C/2024/1423

19.2.2024

Action brought on 23 December 2023 — Neuraxpharm Pharmaceuticals v Commission

(Case T-1182/23)

(C/2024/1423)

Language of the case: English

Parties

Applicant: Neuraxpharm Pharmaceuticals SL (Barcelona, Spain) (represented by: K. Roox, T. De Meese, J. Stuyck and C. Dumont, lawyers)

Defendant: European Commission

Form of order sought

The applicant claims that the Court should:

— declare Neuraxpharm Pharmaceuticals' request for annulment admissible and well-founded;

— annul the Commission Implementing Decision C(2023) 8921 final of 13 December 2023 revoking Decision C(2022) 3254 (final) granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for 'Dimethyl fumarate Neuraxpharm — dimethyl fumarate', a medicinal product for human use ('the contested decision');

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

Pleas in law and main arguments

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

1. First plea in law, alleging a breach of Articles 81, 14(11), 13 and 5 of Regulation EC No 726/2004 of the European Parliament and of the Council. ([1])

2. Second plea in law, alleging that the contested decision amounts to a misuse of power by the European Commission.

3. Third plea in law, alleging that the European Commission misapplies the law, as it erred with respect to the scope of judgment of 16 March 2023, Joined Cases C-438/21 P, *Commission* v *Pharmaceutical Works Polpharma and EMA*, C-439/21 P, *Biogen Netherlands* v *Pharmaceutical Works Polpharma and EMA* and C-440/21 P, *EMA* v *Pharmaceutical Works Polpharma* (EU:C:2023:213) and in particular by considering the ad hoc assessment report of 11 November 2021 irrelevant.

4. Fourth plea in law, alleging that the European Commission made an error in basing the contested decision on the wrong scientific facts available at the time of its decision.

5. Fifth plea in law, invoking a plea of illegality against Biogen's marketing authorisation granted by the Implementing Decision C(2014)601(final) of 30 January 2014 granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for 'Tecfidera — Dimethyl fumarate', a medicinal product for human use, and requesting the annulment of the contested decision as a consequence.

6. Sixth plea in law, alleging infringement of the fundamental rights and in particular, the right to a fair trial, the right of defence, the right to be heard, and the right to a legal basis pursuant to Article 47 of the Charter of Fundamental Rights of the European Union ('the Charter').

7. Seventh plea in law, alleging that the contested decision infringes the applicant's legal certainty.

8. Eighth plea in law, alleging that the contested decision violates the applicant's legitimate expectations.

9. Ninth plea in law, alleging that the contested decision violates the applicant's right to property, laid down in Article 17 of the Charter.

([1]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1).