The Supreme Court confirms that companies have locus standi to challenge the marketing authorisation granted to a competitor

Judgments of the Supreme Court, Nos. 827/2024 and 1241/2024, of 14 May and 10 July

Background

Both judgments have been issued in proceedings initiated in Spain by an innovator company that challenged the marketing authorisations ("MAs") granted to certain competing medicinal products. The Spanish Agency for Medicines and Medical Devices ("AEMPS") granted these MAs through a decentralised procedure, in which the Netherlands acted as reference Member State and Spain as concerned Member State.

To understand the dispute, the following facts are relevant:

1. The claimant is the local representative of the MA holder of two medicinal products. One is for a product with a single active ingredient (ezetimibe), whose data protection period ended in 2011. The second MA is for a product with a fixed-dose combination of ezetimibe and atorvastatin, whose data protection period ended in September 2022.

2. Before September 2022, Cinfa and Normon applied for a MA for their generic versions of the combination of ezetimibe and atorvastatin. They provided bioequivalence studies comparing their combination products, not to the innovative combination, but to the concomitant use of the single active ingredients ezetimibe (whose data protection period had expired at that time) and atorvastatin. In addition, Cinfa and Normon relied on certain data on the combined use of ezetimibe and atorvastatin in the dossier of the innovative single active ingredient (ezetimibe) product. These data had been included in the MA of the single active ingredient (ezetimibe) product to fulfil the obligation of keeping the registration dossier updated with all available information on its use.

3. Despite the fact that the ezetimibe and atorvastatin combination had already been authorised in the past (in the innovative fixed-dose combination), and that it was therefore not the first time that a fixed-dose combination of these substances had been approved, the Cinfa and Normon combinations were not authorised as generic versions of the innovative product (ex. Article 10.1 of Directive 2001/83/EC), but as standard combinations on the basis of Article 10b of Directive 2001/83/EC. It is noteworthy that the legal basis of Article 10b is foreseen for medicinal products containing active substances already used in the composition of authorised medicinal products but not hitherto used in combination for therapeutic purposes at the time of the MA application.

4. The MA holder of the innovative combination initiated legal action against these generic combinations in several countries, including in the Netherlands, that acted as reference Member State.

5. In Spain, as explained in the judgements, it was argued that the Cinfa and Normon combinations were generic versions that should not have been evaluated until after September 2022, and that the use of Article 10b as a legal basis was a mechanism to circumvent regulatory data protection of the innovative combination.

6. While the case was pending before the Supreme Court, the MAs granted to generic combinations by the reference Member State were annulled in the Netherlands. This decision was based on the grounds that Article 10b of Directive 2001/83/EC could not be used as a legal basis, as the substances in question had already been combined for therapeutic purposes in the innovative fixed-dose combination, whose data protection period expired in September 2022.

Matters of interest to the Supreme Court

The appeals were formulated around two matters of interest to the Court. The first matter sought to determine the scope of the locus standi of a MA holder for a medicinal product to appeal the marketing authorisation of a competing product when it believes that such authorisation infringes its rights. The second matter aimed to clarify whether, in the decentralised procedure where Spain acts as a concerned Member State, the AEMPS must rule on substantive aspects of the case.

About the locus standi

The first and second instance judgments denied the innovator's locus standi on the grounds that the doctrine established by the Court of Justice of the European Union ("CJEU") in the Olainfarm case (C-104/13) was not applicable in this case. Both courts considered that, in the Olainfarm case, the substantive issue concerned a MA for a generic medicinal product granted on the basis of Article 10(1) of Directive 2001/83/EC. However, the legal basis used in this case was Article 10b of Directive 2001/83/EC.

The first and second instance judgments also rejected the locus standi of the claimant on the grounds that the innovator had no legal basis to require the AEMPS to object to the fact that Cinfa's and Normon's applications had been processed under Article 10b of Directive 2001/83/EC procedure.

The Supreme Court rectifies the position of first and second instance judgments and confirms that the innovator has locus standi to bring the case before the courts.

The Supreme Court establishes that the authorisation procedure for a medicinal product is a bilateral process between the applicant and the competent national authority; however, this does not prevent a third party, that considers itself harmed by the MA granted (such as the MA holder of a competing medicinal product), from having locus standi to challenge the granting of such MA in court. According to the Supreme Court, denying this right would be contrary to the principle of effective judicial protection.

In this regard, the Supreme Court points out that it is irrelevant (i) whether the legal basis used to grant the contested MAs was Article 10b of Directive 2001/83/EC, (ii) whether the contested MAs were granted in a decentralised procedure or (iii) whether the Olainfarm judgment concerned a MA for a generic medicinal product granted under Article 10(1) of Directive 2001/83/EC.

According to the Supreme Court, the Olainfarm judgment confirms that the MA holder has locus standi to act in defence of its rights if it consi-

ders that the MA granted to a competing medicinal product infringes those rights and does so on the basis of Article 47 of the Charter of Fundamental Rights of the European Union.

In relation with this first matter, therefore, the Supreme Cout established repeatedly in these two judgements (thus creating case law in this regards) that the MA holder for a medicinal product has locus standi to challenge the MA of a competing product if it considers that the granting of that MA infringes its rights.

About the scope of the AEMPS in decentralised procedures

Regarding the second matter, the Supreme Court dismisses the appeal, stating that it involves a question of factual grounds that cannot be reviewed at this stage of the cassation process before the Supreme Court.

Despite this ruling, these judgments are relevant because on their basis, in future cases, and before lower courts, it will be possible to request a judicial review of the actions of the AEMPS on such relevant issues as whether the legal basis of a MA procedure is correct or not; or whether the data on which the application for a MA is based should be considered protected or not.

Finally, it is unfortunate that the Supreme Court downplays the importance of the judgment handed down in the Netherlands annulling the MAs granted on the reference Member State. One more case in which “Spain is different”.