Kluwer Patent Blog

Escitalopram Revisited – Federal Patent Court Rules in Favor of Validity of SPC for Enantiomer over Earlier Marketing Authorization for Racemate

Thorsten Bausch (Hoffmann Eitle) · Friday, May 13th, 2011

After the Federal Court of Justice (Bundesgerichtshof, BGH) had confirmed the validity of the German SPC for the enantiomeric escitalopram (and its underlying patent) in 2009, the Federal Patent Court (Bundespatentgericht) now confirmed in further nullity proceedings the validity of the SPC.

In 2007, the Federal Patent Court revoked the German part of EP 0 347 066, which protects the enantiomeric antidepressant escitalopram for H. Lundbeck A/S. The decision of revocation 3 Ni 9/05 (EU) was based on lack of patentability of the claimed enantiomer and process for its manufacture, thus following the requests in the nullity actions lodged by four Plaintiffs and further supported by one Intervener. At the same time, the corresponding Supplementary Protection Certificate (SPC) was revoked for lack of patentability of the basic patent pursuant to Article 15(1) in combination with Article 3(a) of Regulation (EEC) No. 1768/92 ("SPC Regulation"; meanwhile replaced by Regulation (EC) 469/2009).

Lundbeck appealed the decision, and in decision Xa ZR 130/07 of September 10, 2009, the Federal Court of Justice reversed the first instance decision of the Federal Patent Court. The BGH held that the invention claimed in the patent in suit is both novel and inventive, so that Article 3(a) of the SPC Regulation no longer prejudiced the validity of the SPC. One of the Plaintiffs additionally asserted that the SPC in suit had been incorrectly granted since the marketing authorization granted for the product, escitalopram, was not the first authorization within the meaning of Art. 3(d) of the SPC Regulation. In particular, it was alleged that the earlier marketing authorization for the underlying racemate, citalopram, also covered the enantiomer, escitalopram.

The BGH did not follow the Plaintiff's argument and ruled that

"*A marketing authorization for a medicinal product that contains a chemical compound in racemic form as the active ingredient does not present a bar to the issuance of a supplementary protection certificate for a medicinal product which contains an enantiomer of the compound as the active ingredient and which is the subject matter of a later marketing authorization and a substance patent of its own.*" (decision "Escitalopram", headnote d)

One of the Plaintiffs, or rather one of its newly acquired subsidiaries, did not accept the decision of the BGH, and in 2010, filed a new nullity action against the SPC on the sole ground of lack of

nullity pursuant to Article 3(d) (Case No. 3 Ni 22/10). For substantiation, the new Plaintiff inter alia referred to findings of national authorities in the Netherlands and Germany responsible for authorizing the marketing of medicinal products or deciding on price reimbursement of the health insurance funds. Those authorities had held (in non-final decisions, and after the BGH decision) that the enantiomer escitalopram has no substantially different or improved pharmaceutical effect over the racemate citalopram and, therefore, the enantiomer should not be regarded as a new substance for the purpose of the underlying proceedings. Lundbeck argued that the finding of the national authorities was irrelevant for the legal questions underlying the grant and validity of an SPC and that, moreover, they had incorrectly assessed the pharmacological data presented by Lundbeck and other researchers. The Plaintiff attempted to have the matter referred to the European Court of Justice (ECJ) in view of allegedly deviating decisions by national Courts and authorities. In response, Lundbeck pointed out that the BGH had already previously ruled in its Escitalopram decision that there was no doubt that escitalopram is a compound different from citalopram and that, hence, there was no need for a referral to the ECJ. This view was also supported by Court decisions in Austria and France.

The case was heard by the Federal Patent Court on March 29, 2011, and – after consideration of the Court on the same day – the nullity action was dismissed. So far, no grounds for the decision are available, but the Court evidently must have agreed with Lundbeck that escitalopram and citalopram are different active substances and that, further, the finding of national authorities concerning marketing authorization and price reimbursement does not create a legal issue to be resolved by the ECJ or otherwise relevant for the validity of an SPC.

We will report on the considerations of the Federal Patent Court once the written grounds are available.

This entry was posted on Friday, May 13th, 2011 at 2:53 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.