



The disclosure bargain

J. Sheldon Hamilton considers patent disclosure requirements in Canada in light of the sildenafil decision.

In November 2012, the Supreme Court of Canada ruled that Pfizer's patent for the use of sildenafil (the active ingredient in VIAGRA) for the treatment of erectile dysfunction failed to meet the statutory requirement for disclosure of an invention: *Teva Canada Limited v Pfizer Canada Inc*, 2012 SCC 60 (*Teva*). While the patent specifically disclosed and claimed the use of sildenafil, the presence of other, allegedly non-useful embodiments meant that a skilled person could not identify the invention without testing. As a result, the patent did not meet the statutory requirement to "correctly and fully describe the invention and its operation or use as contemplated by the inventor". If Canadian Courts apply the *Teva* decision broadly, the decision may be a potential watershed in Canadian patent law and may cast doubt over the validity of similar patents.

Background: The '446 patent

The patent at issue (Canadian Patent No. 2,163,446 ('446)) discloses and claims the use of compounds for the treatment of erectile dysfunction (ED). In particular, the patent describes four classes of compounds:

- a general class,
- "preferred,"
- "more preferred", and
- "particularly preferred".

The patent also identifies nine specific compounds, including sildenafil, as especially preferred.

The patent includes claims for the new use for various classes of compounds and for the nine especially preferred compounds (as a group). The patent also individually claims the use of two compounds in claims 6 and 7, including sildenafil (claim 7).

Two findings formed the underpinning for the decision. First, while the patent asserts that one especially preferred compound "induces penile erection in impotent

males," the patent does not identify the compound tested. Second, on the facts before the Court, sildenafil was the *only* compound that had been shown to have utility.

As a result, Teva argued that Pfizer knew the identity of the active compound (sildenafil), but failed to disclose that particular compound, obscuring its identity by disclosing other, presumably non-useful, compounds.

Statutory provision: Section 27 of the *Patent Act* is the statutory provision governing disclosure of inventions. The provision requires, in part, that a patent must "correctly and fully describe the invention and its operation or use as contemplated by the inventor". Canadian Courts have historically taken the view that such disclosure is an essential element of the patent bargain: in return for disclosure of the invention, the inventor receives a monopoly.



Résumé

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Sheldon is a Partner in the Toronto office and has advised and acted for clients in all aspects of litigation, particularly in the area of pharmaceuticals, for over 15 years. His client activities include assisting sophisticated multinational clients with multi-jurisdiction patent litigation and he has appeared as counsel before both the Ontario and Federal Courts, including the Federal Court of Appeal.



A corner view of the Supreme Court of Canada on Wellington Street in the capital city Ottawa, Canada.

Judicial history

The *Teva* decision arose from an application brought under the *Patented Medicines (Notice of Compliance) Regulations (PMNOC Regulations)*. Such proceedings link regulatory approval for generic pharmaceuticals (and subsequent entry biologics) to issues of patent infringement and validity.

Teva had alleged that the '446 patent was invalid, including for insufficiency of disclosure. Pfizer sued under the *PMNOC Regulations*, seeking an order prohibiting the Minister of Health from issuing marketing approval to Teva for sildenafil. Justice Kelen of the Federal Court rejected Teva's allegation and granted the order of prohibition. The Federal Court of Appeal affirmed his decision.

Trial: 2009 FC 638: Justice Kelen ruled that sufficiency of disclosure must be considered for the specific claim in issue. Hence, the Court needed to consider whether the invention of claim 7 (the use of sildenafil in the treatment of ED) was sufficiently disclosed. Focusing on the *claimed* invention, Justice Kelen found that (i) sildenafil was the only compound in the patent found to induce erections, and (ii) the skilled person would not have known from the specification that the tested compound was sildenafil. However, he ruled that the skilled person could conduct tests on the two individual compounds claimed and determine which compound worked.

While Justice Kelen rejected the insufficiency allegation, he expressed significant concerns in *obiter* about the patentee's failure to identify the tested compound:

"[136] *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. Obviously Pfizer made a conscious choice not to disclose the identity of the only compound found to work, and left the skilled reader guessing. This is contrary to the statutory requirement to fully disclose the invention." [emphasis added]

Federal Court of Appeal (2010 FCA 242): The Federal Court of Appeal affirmed the decision of Justice Kelen, agreeing that sufficiency of disclosure should be assessed through the prism of claim 7. The patent was sufficient since it answered the questions "What is your invention?" and "How does it work?"

Supreme Court ruling

Supreme Court of Canada (2012 SCC 60): Teva sought and was granted leave to appeal to the Supreme Court.

In addressing the disclosure issue, the Supreme Court stated that "the first step is to define the nature of the invention" in the patent. The Court rejected the claim-based approach used, looking instead to the entire specification to identify the invention disclosed. (The Court left open the possibility that different claims may disclose separate inventions, but this must be determined on a case-by-case basis.)

In the case of the '446 patent, the Court found only one inventive concept: the use of sildenafil and other compounds in the treatment of ED. The Court did not accept that the use of sildenafil was a distinct invention. In concluding that the patent only related to one invention the Court emphasized the following factors:

- "No specific attributes or characteristics are ascribed to sildenafil that would set it apart from the other compounds."

- "...nothing ...distinguishes it [sildenafil] from the other eight 'especially preferred compounds.'"
- "...the patent itself suggests that the entire class of claimed compounds will be effective in treating ED." "The plural word 'inventions' does not appear in Patent '446.'"
- "There is no evidence on the record to suggest that Pfizer filed a divisional application..."

On the question of whether the disclosure was sufficient, the Court looked first to Pfizer's actual work (presumably to determine what Pfizer actually invented) before turning to the specification to see whether Pfizer had disclosed that invention.

As Pfizer's testing only demonstrated that sildenafil was effective, the Court concluded that the actual invention made by Pfizer was the use of sildenafil for the treatment of ED. Accordingly, this invention (the use of sildenafil) would need to be disclosed in order to satisfy the statutory disclosure requirement.

In considering the invention *actually* disclosed by the specification, the Court noted that "the specification does not indicate that sildenafil is the effective compound." Further, the disclosure would not enable the public to make the same successful use of the invention as the inventor since, even if a skilled reader could have narrowed the effective compound down to the two compounds that were individually claimed (claims 6 and 7), a skilled person would need to test to determine which of the two compounds worked.

Hence a disconnect existed between the inventor's actual work (the invention of sildenafil) and the inventor's disclosure of that work (the class including sildenafil).

The Court was unsympathetic to the argument that Teva was able to use the invention having only the specification, since it had filed a submission for regulatory approval of sildenafil. The Court was particularly troubled by the need to conduct a minor research project to identify the invention:

"...The fact that Teva carried out this minor research project is irrelevant to Pfizer's obligation to fully disclose the invention. 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. The trial judge clearly found that the skilled reader would have had to undertake a minor research project to determine what the true invention was."

Cascading claims: In concluding that the '446 patent was insufficient, the Court commented on the practice of cascading claims (broad genus claims that progressively narrow). According to the Court, such claims do not necessarily interfere with the public's right to disclosure since the useful claim is usually the claim at the end for the individual compound. The problem in *Teva* was that the "claims ended with two individually claimed compounds, thereby obscuring the true invention."

Need for proper disclosure: The Court provides a stark warning to patentees about the need for proper disclosure:

"...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. This, in my view, is the key issue in this appeal. It must be resolved against Pfizer."

As a result of the failure to properly disclose the invention, the Court ruled that the '446 patent is invalid and void. This disposition appears to have been an oversight by the Court. Since the proceeding arose under the *PMNOC Regulations*, the only issue was whether the allegation of invalidity was justified. Accordingly, the Court would not appear to have jurisdiction on this appeal to void the patent. As of the writing of this article Pfizer had brought a motion to the Supreme Court for clarification on this issue.

Potential impact

The full impact of the *Teva* decision will not be known for some time. While the unusual fact pattern may suggest a limited impact, decisions by the Supreme Court are often applied broadly. In practice, the implementation of the *Teva* principles will fall to the Canadian Federal Court and the Federal Court of Appeal, which are the Courts that hear the majority of patent cases. While the scope of the impact of the decision is highly speculative at this time, questions that the Courts may need to address in future include:

What constitutes (in)proper disclosure?

In *Teva*, the patentee separately claimed the use of two compounds, when only one, unidentified compound, had been shown to work. How would these principles apply to similar patents claiming the use of different numbers of individual species? How would the Court address a patent that had three species claims, two of which had utility? What would have happened if the Pfizer patent only had a single species claim (instead of two)? Would the patent have survived?

Is intention relevant?

What if a patentee had claimed two compounds individually and had a subjective, but incorrect belief, at the time of filing that both compounds had utility? Is that fact pattern distinguishable from *Teva*?

What steps can patentees take during drafting and prosecution to ensure sufficient disclosure?

Conclusion

The *Teva* decision is already being asserted in patent litigation before the Federal Court. As a result, guidance on the scope of the principles may be available very shortly. Patentees and their counsel will need to follow the development of this jurisprudence with care as they file, prosecute and assert patents in Canada.