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Canadian Patentees Finally Reach the [no] Promised Land

On June 30, 2017, the Supreme Court of Canada unanimously granted AstraZeneca's appeal in the long-awaited conclusion of the "Promise Doctrine" saga in *AstraZeneca Canada Inc v Apotex Inc.*

The "Promise Doctrine" was a methodology developed by the Federal Court and Federal Court of Appeal over the last ten or so years, for evaluating the utility of a patent. As described by the Supreme Court in its decision, the Promise Doctrine involved reviewing the claims and disclosure of a patent to identify potential promises. Those promises would then become the standard by which the "utility" of the patent was measured. The Court would go on to determine whether those promises had been met, by demonstration or sound prediction, by the Canadian filing date. The failure to meet any of the patent's promises by that date would invalidate the patent for lack of utility.

In *AstraZeneca*, the Supreme Court left no room for debate about its views of the Promise Doctrine. In unusually direct language, it held that the Promise Doctrine was "not the correct method of determining whether the utility requirement under s. 2 of the *Patent Act* is met", "incongruent with both the words and the scheme of the *Patent Act*" and "not good law."

The Supreme Court replaced the Promise Doctrine with a much simpler test, designed to only invalidate patents that are "devoid of utility" or where the utility is "entirely unrelated" to the subject matter. Once a Court finds that the subject matter of a patent is "capable of a practical purpose" that is somehow related, then even a "scintilla of utility will do".

The primary legal consequence of the *AstraZeneca* decision is clear, as the Supreme Court has reset the utility test and eliminated the Promise Doctrine. However, it is worth making three additional observations about what this decision means for patentees and patent challengers alike.

First, *AstraZeneca* moves Canadian utility law much closer to US utility law, but not into perfect alignment. The utility test in *AstraZeneca* still requires the utility to be "established by either demonstration or sound prediction as of the filing date", citing the Supreme Court's prior decision in *AZT* (*Apotex Inc v Wellcome Foundation Ltd*). As a result, unlike in the US,

evidence of utility collected after the filing of the Canadian application cannot be used retroactively to support the patent.

Second, *AstraZeneca* is yet another in a long line of decisions where the Supreme Court has shown little or no deference to the Federal Courts. In its decision, other than noting a handful of examples of the Promise Doctrine, the Supreme Court did not even attempt to address the significant body of case law that the Federal Courts had developed in the area. As a result, even though the chances of getting leave to appeal to the Supreme Court are low (around 10%), it appears that once leave is granted from a decision of the Federal Court of Appeal, there is no comfort in being the respondent. All bets are off, and one must argue the case at the Supreme Court with that in mind.

Finally, what of the cases where patents were invalidated under the now-disgraced Promise Doctrine? For actions where the decisions are final and all appeals have run out, there may be nothing to be done. However, where actions or appeals are ongoing, and for applications under the *PM(NOC) Regulations* where innovators lost due to lack of utility, the ground has shifted dramatically. Indeed, this is the case for Apotex and the half-dozen other companies that have been selling generic esomeprazole since 2012, on the basis of multiple decisions of the Federal Court and Federal Court of Appeal holding the patent invalid, only to have the Supreme Court rule in favor of AstraZeneca. Wise patentees (and patent challengers) will be reviewing their ongoing and past cases to re-evaluate their chances of success. Welcome to the [no] promised land.