



Rx IP UPDATE

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Supreme Court upholds PLAVIX selection patent

In a unanimous decision, the Supreme Court of Canada has upheld the validity of a patent claiming a single isomer despite the grant of an earlier patent claiming a broad genus, which included the isomer, its mirror-image enantiomer, and the mixture of the two (the racemate): *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61. Justice Rothstein, writing for the Court, upheld the lower and appellate court rulings (*Apotex v. Sanofi-Synthelabo*, 2005 FC 390, aff'd 2006 FCA 42), which rejected Apotex's contention that the patent claiming clopidogrel bisulfate (PLAVIX) was invalid on the bases of anticipation, obviousness and double patenting. The decision is the first time that the Supreme Court has expressly addressed the doctrine of selection patents.

The patent at issue ('777) discloses and claims clopidogrel and its bisulfate salt. Clopidogrel (the dextro-rotary isomer) is disclosed by the '777 patent to be less toxic and better tolerated than the levo-rotary isomer and the racemate (the mixture of the two isomers). The earlier patent ('875) encompassed clopidogrel bisulfate within its claims and included an example describing the racemate.

In a proceeding under the *Patented Medicines (Notice of Compliance) Regulations*, Apotex asserted that the '777 patent was invalid in view of the earlier '875 patent. The courts below had rejected Apotex's assertions and prohibited the Minister of Health from issuing a notice of compliance to Apotex for its generic product.

Justice Rothstein began by noting the distinction in the jurisprudence between originating patents and "patents based on a selection of compounds from those described in general terms and claimed in the originating patent." He also noted the conditions that must be satisfied for a selection patent to be valid:

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.

The Court then turned to a consideration of anticipation, obviousness and double patenting.

In considering **anticipation**, the Court laid down two requirements: prior disclosure and enablement, which it termed a “refinement” of the approach set out in the jurisprudence.

As to prior disclosure, a genus patent does not anticipate the species patent if in reading the genus patent, the special advantages of the selection patent are not disclosed. In the case of clopidogrel, it was not made and its special advantages were not known; the invention was therefore not disclosed in the genus patent ('875).

As to whether the prior disclosure was enabling, an inventive step is not permitted. The Court outlined a non-exhaustive list of factors, including that the prior patent must provide enough information to allow the subsequently claimed invention to be performed without undue burden. While the Court did not decide the issue, it noted that one might infer, on the basis of the work done by the patentee to separate the single isomer, that the Applications Judge would have found an undue burden in this case. The Court concluded that the '777 patent was not anticipated.

On **obviousness**, the Court considered U.K. and U.S. jurisprudence, noting that in both jurisdictions, “obvious to try” can be relevant to an obviousness inquiry. However, the Court expressly noted that the “obvious to try” test “will work only where it is very plain or ... more or less self-evident that what is being tested ought to work” and that it is only one factor to assist in the obviousness inquiry; “[i]t is not a panacea for alleged infringers”. The Court noted: “[m]ere possibility that something might turn up is not enough.”

The Court endorsed a four-step approach to obviousness (the restated *Windsurfing* questions):

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 that would have been obvious to the person skilled in the art or do they require any degree of invention?

After noting that “obvious to try” may be appropriate as part of the fourth step of the obviousness inquiry in considering some pharmaceutical inventions, the Court provided a non-exhaustive list of factors as possible considerations. These include:

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 considering the actual course of conduct that culminated in the making of the invention. Evidence of the history of the invention may therefore be relevant.

On the facts of the case, the Court applied the four steps of the restated *Windsurfing* questions, including the obvious to try test, finding, “it was not self-evident from the '875 patent or common general knowledge what the properties of the dextro-rotatory isomer of this racemate would be or what the bisulfate salt's beneficial properties would be and therefore that what was being tried ought to work”. The Court concluded that the invention was not obvious.

Finally, the Court addressed the application of **double patenting** in the context of selection patents. Apotex challenged the validity of the doctrine of selection patents itself on this

basis, submitting that a selection patent claims the same invention as the genus patent and, as a result, the selection patent cannot be valid. While the Court recognized that “evergreening” is a legitimate concern, it is not a basis for rejecting selection patents. First, the Court noted that selection patents are not limited to the owner or inventor of the original genus. Second, selection patents encourage improvements. On the facts, the Court rejected Apotex’s arguments of same invention and obviousness double patenting.

The decision in *Apotex v. Sanofi-Synthelabo* is a significant victory for pharmaceutical innovators. The Supreme Court has expressly endorsed the concept of selection patents, recognizing the importance and nature of ongoing innovation. Moreover, the Court has significantly refined and clarified the tests for anticipation, obviousness and double patenting. However, the full impact of these refinements in future litigation remains to be seen.

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