

SUPREME COURT OF CANADA UPHOLDS SELECTION PATENTS



Katie Wang
Shapiro Cohen

In the recent decision of *Apotex Inc. v. Sanofi Synthelabo Canada Inc.*, 2008 SCC 61, the Supreme Court of Canada considered the validity of selection patents. The decision related to Sanofi's application seeking to prohibit Health Canada from issuing a Notice of Compliance to Apotex until the expiry of Sanofi's Canadian patent no. 1,336,777 ('777 patent), which claims clopidogrel bisulfate, the active ingredient of Sanofi's Plavix as an anti-coagulant inhibiting platelet aggregation in the blood. At the centre of the litigation was the validity of the '777 patent, a selection patent, as Sanofi had previously disclosed in patent no. 1,194,875 ('875 patent), a genus or class of compounds useful in inhibiting platelet aggregation activity in the blood, including clopidogrel bisulfate.

On the question of anticipation, the court adopted a two-step approach:

1. Prior disclosure: A person skilled in the art is reading the prior patent to understand whether it discloses the special advantages of the second invention. No trial and error is permitted. If in reading the genus patent, there is no discovery of the special advantages of the selection patent, the genus patent does not anticipate the selection patent and the disclosure requirement to prove anticipation fails.
2. Enablement: A person skilled in the art must have been able to perform the invention without undue burden. If an inventive step were required to get to the invention of the second patent, the specification of the first patent would not have provided enabling disclosure. The skilled person may use his or her common general knowledge of the relevant art at the relevant time to supplement information contained in the prior genus patent and may conduct routine trials without being considered an undue burden, but prolonged or arduous trial and error experiments would not be considered routine.

In relation to obviousness, the court considered UK and US jurisprudence, noting that in both jurisdictions, consideration of "obvious to try" can be relevant, and adopted a four-step approach:

- Step 1: (a) Identify the notional person skilled in the art, and
(b) Identify the relevant common general knowledge of that person.
- Step 2: Identify the inventive concept of the claim in question, or if that cannot readily be done, construe it.
- Step 3: Identify what, if any, differences exist between the matter cited as forming part of the 'state of the art' and the inventive concept of the claim or the claim as construed.

- Step 4: If viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps that would have been obvious to the person skilled in the art or do they require any degree of invention?

The court noted that "obvious to try" may be appropriate as part of the fourth step for inventions in areas where "advances are often won by experimentation", such as the pharmaceutical industry. For a finding that an invention was "obvious to try", there must be evidence to convince a judge on a balance of probabilities that it was more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough. The court provided a non-exhaustive list of factors as possible considerations:

1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
3. Is there a motive provided in the prior art to find the solution the patent addresses?

The court noted that another important factor may arise from the actual course of conduct that culminated in the making of the invention.

Finally, on double patenting, the court noted that a generalised concern about evergreening is not a justification to attack selection patents. The court held that a party other than the owner of the genus patent may seek a selection patent, so evergreening does not arise. Secondly, selection patents encourage improvements over the subject matter of the original genus patent.

The court applied the tests using the facts of the case and upheld the '777 patent. The decision is viewed as a victory for innovative pharmaceutical companies in that the Supreme Court of Canada has expressly endorsed the doctrine of selection patents, and refined the tests for anticipation, obviousness and double patenting.

Katie Wang is an attorney at law and a registered Canadian patent agent at Shapiro Cohen. She can be contacted at: kwang@shapirocohen.com