Supreme Court issues clear warning of need to respect the "Patent Bargain"

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On Thursday, November 8, 2012, a unanimous Supreme Court of Canada issued a decision with significant implications for those wishing to obtain or enforce Canadian patent rights. Owners of issued patents seeking to enforce such rights should carefully scrutinize the disclosure and claims of their issued patents in light of this decision, and patent applicants should consider this decision when drafting the specifications of new applications.

The case of ***Teva Canada Ltd. v. Pfizer Canada Inc***. arose out of a **Patented Medicines (Notice of Compliance)** [PMNOC] proceeding in which Novopharm Limited (now, Teva Pharmaceuticals Limited) sought approval from Health Canada to market and sell a generic version of Pfizer's Viagra-branded sildenafil tablets. To obtain such approval, the decision-maker had to be convinced that Pfizer's patent (the '466 Patent) was invalid. However, Teva was unsuccessful at both the Federal Court of Canada and the Federal Court of Appeal, each of which held that Teva's allegations of invalidity were not justified.

Teva appealed to the Supreme Court. The primary issue on appeal was whether Pfizer complied with section 27(3) of the ***Patent Act*** and properly disclosed its invention in the '466 Patent. In considering this issue, the Supreme Court reiterated the importance of a patent applicant respecting the "patent bargain". The essence of the patent bargain is that in exchange for a time limited monopoly granted to an inventor for a new and useful invention, the inventor discloses this invention to the public so that society can benefit from the inventor's knowledge. From a societal perspective, the patent bargain exchanges short term inefficiencies (the potential for "monopoly" rents for the patent rights) for long-term gains (the encouragement of efficiencies gained through innovation). However, the bargain cannot be one-sided: adequate disclosure in the specification is a precondition for the granting of a patent.

Pfizer's '446 Patent is directed to compounds for treating erectile dysfunction (ED). The claims are arranged in a cascading structure in which claim 1 is directed to over 260 quintillion compounds (i.e. 260,000,000,000,000,000,000!), claims 2 to 5 directed to gradually fewer compounds, and claims 6 and 7 each directed to a single compound. Most importantly, claim 7 is directed to sildenafil, which is the only active ingredient in Pfizer's Viagra product.

Section 27(3) of the *Patent Act* requires that the "specification of an invention must correctly and fully describe the invention and its operation or use as contemplated by the inventor…". The "specification" includes both the claims of a patent and the disclosure made in the patent.

The Supreme Court affirmed previous decisions that a patent specification must answer two questions: (1) what is the invention; and (2) how does it work? If the patent disclosure answers these questions, the applicant has held up his or her part of the patent bargain. More particularly, the specification must provide sufficient information to enable a person of skill in the art to which the invention relates to be able to use the invention, using only the instructions of the specification.

The Supreme Court was of the view that the lower courts erred in considering the sufficiency of disclosure (and therefore the validity) of a single claim independently of the rest of the specification. As a result, the lower Courts erroneously confused the principle that the claims of a patent define the scope of the exclusive right being sought with the principle that the content of the specification determines whether the disclosure requirements have been met.

The Supreme Court found that Pfizer was aware through testing, as of the filing date of the '466 Patent, that only sildenafil was effective in treating ED, and that none of the other compounds were effective in treating ED. Despite this, Pfizer provided no indication in its disclosure as to which one of the preferred compounds was effective in treating ED. The Supreme Court held that by failing to expressly disclose the use of sildenafil to treat ED, Pfizer did not adequately disclose the invention in its specification.

Pfizer had argued that its specification was adequate, because one of the claims in the '466 Patent clearly described the use of sildenafil as effective in treating ED. The Supreme Court did acknowledge that a skilled reader would know that "when a patent contains cascading claims, the useful claim will usually be the one at the end concerning an individual compound". However, this acknowledgement did not assist Pfizer because in the case of the '466 Patent, the cascading claim ended with two individually claimed compounds, thereby obscuring the true invention. A person skilled in the art would still have to perform further testing to determine which of the two compounds was actually effective in treating ED. The Supreme Court therefore held that the specification of the '466 Patent did not meet the requirements of section 27(3) of the *Patent Act*.

This case has important repercussions when drafting a patent application. While emphasis is typically placed on the claims because they define the scope of the monopoly, this case shows that identifying the invention in the specification can be equally important, particularly in relation to pharmaceutical patents. The Supreme Court has clearly warned patent holders against "playing games" with the public by not providing a complete disclosure of the invention and therefore not upholding their end of the patent bargain.

Interestingly, the Supreme Court's remedy was to "invalidate the patent". Normally in an appeal of a PMNOC proceeding and given the Supreme Court's findings, the remedy would be to deny Pfizer's application seeking obtain a prohibition order, thereby permitting the Minister of Health to issue Teva a Notice of Compliance and thus allowing Teva to manufacture and sell sildenafil tablets. The Court may give further directions in this respect.