Supreme Court Issues Decision Discussing Test for Sufficiency of Disclosure in a Patent

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On November 8, 2012, the Supreme Court of Canada (SCC) released its decision in *Teva Canada Limited v. Pfizer Canada Inc.* This was the first time the SCC had considered the issue of sufficiency of a patent's disclosure pursuant to s. 27(3) of the Patent Act, since 1981.

The proceeding was commenced pursuant to the *Patented Medicines (Notice of Compliance) Regulations* seeking an order of prohibition, to prevent Teva from entering the market with its generic version of Pfizer's VIAGRA® sildenafil product. At issue was one patent that claimed a large genus of compounds, including sildenafil, for treating erectile dysfunction. In the result, the SCC found the patent to be void, notwithstanding that the relief sought in the proceeding was only an order of prohibition.

The facts of this case are unique. The patent disclosed that one compound had been tested and demonstrated to be effective in treating erectile dysfunction (ED). However, the patent did not disclose which compound had been tested. Teva alleged that the requirements of section 27(3) of the *Patent Act* had not been met, namely that the invention had not been sufficiently disclosed. The Court considered the traditional questions for sufficiency: "What is your invention?" and "How does it work?" and held that these questions are relevant. However, the description must also enable a person skilled in the art to produce the invention using only the instructions in the disclosure. "The nature of the invention must be disclosed, and the entire specification, including the claims, must be considered in determining the nature of the invention and whether disclosure was sufficient."

The SCC held that the invention was: the use of sildenafil to treat ED. However, because the disclosure did not identify which compound was effective, the public would have to complete a research project in order to determine which compound was actually effective to treat ED. The SCC held that a person skilled in the art would not be able to make use of the invention having only the specification because the identity of the only compound indicated to have been tested in humans was not disclosed.

The SCC did not consider other issues that were raised, namely whether relying on a sound prediction of utility imposes an increased disclosure obligation. The SCC found that this is a case of demonstrated utility, and not sound prediction, as clinical testing had been performed at the filing date of the patent application. The SCC further noted that utility is not a disclosure requirement.

The SCC rarely deals with patent cases, and when it does, everyone who deals with patents must pay attention. However, in this case, the SCC simply confirmed that its decision in *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.* still governs the disclosure requirements of section 27(3): tell the public how to make and use your invention when you file the patent, and if you test something and it works, tell the public what you tested. That is part of the bargain theory behind the patent system.

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