

Appeal brought on 4 April 2022 by Mylan IRE Healthcare Ltd against the judgment of the General Court (Ninth Chamber) delivered on 26 January 2022 in Case T-303/16, Mylan IRE Healthcare v Commission

(Case C-237/22 P)

(2022/C 213/46)

Language of the case: English

Parties

Appellant: Mylan IRE Healthcare Ltd (represented by: I. Vernimme and L. Bidaine, avocats)

Other parties to the proceedings: European Commission, UAB VVB

Form of order sought

The appellant claims that the Court should:

- declare the appeal admissible and well founded;
- set aside in its entirety the judgment under appeal;
- if the Court considers that the state of the proceedings so permits, annul Commission Implementing Decision C(2016) 2083 final of 4 April 2016 concerning, in the framework of Article 29 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations for ‘Tobramycin VVB and associated names’, medicinal products for human use which contain the active substance ‘tobramycin’ (the contested decision); otherwise, refer the case back to the General Court;
- order the Commission to pay the costs of the appellant incurred as a result of both the present proceedings and those of the proceedings at first instance;
- order UAB VVB to support its own costs incurred as a result of both the present proceedings and those of the proceedings at first instance.

Pleas in law and main arguments

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

First plea in law alleging an error in law in the interpretation of the concept of ‘clinical superiority’ in the sense of Article 8 (3)(c) of the Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products ⁽¹⁾ (the Orphan Regulation), especially in the light of the interpretation given by the General Court to the concept of ‘significant benefit’ within the meaning of Article 3 of the Orphan Regulation.

Second plea in law alleging an insufficient reasoning of the General Court to base its conclusion that TOBI / Tobramycin VVB was safer than Tobi Podhaler in a substantial portion of the target population especially in the light of the content of contested decision.

⁽¹⁾ OJ 2000 L 18, p. 1.

Appeal brought on 8 April 2022 by Scania AB, Scania CV AB, Scania Deutschland GmbH against the judgment of the General Court (Tenth Chamber, Extended Composition) delivered on 2 February 2022 in Case T-799/17, Scania and Others v Commission

(Case C-251/22 P)

(2022/C 213/47)

Language of the case: English

Parties

Appellants: Scania AB, Scania CV AB, Scania Deutschland GmbH (represented by: D. Arts, advocaat, F. Miotto, avocate, N. De Backer, advocate, C.E. Schillemans, advocaat, C. Langenius, S. Falkner, L. Ulrichs, P. Hammarskiöld, advokater)