



SUPREME COURT OKAYS SELECTION PATENTS WHILE REFINING NOVELTY AND OBVIOUSNESS TESTS

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The subject of selection patents was addressed by a recent unanimous decision of the Supreme Court of Canada in *Apotex Inc. v. Sanofi Synthelabo Canada Inc.*¹ In this case, the Supreme Court reaffirmed the rules associated with the granting and validity of selection patents in Canada, more particularly in the pharmaceutical field. In rendering its decision, the Supreme Court also clarified important judicial tests to be applied when evaluating the novelty and obviousness of inventions in general. Given that novelty and obviousness are issues that are at the core of the validity of any patent and are thus frequently addressed in most patent court cases, this case is likely to be cited or considered often in future Canadian patent jurisprudence.

Factual Background

Sanofi-Synthelabo Canada Inc. (Sanofi) is the owner of two patents. The first patent '875 generally claims a family of 250 000 molecules having anti-coagulant properties. The second patent '777 claimed a more specific molecule from this family, known as "Clopidogrel" and its bisulfate salt. Clopidogrel bisulfate also has anti-coagulant properties and is marketed by Sanofi under the trade name Plavix®. A product based on the original family of 250 000 molecules described in '875 typically contains equal parts of mirror-image molecules called enantiomers. The '777 patent disclosed a method of extracting a selected one of these two enantiomers which offered advantages that the mirror-image counterpart molecule did not.

In 2003, the Canadian generic pharmaceutical company Apotex Inc. (Apotex) notified the Minister of Health of its intention to commercialize a generic version of Plavix®, and thus attempted to duly obtain a Notice of Compliance for commercializing the medicine. In doing so, Apotex served a Notice of Allegation to

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Sanofi, claiming that its commercialization of the generic version of Plavix® would not affect Sanofi's rights conferred by the '777 patent, since Apotex would not be infringing this patent. Indeed, in its Notice of Allegation, Apotex claimed that the '777 patent was invalid for lack of novelty and obviousness in view of the more general '875 patent. Additionally, Apotex suggested that the '777 patent was invalid on the grounds of double patenting.

Sanofi then sought an order from the Federal Court of Canada prohibiting the Minister of Health from issuing a Notice of Compliance on the grounds that Apotex would indeed infringe the '777 patent by commercializing a generic version of Plavix®. The Federal Court granted the order and concluded that the '777 was indeed valid. The Federal Court of Appeal upheld the lower court's decision, which brought Apotex to appeal its case to the Supreme Court of Canada.

The main issue addressed by the Supreme Court consisted of determining whether selection patents are valid in principle or on the facts of this case. The validity of selection patents was thus assessed on the grounds of anticipation, obviousness and double patenting.

Selection Patents

In his reasons representing the unanimous view of the majority of the Court, Justice Rothstein first confirmed the three conditions to be satisfied for a selection patent to be valid. According to the Court, these conditions were established in the oft-cited and well accepted decision of Maugham J. in *In re I. G. Farbenindustrie A. G.'s Patents* (1930), 47 R.P.C. 289 (Ch. D.):

1. There must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members.
2. The whole of the selected members (subject to "a few exceptions here and there") possess the advantage in question.
3. The selection must be in respect of a quality of a special character peculiar to the selected group. If further research revealed a small number of unselected compounds possessing the same advantage, that would not invalidate the selection patent. However, if research showed that a larger number of unselected compounds possessed the same advantage, the quality of the compound claimed in the selection patent would not be of a special character.²

² *Ibid.* at paragraphs 8-11.

This represented a starting point from which the validity of the '777 patent was to be evaluated with respect to anticipation, obviousness and double patenting.

Clarification of the Law on Anticipation

In recent years, the courts have established that the test for anticipation in Canada is described in *Beloit Canada Ltd. v. Valmet OY* (1986), 8 C.P.R. (3d) 289 (F.C.A.), at p. 297:

One must, in effect, be able to look at a prior, single publication and find in it all the information which for practical purposes, is needed to produce the claimed invention without the exercise of any inventive skill. The prior publication must contain so clear a direction that a skilled person reading and following it would in every case and without possibility of error be lead to the claimed invention.³

In the case at hand, Justice Rothstein affirmed the validity of this test, but stated that it could lead to stringent interpretations as the “exact invention” would have to be already made or publicly disclosed. The Court then referred to a decision of the House of Lords (United Kingdom) to provide a refinement of the approach set out in *Beloit*.

In *Synthon B.V. v. SmithKline Beecham plc*⁴, the House of Lords set out two requirements for anticipation, prior disclosure and enablement. The enablement requirement is not expressed in the *Beloit* test.

The prior disclosure requirement is expressed in *Synthon* as follows:

If I may summarise the effect of these two well-known statements [from *General Tire and Hills v. Evans*], the matter relied upon as prior art must disclose subject matter which, if performed, would necessarily result in an infringement of the patent ... It follows that, whether or not it would be apparent to anyone at the time, whenever subject matter described in the prior disclosure is capable of being performed and is such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied.⁵

The Court then went on to state that once the prior disclosure requirement is satisfied, the person skilled in the art is assumed to be willing to make trial and error

³ *Ibid.* at paragraph 20.

⁴ [2006] 1 All E.R. 685, [2005] UKHL 59

⁵ *Supra* note 1 at paragraph 25

experiments to get it to work. According to Justice Rothstein, “For purposes of enablement, the question is no longer what the skilled person would think the disclosure of the prior patent meant, but whether he or she would be able to work the invention.”⁶

The Court then had to address two issues: (1) what constitutes disclosure at the first stage of the test for anticipation, and (2) how much trial and error or experimentation is permitted at the enablement stage?⁷

The Court assessed the disclosure requirement with respect to genus and selection patents by stating that the genus patent does not anticipate the selection patent if there is an absence of a discovery of special advantages associated with the selection patent at the stage of development of the genus patent. No trial and error experimentation is allowed at this point.

For the enablement requirement, Justice Rothstein considered recent UK jurisprudence and set out four factors to be applied:

1. Enablement is to be assessed having regard to the prior patent as a whole including the specification and the claims. [...]
2. The skilled person may use his or her common general knowledge to supplement information contained in the prior patent. [...]
3. The prior patent must provide enough information to allow the subsequently claimed invention to be performed without undue burden. [...]
4. Obvious errors or omissions in the prior patent will not prevent enablement if reasonable skill and knowledge in the art could readily correct the error or find what was omitted.⁸

In view of these factors, the Court concluded that the ‘777 patent was not anticipated.

Clarification of the Law on Obviousness

In recent years, courts have also established that the test for obviousness in Canada is also set out in *Beloit*:

⁶ *Ibid.* at paragraph 27.

⁷ *Ibid.* at paragraph 30.

⁸ *Ibid.* at paragraph 37.

The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be asked is whether this mythical creature (the man in the Clapham omnibus of patent law) would, in the light of the state of the art and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy.⁹

The Court stated that this test precludes the possibility of using an “obvious to try” concept when evaluating obviousness. This concept has been generally accepted in recent American and UK case law. Justice Rothstein thus adopted a four-step approach to obviousness described in *Pozzoli SPA v. BDMO SA*¹⁰, which restates an obviousness test originally stated in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*¹¹:

- (1) (a) Identify the notional “person skilled in the art”; (b) Identify the relevant common general knowledge of that person;
- (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
- (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;
- (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?¹²

The Court then proposed that the “obvious to try” issue could arise when assessing the fourth step, especially for inventions that require development through experimentation. The Court thus offered a non-exhaustive list factors to consider when determining whether an invention was obvious to try:

- 1) Is it more or less self-evident that what is being tried ought to work? [...]
- (2) What is the extent, nature and amount of effort required to achieve the invention? [...]
- (3) Is there a motive provided in the prior art to find the solution the patent addresses?¹³

⁹ *Ibid.* at paragraph 52.

¹⁰ [2007] F.S.R. 37, [2007] EWCA Civ 588.

¹¹ [1985] R.P.C. 59 (C.A.)

¹² *Supra*, note 1 at paragraph 67.

¹³ *Ibid.* at paragraph 69.

Using these different approaches to address the facts of the case, the Court concluded that the '777 patent was not obvious in view of patent '875.

Double Patenting

In this case, Apotex also claimed that selection patents should be challenged on the basis of double patenting as the patent holder can “evergreen” a first invention by extending the original period of monopoly accorded by an original genus patent through filing of a subsequent selection patents. The Court rejected this claim based on two arguments. Firstly, a selection patent may be obtained by a party who is not the owner or original inventor of the genus patent. Consequently, the evergreening concern does not arise in all cases. Secondly, the possibility of obtaining selection patents encourages innovation as researchers can be motivated to search for improvements over the subject matter disclosed in the original genus patent.

Conclusion

In this decision, the Supreme Court of Canada has confirmed the validity of selection patents, as long as they respect the requirements of novelty and non-obviousness. This confirmation should favour patentees in the pharmaceutical field and motivate them to search for further improvements with respect to existing genus patents. The Supreme Court also used this occasion to refine the more general tests for evaluating the novelty and obviousness of inventions and thus better align Canadian case law with American and UK jurisprudence. However, as this judgment was based on patents governed by the pre-1989 version of the Canadian *Patent Act*, it remains to be seen if any of the concepts introduced in this decision will be followed, distinguished or rejected in future Canadian patent court cases.



