
# The Supreme Court of Canada rejects the promise doctrine and confirms the correct approach for utility determination

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In a unanimous decision published on June 30th 2017 (AstraZeneca Canada v. Apotex Inc.[i]), the Supreme Court of Canada (SCC) decided that the promise doctrine was not the correct method of determining whether the utility requirement under section 2 of the *Patent Act* was met.

*The facts*

AstraZeneca appealed to the SCC, arguing that its patent No. 2,139,653 ("the 653 patent") claiming optically pure salts of omeprazole, including esomeprazole a proton pump inhibitor (PPI), was improperly invalidated for lack of utility on the basis of the promise doctrine. AstraZeneca argued that the promise doctrine was an extra-statutory requirement of utility with no foundation in the *Patent Act* or the Patent jurisprudence of the SCC.

*The Patent Act and the promise doctrine*

Section 2 of the *Patent Act* states that "an invention means any new and useful art, process, machine, manufacture, composition of matter or any new and useful improvement and in the art process machine, manufacture or composition of matter".

The promise doctrine was developed and applied by Federal courts over the years in several cases to determine whether the utility requirement under section 2 of the *Patent Act* was met.



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In the decision, the SCC has summarized the promise doctrine as follows:

> [29] 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: *Consolboard*; *Pfizer Canada Inc. v. Canada (Minister of Health*[ii]*)*.
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> [31] The Promise Doctrine (…) directs courts to read both the claims and the disclosure to identify potential promises, rather than the claims alone, even in an absence of ambiguity in the claims. After a process of identifying promises, the doctrine equates the fulfillment of these promises (by demonstration or sound prediction) with the requirement in s. 2 that an invention be useful. The doctrine then goes on to provide that if any one of the promises is not fulfilled, then the utility requirement in s. 2 is not met and the patent, in its entirety, is invalid.

*The Federal Court decisions*

Applying the promise doctrine, the Federal Court found that the '653 patent contained an explicit promise of improved pharmacokinetic and metabolic properties which was not demonstrated nor soundly predicted as of the filing date. The Federal Court also found that the '653 patent contained a promise of utility for use as PPI which was soundly predicted as of the filing date. Nonetheless, the Federal Court invalidated the entire patent for lack of utility under section 2 of the *Patent Act* on the basis that the '653 patent *"promised more than it could provide".*This decision was upheld by the Federal Court of Appeal, which affirmed that the promise doctrine was the correct method to determine whether the utility requirement of section 2 of the *Patent Ac*t has been met.

*The Supreme Court decision*

In its judgement, the SCC addressed the following two issues: 1) What is the correct approach for determining whether the utility requirement of section 2 of the *Patent Act* is met and 2) Was the '653 patent claiming optically pure salts of omeprazole useful within the meaning of section 2 of the *Patent Act* at the filing date.

1) Approach for determining whether the utility requirement of section 2 of the *Patent Act* is met

The SCC concluded that the promise doctrine was not the correct method of determining whether the utility requirement under section 2 of the *Patent Act* was met. Justice Rowe, writing for the majority found that the promise doctrine was

unsound and incongruent with both the words and scheme of the *Patent Act* and was too onerous for requiring that any promised utility disclosed in a patent be demonstrated or soundly predicted at the time of filing in order for a patent to be valid.

In the decision, the SCC provides guidance on the correct method for determining whether the subject matter of a patent is useful in a sense of section 2 of the *Patent Act*. This correct approach is articulated in paragraphs 55 and 56 of the decision (emphasis added):

> [55] The Act does not prescribe the degree or quantum of usefulness required, or that every potential use be realized – a scintilla of utility will do. A single use related to the nature of the subject-matter is sufficient, and the utility must be established by either demonstration or sound prediction as of the filing date (*AZT*[iii], at para. 56).
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> [56] The utility requirement serves a clear purpose. To avoid granting patents prematurely, and thereby limiting potentially useful research and development by others, the case law has imposed a requirement that an invention's usefulness be demonstrated or soundly predicted at the time of application, rather than at some later point. This ensures patents are not granted where the use of the invention is speculative. What matters is that an invention "be useful, in the sense that it carries out some useful known objective" and is not merely a "laboratory curiosity whose only possible claim to utility is as a starting material for further research" (*Re Application of Abitibi Co*. (1982)[iv], at para. 91).

According to the SCC, there is no requirement to fulfill every potential use recited in a patent for the patent to be valid. A single use - a scintilla of utility related to the subject-matter of the patent is sufficient. While a scintilla of utility will do, the SCC also clearly stated this utility must be established by demonstration or sound prediction at the time of the application.

1) Was the '653 patent claiming optically pure salts of omeprazole useful within the meaning of section 2 of the *Patent Act* at the filing date

Applying the correct method for determining whether the subject matter of a patent is useful in a sense of section 2 of the *Patent Act*, the SCC found that the use of optically pure salts of omeprazole as PPI was appropriately related to the subject-matter of the patent and that this use was soundly predicted at the filing date. The SCC found that this single soundly predicted use was sufficient to meet the utility requirement under section 2 of the *Patent Act* and declared the '653 patent to be valid.

*Conclusion*

The SCC decision has effectively put Canada's Patent Law in step with international standards. It will be interesting to see how this decision will impact ongoing and future litigation, especially in the pharmaceutical field. While the SCC rejected the promise doctrine for good, it is important to note that the SCC has re-affirmed that the utility of a claimed invention must be demonstrated or soundly predicted at the time of application rather than at some time later in the future. Patentees can't therefore rely on data obtained after the filing date to meet the utility requirement of Section 2 of the *Patent Act.* In this regard, including data showing that analogues and/or variants possess utility in the application at the time of filing will help establishing that utility was demonstrated or soundly predicted at the time of the filing and will increase the likelihood of securing broader claims in Canada.



[i] *AstraZeneca Canada v. Apotex* Inc. 2017 SCC 31

[ii] *Consolboard*; *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FCA 108, [2009] 1 F.C.R. 253 (*Ranbaxy*)

[iii] *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153

[iv] *Re Application of Abitibi Co*. (1982), 62 C.P.R. (2d) 81, (Patent Appeal Board and Commissioner of Patents)