

Sound Prediction and Promise of the Patent



November 20, 2015



Your Panel

- Moderator: The Hon. Justice Roger T. Hughes
- Panelists:
 - Scott MacKendrick, Bereskin & Parr
 - Marguerite Ethier, Lenczner Slaght
 - Don Cameron, Bereskin & Parr

Inflection/Point of Inflection

- per Wikipedia
 - In differential calculus, an **inflection point**, **point of inflection**, **flex**, or **inflection (inflexion)** is a point on a curve at which the curve changes from being concave (concave downward) to convex (concave upward), or vice versa
- The point where things change
- Where did “things change” for sound prediction and promise of the patent?

The Inflection Points

Sound
Prediction

2 Dec, 2002

Apotex v. Wellcome
(AZT)
SCC Binnie



Promise

3 Oct, 2005

BMS v. Apo
(nefazodone)
FC Kelen:
echoes *Consolboard*

Back to the Future

- 3 Time Periods:
 - I. The Inflections: 2002-2005 – AZT, nefazodone etc.
 - II. Pre-Inflection: Back to the Past – 0-2002
 - III. Post-Inflection: 2002/2005 & Into the Future

I. The Inflection: 2002-2005 AZT, nefazodone etc.



Sound Prediction

Inflection points:

- 2002 AZT, and the 3-part test of what needs to be in patent
 1. Data
 2. Predictive theory
 3. Proper disclosure
- 2008 raloxifene

Sound Prediction: AZT (*Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 per Binnie J.)

- “Firstly, as here, there must be a factual basis for the prediction.”
- “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.”
- “Thirdly, there must be proper disclosure.”

5. The Requirements of the Doctrine of “Sound Prediction”

70

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

Sound Prediction: raloxifene (*Eli Lilly Inc. v. Apotex Inc.*, 2008 FC 142 per Hughes J.)

- “Patents are not meant to constitute a game where those with deep pockets and ingenuity can ... make predictions on a “shot-gun” basis hoping that ... those predictions might serendipitously turn out to be correct. **Sufficient work must be done such that the result claimed was actually achieved or was soundly predicted.** However, that achievement or that **basis** from which the sound prediction was made **must also be disclosed.**”

Sound Prediction: raloxifene (*Eli Lilly Inc. v. Apotex Inc.*, 2009 FCA 97 per Noël J.A.)

- “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.”

Inflection point:

- 2005 nefazodone
- BMS v. Apotex 2005 FC 1348 (per Kelen J.)

Promise: nefazodone (*Bristol-Myers Squibb Company v. Apotex Inc.*, 2005 FC 1348)

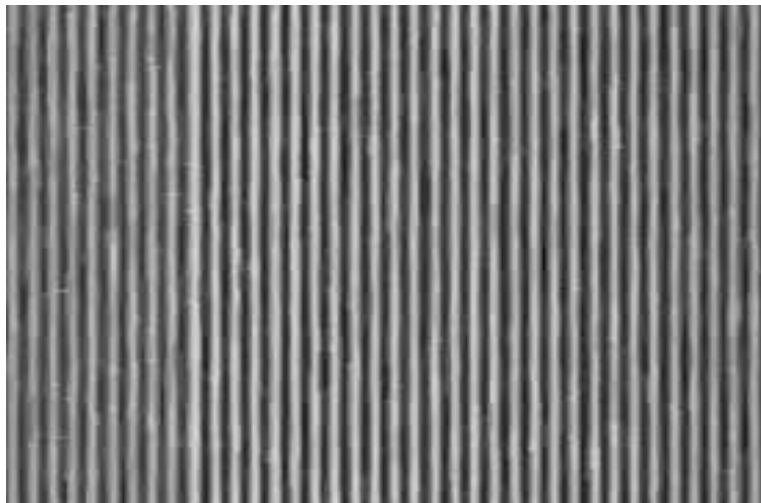
- “ As discussed above, the practical usefulness of an invention does not matter, nor does its commercial utility, unless the patent specification or disclosure promises commercial utility or in this case, minimal side effects.”

II. Pre-Inflection: 0 - 2002



Sound Prediction, or Promise

- Old school:
 - “blurred lines”



Sound Prediction

- Old school:
 - What's your invention?
 - Claims > invention made
 - Sound prediction is a claim scope doctrine

Sound Prediction

"... 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 ... an outlaw ..."

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

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.”

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

Sound Prediction

- “[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**.”

Monsanto Co. v. Canada
(Commissioner of Patents),
(1979), 42 CPR (2d) 161 (SCC
per Pigeon) at p. 179

Sound Prediction

- Old school, cont'd
 - Utility satisfied if “mere scintilla”
 - Patents rarely invalidated for lack of utility

- Old school
 - Bargain theory
 - Promise result = promise
 - Promise advantage of result $<$ promise
 - Object clauses

Promise: *Consolboard*, SCC 1979

- The FCA 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 claim the "part, improvement or combination which he claims" having "correctly and fully" described, *inter alia*, its utility.”

Promise: *Consolboard*, cont'd

- The Supreme Court of Canada disagreed:

“[The FCA] 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.

... 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.

Promise: *Consolboard*, cont'd

“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.”

Promise: *Consolboard*, cont'd

- Section 36(1) does not impose upon a patentee the obligation of establishing the utility of the invention.

“The Federal Court of Appeal has confused the requirement of Section 2 of the *Patent Act*, defining an invention as new and “useful” with the requirement of Section 36(1) of the Patent Act that the specification disclose the “use” to which the inventor conceived the invention could be put. The first is a condition precedent to an invention, and the second is a disclosure requirement, independent of the first.”

Promise: *Amfac Foods Inc v. Irving Pulp & Paper* (1986) 12 CPR 3d 193

- Per Strayer J.:
 - “...an invention whose major advantage is that it separates outside slabs of potatoes from the center portion at the point of cutting...”
- Per Urie J.A.:
 - “The device claimed ... will not produce the promised result since no reference is made to the essential outer stabbing blades and the separation of such outer slabs at the cutter.”

III. Post Inflection: 2002/2005 to now



Sound Prediction

- Some retrenchment
- 2014: *AstraZeneca* (esomeprazole)
 - Just “new use”
- Selection patent: can utility of genus be utility of species too?
 - e.g., Plavix: anti-thrombogenic

Sound Prediction

2013: *Eurocopter*

- needn't include data if common general knowledge

2015: *Lumigen*
(bimatoprost) per FCA

- self evident elements of sound prediction need not be disclosed

- Flow:
 - 2010 *Eli Lilly* (olanzapine) per FCA
 - find the promise
- Ebb:
 - 2013 Plavix 2 per FCA
 - if there's one
 - 2014 Pfizer (celecoxib) per FCA
 - Construe in favour of the patentee as excluding a promise

- Competing threads
 - Mere scintilla test not seen to be objectionable
 - Don't invalidate a meritorious invention on a technicality

Promise

- The Courts have said that they should not strive to find ways to defeat patents for good faith inventions:

“We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance ... being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and public. **There is no occasion for being too astute or technical in the matter of objections to either title or specification** for ... "where the ... specification ... 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".”

Whirlpool Corp. v. Camco Inc., 2000 SCC 67 at para. 49(g), reiterating *Consolboard*



- Competing threads, cont'd
 - Bargain theory
- What's the policy reason for potential mere puffery invalidating a patent, where there is some utility?

**PARENTAL
ADVISORY
EXPLICIT CONTENT**

- What's explicit?
 - ✓ Will/Will not
 - ? Can
 - x May, could
 - x Object = goal?
 - x advantage

- *AstraZeneca v Apotex*, 2014 FC 638 (esomeprazole) (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.”
 - 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.**”

- “May” means “may”

In *Pfizer v Mylan*, 2014 FC 38 (CELEBREX)

- 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.”

- “Advantages”, “Goals” or “An Object of the Invention” are not promises

Bayer v Cobalt Pharmaceuticals

- the patent said: “The advantages of a combination preparation for oral contraception ... can be characterized as follows” and listed advantages.
- Justice Hughes 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”.

AstraZeneca Canada Inc v Mylan Pharmaceuticals ULC

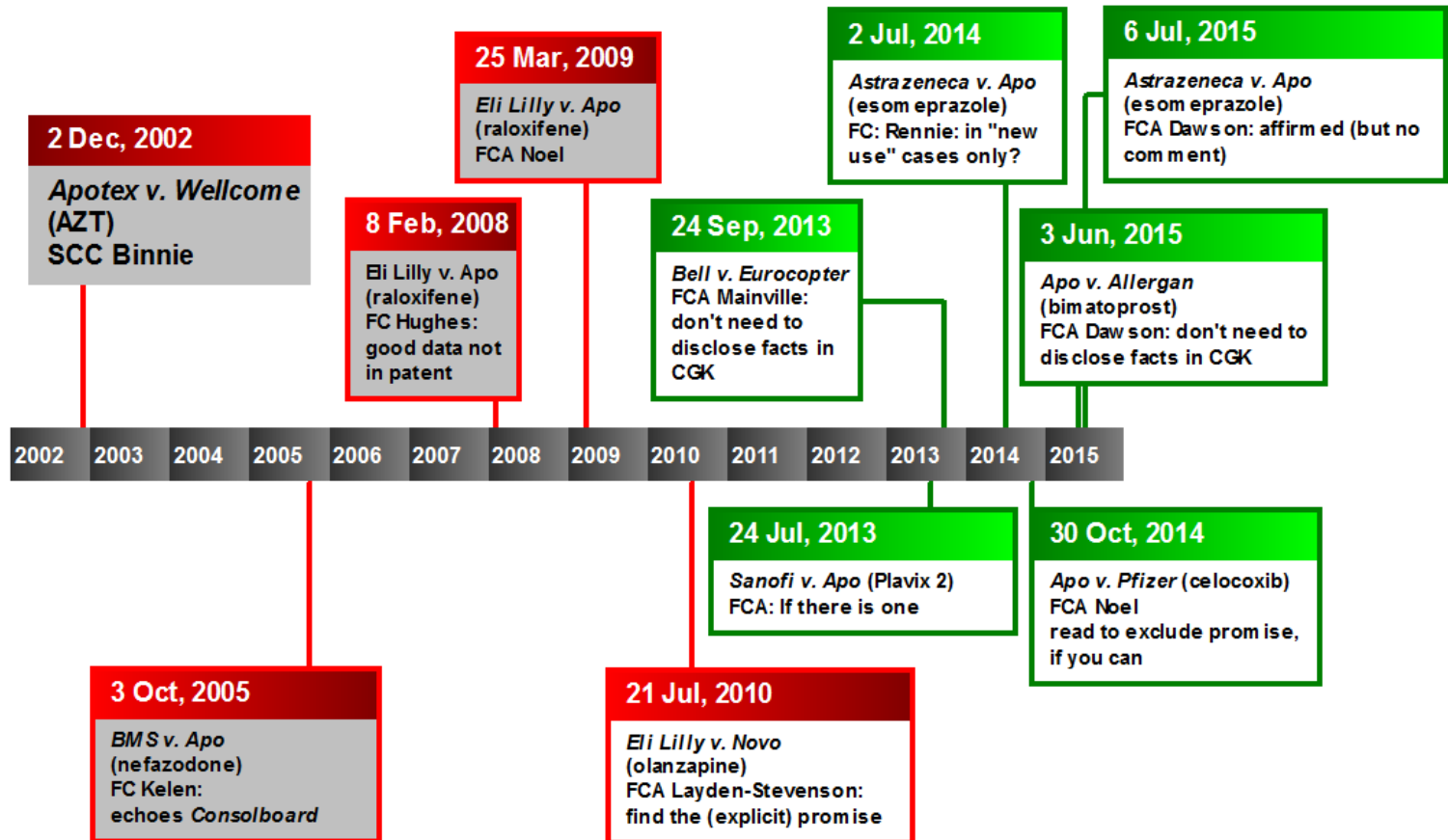
- the patent said: “It is a particular object of the present invention to provide aromatase inhibitory compounds with fewer undesirable side effects than aminoglutethimide”,
- Justice Rennie concluded that: “not all statements of advantage in a patent rise to the level of a promise. A goal is not necessarily a promise. The third paragraph of the 420 Patent refers to a forward looking goal, a hoped-for advantage of the invention.”

- Could “could” mean “can” or “will”?
 - “... this device could be used as a hammer, a paperweight or a doorstop”.
 - “... this compound could be used for the treatment of cancer, hair loss or headaches.”

Sound Prediction

Promise

Sound Prediction



Promise

IV. What's next?



IV. What's next?

- *AstraZeneca Canada Inc. v. Apotex Inc.* (esomeprazole), 2015 FCA 158 leave application
 - Might promise be the subject of Supreme Court consideration?
- Are we out of step internationally?
- Does the Lilly NAFTA arbitration cast a shadow?



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