

# The “promise” in Canadian patents, a recipe for disaster?

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# Utility: Requirements

Statute: Section 2 of the *Patent Act*

*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.*

How do you support utility of the claimed invention?

- Demonstrate directly in working examples
- Extrapolate from working examples via **sound prediction**
- As of the filing date of the application

# Doctrine of sound prediction

- Supreme Court: *Apotex Inc. v. Wellcome Foundation Ltd.*
- To extrapolate claim scope to include subject matter disclosed but not tested/exemplified in working examples of application

## Three components:

- A factual basis for the prediction;
- An articulable and sound line of reasoning, from which the desired result can be inferred from the factual basis; and
- A proper disclosure of the foregoing in the application

Assessed as of the filing date of the application

# Utility: Promise doctrine

- While not new, has been more frequently applied by the Courts since 2005
- Assessed early on in Court's analysis
- Consideration of patent description and expert testimony

*...the promise of the patent is to be ascertained **at the outset of an analysis with respect to utility**. 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.*

*Eli Lilly v. Novopharm (olanzapine; 2010 FCA 197)*

# Promise doctrine: What is required?

*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.***

*Eli Lilly v. Novopharm (olanzapine; 2010 FCA 197)*

- Depends on what is disclosed
- Many statements in description cannot be elevated to the level of a “promise”
- Can be based on a sound prediction (*Ibid.*, para 82):

*If the alleged infringer is able to establish that there was insufficient information upon which to base the promise, the patentee may nevertheless have had sufficient information upon which to make a sound prediction of the promise. ... Consequently, **the promise need not have been met at the date of filing although it must ultimately be borne out.***

# Promise doctrine: *Laboratoires Servier v. Apotex*

Perindopril; 2008 FC 825, aff'd 2009 FCA 222

- ACE inhibition vs. treating hypertension

Promise: ...*all of the compounds claimed will have some level of ACE inhibition and some of the compounds will have sufficient activity to treat hypertension and cardiac insufficiency.*

*The trial judge did not err in construing the promised utility of the invention. Her conclusion that therapeutic use was expressed to be **possible, but not guaranteed**, in the claims, was supported by the evidence. The abstract was not a factor in determining the promise of the patent.*

# Promise doctrine: *GSK v. Pharmascience*

## Rosiglitazone; 2011 FC 239 (NOC)

- Lowering glucose in mice vs. treating Type II diabetes

*Rosiglitazone had, before September 2, 1988 passed the primary screen which formed the basis upon which a skilled person could conclude that the compound could progress to further testing. One would not know for certain, at that time, that rosiglitazone would be useful for instance, in treating Type II diabetes. However at that time a "potential" had been established. That is all that the '452 Patent promises. Pharmascience has unreasonably elevated that promise to a promise that rosiglitazone will work.*

# Promise doctrine: *Astrazeneca v. Mylan*

Anastrozole; 2011 FC 1023, aff'd 2012 FCA 109 (NOC)

- Aromatase inhibitor for treatment of estrogen-dependent breast cancer
- Analysis of one sentence: *"It is a particular object of the present invention to provide aromatase inhibitory compounds with fewer undesirable side effects than [AG]."*
- Object clause is not a promise

*The fact that such an ordinary word as "provide" is used in sentences containing the claims of the patent does not mean that when used in other sentences, it should be construed as connoting a promise of the patent.*

*I agree with the Judge that an examination of the patent as a whole supports the conclusion that, unlike the express claims of the patent, the object clause contains no more than a forward-looking aim of the invention.*



# Promise doctrine: *Pfizer v. Mylan*

Donepezil; 2011 FC 547, aff'd 2012 FCA 103 (NOC)

- AChE inhibition vs. treatment of Alzheimer's with acceptable toxicity
- Potential advantages over the prior art are not a promise
- Distinguished from an earlier case (*Apotex v. Pfizer* (latanoprost) 2001 FCA 236) where reduce side effects recited in **claims**.

*Though some references are made ... to potential toxicity and efficacy benefits of donepezil, and to its potential advantages over prior art compounds, the application judge... rightly concluded that **these references are not to be construed as promises**. He noted that the use of the specification of a patent in order to construe its promise "is **not to serve as an invitation to a zealous lawyer to read a patent specification in such a way as to persuade a Court, one way or the other, as to what the promise is**" ... As recently aptly noted by Zinn J. of the Federal Court, "the jurisprudence **does not permit an unescorted and unchaperoned romp through the disclosure**"*

# Promise doctrine: *Fournier v. Sandoz*

## Fenofibrate; 2012 FC 741 (NOC)

- New composition having specific dissolution profile as defined in claim vs. new composition with improved dissolution profile and bioavailability over prior art
- References to improvements over the prior art are not a promise

*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. **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.*

# Promise doctrine: *Teva v. Novartis*

Imatinib mesylate; 2013 FC 141 (NOC+impeachment)

- Enzyme inhibition vs. therapeutic treatment (of cancer)
- “can be used” = potential, when read in context
- Assessment of promise differs depending on claim: compound vs. use vs. method claims

*1. For Claims 1 to 39, the promise or utility is that the compounds will selectively inhibit PKC, PDGF-R or ABL. That is all.*

*2. For Claims 45 to 48, the patent provides a more explicit utility: that a compound included in Claims 1 to 39 can be used to treat atherosclerosis ... and for the "chemotherapy of tumours" ... In my view and in the opinion of the experts, this would incorporate the notion of in vivo efficacy - either demonstrated or soundly predicted...*

*3. For Claim 44, the utility is to provide a process to make the claimed compounds.*

# Promise doctrine: Principles from the courts

- Not every statement in description is a promise
- Varies depending on claim
- Statements must be assessed in context, notably role of promised feature in relation to the point of invention

Thank you!

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Questions?