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Everolimus breast cancer use patent considered valid in preliminary injunction proceedings in Italy and then upheld at first instance in the EPO

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On 9 July 2021, the Court of Milan issued a preliminary injunction (PI) prohibiting a generic company from selling everolimus for use in combination with an aromatase inhibitor in the treatment of hormone receptor positive breast tumours. The PI was issued on the basis of EP 3351246, which is one of the patents held by Novartis protecting the second and further medical uses of everolimus, a medicine initially approved for use in organ transplantation, and later found to be useful in the oncology setting for the treatment of solid tumors. The PI decision of first instance was later upheld in the appeal decision issued on 4 October 2021, shortly before the first instance hearing of the oppositions filed against the patent took place in the EPO.

The Court of Milan's evaluation of the patent's validity when deciding to grant and maintain the PI is in line with the views already expressed by the EPO's Opposition Division in its preliminary opinion. And subsequently, at the end of the oral proceedings that took place over three days from 19-21 October 2021, the Opposition Division maintained the patent as granted by rejecting all grounds of invalidity raised by the nine opponents, including added subject matter, novelty, inventive step and sufficiency of disclosure (appeals pending). Similar arguments about validity of the patent have also been rejected in other national proceedings: once by the Dutch judge in the framework of preliminary injunction appeal proceedings (whereas proceedings in the merits are presently pending), and twice by the German court in Düsseldorf in the framework of first instance infringement proceedings on the merits (where appeals are pending).

Both the first instance and appeal decisions of the Court of Milan are noteworthy in many ways.

As far as the first instance decision is concerned, the order contains a rather thorough analysis of the validity requirements of the patent enforced, by means of a detailed reference to the conclusions reached by the Court Appointed Advisor (CTA) during the technical phase that characterizes Italian patent litigation, not only in merits proceedings but for PIs as well. The various passages on plausibility seem to be particularly worthy of consideration as they represent one of the few examples in which the Italian courts have tackled this requirement. Plausibility was considered mainly in the framework of the sufficiency attack, in connection with the fact that the patent does not contain data relating specifically to everolimus for the more precise use in treating the solid tumour type in the combination recited in the patent claim. Here the Court noted that the data contained in the patent however refer to several other tumour types, all of which have in common the fact that they are solid. The Court in this case then concluded that a positive example

of the treatment of the specific claimed tumour is unnecessary to support plausibility. The other allegations of invalidity were also rejected in line with the CTA opinion.

Second, this is virtually the first case in which an Italian Court explicitly acknowledges that as far as hospital medicines are concerned, irreparable harm is inherent to the functioning of tender procedures. In particular, the Court accepted that, the longer the generic product remains available, the higher the risk that the auction base price is adjusted to the price of the generic and cannot be brought back to pre-infringement levels. This justifies the issue of a preliminary injunction as opposed to waiting for the outcome of the (longer) merits proceedings.

Last but not least, the format of the injunction is notable because the Court also endorsed the principle that a skinny label alone is insufficient to avoid infringement of a second medical use claim. Indeed, in addition to a traditional order to refrain from selling the product *for use* in the protected indication, the Court ordered the generic company to refrain from selling the product *unless* the protected indication is 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 must not be used in the protected indication.

The appeal decision entirely confirmed the decision of first instance. Particularly interesting is the section relating to irreparable harm, where the Court stated that the sales of the infringing generic product have repercussions on the originator sales that by definition cannot be compensated through a damage award; that the balance of convenience is in favour of the patentee in consideration of the fact that the infringement results in the reduction of the period during which the research investments can be recouped compared to the duration of the exclusivity granted by the patent; that whether the generic company has undertaken to cease bidding in new procurement procedures does not eliminate the basis for issuing an injunction given the inherent minor efficacy of a private undertaking as opposed to a court order that is backed up by penalties. Merits proceedings are pending.

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