Action brought on 21 June 2016 — Bristol-Myers Squibb Pharma v Commission and EMA

(Case T-329/16)

(2016/C 314/37)

Language of the case: English

Parties

Applicant: Bristol-Myers Squibb Pharma EEIG (Uxbridge, United Kingdom) (represented by: P. Bogaert and B. Van Vooren, lawyers, and B. Kelly, Solicitor)

Defendants: European Commission and European Medicines Agency,

Form of order sought

The applicant claims that the Court should:

— declare the action admissible and well founded;

— annul the Contested Acts; and

— order the European Commission and the EMA to pay the applicant's costs.

Pleas in law and main arguments

By its action, the applicant seeks the annulment of an act of the European Commission removing 'elotuzumab' from the Union Register of orphan medicinal products for human use and/or a possible act of the European Commission or the European Medicines Agency determining that the orphan designation criteria for 'elotuzumab' were not met any more at the time of marketing authorisation of the medicinal product 'Empliciti'.

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

1. First plea in law, alleging that the contested acts violate Article 5 (12) (b) of the Orphan Medicines Regulation (EC) No 141/2000 ([1]), in conjunction with the principle of proportionality:

   — First, pursuant to Article 5(12)(b) Orphan Medicines Regulation (EC) No 141/2000, a medicinal product that received a marketing authorisation after the application for marketing authorisation for the orphan medicine, cannot be taken into account under Article 3 (b) Orphan Medicines Regulation (EC) No 141/2000.

   — Second, pursuant to Article 5(12) Orphan Medicines Regulation (EC) No 141/2000, the orphan designation can only be withdrawn when the criteria of Article 3 Orphan Medicines Regulation (EC) No 141/2000 are no longer met.

   — Third, pursuant to Article 5(12)(b) Orphan Medicines Regulation (EC) No 141/2000, the EMA and the Commission must apply a standard of proof that supports the objective of the Regulation.

2. Second plea in law, alleging that the contested acts infringe Article 5(12)(b) Orphan Medicines Regulation (EC) No 141/2000, in conjunction with Article 5(8) Orphan Medicines Regulation (EC) No 141/2000, as there is no formal Commission decision.

([1]) Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1)

Action brought on 26 June 2016 — City of Paris v Commission

(Case T-339/16)

(2016/C 314/38)

Language of the case: French

Parties

Applicant: City of Paris (Paris, France) (represented by: J. Assous, lawyer)

Defendant: European Commission