Operative part of the order

1. The application for interim measures is dismissed.

2. The costs are reserved.

Action brought on 16 May 2022 — Biogen Netherlands v Commission

(Case T-268/22)

(2022/C 284/60)

Language of the case: English

Parties

Applicant: Biogen Netherlands BV (Badhoevedorp, Netherlands) (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 of 13 May 2022 (C(2022)3251(final)) amending the marketing authorisation granted by decision C(2014)601(final) for 'Tecfidera — Dimethyl fumarate', a medicinal product for human use; and

— order the Commission to pay the costs.

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 a failure to observe the system of Directive 2001/83/EC [1] in relation to the rules on regulatory data protection, including Article 6(1) of that Directive, and the obligations of generic applicants under Article 10(1) of that Directive.

2. Second plea in law, alleging a failure to recognise the consequences of the opinion of the Committee for Medicinal Products for Human Use of 11 November 2021 for the question whether the marketing authorisation for the medicinal product Fumaderm was capable of commencing a global marketing authorisation for the medicinal product Tecfidera in accordance with Article 6(1), second subparagraph, of Directive 2001/83/EC.

[1] 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).

Action brought on 16 May 2022 — Biogen Netherlands v Commission

(Case T-269/22)

(2022/C 284/61)

Language of the case: English

Parties

Applicant: Biogen Netherlands BV (Badhoevedorp, Netherlands) (represented by: C. Schoonderbeek, lawyer)

Defendant: European Commission