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For the first time, the holder of a reference medicinal product is allowed to challenge a generic approval in Court in Spain

The Judgement of the Contentious-Administrative Central Court No. 1, of July 2, 2018 recognizes locus standi to defend the data exclusivity of the registration dossier

Background

Can holders of reference medicinal products appeal against the approval of generics? Can such holders ask the Spanish Medicines Agency (AEMPS) or a Court in Spain to review the grant of a marketing authorization if they consider that there has been any violation of any regulation? This has been one of the most troublesome issues for many companies in recent years. In Spain, the Law governing the Administrative Court Proceedings states that any person or entity having a legitimate right or interest is entitled to appeal administrative decisions. At first glance, it seems that the holder of the reference medicinal product has a legitimate right or interest to prevent irregularities from occurring in the authorization procedure of generic medicinal products.

Traditional case law contrary to locus standi

However, for many years, Spanish Courts have denied the holders of reference medicinal products their right to challenge decisions granting marketing authorization for generic products. In the first cases dealing with this issue, judges understood that the holders of reference medicinal products were claiming that the authorization of generic medicinal products was an infringement of their patent rights. Based on this, several judgements stated that the legitimate interest to prevent a patent infringement could be defended in a civil suit against the alleged infringer; and that it was not possible to file Court appeals against the health administration, which should remain separate from industrial property rights related matters. Traditionally, AEMPS has relied on such caselaw to deny innovative companies their right to appeal against the its decisions approving generics.

Later on, in other cases, Spanish judges pointed out that having a marketing authorization is only a condition to place a product on the market, and that whether the holder of such authorization launches the product or not is the holder's own decision. On this basis, several judgments ruled that the damages that an innovator could suffer as a result of the appearance of generic medicinal products on the market would derive not from the decision of the authorities approving such generics, but from the decision to launch them, which was taken by the holder. Back then, this argument was used by Administrative Courts to decline their own jurisdiction, arguing that this was without prejudice of the innovator's right to initiate a civil case against the generic company.

Olainfarm Case

In 2014, the Court of Justice of the European Union (CJEU) issued an important judgement on this matter (Case C-104/13, Olainfarm).

According to the Olainfarm decision, the administrative procedure by which the authorization of a generic medicinal product is granted or not is a bilateral procedure in which the holder of the reference medicinal product may not be involved.

However, the CJEU added that the holder of the reference medicinal product has the right to require a Court of Law to revise whether the conditions foreseen for the approval of generics have been fulfilled or not, at least in connection with issues that concern the innovator. Otherwise the Charter of Fundamental Rights of the European Union would be violated, because such Charter provides that any person whose rights guaranteed by European Union law are violated must have the right to an effective remedy before Courts. Based on this, the CJEU concluded that the holder of the reference medicinal product should be allowed to file a judicial remedy aiming to review if such product could be considered as the reference product; if the composition and pharmaceutical form similarity requirements between the reference product and the generic have been met; or if the applicable data exclusivity period has been observed.

Spanish caselaw shift

In this case, our firm represented the holder of the reference medicinal product. We explained to the Court the need to analyze the matter in the light of the Olainfarm Judgment and, thus, to allow our client to exercise the right to effective judicial protection.

To our knowledge, this is the first Judgement issued by a Spanish Court stating that locus standi of the holder of the marketing authorization of a medicinal product, in order to obtain judicial protection regarding the prerogatives contained in Article 10 of Directive (2001/83/EC) should be recognized.

The Contentious-Administrative Central Court also points out that Article 10 of said Directive "contemplates different procedures having different scopes and that the technical and scientific requirements to demonstrate the quality, safety and efficacy of a medicinal product may vary depending on the legal arguments on which the request is based. Consequently, the type of specific procedure of the dispute must be taken into consideration to analyze the scope and conditions for exercising the right".

What does this change mean?

First of all, this caselaw shift means that the entire relevant legal context must be taken into account when a Spanish Court is deciding on cases like this one. In this particular case, the Court considers that the plaintiff could not expect a review as to whether or not the active ingredient of the generic was the same as the reference medicinal product. Basically, the Court states, because this issue had already been assessed in the reference Member State during the generic approval procedure, in which the holder of the reference medicinal product was able to participate by presenting arguments, which would have been considered back then.

On the other hand, the ruling of the Court supports the right of holders of reference medicinal products to litigate against the approval of generics if they consider that their right to data exclusivity has been violated.

In short, everything seems to indicate that those days on which administrative decisions could not be reviewed before Courts are over.

It is possible that Courts will continue to be rigorous regarding the scope and extent of the rights of innovators, but finally, after many years, a door has been opened. There will be those who think that this will have negative effects because it will increase litigious cases; but it may also serve to improve the quality of administrative procedures, which is always something desirable.