

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

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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 valsaran 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.