VIAGRA®'S PATENT INVALIDATED BY THE SUPREME COURT OF CANADA

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The patent that covers the use of the active molecule of Viagra®, sildenafil was the subject of a unanimous decision by seven judges of the Supreme Court of Canada on November 8th, 2012 [*Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60]. It considered that the Canadian Patent 2,163,446 was invalid, reversing the decisions of the Federal Court and Federal Court of Appeal, on the grounds that the description of the invention was insufficient at the date of patent filing, and therefore not in compliance with Section 27 (3) of the Patent Act, which reads **:**

> The specification of an invention must(a) correctly and fully describe the invention and its operation or use as contemplated by the inventor.

The expiration of the patent was expected in May 2014, 20 years after the date of filing of the patent application, but this decision will allow the generic drug company, Teva Pharmaceutical Industries (formerly Novopharm Limited), to obtain a notice of compliance of the Ministry of health and to enter the market now[4].

Pfizer's patent discloses and claims the use of a family of compounds for the treatment of male impotence. In the short description of 12 pages, it is only mentioned that "one of the especially preferred compounds induces penile erection in impotent males", without specifying the exact structure of the compound having this property. Then, in the claims written in "cascade", the compound is first claimed by a generic chemical formula "for 260 quintillion possible compounds." The claims end with claims 6 and 7, added after the filing of the application, each covering a single compound. Claim 7 covers the active drug in Viagra™ (sildenafil), but nothing in the patent indicates that it is the molecule claimed in claim 7, which is sildenafil.

Citing the AZT [AZT is the common name of the Supreme Court Judgement *Apotex Inc. C. Wellcome Foundation Ltd.,* 2002 SCC 77] decision and incorporating Article 27 (3) of the Patent Act, the Supreme Court held that the patentee had not fulfilled its obligations under the *quid pro* quo contract that applies according to the Patent Act: the Canadian government provides a monopoly on an invention for 20 years on condition that the invention is novel, inventive, useful, but also fully disclosed at the

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date of filing of the application, so that a person skilled in the art would be able to reproduce the invention at the expiry of the patent.

In the AZT decision, the Supreme Court had clarified the nature of this market:

> A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the Patent Act.

The Court found that doing more tests to check which of the 2 compounds of claims 6 and 7 was active and represented the invention on the date of filing of the application, did not allow the public to use of the invention with the same success as the inventor. Indeed, as mentioned above, it is not stated in the description that sildenafil is the effective compound and that "even though a skilled reader will know that, when a patent contains cascading claims, the useful claim will usually be at the end concerning an individual compound, the claims in the patent ended with two individually claimed compounds." In fact, the Court considers that "Pfizer had the information needed to disclose the useful compound and chose not to release it", as if Pfizer had wanted to "hide" their invention. Following this decision, it becomes even more important to ensure that you have full disclosure of the invention in the patent application at the time of filing.

Another reason discussed before the Supreme Court was the lack of disclosure of the Sound Prediction doctrine used to demonstrate the utility when it is not clear from the description. This reason was quickly rejected by the Supreme Court on the grounds that the utility was well demonstrated in the application, where Pfizer refers to tests. It was therefore not necessary to invoke the doctrine of Sound Prediction.

The final impact of this decision is not yet known. Indeed, this decision was made under a simplified procedure called PMNOC, allowing generics to ask the Minister of Health for a notice of compliance for their generic product if their allegations regarding the lack of valid patents having the ability to prevent the manufacture, sale or use of the invention have been verified. This type of decision is binding between the parties to the dispute. Thus, in this case, only Teva should get a notice of compliance in light of this decision. Other generic companies should pursue parallel proceedings. Only a decision on the merits, would invalidate the patent and remove it from the Patent Registry. However, the conclusion of the decision "the patent is invalid" is confusing and the patentee sought to obtain clarifications or modifications regarding the conclusion of the decision, pursuant to Articles 76 and 81 of the Rules of Procedure of the Supreme Court, the patent should not be removed from the registry, following this decision. Moreover, in parallel proceedings involving Pfizer and Apotex for the same patent [File number in federal court T-772-09 decision not yet published at the time of writing this article] , the judge of the Federal Court has since noted that although the Supreme Court decision was rendered in the PMNOC

proceedings, the question raised as a matter of law, the Federal Court is bound to respect and make the same decision that the Supreme Court did, that is to allow the Minister of Health to issue a notice of compliance to Apotex for sildenafil.

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