

Judgment of the General Court of 11 June 2015 — Laboratoires CTRS v Commission**(Case T-452/14) ⁽¹⁾****(Medicinal products for human use — Orphan medicinal products — Marketing authorisation for the medicinal product Cholic Acid FGK (renamed Kolbam) — Therapeutic indications — Market exclusivity — Article 8(1) of Regulation (EC) No 141/2000)**

(2015/C 245/20)

Language of the case: English

Parties

Applicant: Laboratoires CTRS (Boulogne-Billancourt, France) (represented by: K. Bacon, Barrister, M. Utges Manley and M. Vickers, Solicitors)

Defendant: European Commission (represented by: E. White, P. Mihaylova and A. Sipos, acting as Agents)

Re:

Application for annulment in part of Commission Implementing Decision C(2014) 2375 of 4 April 2014 granting, in exceptional circumstances, marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for 'Cholic Acid FGK — cholic acid', an orphan medicinal product for human use, as amended by Commission Implementing Decision C(2014) 6508 of 11 September 2014 transferring and amending the marketing authorisation granted in exceptional circumstances by Decision C(2014) 2375 for 'Kolbam — cholic acid', an orphan medicinal product for human use, in so far as that decision in substance indicates that that medicinal product is authorised for the therapeutic indications for Orphacol or, in the alternative, for annulment of Article 1 of that decision.

Operative part of the judgment

The Court:

1. *Annuls Commission Implementing Decision C(2014) 2375 of 4 April 2014 granting, in exceptional circumstances, marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for 'Cholic Acid FGK — cholic acid', an orphan medicinal product for human use, as amended by Commission Implementing Decision C(2014) 6508 of 11 September 2014 transferring and amending the marketing authorisation granted in exceptional circumstances by Decision C(2014) 2375 for 'Kolbam — cholic acid', an orphan medicinal product for human use;*
2. *Orders the European Commission to bear its own costs and to pay those of Laboratoires CTRS;*
3. *Orders ASK Pharmaceuticals GmbH to bear its own costs.*

⁽¹⁾ OJ C 253, 4.8.2014.