



Patenting Biotechnology

How early is too early?

Geoffrey D. Mowatt, Dimock Stratton LLP
BIO World Congress on Industrial Biotechnology
San Diego, CA
April 18, 2016

Balance to Strike

Innovators must strike a balance:

- Win the race to the patent office
- Sufficient testing and data to support the claimed utility (as of the Canadian filing date)



Timing and Data

Too early?

- How much testing must have been done?
- How much data should be included in the patent application?



Patentability

Section 2 of the *Patent Act*:

- To be patentable:

*“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”*

Key requirements:

- New (i.e. novelty) – if not novel, will be invalid for anticipation
- Inventive (i.e. non-obvious) – if not inventive, will be invalid for obviousness
- Useful (i.e. utility) – if no stated or implied practical use, will be invalid for lack of utility or lack of sound prediction



In reality, the “fences” often consist of complex layers of definitions of different elements (or “components” or “features” or “integers”) of differing complexity, substitutability and ingenuity. A matrix of descriptive words and phrases defines the monopoly, warns the public and ensnares the infringer.

– Supreme Court of Canada in *Free World Trust v Électro Santé Inc*, 2000 SCC 66 at para 15

Patent Utility and Promises

Patent utility in Canada

- Surge of patent validity challenges based on lack of utility – **Why?**
- How do you support utility?
 - Normally, a **scintilla of usefulness** is enough
 - Inventor not obligated to disclose utility data in a patent specification
 - Demonstrate directly in working examples
 - Extrapolate from working examples via sound prediction

BUT



Promises, Promises



Did the patentee make a promise?

- If the patentee **promises** something more in the patent specification, he or she will be held to that promise

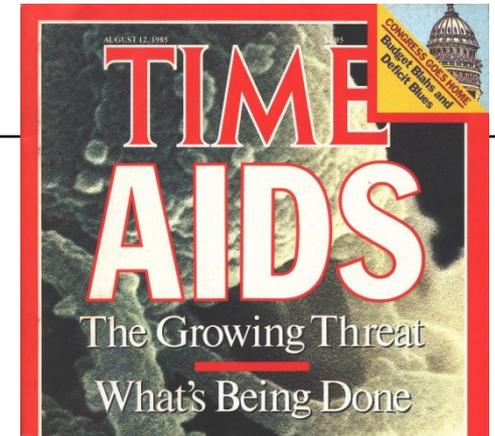
*“Where the specification does not promise a specific result, no particular level of utility is required; a ‘mere scintilla’ of utility will suffice. However, where the specification sets out an explicit ‘promise’, **utility will be measured against that promise.**”*

Eli Lilly v Novopharm, 2010 FCA 197 (olanzapine)

- Result: 23 patents deemed invalid* for innovative medicines since 2005 (despite Health Canada approval for these drugs as safe and effective)
- Previous 25 years – only two patents invalidated due to lack of utility
- The Federal Court of Appeal has provided a more **restrained approach** – still an issue for patentees

“Promise Doctrine”

- Where did the “promise doctrine” come from?
- What are its limits and scope?



Sound Prediction of Utility

- To extrapolate claim scope to include subject matter disclosed but not tested/exemplified in working examples of application
- Three prong test:
 - i. A factual basis for the prediction;
 - ii. An articulable and sound line of reasoning, from which the desired result can be inferred from the factual basis; and
 - iii. A proper disclosure of the foregoing in the application
- Assessed as of the filing date of the application in Canada



“Promise Doctrine” – What’s the big deal?

Innovators:

- Labelled as innovation killing “Promise Doctrine”
- Reason Canada has slipped in 2015 from the 12th most innovative country in the world to the 25th?
- Cloud of uncertainty
- Imposes subjective utility standard that is arbitrary and unpredictable
- Invalidating patents on the basis of lack of utility despite the fact that the inventions at issue actually had a high degree of utility

Response:

- Constraining innovators from overpromising is a reasonable approach to preserving the core policy objectives of patent law that:

“serve to create consistency and clarity in the bargain struck between innovators and the public”

Justice Rennie, *AstraZeneca v Apotex*, 2014 FC 638

Eli Lilly v Canada – NAFTA Challenge

- On June 13, 2013, Eli Lilly initiated a \$500 million CAD claim against the Government of Canada
 - Canada’s patent laws violate the intellectual property standards set out in the North America Free Trade Agreement (NAFTA)

- Heart of the claim: use of the “promise doctrine” to invalidate patents in Canadian courts for lacking the level of utility promised in the patent specification
 - Lilly’s Canadian patents directed to Zyprexa® and Strattera® were invalidated under this doctrine
 - Lilly alleges that Canada’s utility test discriminates against pharmaceuticals as a field of technology



“Promise Doctrine” – Examples

Scope of “Promise Doctrine”

- Xalatan® (latanoprost) – *Apotex v Pfizer*, 2011 FCA 236
 - A glaucoma eye drop patent was invalid because it “promised” less eye irritation and the supporting data was insufficient
 - Testing data reported in the patent were single-dose tests as opposed to long-term studies
 - Court found fault in the single-dose data because glaucoma is a chronic disease—eye irritation could have appeared upon long-term use, which remained untested



No Promises Made – Examples

Examples where the Court rejected promise arguments:

- Coversyl® (perindopril) – *Laboratoires Servier v Apotex*, 2008 FC 825, aff'd 2009 FCA 222
 - ACE inhibition versus treating hypertension
 - Only promise found to be: “... 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”
 - Therapeutic use was expressed to be **possible, but not guaranteed**, in the claims, was supported by the evidence

- Arimidex® (anastrozole) – *Astrazeneca v Mylan*, 2011 FC 1023, aff'd 2012 FCA 109
 - 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”
 - **Object clause is not a promise** – “no more than a forward-looking aim of the invention”

No Promises Made – Examples

Advantages over prior art – not necessarily promises

- Fenofibrate – *Fournier v Sandoz*, 2012 FC 741
 - “Promise of a patent” nothing more than the utility the inventor claims for his invention
 - If the 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

Promises may vary between claims

- Gleevec[®] (imatinib mesylate) – *Teva v Novartis*, 2013 FC 141
 - Promise may differ depending on claim
 - Certain claims provided more explicit utility:
“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 ...”

“Promise Doctrine” – Restrained Approach

PLAVIX® – *Sanofi-Aventis v Apotex*, 2013 FCA 186

- Federal Court of Appeal continues to distance itself from validity attacks based on alleged promises
 - Inventor is not obligated to disclose utility data in a patent specification
 - Data must be available to the patentee when filing the patent application; otherwise the utility of the invention would be speculative
 - Not all patents contain a promise and “Courts should not strive to find ways to defeat otherwise valid patents”

Promises?

- Court took issue with the trial judge’s finding that the patent “promised” utility in humans on the basis of inferences as opposed to clear language
- Statements of objectives or advantages in a patent specification will not automatically rise to the level of a “promise”
- A “promise” will only be found in cases of **clear and unambiguous statements**

“Promise Doctrine” – Post-*Plavix*

Sample of cases since *Plavix* – mixed results

- Celebrex[®] (celecoxib) – *Pfizer Canada v Apotex*, 2014 FC 38
- Yaz[®] (drospirenone) – *Bayer v Cobalt Pharmaceuticals*, 2013 FC 1061
- Alimta[®] (pemetrexed disodium) – *Eli Lilly Canada v Hospira Healthcare*, 2016 FC 47 – **Invalidity of patent found justified**



“Promise Doctrine” – Post-*Plavix*

Nexium® (esomeprazole) – *AstraZeneca Canada v Apotex*, 2014 FC 638, 2015 FCA 158

- Lower Court held that the patent “promised more than it could provide”
 - Promised utility of the claims comprised three elements, including “improved pharmacokinetic and metabolic properties which will give an improved therapeutic profile”
 - This element was **not demonstrated** by the Canadian filing date for the patent, and the Court held it was also **not soundly predictable** as of that date
 - Court ultimately held that there is **no heightened disclosure in sound prediction cases**, except in the context of “new use” patents

- Affirmed by Federal Court of Appeal
- AstraZeneca has appealed to the Supreme Court of Canada
 - Leave granted in March 2016



Lessons to be Learned

- Despite the reduced threat of patent invalidity based on “promise” attacks, patentees should remain cautious
 - 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
 - Sound prediction is not limited to drug cases – *Bell Helicopter v Eurocopter*, 2013 FCA 219 (helicopter fuselage forward attachment points)



Lessons to be Learned

Tips for patentees:

- i. **Avoid overstating advantages**
- ii. If utility is based on “sound prediction”, indirect test data or mathematical correlations **should be referred to and explained in the patent specification**
- iii. Diligently vet any **promissory language** in that patent



Thanks!



Geoffrey D. Mowatt
Partner

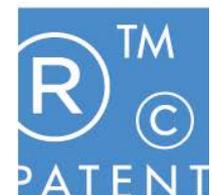
DIMOCK STRATTON LLP
t: 647.288.9539
e: gmowatt@dimock.com
w: www.dimock.com



EXPERIENCE. RESULTS.

DIMOCK STRATTON

INTELLECTUAL PROPERTY LAW



20 Queen W. 32nd fl, Toronto, Canada M5H 3R3 | 416.971.7202 | dimock.com