required to meet the utility requirement in s. 2 is that the invention described in the patent do what the patent says it will do, that is, that the promise of the invention be fulfilled."[23]

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17 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 144. ["the esomeprazole impeachment trial"]. *Patent Act* s. 27(3) provides:

> The specification of an invention must:
>
> (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
>
> (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;
>
> (c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and
>
> (d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.

18 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] S.C.R. 504 (S.C.C. per Dickson J.) at p. 527.

19 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 160. ["the esomeprazole impeachment trial"]

20 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 144. ["the esomeprazole impeachment trial"]

21 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 144. ["the esomeprazole impeachment trial"]

22 *Teva Canada Limited v. Pfizer Canada Inc. et al* (sildenafil), 2012 SCC 60 (S.C.C. per LeBel J.) at para. 40. *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 144. ["the esomeprazole impeachment trial"]

23 *Apotex Inc. v Wellcome Foundation Ltd*, 2002 SCC 77 (CanLII), 2002 SCC 77 at paras. 53-59, 2002 SCC 77 (CanLII), [2002] 4 SCR 153. [AZT]; *Teva Canada Limited v. Pfizer Canada Inc. et al* (sildenafil), 2012 SCC 60 (S.C.C. per LeBel J.), at paras. 37,42 & 80; DMCDMC quoted in *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 154. ["the esomeprazole impeachment trial"]; *Astrazeneca Canada Inc. et al v. Apotex Inc et al*, 2015 FCA 158 (FCA per Dawson J.A., Ryer and Webb JJ.A. concurring) (esomeprazole FCA) at para. 4.

8.3. Claim-based: One bad apple spoils the bunch

Utility, like novelty and obviousness, is to be determined on a claim-by-claim basis.[24]

[25]

Claiming substances that are found not to work can invalidate a patent for lack of utility.[26]

If there is one embodiment that lacks utility that fits within a claim, then the claim is invalid.

In *Société des Usines Chimiques Rhone-Poulenc et al. v. Jules R. Gilbert Ltd. et al*.,[27] it was shown that one of the hydrohalide salts (hydrofluoride) could not be safely used as oral medication, and the patent was declared invalid.

For example, inventors sometimes discover one chemical compound and predict that others like it will work just as the one tested. If one compound within a claim containing many compounds is shown not to work, then the entire claim is invalid. (NTD: example)

> "If it is shown that some bodies falling within such claim have no utility, then, apart possibly from a *de minimis* case where there are only a few exceptions, such as Maugham, J., had in mind in the case of *I.G. Farbenindustrie A.G.'s Patents* (1930) 47 R.P.C. 289 at 323, line 14, the claim is bad ..."[28]

NTD: explore the *de minimus* case. Monsanto SCC "with certain exceptions of inutility".

Where an inventor predicts utility, and is later proven wrong, the claim is invalid. The true cause of the invalidity is the fact that they were without utility, not that they had not been tested before the patent was applied for.[29]

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[24] *Canada (Attorney General) v. Amazon.com, Inc.*, 2011 FCA 328 (F.C.A. per Sharlow, J.A., Trudel & Stratas JJ.A. Concurring) at para . 41

[25] *Astrazeneca Canada Inc. et al v. Apotex Inc et al*, 2015 FCA 158 9fca PER Dawson J.A., Ryer and Webb JJ.A. concurring) (esomeprazole FCA) at para. 4.

[26] *Société des Usines Chimiques Rhone-Poulenc* v. *Jules R. Gilbert Ltd.* [1968] S.C.R. 950, 55 C.P.R. 207, at pp. 228-234, 69 D.L.R. (2d) 353.

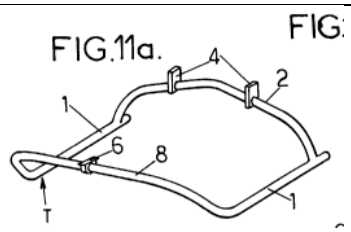
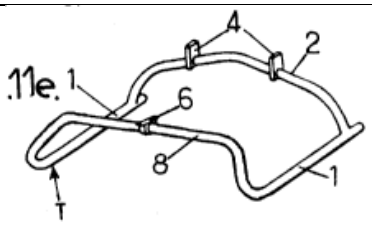
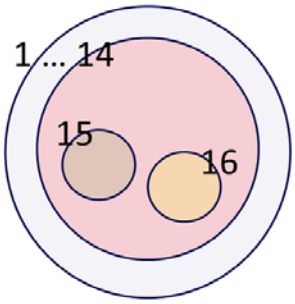
[27] *Societe des Usines Chimiques Rhone-Poulenc et al. v. Jules R. Gilbert Ltd. et al*., (1968), 55 C.P.R. 207 (S.C.C. per Hall J.) at pp. 266-267, 69 D.L.R. (2d) 353, [1968] S.C.R. 950 at p. 953.

[28] *Olin Mathieson Chemical Corp. et al. v. Biorex Laboratories Ltd. et al*., [1970] R.P.C. 157 (per graham J.) at pp. 192-193; quoted and "fully agreed with" in *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Pigeon J.) at p. 175.

[29] *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Pigeon J.) at p. 175, discussing *Olin Mathieson Chemical Corp. et al. v. Biorex Laboratories Ltd. et al*., [1970] R.P.C. 157 (per Graham J.) at p. 192-193.

8.3.1. Dependent claims: one bad apple spoils the bunch from which it depends

A dependent claim is a subset of its parent claim. Thus, if a dependent claim is invalid for inutility, then so too is every claim from which it depends, because those claims also include the same inoperative embodiment. For example, in the *Eurocopter* case[30], the embodiment covered by claim 15 had been built, tested and shown to have worked. Claim 15 was dependent from claims 1-14. The embodiment of claim 16 was never built or simulated, and, accordingly, the inventor had predicted that it would work. The court found that the prediction did not meet the test of sound prediction of utility (discussed below) and, therefore, was invalid as lacking utility. So too were claims 1-14 from which claim 16 depended. Claim 15 remained valid since it covered only embodiments that worked and did not include claim 16 that failed to meet the utility test.

Claim 15: front tip inclined forward valid	**Claim 16: front cross piece that was offset towards the rear invalid**	**Claim 15: valid Claim 16 invalid: so too 1-14**
		

Independent claims should not be affected by an inutility finding of another claim in the same patent. NTD: drug case ~2014.DMC colon cancer[31]?

8.4. When: Useful as of the claim date or date of filing the application

The invention must be useful as of the claim date or as of the time of filing:

> Where the new use is the *gravamen* of the invention, the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available.[32]

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30 *Bell Helicopter Textron v Eurocopter*, 2013 FCA 219 (F.C.A. per Mainville J.A.)

31 NTD: Colorectal cancer dealt with in celecoxib cases – Apotex v Pfizer Canada, 2014 FCA 250, appeal decision from two lower court decisions (Pfizer Canada v Apotex, 2014 FC 314 and Pfizer Canada v Mylan Pharmaceuticals, 2014 FC 38)

32 NTD: AZT at para 56 quoted in Teva sildenafil, at para 37, Justice Lebel, quoted in *Astrazeneca Canada Inc. et al v. Apotex Inc. et al*., 2014 FC 638 (F.C. per Rennie J.) at para. 154. ["the

Formerly, in the “first-to-invent” times, utility had to exist as of the date of invention.[33]

8.5. The Onus of Proof is on the party attacking validity

The presumption of validity of a patent applies to a utility analysis and the onus is on the party attacking validity to establish that the patent lacks utility.[34]

8.6. How much utility is needed?

Nothing in the *Patent Act* sets out the quantum of utility required for an invention to be patentable.

8.6.1. Where no explicit promise of a specific result: a scintilla

Where the specification does not promise a specific result, no particular level of utility is required; a “mere scintilla” of utility will suffice.[35] As described by one practitioner, there must be “some” utility.[36]

Unless it was promised, an invention need not have commercial utility, that is, to be in commercial demand or be profitable to manufacture.[37]

8.6.2. Where an explicit result is promised: a self-imposed threshold

As discussed further below, in the context of the “promise of the patent” where the specification sets out an explicit "promise", utility will be measured against that promise: The question is whether the invention does what the patent promises it will do.” [38]

8.7. Awareness of Utility vs Knowing How The Invention Works

[NTD: what was that English case Merrill Dow about the jungle material?]

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esomeprazole impeachment trial"]

33 NTD: check: *Aventis Pharma v. Apotex*, (2005), 43 C.P.R. (4th) 161, at paras. 88-91

34 *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197, (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), [2012] 1 F.C.R. 349 [Olanzapine] at para. 107.

35 *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), (Olanzapine) at para 76; *Sanofi-Aventis v. Apotex Inc*., (Plavix 2) 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at paras. 49 & 50; *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 65.

36 Hill, Donald; “*Claim Inutility*”; (1960), 35 C.P.R. 185 at 186.

37 *Badische Anlin Und Soda Fabrik v. Levinstein*, (1887), 4 R.P.C. 449 (H.L. per Lord Herschell) at p. 466.

38 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd*., [1981] 1 S.C.R. 504 (S.C.C. per Dickson J.), at p. NTD; *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2009] 1 F.C.R. 253, 2008 FCA 108 at para. NTD (Ranbaxy). *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), (Olanzapine) at para 76

NTD: You don't have to know "how it works" – case with loose language saying the opposite.

If an inventor has adequately defined his invention, he is entitled to its benefit even if he does not fully appreciate or realize the advantages that flow from it or cannot give the scientific reasons for them.[39]

8.8. Disclosure of Usefulness in the Patent

There is no obligation in s. 27(3) of the *Patent Act* obligating the inventor in his disclosure or claims to describe in what respect the invention is new or in what way it is useful:

> Although (i) s. 36(1) requires the inventor to indicate and distinctly claim the part, improvement or combination which he claims as his invention and (ii) to be patentable an invention must be something new and useful (s. 2), and not known or used by any other person before the applicant invented it (s. 28(1)(*a*)), I do not read the concluding words of s. 36(1) as obligating the inventor in his disclosure or claims to describe in what respect the invention is new or in what way it is useful. He must say what it is he claims to have invented. He is not obliged to extol the effect or advantage of his discovery, if he describes his invention so as to produce it. [40]

8.8.1. In the claims

8.8.1.1. <u>In the preamble</u>

Arguably, utility is explicitly stated in a claim when the preamble describes the invention as a specific apparatus, method or use.

For example, a claim for "A mousetrap comprising…", expressly claims usefulness as a mousetrap. Likewise, a claim for the use of sildenafil for the treatment of erectile dysfunction[41] claims uselfulness as a treatment of erectile dysfunction.[42] If the invention

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39 *R. v. American Optical Company et al*, (1950), 11 Fox Pat. C. 62 (Ex. Ct. per Thorson P.) at p. 85; quoted in *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] S.C.R. 504 (S.C.C. per Dickson J.) at p. 526.

40 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd*., [1981] 1 S.C.R. 504 (S.C.C. per Dickson J.), at p. 526, referring to the predecessor of s. 27(3), then s. 36(1).

41 *Teva Canada Ltd. v. Pfizer Canada Inc*., [2012] 3 SCR 625, 2012 SCC 60 (CanLII). Claim 7 which provided:

> The use according to claim 4 wherein the compound of formula (I) is 5-[2-ethoxy-5-(4-methyl-1-piperazinyl-sulphonyl)-phenyl]-1-methyl-3-n-propyl-1,6-dihydro-7H-pyrazolo[4,3-d]pyrimidin-7-one or a pharmaceutically acceptable salt thereof … for the manufacture of a medicament for the curative or prophylactic treatment of an erectile dysfunction in a male animal or sexual dysfunction in a female animal.

42 However see *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per

claimed is not useful as a mousetrap or for the treatment of erectile dysfunction then, paraphrasing *Consolboard*,[43] the invention does not do what the patent promises it will do.[44]

In the case of a new chemical compound, a claim will likely only describe the structure of the compound; it will be silent on the compound's utility. Such claim will lack any description of its practical use. Although such claim need not claim a particular use, what is claimed must be useful in some respect and its utility must be disclosed elsewhere in the patent. [NTD; authority?]

8.8.2. In the disclosure

As discussed above,[45] a patent for a new chemical compound will likely not disclose the compound's utility in the claim, but instead will disclose the compounds utility in the disclosure.

8.9. 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.[46]

However, where the specification sets out an explicit "promise", utility will be measured against that promise[47] and assessed by reference to the terms of that explicit promise.[48] In other words, the invention must be "useful" for the purpose for which it was designed[49] as specified in the disclosure and the claims.[50]

Noël, C.J., Trudel and Biovin JJ.A. concurring) at paras. 70-71 where the court said that *Bauer* does not support the broad proposition that where a patent "lays claim" to a particular use, the patent cannot conceivably be read as not including a promise for that very use.

43 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd*., [1981] 1 S.C.R. 504 (S.C.C. per Dickson J.), at p. 525-526.

44 *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), (Olanzapine) at para 76.

45 8.8.1, above.

46 *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), (Olanzapine) at para 76; *Sanofi-Aventis v. Apotex Inc*., (Plavix 2) 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at paras. 49 & 50; *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 65.

47 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd*., [1981] 1 S.C.R. 504 (S.C.C. per Dickson J.), at p. 525; *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2009] 1 F.C.R. 253, 2008 FCA 108 at para. NTD (Ranbaxy). *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), (Olanzapine) at para 76

48 *Sanofi-Aventis v. Apotex Inc*., (Plavix 2) 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at paras. 49 & 50.

49 *Mullard Radio Valve Co. Ltd.* v. *Philco Radio & Television Corp. of Great Britain Ltd. et al.* (1935), 52 R.P.C. 261 (per Maugham L.J.) at p. 287.

The promise of the patent is to be determined at the start of the utility analysis with a view to the entire patent:

> "[T]he promise of the patent is to be ascertained at the outset of [a utility] analysis…. The promise is to be construed by the trial judge within the context of the patent as a whole, through the eyes of the POSITA in relation to the science and information available at the time of filing. The promise of the patent is fundamental to the utility analysis."[51]

8.9.1. Determining a Promise: a question of law

Determining a "promise" is an aspect of claim construction and is a question of law.[52]

8.9.2. The early case law: Promising a Result

The early case law discusses "promised results". The older authorities[53] distinguish between:

> "… a case where the patentee claims a result and bases his claim for a patent on the production of that result, and a case where a patentee merely points to certain advantages that will accrue from the use of his invention. In the former case failure to perform the promise of the specification is fatal to the patent." [54]

In *Alsop's Patent,*[55] where a claim was made for a process that achieved a certain result and if, following the instructions of the disclosure, the result is not produced, then the consideration for the patent fails. This appears to be a case of either a non-enabling disclosure, or claiming something that does not work, rather than the foundation of a "promise" doctrine.

> "In considering the validity of a patent for a process, it is, therefore, material to ascertain precisely what the patentee claims to be the result of the process for which the patent has been granted; the real consideration which he gives for the grant is the disclosure of a process which produces a result and not the disclosure of a process which may or may not produce any result at all. If the

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50 *Rodi & Weinberger A.G.* v. *Metalliflex Ltd.* (1959) 19 Fox Pat. C. 49 at p. 53.

51 *Eli Lilly Canada Inc v Novopharm Limited*, 2010 FCA 197, (F.C.A. per Layden-Stevenson J.A., Nadon J.A. and Sharlow J.A. concurring) para 93. This was applied in *AstraZeneca v Apotex*, 2014 FC 638 (F.C. per

52 *Apotex Inc. v. ADIR and Servier Inc.* [perindopril], 2009 FCA 222 (F.C.A. PER Layden-Stevenson J.A., Linden & Evans JJ.A. concurring) at para 101.

53 including Fox, "*The Canadian Law and Practice Relating to Letters Patent for Inventio*ns"; 4th Ed., Carswell, 1969, at p. 152.

54 including Fox, "*The Canadian Law and Practice Relating to Letters Patent for Inventio*ns"; 4th Ed., Carswell, 1969, at p. 152.

55 24 R.P.C. 733 (per Parker J.) at p. 752, quoted in *Hatmaker v Joseph Nathan & Co Ltd.* (1919), 36 RPC 231 (HL per Lord Birkenhead) at page 237 and in *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, (donepezil), 2011 FC 547 (F.C. per Hughes, J.) at para. 212.

> patentee claims protection for a process for producing a result, and that result cannot be produced by the process, in my opinion the consideration fails."[56]

In *Hatmaker*,[57] the patent related to a process for producing dried milk. The disclosure included two material statements, which were repeated in the claims:

> "(1) The dry milk solids obtained by my process … are in so perfect a state that they can be restored to milk of excellent quality by the addition of hot water.
>
> (2) By drying milk rapidly by the employment of a high temperature as above described, I obtain the milk sugar as well as the other solids of milk in a dry but otherwise unaltered condition." [58]

When reconstituted, and allowed to stand, fat rose to the surface and insoluble casein settled to the bottom. The trial judge considered that the first representation (of excellent quality) "was not fully and sufficiently borne out by the result."[59] The trial judge also held that, during the water evaporation stage of the process, material changes occurred in the physical condition of the fat and the physico-chemical condition of the casein. Lord Birkenhead characterized *Alsop* in this way:

> "… protection is purchased by the promise of results. It does not, and ought not to, survive the proved failure of the promise to produce the results."[60]

8.9.3. Consolboard

Consolboard is the source of the current promise doctrine in Canadian law. [61]

In *Consolboard*, the Federal Court of Appeal had held that s. 36 required all objects of the invention (including its utility) to be in the disclosure and required that the "… specification distinctly claims the "part, improvement or combination which he claims" having "correctly and fully" described, *inter alia*, its utility."[62] Dickson J., on behalf of the

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56 *Alsop's Patent*, (1907) 24 R.P.C. 733 (per Parker J.) at p. 752, quoted in *Hatmaker* v *Joseph Nathan & Co Ltd.* (1919), 36 RPC 231 (H.L. per Lord Birkenhead in) at page 237, quoted in *Pfizer Canada Inc.* v *Mylan Pharmaceuticals ULC*, 2011 FC 547 (F.C. per Hughes J.), 93 CPR (4th) 81, at para. 212.

57 *Hatmaker v Joseph Nathan & Co Ltd.* (1919), 36 RPC 231 (HL per Lord Birkenhead) at page 237, quoted in *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, (donepezil), 2011 FC 547 (F.C. per Hughes, J.) at para. 212.

58 *Hatmaker v Joseph Nathan & Co Ltd.* (1919), 36 RPC 231 (HL per Lord Birkenhead) at page 237.

59 *Hatmaker v Joseph Nathan & Co Ltd.* (1919), 36 RPC 231 (HL per Lord Birkenhead) at page 237.

60 *Hatmaker v Joseph Nathan & Co Ltd.* (1919), 36 RPC 231 (HL per Lord Birkenhead) at page 237, quoted in *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, (donepezil), 2011 FC 547 (F.C. per Hughes, J.) at para. 212.

61 *Apotex Inc. et al v. Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël J.A., Trudel and Biovin JJ.A., concurring) at para. 66.

62 *MacMillan Bloedel (Saskatchewan) Ltd. v. Consolboard Inc*., (1979) 41 C.P.R. (2d) 94 (F.C.A.) at p. 96. The mention of the utility in the context of a preferred embodiment of the invention was not

Supreme Court of Canada disagreed:

> "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. [Footnotes omitted.]
>
> 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. [Footnotes omitted.]
>
> Canadian law is to the same effect. In *Rodi & Wienenberger A.G. v. Metalliflex Limited*[11], (affirmed in this Court [1961] S.C.R. 117) the Quebec Court of Appeal adopted at p. 53 the following quotation from the case of *Unifloc Reagents, Ld. v. Newstead Colliery, Ld.* [NTD12] at p. 184:
>
> > "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. The question to be asked is whether, if you do what the specification tells you to do, you can make or do the thing which the specification says that you can make or do."[63]

Firstly, it should be noted that Dickson J. was discussing the disclosure requirements of the definition of "invention" in section 2. As discussed above regarding s. 2, section 27(3)(a) (then s. 36(1)) is a disclosure requirement, independent of the requirement of

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sufficient:

> "The main reference to it [the utility] is in col. 8 (out of 16 cols.) in a discussion of a particular application of the "invention". In our view, this is not a distinct indication of the real utility of the invention in question by which the public would be made aware of the invention in the manner required by s. 36 and the *Patent Act* does not, therefore, authorize a monopoly for the invention."

63 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] S.C.R. 504 (S.C.C. per Dickson J.) at p. 525-526.

section 2 that an invention be useful.[64] Utility and disclosure should be treated separately in the jurisprudence as well.[65]

Further, the comment from *Halsbury* that "the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice" appears to be a conflation of several concepts of patentability including novelty ("a new article"), non-obviousness ("a better article – an improvement, a cheaper article" – less giving more), or merely a circular definition ("affords the public a useful choice" – something being useful if it is useful). At best, it is a colourful exposition rather than a rigorous definition.

This language from *Consolboard* has been summarized as: The question is then whether the invention does what the patent promises it will do.[66]

NTD: add more re history of promise

The explicitly promised utility becomes a self-imposed threshold of utility over and above the mere scintilla otherwise required. An inventor whose invention is described in a patent which would otherwise be valid can nonetheless promise more for his or her invention than required by the *Act* so as to render his or her patent invalid. If he or she does so, so be it; it is a self-inflicted wound.[67] That the invention may well have satisfied the scintilla threshold is of no assistance in establishing utility where a promise, if it be made, cannot be met.[68]

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64 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] S.C.R. 504 (S.C.C. per Dickson J.) at p. 527.

65 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 160. ["the esomeprazole impeachment trial"]

66 *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), (Olanzapine) at para 76.

67 *Sanofi-Aventis v. Apotex Inc*., (Plavix 2) 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at para. 54 referring to *Free World Trust v. Électro Santé Inc*., 2000 SCC 66, [2000] 2 S.C.R. 1024, at paragraph 51.

68 *Apotex Inc. et al v. Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 65; *Sanofi-Aventis v. Apotex Inc., (Plavix 2)* 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at para. 54.

The “promise of the patent” might be better described as a self-inflicted hurdle. The question is, if you don’t need to create a hurdle, why would you?

8.9.4. Where utility is necessarily disclosed: when the utility is what’s new

A description (amounting to a promise?) of utility is necessary when that utility is what differentiates the invention from the prior art, such as:

- A new chemical compound;
- A new use for an old thing; and
- Some selections from a broader class, in the case of a selection patent.

8.9.4.1. A new chemical compound.

In the case of a new chemical compound, a claim will likely only describe the structure of the compound; it will therefore be silent on the compound’s utility. Its utility (other than as “merely occupying space”) must be disclosed elsewhere in the patent.

NTD: Check cases:[69]

8.9.4.2. A New Use for an Old Thing

A patent can be granted for a new use for an old thing. Ntd add authorities.

In such case, the new use is what differentiates the invention from the prior art: the prior uses of the item. The new use must be spelled out in the patent and, in particular, in the claims[70] and in the disclosure.[71]

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[69] *Aventis Pharama Inc. v. Apotex Inc. et al*, 2005 FC 1283 at paras. 82-83, aff’d 2006, 46 C.P.R. (4th) 401 (F.C.A.); *Janssen-Ortho Inc. v. Novopharm Limited*, 2006 FC 1234 at para. 96, aff’d on other grounds 2007 FCA 217; *AstraZeneca Canada Inc. et al. v. Apotex Inc., et al*, 2010 FC 714 at para. 73; *Monsanto Canada Inc. v. Schmeiser* (2001), 12 C.P.R. (4th) 204 at para. 26, aff’d (2002) 21 C.P.R. (4th) 1 (FCA) at paras 41-46, aff’d [2004] 1 S.C.R. 902.

[70] *AstraZeneca Canada Inc. v. Apotex Inc*. (esomeprazole), 2010 FC 714 (F.C. per Hughes J.) at

Where the new use is the (oddly chosen phrase) *gravamen*[72] of the invention, the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available.[73]

8.9.4.3. Selection Patents

Although we have included selection patents in this section,[74] it doesn't really belong here. As discussed more fully below, selection patents require the advantage of the selection (or the disadvantage avoided) over the genus in the prior art to be stated; the utility of the selection can be the same as that of the genus. NTD: confirm below.

Selection patents are strange animals. They claim compounds that are old and previously disclosed, but which are a subset (species) of a larger set (genus) which subset has properties that are better than the rest of the genus. [NTD]

Although not restricted to chemical patents, selection patents more commonly arise in that context. Simply stated, the originating (or genus) patent typically refers, in general terms, to a group of products or processes from all of which a particular result (or results) may be obtained or predicted. If a substantial advantage to be secured or disadvantage to be avoided in relation to one or more members of the genus is subsequently discovered, that advantage/avoided disadvantage may be an invention giving rise to a valid selection patent. As explained in *Pfizer* and *Sanofi*, selection patents exist to encourage researchers to further use their inventive skills so as to discover new advantages for compounds within the known class.[75]

A selection patent is subject to the same validity attacks as any other on any of the

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para. 74, citing *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 SCR 536;

71 *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, (donepezil), 2011 FC 547 (F.C. per Hughes, J.) at para. 202 (aff'd *Mylan Pharmaceuticals ULC v. Pfizer Canada Inc*., 2012 FCA 103 (F.C.A. per Mainville J.A., Sharlow & Gauthier JJ.A. concurring), citing *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 SCR 536; *Novo Nordisk Canada Inc. v. Cobalt Pharmaceuticals Inc.*, 2010 FC 746 at para. 157.

72 Defined by Merriam-Webster as "the material or significant part of a grievance or complaint".

73 NTD: AZT at para 56 quoted in Teva sildenafil, at para 37, Justice Lebel, quoted in *Astrazeneca Canada Inc. et al v. Apotex Inc. et al*., 2014 FC 638 (F.C. per Rennie J.) at para. 154. ["the esomeprazole impeachment trial"]

74 As did Ronald E. Dimock in his affidavit [NTD: get link] in support of the Canadian government's case in the Lilly challenge (In the Matter of an Arbitration under Chapter 11 of the North American Free Tarde Agreement and the Uncitral Arbitration Rules (1976) between Eli Lilly and Company and Government of Canada, Case No. UNCT/14/2, at para. 119, where he stated ' "Selection" patents are another type of patent in which a particular utility or "advantage" must be disclosed within the patent specification.' Only the "advantage" or lack of disadvantage need be disclosed in a selection patent.

75 *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), (Olanzapine) at para 20.

grounds set out in the *Act*.[76]

In *Sanofi*[77] Justice Rothstein relied on the reasons of Lord Maugham in *In re I.G. Farbenindustrie A.G.'s Patents* (1930), 47 R.P.C. 289 (Ch.D.) in support of the conclusion that a system of genus and selection patents is acceptable in principle. At paragraph 10 of his reasons, Rothstein J., described the characteristics of a valid selection patent as follows:

> "1. There must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members.
>
> 2. The whole of the selected members (subject to "a few exceptions here and there") possess the advantage in question.
>
> 3. The selection must be in respect of a quality of a special character peculiar to the selected group. If further research revealed a small number of unselected compounds possessing the same advantage, that would not invalidate the selection patent. However, if research showed that a larger number of unselected compounds possessed the same advantage, the quality of the compound claimed in the selection patent would not be of a special character."[78]

Here "characteristic" likely means "advantage secured or disadvantage avoided". Note that the language from *Farbenindustrie* does not require the selection to have improved utility over the genus, but rather "a substantial advantage" over the rest of the genus or a "quality of a special character" peculiar to the selected group.

However, a court has said that the same utility is not enough [NTD: but I disagree[79]]:

> [110] In my view, Lilly's submission with respect to the promise of the '113 patent does not line up with the plain words of the patent. Nor does it accord with the preponderance of the expert evidence about what those words conveyed to them. Nor would that reading, in my view, meet the utility requirement for a selection patent, or conform to the approach to selection patents laid out by Justice Layden-Stevenson. The promise of the '113 patent must be greater than that of the '687 patent which, as outlined above, related to a family of compounds useful in the treatment of schizophrenia and other disorders, and that would be expected to have low EPS liability (i.e., second generation antipsychotics).
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> [111] It is simply not enough for a selected compound to achieve what was promised in the genus patent. Justice Brian Malone of the Federal Court of

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76 *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), (Olanzapine) at para 33.

77 *Apotex Inc. v. Sanofi-Syntholabo Canada Inc*., [2008] 3 S.C.R. 265 (*Plavix* 1).

78 *Apotex Inc. v. Sanofi-Syntholabo Canada Inc*., [2008] 3 S.C.R. 265 (*Plavix* 1) at para. 10.

79 It MAY have greater utility than the genus, but why can't it have the same utility, but have some advantage or lack some disadvantage of the genus?

> Appeal addressed this point when he said that a valid selection patent involves a "discovery that the selected members possess qualities hitherto undiscovered, particular to themselves and not attributable to them by virtue of the fact of their belonging to a class specified by an earlier invention" (*Pfizer Canada Inc v Canada (Minister of Health)*, 2006 FCA 214, para 22, citing *Dreyfus and Other Applications* (1945), 62 RPC 125 at 133).
>
> [112] In other words, it is not enough, in my view, for Lilly to maintain that the stated utility of olanzapine – the promise of the '113 patent - is simply that it actually does or could be soundly predicted to do what the '687 patent said that all members of that class did, or were soundly predicted to do.[80]

Not only must the selected group have the advantage, but the specification must define in clear terms the nature of the characteristic which the patentee alleges to be possessed by the selection.[81] The novelty of the selection and its advantages (including disadvantages to be avoided) are the invention and must be described in the patent.[82]

It is simply not enough for a selected compound to achieve what was promised in the genus patent.[83] Justice Brian Malone of the Federal Court of Appeal addressed this point when he said that a valid selection patent involves a "discovery that the selected members possess qualities hitherto undiscovered, particular to themselves and not attributable to them by virtue of the fact of their belonging to a class specified by an earlier invention".[84] It is not enough that the stated utility of olanzapine – the promise of the '113 [selection] patent - is simply that it actually does or could be soundly predicted to do what the '687 [genus] patent said that all members of that class did, or were soundly predicted to do.[85]

Although there must be "something more" ("qualities" as referred to by Justice Malone or an advantage over the genus as referred to in the other cases), we do not believe that this requires greater "utility" as such. The selection may still have the same usefulness (for example in Plavix, as an anti-thrombogenic compound) but have greater advantages (twice as effective as the genus) and fewer disadvantages (lesser toxicity). Whether this is described as greater utility may be semantic. The selection cannot be just the same as the genus; it must have some advantage over the genus or lack a

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80 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (Olanzapine FC 2).

81 *Apotex Inc. v. Sanofi-Syntholabo Canada Inc*., [2008] 3 S.C.R. 265 (*Plavix* 1) at para. 114.

82 *Sanofi-Aventis v. Apotex Inc*., (*Plavix 2*) 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at para. 51.

83 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 111.

84 *Pfizer Canada Inc v Canada (Minister of Health)*, 2006 FCA 214 (FCA per Malone J.) at para. 22, citing *Dreyfus and Other Applications* (1945), 62 RPC 125 at 133; quoted in *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 111.

85 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 112.

disadvantage of the genus. In such way, it must be "better".

No specific number of advantages is required. One advantage may be enough or any number of seemingly less significant advantages (when considered separately) may suffice when considered cumulatively, provided that, in either case, the advantage is substantial.[86]

The selection must have the advantage(s) over a large number of the other members of the genus. Where the patentee had merely stated that one particular compound, valacyclovir, was better than two other members of the class,[87] that was not enough to establish an advantage over the whole class. It would not be necessary to conduct tests of all members of the class, but there must be "sufficient representative testing that a person skilled in the art could soundly predict that the surprising characteristic would not be expected to be found in a large number of the other members of the genus." [88]

[NTD: Dimock Lilly affidavit said [89]selection patents needed "enhanced utility"[90] citing Olanzapine FCA. The decision doesn't say that.]

Except for selection patents, there is no obligation on the part of an inventor to disclose the utility of his or her invention in the patent.[91]

[70] *Bauer* FC. In that case, Gauthier J., sitting as a trial judge, stated (at para. 289): DMC NTD Mylan FCA[92]

> It is settled law that results or advantages included in the claims must be met. Similarly, in the context of selection patents where the advantages described are really the basis upon which the patentee is given the right to monopolize a substance or product already covered in a prior patent as part of a larger group of substances or products, the inventor will be held to its promise (*Ratiopharm Inc. v. Pfizer Ltd*., 2009 FC 711, 76 C.P.R. (4th) 241, 350 F.T.R. 250 (Pfizer (2009)).[93]

Olanzapine (Zyprexa) Cdn patent No. 2,041,113 (NTD to Erika: create another style

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86 *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), (Olanzapine) at para 79.

87 *GlaxoSmithKline Inc v Pharmascience Inc*, 2008 FC 593 (F.C. per Barnes J.), at para. 63.

88 *GlaxoSmithKline Inc v Pharmascience Inc*, 2008 FC 593 (F.C. per Barnes J.), at para. 70.

89 Ntd: Dimock para. 167 and 201

90 *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), (Olanzapine) at para NTD.

91 NTD: Consolboard too? *Sanofi-Aventis v. Apotex Inc*., (*Plavix 2*) 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at para. 50.

92 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 71.

93 *Bauer Hockey Corp. v. Easton Sports Canada Inc*., 2010 FC 361, [2010] F.J.C. No. 431 at para. 289 [Bauer FC], aff'd 2011 FCA 83, [2011] F.C.J. No. 331

level here)

The olanzapine patent was a selection patent.[94] Olanzapine is a treatment for schizophrenia.

The '113 patent included the statement:

> Overall, therefore, in clinical situations, the compound of the invention shows marked superiority and a better side effects profile than prior known antipsychotic agents, and has a highly advantageous activity level.[95]

In one of the first olanzapine cases, the Federal Court of Appeal had difficulty determining the Federal Court judge's findings were with respect to the promise of the patent as they did not appear to have been "explicit":

> [94] The trial judge does not refer specifically to the promise of the patent. In a section of his reasons entitled "olanzapine advantages over the other '687 compounds", various terms are used. For example, he states that the '113 Patent proclaims a number of advantageous qualities for olanzapine; it identifies certain advantages of olanzapine over the other compounds from the '687 Patent; it boasts the superiority of olanzapine over other known antipsychotic drugs used in the treatment of schizophrenia and related conditions (para. 33); and it displays surprising and unexpected properties as compared to flumezapine and other related compounds (para. 34).
>
> [98] I have difficulty concluding that the summarized paragraphs constitute a construction of the patent or an analysis of its promise. If that is their intent, then I have difficulty determining exactly what the trial judge construed the promise of the patent to be. Regardless, assuming for the moment that the noted paragraphs do constitute construction of the patent's promise, there are problems with it.
>
> [100] While I have difficulty concluding that the trial judge's comments constitute a construction of the promise of the patent, it is possible that he had reason to construe the patent's promise in such a manner for he had the benefit of hearing the expert evidence. This gives rise to another problem.
>
> [101] There is no reference in the trial judge's reasons to the expert evidence regarding the promise of the patent…
>
> [104] In summary on this issue, the assessment and weighing of the evidence are the domain of the trial judge, subject to appellate review only for palpable and

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94 *Eli Lilly Canada Inc. v. Novopharm Limited*, 2009 FC 1018 (O'Reilly J.) [Olanzopine FC 1], 2010 FCA 197 per Layden-Stevenson J.A.), *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para 86-88)

95 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (Olanzapine FC 2) at para. 45

> overriding error. In the absence of any reference to the evidence relied upon by him to determine the promise of the patent, meaningful appellate review cannot be conducted.

Given the deficiency in the record, the issue of utility was returned to the Federal Court for determination.[96]

In the second round of olanzapine, when referred back to Justice O'Reilly,[97] the "Overall, therefore …" statement was considered to be a promise.[98]

> "…the patent mainly asserts the superiority of olanzapine in respect of the particular side effects specifically mentioned in the patent, most especially EPS and agranulocytosis."[99]

> "Therefore, the promise of the '113 patent is that olanzapine is substantially better ("marked superiority") in the clinical treatment of schizophrenia (and related conditions) than other known antipsychotics, with a better side-effects profile, and a high level of activity at low doses. This promise expresses a substantial advantage for olanzapine over the other '687 compounds, which had never actually been used to treat schizophrenia. The individual advantages asserted in the patent (other than in relation to cholesterol) form the foundation for the overall promise of the patent."[100]

The genus patent, the '687 patent, covered 15 trillion compounds, including olanzapine which fell within the group pf "most preferred compounds", although it was not specifically named.[101] By 1983, Lilly had selected olanzapine as a candidate drug and it had showed potential as an antipsychotic based on animal and *in vitro* tests. Studies continued and Lilly's hopes were confirmed by further preliminary results. Beginning in 1986, Lilly gave olanzapine to healthy volunteers and, in 1989, started clinical trials in patients.[102] By the time it filed the '113 patent, Lilly had received the results of its healthy volunteer studies, as well as some preliminary data from clinical trials. It had

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96 *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), (Olanzapine FCA 1) at para 109.

97 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (Olanzapine FC 2).

98 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 120.

99 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 122.

100 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 1240

101 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para 18.

102 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 26.

also concluded a six-month study in dogs.[103]

The '113 patent set two main categories of advantageous qualities of olanzapine:[104]

1. certain advantages of olanzapine over the other compounds from the '687 patent;

    a. lower incidence of liver enzyme elevations compared to flumezapine;

    b. lower CPK levels than flumezapine;

    c. lower EPS than flumezapine; and

    d. no increase in cholesterol compared to ethyl olanzapine;[105] and

2. Second, the '113 patent stated that olanzapine is superior to other known antipsychotic drugs used in the treatment of schizophrenia and related conditions:[106]

    a. a high level of efficacy at low doses;

    b. lower elevation of prolactin;

    c. lower EPS liability; and

    d. no alteration of white blood cell count.[107]

Justice Layden-Stevenson concluded that the '113 patent sets out a sufficient factual basis for a sound prediction of the patent's promise. She cited the studies in mice and rats to determine olanzapine's potential as an anti-psychotic drug, a small open-label clinical trial with 8 patients, and four studies involving a total of 20 healthy volunteers. She stated, therefore, that the real question in respect of the '113 patent's validity was not whether there was a factual basis for a sound prediction of its utility, but whether there was an articulable line of reasoning – that is, a *prima facie* reasonable inference - from that factual basis to the patent's promise.[108]

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103 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 27.

104 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 36.

105 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 41.

106 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 36.

107 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at paras. 48 & 71.

108 *Eli Lilly Canada Inc v Novopharm Limited*, 2010 FCA 197 ((Layden-Sevenson J.A., Nadon &

Schizophrenia is a chronic condition. The evidence available to Lilly in April 1991 did not demonstrate that olanzapine could meet the promise of the '113 patent that it would provide markedly superior clinical treatment of schizophrenia with a better side effects profile than other known antipsychotics.[109]

The studies done by Lilly, including the E001 study, supported the prediction of certain properties of olanzapine (olanzapine had some antipsychotic properties, and had prolactin liability in a safe range[110]), but did not support a sound prediction of the stated utility of the '113 patent, the advantages over other compounds.[111] The evidence shows that the inventors could not draw a prima facie reasonable inference from the information available in April 1991 to the promise of the '113 patent that olanzapine could treat schizophrenia patients significantly better, and with fewer side-effects, than other known antipsychotic drugs.[112]

Justice O'Reilly held that there was no evidence before him of a line of reasoning that would link the factual basis with the specific promise of the '113 patent. To begin with, with regard to olanzapine's alleged superiority in the clinical treatment of schizophrenia, the factual basis consisted solely of the E001 study. The expert evidence consistently described that study as preliminary, hypothesis-generating and, at best, providing early, positive signals that would warrant further study of olanzapine. None of the witnesses went so far as to suggest that the results of E001 would support a sound prediction that olanzapine would treat schizophrenia in a markedly superior manner to other known antipsychotics. In fact, the E001 investigators themselves thought olanzapine's effect might be comparable to that of conventional antipsychotics, but acknowledged that it was difficult to make any predictions based on such a short study with so few patients.[113] Likewise with the other advantages expressed.

Although the '113 patent set out a rational basis for making a sound prediction that olanzapine would be useful in the treatment of schizophrenia, it did not set out grounds

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Sharlow JJ.A. concurring); NTD: check cite – why here? *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 91.

109 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 210 & 213.

110 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 218.

111 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 216 & 218: "With regard to EPS, olanzapine appeared to have some liability, which might have been lower than that of conventional antipsychotics. On the other hand, one could not reasonably infer from the available evidence that olanzapine would treat schizophrenia patients in the clinic in a markedly superior way. Its antipsychotic effect was, at best, comparable to that of conventional antipsychotics. Olanzapine's liver enzyme and CPK liabilities were a concern. Its effect on white blood cells could not be predicted, on the basis of the available evidence, nor could its overall side-effects liability."

112 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 219.

113 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 210 & 213.

for a sound prediction that olanzapine would treat schizophrenia in a markedly superior fashion, with a better side-effects profile than other known antipsychotics.[114]

Justice O'Reilly said the evidence suggested to him that Lilly filed the '113 patent before it had a basis on which to found a sound prediction of olanzapine's advantages, if any, over the '687 compounds or other antipsychotics.[115] At the time the patent was filed in April 1991, Lilly had not found any special qualities of olanzapine that would justify a fresh monopoly. Lilly had carried out routine testing of olanzapine's properties. It had some early signals of safety and efficacy in a few small studies of healthy volunteers and patients. While Lilly scientists showed persistence, diligence and sound science in getting olanzapine that far, that is not necessarily enough for a patent. There must be an invention. And, in the context of a selection patent, the invention is the discovery of a substantial advantage over the genus compounds.[116]

[NTD: move elsewhere?] But see *Plavix 2*, a selection patent case, where Gauthier JA said there was no enhanced disclosure requirement:

> "In contradistinction with the situation in *AZT*, where the invention claimed was the new use/utility and thus the *quid pro quo* for the grant of the monopoly was a full disclosure in respect of such utility, the public here received all the information necessary to make and use clopidogrel."[117]

8.9.5. Where the invention has been made

Where, at the time of the filing of the application, the invention has been made, the promise becomes a yardstick against which utility is measured. Ntd add more law

8.9.6. Where the invention is a prediction

The situation is more complicated when the invention has not yet been made. NTD.

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114 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 255.

115 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 264.

116 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 265.

117 *Sanofi Aventis v. Apotex Inc. (Plavix 2)*, 2013 FCA 186 (F.C.A. per Gauthier J.A.) at para 135:

8.9.7. Construe the Promise within the context of the patent as a whole.

> [12] AstraZeneca also argues that the Federal Court gave the disclosure elevated emphasis when construing the promise. As noted by Apotex, at trial AstraZeneca conceded that resort to the disclosure was warranted in order to construe its truncated promise of utility that the compound claims promised improved pharmacokinetic and metabolic properties. In my view, the Federal Court did not err by construing the promise within the context of the patent as a whole (*Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197, 405 N.R. 1 (Olanzapine), at paragraph 93). Similarly, on the evidence it accepted, the Federal Court did not err by giving effect to all, not just a portion, of the sentence in the disclosure relied upon by AstraZeneca to establish the promise of pharmacokinetic and metabolic properties.

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8.9.8. The promise must be "explicit" or "clear and unambiguous"

Recent case law suggests the courts may require the promise to be "explicit" or "clear and unambiguous" rather than inferred.

8.9.8.1. Explicit

An "explicit" promise meets the threshold.[119]

In 2010, Justice Layden-Stevenson added "explicit" to describe the promise that would trigger a higher standard:

> "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: *Consolboard* ; *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2009] 1 F.C.R. 253, 2008 FCA 108 (*Ranbaxy*). The question is whether the invention does what the patent promises it will do." [120]

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118 *Astrazeneca Canada Inc. et al v. Apotex Inc et al*, 2015 FCA 158 (FCA per Dawson J.A., Ryer and Webb JJ.A. concurring) (esomeprazole FCA) at para. 4.

119 *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), (Olanzapine) at para 76. NTD check also *Pfizer Canada Inc. v. Canada (Minister of Health Ranbaxy)*, [2009] 1 F.C.R. 253, 2008 FCA 108 ().

120 NTD *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd*., [1981] 1 S.C.R. 504 (S.C.C. per Dickson J.), at p. NTD; *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2009] 1 F.C.R. 253, 2008 FCA 108 at para. NTD (Ranbaxy). *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197 (F.C.A. per

In *Plavix 2*, Justice Pelletier of the Federal Court of Appeal followed suit, requiring an explicit promise.[121] In *Plavix 2*, the Federal Court of Appeal held that the Trial Judge erred in construing the patent as specifically promising a result when the invention was used in humans and then assessing the utility of the patent against that specific promise. Properly construed, the '777 Patent made no such promise.[122]

Eli Lilly and Company v. Teva Canada Limited, 2011 FCA 220, [2011] F.C.J. No. 1028 at paras. 18 to 21 [Atomexetine],

8.9.8.2. Clear and unambiguous

In the celecoxib case,[123] Chief Justice Noël held that the promise doctrine will hold an inventor to an elevated standard only where a "clear and unambiguous promise" has been made:

> "The promise doctrine will hold an inventor to an elevated standard only where a clear and unambiguous promise has been made."

NTD: Drawing an analogy to the threshold test applicable to selection patents, the Court in *Plavix FCA* expressed the need for explicitness by saying that a promise must be supported by language "… at least as clear and unambiguous as that used to establish the advantages of the selection over the compounds of a genus patent" (*Plavix FCA* at para. 66). It follows that it is not enough to merely label a promise as "explicit" if it can only be supported on the basis of equivocal inferences and ambiguous indications (*Plavix FCA* at paras. 64-66).[124]

NB – followed very recently to exclude a promise in *Gilead v. Idenix* (sofosbuvir) at paras. 227, 241.

Zinn: NTD example of not a promise!

8.9.8.3. Construe in favour of patentee if a reasonable reading excludes a promise

Where the validity of a patent is challenged on the basis of an alleged unfulfilled promise, the patent will be construed in favour of the patentee where it can reasonably be read by the skilled person as excluding this promise.[125] This approach can be traced

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Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), (Olanzapine) at para 76.

121 *Sanofi-Aventis v. Apotex Inc*., (Plavix 2) 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at paras. 49 & 50.

122 *Sanofi-Aventis v. Apotex Inc*., (*Plavix 2*) 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at para. 71.

123 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 66.

124 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, (celebrex) 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 67.

125 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 66.

back to the earliest mentions of the promise doctrine: Consolboard and Western Electric.[126]

> Where the validity of a patent is challenged on the basis of an alleged unfulfilled promise, the patent will be construed in favour of the patentee where it can reasonably be read by the skilled person as excluding this promise. This approach can be traced back to the earliest mentions of the promise doctrine. In Consolboard, the source of the promise doctrine in Canadian law, the Supreme Court of Canada reiterated the longstanding principle that (Consolboard at 521, citing Western Electric Company, Incorporated, and Northern Electric Company v. Baldwin International Radio of Canada, [1934] S.C.R. 574 at 570):
>
> > … where the language of the specification, upon a reasonable view of it, can be so read as to afford the inventor protection for that which he has actually in good faith invented, the court, as a rule, will endeavour to give effect to that construction.
>
> [67] This rule in favour of saving an invention rather than invalidating it in case of ambiguity has been consistently applied by this Court. While the principle is sometimes invoked by reference to the original language found in Consolboard (Anastrozole at paras. 17 and 19) affirming AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC, 2011 FC 1023, [2011] F.C.J. No. 1262 at para. 88), it is at other times given effect through the requirement that promises be "explicit" (see Olanzapine at para. 76, Eli Lilly and Company v. Teva Canada Limited, 2011 FCA 220, [2011] F.C.J. No. 1028 at paras. 18 to 21 [Atomexetine], Plavix FCA at para. 49). Drawing an analogy with the threshold test applicable to selection patents, the Court in Plavix FCA expressed the need for explicitness by saying that a promise must be supported by language "… at least as clear and unambiguous as that used to establish the advantages of the selection over the compounds of a genus patent" (Plavix FCA at para. 66). It follows that it is not enough to merely label a promise as "explicit" if it can only be supported on the basis of equivocal inferences and ambiguous indications (Plavix FCA at paras. 64-66). [127]

However, the Courts should not strive to find ways to defeat otherwise valid patents. As the Supreme Court said in *Consolboard,*[128] and reiterated some twenty years later in *Whirlpool*, at paragraph 49(g):

> "We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance, (*Noranda Mines Limited*

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126 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 66.

127 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 66.

128 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd*., [1981] 1 S.C.R. 504 (S.C.C. per Dickson J.), at p. NTD.

> *v. Minerals Separation North American Corporation* ([1950] S.C.R. 36]) being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and public. There is no occasion for being too astute or technical in the matter of objections to either title or specification for, as Duff C.J.C. said, giving the judgment of the Court in *Western Electric Company, Incorporated, and Northern Electric Company v. Baldwin International Radio of Canada* [1934] S.C.R. 570], at p. 574, "where the language of the specification, upon a reasonable view of it, can be so read as to afford the inventor protection for that which he has actually in good faith invented, the court, as a rule, will endeavour to give effect to that construction".”[129]

8.9.9. Ascertain the Promise – if there is one…

In 2010, in the *olanzapine* case, the Federal Court of Appeal issued a general mandate for everyone to ascertain what was the promise of a patent:

- “… The promise of the patent must be ascertained.”[130]
- “… the promise of the patent is to be ascertained at the outset of an analysis with respect to utility. …The promise of the patent is fundamental to the utility analysis.”[131]

That directive was revoked in 2013 by the Federal Court of Appeal, perhaps as a result of their recognition of their previous overstatement. They recognized that not every patent contains an explicit promise of utility:

> “When this Court said at paragraph 80 of *Olanzapine*, cited above, that the promise of the patent must be ascertained, it should not be taken to have assumed that every patent contains an explicit promise of a specific result since, subject to what is said below with respect to selection patents, there is no obligation on the part of the inventor to disclose the utility of his invention in the patent. In *Olanzapine*, the Court was simply indicating that the first step in assessing utility was to determine the standard against which utility will be measured. This requires the Court to construe the patent to determine if a person skilled in the art would understand it to contain an explicit promise that the invention will achieve a specific result. If so, the inventor will be held to that promise.”[132]

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129 NTD: Whirlpool cite, quoted in *Sanofi-Aventis v. Apotex Inc*., (Plavix 2) 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at para. 54 and *Bayer Inc. et al v. Cobalt Pharmaceuticals Company et al,* 2013 FC 1061 at para. 93. DMC

130 *Eli Lilly Canada Inc. v. Novopharm Ltd, (Olanzapine)*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), at para 80.

131 *Eli Lilly Canada Inc. v. Novopharm Ltd, (Olanzapine)*, 2010 FCA 197 (F.C.A. per Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), at para 93.

132 *Sanofi-Aventis v. Apotex Inc.*, (Plavix 2) 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at para. 50.

Thus, the Court must construe the patent to determine whether a person skilled in the art would understand it to contain an explicit promise that the invention will achieve a specific result.[133]

8.9.9.1. Examples of no promise

Alluding to a possible use is not a promise to achieve a specific result.

> "As Dr. Byrn made clear, the inventive step was in the differential activity and tolerability of clopidogrel as demonstrated in rats. The pharmaceutical industry's interest of the invention obviously lay in its potential use in humans which the invention foreshadowed. The person skilled in the art would understand that in alluding to this possibility, the inventors were not promising that this result had been or would be achieved." [134]

a) "may"

- *Pfizer Canada Inc.* v *Mylan Pharmaceuticals ULC et al*,[135], Canadian Patent No. 2,177,576 ('576) covering the drug celecoxib (CELEBREX®)
    - The issue was whether the '576 patent promised that it would be useful in significantly reducing harmful side effects in humans, as compared to other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)[136] Mylan alleged that Celebrex® does not have significantly less side effects.[137]
    - The disclosure of the patent said:
        - "The compounds are useful as anti-inflammatory agents, such as for the treatment of arthritis, with the additional benefit of having

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133 *Sanofi-Aventis v. Apotex Inc*., (*Plavix 2*) 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at para. 50.

134 *Sanofi-Aventis v. Apotex Inc*., (*Plavix 2*) 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at para. 67.

135 2014 FC 38, (F.C. per Harrington J.) NTD: See also Pfizer Canada Inc v Apotex Inc, 2014 FC 314 at paras 30-35 (also celecoxib)

136 The same patent was previously considered in *G. D. Searle & Co v Novopharm Limited*, 2007 FC 81, 56 CPR (4th) 1, [2007] FCJ No 120 (QL). Mr. Justice Hughes held that the utility of the '576 patent was "the duality of treatment of inflammation and reduction of unwanted side effects such as ulcers of the gastrointestinal system."(para 27) Although he found that Novopharm's allegations as to invalidity (insufficiency and lack of utility) were not justified, other allegations were justified (obviousness and abandonment), and so the Minister was not prevented from issuing a Notice of Compliance. Mr. Justice Hughes was reversed on the other issues by the Federal Court of Appeal, 2007 FCA 173, 58 CPR (4th) 1,[2007] FCJ No 625 (QL), but his findings with respect to utility were not disturbed. (*Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at para. 13.)

137 *Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at para. 21; *Apotex Inc. et al v. Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 9.

significantly less harmful side effects."[138]

- The next paragraph stated that the invention "preferably includes" compounds selectively inhibiting COX-2 over COX-1: "Such preferred selectivity may indicate an ability to reduce the incidence of common NSAID-induced side effects."[139]

- Harringon J. ruled that the '576 Patent did not promise reduced side effects.[140] Harrington J. considered the use of the word "may" to be important.[141] "The word "may" connotes a possibility; maybe yes, maybe no. While it was hoped the selectivity would reduce side effects, no such claim was made.[142] The word "may" as it appeared in the specification represented a clear indication that the patent made no promise of reduced side effects. Whether read within the context of standard statutory interpretation principles or from the perspective of a skilled addressee, the word "may" could not be taken to imply anything more than a possibility of reduced side effects.[143]

- Taking a page from claim construction case law, Justice Harrington was comforted by the fact that there was not a word of reduced side effects in the claims.[144] Citing Federal Court jurisprudence, he

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138 *Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at para. 30;

139 *Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at para. 32; *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 9.

140 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 9.

141 *Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at para. 62: "As a skilled addressee, Professor Young seizes on the word "may". While I accept that words may take on different meanings in different contexts, nevertheless there are grammatical limits: "When I use a word, Humpty Dumpty said, in a rather scornful tone, it means just what I choose it to mean - neither more nor less." (Lewis Caroll, *Through the Looking-Glass*)."

142 *Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at para. 63.

143 *Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at para. 65; *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 18.

144 *Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at para. 63: "What is usually not claimed is disclaimed. The claims take precedence of the disclosure portion of the specification, as the disclosure may lead to an understanding of what is meant by a word in the claims but neither contracts nor enlarges its scope." NTD What's the FCA talking about here: [25] On the question of utility in treating side effects in humans, the Federal Court judge rejected Apotex' argument on the basis of a revised version of his reasons in the *Mylan* decision. He conceded the "inappropriate" nature of some of his justifications in that decision for ruling that the '576 Patent did not promise reduced side effects in humans, namely his discussion at paragraph 44 of the principle that what is not claimed is generally disclaimed

held that uses which do not appear in the claims specification ought to be considered as mere statements of advantage, absent clear and unequivocal language promising such uses.[145] He found further support for the distinction between promises and statements of advantage or potential use in the concurring opinions issued by this Court in *Sanofi-Aventis v. Apotex Inc.*[146]

- In the *Novopharm FC* decision, "(a)fter some discussion, counsel for Pfizer conceded that both the anti-inflammatory properties and lesser side effects were necessary to the utility of the claimed invention" (Mylan decision at para. 74, quoting *Novopharm FC* at para. 14). In construing claim 4 of the patent specifically, he further stated (Mylan decision at para. 74, quoting *Novopharm FC* at para. 27):

  > [No use of (celecoxib) is stated in that claim but,] as conceded by counsel for the applicants, the utility of that compound is set out in the specification as being the duality of treatment of inflammation and reduction of unwanted side effects such as ulcers of the gastrointestinal system."[147]

- (NTD: move elsewhere) A concession made by Pfizer in one NOC proceeding was not an admission binding upon it in another.[148] If the *G.D. Searle* case turned on the construction of the patent, a pure question of law, Harrington J. would have been bound by the decision of the Court of Appeal on the basis of *stari decisis* (*Apotex Inc. v Pfizer Ireland Pharmaceuticals*, 2012 FC 1339, a decision of Mr. Justice Zinn, currently in appeal). However, utility, whether demonstrated or predicted, is a matter of fact, so he was not. (*Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC

(Apotex decision at paras. 30 and 36). *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 25.

145 *Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at para. 70 citing *Fournier Pharma Inc. v. Canada (Health)*, 2012 FC 741, [2012] F.C.J. No. 901 at para. 126; *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 19.

146 2013 FCA 186, [2013] F.C.J. No. 856 (Leave to Appeal to SCC granted on January 30, 2014, 35562); *Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at paras. 68 & 69; *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 19.

147 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 9.

148 *Apotex* decision at p. 61, referred to but not yet followed in *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 32.

38, (F.C. per Harrington J.) at para. 78.).[149]

- *Dow Chemicals et. al. v Nova Chemicals*,[150] Canadian Patent No. 2,160,705 directed to ethylene polymer compositions
    - The disclosure of the patent stated:
        - "Surprisingly, we have now discovered compositions useful in films and moulded parts having synergistically enhanced physical properties."[151]

8.9.10. Where to look for a Promise

8.9.10.1. <u>In the claims</u>

Where a result or advantage is asserted in a patent's claims, it will generally be seen as a promise of utility.[152] Results or advantages included in the claims must be met.[153]

As stated by Justice Zinn:

> "The promise of a patent, as that term is used in patent law, is nothing more than the utility the inventor claims for his invention. Where that promise - that claimed utility - is clearly and unequivocally expressed by the inventor in the claims of the patent, then that expression ought to be viewed as the promise of the patent."[154]

[With respect, however, the question that should be asked is "What is the utility of the invention claimed (in each claim)?" not "What is the claimed utility?"]

In *Eurocopter*[155]*,* in first instance, Mr. Justice Martineau stated that: "The specification mentions a number of advantages […]"[156] However, as noted by Mr. Justice Mainville, speaking for the Federal Court of Appeal,[157] the advantage "was principally embodied in

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149 *Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at paras. 77 & 78; *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 17.

150 2014 FC 844 (F.C. per O'Keefe J)

151 *Dow Chemicals et. al. v Nova Chemicals*, 2014 FC 844 (F.C. per O'Keefe J) at para 9.

152 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 71.

153 *Bauer Hockey Corp. v. Easton Sports Canada Inc*., 2010 FC 361, [2010] F.J.C. No. 431 at para. 289 [Bauer FC], aff'd 2011 FCA 83, [2011] F.C.J. No. 331

154 *Fournier Pharma Inc. v. Canada (Minister of Health)*, 2012 FC 741 (F.C. per Zinn J.) at para. 126.

155 *Eurocopter v Bell Helicopter Textron Canada Limitée*, 2012 FC 113 at para. 214, 100 CPR (4th) 87, [2012] FCJ No 107 (QL), aff'd 2013 FCA 219, [2013] FCJ No 1043 (QL).

156 *Eurocopter v Bell Helicopter Textron Canada Limitée*, 2012 FC 113, 100 CPR (4th) 87, [2012] FCJ No 107 (QL), aff'd 2013 FCA 219, [2013] FCJ No 1043 (QL).

157 NTD Add complete cite

claim 1 of the […] Patent."[158]

The promise of a patent, as that term is used in patent law, is nothing more than the utility the inventor claims for his invention. Where that promise – that claimed utility – is clearly and unequivocally expressed by the inventor in the claims of the patent, then that expression ought to be viewed as the promise of the patent.[159]

The interpretation should be focused on the claims because an inventor is not obliged to claim a monopoly on everything new, ingenious, and useful disclosed in the specification.[160] If the claims are certain and unambiguous in stating the promise, then the disclosure should not be examined microscopically to find additional promises that are outside the scope of the inventor's claimed monopoly.[161]

The law generally presumes such statements to be aimed at advantages (as opposed to promises)[162]

8.9.10.2. In the disclosure

A promise need not be found only in a claim; it can also appear in the disclosure.[163]

Statements outside of the claims should not be presumed to be promises,[164] unless the language is clear and explicit.[165] Any statement found elsewhere should be presumed to be a mere statement of advantage unless the inventor clearly and unequivocally states that it is part of the promised utility.[166]

Justice Zinn found the following to not be a promise but, rather, a mere statement of advantage found on the first page of the patent:

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158 at para 26 quoted at *Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at para. 71.

159 *Fournier Pharma Inc. v. Canada (Minister of Health)*, 2012 FC 741 (F.C. per Zinn J.) at para. 126.

160 *Fournier Pharma Inc. v. Canada (Minister of Health)*, 2012 FC 741 (F.C. per Zinn J.) at para. 127.

161 *Fournier Pharma Inc. v. Canada (Minister of Health)*, 2012 FC 741 (F.C. per Zinn J.) at para. 127.

162 Referring to *Apotex* below in *Mylan Pharmaceuticals ULC v. Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at paras. 26 & 77. NTD; What did the judge say in the lower decision?: 2014 FC 314, the Apotex decision? See 2014 FC 314 at para 36

163 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 77.

164 *Mylan Pharmaceuticals ULC v. Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 48 citing Mylan decision at para. 70, Apotex decision at para. 36.

165 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 77. See also *Fournier* NTD

166 *Fournier Pharma Inc. v. Canada (Minister of Health)*, 2012 FC 741 (F.C. per Zinn J.) at para. 126; *Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at para. 70.

> "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, which are novel salts of single enantiomers of omeprazole. [Emphasis added]"[167]

[NTD: This sure looks like an explicit promise to me.]

8.9.11. A goal is not necessarily a promise

NTD: add stuff from each case

> "I accept AstraZeneca's argument that not all statements of advantage in a patent rise to the level of a promise. A goal is not necessarily a promise. The third paragraph of the 420 Patent refers to a forward looking goal, a hoped-for advantage of the invention. (my emphasis) *AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023, [2011] F.C.J. No. 1262 (Q.L.) at paragraph 139. For other examples of this distinction, see *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, 2012 FCA 103, [2012] F.C.J. No. 386, at paragraph 61, *Mylan Pharmaceuticals ULC v. Canada (Minister of Health)*, 2012 FCA 109, [2012] F.C.J. No. 422, at paragraphs 32-33."[168] NTD; add more from these cited cases

[76] not every research goal will form the basis for a later patent's promised utility and these statements all spoke merely to goals (Mylan decision at para. 68, citing Plavix FCA).[169]

8.9.12. Utility in "subjects" need not be in humans; could be utility in rats

> [24] The Federal Court judge rejected these contentions. On the question of utility in treating inflammation, he accepted the respondent's argument that rats could be considered to constitute "subjects" and that, to the extent that the patent had promised to treat inflammation in a subject, this promise had been demonstrated to have been met (Apotex decision at paras. 28 and 29, citing Plavix FCA and Mylan Pharmaceuticals ULC v. Pfizer Canada Inc., 2012 FCA 103, 2012 F.C.J. No. 386 [Donepezil FCA]).[170]
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> [72] the claims speak only of "subjects", and nothing outside the claims could be

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167 *Fournier Pharma Inc. v. Canada (Health)*, 2012 FC 741, [2012] F.C.J. No. 901 at para. 126 quoting from page 1 of the patent in AstraZeneca Canada Inc v Apotex Inc, 2010 FC 714.

168 *AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023 at para. 61 NTD add material from this case , quoted in *Sanofi-Aventis v. Apotex Inc*., (*Plavix 2*) 2013 FCA 186 (F.C.A. per Pelletier J.A., Noël and Gauthier JJ.A. concurring) at para. 67.

169 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 76.

170 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, (celebrex) 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 24.

said to represent the sort of unequivocal language contemplated by the reasoning in Plavix FCA. In my view, the Federal Court judge correctly held that the promise of the patent did not extend to humans.[171]

8.9.13. Don't adopt foreign decisions on promise

Hearing judge in Apotex lower decision rejected Apotex's invitation to apply an English case constructing the European celecoxib patent such that its utility included reduced side effects. In essence, he reasoned that English patent law varies from Canadian patent law in a number of areas, including questions of utility and, more specifically, promise.[172]

8.9.14. A promise can be overarching or not including some claims

A promise need not extend to all claims of a patent, but can be limited to some claims.[173]

In *celebrex*,[174] the promise of colorectal cancer prevention, which was not shown to have been met, resulted in claim 16 potentially being held invalid. Other claims to the compound celecoxib itself and claim 10 for the use of the claimed compounds to treat inflammation in the subjects, were not declared invalid. Section 58 of the patent Act provides that any valid claim survives despite the existence of invalid claims.[175]

8.9.14.1. <u>The promise of a claim can be established separate from that of other claims</u>

[29] Concerning the claim regarding prevention of colorectal cancer, the Federal Court judge concluded that Apotex had provided evidence of the claim's invalidity, but agreed with the respondent that, under section 58 of the Patent Act, R.S.C., 1985, c. P-4 (the Act), this claim could be severed from the rest, and that the remaining claims could support the prohibition order sought by the respondent.[176]

[87] A review of the jurisprudence reveals a lack of support for the proposition

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171 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, (celebrex) 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 72.

172 NTD: 2014 FC 314, the Apotex decision, mentioned but not decided in *Mylan Pharmaceuticals ULC v. Pfizer Canada Inc. et al*, (celebrex) 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para.

173 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, (celebrex) 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at paras. 86-89; *Astrazeneca Canada Inc. et al v. Apotex Inc et al*, 2015 FCA 158 9fca PER Dawson J.A., Ryer and Webb JJ.A. concurring) (esomeprazole FCA) at paras. 5 & 9.

174 *Pfizer Canada Inc. v. Apotex Inc.*, 2014 FC 314 (F.C. per Harrington J.) at paras. 46-47.

175 *Pfizer Canada Inc. v. Apotex Inc.*, 2014 FC 314 (F.C. per Harrington J.) at paras. 46-47 quoting Viagra SCC NTD – add cite at para. 80.

176 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 29.

advanced by Apotex. Not one case cited by Apotex stands for the proposition that a promise, once made and shown not to have been met, must be construed as invalidating the invention as a whole. Of the eight cases cited at paragraphs 54 and 55 of Apotex' memorandum of fact and law, only two could be read as addressing the extent to which a given promise may extend to various claims within the patent containing it (Furthermore, each of these cases illustrates, at most, that (see *Sanofi* or *New Process Screw* at 45 to 46). In each case, the court did no more than construe the promise and made no general statement of law on the matter. The respondent's proposition, namely that some promises are properly construed so as to touch only a subset of claims, is therefore not inconsistent with the cases cited by Apotex, which merely feature promises that were not so narrow.[177]

A promise can be construed so as to extend to each of a patent's claims (as it was in *Sanofi*[178] and *New Process Screw*[179]) or the promise can be construed so as to touch only a subset of claims.[180]

[88] The respondent provides compelling support for its alternative proposition by citing examples where a promised utility is more narrowly construed. Of particular relevance to the case at bar is a decision by Snider J. wherein she specifically distinguished claims for a compound from claims for its uses, and held that the latter are "directed at the use of [the claimed compounds] for specified maladies and their utility should be assessed on that basis" (Imatinib at para. 177). The issue is one of patent construction and the respondent's proposition in my view represents the correct approach.

8.9.14.2. <u>Misc: reducing side effects: sometimes a promise, sometimes not.</u>

[41][181] Turning to the Federal Court judge's own construction of the '576 Patent, Mylan cites two decisions of this Court in which a promise was found to extend to reduced side effects (Mylan memorandum at paras. 55 and 56, citing Eli Lilly Canada Inc. v. Novopharm Limited, 2010 FCA 197, [2012] 1 F.C.R. 349 [Olanzapine] at paras. 27 and 99 and Apotex Inc. v. Pfizer Canada Inc., 2011 FCA 236, [2011] F.C.J. No. 1234 [Latanoprost]) and two decisions in which a promise was found not to so extend (Mylan

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177 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 87.

178 *Sanofi-Aventis Canada Inc. v. Apotex Inc*., 2009 FC 676 at paras. 119 to 124. NTD check, cited in *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 87.

179 *New Process Screw v. PL Robertson Manufacturing* (1961), 39 C.P.R. 31 at paras. 45 to 46. NTD cited in *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 87.

180 In *Teva Canada Ltd. v. Novartis AG*, 2013 FC 141 (F.C. per Snider J.) [Imatinib] at para. 177, Snider J. specifically distinguished claims for a compound from claims for its uses, and held that the latter were "directed at the use of [the claimed compounds] for specified maladies and their utility should be assessed on that basis". Quoted in *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 88.

181 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 41.

memorandum at paras. 58 and 59, citing Plavix FCA at para. 67 and Mylan Pharmaceuticals ULC. v. AstraZeneca Canada Inc., 2012 FCA 109, [2012] F.C.J. No. 422 [Anastrozole] at paras. 6, 22, 29 and 30). Mylan argues that the '576 Patent is "qualitatively more similar" to the patents in the first set of cases (Mylan memorandum at para. 60).

Where a promise is made in a patent, that promise is "overarching and inherent to the invention and thus all of the claims" (Apotex memorandum at para. 54, citing Merck & Co. v. Apotex Inc. (1995), 60 C.P.R. (3d) 356 (FCA) at 373, Merck & Co. Inc. v. Apotex Inc., 2006 FC 524 at paras. 122 to 125 and Sanofi-Aventis Canada Inc. v. Apotex Inc., 2009 FC 676 [Sanofi]at paras 119 to 124 and 138, aff'd 2011 FCA 300 at para. 3). Where this promise cannot be met the entire patent is rendered invalid (Apotex memorandum at para. 55, citing AZT at para. 92, Plavix FCA at para. 54, Pfizer Canada Inc.v. Pharmascience Inc., 2008 FC 500 at para. 95, New Process Screw v. PL Robertson Manufacturing (1961), 39 C.P.R. 31 [New Process Screw] at paras. 27 to 28, 31, and 38 to 39 (CT) and Turner v. Winter (1787), 99 ER 1274 at 1276 (KB)).[182]

[60] However, whether utility has been made out, by being demonstrated or predicted, is a question of fact to be reviewed only for palpable and overriding error (*Novopharm Limited v. Pfizer Canada Inc.*, 2010 FCA 242, [2012] 2 F.C.R. 69 [Pfizer] at paras. 91-93; Housen at para. 10).[183]

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182 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 48.

183 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 60.

1. Proposed Globe piece: (Nov. 3, 2014)

What's the Use?

In our patent laws, we need a decision that matches reality.

Don Cameron

It's a fundamental principle of patent law that you cannot get a patent if your invention doesn't work. It has to be "useful".

But over the last twelve years, Canadian courts have decided that, according to their interpretation of Canadian patent laws, the following blockbuster drugs are not "useful" under Canadian patent law: Mevacor (lovostatin), Nexium (esomeprazole), Evista (raloxifine), Strattera (atomoxetine), Zyprexa (olanzapine), Altace (ramapril) and Xalatan (latanaprost). Drug giant Eli Lilly alleges that decisions invalidating its patents have cost it $1 billion in sales and 280 Canadian jobs. This plague on patents is unique to Canada. In 2012, Eli Lilly launched a $500 million challenge against the Canadian government claiming that our patent law violates Canada's obligations under the World Trade Organization, NAFTA and other treaties.

These patents were attacked on the ground of lack of usefulness or, in patent language, "utility," not because the drugs don't work, but because, in fact, they do. Having the patents declared invalid was the route to clearing the path for generic versions.

Two legal principles have combined over the twelve years to cause havoc for pharmaceutical patents: the "promise of the patent" and "sound prediction".

Generally speaking, an inventor does not have to explain in the patent in what way the invention is useful. In most cases, the usefulness is self-evident: a mousetrap is useful for trapping mice; a screwdriver for driving screws. When a patent is granted for a new, unexpected or special use of an old thing (e.g., an old drug having a new application), the new use is the invention, and the new use must necessarily be disclosed to differentiate it from the prior use.

The usefulness of a new chemical compound may not, however, be self-evident. Is it useful as glue? A paint thinner? A cure for baldness? In such cases, most inventors explicitly state in the patent at least one use for the new compound. The case law has characterized this explicit use statement as a "promise" of utility, or the "promise of the patent". If, in fact, the compound does not have that use, then the patent is invalid for lack of utility. The explicit statement is, in effect, a self-imposed threshold of utility.

In 2002, the Supreme Court of Canada mentioned (without expressly deciding the point) that inventions based on predictions should have (1) a sound basis in data and (2) a sound theory to make the prediction. Nothing revolutionary there. But the Court added a third component (again, without expressly deciding the point): "proper disclosure". Later, lower courts decided that "proper disclosure" meant that the (1) data, and (2) predictive theory had to be spelled out in the disclosure. This third requirement came as a surprise to owners of existing patents, who had never included the (1) data, and (2)

predictive theory (because no prior case ever said they had to do so), and they were not able to amend the patents after they had been granted to add the missing information. One trial judge commented, in the aftermath of this case law, that the law of sound prediction was never meant to give a crushing hammer to those who challenge patents.

In the Federal Court, the pendulum on these two points has begun to swing back. On "sound prediction" one trial-level judge recently held that the data and predictive theory need only be included in cases like the 2002 Supreme Court decision, where the patent predicting a new use for an old thing. On the "promise" issue, the Federal Court of Appeal recently said that not all patents necessarily have a promise. Some judges have held that certain statements are merely describing potential uses or advantages of the invention and are not explicit promises that must be met.

The next drug up for consideration at the Supreme Court of Canada on November 4th is Plavix (clopidogrel), an antiplatelet agent used to inhibit blood clots in coronary artery disease. Is it useful? Commercially, very. In 2010, Plavix was the second most prescribed drug in the world with over $9 billion in global sales.

In science, when a theory does not comply with observed phenomena, scientists know that there's something wrong with their theory. The old theory needs to be tossed and replaced with a better one that corresponds to reality. If Canadian patent law decides that Plavix (clopidogrel) is not "useful" under Canadian patent law, when Plavix is clearly useful to Canadian patients, then there is something wrong with the theory of the law. Common sense dictates that our patent laws should protect such useful inventions.

NOT A PROMISE

NTD: quote from FM radio inventor: argue over the words.

"May"

In Pfizer v Mylan, (CELEBREX)[184] the patent said: "Such preferred selectivity may indicate an ability to reduce the incidents of common NSAID-induced side effects." The judge concluded that "may" was not a promise: "The word "may" connotes a possibility; maybe yes, maybe no. While it was hoped the selectivity would reduce side effects, no such claim was made."[185]

"Advantages", "Goals" or "An Object of the Invention" are not promises

In Bayer v Cobalt Pharmaceuticals,[186] the patent said: "The advantages of a combination preparation for oral contraception … can be characterized as follows" and listed advantages.[187] The judge concluded that: "The list of "advantages" should not be elevated to a "promise"; it is "simply an observation as to advantages expected to be achieved".[188]

Likewise, in *AstraZeneca Canada Inc v Mylan Pharmaceuticals ULC*,[189] where the patent said: "It is a particular object of the present invention to provide aromatase inhibitory compounds with fewer undesirable side effects than aminoglutethimide",[190] Justice Rennie concluded that: "not all statements of advantage in a patent rise to the level of a promise. A goal is not necessarily a promise. The third paragraph of the 420 Patent refers to a forward looking goal, a hoped-for advantage of the invention."[191]

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184 *Pfizer v Mylan*, 2014 FC 38 (CELEBREX) 2014 FC 38, (F.C. per Harrington J.) at paras. 32 & 63.

185 See also *AstraZeneca v Apotex*, 2014 FC 638 (esomeprazole) (F.C. per Rennie J.) at para. 120 where he differentiated "will" from :"may":

> "Had the patent stated that such compounds "may" or "could" give an improved therapeutic profile, then the argument that such statements referred merely to a goal would be more compelling."

186 *Bayer v Cobalt Pharmaceuticals*, 2013 FC 1061 at para 152 (F.C. per Hughes J.)

187 *Bayer v Cobalt Pharmaceuticals*, 2013 FC 1061 at para 152 (F.C. per Hughes J.) at para. 120.

188 *Bayer v Cobalt Pharmaceuticals*, 2013 FC 1061 at para 152 (F.C. per Hughes J.) at para. 152.

189 *AstraZeneca Canada Inc v Mylan Pharmaceuticals ULC*, 2011 FC 1023 (F.C. per Rennie J)

190 *AstraZeneca Canada Inc v Mylan Pharmaceuticals ULC*, 2011 FC 1023 (F.C. per Rennie J) at para. 119.

191 *AstraZeneca Canada Inc v Mylan Pharmaceuticals ULC*, 2011 FC 1023 (F.C. per Rennie J) at para. 139.

PROMISE

"Will"

Where the patent says the invention "will" do something, that is an explicit promise.

AstraZeneca v Apotex, 2014 FC 638 (esomeprazole)[192] (F.C. per Rennie J.) at paras. 113 and 120

- The patent said:
  - "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 individual variation. The present invention provides such compounds, which are novel salts of single enantiomers of omeprazole."[193] (emphasis added)
- The judge said:
  - "Had the patent stated that such compounds "may" or "could" give an improved therapeutic profile, then the argument that such statements referred merely to a goal would be more compelling. The same cannot be said of "will." Will does not convey a low threshold of potential outcomes, but to the contrary, a high threshold of probable or certain outcomes that will occur, which in turn, suggests that such outcomes are promised by the patent."[194]
- This construction of the promise was reached reading the patent as a whole through the eyes of the skilled reader and was not a non-contextual construction of the promise by embracing an overly narrow definition of the word "will".[195]

Alcon Canada Inc. v. Cobalt Pharmaceuticals Company, 2014 FC 149 (olopatadine) (F.C. per Gleason J.)[196] at para 63

- "This interpretation of the promise is buttressed by the text of the patent itself. At page 3, the 924 Patent explicitly indicates that two of the excluded excipients (i.e. PVA and Carbopol 974P) will not enhance the stability of the olopatadine solutions, and these two excipients are listed in the same fashion as the other three excluded excipients in the various claims. Therefore, I believe that the promised impact of all five should be viewed in the same manner, namely, that their addition will not enhance the physical stability of the solutions of Claims 2 and 7, or at least will not enhance stability as well as PVP. Moreover, I find it

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192 *AstraZeneca v Apotex*, 2014 FC 638 (esomeprazole) (F.C. per Rennie J.)

193 *AstraZeneca v Apotex*, 2014 FC 638 (esomeprazole) (F.C. per Rennie J.) at para. 113.

194 *AstraZeneca v Apotex*, 2014 FC 638 (esomeprazole) (F.C. per Rennie J.) at para. 120.

195 *Astrazeneca Canada Inc. et al v. Apotex Inc et al*, 2015 FCA 158 (FCA per Dawson J.A., Ryer and Webb JJ.A. concurring) (esomeprazole FCA) at para. 13.

196 *Alcon Canada Inc. v. Cobalt Pharmaceuticals Company*, 2014 FC 149 (olopatadine) (F.C. per Gleason J.)

> incongruous, in the context of this patent, to argue that the inventive concept is something different from the promise made in the patent and, therefore, accept the position of Cobalt on this point."[197]

Re inventive concept and promise coterminous or not:

> [11] Again, I disagree that the Federal Court erred. The Court's reasons show that the Federal Court directed itself to the correct legal tests applicable to claims construction, inventive concept and utility. In oral argument, AstraZeneca was unable to show that its submission was supported by the jurisprudence. While it pointed to an admittedly *obiter* passage in *Canada (Attorney General) v. Amazon.com, Inc.*, 2011 FCA 328 , [2012] 2 F.C. 49, at paragraphs 37 to 41, the *obiter* comments found there do not support AstraZeneca's submission that a promise of utility
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> Page: 5
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> must be construed to be virtually coterminous with the inventive concept of the relevant claim or claims.

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"Could"

"Could" is a funny word. In one sense, it can mean something might work, as in "… it could work, but it might not", whereas in another sense, it can mean "… this device could be used as a hammer", expressing that it has the capability of functioning as such and, therefore, can be used as a hammer. The latter promises utility, whereas the former does not. The meaning of the term "could" depends on the context in which it is used.

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197 *Alcon Canada Inc. v. Cobalt Pharmaceuticals Company*, 2014 FC 149 (olopatadine) (F.C. per Gleason J.) at para. 63.

198 *Astrazeneca Canada Inc. et al v. Apotex Inc et al*, 2015 FCA 158 (FCA per Dawson J.A., Ryer and Webb JJ.A. concurring) (esomeprazole FCA) at para. 11.

8.10. Demonstrated Utility before the Filing Date

What utility was demonstrated before the filing date?

There is no requirement that the utility of a patent be demonstrated in the patent disclosure so long as the trier of fact can find that its utility has been proven when the patent is challenged.[199]

The AZT case did not mention a requirement to prove utility in the disclosure.[200]

> "Where the new use is the *gravamen* of the invention, the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available. … [Italics in original; underlining added.][201]

> NTD clean up: [40] Nothing in this passage suggests that utility is a disclosure requirement; all it says is that "the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction". Utility can be demonstrated by, for example, conducting tests, but this does not mean that there is a separate requirement for the disclosure of utility. In fact, there is no requirement whatsoever in s. 27(3) to disclose the utility of the invention: see, e.g., Consolboard, at p. 521, per Dickson J.: "I am further of the opinion that s. 36(1) [now s. 27(3)] does not impose upon a patentee the obligation of establishing the utility of the invention".

> [41 In any event, Pfizer disclosed the utility of sildenafil by disclosing that tests had been conducted. Sildenafil was found to be useful before the priority date, which means that the requirement in AZT is met.

Once challenged, the utility of a claimed invention can be satisfied by proof that embodiments of the invention worked as of or before the filing date.[202] Such proof can be:

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199 *Teva Canada Ltd v Pfizer Canada Inc* 2010 FCA 242, (F.C.A. per Nadon JJ.A., Blais C.J. & Trudel JJ.A. concurring) at para. NTD, cited in *Teva Canada Ltd v Pfizer Canada Inc,* 2012 SCC 60 at paras 39-40, [2012] 3 SCR 625 at para. 25 and 38:

> "Patent '446 states that the claimed compounds, including sildenafil, will be useful in treating ED. At the time the application was filed, sildenafil could assist in treating ED. This is all that is required. The fact that Pfizer did not disclose that the tested compound was sildenafil goes to the issue of disclosure of the *invention*, not to that of disclosure of the invention's *utility*."

200 Teva (FCA) per Nadon at para. NTD; Referring to *Apotex Inc. v. Wellcome Foundation Ltd*., 2002 SCC 77, [2002] 4 S.C.R. 153 ("AZT"), cited in Cited in *Teva Canada Ltd v Pfizer Canada Inc,* 2012 SCC 60 at paras 39-40, [2012] 3 SCR 625 at para. 25

201 AZT para. 56 quoted in *Teva Canada Ltd v Pfizer Canada Inc,* 2012 SCC 60 at paras 39-40, [2012] 3 SCR 625 at para. 39

202 NTD: check *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197 at para. 74; *GlaxoSmithKline Inc. et al v. Pharmascience Inc. et a*l, 2011 FC 239 at para. 97.

1. Evidence of experiments of claimed embodiments.[203] The experiments need not be conclusive[204] but need only be strongly suggestive of the utility. They need not meet the high standard of clinical testing to show utility[205] nor to be safe and effective so as to meet regulatory standards for approval[206];

2. Evidence of experiments of related things from which utility of the claimed embodiment can be inferred.

Failed experiments are not proof of utility.[207]

NTD: Consolboard: no need to have it in the disclosure; Snider; if you say a test was done, don't need to include data.

NTD;

Seems pretty clear that demonstrated utility must refer to the study in the patent. Question is whether the examples in the '282 patent are sufficient.

2010 FCA 242

[90] The appellant's argument that Pfizer was required to include evidence of demonstrated utility in the patent disclosure is without merit. The requirements for demonstrated utility can be provided in evidence during invalidity proceedings as opposed to in the patent itself. So long as the disclosure makes reference to a study demonstrating utility, there do not appear to be any other requirements to fulfil section 2.

2011 FCA 236

[30] Section 2 of the Act requires that the subject matter of a patent be new and

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203 NTD

204 Ntd CHECK: *Pfizer Canada Inc. v. Novopharm Limited et al*, 2009 FC 638 (F.C. per Kelen J.) at para. 87, aff'd 2010 FCA 242, reverserd S.C.C Docket 33951; *AstraZenenca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023 at paras. 161-168, aff'd 2012 FCA 109

205 Ntd CHECK: *Pfizer Canada Inc. v. Novopharm Limited et al*, 2009 FC 638 (F.C. per Kelen J.) at paras. 87-88, aff'd 2010 FCA 242, reversed S.C.C Docket 33951; *AstraZenenca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023 at paras. 161-168, aff'd 2012 FCA 109

206 *Apotex v. Wellcome*, (1998) 79 C.P.R. (3d) 193 (F.C. per Wetston J.) at paras. 104-5; : *Pfizer Canada Inc. v. Novopharm Limited et al*, 2009 FC 638 (F.C. per Kelen J.) at para. 87, aff'd 2010 FCA 242, reversed S.C.C Docket 33951.

207 NTD check *W.L. Gore & Associates, Inc. v. Goldfarb*, (2001), 11 C.P.R. (4th) 129 (F.C.T.D Per NTD); aff'd (2002), 23 C.P.R. (4th) 1 (F.C.A. PER ntd)

useful. The granting of a patent is dependant upon the disclosure of how the patent intends to fulfill its promise (Pfizer Canada Inc. v. Canada (Minister of Health), 2008 FCA 108 (CanLII), [2009] 1 F.C.R. 253, at paragraph 34; Wellcome AZT, at paragraph 66). The general principle is that, as of the date of the filing, a patent must disclose either an actually achieved result (i.e., prove that it does what it claims) or a basis for sound prediction of the result (i.e., show that it is likely to do what it claims). There is no requirement to prove demonstrated utility in the disclosure of the patent; so long as the disclosure makes reference to a study demonstrating that the patent does what it promises to do, this criteria is met (Pfizer Canada Inc. v. Novopharm Ltd., 2010 FCA 242 (CanLII), at paragraph 90). In our case, utility would be demonstrated if the patent disclosed studies showing that latanoprost, when administered on a chronic basis, reduced intraocular pressure without causing substantial side effects.

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[213] In the view of Servier, it suffices that there be, as of April 24, 2008, a demonstration of the invention's usefulness. Servier relies on two bioequivalence studies which it claims prove utility. However, it is not disputed that neither of those studies is alluded to, let alone referenced, in the specification. It is only when utility is challenged that Servier pulls two studies which, it claims, prove utility.

[214] The difficulty posed is that the Federal Court of Appeal in its decision in Latanoprost, supra, states that the law requires such references:

[30] Section 2 of the Act requires that the subject matter of a patent be new and useful. The granting of a patent is dependant upon the disclosure of how the patent intends to fulfill its promise (Pfizer Canada Inc. v. Canada (Minister of Health), 2008 FCA 108 (CanLII), [2009] 1 F.C.R. 253, at paragraph 34; Wellcome AZT, at paragraph 66). The general principle is that, as of the date of the filing, a patent must disclose either an actually achieved result (i.e., prove that it does what it claims) or a basis for sound prediction of the result (i.e., show that it is likely to do what it claims). There is no requirement to prove demonstrated utility in the disclosure of the patent; so long as the disclosure makes reference to a study demonstrating that the patent does what it promises to do, this criteria is met (Pfizer Canada Inc. v. Novopharm Ltd., 2010 FCA 242 (CanLII), at paragraph 90). In our case, utility would be demonstrated if the patent disclosed studies showing that latanoprost, when administered on a chronic basis, reduced intraocular pressure without causing substantial side effects. [My emphasis.]

[215] That decision is binding on this Court. No one suggests that the patentee must extol the virtues of its discovery. But without any reference to studies that will show, once they have to be produced, the existence of the promised utility, how is the public to know that utility is demonstrated?

8.11. When utility is predicted – Sound Prediction

When utility is predicted, it must be based on a sound prediction. What "sound prediction" means, has been evolving.

As described by Graham, J. in *Olin Matheson*:

> "Where, then, is the line to be drawn between a claim which goes beyond the consideration and one which equiparates with it? In my judgment this line was drawn properly by Sir Lionel when he very helpfully stated in the words quoted above that it depended upon whether or not it was possible to make a sound prediction. If it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so. Of course, in so doing he takes the risk that a defendant may be able to show that his prediction is unsound or that some bodies falling within the words he has used have no utility or are old or obvious or that some promise he has made in his specification is false in a material respect; but if, when attacked, he survives this risk successfully, then his claim does not go beyond the consideration given by his disclosure, his claim is fairly based on such disclosure in these respects, and is valid."[208]

Sound prediction is a question of fact.[209]

8.11.1. Early case law: Claims broader than the invention?

A patent should not claim more than what the inventor has invented.

> "... a patent which includes in its specification a claim which claims more than the inventor has invented purports to grant an exclusive property in more than the inventor has invented and at least in so far as that claim is concerned the patent, in my opinion, is not granted under the authority of the statute and is therefore not lawfully obtained. ... a claim which is invalid because it claims more than the inventor invented is an outlaw and its existence as defining the grant of a property right is not to be recognized as having any validity or effect." [210]

Often in chemical or pharmaceutical cases, claims are made for many more compounds than have been tested. The earlier case law asked the question, "Although the inventor may have described compounds that have not yet been made, do they cover more than what the inventor invented?":

> "We come to the conclusion that the disclosure provides sufficient direction so that a skilled chemist could prepare the compounds using methods previously known in the art. We also recognize that the disclosure has mentioned all the compounds covered by claim 16. The Board is left, however, with a more difficult problem, one of assessing whether the rejected claims are too broad in the sense that they cover more than the invention made. We are concerned about

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208 *Olin Mathieson Chemical Corp. et al. v. Biorex Laboratories Ltd. et al*., [1970] R.P.C. 157 (per Graham J.) at p. 192-193; quoted with approval in *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Pigeon J.) at pp. 175-176.

209 *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 229.

210 *C.H. Boehringer Sohn v. Bell-Craig Ltd*. (1962), 39 C.P.R. 201 at pp. 243-4, [1962] Ex. C.R. 201 at p. 241, 22 Fox Pat. C. 190, quoted in *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Martland J., dissenting.).at p. 165.

> such issues as "speculative claiming", and "paper inventions". Section 36 is satisfied in that the applicant has fully described something, but is it his invention which he has described? What we must now determine is whether the applicant completed the invention in sufficient detail that it can be fairly said that he invented all the compounds of the two claims." [211] [emphasis added]

Making correct predictions in the chemical arts is sometimes difficult:

> "The objection that a claim is too broad because it covers unknown and uncharted areas where the applicability of the invention is unpredictable, and further inventive experiments would be needed, arises most frequently in the chemical arts, because as has been recognized " 'There is no prevision in chemistry' " (*Chipman Chemicals Ltd. v. Fairview Chemical Co. Ltd*., [1932] Ex. C.R. 107 at p. 115). While that may be an overstatement, nevertheless it indicates the special caution to be exercised when extrapolating in the chemical arts. Since claims are defective if they are speculative, there are important limitations upon an inventor's right to claim a generalization from his disclosure."[212]

If predictions in the chemical arts are difficult, predicting the behaviour of pharmaceuticals and how they will act in the complicated environment of the human body is even more difficult.[213] Justice Graham, in *Olin Matheson*, explained the inventor's problem:

> "In the drug field in particular research is very expensive and the number of "winners" found is only a minute proportion of those synthesized and tested. Once a winner is found, however, it is very common also to find that bodies more or less closely related to it have the same or even greater activity. Here, for example, trifluoperazine is some five times more active than chlorpromazine, and fluphenazine some twenty times more active than chlorpromazine. All are phenothiazine derivatives, all substituted in the "2" position, trifluoperazine and fluphenazine having the new -CF3 substitution rather than the -C1 substitution of chlorpromazine, and therefore falling within claim 1 ... Unless, therefore, the original inventor of the -CF3 substitution can properly be given reasonably broad cover, it is likely that soon after others hear of his success similar bodies will be made by others having as good or better activity. Unless he can control such activities, any reward he may obtain for his invention and research is likely to be of little value."[214]

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211 *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Martland J., dissenting.).at p. 165.

212 *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Pigeon J.) at p. 174 quoting from the Patent Appeal Board's decision at p. 9.

213 *C.H. Boehringer Sohn v. Bell-Craig Ltd.* (1962) 39 C.P.R. 201 (ex. Ct. per Thurlow J.) at p. 287.

214 *Olin Mathieson Chemical Corp. et al. v. Biorex Laboratories Ltd. et al*., [1970] R.P.C. 157 (per graham J.) at p. 192-193; quoted with approval in *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Pigeon J.) at p. 175.

8.11.1.1. A claim of infinite size is broader than the invention

In *Hoechst Pharmaceuticals of Canada Ltd. et al. v. Gilbert & Co. et al.*,[215] Hoescht had invented tolbutamide, a sulphonyl urea that was shown to be useful in the treatment of diabetes. [216] Tolbutamide, standing by itself, could have been the subject-matter of a valid patent if claimed as such when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent or by their obvious chemical equivalent. [217] What was claimed, however, was found to include an infinite number of compounds:

> "It will be observed that the number of mathematically conceivable substances embraced in the class defined in this claim is infinite. More than one hundred substances are conceivable by taking any one of the left hand or R substituents and applying all the possible variations of the finite class defined for the right hand or R 1 group. A group many times the size of that number is also conceivable by applying it to the various substituents embraced within the finite portions of the left hand or R group. But in using the expressions 'alkyl' and 'alkoxy' and in embracing both single substituents in the phenyl ring in any of three positions and combinations of any two substituents in any two positions, the language places no mathematical limit whatever on the number of carbon atoms or the formations thereof which such groups can have and thus makes the number of members of the class mathematically infinite. Nor is there evidence of how many members of this class are conceivable either as a matter of practical chemistry or for the purposes of practical commercial manufacture. As a matter of interpretation, however, it is in my opinion clear that the claim refers to every mathematically conceivable sulphonyl urea of the class, for I can see no basis upon which anyone who might contrive to make a substance of the class, however inconceivable the preparation of such a substance may have been at the time of the drafting of the claim, could successfully maintain that his substance was not within the class."[218] [emphasis added]

The overly broad claims were held invalid by the Supreme Court:

> "In challenging the validity of the patents in question, counsel for the respondents put his case upon the footing that no one could obtain a valid patent for an unproved and untested hypothesis in an unchartered field. That is what the appellant has tried to do in claim 1 of each of the patents. It has sought to cover, in the words of Thurlow, J., 'every mathematically conceivable sulphonyl area of

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215 (1965), 50 C.P.R. 26 (S.C.C. per Hall J.) at p. 58, [1966] S.C.R. 189 at p. 194, 32 Fox Pat. C. 56.

216 *Hoechst Pharmaceuticals of Canada Ltd. et al. v. Gilbert & Co. et al*, (1965), 50 C.P.R. 26 (S.C.C. per Hall J.) at p. 55.

217 *Hoechst Pharmaceuticals of Canada Ltd. et al. v. Gilbert & Co. et al* (1965), 50 C.P.R. 26 (S.C.C. per Hall J.) at p. 55.

218 *Hoechst Pharmaceuticals of Canada Ltd. et al. v. Gilbert & Co. et al* (1965), 50 C.P.R. 26 (S.C.C. per Hall J.) at p. 57 quoting Justice Thurlow in *Hoechst Pharmaceuticals of Canada Ltd. et al. v. Gilbert & Co. et al,* (1965), 50 C.P.R. 26 (F.C.A. per Thurlow J.) at p. 42-43.

> the class' and has consequently overclaimed, and, in so doing, invalidated claim 1 in each patent." [219] [emphasis added]

Claiming an infinite number of compounds was an example of a patent "for an unproved and untested hypothesis in an unchartered field".

8.11.1.2. No evidence the compounds have therapeutic value = no utility

If there is no evidence that compounds within a claim for a pharmaceutical will have therapeutic value, the claim will be held invalid. In these cases, either:

- the patent fails because the inventor/patentee hasn't convinced the court that the predicted compounds have utility, and have failed to meet some onus; or
- the courts equate no evidence of utility, to there being no utility.

The latter basis seems to be how it is stated in the case law, however the correct basis is likely the former: the patentee must establish that the invention is useful.

May & Baker Ltd. et al. v. Boots Pure Drug Co. Ltd.[220] was characterized in *Commissioner of Patents v. Ciba Ltd*.[221] by Martland, J. in support of the proposition that "no evidence" means "no utility":

> "Jenkins J. granted the petition for revocation on the ground that, although the two named thiazoles were of considerable therapeutic value, there was no evidence that this was true of any other derivatives covered by the claims, and accordingly the patent was bad for want of subject-matter, since the claims covered substances which were not useful." [222] [emphasis added]

Although the same fate could have followed the patent in *Societe des Usines Chimiques Rhone-Poulenc et al. v. Jules R. Gilbert Ltd. et al*.,[223] the patent was held invalid because some compounds were " … not shown to be therapeutically valuable anti-histamines, the effective antihistamine, tripelennamine, being the alpha isomer. It is also established that at least one of the hydrohalide salts cannot be safely used as oral medication, namely the hydrofluoride." [224] This patent was held invalid on the basis that utility was not shown and one compound was shown not to be safe as an oral

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219 *Hoechst Pharmaceuticals of Canada Ltd. et al. v. Gilbert & Co. et al* (1965), 50 C.P.R. 26 (S.C.C. per Hall J.) at p. 58.

220 (1950), 67 R.P.C. 23; 66 R.P.C. 8; 65 R.P.C. 255.

221 (1959) 30 C.P.R. 135 , 19 Fox Pat. C. 18, 18 D.L.R. (2d) 375, [1959] S.C.R. 378.

222 (1959) 30 C.P.R. 135 (S.C.C. per Martland J.) at p. 139, 19 Fox Pat. C. 18, 18 D.L.R. (2d) 375, [1959] S.C.R. 378, citing *May & Baker Ltd. et al. v. Boots Pure Drug Co. Ltd.,* (1950), 67 R.P.C. 23

223 *Societe des Usines Chimiques Rhone-Poulenc et al. v. Jules R. Gilbert Ltd. et al*., (1968), 55 C.P.R. 207 (S.C.C. per Hall J.) at pp. 266-267, 69 D.L.R. (2d) 353, [1968] S.C.R. 950 at p. 953.

224 (1968), 55 C.P.R. 207 (S.C.C. per Hall J.) at pp. 266-267, 69 D.L.R. (2d) 353, [1968] S.C.R. 950 at p. 953.

medication.

DMCnow

8.11.2. 1. Factual basis – (reliable data)

The first criterion is reliable data upon which the predictive theory can be applied to make the sound prediction.

Each case will depend on the evidence.[225]

8.11.2.1. Galantamine – no head-to-head study

In *Janssen Inc. et al v. Mylan* (galantamine), the patent was declared invalid on the basis that it claimed a method of medical treatment. In paragraphs 17 & 18, the judge also said to the patentee: "You didn't have good data – you have compared results from 2 different experiments":

> "I also do not accept Janssen's other inventive premise that the proposed method of slowly titrating galantamine can lead to a lower maintenance dose (16 mg) than would otherwise be required. This is an unwarranted and unsound conclusion that cannot be drawn or predicted by comparing the clinical study underlying the '950 Patent with the results of an earlier non-comparative clinical study which, according to the '950 Patent, found a dose of 18 mg of galantamine to be "sub-optimal".
>
> In the field of pharmaceutical research, it is common that the results of one clinical study are not replicated in another, even where the study designs are equivalent. In the absence of a well-designed head-to-head study of galantamine comparing different approaches to titration, no one could reasonably conclude that these marginally different study outcomes were caused by the slowed titration of galantamine and not for some other reason."

8.11.2.2. Atomoxetine – only inconclusive data

The *atomoxetine* case[226] involved a new use for an old compound.[227] Claim 1 provided:

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225 *Eli Lilly and Company v. Teva Canada Limited*, 2011 FCA 220 (F.C.A. per Evans, J.A., Noël & Dawson JJ.A. concurring) at para. 42:

> However, utility is largely a question of fact that is decided in each case on the basis of the evidence and the judge's assessment of it. That a judge in one case concluded that utility was shown on the basis of the evidence before her is of little value in persuading an appellate court that a judge in another case, where the evidence was somewhat similar, must have applied too high a standard of proof or committed a palpable and overriding error because he reached the opposite result.

226 *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915 (F.C. per Barnes J.) [atomoxetine]

227 *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915 (F.C. per Barnes J.) at para. 88

> 1. The use of tomoxetine for treating attention-deficit/hyperactivity disorder in a patient in need thereof.

Justice Barnes held that the promise of the patent was that atomoxetine was somewhat useful for treating ADHD in three of its manifestations among all age groups (children, adolescents and adults).[228] Justice Barnes held that Lilly's reported results did not demonstrate the clinical utility of atomoxetine to treat ADHD in adults let alone in children and adolescents.[229] The data related to a clinical trial that was too small in size and too short in duration to provide anything more than interesting but inconclusive data.[230]

The patent acknowledged that atomoxetine was a well-known drug with a recognized mechanism of activity as a norepinephrine reuptake inhibitor ('735 Patent at p. 2, line 15).[231] The specification also stated:

> Tomoxetine is quite active in that function, and moreover is substantially free of other central nervous system activities at the concentrations or doses at which it effectively inhibits norepinephrine reuptake. Thus, it is quite free of side effects and is properly considered to be a selective drug.
>
> Tomoxetine is a notably safe drug, and its use in ADHD, in both adults and children, is a superior treatment for that disorder because of its improved safety. Further, tomoxetine is effective at relatively low doses, as discussed below, and may safely and effectively be administered once per day. Thus, difficulties created by the multiple dosing of patients, particularly children and disorganized adults, are completely avoided." ('735 Patent at p. 2, lines 21-35)[232]

Lilly relied on a clinical trial called the Massachusetts General Hospital Study (the "MGH Study") to try to establish that atomoxetine was an active norepinephrine reuptake inhibitor and had utility for the clinical treatment of ADHD. Justice Barnes held that the inventive promise of the patent was not in dispute and, for all claims, involved the use of atomoxetine for treating ADHD in three of its manifestations among all age groups (children, adolescents and adults).[233] The patent did not assert (nor would it have been expected by a person of skill) that atomoxetine would work for every person.[234] Lilly

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228 *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915 (F.C. per Barnes J.) at paras. 32 and 93; aff'd *Eli Lilly and Company v. Teva Canada Limited*, 2011 FCA 220 (F.C.A. per Evans, J.A., Noël & Dawson JJ.A. concurring) at para. 20.

229 *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915 (F.C. per Barnes J.) at para. 113.

230 *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915 (F.C. per Barnes J.) at para. 113.

231 *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915 (F.C. per Barnes J.) at para. 34.

232 *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915 (F.C. per Barnes J.) at para. 34.

233 *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915 (F.C. per Barnes J.) at para. 32; aff'd *Eli Lilly and Company v. Teva Canada Limited*, 2011 FCA 220 (F.C.A. per Evans, J.A., Noël & Dawson JJ.A. concurring) at para. 20.

234 *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915 (F.C. per Barnes J.) at para. 32.

need to have shown only that atomoxetine was "somewhat useful to treat ADHD".[235] The Federal Court of Appeal considered this to be an explicit promise.

Justice Barnes did not accept the evidence that Lilly had established demonstrated utility through the MGH Study to support the promise that atomoxetine worked to treat ADHD in some patients:

> "I do not accept the point that utility in this case should be measured against a hypothetical or theoretical standard that is lower than the inventive promise of the patent. ADHD is a chronic disorder requiring sustained treatment. Only where experimental results are sufficiently compelling to independently support the inventive promise (or to support a sound prediction) is utility established. In the case of the '735 Patent, the inventors claimed a new use for atomoxetine to effectively treat humans with ADHD. What is implicit in this promise is that atomoxetine will work in the longer term. If the MGH Study was not adequate to demonstrate the clinical usefulness of atomoxetine to treat ADHD the bare fact that some positive experimental data emerged is not enough. Mr. Creber is correct when he argues that utility does not mean commercial usefulness and I agree with him that there is no requirement that atomoxetine be demonstrated to work for every patient. I do not, however, agree with him when he argues that if a single case study involving one patient showed a clinical benefit, this "scintilla of utility" would, as a matter of course, be sufficient to establish utility. I also do not agree that it is correct in law to equate the evidence in proof of anticipation with what is needed to prove utility. The evidence to demonstrate utility must be sufficient to support the promise that atomoxetine works to treat ADHD in some patients."[236]
>
> "… For the most part, I accept Dr. Virani's evidence about the limitations of the MGH Study and find that its reported results do not demonstrate the clinical utility of atomoxetine to treat ADHD in adults let alone in children and adolescents. This was a clinical trial that was too small in size and too short in duration to provide anything more than interesting but inconclusive data. With a patient sample of this uniformity and size, an exposure to atomoxetine of only three weeks and a degree of subjectivity in the testing, one can only conclude, as the researchers themselves stated, that the study had "limitations" and the results were promising but only preliminary. In some cases an initial study of this sort might provide a basis for a sound prediction of utility but, as explained below, there the patent would be required to exemplify the basis of the prediction so that

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235 *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915 (F.C. per Barnes J.) at para. 93.

236 *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915 (F.C. per Barnes J.) at para. 112. The Federal Court of Appeal agreed *Eli Lilly and Company v. Teva Canada Limited*, 2011 FCA 220 (F.C.A. per Evans, J.A., Noël & Dawson JJ.A. concurring) at paras 32 & 29: "In my view, this argument does not assist Lilly. The better reading of the Judge's reasons is that he found that the evidence was insufficient to demonstrate that atomoxetine was an effective clinical treatment, regardless of the length of time for which it was taken, and I see no basis for disturbing this conclusion."

the skilled reader could independently evaluate the utility promise."[237]

With respect to Lilly's alternate claim that the invention was soundly predicted based on the MGH Study, Justice Barnes held that the argument failed because some reference to the findings of the MGH Study was not set out in the patent.[238]

The Federal Court of Appeal affirmed Justice Barnes' decision holding that Justice Barnes' comment that ""[w]hat is implicit in this promise is that atomoxetine will work in the longer term", he was simply interpreting what "treatment" meant in this patent in the context of ADHD, a chronic disorder requiring sustained treatment. He was not adding a promise above and beyond that already expressed in the words of the patent, namely that atomoxetine is an effective treatment of ADHD.[239] Since Justice Barnes' found the evidence to be insufficient to demonstrate that atomoxetine was an effective clinical treatment, regardless of the length of time for which it was taken, the Court saw no basis to interfere with this conclusion. [240]

8.11.2.3. Chronic conditions require data supporting chronic usefulness

Where the promise is for the treatment of a chronic disease or condition, a short term study does not provide the factual basis for a sound predicvtion:

- Latanapost –for glaucoma. The promise of a patent for a compound (latanoprost), which was claimed to be safe and effective in the treatment of glaucoma, a chronic condition, must be supported by a factual basis and line of reasoning consistent with the use of the compound over a long term.[241]

- Atomoxetine, for ADHD. The utility of a compound (atomoxetine), which was claimed to be useful in the treatment of ADHD, a chronic condition, could not be demonstrated on the basis of a short-term study. Justice Evans concluded that the meaning of the word "treatment" must be considered in the context of a patent for a compound claimed to be useful in addressing the symptoms of a chronic condition.[242] DMCAUG

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237 *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915 (F.C. per Barnes J.) at para. 113.

238 *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915 (F.C. per Barnes J.) at para. 113. Somewhat surprisingly, Justice Barnes did not point out that because the MGH Study was inadequate to prove demonstrated utility, it could not form the basis of a sound prediction of utility even if it had been in the patent.

239 *Eli Lilly and Company v. Teva Canada Limited*, 2011 FCA 220 (F.C.A. per Evans, J.A., Noël & Dawson JJ.A. concurring) at para. 21.

240 *Eli Lilly and Company v. Teva Canada Limited*, 2011 FCA 220 (F.C.A. per Evans, J.A., Noël & Dawson JJ.A. concurring) at para. 29.

241 *Pfizer Canada Inc v Canada (Minister of Health),* 2011 FCA 236, para NTD [Pfizer 2011]; *Eli Lilly and Company et al. v. Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) [O FC 2] at para. 232.

242 *Eli Lilly and Company v. Teva Canada Limited*, 2011 FCA 220 (F.C.A. per Evans, J.A., Noël & Dawson JJ.A. concurring) at para. 29; *Eli Lilly and Company et al. v. Novopharm Limited*, 2011

8.11.3. 2. Sound Line of Reasoning

How Science Works

Before one can understand how judges deal with sound prediction, it would be useful to discuss how scientists make and validate (or invalidate) their predictions (usually called scientific “theories” or “laws”) and what evidence they use to prove that a theory or law is “unsound” or wrong.

Scientists make theories based on facts and their knowledge of how things work. A theory is “sound” if it can be used to predict future behaviour. If a theory correctly predicts some events, but does not correctly predict other events, then the theory is inherently wrong and needs to be replaced with another theory that correctly predicts all events (Being close only counts in horseshoes). For example: the theory that the sun travelled around the earth was “true” based on the observations and experience of our distant ancestors but was proven to be untrue by further observations that were consistent with the theory that the earth travels around the sun.

Any evidence (past, present or future) can be used to invalidate a scientific theory or law.

Any evidence (past, present or future) can be consistent with a scientific theory and can reinforce it as being “correct” to a greater degree of certainty, but a theory or law can never be “proven” to be 100% correct. It is always open to be disproven by evidence.

243

FC 1288 (F.C. per O’Reilly J.) [O FC 2] at para. 234.

243 As viewed by Richard Feynman, one of the top physicists and teachers of the 20th Century (as described in “*Genius*”, by James Gleick, Vintage Books, New York, 1992):

At p. 234:

> "... progress in science comes when experiments contradict theory."

At p. 365:

> "...All satellites travel in elliptical orbits. Why? Because objects tend to travel in a straight line when left alone (the law of inertia) and the combination of that unchanging motion and a force exerted toward a center of gravity -- by the law of gravitation -- creates an ellipse. What validates the law of gravitation? Feynman expressed the scientist's modern view, a blend of the pragmatic and the aesthetic. He cautioned that even so beautiful a law was provisional: Newton's law of gravitation gave way to Einstein's and a necessary quantum modification eluded physicists even now.

At pp. 368 and 369:

> "...And the century's history had shown that when even so elegant and pure a theory as Newton's had to be replaced, slight modifications could not suffice.
>
> To get something that would produce a slightly different result it had to be completely

In *Monsanto*,[244] Pigeon J. said there were "… just two possible reasons for rejecting claims such as those in issue.

1. There is evidence of lack of utility in respect of some of the area covered;

2. It is not a sound prediction."[245]

Justice Pigeon appeared to put the onus on the Commissioner to establish that the claimed compounds lacked utility or were not soundly predicted or, at least, to give a reason why the Commissioner believed that the utility of the compounds were not soundly predicted. He allowed the appeal (and the patent claims in issue) because: (1) It was not contended that any of the 126 substances covered did not have utility; and (2) it does not appear that the Board really found that the claims in issue did not involve a sound prediction. The Board's only reason was that "we are not satisfied that three specific examples are adequate" to predict utility for the other 126 substances in claim 9. Justice Pigeon seems to say that the chemistry in this area was predictable and "a matter of common knowledge among scientists":

> "Although the report of the Board is quite lengthy, in the end with respect to claim 9 all it says after stating the principle with which I agree, is that a claim has to be restricted to the area of sound prediction and "we are not satisfied that three specific examples are adequate". As to why three is not enough nothing is said. In my view this is to give no reason at all in a matter which is not of speculation but of exact science. We are no longer in the days when the architecture of chemical compounds was a mystery. By means of modern techniques, chemists are now able to map out in detail the exact disposition of every atom in very complex molecules. It, therefore, becomes possible to ascertain, as was done in *Olin Mathieson*, the exact position of a given radical and also to relate this position to a specific activity. It thus becomes possible to predict the utility of a substance including such radical. As this is a matter of general knowledge among scientists, it will be readily apparent to a competent person that if a patent covers only a few of the substances which yield the desired result, all he has to do is to prepare another which will have the same properties. The report of the Board indicates that it is aware of this. However, it gives no indication of the reasons for which it was not satisfied of the soundness of the prediction of utility for the whole area covered by claim 9. Evidence had been submitted in the form of affidavits based on scientific principles, it does not take issue with those principles, it just says: "We are not satisfied that this is adequate". In my view this is insufficient because, if accepted, it makes the right of appeal illusory."[246]

> different. In stating a new law you cannot make imperfections on a perfect thing; you have to have another perfect thing."

244 *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Pigeon J.).

245 *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Pigeon J.) at pp. 176.

246 *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Pigeon

[emphasis added]

> "In the present case, the Board's decision leaves the Court completely in the dark respecting the reasons for which they were not satisfied that what the inventors claimed did meet the test for a sound prediction."[247]

> "In the instant case, the Board, in spite of a complete absence of any evidence of unsoundness of the prediction, deny the claims and would in the end limit them to the area of proved utility instead of allowing them to the extent of predicted utility. In my view this is contrary to s. 42 of the *Patent Act*."[248]

Thus there was not a lack of evidence of sound prediction from the patentee or in the patent itself, but rather a lack of any evidence of unsoundness from (or relied on by) the Commissioner. And so the claims were allowed. The case turned on the expert evidence that established that "… it will be readily apparent to a competent person that if a patent covers only a few of the substances which yield the desired result, all he has to do is to prepare another which will have the same properties."[249]

8.11.3.1. Soundly Predictable by Who? The inventor or a POSITA?

The PAB in *Monsanto* (1977 NTD at p. 170) adopting the words of Graham J. in *Olin Mathieson* said:

> "If it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so." [emphasis added]

In *AZT*, Binnie J. equivocates on who must be able to soundly predict that the invention will work: the inventor or a POSITA reading the patent? At para. 70, he said:

> "Secondly, the inventor must have, at the date of the patent application, an articulable and sound line of reasoning from which the desired result can be inferred from the factual basis," [emphasis added]

but at para. 83 he seemed to suggest that it is the skilled reader who must be able to predict utility:

> "On the other hand, if the patent failed to disclose the essentials of a heavier-than-air flying machine, such that no one could "soundly predict" whether or not the ill-defined thing could get off the ground, then the patent would be rightly

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J.) at pp. 177-178.

247 *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Pigeon J.) at p. 178.

248 *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Pigeon J.) at p. 178.

249 *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Pigeon J.) at p. 178.

invalidated, even though the inventors had subsequently flown some sort of machine in the meantime." [emphasis added]

[NTD: perhaps because the inventor must (a) have it and (b) share it in the patent if the POSITA doesn't already have the predictive theory.]

8.11.3.2. Based on common general knowledge or inference from data in the patent

If a person skilled in the art can reasonably predict that the invention will have utility based on what is disclosed in the patent along with his/her common general knowledge or expertise, why does the basis for the prediction need to be set out in the patent? Wouldn't it thereby be obvious to all that it was useful?

In *Eurocopter v. Bell Helicopter Textron Canada Ltée*[250] the Federal Court of Appeal held that, the factual basis, line of reasoning and level of disclosure required by the doctrine of sound prediction are to be assessed as a function of both the knowledge that the skilled person would have to base that prediction on and what the skilled person would understand as a logical line of reasoning leading to the utility of the invention. Those elements of the doctrine of sound prediction that would be self-evident to the skilled person need not be explicitly disclosed in the patent.[251]

Eurocopter was in the mechanical arts, but the same principle was applied in a pharmaceutical case in *Apotex Inc. v. Allergan Inc. et al* (Lumigan RC/bimatoprost). The case involved new Lumigan that had one-third the amount of bimatoprost (Bp) than old Lumigan (and thus fewer side effects), but had four times as much benzalkonium chloride (BAK) than old Lumigan.[252] Allergan predicted that this would result in a comparable reduction in intraocular pressure with fewer side effects than old Lumigan.[253] The hearing judge decided that the sound line of reasoning was implicit in the data itself and would be apparent to the skilled reader; it did not have to be explicitly laid out[254] and the invention was thus soundly predicted.[255] The Federal Court of Appeal agreed:[256] For the skilled reader, the line of reasoning flowed from the factual

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250 *Eurocopter v. Bell Helicopter Textron Canada Ltée* , 2013 FCA 219, 449 N.R. 111, at paras. 152 & 153

251 *Eurocopter v. Bell Helicopter Textron Canada Ltée* , 2013 FCA 219, 449 N.R. 111, at paras. 152 & 153; *Apotex Inc. v. Allergan Inc. et al* (Lumigan RC/bimatoprost),2015 FCA 137 (F.C.A. per Dawson J.A., Webb & Biovin JJ.A. concurring) at para. 9.

252 *Allergan Inc. et al v. Apotex Inc*. (Lumigan RC/bimatoprost), 2014 FC 567 (F.C. per O'Reilly J.) at para. 6.

253 *Allergan Inc. et al v. Apotex Inc*. (Lumigan RC/bimatoprost), 2014 FC 567 (F.C. per O'Reilly J.) at para. 6.

254 *Allergan Inc. et al v. Apotex Inc*. (Lumigan RC/bimatoprost), 2014 FC 567 (F.C. per O'Reilly J.) at para. 40.

255 *Allergan Inc. et al v. Apotex Inc*. (Lumigan RC/bimatoprost), 2014 FC 567 (F.C. per O'Reilly J.) at para. 45.

256 *Eurocopter v. Bell Helicopter Textron Canada Ltée* , 2013 FCA 219, 449 N.R. 111, at paras. 152 & 153; *Apotex Inc. v. Allergan Inc. et al* (Lumigan RC/bimatoprost),2015 FCA 137 (F.C.A. per Dawson J.A., Webb & Biovin JJ.A. concurring) at para. 9.

basis for the prediction (the minimum inhibitory concentration values of several compounds tested against a number of bacteria species together with comparative data).[257]

8.11.3.3. Where there's no sound basis for the prediction

***AstraZeneca v Apotex,* 2011 FCA 236 (F.C.A. per Trudel J.A.) at paras 31 and 40**

- "The evidence from experts on both sides also reveals that the '132 patent was based on a prediction of utility, i.e., that which was observed in the single dose study could soundly be predicted to apply to chronic use [for the treatment of glaucoma]"
- The judge said: "However, the factual basis supporting the promise of the patent is clearly not a chronic use study. None of the studies used multiple doses" and held the patent invalid

[NTD: Move elsewhere?] Where a patented compound is claimed to be safe and effective in the treatment of a chronic condition, utility will be demonstrated if the patent discloses studies showing that the patented compound, when administered over a long term, meets that promise.[258] DMCAUG

Speculation, even if afterwards proves justified, does not provide valid consideration.[259] It was like a lucky guess.

By sound predictions, Binnie J. must have been referring to the predictive theory, not the prediction itself. He said "Not all predictions, even sounds ones, turn out to be correct."[260] [Elsewhere: Must be prima facie reasonable inference but doesn't have to be a certainty.] Binnie J. was saying that even a sound prediction can be wrong. If so, then a prediction that X will work, if subsequently determined to be wrong (because, as it turns out, X does not work), may, under Binnie J.'s scenario still have been based upon a sound prediction. If a prediction subsequently is shown to be wrong, the patent would be invalid for want of utility.[261] If X doesn't work, it lacks utility.

Likewise, if the sound prediction theory is later proven to be wrong, the result is the same as if the prediction had been made based on mere speculation: there is no consideration being paid for the invention and the claim should be declared invalid.

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257 *Apotex Inc. v. Allergan Inc. et al* (Lumigan RC/bimatoprost),2015 FCA 137 (F.C.A. per Dawson J.A., Webb & Biovin JJ.A. concurring) at para. 9.

258 *Pfizer Canada Inc v Canada (Minister of Health),* 2011 FCA 236, para 30 [Pfizer 2011]. *Eli Lilly Canada Inc v Novopharm Limited,* 2011 FC 1288 (F.C. per O'Reilly J.) (O FC 2) at para. 210.

259 *Apotex Inc. v Wellcome Foundation Ltd*, 2002 SCC 77 (CanLII), 2002 SCC 77 at para 76, 2002 SCC 77 (CanLII), [2002] 4 SCR 153. [AZT]

260 *Apotex Inc. v Wellcome Foundation Ltd*, 2002 SCC 77 (CanLII), 2002 SCC 77 at para 76, 2002 SCC 77 (CanLII), [2002] 4 SCR 153. [AZT]

261 *Apotex Inc. v Wellcome Foundation Ltd*, 2002 SCC 77 (CanLII), 2002 SCC 77 at para 83, 2002 SCC 77 (CanLII), [2002] 4 SCR 153. [AZT]

8.11.3.4. Where there's a sound basis for the prediction, but it's not disclosed

8.11.3.5. How predictable? A *prima facie* reasonable inference of utility

See [262]

Year	Case	Proven utility	Predicted utility	Outcome
1979	*Monsanto*[263]	3 compounds	192 compounds[264]	**Soundly predicted**

8.11.4. 3. Proper Disclosure of facts and predictive theory in the patent

AZT was the first case that mentioned or required there to be disclosure the factual basis and the sound line or reasoning in the patent disclosure itself.

NTD: Effect has been devastating

Justice Rennie in the esomeprazole impeachment trial[265] and Justice Gauthier in *Sanofi-Aventis (Plavix)*,[266] noted the negative policy consequences of an enhanced disclosure requirement for sound prediction identified in the Siebrasse article:

> [158] I am compelled to follow the Supreme Court's remarks in *Teva sildenafil* and the interpretation of *AZT* endorsed by Justice Gauthier in *Sanofi-Aventis*

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262 *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197 (FCA per Layden-Stevenson J.A.), quoted by *Eli Lilly Canada Inc. v. Novopharm Limited*, 2011 FC 1288 (F.C. per O'Reilly J.) at para 86-88 [O FC 2].

263 *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Pigeon J.).

264 The decision is unclear; The PAB and Martland refer to 126 species; Pigeon refers to 126 compounds. NTD: check the patent

265 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 159. ["the esomeprazole impeachment trial"]

266 NTD Sanofi-Aventis Plavix 2013 FCA 186add cite, at para 132.

> *Plavix*. As a final note, I would also add that Professor Siebrasse's remarks on this very question provide further support to this interpretation. In his paper, "*Must the Factual Basis for Sound Prediction be Disclosed in the Patent?*" (2012) 28:1 CIPR 39, Professor Siebrasse concluded that:
>
> > "the requirement that the factual basis for a sound prediction of utility must be disclosed in the patent itself, is unsound in both law and policy. There is no basis in the text of the *Patent Act*, in legal principle, or in practice, for a distinction between utility based on sound prediction and demonstrated utility."
>
> [159] Having reviewed Professor Siebrasse's article, I generally agree with his observations, and echo Justice Gauthier's view in *Sanofi-Aventis* Plavix, at para 132, that the article identifies negative policy consequences of an enhanced disclosure requirement for sound prediction.
>
> [132] If this is not so, then this case demonstrates the seriousness of some of the criticisms set out in Professor Norman Siebrasse's article "*Must the Factual Basis for Sound Prediction be Disclosed in the Patent?*" (2012) 28 C.I.P.R. 39. In that article, Professor Siebrasse argues that Binnie J.'s brief statement at paragraph 70 of AZT is not a proper basis for the heightened level of disclosure applied in recent case law, especially in cases where no use or specific result is referred to in claims where the inventor defines the invention for which he is seeking a monopoly, or where a specific advantage/utility is required to support the right to claim a particular invention (selection)..

8.11.4.1. <u>"proper disclosure" of utility in the patent is not required by the *Patent Act*</u>

Section 27(3) of the Patent Act does not impose upon a patentee the obligation of establishing the utility of the invention".[267]

In the esomeprazole impeachment trial,[268] Justice Rennie generally agreed with the observations of Professor Siebrasse in his paper, "*Must the Factual Basis for Sound Prediction be Disclosed in the Patent?*" (2012) 28:1 CIPR 39, where he concluded that:

> "… the requirement that the factual basis for a sound prediction of utility must be disclosed in the patent itself, is unsound in both law and policy. There is no basis in the text of the *Patent Act*, in legal principle, or in practice, for a distinction between utility based on sound prediction and demonstrated utility."

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267 *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd*., [1981] 1 S.C.R. 504 (S.C.C. per Dickson J.), at pp. 521, 525 and 526; *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 64.

268 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 158. ["the esomeprazole impeachment trial"]

8.11.4.2. 2002: *Apotex Inc v Wellcome* SCC - The *AZT* decision

The leading case is *Apotex Inc v Wellcome Foundation Ltd* (*AZT*). [269]

Soundly predicted utility is based on the three part test set out by the Supreme Court of Canada in the *AZT* case.[270]

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

2. the inventor must have, at the date of the patent application, an articulable and sound line of reasoning from which the desired result can be inferred from the factual basis, and

3. there must be proper disclosure.[271]

In the *AZT* case itself, the invention had been made by the relevant date:

> "[The trial judge] concluded that utility was not shown as of the February 6, 1985 draft application date. At that time there was no more than a belief that AZT "might be useful" to treat AIDS, and the claims at that date exceeded the invention. By March 16, 1985, however, the patent met the s. 2 requirements and did not exceed the invention claimed. The Glaxo/Wellcome researchers had received the initial NIH data showing that AZT was active in arresting the HIV retrovirus in human cells."[272]

Arguably, Justice Binnie's requirement that there be "proper disclosure" of utility in the patent may be *obiter dicta*. Justice Binnie elected to not elaborate on this exception because it made no difference in the *AZT* case:

> "Precise disclosure requirements in this regard do not arise for decision in this case because both the underlying facts (the test data) and the line of reasoning (the chain terminator effect) were in fact disclosed, and disclosure in this respect did not become an issue between the parties. I therefore say no more about

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269 2002 SCC 77, [2002] 4 SCR 153, [2002] SCJ No78; *Pfizer Canada Inc. v Mylan Pharmaceuticals ULC et al*, 2014 FC 38, (F.C. per Harrington J.) at para. 36.

270 *Apotex Inc. v Wellcome Foundation Ltd*, 2002 SCC 77 (CanLII), 2002 SCC 77 at para 70, 2002 SCC 77 (CanLII), [2002] 4 SCR 153. [AZT]

271 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 141. ["the esomeprazole impeachment trial"] At para 140, Justice Rennie noted that Astrazeneca argued that the promises of stability against enzyme-mediated racemization and an improved therapeutic profile were soundly predicted because of studies that were internal to AstraZeneca and not disclosed in the '653 patent. Justice Rennie concluded that the patent promised reduced interindividual variation, and that none of the studies, disclosed or otherwise, demonstrate or soundly predict such utility. If the validity of the patent were to depend on the sound prediction of the second or third promises, Apotex argued that such a sound prediction is invalid in law because it failed to satisfy the requirement of proper disclosure.

272 *Apotex Inc. v. Wellcome Foundation Ltd*. [2002] 4 S.C.R. 153 at para. 25

it."[273]

Item #3, the requirement for "proper disclosure" was new. No court had ever suggested that a patent include the underlying data needed to make a sound prediction along with the predictive theory. This was revolutionary.

8.11.4.3. The "Butterfly Effect" – The decisions that followed and made things worse

Wikipedia defines the "butterfly effect" as follows. It relates to small deviations eventually resulting in large perturbations:

In chaos theory, the butterfly effect is the sensitive dependence on initial conditions in which a small change in one state of a deterministic nonlinear system can result in large differences in a later state. The name of the effect, coined by Edward Lorenz, is derived from the metaphorical example of the details of a hurricane (exact time of formation, exact path taken) being influenced by minor perturbations such as the flapping of the wings of a distant butterfly several weeks earlier. Lorenz discovered the effect when he observed that runs of his weather model with initial condition data that was rounded in a seemingly inconsequential manner would fail to reproduce the results of runs with the unrounded initial condition data. A very small change in initial conditions had created a significantly different outcome.

8.11.4.4. The raloxifene (EVISTA) case

The first perturbation of the *AZT* sound prediction conditions occurred in the *raloxifene* case, which was a compound for use in the treatment of osteoporosis, marketed by Eli Lilly under the brand name EVISTA.[274]

NTD: Was it a new use case?

At the PM(NOC) hearing, Justice Hughes found that the invention (the effect of pharmacological agents on the skeleton at least regarding estrogen deficiency induced bone loss) was soundly predicted by a document referred to as the Hong Kong abstract, but, because the information was not included in the patent itself,[275] the patent was invalid since, under the *AZT* doctrine, it lacked the proper disclosure and, therefore there was no sound prediction.[276] The Federal Court of Appeal agreed:[277]

> "In sound prediction cases there is a heightened obligation to disclose the underlying facts and the line of reasoning for inventions that comprise the

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273 *Apotex Inc. v Wellcome Foundation Ltd*, 2002 SCC 77 (CanLII), 2002 SCC 77 at para 70, 2002 SCC 77 (CanLII), [2002] 4 SCR 153. [AZT], quoted at *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 148. ["the esomeprazole impeachment trial"]

274 *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142 (F.C. per Hughes J.) at paras. 164-165, (2008) 63 C.P.R. (4th) 406.

275 *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142 (F.C. per Hughes J.) at para 163, (2008) 63 C.P.R. (4th) 406.

276 *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142 (F.C. per Hughes J.) at para 163, (2008) 63 C.P.R. (4th) 406.

277 *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97 (F.C.A. per Noël J.A., Desjardins & Trudel JJ.A. concurring) at para. 15, 78 C.P.R. (4TH) 388

prediction."[278]

8.11.5. Can claim what you can soundly predict

In *Monsanto*, the Supreme Court of Canada held that a patentee is entitled to claim that which the patentee can soundly predict.

> "If it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so."[279]

In the *Monsanto* case, in 1979, the Supreme Court of Canada held that the Commissioner of Patents could not refuse a patent claiming large number of chemicals used in vulcanizing rubber solely because the inventor had not fully tested all potential embodiments.

> "[T]he Commissioner cannot refuse a patent because the inventor has not fully tested and proved it in all its claimed applications. … At present there is … no … evidence that the prediction of utility for every compound named is not sound and reasonable."[280]

NTD; add more: Where the inventor is called upon to prove the utility of the invention, utility can be shown to be demonstrated or soundly predicted as of the patent's filing date (AZT). [281]

In 2012, in the Viagra case[282], the Supreme Court of Canada repeated the *Consolboard* conclusion that utility need not be disclosed. Utility must simply have been shown by experiment or be a sound prediction:

> "That the invention must be useful as of the date of the claim or as of the time of filing is consistent with this Court's comments in *AZT*, at para. 56:
>
> > "Where the new use is the *gravamen* of the invention, the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available. If a patent sought to be supported on the basis of sound

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278 *Eli Lilly Canada Inc. v. Apotex Inc*., 2009 FCA 97 (F.C.A. per Noël J.A., Desjardins & Trudel JJ.A. concurring) at para. 14, 78 C.P.R. (4TH) 388

279 *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (SCC) at p. 174 quoting from the Patent Appeal Board's decision at p. 9.

280 *Monsanto Co v Canada (Commissioner of Patents),* (1979), 42 CPR (2d) 161 (SCC) at p. 179 [*Monsanto*]

281 *Mylan Pharmaceuticals ULC v.Pfizer Canada Inc. et al*, 2014 FCA 250 (F.C.A. per Noël, C.J., Trudel and Biovin JJ.A. concurring) at para. 48

282 *Teva Canada Ltd v Pfizer Canada Inc,* 2012 SCC 60 at paras 39-40, [2012] 3 SCR 625 (Sildenafil).

> prediction is subsequently challenged, the challenge will succeed if the prediction at the date of application was not sound, or, irrespective of the soundness of the prediction, "[t]here is evidence of lack of utility in respect of some of the area covered". [Italics in original; underlining added.]

Nothing in this passage suggests that utility is a disclosure requirement; all it says is that "the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction". Utility can be demonstrated by, for example, conducting tests, but this does not mean that there is a separate requirement for the disclosure of utility. In fact, there is no requirement whatsoever in s. 27(3) to disclose the utility of the invention: see, e.g., *Consolboard*, at p. 521, per Dickson J.: "I am further of the opinion that s. 36(1) [now s. 27(3)] does not impose upon a patentee the obligation of establishing the utility of the invention".

Rennie: There is no requirement whatsoever in s. 27(3) to disclose the utility of the invention[283]:

If a patent sought to be supported on the basis of sound prediction is subsequently challenged, the challenge will succeed if ... the prediction at the date of application was not sound, or, irrespective of the soundness of the prediction, ""[t]here is evidence of lack of utility in respect of some of the area covered."[284]

Nothing in *AZT* para. 56[285] suggests that utility is a disclosure requirement; all it says is that "the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction". Utility can be demonstrated by, for example, conducting tests, but this does not mean that there is a separate requirement for the disclosure of utility.[286] (At paras 38-40)

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283 *Teva Canada Ltd v Pfizer Canada Inc,* 2012 SCC 60 at paras 39-40, [2012] 3 SCR 625 (Sildenafil).; quoted in *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 152. ["the esomeprazole impeachment trial"]

284 NTD AZT SCC, at para. 56

285 "Where the new use is the *gravamen* of the invention, the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available. If a patent sought to be supported on the basis of sound prediction is subsequently challenged, the challenge will succeed if ... the prediction at the date of application was not sound, or, irrespective of the soundness of the prediction, ""[t]here is evidence of lack of utility in respect of some of the area covered."[

286 According to Justice Rennie in *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 156. ["the esomeprazole impeachment trial"], Justice Lebel's remarks in *Teva sildenafil* NTD are instructive:

> "Justice Lebel's remarks in *Teva sildenafil* were *obiter dicta* because sound prediction was not "the main issue" on appeal (at para 36) and because "in any event, Pfizer disclosed the utility of sildenafil" (at para 41). Still, the Supreme Court's view that this secondary topic deserved such explicit treatment places this commentary within the "wider circle of analysis which is obviously intended for guidance and which should be accepted as authoritative," or, at the very least, makes the remarks "commentary,

In *Eurocopter FCA*[287], the Federal Court of Appeal, in *obiter dicta*, was equivocal as to the necessity of disclosure of the factual basis of the prediction. The Federal Court of Appeal observed that "where the factual basis is reliant on data which does not form part of the common general knowledge, then disclosure in the specification *may* indeed be required to support a sound prediction"[288] (*emphasis* added).

In *Apotex Inc. v. Allergan Inc. et al*, 2015 FCA 137 (FCA per Dawson J.A., Webb and Boivin JJ.A. concurring) (Lumigan RC/ bimatoprost) at para. 9 the court held that elements of the doctrine of sound prediction that would be self-evident to the skilled person need not be explicitly disclosed in the patent.

> [9]The Federal Court identified the factual basis for the prediction (the minimum inhibitory concentration values of several compounds tested against a number of bacteria species together with comparative data) and the line of reasoning that would, to the skilled reader, flow from that data. As this Court observed in Eurocopter v. Bell Helicopter Textron Canada Ltée, 2013 FCA 219, 449 N.R. 111, at paragraphs 152 and 153, the factual basis, line of reasoning and level of disclosure required by the doctrine of sound prediction are to be assessed as a function of both the knowledge that the skilled person would have to base that prediction on and what the skilled person would understand as a logical line of reasoning leading to the utility of the invention. Those elements of the doctrine of sound prediction that would be self-evident to the skilled person need not be explicitly disclosed in the patent.

Ntd: If there is a promise, a mere scintilla won't do.

very least a useful choice, and yet the patent was held invalid. As a recent Canadian case involving helicopter landing gear states in applying the promise of the patent doctrine, "[t]he Court has rejected any suggestion by [the patentee's] experts that the utility of the [patent in issue] is simply to provide a working landing gear."[107] 289

Justice Binnie's discussion in *AZT* of "proper disclosure" can be characterized as a general rule with an exception. First, he describes the general rule:

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examples or exposition that are intended to be helpful and may be found to be persuasive" (*R v Henry*, 2005 SCC 76 at para 57, [2005] 3 SCR 609)"

287 *Ibid* at para 52.

[287] *Bell Helicoptor Textron Canada Ltee v Eurocopter,* 2013 FCA 219 at para 153, 449 NR 111, Mainville, JA) (*Eurocopter FCA)*, aff'g 2012 FC 113, 100 CPR (4th) 87, Martineau J (*Eurocopter FC*)., quoted in *Astrazeneca Canada Inc. et al v. Apotex Inc. et al*., 2014 FC 638 (F.C. per Rennie J.) at para. 157.

288 *Ibid* at para 52.

[288] *Bell Helicoptor Textron Canada Ltee v Eurocopter,* 2013 FCA 219 at para 153, 449 NR 111, Mainville, JA) (*Eurocopter FCA)*, aff'g 2012 FC 113, 100 CPR (4th) 87, Martineau J (*Eurocopter FC*)., quoted in *Astrazeneca Canada Inc. et al v. Apotex Inc. et al*., 2014 FC 638 (F.C. per Rennie J.) at para. 157.

289 *Eurocopter* per Martineau 2012 FC 113 at para. 337.

> "Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practised […] It is generally not necessary for an inventor to provide a theory of why the invention works. Practical readers merely want to know that it does work and how to work it."[290] (emphasis added)

Then he describes the exception:

> "In this sort of case, however, the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly."[291] (emphasis added)

8.11.6. "In this sort of case"

The Federal Court of Appeal interpreted this to mean in cases of sound prediction:

> "The decision of the Supreme Court in AZT is particularly significant to the disposition of this appeal. […] As was said in that case (para. 70): "the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly." In sound prediction cases there is a heightened obligation to disclose the underlying facts and the line of reasoning for inventions that comprise the prediction.[292] [emphasis added]

In the esomeprazole impeachment trial, Justice Rennie held that Justice Binnie's comments in AZT did not support an enhanced disclosure requirement in all cases of sound prediction:

1. It is clear from Justice Binnie's reasoning that "this sort of case" was a subset of sound prediction cases and not a reference to all sound prediction cases. As he writes, "[i]n this sort of case, the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly" (at para 70). By implication, Justice Rennie reasoned, there are other "sort[s] of case[s]" where the sound prediction is not the *quid pro quo* offered by the applicant[293] and

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290 *Apotex Inc. v Wellcome Foundation Ltd*, 2002 SCC 77 (CanLII), 2002 SCC 77 at para 70, 2002 SCC 77 (CanLII), [2002] 4 SCR 153. [AZT], quoted at *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 146. ["the esomeprazole impeachment trial"]

291 *Apotex Inc. v Wellcome Foundation Ltd*, 2002 SCC 77 (CanLII), 2002 SCC 77 at para 70, 2002 SCC 77 (CanLII), [2002] 4 SCR 153. [AZT], quoted at *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 147. ["the esomeprazole impeachment trial"]

292 *Eli Lilly Canada Inc v Apotex Inc*, 2009 FCA 97 at para 14; emphasis added in *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 149. ["the esomeprazole impeachment trial"]; *Novopharm Ltd v Eli Lilly and Co*, 2011 FCA 220 at paras 47-51 – though that affirmation was phrased in terms of judicial comity as opposed to a full consideration of the issue (at para 50).

293 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 151. ["the esomeprazole impeachment trial"]

2. Even more critically, limiting "this sort of case" to "new use" cases, rather than sound prediction cases generally, is consistent with the rationale provided by Justice Binnie. In a "new use" case (which *AZT* was), there may be an enhanced disclosure requirement because utility is the only thing being offered in exchange for the patent monopoly since the compound itself was previously disclosed. Theoretically, without such an enhanced disclosure requirement in "new use" cases, a new use patent could consist of a single sentence alleging a new use and a reference to a prior patent disclosing the compound to which the use attaches. None of the research or studies supporting that new use would have to be disclosed. While new uses can be of tremendous importance (see *AZT*), such seemingly sparse patents would fairly raise concerns for the court when evaluating the bargain between innovators and the public. That Justice Binnie was emphasizing "new use" cases and not sound prediction cases in general is further supported by his earlier comments in *AZT* at paragraph 56 where he expressly described the "new use" as the "gravamen" (i.e. the essence or the *quid pro quo*) of the invention in that case.[294]

According to Justice Rennie, this reading of *AZT* is supported by subsequent appellate authorities from the Federal Court of Appeal and the Supreme Court:

1. In *Sanofi-Aventis Plavix*, Justice Gauthier observed:

   'In contradistinction with the situation in *AZT*, where the invention claimed was the new use/utility and thus the *quid pro quo* for the grant of the monopoly was a full disclosure in respect of such utility, the public here received all the information necessary to make and use clopidogrel.'[295]

8.11.6.1. Just for "New Use" patents?

At the esomeprazole impeachment trial,[296] Justice Rennie held that (assuming such a utility disclosure requirement exists at all[297]) the requirement for proper disclosure of utility was limited to the context of "new use" patents,[298] and that there is no enhanced disclosure requirement in all sound prediction cases.[299] Justice Rennie's view was

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294 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 152. ["the esomeprazole impeachment trial"]

295 *Sanofi Aventis v. Apotex Inc*. (Plavix 2), 2013 FCA 186 (F.C.A. per Gauthier J.A.) at para 135; quoted in *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.). ["the esomeprazole impeachment trial"]

296 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 138. ["the esomeprazole impeachment trial"]

297 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 141. ["the esomeprazole impeachment trial"]

298 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 151 & 152. ["the esomeprazole impeachment trial"]

299 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 160. ["the esomeprazole impeachment trial"]

based upon:

- his reading of *AZT*[300];
- the Supreme Court's recent *obiter* remarks in *Teva sildenafil*[301], which he noted had not generated any subsequent binding remarks from the Federal Court of Appeal. In their *Eurocopter*[302] decision, the Federal Court of Appeal, in *obiter dicta*, merely said:

  > "where the factual basis is reliant on data which does not form part of the common general knowledge, then disclosure in the specification *may* indeed be required to support a sound prediction" (emphasis added); and

- his reading of AZT found support in Justice Gauthier's comments at the Federal Court of Appeal in her concurring remarks in *Sanofi-Aventis Plavix*[303] – a decision released after *Teva sildenafil.*[304]

8.11.7. Promise of the patent is a question of law

The promise of the patent (assuming there is one[305]) must be ascertained. Like claims construction, the promise of the patent is a question of law.[306]

> "The promise of the patent must be ascertained. Like claims construction, the promise of the patent is a question of law. Generally, it is an exercise that requires the assistance of expert evidence: *Bristol-Meyers Squibb Co. v. Apotex Inc.,* 2007 FCA 378, F.C.J. No. 1579 at para. 27. This is because the promise should be properly defined, within the context of the patent as a whole, through

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300 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 145-152, 154. ["the esomeprazole impeachment trial"]

301 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. & 155-158 & 160. ["the esomeprazole impeachment trial"] referring to *Novopharm Ltd v Eli Lilly and Co*, 2011 FCA 220 at paras 47-51.

302 *Bell Helicopter Textron v Eurocopter*, 2013 FCA 219 (F.C.A. per Mainville J.A.) at para. 153 , quoted in *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 157.

303 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 153 & 158. ["the esomeprazole impeachment trial"]

304 *Astrazeneca Canada Inc. et al v. Apotex Inc. et al.*, 2014 FC 638 (F.C. per Rennie J.) at para. 142.

305 NTD: 2013 Plavix 2 FCA.

306 *Eli Lilly Canada Inc*. v *Novopharm Limited*, 2010 FCA 197, 85 CPR (4th) 413, (F.C.A. per Layden-Stevenson J.A., Nadon & Sharlow JJ.A. concurring) at para 80); quoted in *Apotex Inc*. v. *Sanofi-Aventis et al*, 2011 FC 1486 (F.C. per Boivin J.) at para. 141; *Laboratoires Servier* v *Apotex Inc*., 2009 FCA 222 (F.C.A. per Layden-Stevenson J.A., Linden and Evans JJ.A. concurring) at para 101; *Pfizer Canada Inc.* v *Mylan Pharmaceuticals ULC*, 2011 FC 547 (F.C. per Hughes J.), 93 CPR (4th) 81, at para. 214.

> the eyes of the POSITA, in relation to the science and information available at the time of filing."[307]

Generally, it is an exercise that requires the assistance of expert evidence:[308] This is because the promise should be properly defined, within the context of the patent as a whole, through the eyes of the POSITA, in relation to the science and information available at the time of filing.[309]

> "Thus, in construing the specification of a patent, in particular the "promise", the Court is to look at the specification through the eyes of a person skilled in the art, bearing in mind commercial realities, being neither benevolent nor harsh, in order to determine fairly the true intent".[310]

Compound: what's it good for?

Machine: disclose 6, claim 1 that works, ok

Machine utility self evident; compound molecule less so

Selection patent: compound has utility of the genus

New compound: solution looking for a problem

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307 *Eli Lilly Canada Inc. v Novopharm Limited*, 2010 FCA 197 (F.C.A per Layden-Stevenson JA) at para. 80

308 *Bristol-Meyers Squibb Co*. v. *Apotex Inc*., 2007 FCA 379, [2007] F.C.J. No. 1597 at para. 27; *Laboratoires Servier* v *Apotex Inc*., 2009 FCA 222 (F.C.A. per Layden-Stevenson J.A., Linden and Evans JJ.A. concurring) at para 101; *Pfizer Canada Inc.* v *Mylan Pharmaceuticals ULC (donepezil)*, 2011 FC 547 (F.C. per Hughes J.), 93 CPR (4th) 81, at para. 215; Also NTD Mylan 2015 at para 81.

309 *Eli Lilly Canada Inc*. v *Novopharm Limited*, 2010 FCA 197, 85 CPR (4th) 413, (F.C.A. per Layden-Stevenson J.A., Nadon & Sharlow JJ.A. concurring) at para 80); quoted in *Apotex Inc*. v. *Sanofi-Aventis et al*, 2011 FC 1486 (F.C. per Boivin J.) at para. 141.

310 *Pfizer Canada Inc.* v *Mylan Pharmaceuticals ULC (donepezil),* 2011 FC 547 (F.C. per Hughes J.), 93 CPR (4th) 81, at paras 212-217; quoted in *Apotex Inc*. v. *Sanofi-Aventis et al*, 2011 FC 1486 (F.C. per Boivin J.) at para. 142.

Apotex Inc. et al v. Pfizer Canada Inc. et al 2014 fca 250 where’s Mylan?

From Monsanto [311]SCC dissent by Martland J. DMC (NTD add numbers

In

[p. 167]

Mr. Justice Thurlow found the claim in suit to be too broad because it covered a large number of substances of which only a limited number has been prepared. The Supreme Court (41 C.P.R. at pp. 3-4, 41 D.L.R. (2d) 611, [1963] S.C.R. 410 at p. 412) supported his findings. The Boehringer Sohn case did involve, of course, pharmacological substances whose properties may be even less predictable than other chemical substances, and the group of compounds claimed was extremely large. Similar conclusions in comparable circumstances were reached Hoechst Pharmaceuticals of Canada Ltd. et al. v. Gilbert & Co. et al. (1964) 50 C.P.R. at p. 28, [1965] 1 Ex. C.R. 710, 28 Fox Pat. C. 120; affirmed 50 C.P.R. 26 , [1966] S.C.R. 189, 32 Fox Pat. c. 56, in which case there was evidence that some 700 members of the class had been synthesized, and in Re May & Baker, Ltd. and Ciba, Ltd.'s Letters Patent (1948), 65 R.P.C. 255; affirmed 66 R.P.C. 8 (C.A.): affirmed sub nom. May & Baker, Ltd. v. Boots Pure Drug Co. Ltd., 67 R.P.C. 23 (H.L.). The Supreme Court, in the Hoechst decision, adopted the view that "no one could obtain a valid patent for an unproved and untested hypothesis in an unchartered field". The dangers of overclaiming were also explored in Societe des Usines Chimiques Rhone-Poulenc et al. v. Jules R. Gilbert Ltd. et al. (1967), 55 C.P.R. 207 at pp. 236-41, 35 Fox Pat. C. 174 at pp. 201-5; affirmed C.P.R. loc cit., 69 D.L.R. (2d) 353, [1968] S.C.R. 950, in which a broad claim was found invalid because the majority of the substances of the class had never been made or tested by anyone.

From *Ciba Geigy*[312] 1982:

> The predictability of a particular result seems to me to be essentially a question of fact, though in some situations it may be a matter of common knowledge. With respect to chemical reactions it is apparent from the foregoing that knowledge in the chemical art as to the predictability of chemical reactions has advanced considerably in the 50 years since Chipman Chemicals Ltd. v. Fairview Chemical Co. Ltd., [1932] Ex. C.R. 107, was decided. The predictability of chemical reactions should not, however, be confused with predictability of the pharmacological effects and thus of the pharmacological utility of new substances. Compare C. H. Boehringer Sohn v. Bell-Craig Ltd. (1962), 39 C.P.R. 201 at pp. 247-8, 22 Fox Pat. C. 190, [1962] Ex. C.R. 201 at pp. 244-5, and Hoechst Pharmaceuticals of Canada Ltd. et al. v. Gilbert & Co. et al. (1965), 50

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311 *Monsanto Co v Canada (Commissioner of Patents)*, (1979), 42 CPR (2d) 161 (S.C.C. per Martland J., dissenting.).

312 *Ciba-Geigy AG v. Commissioner of Patents*, (1982) 65 C.P.R. (2d) 73 (F.C.A. per Thurlow C.J., Pratte and Heald JJ concurring) at pp. 77-78

> C.P.R. at p. 28, [1965] 1 Ex. C.R. 710 at p. 731, 28 Fox Pat. C. 120 [affirmed 50 C.P.R. 26 , [1966] S.C.R. 189, 32 Fox Pat. C. 56], in both of which cases evidence had been given that pharamacological effects were not generally predictable and when predictable at all were not predictable to any great extent." [313]

In *Ciba-Geigy*,[314] the question was whether a patentee should be permitted to retain claims on the basis of something done after the filing of the application and not part of the original disclosure. The Chief Justice said:

> "But even assuming that the reactions or methods identified as (c) to (g) inclusive had not in fact been carried out or tested before the application was filed, the board appears to have been satisfied by the examples subsequently submitted and to have found that the amines referred to in the specification can in fact be produced by the application of the methods to materials of the kinds defined. It seems to me to follow that if indeed what is in the patent specification was mere speculation or prediction, the speculation or prediction having turned out to be true, ought to be considered to have been well founded at the time it was made. Even at the time it was made it is not improbable that it would have been considered well founded."[315] [emphasis added]

In applying *Monsanto*, the Court held that sound prediction having been satisfied, the second question was answered by there being "… nothing in the record which shows or tends to show that the processes will not work to produce the amines which are said to have the novel pharmacological usefulness … "[316]

> "In an invention of this kind the utility of the processes depends on the utility of the new substances produced by them and, on the basis that the novel application of the known methods to the defined materials will produce the new and useful products, the process itself has the required utility to warrant its being the subject of a patent claim: see *Com'r of Patents v. Ciba Ltd*. (1959), 30 C.P.R. 135 , 19 Fox Pat. C. 18, [1959] S.C.R. 378."[317]

The claims were held not to be speculative.[318]

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313 *Ciba-Geigy AG v. Commissioner of Patents*, (1982) 65 C.P.R. (2d) 73 (F.C.A. per Thurlow C.J., Pratte and Heald JJ concurring) at pp. 77-78

314 *Ciba-Geigy AG v. Commissioner of Patents*, (1982) 65 C.P.R. (2d) 73 (F.C.A. per Thurlow C.J., Pratte and Heald JJ concurring) at p. 78.

315 *Ciba-Geigy AG v. Commissioner of Patents*, (1982) 65 C.P.R. (2d) 73 (F.C.A. per Thurlow C.J., Pratte and Heald JJ concurring) at pp. 76-77.

316 *Ciba-Geigy AG v. Commissioner of Patents*, (1982) 65 C.P.R. (2d) 73 (F.C.A. per Thurlow C.J., Pratte and Heald JJ concurring) at p. 79.

317 *Ciba-Geigy AG v. Commissioner of Patents*, (1982) 65 C.P.R. (2d) 73 (F.C.A. per Thurlow C.J., Pratte and Heald JJ concurring) at p. 79.

318 *Ciba-Geigy AG v. Commissioner of Patents*, (1982) 65 C.P.R. (2d) 73 (F.C.A. per Thurlow C.J., Pratte and Heald JJ concurring) at p. 80.