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Canada's Supreme Court Rules on the Promise of the Patent Doctrine

The Supreme Court of Canada has released its long-awaited decision in what has become perhaps one of the most hotly debated topics in Canadian patent law: Whether or not the judicially created “Promise of the Patent” utility doctrine has a proper place in the analysis of the validity of Canadian patents.

The decision starts with the Supreme Court's observation that “[t]he Promise Doctrine is not the correct method of determining whether the utility requirement under s. 2 of the Patent Act is met,” and later concludes that “it is not good law.” The judgment is very good news for patentees in Canada, in particular in the pharmaceutical field, where numerous Applicants have had their patents held invalid for lacking utility because they failed to demonstrate or soundly predict all uses that were “promised” in the description of their application.

This specific case centres on an appeal of the Federal Court of Appeal (FCA) 2015 FCA 158, which upheld the Federal Court (FC) decision in *Astrazeneca Canada Inc. v. Apotex, Inc.* [2014 FC 638].

The subject of this series of cases is an infringement/impeachment motion that involved the assertion of claims 8, 26, and 27 in AstraZeneca's Canadian patent no. 2,139,653 ('653) against Apotex. These claims cover the optically pure (-)-enantiomer of omeprazole (esomeprazole, brand name Nexium™) having an

optical purity of 99 percent or greater (claim 8), as well as the use of this compound for preparing a pharmaceutical formulation for inhibiting gastric acid secretion (claim 26) and for the treatment of gastrointestinal inflammatory diseases (claim 27). While the trial judge found that omeprazole was soundly predicted to be useful as a proton pump inhibitor (PPI), the patent was invalidated on the “promise” that the compounds of the invention “will give an improved therapeutic profile such as a lower degree of interindividual variation.”

The Supreme Court saw the Promise Doctrine as “excessively onerous,” and regarded it as running “counter to the words of the Act by requiring that where multiple promised uses are expressed, they all must be satisfied for the patent to meet the utility requirement.” After completing its review of the evolution of the Promise Doctrine, the Supreme Court found that the Doctrine undermines a key part of the Patent Act by discouraging patentees from disclosing their inventions fully, which disclosure is to the advantage to the public. The Court has cautioned, however, that the Patent Act can still treat the “mischief” of overpromising in several ways. For example, overpromising may run afoul of the disclosure requirements of Subsection 27(3), or could render the patent void according to Section 53 if the overpromising was willfully made for the purposes of misleading.

The Supreme Court then set out how one is to properly determine if the utility requirements that are set out in the Act are satisfied. The Court stated that Section 2 of the Patent Act requires only that an invention be

useful; however a single use will suffice. Practically speaking, on utility, a court must:

1. Identify the subject-matter of the invention as claimed in the patent; and
2. Ask whether that subject-matter is useful—is it capable of a practical purpose (*i.e.*, an actual result)?

The Court further held that “[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.”

As the trial judge found that omeprazole was soundly predicted to be useful as a PPI, the appeal was allowed and AstraZeneca's Canadian patent no. 2,139,653 was held not to be invalid for lacking utility.

With the Supreme Court's ruling, the “Promise of the Patent” doctrine, applied so often to invalidate patents by the Federal Court and the Federal Court of Appeal, is history. As stated by the Supreme Court, “[t]his doctrine [...] is unsound. It is an interpretation of the utility requirement that is incongruent with both the words and the scheme of the Patent Act.” Ring the bell, the promise doctrine is dead.

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