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Supreme Court holds that promises are not the yardstick to measure patent utility in Canada

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In this Update

- The Supreme Court of Canada issued its highly anticipated reasons in *AstraZeneca v Apotex* 2017 SCC 36. In its decision, the Supreme Court rejected the "promise doctrine" as a method to determine whether the utility requirement in the *Patent Act* has been met.
- The correct method to evaluate the utility requirement is to first identify the subject-matter of the invention as claimed in the patent, and then ask whether that subject-matter is useful.
- The subject-matter must be "capable of a practical purpose."
- Only one potential use of an invention needs to be realized even if additional uses are disclosed in the patent specification.

The Supreme Court of Canada has issued its highly anticipated reasons in *AstraZeneca v Apotex*, 2017 SCC 36 (June 30, 2017) (*AstraZeneca*), in which it considered the so-called "promise doctrine" that has been the subject of many Canadian patent decisions and of much debate, as it is unique to Canada. Given the potential implications, this case has been watched internationally by patentees who were of the view that the incorporation of this doctrine into Canadian law was "out of step" with other major jurisdictions. The Supreme Court held that the "promise doctrine" is not good law and is not the correct method to determine whether the utility requirement in the *Patent Act* (*Act*) has been met. Rather, the correct approach is to first identify the subject-matter of the invention as claimed in the patent, and then ask whether that subject-matter is useful.

Background

Esomeprazole, sold under the name Nexium® by AstraZeneca, is a proton pump inhibitor (PPI) used to treat gastric diseases. AstraZeneca owns Canadian Patent No. 2,139,653 (CA 653), which claims optically pure salts of esomeprazole.

Shortly after Apotex received a notice of compliance from the Minister of Health to permit it to sell its generic version of esomeprazole, AstraZeneca brought an action for patent infringement of CA 653 against Apotex, which in turn counterclaimed, seeking a declaration that CA 653 was invalid. The Federal Court found the subject-matter of CA 653 to be novel and inventive, but held that the patent was invalid for lack of utility. In reaching its decision, the Federal Court relied upon the "promise of the patent" doctrine, according to which federal courts have held that if the specification of a Canadian patent sets out an explicit

promise of utility, then utility will be measured against that promise. In this case, the Federal Court had construed CA 653 as containing two promises but found only one of the promises to have been met and, as a result, CA 653 was invalid for lack of utility.

The Federal Court of Appeal upheld the lower court's decision, concluding that AstraZeneca had not demonstrated any legal error in the Federal Court's construction of the promise of the relevant claims or in its appreciation of the evidence.

AstraZeneca appealed to the Supreme Court on the issue of the promise doctrine, arguing that it was an extra-statutory requirement of utility without any basis in law. Half a dozen organizations intervened, arguing *inter alia* that the promise doctrine had put Canada's patent law out of step with international standards; changes to patent law to harmonize Canadian law with that of other major jurisdictions should be left to Parliament; or that the promise doctrine was rooted in well-established jurisprudence.

The Supreme Court's reasons

In its brief reasons, the Supreme Court declared that the promise doctrine is an interpretation of the utility requirement that is incongruent with both the words and the scheme of the *Act*. It concluded that the promise doctrine runs counter to the scheme of the *Act* by conflating the requirement that an invention be "useful" (under section 2) and the requirement to disclose an invention's "operation or use" (under section 27(3)). The Supreme Court also stated that, where multiple promised uses are expressed, to require that all multiple uses be met for the patent's validity to be upheld is punitive and has no basis in the *Act*.

The Supreme Court held that the correct approach to determining whether a patent discloses an invention with sufficient utility is to (i) identify the subject-matter of the invention as identified by claims construction and (ii) ask whether that subject-matter is capable of a practical purpose. The Supreme Court noted that this usefulness must be related to the nature of the subject-matter as claimed, rather than an entirely unrelated usefulness. Consistent with established law, the Supreme Court noted that the *Act* does not prescribe the degree or quantum of usefulness required: a scintilla of utility will do. Courts must ask whether that subject-matter is "capable of a practical purpose." Thus, not every potential use of an invention needs to be realized, even if it is disclosed in the patent specification; only one will suffice.

Based on this approach, the Supreme Court found the use of optically pure salts of esomeprazole as a PPI to be appropriately related to the subject-matter of CA 653, and allowed the appeal declaring that CA 653 is not invalid for want of utility.

Implications of *AstraZeneca*

AstraZeneca lowers the threshold for establishing the utility of a Canadian patent because it holds that statements relating to the utility of an invention in a patent disclosure need not be correct or substantiated for utility purposes. Rather, the Supreme Court held that only the utility of the invention claimed needs to be established, and that any utility related to the claimed subject-matter will do.

However, the Supreme Court also confirms that overpromising in a Canadian patent is a mischief that may invalidate a patent because "[a] disclosure which is not correct and full, or states an unsubstantiated use or operation of the invention, may be found to fail to fulfill the requirements of s. 27(3)." Moreover, overpromising may result in a patent being void where

such statements amount to an omission or addition that is "willfully made for the purpose of misleading," under section 53 of the *Act*.

Overall, the Supreme Court reaffirmed the primacy of claims in a Canadian patent. Following construction of the claims, it is against the subject-matter of claims that an allegation of lack of utility must be assessed. The reasons in *AstraZeneca* also suggest that Canadian patent claims may still be subject to attacks based on lack of utility if the applicant had not demonstrated or soundly predicted some practical usefulness of the claimed subject-matter, related to the patent, by the Canadian filing date of the patent application.