— in the alternative, annul Article 4 of the contested decision, in so far as it makes a determination as to the lawfulness of private contracts between the investors and other entities, in full or in such a way as to limit the bar on passing on the burden of recovery to the profitability of the operations; and

— order the Commission to pay the costs of these proceedings.

Pleas in law and main arguments

The pleas in law and main arguments are those raised in Case T-401/14 *Duro Felguera SA* v *Commission*.

Action brought on 17 June 2014 — Laboratoires CTRS v Commission

(Case T-452/14)

(2014/C 253/84)

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

Form of order sought

The applicant claims that the Court should:

— annul Article 1 of the contested decision, in so far as the decision in substance indicates that Cholic Acid FGK is authorised for the Orphacol Indications; or in the alternative annul Article 1 of the decision in its entirety; and

— order that the Commission pays the applicant's costs.

Pleas in law and main arguments

The applicant is the marketing authorisation holder of the orphan medicinal product Orphacol, which is authorised for the treatment of two very rare and serious genetic liver disorders and whose active ingredient is cholic acid. Orphacol benefits as of 16 September 2013 from a 10-year period of market exclusivity in respect of these two indications in accordance with Article 8 of Regulation No 141/2000 ([1]).

By the contested decision dated 4 April 2014, the Commission granted a marketing authorisation for another orphan medicinal product (Cholic Acid FGK) with cholic acid as the active ingredient. Although Cholic Acid FGK was authorised for three other therapeutic indications than those for which Orphacol was authorised, the Summary of Product Characteristics and the Assessment Report for Cholic Acid FGK, which according to the applicant form an integral part of the contested decision, contained extensive references to the efficacy as well as references to the safety of Cholic Acid FGK in the therapeutic indications for which Orphacol was authorised.

In support of the action, the applicant relies on a single plea in law, alleging infringement of Article 8(1) of Regulation No 141/2000, as the Commission has, by granting a marketing authorisation for Cholic Acid FGK on the terms set out in the Summary of Product Characteristics and the Assessment Report, circumvented the applicant's market exclusivity, since the terms upon which the marketing authorisation for Cholic Acid FGK was granted imply, in substance, that Cholic Acid FGK is also authorised for the two therapeutic indications for which Orphacol is authorised.

([1]) Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ 2000 L 18, p. 1).