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Supreme Court of Canada Upholds Selection Patents

By Peter Wilcox, Andrew Bernstein, Conor McCourt and Damien McCotter

Selection patents represent a crucial instrument for protecting beneficial technological advances. This is particularly so for the pharmaceutical and biotechnology industries, in which innovators commonly seek protection for one or more members of a previously known class of therapeutic compounds on the basis of special qualities.

On November 6, 2008, in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*,[1] the Supreme Court of Canada unanimously confirmed that a selection patent (described as a patent whose subject matter is a fraction of a larger known class of compounds that was the subject matter of a prior patent) is permissible under the Canadian *Patent Act.* Indeed, the Court confirmed that a selection patent "does not in its nature differ from any other patent," and its validity should be evaluated by the usual statutory criteria, such as novelty and inventiveness. The Court also refined the tests for these important prerequisites to patentability.

Facts

The selection in this *Sanofi* case was clopidogrel bisulfate, marketed as Plavix. The invention was the selection of clopidogrel and its bisulfate salt. A prior patent disclosed a class of compounds that included clopidogrel, but not its beneficial properties, which include enhanced inhibition of platelet aggregation (clotting) and a superior toxicity and tolerability profile. The prior patent also did not disclose the benefit of the bisulfate salt, which was found to have superior properties over other salts.

Earlier Decisions and the Selection Patents Controversy

Apotex argued that the patent for clopidogrel bisulfate was invalid for lack of novelty, obviousness and double patenting, because it had been disclosed generically in the prior patent. The lower courts disagreed, finding that it was a valid selection from the previous class. Apotex appealed to the Supreme Court, asking it to abolish selection patents altogether. The Court refused, holding that an inventor who makes and discovers the special advantages of a member of a class should be entitled to a patent for that member. The Court then considered the validity of the clopidogrel bisulfate patent in light of Apotex's validity attacks: anticipation, obviousness and double patenting. In doing so, the Court refined the law for each of these requirements.

To discuss these issues, please contact the authors.

For media calls, please contact Stuart Wood, Director, Marketing & Business Development, 416.865.8205.

To contact us, please email info@torys.com.

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[1] 2008 SCC 61 [*Sanofi*]. Torys LLP represented the intervener BIOTECanada in this case.

Anticipation

The Court noted two requirements for the test for anticipation: prior disclosure and enablement. The test is not simply whether "the exact invention has already been made and publicly disclosed."

"Prior disclosure" means that the prior patent must disclose subject matter that, if performed, would necessarily result in infringement of that patent. At this first stage, the skilled reader must find a disclosure: the skilled person cannot say that there would be a disclosure with some trial and error or experimentation. The skilled person is simply reading the prior patent to understand and try to find the disclosure of the invention – and not as a precursor. Most importantly in the context of selection patents, if the genus patent does not disclose the special advantages of the invention covered by the selection patent, the disclosure requirement is not met and the selection patent is therefore not anticipated by the genus patent.

"Enablement" means that the person skilled in the art would have been able to perform the subject matter of the prior art constituting the asserted anticipation. For purposes of enablement, the question is not what the skilled person would think the disclosure of the prior patent meant, but whether he or she would be able to work the subject matter. The Court asked itself, how much trial and error and experiment is permitted at the enablement stage? The answer: the prior patent must provide enough information to allow the subsequently claimed invention to be performed without "undue burden." Routine trials are acceptable, but inventive steps are not permitted. If inventive steps are required, the prior art will not be considered enabling.

The Court concluded that since the genus patent in this case did not disclose the special advantages of the dextro-rotatory isomer and of its bisulfate salt, the invention of the selection patent was not disclosed and therefore was not anticipated.

Obviousness

The Court began its obviousness analysis with the well-known test in *Beloit*: whether the skilled person, in light of the state of the art and common general knowledge, would have come directly and without difficulty to the solution taught by the patent. Since *Beloit*, lower courts had explicitly rejected an "obvious to try" approach. Because both the United States and United Kingdom have accepted a (stringent) version of an "obvious to try" test, the Court examined the question whether it might be appropriate, in certain circumstances, to use a similar standard in Canada.

Noting that "obvious to try" is not a mandatory test in the United States and United Kingdom, the Court stated that it must be approached cautiously. The Court concluded that in Canada, it is not sufficient if an invention was simply "obvious to try;" rather, an invention would be obvious when it is "more or less self-evident that what is being tested ought to work." The mere possibility that something might turn up is simply not enough. Moreover, the Court was clear that the "obvious to try" inquiry is but one factor to assist in the obviousness inquiry, which becomes relevant only in narrow circumstances. The invention must still be self-evident from the prior art and common general knowledge to satisfy the obviousness test.

On the facts of this case, the Court held that Apotex had not established obviousness.

Double Patenting

Apotex argued that a genus patent and selection patent covering the same compound necessarily amounted to double patenting. The Court rejected this argument, stating that a generalized concern about

evergreening does not justify an attack on the doctrine of selection patents. The reasons are two-fold: first, a selection patent may be sought by a party other than the inventor or owner of the original genus patent. Second, selection patents encourage improvements by selection. The Court agreed that the focus in a double-patenting challenge is on the claims of the two patents rather than on the disclosure. Because the claims of the genus patent are broader than those of the selection patent, there cannot be "same-type" double patenting. Furthermore, where a selection patent claims a compound that is patentably distinct from the genus patent (i.e., not obvious), it will not be invalid for obviousness double patenting.

On the facts of this case, the Court found that there was no double patenting.