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1 March 2017 – *IAM Weekly Email* (*)

Chemical intermediates: patentability and infringement under the doctrine of equivalents

The Supreme Court has written the final chapter in a long-running litigation between Industriale Chimica and Bayer in connection with the production of drospirenone when it ruled that a chemical intermediate might not be patentable per se, despite being novel, inventive and provided in a stable form. The court found that the determining factor is whether an intermediate which is produced in a synthesis process for the production of a given final product, can be used in that process only or if it can be used in different processes for obtaining other final products.

Factual background

Bayer owns European patent EP 0918791, which relates to a new method of synthesis of the pharmaceutical active ingredient drospirenone, a steroidal progestin.

Claim 1 of the Bayer patent refers to a two-step synthesis method, the first step of which is to reduce the precursor ZK34506 to the intermediate ZK92836, followed by the second step of oxidising ZK92836 to provide the intermediate ZK90965 (IDROX). According to this claim, the oxidation step is carried out in the presence of ruthenium salts as the catalyser.

Claim 2 of the Bayer patent protects the stable intermediate IDROX per se. The patent also includes method claims for obtaining drospirenone, as well as product-by-process claims.

With respect to the prior art, the process described and claimed by Bayer in EP 0918791 is more straightforward, avoids the use of toxic chromium salts (which were used in the previously known methods for preparing drospirenone) and reduces the amount of impurities in the final product.

Legal background

In 2005 Industriale Chimica brought an invalidity action against Bayer before the Court of Turin, requesting the revocation of the Italian portion of Bayer's EP 0918791. Bayer counterclaimed and alleged that its patent had been infringed by the process used by Industriale Chimica, which utilised a different catalyser (TEMPO) but nonetheless resulted in the formation of the claimed IDROX intermediate.

In the first instance, the court revoked Claim 2 of Bayer's patent, directed to IDROX per se. More specifically, it held that although the IDROX intermediate was novel and inventive, it was not industrially applicable as it had no "autonomous function and utility that is conceptually separable from the process of synthesis resulting in the production of drospirenone". Therefore, according to the Turin court, the IDROX intermediate was not separately patentable.

With respect to infringement, the court rejected Bayer's counterclaim finding that the process used by Industriale Chimica to produce drospirenone was different from that recited in Claim 1 of the Bayer patent because it used a different catalyser.

The Court of Appeal subsequently reversed the first instance decision and determined that Claim 1 had been infringed under the doctrine of equivalents.

Supreme Court decision

Italian case law (at least in part) and the majority of the IP legal community, including academics, have spoken in favour of the patentability of chemical intermediates. However, the Supreme Court has now confirmed the Turin court's finding with respect to the invalidity of Claim 2 relating to the IDROX intermediate.

In its decision (Cass, October 14 2016, no 1651) the Supreme Court quoted two previous decisions from the 1990s (Cass, September 1 1997, no 8324; Cass, November 16 1990, no 11094) in which it held that as far as industrial inventions in the chemical field are concerned, a so-called 'intermediate' which is essential to a synthesis process is not separately patentable when it can be used in connection with the process's realisation only.

The court further noted that IDROX would have been patentable per se if, besides being novel and inventive, it could be used not only in the claimed process for the production of drospirenone but also in the production of other final products.

More surprisingly, with respect to infringement the Supreme Court confirmed the appeal court's finding, according to which the process carried out by Industriale Chimica infringes Claim 1 of EP 0918791 under the doctrine of equivalents. In doing so, it explicitly rejected the so-called triple test (ie, evaluating the function, way and result of the accused product or process) which had previously been adopted broadly by Italian courts assessing infringement under the doctrine of equivalents.

According to the Supreme Court, although the process carried out by Industriale Chimica does not use the same catalyser as the Bayer process, the critical factor is that the process results in the formation of the same IDROX intermediate, which is the inventive idea of the Bayer process. The differences in the synthesis process used by Industriale Chimica, therefore, should be considered marginal and insufficient to exclude infringement by equivalents.

Conclusion

The Supreme Court's decision rejects the triple test in favor of a more nebulous inventive idea approach. It is unclear if and how lower courts in Italy will apply this test going forward. While the case has received a great deal of attention for its alteration of the doctrine of equivalents standard, it should not be forgotten that it also significantly reduces the chances of obtaining patent protection for stable chemical intermediates.

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