

Kluwer Patent Blog

The Court of Rome endorses the “infringement test” in a case concerning Novartis combination SPC

Daniela Ampollini (Trevisan & Cuonzo) · Saturday, November 12th, 2011

On 11 November 2011 the IP Chamber of the Court of Rome granted the motion for preliminary injunction requested by Novartis AG and Novartis Farma S.p.A. against Mylan S.p.A. on the basis of Novartis’ Italian valsartan and hydrochlorothiazide SPC, the active ingredients in Novartis’ Co-Diovan medicinal product (which is marketed in Italy as Co-Tareg).

The motion had been filed in the framework of a nullity action initiated last September by Mylan, aiming at the revocation of Novartis’ SPC for alleged violation the provisions of the SPC Regulation, in which action Novartis had cross-claimed the infringement of its rights.

The grounds of invalidity raised by Mylan were substantially based on the assumption that: (i) the SPC would be invalid as the medicinal product Co-Diovan would not be “protected by a basic patent in force” considering that basic patent EP 443983 does not claim the combination of valsartan and hydrochlorothiazide as such and that the “infringement test” (according to which a product is protected by a patent if it “infringes” the patent) would not be the correct test to use in interpreting Art. 3(a) of the SPC Regulation; and (ii) Art. 3 (c) of the SPC Regulation would have also been breached by the valsartan and hydrochlorothiazide SPC as another SPC on valsartan had already been granted based on the same EP ‘983 patent.

The Court of Rome, after having noted that the urgency requirement had been met based on the fact that Novartis had produced pre-orders indicating that Mylan had pre-marketed the drug, as well as the fact that Mylan had officially communicated to the association of Italian wholesalers that its generic version of Co-Diovan would be in the market as of 15 November 2011 (i.e. after the expiry of the valsartan SPC; but not after the expiry of the valsartan and hydrochlorothiazide SPC), endorsed the application of the infringement test as to Art. 3(a) of the SPC Regulation and clarified that Art. 3(c) of the SPC Regulation is not breached if the products in question (in this case the product valsartan and the combination product valsartan and hydrochlorothiazide) are different, and therefore found that the infringement of a valid SPC was being committed.

The injunction is noteworthy also as it includes a prohibition that Mylan make pre-marketing activity (such as the collection of orders and pre-orders) before the expiry of the SPC, an order of recall of the products that have already been delivered to Mylan’s customers, and an order to notify the Italian Drugs Regulatory Authority with a view to preventing the inclusion of the generic in the substitution list of equivalent drugs.

The preliminary injunction is now subject to appeal and, in any event, to confirmation at the outcome of the merits proceedings.

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

Kluwer IP Law

The **2022 Future Ready Lawyer survey** showed that 79% of lawyers think that the importance of legal technology will increase for next year. With Kluwer IP Law you can navigate the increasingly global practice of IP law with specialized, local and cross-border information and tools from every preferred location. Are you, as an IP professional, ready for the future?

Learn how **Kluwer IP Law** can support you.

79% of the lawyers think that the importance of legal technology will increase for next year.

Drive change with Kluwer IP Law.

The master resource for Intellectual Property rights and registration.



2022 SURVEY REPORT
The Wolters Kluwer Future Ready Lawyer
Leading change

This entry was posted on Saturday, November 12th, 2011 at 4:31 pm and is filed under ([Indirect infringement](#), [Injunction](#), [Italy](#), [SPC](#))

You can follow any responses to this entry through the [Comments \(RSS\)](#) feed. Both comments and pings are currently closed.