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Intellectual Property

Supreme Court of Canada Upholds Standard of Disclosure

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The Supreme Court of Canada, in *Teva Canada Ltd. v. Pfizer Canada Inc.* held Pfizer's patent for the use of sildenafil, commercially known as Viagra®, void, thereby allowing Teva to market a generic version of the drug prior to expiry of the patent in 2014. In overturning the lower court decisions, the Supreme Court unanimously held that the patent failed to adequately disclose sildenafil's efficacy in treating erectile dysfunction (ED).

In interpreting the requirements under Canadian law for sufficiently disclosing a claimed invention, the Supreme Court's decision provides valuable guidance on how such requirements must be met when preparing a patent application.

The issue before the Supreme Court was Teva's application for a Notice of Compliance (NOC) from Health Canada to produce a generic version of sildenafil. In its decision, rather than disposing of this single issue, the Supreme Court arguably overextended its jurisdictional reach in holding the patent to be void. Pfizer has responded by moving to have the Supreme Court's decision amended to address only the NOC application or, alternatively, to have a re-hearing on the remedy awarded.

In a separate action, *Apotex v. Pfizer Ireland,* another major generic drug company, Apotex, sought impeachment of the patent. Following the Supreme Court's decision, and several days before a hearing in this case, Apotex successfully moved for summary judgment on its impeachment action. The Federal Court held the patent invalid and void.

BACKGROUND

Pfizer obtained the patent, which is directed to a known genus of compounds having formula (I) claimed to have utility as an orally administered medication for the treatment of ED. The genus was found to encompass approximately 260 quintillion possible compounds.

The patent generally discloses a genus of compounds and a number of "especially preferred" members of the genus for use in treating ED. The patent briefly refers to a study that was conducted on one of the compounds, which was found to have the desired utility. This compound was not specifically identified in the disclosure but was later shown to be sildenafil. No further data were presented in the patent indicating the effectiveness or lack of effectiveness of other compounds of the genus.

The Supreme Court noted that the patent includes "cascading claims", starting with a claim to the use of a genus of pyrazolopyrimidinones followed by subsequent claims of narrowing scope. Claims 6 and 7 are directed to the use of individual compounds of the genus, with claim 7 being directed to use of sildenafil.

Teva Canada sought an NOC to market a generic version of sildenafil, alleging that the patent was invalid on various grounds, namely, obviousness, lack of utility and insufficiency of disclosure. These allegations were successfully denied by Pfizer before the Federal Court, in a decision that was upheld by the Federal Court of Appeal. Teva then appealed to the Supreme Court.

THE DECISION

The Supreme Court focused on two issues: lack of utility and sufficiency of disclosure. The obviousness argument was not asserted by Teva on appeal.

Lack of Utility

The Supreme Court readily dealt with the lack of utility allegation by acknowledging that the utility of one compound, sildenafil, was demonstrated by the patentee as of the filing date of the application. The Supreme Court also confirmed that there exists no requirement under Canadian law that the utility of an invention must be disclosed in the patent. The Supreme Court further indicated that, even if such a disclosure requirement existed, it was met by the reference to the study that was conducted by Pfizer, even though the identity of the effective compound was not mentioned.

CONT'D ON PAGE 2

CONT'D FROM PAGE 1

Sufficiency of Disclosure

The Supreme Court, however, found that the patent failed to sufficiently disclose the subject invention. In allowing Teva's appeal, the Supreme Court stated that: "Sufficiency of disclosure lies at the very heart of the patent system" and that a sufficient disclosure, as required under the *Patent Act,* is a precondition for the grant of a patent.

The Supreme Court began its analysis by identifying the "nature of the invention". In the lower court decisions, each claim of the patent was found to comprise a separate invention and the sufficiency of disclosure assessment was therefore made on a claim-by-claim basis. In so doing, the lower courts found the use of sildenafil, covered by claim 7, was adequately disclosed. Specifically, the lower courts found that the disclosure of one compound at the narrow end of cascading claims of the genus having the required utility was sufficient to allow a person skilled in the art to conclude, without undue experimentation, that the one compound effective for treating ED was sildenafil.

The Supreme Court rejected the lower courts' approaches and stated that a patent must be directed to a single inventive concept, the nature of which must be determined based on a review of the whole specification, including the disclosure and the claims. The Supreme Court found that the inventive concept covered by the patent is the use of a genus of compounds that is effective in treating ED. However, the Supreme Court went on further to state that, since Pfizer's study identified only sildenafil as being effective in treating ED, the use of sildenafil in the treatment of ED was in fact the "true" invention that must be disclosed in the patent to satisfy the disclosure requirements of the Act.

While the Supreme Court agreed that the specification disclosed one compound having the desired utility, such teaching was found to be insufficient to enable a skilled reader to conclude that the identity of that one compound was sildenafil. The Supreme Court said: "More importantly, what must be considered is whether a skilled reader having only the specification would have been able to put the invention into practice."

While wilful intent to mislead was not alleged in this case, the Supreme Court was critical of the lack of detail provided in the specification, particularly in view of the fact that Pfizer had obtained data on sildenafil as of the filing date of the application but failed to include such data in the patent specification. The Supreme Court said: "The disclosure failed to state in clear terms what the invention was. Pfizer gained a benefit from the Act – exclusive monopoly rights – while withholding disclosure in spite of its disclosure obligations under the Act. As a matter of policy and sound statutory interpretation, *patentees cannot be allowed to "game" the system in this way."* (emphasis added)

COMMENTARY

The Supreme Court's decision provides a roadmap for both applicants and patentees.

First, the decision serves to emphasize the importance of including in a patent specification a clear and unambiguous definition of the "inventive concept" underlying the invention. The Supreme Court's decision adds to the body of law developing in Canada that the applicant for a patent should clearly indicate the "inventive concept", or "promise of the invention", so as to avoid the adoption of an unintended interpretation later. An incorrect interpretation of the inventive concept may result in unforeseen utility or disclosure requirements.

Second, once the inventive concept has been identified, the specification should provide a clear and enabling disclosure of the claimed invention. As the Supreme Court's decision highlights, a patentee cannot rely solely on the claims for disclosure of specific embodiments of the invention or on ambiguous statements in the specification.

Third, a patent specification should include sufficient and specific data to support all claimed embodiments and, in particular, each working embodiment. The inclusion of all test data, both positive and negative, and identification of the tested species may prove to be crucial for supporting claims to such embodiments. In the case of sildenafil, while the testing conducted by Pfizer was found sufficient to establish the utility of sildenafil, the failure to specifically identify sildenafil as the effective compound resulted in a finding that the sufficiency of disclosure requirements were not met. Arguably, had Pfizer's test data been included in the specification, a different conclusion may have been reached. In particular, if test data are available for only a certain subset of claimed compounds, such data should

CONT'D ON PAGE 3

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be clearly associated with the relevant compounds. As noted by the Supreme Court, the patent disclosed only one compound to be effective while the patent "ended with two individually claimed compounds, thereby obscuring the true invention".

Fourth, the Supreme Court has reiterated that there is no requirement to disclose demonstrated utility in a specification. It is sufficient for the patentee to have conducted the required investigation as of the filing date of the application. As stated by the Supreme Court: "The fact that Pfizer did not disclose that the tested compound was sildenafil goes to the issue of disclosure of the *invention*, not to that of disclosure of the invention's *utility*."

Fifth, for patent applications that are currently pending, applicants may be advised to review the pending claims and to amend the claims or disclosure accordingly to address any deficiencies in the specification. For example, where needed, suitable claim amendments may be considered so as to limit specifically claimed compounds to those that are explicitly described in the specification.

Finally, for issued patents, patentees may consider assessing their Canadian patents to determine whether disclaimers may avoid any unsupported claims from jeopardizing other claims.

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