lavery
Lawyers

The rise and fall of the “promise” attack – A sigh of relief for the pharmaceutical industry

January 1, 2014

Canada has recently seen a surge of patent validity challenges based on lack of utility. Utility is a legal requirement for patent validity; an “invention” must have some stated or implied practical use to fulfill the requirements of the *Patent Act*. Normally, a scintilla of usefulness is enough. However, if the patentee promises something more in the patent specification, he or she will be held to that promise.

In the pharmaceutical area, the legal concept requires that at the date of the filing of the patent application, the applicant must possess utility data based on actual tests showing drug activity for the intended use or, at the very least, indirect tests showing a “sound prediction” that the claimed invention will perform the intended use. This is the so-called doctrine of “sound prediction”.

The doctrine of “sound prediction” is not limited to pharmaceutical patents. As the recent Eurocopter decision shows (2013 FCA 219), it also applies to mechanical inventions. In the Eurocopter case, an improved sleigh-type landing gear with forward-offset helicopter fuselage forward attachment points were tested and found to reduce “ground resonance” upon landing. Although claimed, the backward-offset attachment points were not similarly tested and “sound prediction” of utility was not found. Thus, many of the claims were found invalid for lack of utility.

This has fueled the trend for patent challengers to show that a patent “promises” more than it delivers. For example, the patent specification promises a given result or given use and fails to deliver on that “promise” and is therefore invalid as lacking the promised utility.

Case in point, in *Apotex v. Pfizer* (2011 FCA 236), the Federal Court of Appeal found that a glaucoma eye drop patent was invalid because it “promised” less eye irritation and the supporting data was insufficient. The testing data reported in the patent were single-dose tests as opposed to long-term studies. The Court of Appeal found fault in the single-dose data because glaucoma is a chronic disease. In other words, eye irritation could have appeared upon long-term use, which remained untested. This decision raised eyebrows (pun intended) all over the world. Canada was quickly becoming the “odd man out” with regards to imposing strict requirements for utility.

In 2012, the same Court of Appeal began to downplay the “promise” attack. In *Mylan Pharmaceuticals v. Pfizer* (2012 FCA 103), the patent on the Alzheimer disease drug ARICEPT® was found valid despite a “promise” attack. Mylan was asserting that the patent promised higher efficacy and lower toxicity than other known drugs. The Court disagreed and focused on the language of the claims, which held no such promise and concluded that other statements in the patent specification were merely “potential advantages” as opposed to promises.

This tendency has now been confirmed in 2013. The Federal Court of Appeal in *Sanofi-Aventis v.*

Copyright (c) Lavery, de Billy, S.E.N.C.R.L. - L.L.P.

Apotex (2013 FCA 186) continues to distance itself from validity attacks based on alleged promises. This decision is the latest chapter in an epic legal battle pitting generic powerhouse Apotex Inc. and Sanofi-Aventis over the successful blood thinning (anti-platelet) drug PLAVIX®.

Sanofi had initially blocked Apotex from entering the market by filing a motion in the Federal Court for an order prohibiting the Minister of Health from issuing a Notice of Compliance (NOC), because Apotex would infringe the patent if it was given marketing approval. In a NOC proceeding, the sole aim is to have a court decide if, on a balance of evidence, the arguments put forth by the generic applicant on issues of patent invalidity or non-infringement, are justified. Once an argument is presented by the generic applicant the patent holder or licensee must show that the argument is not justified. If this is shown, the Minister of Health will be prohibited from allowing marketing approval. Apotex did not prevail on the NOC proceeding but did appeal the case all the way to the Supreme Court of Canada, which ultimately sided with Sanofi in a landmark decision that found the claimed invention to possess the required utility and to be non-obvious.

Undeterred, Apotex launched a formal invalidity action (as opposed to a NOC proceeding) in the very same Federal Court, based on lack of utility and obviousness. Stunningly, Apotex won and the patent was found invalid for lack of utility and obviousness (2012 FC 1486). The judge reasoned that the evidence before him was different than the evidence presented in the NOC proceedings and that he was not bound by earlier decisions, including the Supreme Court decision.

With the patent out of the way, Apotex was quickly granted marketing approval for its generic version of PLAVIX®. Sanofi appealed and sued for patent infringement.

The Federal Court of Appeal, in a unanimous decision (2013 FCA 186), overturned the trial decision and took time to clarify the concept of “promise of the patent”.

The court began by noting that an inventor is not obligated to disclose utility data in a patent specification. The data must however have been available to the patentee when filing the patent application; otherwise the utility of the invention would be speculative.

The court then cautioned that if a patentee chooses to promise a particular result in a patent specification, the patentee will be held to that promise (*Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, 1981, 1 S.C.R. 504 (SCC)). But then again not all patents contain a promise and “Courts should not strive to find ways to defeat otherwise valid patents.”

The patent in question contained animal model data as opposed to data from studies on human subjects. The trial judge had found that the patent contained an implied promise of utility in humans and failed to deliver on that promise. The Court of Appeal disagreed. It 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. The decision reminds us that the commonly found 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.

Finally, the Court of Appeal was of the view that evidence on the issue of obviousness had already been considered by the Supreme Court and that the trial judge was wrong to depart from the earlier finding of the Supreme Court.

Despite the receding threat of patent invalidity based on “promise” attacks, patentees should remain cautious. It is important to avoid overstating advantages of the invention for fear of not having enough data to support such statements. Also, if any utility is based on “sound prediction”, indirect test data or mathematical correlations should be referred to and explained in the patent specification. After filing, it will be too late to generate further evidence of utility.

At the time of publishing this article, Apotex is seeking leave to appeal the case in the Supreme

Copyright (c) Lavery, de Billy, S.E.N.C.R.L. - L.L.P.

Court of Canada. It is hoped that the Supreme Court of Canada, should it hear the case, will shed better light on the utility requirements, the notion of “promise” and the doctrine of “sound prediction”.

Author’s Note: This review article does not constitute legal advice and should not be substituted for legal advice. The views expressed are those of the author alone.

Copyright (c) Lavery, de Billy, S.E.N.C.R.L. - L.L.P.