**Novartis Pharma vs. Medac Farma**

**Court of Milan, 10 January 2022, case number 11933/2022**

**Headnote**

A decision on second medical use patent and skinny labelling in Italy was handed down by the Court of Milan on 10 January 2022. The Court held skinny label alone as insufficient to avoid infringement of second medical use claims and imposed various obligations on the generic company in order to lawfully market its drug.

**Summary**

On 10 January 2022 the Court of Milan issued its decision – at the end of an urgent procedure – on the infringement of the second medical use patents EP 3342411 (EP’411) and EP 3351246 (EP’246) (and incidentally on their validity) by the generic of Afinitor (everolimus), marketed by Medac Pharma S.r.l. (“Medac” or “defendant”).

Novartis Pharma AG and Novartis International Pharmaceutical AG (jointly “Novartis” or “Applicant”) were sued by Medac, which sought a declaration of invalidity of the Italian portion of both the aforementioned patents and a declaration of non-infringement of its Everolimus Medac product with respect to EP'411.

Novartis in its reply brief requested rejection of the plaintiff’s claims and - by way of counterclaim - a declaration for infringement of EP’246 and EP’411, a request for injunction and for compensation for damages. EP’246 and EP’411 are two patents for second medical use providing protection respectively to the treatment of hormone receptor positive breast cancer (EP’246) and to the use of Everolimus in treating Pancreatic Neuroendocrine Tumour (PNET) (EP’411).

Medac, a company engaged in the production of equivalent medicines, is the holder of the marketing authorization (MA) of the generic drug "Everolimus Medac" based on the active ingredient Everolimus (indicated for the treatment of certain tumors including PNET and Breast cancer).

A series of carve-outs were made to the therapeutic indications of ”Evorolimus Medac”, in order to avoid interference with EP’246. Medac pointed out that it had carved out from the package leaflet any reference to the use for the treatment of breast cancer and initiated the process for eliminating such indication also from the MA and SmPC (at the time of the trial such elimination was not yet completed).

Novartis filed in the course of the proceedings a motion for interim injunction enforcing both patents and seeking an injunction – against Medac - in relation to both medical uses.

Medac argued that the patent coverage of the Everolimus molecule has expired and, that the second medical use patents were invalid. Further, Medac argued the absence of *prima facie case* (*fumus boni iuris*) based on non-infringement of the second medical use claims. Furthermore, Medac argued the lack of the urgency requirement (so called *periculum in mora)* since the use of its drug was limited to PNET indications.

The Court ordered a technical expertise on both patents.

With respect to the validity of the Italian portion of EP'246, the Court appointed technical expert availed himself of a technical expertise report delivered in another preliminary proceedings brought by Novartis against a third company, at the end of which the validity of such patent was confirmed.

In particular, the Court appointed technical expert relied on the conclusions of such expertise with respect to the alleged invalidity of EP’246 for breach of Article 123 paragraph 3 of the EPC. Indeed, EP’246 is a divisional patent and the expert concluded that the scope of the claims of EP'246 does not extend beyond the subject matter of the original patent application (as well as of the previous divisional patent applications). It was also confirmed compliance with the requirement of sufficiency of disclosure, since the solution proposed - in the light of the data provided - was considered a plausible solution to the objective technical problem. Finally, the claims of EP'246 were considered novel.

The technical expert of the previous proceeding did not assess the inventive step which - in any case - was recognized by the technical expert appointed by the Court.

With respect to the validity of the Italian portion of EP'411, the panel of technical experts found the claimed invention to be both sufficiently disclosed due to the plausibility of the solution (indeed, the test results presented in relation to the exocrine tumour models were confirmed by the post-filing evidence) as well as novel and inventive. Furthermore, the technical expert confirmed that the subject matter of the invention does not go beyond the subject matter of the original patent application.

The Court agreed with the conclusions reached by the technical expert.

Infringement by the generic drug of the two patents was also assessed.

With reference to EP'246, the appointed technical expert underlined that Medac had removed the indication for the treatment of the breast cancer from the package leaflet and requested AIFA (Italian Authority) to remove the indication from the MA and the SmPC (but when the proceedings commenced, the indication was still present).

With respect to such circumstance, the judge, noted that if, on the one hand, Medac both removed the indication for the treatment of breast cancer from the package leaflet and submitted a carve-out request to AIFA for the MA and SmPC, on the other hand, Medac was awarded tenders for the supply of Everolimus to the regional health system without any specification/limitation for the use of Everolimus. In addition, Novartis reported that it had not received further requests for supplies of the drug (expected for the patented treatment of breast cancer), arguing that this was the result of the participation of Medac to the tenders.

For these reasons and – referring to the proceedings on merits for a more in-depth assessment - the Court held that it had to restrict the circulation of the drug also with reference to EP'246.

With reference to EP'411, on the other hand, the judgement on infringement was immediate as the PNET indication was present in the documentation provided by Medac and thus skinny labelling did not come at stake.

The judge found the urgency requirement because of the publishing of new regional tenders with the starting price lowered to the price of the generic. According to the judge, the immediate consequence was the high probability for the originator to lose the tenders and market shares, with the risk that the contracting authorities - even after an assessment at the end of proceedings on the merits favourable to Novartis – would not adjust the tender price for the supply of Everolimus.

Consequently, the Judge upheld the requests made by Novartis and thus i) preliminary injuncted production, marketing or advertising of Everolimus Medac and/or any other drug containing Everolimus for use in the PNET and breast cancer indications; ii) preliminary injuncted production, marketing or advertising of Everolimus Medac and/or any other drug containing Everolimus without having taken all necessary and appropriate measures to prevent such drug from being used in the PNET and breast cancer indications, and in particular without having taken the following measures (i) ensure that any MA and related SmPC and package leaflet of any Medac product containing Everolimus does not contain any reference to the patented therapeutic indications; ii) for products already authorized with the indication Breas Cancer in the MA, SmPC and package leaflet initiate and complete the process of eliminating the Breast Cancer and PNET indications. The amended MA has to be published in the Official Journal and these changes have to be implemented in the package leaflet and SmPC; iii) inform in writing all interested parties and entities including medical and pharmacist associations, hospitals and ASLs, hospital companies, procurement entities and database organizations (a list of which was provided by the Judge) of the fact that medications containing Everolimus Medac are not indicated and should not be used for patent-protected uses.

The Court, moreover, established the obligation for Medac to communicate in writing every time it makes a commercial offer in a tender or otherwise supplies any product containing Everolimus (however named) that the product supplied is not indicated and must not be used for the PNET and breast cancer indications.

The Court also set forth certain ancillary measures such as preventing Medac Pharma srl from transferring and/or licensing Medac's Everolimus AIC to third parties unless the third parties have committed in writing to comply with the stated measures.

This decision appears consistent with the European trend according to which skinny labelling might not be sufficient as such to rule out infringement. However, it should be noted that the obligations were imposed in a scenario where the SmPC originally did not carve out the patented indications and thus the approach of the Court was arguably particularly strict for such reason.

Luca Giove – Giorgia Zecchin (GR Legal)