CAPSULAS
Boletín de información jurídica

Number 163 | Faus & Moliner Abogados | September 2015

New therapeutic indications and generics approved under centralised procedure

Judgment of the General Court of the European Union, of 15 September 2015, Case T-472/12, Novartis v. European Commission

Background

This case originated when Novartis brought an action seeking the annulment of the European Commission (EC) decision which granted a marketing authorisation (MA) to Teva for "Zoledronic acid Teva". Novartis argued that this decision was unlawful because it infringed its data exclusivity period in respect of its medicinal product Aclasta® .

In addition to addressing several interesting matters of substance, the judgment is significant because at no point does it question the legitimacy of Novartis to bring judicial actions against the granting of a MA to Teva. In contrast, we must recall that in Spain the courts have frequently denied the right of companies which are holders of marketing authorisations for reference medicinal products to file a judicial action against decisions granting authorisations for generic versions of their products.

Facts underlying the dispute

In March 2001, Novartis obtained a MA for the medicinal product Zometa® , indicated for treating certain bone complications in patients with cancer. In the years that followed, Novartis conducted several trials on the use of zoledronic acid to treat non-oncology pathologies. As a result, in April 2005, Aclasta® was authorised for non-oncology indications and with a different strength than Zometa® . Both medicinal products were authorised following the centralised procedure.

In May 2011, Teva filed a MA application for the medicinal product "Zoledronic acid Teva" as a generic version of Aclasta® . Teva's application referred to data submitted by Novartis in the procedures for authorisation of both Zometa® and Aclasta® .

In October 2012, Novartis filed an appeal with the General Court seeking the annulment of the European Commission's decision because, in their opinion, the EC should not have accepted an MA application for generic medicinal products based on the data that Novartis had submitted in respect of Aclasta® until April 2015. The EC and Teva opposed on the grounds that Aclasta® could not benefit from an independent regulatory data exclusivity period different from the one previously granted to Zometa® , given that the MAs for Zometa® and Aclasta® should be considered as part of the same global marketing authorisation.

Concept of global marketing authorisation

In its ruling, the Court recalled that the notion of a global marketing authorisation is derived from solid jurisprudence and is contained in Article 6 of Directive 2001/83. By virtue of such provision, when a medicinal product has been granted an initial MA, any additional strengths, pharmaceutical forms, administration routes, presentations and any other variations or extensions must also be granted authorisation, and all such marketing authorisations will be regarded as belonging to the same global marketing authorisation and will not enjoy an independent exclusivity protection period.

Before the Court, Novartis argued that this concept should be limited to variations and extensions of the initial MA, and should not apply to those that lead to a new MA. The Court rejected this argument, referring to the literal sense of the law and the objectives it pursues. The Court pointed out that Directive 2001/83 stipulates that, for the purpose of the application of the exclusivity period, all innovations developed from the original medicinal product form part of the same global MA, irrespective of whether they are granted a new MA or added to the original MA.

Analysing the issue in the light of the objectives of the regulation, the Court observed that when Novartis requested the MA for Aclasta® , it could just as well have applied for a variation of the terms of the MA for Zometa® , in which case there would be no dispute over the non-extension of the exclusivity period for the product's new therapeutic indication. The Court understood the reasons that led Novartis to request a new MA instead of a variation of the original, and it concluded that such commercial reasons were legitimate, but not sufficient to invalidate the application of the global marketing authorisation concept.

In its reasoning, the Court concluded that the efforts of innovative companies were already given due consideration when the exclusivity period was extended by Directive 2004/27 and Regulation No. 726/2004. After their approval, the Court recalled, the data exclusivity period could be extended to a maximum of eleven years if, during the first eight years of the data protection period, the MA holder obtains an authorisation for one or more new indications, which during the scientific evaluation, are considered to bring significant clinical benefit in comparison with existing therapies.

Innovation as an eligibility criterion for the centralised procedure

In its appeal, Novartis also pointed out that Aclasta® was authorised under the centralised procedure, which implies an acknowledgement of Aclasta® as significantly innovative from a therapeutic standpoint. Consequently, Novartis sustained that any new MA granted under the centralised procedure should be considered a new global MA with an independent data exclusivity period, even if the medicinal product in question contains the same active substance as another product previously authorised under the same procedure.

The General Court also rejected this argument by explaining that the purpose of the eligibility criteria for the centralised procedure is simply to govern access to said procedure, and this has no effect whatsoever on data exclusivity periods.