Teva Canada Ltd. V. Pfizer Canada Inc., 2012 SCC 60 (2012)
Supreme Court of Canada

Prepared by UNCTAD's Intellectual Property Unit

Summary

In this case Teva Pharmaceutical Industries Ltd challenged the validity of Pfizer Pharmaceuticals Inc's patent for the drug Viagra. Teva stated that Pfizer had not met the disclosure requirements set out in the Canadian *Patent Act*, R.S.C. 1985, c. P-4 (hereinafter: the Act). The main issue on appeal was whether Pfizer had failed to properly disclose its invention when it obtained the patent for Viagra. The Supreme Court of Canada ruled that if a party attempted to "game" the system by obscuring the invention, they risked losing their exclusive rights to the invention.

The facts

Viagra (Sildenafil) is approved for the treatment of impotence (also known as erectile dysfunction, (ED)). In 1998, Pfizer obtained a patent for the drug Viagra in Canada. At the time the patent application was filed, Pfizer had tested and determined that sildenafil was the effective compound to treat ED.

Within Pfizer's disclosure of its patent was a description of nine compounds, a list which included sildenafil. While Claim 1 of Pfizer's patent extended to 260 quintillion different compounds, two claims (claims 6 and 7) were each directed to a single compound. Claim 7 related to sildenafil alone. However, even though this was known to Pfizer, the patent did not disclose the fact that sildenafil stood as the only compound which had been proven successful in treating ED in clinical studies.

On July 6, 2007, Teva served Pfizer Canada with a Notice of Allegation ("NOA") alleging that the patent was invalid for obviousness, lack of utility and insufficient disclosure. The Federal Court of Canada found Teva's allegation unjustified and issued an order prohibiting the Minister of Health from issuing a Notice of Compliance to Teva, which in turn prevented Teva from marketing a generic version of Viagra. Teva appealed to the Federal Court of Appeal, dropping the allegation of obviousness, but the appeal was dismissed. In 2012 Teva appealed again - to the Supreme Court of Canada (hereinafter: SCC) which unanimously reversed the judgments of both the Federal Court of Canada and the Federal Court of Appeal and ruled that Pfizer's patent covering Viagra was invalid, due to a lack of sufficient disclosure of the invention.

The SCC's decision set the foundations for Teva and others to market generic versions of Viagra before the expiry of the patent in 2014.

The legal issue

The main issue before the SCC was whether the patent met the disclosure requirements under subsection 27(3) of the Act, which requires the court to consider the patent specification as a whole. The court had to consider the claims and the disclosure (as provided in the description of the invention), from the perspective of a person skilled in the art.

The SCC ruled that the patent did not distinguish sildenafil from any of the other "especially preferred compounds" listed in the patent. Further, the SCC held that the disclosure in the specifications would not have enabled the public to make the same successful use of the invention as the inventor could at the time of his application.

The court ruled that by withholding from the public the identity of the only compound tested and found to work, sildenafil, the patent did not fully describe the invention. Pfizer had made a conscious choice not to disclose the identity of the only compound found to work, and left the skilled reader guessing. By failing to specifically disclose the useful compound, Pfizer failed to satisfy the statutory disclosure requirements of the Patent Act. The court held that even if a skilled reader could determine that the effective compound was either of the compounds in Claim 6 and Claim 7, further testing was required to determine which of those two compounds was actually effective in treating ED.

Pfizer argued that Teva had already been able to make the same use of the invention having only the specification, because it had filed a submission with the Minister of Health for a drug product containing sildenafil. The SCC ruled that this did not change the fact that the specification required, at a minimum, "a minor research project" in order to determine whether Claim 6 or Claim 7 contained the correct compound. Teva had carried out this research project to determine which of the compounds was effective. The fact that Teva was able to reproduce the drug with additional testing did not relieve Pfizer of its obligation to fully disclose the invention.

Pfizer did not offer any explanation for why it elected to withhold information in the patent application, despite its knowing that Claim 7 contained the useful compound. By withholding from the public the identity of the only compound tested and found to work, sildenafil, the patent did not fully describe the invention. The SCC came to its conclusion, stating that:

> *"The public's right to proper disclosure was denied in this case, since the claims ended with two individually claimed compounds, thereby obscuring the true invention. 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".*

The SCC ruled that if a party attempted to "game" the system by obscuring the invention, they risked losing their exclusive rights to the invention. The remedy was to declare the patent invalid.

The SCC set out the patent bargain by recognizing:

"The patent system is based on a "bargain", or quid pro quo: the inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge. This is the basic policy rationale underlying the Act. The patent bargain encourages innovation and advances science and technology."

Points of significance

Enabling disclosure

- The obligation of sufficient disclosure reflects the basic concept of patent law: in exchange for receiving a temporary exclusive right, the patent holder makes his/her invention available to the public at large.
- Enabling disclosure requires that a patent application discloses a claimed invention in sufficient detail for the notional person skilled in the art to carry out that claimed invention.

The TRIPS Agreement - *Article 29 paragraph 1*

- Members shall require an applicant for a patent to disclose the invention in a sufficiently clear and complete manner so that the invention may be carried out by a person skilled in the art.
    - Despite the disclosure requirement, patent applications are often not sufficiently detailed or self-explanatory for persons skilled in the art to be able to utilize the disclosed information for future follow-on innovation, particularly in developing countries.
    - The TRIPS Agreement provides some flexibility on how governments may respond to this situation. In particular, they may introduce a best mode requirement, according to which the applicant is required to indicate the best mode for carrying out the invention known to the inventor at the filing date or the priority date. While the best mode requirement is separate from the general disclosure obligation, Article 29 TRIPS leaves Members free to decide that failure to meet the best mode requirement may also result in patent invalidation. See the case summary of *Spectra-Physics, Inc. v. Coherent, Inc,* included in this database.

Canada

- The description must provide a clear and complete disclosure of the invention such that the person skilled in the art:
    - Can unambiguously identify what has been invented.
    - Is enabled to practice this invention.

Key words
Pre-grant flexibilities, Patent, Patentability, Sufficient Disclosure, Enabling Disclosure, Person Skilled in the art, Best Mode Requirement.

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