The Losartan Case in Belgium: One SPC Too Far?

Kluwer Patent Blog
April 28, 2010

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Please refer to this post as: Kristof Roox, 'The Losartan Case in Belgium: One SPC Too Far?', Kluwer Patent Blog, April 28 2010, http://patentblog.kluweriplaw.com/2010/04/28/the-losartan-case-in-belgium-one-spc-too-far/

In the beginning of 2010, Merck Sharp & Dohme (hereafter "Merck") and E.I. Du Pont de Nemours (hereafter "Du Pont") on the one hand and Mylan on the other hand entailed in a fight concerning the launch of a generic version of Cozaar Plus®. The Supplementary Protection Certificate (SPC) of Cozaar Plus®, a combination product consisting of losartan and HCTZ, would expire on 15 February 2010, but Merck and Du Pont tried to prevent the marketing of generic versions of Cozaar Plus® by invoking the SPC for Cozaar®, the monoproduct consisting of Losartan only. In Belgium and France, this case led to very diverging judgments on the interpretation of the SPC Regulation.

I. FACTUAL BACKGROUND

Merck, a pharmaceutical company and exclusive licensee of Du Pont, commercializes a medicinal product comprising losartan as active ingredient under the brand name Cozaar®. Losartan, as a potassium salt, is used to treat high blood pressure (hypertension), through its action as an antagonist of the angiotensin II receptor. Losartan is often used in combination with Hydrochlorothiazide (HCTZ), a first line diuretic drug of the thiazide class. This combination product (co-losartan) is marketed by Merck under the brand name Cozaar Plus®.

Du Pont holds a European patent for the monoproduct (losartan) as well as for the combination product (co-losartan, i.e. losartan + HCTZ), respectively EP 0253310 and EP 0733336. In several Member States of the European Union, such as in Belgium, Du Pont also obtained a SPC extending the term of protection for the mono-product to 2 September 2009 (SPC 96C0020) and for the combination product to 15 February 2010 (SPC nr. 98C0030).

For the mono-product (SPC nr. 96C0020), Du Pont also applied for an additional six months extension in accordance with article 36 of the Regulation on medicinal products for paediatric use. This paediatric extension was granted in Belgium by decision of 25 August 2009, extending the term of protection of SPC nr. 96C0020 to 2 March 2010.

Taking into account the impending expiry of the SPC for co-losartan on 15 February 2010, several pharmaceutical companies, amongst others Mylan, started preparing the launch of a generic version of co-losartan. Merck and Du Pont strongly opposed against this plan, claiming that not only the mono-product falls under the extended term of protection SPC nr. 96C0020, but also the combination product. Since Mylan was clear about its intention to market the generic version of Cozaar Plus® as of 15 February 2010 (i.e. the expiry date of SPC nr. 98C0030), it was summoned by Merck and Du Pont before the President of the Brussels Commercial Court.

II. THE JUDGMENT OF THE BELGIAN COURTS

The debate between the parties can be summarized as follows: Merck and Du Pont argued that the wording of article 4, *in fine* of the SPC Regulation ("*for any use of the product as a medicinal product that has been authorised*") would mean that a certain SPC that was granted for a product Losartan, also protects this product when it is part of a composition with another product (HCTZ) even though a different and separate SPC was granted for this combination product. Mylan claims that the drugs containing only losartan, on the one hand, and those containing losartan combined with HCTZ, on the other hand, constitute different products and that only SPC nr. 96C0020 had obtained a paediatric extension so that the combination product co-losartan was not covered by this paediatric extension.

1. The Order of the President of the Brussels Commercial Court of 12 February 2010

The President of the Brussels Commercial Court was of the opinion that the arguments of Merck and Du Pont regarding the interpretation of article 4 of the SPC Regulation have to be dealt with in proceedings on the merits.

The President came however to the conclusion that the combination product co-losartan cannot enjoy the extension of protection granted to the SPC for the mono-product losartan. The President took into account the fact that both SPC's protect different active ingredients ("products" in the sense of the SPC Regulation), were granted on the basis of different patents ("basic patents" in the sense of the SPC Regulation) and that separate market authorizations had to be obtained for both medicinal products. Furthermore, in order to obtain a paediatric extension Du Pont only filed a paediatric investigation plan with the EMEA for the losartan-SPC covering the mono-product. Hence, the combination product Cozaar Plus® could not benefit from the paediatric extension of the losartan-SPC.

2. The Judgment of the Brussels Court of Appeal of 23 February 2010

Merck and Du Pont filed an appeal against this decision of the President of the Commercial Court. It should be noted that the Brussels Court of Appeal dealt with the case and issued a judgment in less than two weeks! The Court of Appeal was of the opinion that the argumentation of Merck and Du Pont is not in compliance with consideration 10 of the SPC Regulation according to which the granted protection should be strictly limited to the product that falls under the marketing authorization, neither with the wording of article 3 c) and d) of the SPC Regulation nor with the wording of article 4 of that Regulation.

The Court ruled that a first sight ("*prima facie*"), it seems to arise from article 3, c) en d) of the SPC Regulation that only one SPC can be granted for one and the same product (defined in article 1 b) of the Regulation as "*the active ingredient or combination of active ingredients of a medicinal product*") which is protected by a basic patent and already falls under a marketing authorization, even though this product is possibly protected by another (second) patent. The Court of Appeal referred to the fact that in the present case two different market authorizations, as well as two different SPCs were granted for two different products. Therefore the Court came to the conclusion that the combination product cannot fall within the scope of the SPC for the mono-product.

III. THE DISSENTING OPINION OF THE PARIS DISTRICT COURT

In France, Mylan was summoned before the President of the Paris District Court by Merck and Du Pont. By virtue of, on the one hand, article 5 of the SPC Regulation that states that a SPC confers the same rights as the basic patent, and, on the other hand, article 4 of the SPC Regulation that states that the SPC protects any subsequently authorised use of the product as a medicinal product, the President concluded that as a result of the extended protection of claims 1, 2, 2, 4, and 5 of EP 0253310 and of the SPC for the mono-product, any exploitation of a drug containing losartan as a main active ingredient constitutes an infringement of those claims.

Thus the President of the Paris District Court is of the opinion that the SPC for the mono-product covers the combination product in the light of the claims of the basic patent, notwithstanding the fact that the paediatric extension was only granted for the losartan SPC.