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The Italian Supreme Court on the patentability of chemical intermediates and infringement by equivalents, i.e. how to lose another occasion to get it right.

Daniela Ampollini (Trevisan & Cuonzo) · Saturday, December 31st, 2016

By decision no. 1651 of 14 October 2016 (publication reference: 24658/2016), the Italian Supreme Court put an end to the longstanding litigation between Bayer and the Italian company Industriale Chimica in relation to the production of drospirenone. This decision tackles both the issue of the patentability of chemical intermediates and that of infringement by equivalents. On both issues the decision must be criticised, I am afraid.

The story began when, back in 2005, Industriale Chimica filed proceedings at the Court of Turin requesting that the Court revoke the Italian designation of Bayer's European patent relating to the production of drospirenone by a two-step process including the isolation of the intermediate IDROX. In more detail, such a patent *inter alia* contained a Claim 1 protecting the specifics of the Bayer process for obtaining drospirenone (which included a step consisting in the formation of the intermediate IDROX), and a Claim 2 protecting the intermediate IDROX *per se*. In the first instance, the Court of Turin concluded that the Bayer patent had to be partially revoked. In particular, the Court found that the claim protecting the intermediate of drospirenone, IDROX, had to be revoked. The Court also rejected Bayer's counterclaim of infringement, as allegedly the process followed by Industriale Chimica differed from that described in Claim 1 of the Bayer patent (Court of Turin, 14 January 2011).

In more detail, in the first instance, the Court of Turin established that, notwithstanding it was undisputable that the intermediate IDROX was novel and inventive, it was not patentable as it did *"not per se have an autonomous function and a utility conceptually separable from the proceeding of synthesis conducting to the production of drospirenone"*. This decision – which allegedly based itself on some 1990s case-law of the Italian Supreme Court – failed to provide a satisfactory reasoning for concluding that the intermediate IDROX could not be claimed *per se*, as Italian law clearly lacks a principle according to which a legal requirement for patentability would be the existence of an *"autonomous function"* or of a *"conceptually separable utility"*. In fact, the very circumstance that a product – a chemical intermediate – is useful in that it leads to the creation of a final product (the final chemical compound) should be sufficient evidence of the existence of an industrial application, which appears to be the only other substantive requirement of patentability besides novelty and inventive step. This decision was rather heavily criticised by commentators. This notwithstanding, in the second instance, the Court of Appeal confirmed the reasoning of the first instance court, also confirming that Claim 2 of the Bayer patent had to be revoked (Court of

Appeal of Turin, 24 December 2012).

The Supreme Court has now further upheld such a finding, thus determining the final revocation of the claim concerning IDROX in the Italian designation of the Bayer European patent. The reasoning is very similar to that of the previous courts, however with some additional elaboration that has the merit of suggesting from where exactly the Court's conclusions originate. In particular, the Court stated that *"The intermediate, even if described and claimed as a product, remains an integral part of a process invention and, as such, is protectable always and only as the articulation of the claimed process (…) the characters of novelty, inventive step, and industrial application of IDROX coincide with those of the patented process, which is in fact focussed on the production of drospirenone via IDROX: it would have been different if IDROX could be used not only in the process for the production of drospirenone, but also of other final products"*. It would therefore seem that the Court adopted an interpretation according to which – for no better specified reasons – so called *"absolute"* protection of a new chemical compound, when the new chemical compound is a chemical intermediate, would not be possible, with the consequence that the intermediate could be protected only in the framework of the overall production process leading to the final product. This, however, appears to at least bring about an unjustified discrimination of new chemical intermediates as opposed to other new chemical compounds, besides being against what stated by the law, the case-law, and the majority of legal commentators who, in Italy as well, have since long confirmed that intermediates can be patented *per se*.

Eventually, the whole story did not end so badly for Bayer, as, in contrast with what had been established by the Court of Turin in the first instance, the Supreme Court confirmed the finding of the Court of Appeal according to which, notwithstanding the invalidity of Claim 2, Industriale Chimica had to be found to have infringed Claim 1 of the Bayer patent by equivalents. In particular, according to the Court, although the overall process followed by Industriale Chimica differed from that specifically described in Claim 1 of the Bayer Patent (which included the fact that a catalizer was used which was totally different from that of the claimed process), what counted was the fact that the process followed by Industriale Chimica passed through the intermediate IDROX and that the latter constituted the *"inventive idea"* of the claimed process. Needless to say, the reasoning followed by the Court to argue infringement by equivalents also appears to be unsatisfactory, and in any event not in line with the established Italian case-law which revolves around the application of the *"triple test"*. I cannot escape concluding that if the Court had admitted the patentability of the intermediate, it could have easily found for the literal infringement of Claim 2, thus avoiding inconveniencing the doctrine of equivalents and adding further incorrect reasoning to the whole picture. It is hoped that the important issues of patentability of intermediates and infringement by equivalents will soon be clarified and corrected in the cases to come.

This entry was posted on Saturday, December 31st, 2016 at 3:09 pm and is filed under (Indirect) infringement, literally fulfil all features of the claim. The purpose of the doctrine is to prevent an infringer from stealing the benefit of an invention by changing minor or insubstantial details while retaining the same functionality. Internationally, the criteria for determining equivalents vary. For example, German courts apply a three-step test known as Schneidmesser's questions. In the UK, the equivalence doctrine was most recently discussed in Eli Lilly v Actavis UK in July 2017. In the US, the function-way-result test is used.">Equivalents, Italy, Pharma, Validity
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