C/2025/5207

6.10.2025

Appeal brought on 15 July 2025 by Debrégeas et associés Pharma (D&A Pharma) against the order of the General Court (Fourth Chamber) made on 7 May 2025 in Case T-373/24, D&A Pharma v EMA

(Case C-467/25 P)

(C/2025/5207)

Language of the case: French

Parties

Appellant: Debrégeas et associés Pharma (D&A Pharma) (represented by: V. Durget, E. Gouesse and N. Viguié, avocats)

Other party to the proceedings: European Medicines Agency

Form of order sought

The appellant claims that the Court of Justice should:

— set aside the order of the General Court (T-373/24) of 7 May 2025;

— rule that the state of the proceedings permits final judgment to be given, dispose of the case and, consequently:

annul the EMA decision of 13 May 2024 refusing to retract the CHMP opinion of 12 October 2017, to update its website in relation to that matter and to publish D&A Pharma's correspondence of 30 January and 12 April 2024;

— order EMA to pay the costs of the proceedings.

Grounds of appeal and main arguments

In support of the appeal, the appellant puts forward four grounds:

1. **First ground of appeal,** alleging that the General Court made a manifest error of appraisal in holding that D&A Pharma had no interest in bringing proceedings against the contested decision on the ground that a potential annulment of the contested decision would not procure any advantage for it, whereas such an annulment would allow it to obtain the retraction, if not the amendment, of a negative and flawed opinion relating to the proprietary medicinal product of which it is the proprietor, and therefore to remedy the damage caused to its reputation and its commercial interests.

   That situation clearly establishes an interest in bringing proceedings according to the criteria laid down by the case-law of the Court of Justice, which focusses on the benefit that the applicant may derive from the action (Court of Justice, 17 September 2015, *Mory* v *Commission*, C-33/14 P, paragraph 76) and adopts a broad reading of an interest in bringing proceedings.

2. **Second ground of appeal,** alleging that the General Court made a manifest error of appraisal in holding that the appellant did not demonstrate a vested and current interest in bringing proceedings against the contested decision.

   The case-law states, inter alia, that an applicant has an interest in bringing proceedings if it cannot be excluded that the annulment of the contested decision would enable it to put forward certain claims in other future actions and/or to request a re-examination of its application by administrative authorities (General Court, 18 March 2010, *Centre de coordination Carrefour* v *Commission*, T-94/08, paragraph 60), or if it demonstrates that the annulment which it seeks before the Courts of the European Union may improve its position in the context of national proceedings (Court of Justice, 17 September 2015, *Mory* v *Commission*, C-33/14 P, paragraphs 75 and 85).

   In the present case, the fact that the appellant is the proprietor of the proprietary medicinal product concerned by the opinion in question is sufficient to establish a vested and current interest, irrespective of the influence that that opinion may have in the procedures for evaluation or re-evaluation of proprietary medicinal products in which D&A Pharma has an interest at European and national level.

3. **Third ground of appeal,** alleging that the General Court could not, without making a manifest error of appraisal, find that D&A Pharma did not establish a personal interest in bringing proceedings against the contested decision, whereas D&A Pharma is the proprietor of the proprietary medicinal product concerned by the opinion, irrespective of it being directly concerned by the ongoing procedure before the French agency regarding the proprietary medicinal product Lifspecta, in which the opinion has been relied on.

4. **Fourth ground of appeal,** alleging that the General Court made an error of law, coupled with a manifest error of appraisal, in holding that D&A Pharma had to prove that damage had been caused by the refusal to retract.

   In doing so, the General Court added a condition to the determination of whether an interest in bringing proceedings exists, which requires only that it be demonstrated that the action is liable, if successful, to procure an advantage to the party bringing it and that the interest is vested, current and specific to the applicant.

In addition, the appellant claims that the Court of Justice should find that the state of the proceedings permits final judgment to be given and, in accordance with the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union, quash the EMA decision of 13 May 2024 refusing to retract the CHMP opinion of 12 October 2017, in consideration of the pleas annexed to the appeal:

— An irregularity in the procedure following which the decision was adopted;

— The unenforceability of the two-month time limit for bringing an action laid down in the sixth paragraph of Article 263 TFEU;

— An error of law and a manifest error of appraisal made by EMA, having regard to the provisions of EMA Policy 1 on the 'Integrated Quality Management System'.