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More on the Judgment of 12 March 2015 of the CJEU in Actavis v. BI

Miquel Montañá (Clifford Chance) · Wednesday, April 1st, 2015

In the blog published on 17 March 2015, we discussed the judgment dated 12 March 2015 of the Court of Justice of the European Union ("CJEU") handed down in response to the preliminary questions referred by the High Court of Justice (England and Wales), Chancery Division (Patents Court) in a case between Actavis Group EHF, Actavis UK Ltd ("Actavis") and Boehringer Ingelheim Pharma GmbH & Co. KG ("BI") dealing with a combination product (Telmisartan and HCTZ). As highlighted in that blog, in this recent judgment the CJEU appears to have come to the conclusion that for the purposes of article 3 (a) and (c) of Regulation (EC) 469/2009, the relevant test is whether the combination as such constitutes "the subject-matter of the invention". Unlike in Medeva (Case C-322/10) and its saga, the CJEU no longer requires the members of the combination to be "specified" or "identified" in the claims of the basic patent.

If the purpose of Regulation (EC) 469/2009 is to compensate inventors for the time spent proving the quality, efficacy and safety of their pharmaceutical inventions, it does not seem sensible to require all the members of a combination product to be "specified" in the claims of the basic patent. The invention may well cover many valuable embodiments which are not explicitly "specified" in the claims. Therefore, a test based on whether or not a specific embodiment is "specified" in the claims of the basic patent may well fail to compensate inventors for contributions not explicitly reflected in the claims. This was the conclusion reached by the Federal Court of Justice in Germany (albeit in the context of determining the right to co-inventorship) in its judgment of 22 January 2013. Readers may wish to re-visit the blog published by my friend Thorsten Bausch on 24 April 2013 entitled "*You Are Not Alone." Co-inventorship Requirements Further Clarified in Germany*. In that blog he explained that in its judgment the Federal Court of Justice in Germany found that in order to claim co-inventorship, the contribution of the co-inventor need only be found in parts of the description of the patent and does not have to be found in the claims. This seems to be a monument to common sense.

Against this background, abandoning the "specified in the claims" test is a positive development. In our respectful opinion, in future cases it would be sound for the CJEU to stop attempting to introduce in article 3 (a) and (c) of Regulation (EC) 469/2009 concepts which do not form part of article 3. In fact, the CJEU's case law on article 3 (a) and (c) would become more coherent if the CJEU were to revert to the criteria applied in Farmitalia (Case C-392/97), thus leaving it to national courts to determine whether or not the product is protected by the basic patent applying the relevant non-EU rules. Certainly, this might give rise to divergent interpretations across the EU, which would be understandable. But if the EU Legislature avoided the opportunity of harmonising patent law in the EU by excluding substantive patent law from Regulation (EU) 1257/2012, it is simply not right to expect

the CJEU to implement the harmonisation that the politicians failed to do…

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This entry was posted on Wednesday, April 1st, 2015 at 11:46 am and is filed under CJEU
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