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Skinny label insufficient for avoiding infringement of second medical use claims, says the Court of Milan.

Daniela Ampollini (Trevisan & Cuonzo) · Monday, February 14th, 2022

In another chapter of the enforcement of Novartis' patents concerning the second and further uses of everolimus for the treatment of several solid tumors (a first post can be viewed here), the Court of Milan has considered whether eliminating an indication claimed by a second medical use patent from the product label does or does not alone save the generic from a finding of infringement and a consequent injunction. By decision of 10 January 2022 and in the context of preliminary proceedings, the Court of Milan decided it does not.

In the case at hand the generic had carved out all indications of the originator label but one from the label of its product. In particular, the generic had maintained the indication relating to the use of everolimus in treating Pancreatic Neuroendocrine Tumour (PNET) and had launched at risk, arguing invalidity of the relevant second medical use patent, EP 3342411. The generic had then filed merits proceedings aimed at the revocation of that patent, as well as of another Novartis patent, EP 3351246 which is relevant to another indication of the originator label, i.e. the use in combination with an aromatase inhibitor in the treatment of hormone receptor positive breast tumours. Within the revocation action, Novartis filed preliminary injunction (PI) proceedings enforcing both patents and seeking an injunction in relation to both uses.

As a first step in the PI proceedings, the Court considered the validity of both EP 3342411 and EP 3351246. Here the Court endorsed the conclusions that the patents are valid reached by the Court Appointed Advisor. Incidentally, in the meantime, EP 3351246 had also been upheld at first instance by the Opposition Division in the European Patent Office (notices of appeal were filed).

On infringement, the Court first concluded that EP 3342411 was infringed as reference to the PNET indication was clearly contained in the product's label. As regards EP 3351246, the Court noted that, notwithstanding the carve-out, the generic had won public tenders managed by regional administrations for the supply of the product that did not discriminate between uses. Furthermore, those regional administrations had not then sought supply of the originator product for covering the potential residual uses not covered by the label of the generic product. In this situation, according to the Court there was *prima facie* evidence that the product would also be used for the indications not included in the generic's label.

The Court therefore issued the PI on the basis of both patents. In particular, in addition to a traditional order to refrain from selling the product *for use* in both protected indications, the Court ordered the generic company to refrain from selling the product *unless* the protected indications are

carved out *and unless* the generic company has notified all relevant parties involved in the purchase and use of the product that the product is not indicated and should not be used in the protected indication. Merits proceedings are pending.

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This entry was posted on Monday, February 14th, 2022 at 4:38 pm and is filed under Infringement, Injunction, Italy, Patents, Second Medical Use
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