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The Federal Court of Appeal Clarifies the â€œObvious to Tryâ€• Test

The Federal Court of Appeal (“FCA”) has clarified the extent of flexibility afforded when undertaking the “Obvious to Try” test in *Amgen v Pfizer, 2020 FCA 188*. Although it ultimately cautioned against a segmented approach, the FCA did not dismiss the possibility that experimental steps could be assessed individually in order to make conclusions about an experiment as a whole, particularly with respect to the Self-Evident and Extent of Effort factors of the test. Despite agreeing that the Federal Court (“FC”) could have been more expansive and all-embracing in its overall conclusion, the FCA did not deem the FC’s lack of analysis to have amounted to a palpable and overriding error.

Federal Court’s Decision

Amgen v Pfizer, 2020 FC 522 was the first trial decision under the amended *Patented Medicines (Notice of Compliance) Regulations.* The FC found that all of the claims of the 537 Patent (also known as the Filgrastim Patent) asserted by Amgen were obvious and therefore invalid. The 537 Patent, an “Old Act” Patent filed in 1986 and issued in 2007, related to the production of granulocyte colony-stimulating factor (G-CSF) using recombinant genetic technology.

The FC found that the prior art disclosed the purification of naturally occurring G-CSF, in addition to methods for cloning, making, and testing recombinant proteins. The FC also held that there would have been motivation to clone and purify the recombinant version of G-CSF.

In determining whether the differences identified between the state of the art and the alleged invention constituted steps that would have been obvious to the skilled person (i.e., whether the final step in the obviousness test were satisfied), the FC applied the “Obvious to Try” test.

Under the first factor in the “Obvious to Try” test – the Self Evident Factor – the FC found that the skilled person would have found it self-evident that the steps leading to the Claim 43 polypeptide of the 537 Patent ought to work. In particular, the FC found that it would have been more or less self evident to the skilled person that each of the following steps, viewed

individually, ought to work:

i. Obtaining Adequate Amino Acid Sequence Information
ii. Screening cDNA Library
iii. Addressing Glycosylation
iv. Adding an N-Terminal Methionine
v. Solubilizing and Refolding Proteins from Inclusion Bodies

The FC also held that the skilled person was not risk averse and would not be discouraged from attempting the G-CSF project due to known potential problems with identifiable solutions. The FC went on to distinguish the G-CSF project from prior cases that were found *not* to be obvious to try, which involved compounds or combinations with unknown properties that had not previously been made or isolated. In this case, the G-CSF project involved making a recombinant version of a natural protein with known properties.

Under the second factor of "Obvious to Try" test – the Extent of Effort Factor – the FC again concluded that the G-CSF project was obvious to try. In other words, the extent, nature, and amount of effort required to achieve the Claim 43 polypeptide of the 537 Patent would have been within the skilled person's capabilities as of the priority date. Although the FC found that the skilled person would have encountered potential challenges at each step, it ultimately held that any potential challenges could be addressed with *skill* and did not require inventiveness.

In reaching its decision, the FC highlighted the fact that Pfizer's three experts each arrived at the same steps regarding what the skilled person would have done with one of the pieces of prior art without awareness to the 537 Patent. The FC ultimately concluded that it was self-evident to try to obtain the invention of the 537 Patent.

Appeal Decision

Amgen appealed, submitting that the FC had committed a reviewable error when applying the test for obviousness. The FCA dismissed their appeal and upheld the FC's decision that claims 43-47 of the 537 Patent were obvious and invalid.

First, Amgen submitted that the FC had applied the wrong legal standards in the test for obviousness, which includes failing to consider whether the trials were non-routine and prolonged and arduous under the Extent of Effort Factor. Amgen argued that the "creative" or "inventive" standard had been wrongly substituted. The FCA dismissed this assertion, taking no issue

with the FC's approach to the Extent of Effort Factor.

Second, Amgen submitted that as a matter of law, a series of obvious steps, viewed together, may still be deemed non-obvious when evaluated collectively. Amgen argued that the FC erred in failing to consider the "cumulative effect" argument. The FC ultimately rejected this assertion, stating that there was no evidence that the FC had rejected the "cumulative effective" argument, but rather it did not accept the argument on the evidence in this case.

Although the FCA acknowledged that the FC may have adopted a "segmented approach" to its obviousness analysis, this was considered to be merely an artefact of the manner in which the case was argued. It did, however, caution that an overly segmented approach could lead to error but failed to explain how to overcome such an approach aside from applying the obviousness factors from the jurisprudence with due attention.

Implications

This decision provides guidance on how the FC should approach the "Obvious to Try" test, particularly in circumstances where an experiment involves many steps that need to be performed successfully. Although the FCA has discouraged a segmented approach, ultimately the FC is not precluded from evaluating the Self-Evident and Extent of Effort Factors for each experimental step individually in order to make conclusions about the experiment needed as a whole.