Kluwer Patent Blog

Escitalopram Revisited – Federal Patent Court Issues Written Grounds

Thorsten Bausch (Hoffmann Eitle) · Wednesday, August 10th, 2011

In this blog, we reported earlier about a new nullity action initiated in 2010 against the German supplementary protection certificate (SPC) for enantiomeric escitalopram and the judgment of the German Federal Patent Court (Bundespatentgericht – BPatG) in favor of the validity of the SPC (see thislink). Meanwhile, the BPatG issued the written grounds for its decision. The decision (in German) has been published on the BPatG website and can be downloaded using thislink.

In its judgment, the BPatG held that the SPC can only be revoked if there is evidence that the product escitalopram claimed in the SPC is not a product different from racemic citalopram. It would be only in such case that the marketing authorization for escitalopram of 2003 underlying the SPC in suit is not the first authorization of the product within the meaning of Art. 3 (d) of Regulation (EC) 469/2009 Concerning the Supplementary Protection Certificate for Medicinal Products (SPC Regulation).

Scientific studies which were presented to the court by the Plaintiff did not convince the BPatG that escitalopram and citalopram have the same therapeutic effect. Therefore, the BPatG was unable to conclude without doubt that escitalopram and citalopram are the same product under Art. 1 (b) SPC Regulation.

According to the BPatG, decisions of foreign regulatory authorities do not lead to a different result because the criteria used in such regulatory proceedings are different from the requirements employed in nullity proceedings.

The decision of the German Federal Joint Committee (Gemeinsamer Bundesausschuss) on the classification of escitalopram and citalopram in the same group of reference prices under Sec. 35 German Social Security Code V is no significant indication, either, that escitalopram and citalopram have the same effect within the meaning of the SPC Regulation. The SPC Regulation does not refer to price-related aspects of a medicinal product but to new effects and therapeutical improvements of a product.

The BPatG also declined to refer the case to the European Court of Justice (ECJ) for preliminary ruling under Art. 267 of the Treaty on the Functioning of the European Union (TFEU) since the present case only deals with factual questions – whether or not escitalopram has a therapeutic effect of its own and is therefore an active ingredient different from citalopram – which cannot be referred to the ECJ. As a result, the BPatG did not recognize any legal questions requiring

preliminary ruling by the ECJ.

Jan-Hendrik Spilgies and Simon Klopschinski, Hoffmann Eitle

To make sure you do not miss out on regular updates from the Kluwer Patent Blog, please subscribe here.

This entry was posted on Wednesday, August 10th, 2011 at 3:12 pm and is filed under Germany, SPC, Validity
You can follow any responses to this entry through the Comments (RSS) feed. Both comments and pings are currently closed.