ES – Fulvestrant / Court of Appeals of Barcelona, 19 November 2019, Docket Nos. 240/2019 & 505/2019

In two separate orders, both issued on 19 November 2019, the Barcelona Court of Appeals confirmed the dismissal of a preliminary injunction decided by Orders of 18 July 2018, upon request of ASTRANEZECA against TEVA PHARMA S.L.U. (TEVA) and RATIOPHARM ESPAÑA, S.A. (RATIOPHARM) for the sale of generic drugs of fulvestrant.

This case deals with the appeal of two orders issued on the same date, 18 July 2018, in which Barcelona Commercial Court No. 4 refused to grant precautionary measures requested by ASTRAZENECA AB and ASTRAZENECA FARMACÉUTICA SPAIN, S.A. (hereinafter, "ASTRAZENECA") against TEVA and RATIOPHARM, respectively.

In the first case, brought against TEVA, ASTRAZENECA claimed infringement of patent EP 1,250,138 (**EP 138**) and its divisional patent EP 2,266,573 (**EP 573**), which protect a formulation of fulvestrant for the treatment of breast cancer.

In the second case, filed against RATIOPHARM, in addition to patents EP 138 and EP 573, ASTRAZENECA claimed infringement of patent EP 1,272,195 (**EP 195**), which protects not a product or formulation as patents EP 138 and EP 573 but a specific treatment for women with breast cancer.

In both cases, ASTRAZENECA requested Barcelona Commercial Court no. 4 to prohibit TEVA and RATIOPHARM from marketing their generic fulvestrant medicines, TEVA FULVESTRANT® and SUBIDEL®.

In addition, prior to the proceedings against TEVA and RATIOPHARM, ASTRAZENECA had previously requested precautionary measures against the company SANDOZ for the marketing of its generic fulvestrant drug. In the first instance, Commercial Court No. 4 of Barcelona granted the requested preliminary injunction. However, it was lifted by the Court of Appeals, by decision dated 27 December 2017.

Following this decision of the Barcelona Court of Appeals in the case against SANDOZ, Commercial Court No. 4 issued the above-mentioned two orders of 18 July 2018 rejecting the PI requested this time against TEVA and RATIOPHARM.

In both orders, this first instance Court concluded that there was no appearance of good standing (*fumus boni iuris*) with respect to the validity of the patents at stake. The Court considered, on the one hand, that patents EP 138 and EP 573 were presumably invalid for lack of inventive step and, on the other hand, that patent EP 195 would be invalid for lack of novelty.

Upon appeal, Barcelona Court of Appeals, before going on to assess the appearance of good standing (the strength of the patents in terms of their validity and appearance of infringement), referred to the requirement of danger in the delay (*periculum in mora*).

Danger of delay *(periculum in mora)*

In cases of preliminary injunctions requested to refrain the launch of generic drugs, Spanish Courts usually consider that this requirement of *periculum in mora* is met because the "imminent" infringement –caused by the imminent launch of the generic drug– may cause severe reductions on the price of reference drugs. Thus, by granting a preliminary injunction, this harmful situation can be avoided pending issue of a judgment on the merits.

However, in the present case the Court of Appeals took note of the fact that there was no longer any danger of the price of ASTRAZENECA's medicine FALSODEX® being affected, since there were other companies already marketing generic medicines in Spain based on fulvestrant (including SANDOZ, against which the same Court of Appeals lifted the injunction in December 2017).

The Court of Appeals considered that ASTRAZENECA had already lost its de facto exclusivity on the fulvestrant product and that it could no longer be in a position to recoup this exclusivity, even if the appeal was upheld.

Therefore, with regard to the "expulsion" of ASTRAZENECA'S FALSODEX® product from the market, the Court of Appeals stated that although the setting of the reference price of the generic drug undoubtedly put at risk the effectiveness of the possible final judgment upholding ASTRAZENECA's claim, this risk could no longer be eliminated by the adoption of precautionary measures now.

Appearance of good right (*fumus boni iuris)*

The appearance of good right is, along with the danger in the delay, the other main requirement for the granting of precautionary measures in Spain.

In the present case, with the aim of analysing whether this requirement was met, the Court of Appeals of Barcelona first stated that the examination of both requirements should be carried out by weighing

one with each other: that is, the greater *periculum in mora*, the greater laxity when assessing the appearance of good right and vice versa, the lower the danger in delay, the greater the strength of the appearance of good right shall be.

In the present circumstances, given that danger in delay was not very strong, only if the plaintiff's appearance of good right were to become very clear, precautionary measures could be granted.

However, this was not the case as the Court of Appeals of Barcelona considered that there were serious doubts about the validity of ASTRAZENECA's patents.

Regarding patent EP 573, the Court of Appeals noted that although the Board of Appeals of the EPO declared in a resolution issued on 24 January 2019 –that is, during the course of the appeal proceedings– that patent EP 573 met patentability requirements, it did so by analysing a different prior art. The Court also took into account what was decided by foreign courts, which, for the most part, considered that the patent was invalid and, in particular, the German Supreme Court and the Milan Court, which in decisions issued after the resolution of the EPO Board of Appeals also declared that patent EP 573 was invalid.

Furthermore, with regard to patent EP 138, there was a previous Order dated 27 December 2017 (issued in previous PI proceedings against SANDOZ) by which this same Section 15 of the Court of Appeals of Barcelona concluded that patent EP 138 was *prima facie* invalid for lack of inventive step.

Therefore, in view of the above, the Court of Appeals of Barcelona concluded that there was not enough appearance of good right, and in particular not to such an extent as to compensate the lack of *periculum in mora*.

For all the above reasons, the Court confirmed the dismissal of the precautionary measures agreed by orders of 18 July 2018.

Preliminary injunction based on use patent EP 195

Finally, only in the case filed against RATIOPHARM, ASTRAZENECA also invoked use patent EP 195 projecting a specific fulvestrant treatment for women with breast cancer whose previous treatment with an aromatase inhibitor and tamoxifen had failed ("*Use of fulvestrant in the preparation of a medicament for the treatment of a patient with breast cancer who previously has been treated with an aromatase inhibitor and tamoxifen, and has failed with such previous treatment*").

In this case ASTRAZENECA requested, on the one side, a PI against the marketing of RATIOPHARM's medicine SUBIDEL® based on patents EP 138 and EP 573 and, on the other side (and now based on

patent EP 195) the prohibition of its marketing unless the technical data sheet and leaflet of SUBIDEL® were modified in such a way that the treatment under protection was expressly excluded (i) for a patient with breast cancer, (ii) previously treated with tamoxifen and with an aromatase inhibitor, (iii) whose previous treatment had failed.

However, the Court also dismissed precautionary measures based on patent EP 195 as it found that ASTRAZENECA, by not having invoked this patent before, neither in 2016 in the suit against SANDOZ, nor in 2017 in the suit against TEVA, had tolerated for a long time the alleged infringement. Thus, the Court concluded that there was no urgency because of this “tolerance situation” regarding use patent EP 195, which ASTRAZENECA could have asserted earlier in those previous proceedings.

In conclusion, the dismissal of all precautionary measures requested by ASTRAZENECA against TEVA and RATIOPHARM was confirmed on appeal, either based on EP 138 and EP 573 or EP 195.

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