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The Heart of The Patent Bargain: Viagra Patent Invalidated In Canada

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In a recent unanimous decision by the Supreme Court of Canada (*Teva Canada Limited v Pfizer Canada Inc.*), Pfizer Canada's patent to its multi-million dollar selling Viagra was invalidated for insufficient disclosure. The decision allows Teva and others to market generic versions of Viagra® well before the patent's 2014 expiry.

While these are costly consequences for the pharma giant, the case highlights an important lesson regarding patent utility and disclosure requirements in Canada.

Background:

Canadian Patent No. 2,163,446 disclosed and claimed the use of sildenafil, the active component of the hugely successful Viagra, for the treatment of erectile dysfunction. Sildenafil was previously known and initially developed by Pfizer for treatment of hypertension and angina.

Claim 1 of the '446 patent covered a staggering 260 quintillion possible compounds, gradually narrowing to claim 6 covering one compound and claim 7 covering sildenafil. While the specification suggested that "one of the especially preferred compounds induces penile erection in impotent males", it fell silent on the fact that that compound was in fact sildenafil.

Decision:

At the Federal Court and Federal Court of Appeal levels, Pfizer was successful in arguing that in light of Section 58 of the *Patent Act*, possible invalidity of broad claims 1 to 5 should not affect claim 7, thereby maintaining patent protection for use of sildenafil. The FCA also applied the questions a) "What is the invention?" and b) "How does it work?" to assess sufficiency of disclosure, and found that both requirements were met by Claim 7.

These decisions were unanimously overruled by the Supreme Court. The SCC rejected the claim-by-claim approach to validity analysis, stating instead that validity of the invention as a whole must be assessed. If the patent does not sufficiently disclose the invention, then the patent as a whole is invalid, not merely some of the claims.

The SCC further held that the relevant test for sufficient disclosure was not a simple two-question test, but rather whether a skilled person could, using only the information contained in the specification, produce the invention described therein.

In the case of '466 patent, a skilled person would be unable to determine if the compound of claim 6 or claim 7 was the effective compound without extensive experimentation. The patent failed to enable the "public to make the same successful use of the invention as the inventor could at the time of the application", and was consequently found void.

SCC stated: "Pfizer gained benefit under the Act - exclusive monopoly rights - while withholding disclosure in spite of its disclosure obligations. As a matter of policy and sound statutory interpretation, patentees cannot be allowed to "game" the system this way."

The case originated under the *Patented Medicines (Notice of Compliance) Regulations* and the Supreme Court had the option of merely allowing the Minister of Health to issue a Notice of Compliance to Teva. Instead, the SCC chose to rule the patent void. Presently Pfizer is challenging the ruling on the basis that the Supreme Court did not have jurisdiction to invalidate the patent, only to determine the question of the Notice of Compliance.

Whatever the outcome of Pfizer's challenge, the decision emphasizes the importance of providing full and sufficient disclosure an invention in a patent. When it comes to the "heart of the patent bargain", that is public disclosure in exchange for limited monopoly, one

cannot have one’s cake and eat it too.

Contact one of Field Law’s patent professionals in the Intellectual Property & Technology Group for advice on patents and invention protection.