EIP

Intervention request refused

Accord Healthcare B.V. & Others v Novartis AG (UPC_CFI_6984/2024)

Application to Intervene by Zentiva K.S. and Zentiva Portugal, LDA

Order of 27 March 2025 (ORD_10348/2025)[1]

The Claimants ("Accord") had applied for a declaration of non-infringement of EP 2501384 (the "Patent") of Novartis AG ("Novartis") at Milan Central Division. The Patent claimed a particular pyrimidylaminobenzamide (known as nilotinib) for use in a method of treatment of chronic myeloid leukemia orally administered dispersed in apple sauce. Accord's position is that the summary of product characteristics (SmPC) for its generic nilotinib product clearly indicate that it is not suitable for use in dispersion and that patients should use other products for this purpose, therefore there is no infringement. Novartis in its defence said that the carve-out in Accord's SmPC and wording of the product information leaflet was not sufficient to avoid infringement and additional measures would be needed.

The applicant ("Zentiva") filed a request to intervene under Rule 313 RoP on the basis that it too had a generic nilotinib product. It therefore had a parallel interest in intervening in proceedings that were aimed at defining the infringement scope of the Patent. Zentiva's SmPC included the wording "For patients with swallowing difficulties, including pediatric patients that are not able to swallow the hard capsules, other medicines containing nilotinib should be used instead of Nilotinib Zentiva".

Decision

Rule 313.1 provides that:

"An Application to intervene may be lodged at any stage of the proceedings before the Court of First Instance or the Court of Appeal by any person establishing a legal interest

in the result of an action submitted to the Court [...]."

p2 Zentiva argued that it has such a legal interest because of the "identity of factual and legal elements" of the proceedings such as: same medicinal product; same carve out; and aiming to avoid the same patent. Zentiva could itself bring DNI proceedings but it would be uneconomic for it to bring revocation proceedings as the market for nilotinib is small. A decision in these DNI proceedings would bind a future court and so if Zentiva were not permitted to intervene its rights of equal treatment and non-discrimination under Articles 20 and 21 of the Charter of Fundamental Rights of the European Union would be breached.

Novartis argued that a request for intervention is allowable only if the intervener is immediately and directly affected by the ruling of the proceedings; a purely factual interest relating to the grounds for the action, the pleas in law or the outcome which may influence other similar cases is not sufficient.

The Court held that the applicant must show a legally qualified interest to prevent direct impact of consequences of the judgment on itself, not a mere factual interest. This principle had been set out in Ocado v Autostore[2] , where the Court of Appeal explained that "An interest in the result of the action within the meaning of R.313.1 RoP means a direct and present interest in the grant by the Court of the order or decision as sought by the party, whom the prospective intervener wishes to support and not an interest in relation to the pleas in law put forward. It is necessary to distinguish between prospective interveners establishing a direct interest in the ruling on the specific request sought by the supported party, and those who can establish only an indirect interest in the result of the case by reason of similarities between their situation and that of one of the parties. A similarity between two cases is not sufficient".

In the present case Zentiva and Accord have similar interests but parallelism alone is not sufficient to establish a legal interest. The Court observed that res judicata occurs only between the parties who participate in the proceedings. A decision in these proceedings would not be res judicata in any proceedings brought by Zentiva. Therefore there is no breach of the principle of right of defence or equal treatment. Further the Court noted that Art. 33 regulates connected cases for the same patent and provides for separate adjudications (bifurcation) as well as stay of proceedings or joint decisions. Such solutions are part of the UPC and are not prejudicial to the right to defence.

The Court also considered the wording of Rule 313.2 that "An Application to intervene shall be admissible only if it is made in support, in whole or in part, of a claim, order or remedy sought by one of the parties [...]" commenting that the wording 'in whole or in part' seems ambiguous as it is not clear whether it refers to partiality by containment or

by partial overlap. The Court concluded that if the party has a parallel legal interest in the procedure, it should present its defence in a parallel procedure. There was no need for
p3 Zentiva to be heard in the present proceedings because the decision would have no direct effect on it.

The intervention application was a sub-proceeding in which the applicant and respondent are the parties for the purposes of costs under Rule 150. The successful party for Rule 151 includes the winning party at the outcome of the sub-proceeding. Accordingly Novartis was entitled to seek its costs pursuant to Art. 69. Zentiva was ordered to pay the costs; but as there was no indication of the value of the dispute and only drafting of a written submission was involved these would be at the lowest ceiling.

Leave to appeal was not granted because Rule 317 RoP provides "There shall be no appeal against an order refusing an Application to intervene".

[1] https://www.unified-patent-court.org/en/node/78936

[2] UPC_CoA_404/2023 App_584498/2024 https://www.unified-patent-court.org/en/node/529