Reports of Cases

Joined Cases C-629/15 P and C-630/15 P

Novartis Europharm Ltd
v
European Commission

(Appeal — Medicinal products for human use — Marketing authorisation — Regulation (EEC) No 2309/93 — Centralised procedure at EU level — Development of a medicinal product that was the subject of a marketing authorisation for other therapeutic indications — Separate marketing authorisation and new trade name — Directive 2001/83/EC — Second subparagraph of Article 6(1) and Article 10(1) — Concept of a 'global marketing authorisation' — Regulatory data protection period)

Summary — Judgment of the Court (Eighth Chamber) of 28 June 2017

1. *Approximation of laws — Medicinal products for human use — Marketing authorisation — Abridged procedure — Global marketing authorisation — Scope — Developments of a medicinal product that is the subject of a separate marketing authorisation and name — Included — No new regulatory data protection period granted*

   (European Parliament and Council Directive 2001/83, Art. 6(1); Commission Regulation No 1085/2003, Art. 3)

2. *Appeal — Grounds — Inadequate statement of reasons — Reliance by the General Court on implicit reasoning — Lawfulness — Conditions*

   (Art. 256 TFEU; Statute of the Court of Justice, Arts 36 and 53, first para.)

1. The 'global marketing authorisation' referred to in the second subparagraph of Article 6(1) of Directive 2001/83 on the Community code relating to medicinal products for human use is accompanied only by a single regulatory data protection period which applies both to data relating to the original medicinal product and to data presented for its developments, such as additional strengths, pharmaceutical forms, administration routes, presentations, as well as variations and extensions. That period begins with the grant of the marketing authorisation (MA) for the original medicinal product.

In that respect, changes made by an MA proprietor to the strength and to the therapeutic indications of a medicinal product constitute 'variations' within the meaning of Regulation No 1085/2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Regulation No 2309/93, that is to say developments of that medicinal product, referred to in the second subparagraph of Article 6(1) of Directive 2001/83, with the result that the grant of the MA for such developments does not give rise to an independent regulatory data protection period. In that context, the second subparagraph of Article 6(1) of Directive 2001/83 makes no distinction between the developments authorised through the granting of a separate MA and the developments of the initial medicinal product authorised through the variation of the terms of an initial MA. It follows that the

concept of a ‘global marketing authorisation’, within the meaning of that provision, covers all subsequent developments of the original medicinal product, irrespective of their authorisation procedures, namely through the variation of the initial MA for that medicinal product or through the grant of a separate MA.

(see paras 65, 69, 71, 72)

2. See the text of the decision.

(see para. 86)