Cassels

SCC Rejects Promise Doctrine in Seminal Pharmaceutical Patent Case

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The Supreme Court of Canada's (the "Court" or the "SCC") recent judgment in AstraZeneca Canada Inc. v Apotex Inc., (2017 SCC 36, "*AstraZeneca v Apotex*") released on June 30, 2017, constitutes an important paradigm shift in Canadian patent law. As described in greater detail below, the SCC has rejected the "promise of the patent" doctrine (the "Promise Doctrine"), a doctrine which has been a unique and fundamental principle in Canadian patent law, used to determine if the subject matter claimed in a patent is useful, as required by section 2 of the *Patent Act*.

This decision appears to be a victory for those seeking patent protection in Canada, arguably lowering the standard to be met for utility and providing some guidance to patentees and their agents with respect to information that should and should not be included in the specification. However, it should be noted that disclosure requirements in Canada remain unchanged with respect to soundly predicting utility of claimed subject matter and clients and foreign counsel should continue to be made aware of these requirements.

The Background Facts

The patent at issue, applied for by AstraZeneca in 1994 (the "Patent"), claimed the optically pure salts of the (-) enantiomer of omeprazole, esomeprazole (the "drug"). Following their success in gaining market access for the drug through Canada's patented medicines regulatory process, Apotex began selling the generic version of the drug, leading AstraZeneca to bring an action against Apotex for patent infringement, and Apotex to bring a counter-claim against AstraZeneca to have the Patent declared invalid.

Judicial History

The key issue in question in *AstraZeneca v Apotex* was whether the Patent was invalid for lack of utility. Both the Federal Court and the Federal Court of Appeal relied on the Promise Doctrine in their analyses to

find that the Patent held by AstraZeneca was invalid.

What is the Promise Doctrine?

Under section 2 of the *Patent Act* (the "Act"), an invention is defined as a "new and useful art, process, machine, manufacture or composition of matter or any new and useful improvement in any art, process, machine, manufacture or composition of matter", with usefulness being a condition precedent to patentability. The Promise Doctrine is a principle that has been developed and relied on in Canadian Federal courts over the past decade or so to determine whether an invention is "useful", and holds that "if a patentee's patent application promises a specific utility, only if that promise is fulfilled, can the invention have the requisite utility" (*AstraZeneca v Apotex*, para 28). A question of law, the Promise Doctrine required the courts to review a patent's claims and disclosure, identify the promises made, and assess whether the promises were fulfilled, with failure to fulfill any one of the promises grounds to invalidate the patent as a whole.

It is this Promise Doctrine that the SCC considered, and ultimately rejected in *AstraZeneca v Apotex*.

The SCC's Judgment and Reasoning

At issue in AstraZeneca's appeal to the SCC were two questions: (1) Is the Promise Doctrine the correct standard of utility under the *Patent Act* and (2) Was the drug for which AstraZeneca's Patent was granted "useful" within the meaning of the Patent Act.

With respect to the first issue, the SCC ultimately held that the Promise Doctrine was not the correct standard of utility of under the *Patent Act*, and rejected the principle altogether, stating that the doctrine was "an interpretation of the utility requirement that is incongruent with both the words and the scheme of the *Patent Act*" (*AstraZeneca v Apotex*, para 36). Specifically, the Court identified the Promise Doctrine as onerous in that it (a) determined the standard of utility of a patent by reference to the promises expressed (the "**Expressed Promises Objection**") and (b) where multiple promises were expressed, required that all promises be fulfilled in order for the patent to be valid (the "**Multiple Uses Objection**") (*AstraZeneca v Apotex*, para 37).

The Expressed Promises Objection

With respect to the Expressed Promises Objection, the SCC held that the Promise Doctrine was incorrect because it conflated sections 2 and 27(3) of the Act. Section 2 of the Act requires that an invention have utility in order to be patentable. Section 27(3) of the Act requires patentees to sufficiently describe their invention in the specification, such that the invention can be 'used' by a person skilled in the art or science to which the invention pertains. The SCC held that the Promise Doctrine conflated the 'use' requirements in section 2 and section 27(3), with the former being a "condition precedent to an invention" and the latter being a "disclosure requirement independent of the first" (*AstraZeneca v Apotex*, para 43 citing the SCC decision in *Consolboard* [1981] 1 SCR 504). While the SCC acknowledged that the Promise Doctrine might play a role in ensuring that patentees do not "overpromise", they cited a number of other fail-safes and consequences in the Act to deter such mischief.

The Multiple Uses Objection

With respect to the Multiple Uses Objection, the SCC took issue with the far-reaching consequences that result from application of the Promise Doctrine when multiple promised uses are expressed. They reasoned that while "section 2 of the Act requires a 'useful' subject matter; a single use makes a subject matter useful" (*AstraZeneca v Apotex*, para 48). They further reasoned that "the effect of the Promise Doctrine to deprive such an invention of patent protection if even one 'promised' use is not soundly predicted or demonstrated is punitive and has no basis in the Act…such a consequence is antagonistic to the bargain on which patent law is based wherein we ask inventors to give fulsome disclosure in exchange for a limited monopoly" (*AstraZeneca v Apotex*, para 51).

The Correct Approach to Utility

Ultimately, the Court held that the correct approach to determining utility under section 2 of the Act was to consider whether the subject-matter of an invention (or improvement) is useful. While they noted that "utility will differ based on the subject-matter of the invention as identified by claims construction" (*AstraZeneca v Apotex*, para 53) they also acknowledged that an invention cannot be devoid of utility, and cannot also have a use entirely unrelated to the subject matter.

The Court proposed a two step process in order to determine whether a patent discloses an invention with sufficient utility under section 2 of the Act (*AstraZeneca v Apotex*, paras 54-55):

(1) Courts must identify the subject-matter of the invention as claimed in the patent.

(2) Courts must ask whether that subject-matter is useful – that is, is it capable of a practical purpose or an actual result – with even a scintilla of use related to the subject-matter sufficient, as established by either demonstration or sound prediction, as of the filing date.

Using this framework, the SCC held that AstraZeneca's Patent was in fact valid, as utility of the drug as a proton pump inhibitor used to reduce production of gastric acid was soundly predicted. In rejecting use of any other potential promises set out in the patent, the court stated – "promises are not the yardstick against which utility is to be measured" (*AstraZeneca v Apotex*, para 63).

Implications

The implications of this case are far-reaching, not just because it marks a paradigm shift in Canadian patent law, but also because of the implications in international trade.

As discussed in our previous article, in March 2017 a Chapter 11 NAFTA tribunal deferred to the Canadian courts in their application of utility in the context of patent law, in particular the Canadian courts' application of the Promise Doctrine. The Promise Doctrine was challenged at the tribunal in part because this doctrine has contributed to a dramatic increase in the number of successful challenges to pharmaceutical patents in the past decade. While *AstraZeneca v Apotex* has arguably made Canada's analysis of patent utility more in line with other jurisdictions, some commentators have suggested that strengthening the hand of patent holders has deprived Canada of some bargaining power in prospective NAFTA re-negotiations.

Further, one of the early complaints from patentees with respect to the law in Canada regarding utility related to the so called "enhanced or heightened disclosure" requirement as it related to establishing utility through a sound prediction. In *Apotex v. Wellcome Foundation* (often referred to as "*AZT*"), the SCC established the test for soundly predicting utility of subject matter claimed in a patent, namely providing a factual basis and sound line of reasoning that the invention has utility. The court further required that this factual basis and sound line of reasoning be disclosed in the patent (with subsequent cases finding that common general knowledge need not be disclosed – see for example *Bell Helicopter Textron Canada Limitée v Eurocopter*, 2013 FCA 219 at paras 151 to 155 and *Allergan Inc. v. Apotex Inc*., 2016 FC 344 at para 57). Arguments in the past have asserted that such disclosure requirements were incorrect and outside Canada's treaty obligations (see for example *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142) but

these arguments have been routinely rejected and this disclosure requirement remains good law in Canada. The SCC in *AstraZeneca v Apotex* cites *AZT* with approval and makes no ruling or finding that would overturn the sound prediction disclosure requirement. Therefore, while *AstraZeneca v Apotex* appears to be a victory for patentees, clients and foreign counsel should be made aware that if you are soundly predicting utility, especially in the pharmaceutical industry, disclosure is still a live issue.

We will continue to keep you posted on updates in patent law and topics in international trade relevant to intellectual property as they arise.

This publication is a general summary of the law. It does not replace legal advice tailored to your specific circumstances.