October 20, 2016

Federal Court of Appeal Re-Affirms Scope of Promise Doctrine in Patent Law Ahead of Upcoming Supreme Court Hearing

The Supreme Court of Canada is set to take up the important issue of the promise doctrine in patent law in *AstraZeneca Canada Inc. v. Apotex Inc.*, presently scheduled for hearing on November 8, 2016.

In the meantime, the Federal Court of Appeal has re-affirmed key components of that doctrine in its recent decision in *Teva Canada Limited v. Novartis Pharmaceuticals Canada Inc.*

Teva sought to appeal the order of the Federal Court prohibiting the Minister of Health from granting it a Notice of Compliance. The NOC would have allowed Teva to sell its generic version of Novartis' innovator drug EXJADE.

At first instance, the FC had found that Novartis had met its burden of showing that Teva's allegations of inutility, obviousness and insufficiency were not justified. On appeal, the sole issue was inutility, and whether the FC had properly applied the law.

Teva alleged the FC had erred in its construction of the promise of the patent on three grounds:

1. relying on the patent's abstract to construe the promise;
2. distinguishing between the promise made in respect of the patented formula I and formula II compounds; and,
3. applying the doctrine of claim differentiation.

While the FCA agreed with Teva that the FC should not have considered the abstract when construing the promise of the patent, the FC's error was immaterial. The FCA found no errors on the other two grounds.

The patent at issue consisted of two classes of compounds. Teva argued that there could not be different promises for each of these two classes, since formula II was a subset of formula I. According to Teva, the same promised utility should have applied to both classes.

The FCA rejected this argument, affirming that different claims can have different utilities.

The FCA also confirmed two other important aspects of the promise doctrine. Quoting *Apotex Inc. v. Pfizer Canada Inc.*, Dawson J.A. found that a patent claim will only be held to an elevated utility standard “where a clear and unambiguous promise had been made.” The FCA also held that when the validity of a patent is challenged on the basis of an unfulfilled promise the promise should be construed in favour of the patentee when the patent can reasonably be read as excluding this promise.

Ultimately, Teva was unsuccessful, and the NOC was not granted.

Patent holders and litigants should take note – the promise doctrine has been the subject of much recent litigation, including continued refinement by the both the FCA and FC. This decision affirms many of the more recent refinements and contributes to the growing body of jurisprudence and commentary on the promise doctrine all of which will go before the Supreme Court of Canada in *AstraZeneca* in less than a month’s time.

With notes from Kate Costin