Supreme Court Curtails Inutility Challenges With its AstraZeneca Decision

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In Astra-Zeneca Canada Inc. v. Apotex Inc., 2017 SCC 36, the Supreme Court has significantly curtailed the ability to challenge a patent monopoly on the basis of an unsubstantiated promise in the patent application that the claimed subject matter of the patent will provide a particular utility [i.e. the “optically pure” substance will have an “improved therapeutic profile”]. This type of challenge was known as the “promise doctrine”. The doctrine called for an analysis of the specification and its' claims independent of the purposive construction of the claims for the purposes of determining novelty and obviousness. The Supreme Court has now held the “promise doctrine” to be an incorrect approach for determining whether a patent is invalid for want of utility.

In the Astra-Zeneca case, the trial judge had held the “improved therapeutic profile” was not essential to the claims to the “optically pure” substance. Therefore, according to the Supreme Court, it was an error to invalidate the claims on the basis that the improved profile “promised” in the patent application had not been demonstrated or soundly predicted. Going forward, it appears that the claims as purposively construed will be the sole basis on which the utility (as well as the novelty and obviousness) of an invention will be judged.

More particularly, in his construction of the claims for the purposes of obviousness, the Trial Judge, Justice Rennie (as he then was) had held that the improved properties of the patented “optically pure” substance were not part of the “inventive concept” of the claims. The claims were specific enough regarding the level of optical purity to consider the inventiveness of the claims on that basis alone. Recourse to the specification and its mention of “therapeutic effect” was not necessary to understand the meaning of the claims. The Trial Judge held that it would not have been obvious for the skilled person to separate the claimed 99.8% optically pure substance (esomeprazole) from the known substance (omeprazole) based on their common general knowledge and the prior art.

One imagines that, if the Trial Judge had found the “improved therapeutic profile” of the “optically pure” substance to be an essential element of the invention as claimed, the result may have been different.

The promise doctrine was most often applied in pharmaceutical cases, where patents for improved versions of existing drugs are filed soon after initially testing in vitro or in animals but before testing in humans. However, it had begun to make its way in the analysis of patents for mechanical inventions where skilled persons are much more likely to be able to understand the utility of the invention based on the description of a machine or device that embodies the invention, without any need for an explicit statement as to the utility of the invention.

The Supreme Court’s decision in Astra Zeneca makes it clear once again that the utility of an invention is to be judged based on the invention as claimed, by construing the wording of the claims as they would be understood by the skilled person in light of the whole specification. Not based on “stray phrases” in the patent specification describing promised advantages of the invention. Nevertheless, patentees are wise to be cautious about saying more than is necessary in their patent application about what their patented machines will be capable of doing, lest the patent claims are later held to be invalid. Either because by overpromising the claims as worded become broader than the invention that was disclosed in the application because the patent application is held to include statements made for the purpose of misleading.
1 AstraZeneca Canada Inc. v. Apotex Inc., 2014 FC 638 at [264] to [275]

2 Eurocopter v. Bell Helicopter Textron Canada, 2013 FCA 219 at [146] and [155]


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