Court Guidance Needed Under Sound Prediction Doctrine

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The doctrine of sound prediction, and in particular, the proper approach to the construction of the promise of a patent, remains unclear in light of the recent discontinuance of Apotex's appeal to the Supreme Court of Canada (SCC) in *Apotex Inc. v. Sanofi-Aventis*, relating to the drug PLAVIX® clopidogrel. On the day before the appeal was scheduled to be heard by the SCC, namely November 3, 2014, Apotex filed a Notice of Discontinuance. Thus, there was no longer a case before the Court, and no iminent ruling from them on the issue.

This drug, PLAVIX® clopidogrel, was the subject of a decision of the SCC in 2008[1], in which the SCC deliniated the tests for anticipation and obviousness in the context of a proceeding commenced pursuant to the *Patented Medicines (Notice of Compliance) Regulations*. Following that decision, in 2009, Apotex commenced an action for impeachment of the patent, Sanofi-Aventis commenced an action for patent infringement, and the two actions were consolidated. After a trial on the merits, the Trial Judge found the patent to be, *inter alia*, obvious and not soundly predicted[2]. Sanofi appealed to the Federal Court of Appeal, which overturned on both issues[3]. Apotex sought and was granted leave to appeal the decision to the SCC. It was hoped that the SCC would provide guidance to patentees, to potential investors, and to the industry as a whole with respect to the sound prediction issue.

Guidance from the SCC is necessary because of the nature of the current test for sound prediction, which makes it difficult for companies to determine the likelihood of an ultimate finding of patent validity. This uncertainty leads to reluctance on the part of companies to file patent applications in Canada, and to reluctance on the part of investors to invest money in companies holding patent applications and/or patents in Canada.

The uncertainty lies, in large part, in the first step of the analysis, which requires the Court to determine the promise of the patent. It is the promise that must be demonstrated or soundly predicted. Courts have varied significantly in their approach to construing a promise. In some cases, the Court has considered every statement in a patent disclosure to be a promise. Other Courts have considered only what is in the claims of the patent to be the promise. Debate has raged around the use of words such as "may" or "can" or "object" in the specification and whether the use of these words simply suggests a goal of the invention, which is not required to be demonstrated or soundly predicted, or a promise, which must meet the necessary conditions. Patents that were drafted and filed at a time when the doctrine of sound prediction did not exist in the form currently applied by the Court are often found invalid.

It is unfortunate for the industry that the SCC was not able to provide the necessary guidance as to how to apply the doctrine of sound prediction. It is expected that, as a result, Courts will continue to apply lower standards and rules of construction, leading to in unpredictable results until an appropriate case is presented to the SCC. It is hoped that this opportunity will be soon.

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References

[1] *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61.

[2] *Apotex Inc. v. Sanofi-Aventis*, 2011 FC 1486.

[3] *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 186.