

NO MORE PROMISES: SUPREME COURT OF CANADA FINDS THAT THE “PROMISE DOCTRINE” IS NOT A CORRECT METHOD FOR DETERMINING THE UTILITY OF A PATENT

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On June 30, 2017, the Supreme Court of Canada allowed an appeal by Astra Zeneca of a decision that found that its Canadian patent (the 653 patent) was invalid for lack of utility under an application of Canada’s “Promise Doctrine”, as Patent 653 promised more than what the patent could provide. This is a landmark decision in Canada, as the Supreme Court of Canada has essentially done away with a controversial and often contested doctrine that was previously applied to the analysis of the disclosure of a patent and the utility of the invention described therein. [*AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36]

The 653 Patent

Astra Zeneca’s 653 patent claimed optically pure salts of the (-) enantiomer of omeprazole, known as “esomeprazole”. Esomeprazole is used in the mitigation of gastric acid and acid reflux related ailments (a “PPI”).

The Conflict

Apotex sought to sell a generic version of esomeprazole and, after seeking market approval from Health Canada (by way of an “Notice of Compliance” or “NOC”) and after battling with Astra Zeneca under Canada’s Patented Medicines Notice of Compliance¹ administrative process (“PMNOC”); which, briefly, allows for a Patent holder to block the issuance of an NOC to a generic manufacturer if they can show that the generic drug would infringe on a patent that is listed on a register managed by Health Canada. Astra Zeneca challenged Apotex via this PMNOC process but the Court sided with Apotex.

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¹ Patented Medicines (Notice of Compliance) Regulations, SOR/93-133.

An NOC was therefore granted to Apotex and once Apotex began to sell its generic version of esomeprazole, Astra Zeneca sued directly for patent infringement. Apotex counterclaimed alleging the 653 patent was invalid.

At trial, the Court found that while the 653 patent met the criteria for novelty and non-obviousness, the patent lacked utility under an application of the “Promise Doctrine”, because it “promised more that it could provide”, and it was therefore declared invalid.

Astra Zeneca appealed arguing that the Court erred in its application of the Promise Doctrine. The appeal was dismissed.

Promise Doctrine

At trial, the Courts analysis of utility was based on two propositions: 1) that “an alleged patent satisfies the requirement of utility if, from the perspective of the skilled person as of the filing date, its utility is demonstrated, or [...] is soundly predicted”; 2) that the “promise of the patent” was central to this utility analysis.

The Court found that the 653 patent contained at least two promises of utility: i) useful as a PPI (reduce the amount of acid in the stomach) and ii) improved properties giving an overall improved therapeutic profile (work for a wider range of patients). It was this second promise that was found to be neither demonstrated nor soundly predicted at the filing date of the patent. As such, as per the application of the Promise Doctrine, the Court declared the entire patent invalid, even though the first promise was met. This analysis was held by the Federal Court of appeal, who confirmed that the Promise Doctrine was applied correctly, and that this doctrine’s application for determining utility was “settled law”.

Position of the Parties

Before the Supreme Court of Canada, Astra Zeneca argued that the patent should not have been invalidated by a *doctrine requirement* for utility, which is “extra-statutory”. In other words, Astra Zeneca’s position is that the Promise Doctrine has no foundation in the *Patent Act*² (“Act”) and that the law of patents is “wholly statutory”.

Apotex argued that the use of the Promise Doctrine is settled law and that the Court’s application of this doctrine was correctly applied: “The Promise Doctrine merely requires a patentee to be held to what is disclosed in the patent [...] Astra

² Patent Act, RCS 1985, c P-4.

Zeneca's patent specification contained one promise that was neither demonstrated nor soundly predicted at the time it was filed".

Supreme Court Finding

The Supreme Court had to decide on two issues: i) is the Promise Doctrine a correct approach in determining if an invention is "useful" as per the Act? And ii) was the subject matter that was the subject of the 653 patent "useful" at the filing date of the patent?

The Supreme Court of Canada found that the Promise Doctrine is incorrect and should not be used in the determination of utility under the Act.

The Supreme Court of Canada based its decision on its reading of section 2 of the Act, which is the source of the utility requirement for an invention. An invention is a "new and useful art, process, machine, manufacture or composition of matter". Usefulness is therefore a pre-condition to patentability.

The Courts have previously answered the question "useful for what" with the promise that the patent makes. Therefore, previous caselaw was to the effect that "if a patentee's patent application promises a specific utility, *only if* that promise is fulfilled, can the invention have the requisite utility". Further to this, the Federal Court of Appeal had also previously held that "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"

Therefore, the promise doctrine involves identifying any promises in the entire specification of the patent (claims + disclosure) and the Supreme Court of Canada found that this process is unsound and is "incongruent with both the words and the scheme of the *Patent Act*". The Supreme Court of Canada found that the Act establishes the system in which an inventor is granted rights to an invention and the Act also defines what kind of invention benefits from this system. The Supreme Court of Canada's reading of the Act is such that once an invention has been identified and can qualify for patent protection, it needs to be properly disclosed: "a patentee must describe the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention [...]". The Supreme Court found that one needs to differentiate the requirement that an invention be "useful", as per the definition of invention in the Act, and the requirement to disclose this invention (enablement). One is a condition to the existence of an invention, the other is a condition to protecting this invention via a patent.

The Supreme Court found that the Promise doctrine takes this second criteria, that of enablement, and improperly imported it into the analysis of utility such that "any disclosed use [had to] be demonstrated or soundly predicted at the time of filing" and

that “if that is not done successfully, the entire patent is invalid, as the pre-condition of patentability -an invention under [...] the Act- has not been fulfilled”.

The Supreme Court of Canada also found that the definition of invention speaks to “useful” subject matter. Therefore, a *single use* should make an invention useful and not meeting the “promises” of multiple uses, when one use has been established, was punitive and was baseless under the Act:

“To invalidate a patent solely on the basis of an unintentional overstatement of even a single use will discourage a patentee from disclosing fully, whereas such disclosure is to the advantage of the public. The Promise Doctrine in its operation is inconsistent with the purpose of s. 27(3) of the Act which calls on an inventor to “fully describe the invention and its operation or use”. Thus, the Promise Doctrine undermines a key part of the scheme of the Act; it is not good law.”

The Correct Approach to Utility

As per its analysis, the Supreme Court found that the type of utility that is a precursor to an invention is one that applies to the “subject matter” of the invention and the invention itself needs to be capable of being used as an inventive solution to a practical problem. As such, the Supreme Court set out the following test, or analysis: “First, courts must identify the subject-matter of the invention as claimed in the patent. Second, courts must ask whether that subject-matter is useful — is it capable of a practical purpose (i.e. an actual result)?” The application of the utility requirement avoids inventions that are speculative and prevents patenting of “fanciful, speculative or inoperable inventions”.

Utility of the 653 Patent

Regarding the second issue, that is, was the invention of the 653 Patent useful, the Court found that the subject matter was soundly predicted to be useful as a PPI, and under the Supreme Court’s analysis of utility above, this was sufficient to be useful under the Act.

Conclusion

This decision closes a controversial bridge the Courts have used in the past that linked “usefulness” of an invention to proper disclosure or enablement of a patent. In declaring the promise doctrine “incorrect in law”, the Supreme Court of Canada has effectively clarified the path to a proper approach to determining utility. It of course remains to be seen how the Courts will now use this guidance in future patent impeachment cases.

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