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Canadian Supreme Court Upholds the Validity of Selection Patents and Refines the Law of Anticipation and Obviousness

On November 6, 2008, the Supreme Court of Canada released a unanimous landmark decision, *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, involving a Canadian patent for a blockbuster anti-coagulant drug marketed under the brand name PLAVIX by Sanofi-Synthelabo Canada Inc.

Apotex initially served a Notice of Allegation (“the NOA”) under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 on Sanofi, for the purpose of obtaining a Notice of Compliance (“NOC”) from the Minister of Health for a generic version of PLAVIX. One of the bases for the NOA was that Sanofi’s selection patent, CA 1,336,777 (“the ’777 patent”), was invalid for anticipation, obviousness and double patenting. In response to the NOA, Sanofi applied to the Federal Court for a Prohibition Order, i.e. an order prohibiting the Minister from issuing an NOC to Apotex. The Federal Court granted the order to Sanofi ((2005), 271 F.T.R. 159, 2005 FC 390), and the Federal Court of Appeal dismissed Apotex’s appeal ((2006), 282 D.L.R. (4th) 179, 2006 FCA 421).

The Supreme Court held that allegations of invalidity of the patent raised by Apotex were unjustified.

SELECTION PATENTS

Selection patents are patents that claim one or more members of a previously disclosed and patented class (i.e. genus). Until this decision, there was much debate in Canada over whether selection patents are valid in principle. Many argued that such patents are invalid for violating the requirements for novelty and obviousness, as well as the prohibition against double patenting.

In upholding the validity of selection patents in principle, the SCC noted that selection patents do not differ in nature from any other patent. Citing with approval passages from the leading decision of Mr. Justice Maugham in *In re I. G. Farbenindustrie A. G.’s Patents* (1930), 47 R.P.C. 289 (Ch. D.), at pp. 321-323, the Supreme Court stated that, in order to be valid, the selected member must be novel and possess a special property of an unexpected character that would allow the invention to satisfy the “inventive step” requirement. The following criteria must also be satisfied:

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”) must 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.

ANTICIPATION

During the Federal Court proceedings, the applications judge had relied on the Supreme Court's earlier decision in *Free World Trust v. Electro Sante Inc.*, [2000] 2 S.C.R. 1024, 2000 SCC 66, at para. 26, which approved the aspect of the test for anticipation set forth by the Federal Court of Appeal in *Beloit Canada Ltd. v. Valmet OY* (1986), 8 C.P.R. (3d) 289 (F.C.A.), at p. 297 that a 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." The applications judge synthesized the accepted case law to arrive at a definition of anticipation as meaning "that the exact invention has already been made and publicly disclosed."

The Supreme Court held that the Federal Court had overstated the stringency of the test for anticipation that the "exact invention" must have already have been made and publicly disclosed. The Court adopted the approach contained in the 2005 decision of the House of Lords in *Synthon B.V. v. SmithKline Beecham plc*, [2006] 1 All E.R. 685, [2005] UKHL 59, which is a refinement of the approach set forth in the Federal Court of Appeal decision in *Beloit Canada Ltd. v. Valmet OY*. The refined approach to anticipation specifically distinguishes between two requirements for anticipation: prior disclosure and enablement.

There is prior disclosure of claimed subject matter if the performance of the teachings of prior art would necessarily result in infringement of the patent. The prior art is to be read from the standpoint of the person skilled in the art in respect of the disclosure. The skilled person is to try to understand what the author of the prior art intended. In this context, there is no room for trial and error or experimentation by the skilled person.

In the context of genus and selection patents, if the genus patent does not disclose the special advantages of the subject matter claimed in the selection patent, and if the genus patent does not disclose that such subject matter was previously made, then there is no prior disclosure by the genus patent.

The invention is enabled if the person skilled in the art would have been able to perform or work the invention. Here, trial and error is permitted.

On the issue of how much trial and error or experimentation is permitted before a prior disclosure is deemed not to constitute an enabling disclosure, the Court held that the exercise of an inventive step to get to the invention of the second patent is sufficient to disqualify the specification of the first patent for not providing enabling disclosure. However, the Court also noted that even if no inventive step is required, the skilled person must still be able to perform or make the invention of the second patent without undue burden (including routine trials). When considering whether there is undue burden, the skilled person is permitted to use his or her common general knowledge to supplement information contained in the prior patent and the nature of the invention must be taken into a count. If the invention is in a field of technology in which trials and experiments are generally carried out, the threshold for undue burden will tend to be higher than in circumstances in which less effort is normal. As to how long a skilled person can reasonably be expected to perform any required trial and error experimentation, there are no precise time limits; however, the Court noted that such experiments must not be prolonged or arduous, as such would not be considered routine, even in fields of technology in which trials and experiments are generally carried out.

Enablement is to be assessed having regard to the prior patent as a whole including the specification and the claims. There is no reason to limit what the skilled person may consider in the prior patent in order to disco

how to perform or make the invention of the subsequent patent. The entire prior patent constitutes prior art. 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. The Court deliberately refused to consider whether enablement for purposes of anticipation was the same as the test for sufficiency of a patent specification under the Canadian *Patent Act*, s. 34(1)(b) of the pre-October 1, 1989 Act, now s. 27(3)(b).

OBVIOUSNESS

During the Federal Court proceedings, the applications judge held that the test for obviousness as set down in *Beloit* did not accommodate a “worth a try” test by the skilled person. The Supreme Court considered developments in obviousness law in the UK (*Generics (UK) Ltd. v. H. Lundbeck A/S*, [2008] R.P.C. 19, [2008] EWCA Civ 311) and in the US (*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007)), and concluded: “It is now clear that both jurisdictions accept that an ‘obvious to try’ test can be relevant in an obviousness inquiry.” Following the lead of UK and US courts, the Supreme Court accepted “obvious to try” or “worth a try” as one of a number of factors that should be considered, having regard to the context and the nature of the invention, but cautioned against over-reliance on this factor: “It is only one factor to assist in the obviousness inquiry. It is not a panacea for alleged infringers. The patent system is intended to provide an economic encouragement for research and development. It is well known that this is particularly important in the field of pharmaceuticals and biotechnology.”

Moreover, in order to succeed in an obviousness attack based on a charge that the invention was “obvious to try,” there must be convincing evidence, on a balance of probabilities, that it was “more or less self-evident to try to obtain the invention” (i.e. a mere possibility that something might turn up is not enough).

The Supreme Court then cited with approval the four-step approach to assessing obviousness first outlined by Oliver L.J. in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*, [1985] R.P.C. 59 (C.A.), and recently restated by Jacob L.J. in *Pozzoli SPA v. BDMO SA*, [2007] F.S.R. 37, [2007] EWCA Civ 588, at para. 23:

- (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?

The Court noted that it would only be in step (4) of the *Windsurfing/Pozzoli* approach to obviousness that the issue of “obvious to try” would arise, and that it is only appropriate to consider the issue in areas of endeavour where advances are often won by experimentation (e.g. some inventions in the pharmaceutical industry where there are many chemically similar structures that can elicit different biological responses and offer the potential for significant therapeutic advances).

Having regard to the foregoing, the Court offered a non-exhaustive list of factors to consider if it is determined

that an “obvious to try” test is warranted:

- (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?

Finally, the Court noted that the actual course of conduct which culminated in the making of the invention can be relevant. Thus, where an invention is arrived at quickly, easily, directly and relatively inexpensively, in light of the prior art and common general knowledge, that may be evidence supporting a finding of obviousness. On the other hand, if time, money and effort were expended in research in order to arrive at the invention, including fruitless “wild goose chases,” such evidence may support a finding of non-obviousness.

DOUBLE PATENTING

Apotex challenged the validity of the ‘777 patent on the basis of double patenting, in that the doctrine of selection patents allows a patent holder to “evergreen” an invention. Since the original genus patent is granted for a finite period of years, if a selection patent is later obtained by the owner of the genus patent covering the same invention as the genus patent, the number of years the owner is entitled to exclude others from making or using the invention is extended, contrary to the limited period of exclusivity provided by the original patent.

The Court dismissed Apotex’s attack on the doctrine of selection patents on two grounds. First, selection patents may be sought by parties other than the owner of the original genus patent, in which case evergreening does not arise. Second, relying on the fundamental bargain theory underlying the patent system, the Court noted “importantly, selection patents encourage improvements by selection.”

The court agreed with Apotex that a challenge to patent validity based on double patenting does not require the existence of identical language in the two patent claims, but also noted that the wording of the claims, however different, must claim the same invention. According to the facts of the case, the Court held that the invention of the genus patent was not the same as the invention of the ‘777 selection patent “because the former is broader than the latter” and was not invalid for “obviousness-type” double patenting because the claims of the selection patent reflected a patentably distinct compound from that claimed in the genus patent.

To read the complete decision, please go to:

<http://scc.lexum.umontreal.ca/en/2008/2008scc61/2008scc61.html>

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