Pleas in law and main arguments

In support of the action, the applicant relies on two pleas in law.

1. First plea in law, alleging

   — an error in law and manifest error of assessment in the Commission's finding that a full deduction for SG&A and profit from the export price of the CHEMK Group was warranted, and in the Commission's related finding that a single economic entity is irrelevant for the calculation of export price (including adjustments to export price) pursuant to Article 2(9) of the Basic Regulation ([1]). To the extent the Commission may have relied on the rejection of the applicant's claim of existence of a single economic entity, the applicant contends that such rejection is also vitiated by an error in law and/or a manifest error of assessment.

2. Second plea in law, alleging

   — a manifest error of assessment in the Commission's finding that there was a changed circumstance in the sense of Article 11(9) of the Basic Regulation, which warranted the application of a different methodology for the calculation of the final dumping margin. The applicant also invokes a consequential breach of Article 11(9) of the Basic Regulation in the Commission's application of the new methodology, which is different from the respective methodology used in the original investigation.

([1]) Council Regulation (EC) No 1225/2009 of 30 November 2009 on protection against dumped imports from countries not members of the European Community (OJ L 343, p. 51)

Action brought on 30 October 2012 — Novartis Europharm v Commission

(Case T-472/12)

(2012/C 389/13)

Language of the case: English

Parties

Applicant: Novartis Europharm (Horsham, United Kingdom) (represented by: C. Schoonderbeek, lawyer)

Defendant: European Commission

Form of order sought

The applicant claims that the Court should:

— Annul the decision of the European Commission C(2012) 5894 final of 16 August 2012 to grant a marketing authorisation to Teva Pharma BV, in accordance with Article 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1); and

— Order the defendant to pay its own costs and those of the applicant.

Pleas in law and main arguments

In support of the action, the applicant relies on one plea in law, alleging that the contested decision is unlawful in that it constitutes an infringement of the data protection rights of Novartis Europharm Ltd. for its product Aclasta pursuant to Articles 13(4) of Regulation (EC) No 2309/93 ([1]), read in conjunction with Article 89 of Regulation (EC) No 726/2004. As Aclasta was granted a separate independent marketing authorisation through the centralised procedure, the Aclasta authorisation does not fall under the same global marketing authorisation as Zometa (another product of Novartis Europharm Ltd), as specified in article 6(1) of Directive 2001/83/EC ([2]) for the purposes of data protection.

In addition, the contested decision is unlawful in that it constitutes an infringement of Article 10(1) of Directive 2001/83/EC as data protection for the reference medicinal product Aclasta has not expired and hence the conditions for granting a marketing authorisation under this article have not been complied with.

([1]) Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1)

([2]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67)