**AstraZeneca Canada Inc v Apotex Inc**

Topic #4

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**The Promise Doctrine & *AstraZeneca v. Apotex***

The Promise Doctrine was a requirement of the Patent Act, RSC 1985, c P-4, for patentees to establish arguable statements of utility in their patent disclosures.1 The Promise Doctrine, unique to Canada, imposed that every conceivable ‘promise’ of utility must be demonstrated as of the filing date, otherwise the patent may be invalidated. The doctrine required patentees to support the claimed benefits of their invention with evidence, particularly when a patent listed multiple potential advantages. The Canadian Federal Courts established and began applying the Promise Doctrine in 2005, leading to numerous successful patent challenges on the ground of failing to meet a promise of utility.1 During this time, patents were challenged although their invention met every other requirement of the Patent Act. In *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36, the Promise Doctrine played a key role in the decisions of the Federal Court and Federal Court of Appeal. The appeal hearing of this case in the Supreme Court of Canada in 2017 ultimately led to the abolishment of the Promise Doctrine.

In 1994, AstraZeneca applied for the '653 patent”, claiming the optically pure salts of esomeprazole, to act as a proton pump inhibitor to reduce gastric acid, treat reflux esophagitis, and related conditions, as well as having pharmacokinetic and metabolic properties. Apotex applied to the Minister of Health for a Notice of Compliance to sell a generic version of the same drug. A notice of compliance is issued to manufacturers following the satisfactory review of a submission for a new drug, signifying compliance with Food and Drug regulations.2 Apotex began selling their generic version of the drug, initiating the legal action taken by AstraZeneca for patent infringement.

The significance of *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36 is in the demonstration of how the Promise Doctrine influenced patent validity decisions in Canada. The case brought attention to the limitations of the doctrine. The decision of the Supreme Court of Canada to abolish the Promise Doctrine marked a turning point in Canadian patent law, as it clarified utility requirements aligned Canada with international standards.

**Arguments in *AstraZeneca v. Apotex***

In AstraZeneca Canada Inc. v. Apotex Inc., the central argument concerned whether AstraZeneca’s ‘653 patent was invalid for lack of utility under the Promise Doctrine. AstraZeneca argued that their ‘653 patent, which covered optically pure salts of esomeprazole (a proton pump inhibitor), was wrongly invalidated by the Federal Court (2014 FC 638) and Federal Court of Appeal (2015 FCA 158) by evaluating every stated benefit in the patent disclosure rather than the claimed invention itself. The Federal Court had ruled that, while the ‘653 patent was novel and non-obvious, it lacked utility because, under the Promise Doctrine, it promised more than it could provide. Specifically, the court identified two promises:

(1) The drug would function as a proton pump inhibitor (PPI) to reduce stomach acid.

(2) The drug would have improved pharmacokinetic and metabolic properties, leading to better therapeutic effects with less variability between patients.

While the first promise was undisputed, the second was found not to have been demonstrated or soundly predicted at the time of filing. In an appeal filed by AstraZeneca, The Federal Court of Appeal upheld this decision, reinforcing the Promise Doctrine. Apotex defended the decision, arguing that failing to meet even one of these promises meant the entire patent should be invalid. AstraZeneca countered that this was an unfairly rigid standard, as the Patent Act only requires an invention to have some utility, not that every stated benefit be proven. Section 2 of the Patent Act simply states that an invention must be useful, without requiring that all disclosed uses be met for a patent to remain valid.

**Problems with the Promise Doctrine**

The Promise Doctrine created significant obstacles regarding evaluation of utility and non-obviousness, as applied in Canadian patent law. A significant problem with the Promise Doctrine is that it diverted attention from whether the discovery was inventive beyond existing knowledge. By conflating other validity requirements, the Promise Doctrine risked invalidating an invention solely due to a lack of demonstration for one potential use, even if the invention offered another confirmed, demonstrated benefit, and was non-obvious.

A primary reason as to why the Promise Doctrine was problematic was that it imposed an unfairly high standard for patents. If a patent’s text listed many benefits, even as possibilities, failing to prove even one advantage ran the risk of invalidation. In the case of *AstraZeneca Canada Inc vs Apotex Inc.*, the Supreme Court debated that this approach was beyond the law’s intended purpose, which was to ensure at least one credible use is demonstrated, rather than every conceivable benefit. The Promise Doctrine resulted in penalizing inventors who disclosed secondary benefits or potential improvements. As a result, non-obviousness became secondary when it should be independently analyzed.

Overall, the Promise Doctrine hindered the goals that patent law strives to achieve. The Promise Doctrine discouraged full disclosure, as it turned the mentioning of a potential advantage into a binding promise, hence more detail meant increased risk of patent invalidation. The Supreme Court’s abolishment of the Promise Doctrine restores a balanced standard of the previous blurry lines between utility and non-obviousness. The rejection meant that patents require at least one confirmed practical application, and genuine inventions should not be rejected because not all binding potential advantages are proved.

**Court’s Decision and Impact**

In *AstraZeneca Canada Inc. v. Apotex Inc.*, the Supreme Court of Canada overturned the decisions of both the Federal Court and Federal Court of Appeal, ruling in favour of AstraZeneca and abolishing the Promise Doctrine.3 The Court held that the doctrine was inconsistent with the Patent Act, RSC 1985, c P-4, as it imposed an overly stringent utility requirement that was not grounded in the statutory framework.3,4 This decision brought Canadian patent law into closer alignment with international standards by reaffirming that the utility requirement under s. 2 of the Patent Act is met if a patent discloses a single demonstrated or soundly predicted use at the time of filing, rather than requiring that all promised uses be satisfied.

In their decision, the Supreme Court of Canada established a two-step test for utility. First, identify the subject matter of the invention as claimed in the patent, and second, assess whether that subject matter is useful in achieving at least one practical purpose. This ruling reaffirmed the traditional “scintilla of utility” standard, ensuring that a patent remains valid as long as the invention demonstrates some level of usefulness without every anticipated benefit be demonstrated.3,5 The Supreme Court allowed AstraZeneca's appeal; the patent remained valid with sufficient utility.

The elimination of the Promise Doctrine from Patent Act strengthened patents by reducing the potential scope and risk of invalidations that could be applied to patents, as seen by the motion of Apotex inc., ultimately being overturned and protecting the original patent held AstraZeneca Canada. Although this ruling provided more protection and stronger patent rights for inventors in Canada, the removal of the Promise Doctrine significantly changed the strategic landscape that generic drug manufacturers, such as Apotex Inc., would use to bring generic medication formulations to the Canadian market.6 Since this ruling, there have been growing concerns that a meaningful utility requirement provides numerous benefits for the public and pharmaceutical industry. What this could potentially mean is with the stronger patent protections offered to pharmaceutical companies is that the public may have diminished access to novel, potentially lifesaving medications for reasons of availability or high financial barriers which could be avoided with a medication entering the generic sector of the market. Furthermore, it has been argued that the loss of the promise doctrine represents a loss protection against the creation of a legal monopoly within Canada. Larger, more powerful companies could exploit overly strengthened patent laws with a technique deemed ‘evergreening’ where minor variations on existing patents are intentionally sought to further prolong the patent protection and thus monopoly on a given product.6

The Supreme Court’s decision in AstraZeneca Canada Inc. v. Apotex Inc. consequently reinforced the validity of AstraZeneca’s patent by abolishing the Promise Doctrine and clarifying the utility requirement. This ruling not only protected AstraZeneca's intellectual property but also reshaped the patent landscape for generic drug manufacturers, creating new considerations for market entry and competition.

**References**

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