Before refusing a patent application, the Canadian Patent Office convenes a panel of the Patent Appeal Board (the “PAB”) to review the application and provide a recommendation to the Commissioner of Patents. This recommendation and the Commissioner’s determination on the allowability of the application are published together as a “Commissioner’s Decision”.

While Commissioner’s Decisions do not get as much publicity as decisions from Canadian courts, they do provide valuable insight into how the Patent Office handles patent applications that are rejected by a Canadian Examiner.

On December 16, 2016, the Commissioner of Patents released her decision in the case of Canadian Patent Application No. 2,622,609 (the “‘609 Application”) filed by F. Hoffmann-La Roche AG (“Roche”) and entitled “The Use Of An Erythropoietin Moiety To Treat Neurodegenerative Disorders”. The ‘609 Application seeks to claim the use of polyethylene glycol (“PEG”) modified erythropoietin (“EPO”), so-called “PEGylated EPO”, to treat neurodegenerative disorders.

The sole issue in the Commissioner’s Decision was whether the claimed invention would have been obvious to a skilled person, particularly in view of prior art disclosing the use of PEGylated EPO for other therapeutic applications and the use of unmodified EPO for treating neurodegenerative disorders. To treat a neurodegenerative disorder, a molecule that is injected into the blood stream must be able to pass through the blood-brain barrier. While one of the prior art references disclosed that EPO was capable of passing this barrier, there was no prior art disclosing that PEGylated EPO crossed the blood-brain barrier.

Test for Obviousness in Canada

In Apotex Inc. v. Sanofi-Synthelabo Canada Inc., 2008 SCC 61 at para. 67 (“Apotex”), the Supreme Court of Canada set out a four-part test for determining obviousness:

(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 Supreme Court further stated in Apotex that an “obvious to try” inquiry may arise in the fourth step of the test in “areas of endeavor where advances are often won by experimentation”. Where an obvious to try test is warranted, the following non-exhaustive factors are to be considered:

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?

Since the Apotex decision, the Federal Court of Canada has stated that “[t]he obviousness and obvious to try inquiries should not be conceived of as discrete inquiries. Rather, the four-step obviousness test always governs the analysis, with the notion of whether or not a particular experiment was ‘obvious to try’ comprising ‘only one factor to assist in the obviousness inquiry’” [AstraZeneca Canada Inc. v. Apotex Inc., 2014 FC 638 at para. 287, internal citations omitted].

**Application of Law to the ‘609 Application**

In the present case, Roche and the PAB were in agreement regarding the first three steps of the obviousness test. Where they differed was in step four: whether the differences between the state of the art and the inventive concept of the claims would have been obvious to the person skilled in the art.
Roche’s position was that the establishment that PEGylated EPO can cross the blood-brain barrier was unexpected and therefore the use of PEGylated EPO for treating neurodegenerative disorders was not obvious. Roche argued that it would not be obvious for PEGylated EPO to cross the blood-brain barrier because PEGylated EPO is larger and has increased hydrophilicity over EPO.

Conversely, the PAB’s position was that the step of substituting PEGylated EPO to treat neurodegenerative disorders would have been obvious to the skilled person. The Commissioner’s Decision considered motivation in its obviousness analysis, finding that it existed in the prior art based on the known advantages of PEGylated molecules. Interestingly, this is the only factor of the obvious to try test that the PAB considered. The PAB did not consider whether it was more or less self-evident that substituting PEGylated EPO for non-PEGylated EPO in the method disclosed in the cited prior art ought to work. Rather, the Commissioner’s Decision concurred with the PAB’s analysis that “the skilled person would not see any negative indicators of success if PEGylated EPO were to be used instead of non-PEGylated EPO”.

The PAB found that the expected manner of movement of EPO across the blood-brain barrier is by receptor-mediate transport involving endocytosis, which can operate independently of a molecule’s size and hydrophilicity. The PAB also noted that the prior art document that disclosed that EPO can cross the blood-brain barrier also broadly suggested the use of any EPO derivative.

The PAB therefore concluded that the subject-matter of the claims of the ‘609 Application were obvious and recommend that the application be refused. The Commissioner of Patents concurred with this recommendation and refused the application. Roche has six months from the date of the Commissioner’s Decision in which to appeal the decision to the Federal Court of Canada.

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