First Belgian decision on SPC’s coverage of combination products

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The Antwerp Court applied the infringement test to assess the validity of a supplementary protection certificate (SPC) covering a combination product. As a result, the Court decided that Novartis is entitled to invoke its SPC covering the “valsartan/HCTZ” combination product against Teva’s generic version of Co-Diovan.

By its decision of 13 May 2011, the Antwerp Commercial Court dismissed the claim of Teva Pharma Belgium (Teva) to invalidate Novartis’ SPC granted for the combination product “*valsartan/HCTZ*”. At the same time, the Court granted Teva’s second claim to declare that Teva’s medicinal product Co-Valsartan Teva does not infringe Novartis’ SPC granted for valsartan alone.

These two SPC’s indicate the same European patent EP 0443983 as the basic patent. This patent claims the active pharmaceutical ingredient valsartan, processes for the production of valsartan as well as first and second medical uses of valsartan. As this patent expired on 11 February 2011, Teva intended to launch on 12 February 2011 a generic version of Novartis’ blockbuster drug Co-Diovan, containing valsartan and HCTZ as its active pharmaceutical ingredients.

Teva believed that the SPC granted for the combination product “valsartan/HCTZ” was invalid and that its generic version of Co-Diovan did not infringe the SPC granted for valsartan alone. On 29 June 2010, Teva started invalidity proceedings on the merits before the Antwerp Commercial Court. In its writ Teva explicitly stated its intention to launch its generic product on 12 February 2011.

In order to stop this launch, Novartis initiated summary proceedings against Teva before the President of the Antwerp Commercial Court on 9 August 2010. In his decision of 14 December 2010, the President granted an injunction: the injunction was however only declared enforceable starting from the day following that on which Novartis would have initiated accelerated infringement proceedings against Teva. Novartis successfully lodged appeal against this (rather unusual) decision. In its decision of 9 February 2011, the Antwerp Court of Appeal prohibited Teva from launching a product containing valsartan and HCTZ. The preliminary injunction however was granted for a limited period of time, until a decision in the case on the merits relating to the SPC’s was rendered or until 31 May 2011, whichever was earlier.

In the proceedings on the merits, Teva’s first claim related to the validity of Novartis’ SPC for the “valsartan/HCTZ” combination product. Teva argued that this combination product was not protected by the basic patent for valsartan as required by article 3 of the SPC Regulation, which stipulates the basic requirements for obtaining an SPC. Article 3(a) requires that the product – the active pharmaceutical ingredient or a combination of active pharmaceutical ingredients – be “*protected by a basic patent in force*”. Teva’s position was that this was not the case for the “valsartan/HCTZ” combination product as this combination was not specifically disclosed in the claims of the basic patent, and the SPC should therefore be invalidated.

In its decision, the Court considered that there were two different ways to determine whether the product (in this case, the combination of the active pharmaceutical ingredients valsartan/HCTZ) is protected by the basic patent. Some jurisdictions (including the UK, France and Spain) apply the “*identification test*” requiring that the object of the SPC must be identifiable with the invention of the designated basic patent. The combination as such must therefore be expressly disclosed in the basic patent.

In contrast, other jurisdictions (including Germany and Switzerland) seem to follow the “*infringement test*” pursuant to article 69 EPC to determine whether the combination, even if not expressly disclosed, would be protected by the basic patent. The question in this test is whether a combination product containing two active pharmaceutical ingredients that is the object of an SPC would infringe a patent claiming only one active pharmaceutical ingredient. As the combination product fulfils all features of a claim directed to only one active pharmaceutical ingredient, it would infringe the basic patent under this approach. In such situation, the SPC product is regarded as being protected by the basic patent pursuant to article 3(a) of the SPC Regulation.

In essence, Novartis asked the Court to apply the broader infringement test whereas Teva wanted the Court to apply the more narrow identification test. Although prejudicial questions on this matter are pending before the European Court of Justice, that decision is not expected any time soon and the Antwerp Commercial Court did not want to wait for that decision. Delay would have also been detrimental to Teva, as it would not be forced to postpone the launch of its generic product until the European Court of Justice’s decision.

The Antwerp Commercial Court decided to apply the infringement test. The Antwerp Commercial Court considered that “protected by” in the SPC Regulation should be interpreted in the same way as in patent law. It is in this regard irrelevant whether or not a product is disclosed in the basic patent as long as it is protected by the basic patent. Referring to the European Court of Justice’s Farmitalia decision, the Court stated that the question of whether the combination product is protected by a patent in force can be determined only in the light of non-Community rules governing patents: article 69 EPC and its Protocol. Neither the definition of basic patent in article 1 of the SPC Regulation nor the Belgian preparatory acts would allow for a more narrow interpretation. For these reasons, the Antwerp Commercial Court applied the infringement test and considered Novartis’ SPC granted for the combination product “valsartan/HCTZ” to be valid. Teva’s invalidity claim was therefore dismissed and an injunction against Teva was issued not to infringe this SPC.

Teva’s second claim related to the scope of protection of Novartis’ SPC granted for valsartan alone. According to Teva, its valsartan and HCTZ product would not infringe this SPC. The Antwerp Commercial Court agreed and confirmed that an SPC’s scope of protection is limited to the product for which a marketing authorization was granted. The Court considered that Novartis acknowledged this limited scope of protection as it obtained two different SPC’s, one for the mono-product and one for the combination product. When assessing the scope of protection of the SPC, the Court therefore applied the identification test.

In this first decision on the validity of SPC’s covering combination products, the Antwerp Commercial Court took a clear position. When assessing the validity of such SPC’s, the Court will apply the infringement test, also applied by the German courts. The European Court of Justice must now decide whether or not this is the right test. This case also shows that Belgian courts are increasingly able to handle rather complex patent and SPC litigation in an expedient way. Indeed, a decision on the merits in this case was issued within less than a year following the writ of summons. Moreover, with regard to the summary proceedings, a decision in appeal was rendered within less than 6 months. This demonstrates that Belgium is becoming a more interesting forum for patent litigation.