Reports of Cases

ORDER OF THE PRESIDENT OF THE COURT

17 September 2021 *

(Appeal – Intervention – Article 40 of the Statute of the Court of Justice of the European Union – Application by an agency of the European Union – Standing to intervene in a case between Member States and institutions of the Union – Interest in the result of the case – Allowed)

In Joined Cases C-6/21 P and C-16/21 P,

APPEALS under Article 56 of the Statute of the Court of Justice of the European Union, lodged on 7 January 2021,

Federal Republic of Germany, represented by S. Heimerl and J. Möller, acting as Agents,

appellant in Case C-6/21 P,

supported by:

Kingdom of the Netherlands, represented by M.K. Bulterman and J. Langer, acting as Agents,

intervener in the appeal,

the other parties to the proceedings being:

Pharma Mar SA, established in Colmenar Viejo (Spain), represented by M. Merola and V. Salvatore, avvocati,

applicant at first instance,

European Commission, represented by L. Haasbeek and A. Sipos, acting as Agents,

defendant at first instance,

and

Republic of Estonia, represented by N. Grünberg, acting as Agent,

appellant in Case C-16/21 P,

* Language of the case: English.

supported by:

Federal Republic of Germany, represented by S. Heimerl and J. Möller, acting as Agents,

Kingdom of the Netherlands, represented by M.K. Bulterman and J. Langer, acting as Agents,

interveners in the appeal,

the other parties to the proceedings being:

Pharma Mar SA, established in Colmenar Viejo, represented by M. Merola and V. Salvatore, avvocati,

applicant at first instance,

European Commission, represented by L. Haasbeek and A. Sipos, acting as Agents,

defendant at first instance,

THE PRESIDENT OF THE COURT,

having regard to the proposal from D. Šváby, Judge-Rapporteur,

after hearing the Advocate General, J. Richard de la Tour,

makes the following

Order

1 By their respective appeals, the Federal Republic of Germany and the Republic of Estonia ask the Court of Justice to set aside the judgment of the General Court of the European Union of 28 October 2020, *Pharma Mar* v *Commission* (T-594/18, not published, EU:T:2020:512), whereby the General Court annulled Commission Implementing Decision C(2018) 4831 final of 17 July 2018 ('the contested decision'), refusing marketing authorisation under 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) for Aplidin – plitidepsin, a medicinal product for human use.

2 By documents lodged at the Registry of the Court of Justice on 29 April and 20 May 2021, the European Medicines Agency (EMA) applied, under the second paragraph of Article 40 of the Statute of the Court of Justice of the European Union and Article 130 of the Rules of Procedure of the Court of Justice, applicable to appeal proceedings under Article 190(1) of those rules, for leave to intervene in Cases C-6/21 P and C-16/21 P, in support of the forms of order sought by the Federal Republic of Germany and the Republic of Estonia respectively. EMA submits, first, that it has a direct interest in the setting aside of the judgment of 28 October 2020, *Pharma Mar* v *Commission* (T-594/18, not published, EU:T:2020:512), in so far as the General Court based the annulment of the contested decision on the irregularity of the assessment procedure of the marketing authorisation application for Aplidin – plitidepsin for which it was responsible, in

accordance with Regulation No 726/2004. Second, EMA argues that the outcome of the present case may have a bearing on the opinions it will issue in the future, through its scientific committees.

3 By documents lodged at the Registry on 1 and 17 June 2021, Pharma Mar contended that the Court should reject those applications for leave to intervene. It mainly alleges that EMA has not demonstrated that its interests could be regarded as independent of those of the European Commission.

4 By document lodged at the Registry on 26 May 2021, the Commission indicated that it had no objection to EMA's applications for leave to intervene.

The applications to intervene

5 The first paragraph of Article 40 of the Statute of the Court of Justice of the European Union provides that Member States and institutions of the Union may intervene in cases before the Court. Under the first sentence of the second paragraph of that article, the same right is open to the bodies, offices and agencies of the Union and to any other person if they can establish an interest in the result of a case submitted to the Court.

6 The second sentence of the second paragraph of that article precludes, however, natural and legal persons from intervening in cases between Member States, between institutions of the Union or between Member States and institutions of the Union.

7 It thus follows from the wording and scheme of that provision that the exclusion it lays down does not apply to 'the bodies, offices and agencies of the Union'.

8 Consequently, under the second paragraph of Article 40 of the Statute of the Court of Justice of the European Union, the bodies, offices and agencies of the Union, such as EMA, may intervene in an action submitted to the Court in cases between Member States, between institutions of the Union or between Member States and institutions of the Union, provided that they can establish an 'interest in the result of a case'.

9 According to the Court's settled case-law, the concept of an 'interest in the result of a case', within the meaning of that provision, must be defined in the light of the subject matter of the dispute and be understood as meaning a direct, existing interest in the ruling on the form of order sought, and not as an interest in relation to the pleas in law or arguments put forward. The words 'result of a case' refer to the final decision sought, as set out in the operative part of the future judgment (see, inter alia, order of the President of the Court of 5 July 2018, *Uniwersytet Wrocławski and Poland* v *REA*, C-515/17 P and C-561/17 P, not published, EU:C:2018:553, paragraph 7). In principle, an interest in the result of the case can be regarded as sufficiently direct only in so far as that result is capable of altering the legal position of the applicant to intervene (order of the President of the Court of 30 April 2020, *Commission* v *HSBC Holdings and Others*, C-806/19 P, not published, EU:C:2020:364, paragraph 8 and the case-law cited).

10 However, it should be pointed out that the bodies, offices and agencies of the Union, unlike natural and legal persons, are likely to apply for leave to intervene in a case before the Court not to defend private interests or, as in the case of associations, interests connected with the objects set out in their statutes, such as environmental protection for example, but rather where, as in

the present case, the measure giving rise to the dispute was adopted following a procedure in which the body, office or agency in question was called upon to participate, in order to defend the opinion it had issued or the assessments it had made in the course of that procedure.

11 Therefore, so far as concerns applications to intervene by bodies, offices and agencies of the Union, the requirement that the applicant have a direct and existing interest in the result of the case must be applied in a way that reflects that particular situation.

12 Thus, as regards applications to intervene in a case concerning the annulment of an EU measure, or the setting aside of a decision of the General Court annulling such a measure, submitted by bodies, offices and agencies of the Union, the requirement that the relevant body, office or agency should have a direct and existing interest in the result of the case should be regarded as having been met, inter alia, if it is able to establish that the EU measure at issue was adopted following a procedure in which, in accordance with EU law, its participation is envisaged through, as the case may be, the adoption of opinions or the provision of assessments.

13 That is the case here. It is common ground that, in the procedure for the adoption of the contested decision, EMA's Committee for Medicinal Products for Human Use prepared, pursuant to Article 5(2) of Regulation No 726/2004, the opinion of that agency on the application for authorisation to place the medicinal product for human use Aplidin – plitidepsin on the market, which was taken into account by the Commission.

14 Consequently, in accordance with the second paragraph of Article 40 of the Statute of the Court of Justice of the European Union and Article 131(3) of the Rules of Procedure, EMA's application to intervene in support of the forms of order sought by the Federal Republic of Germany and the Republic of Estonia should be allowed.

The intervener's procedural rights

15 Since the applications to intervene have been allowed, EMA will receive a copy of every procedural document served on the parties, pursuant to Article 131(3) in conjunction with Article 190(1) of the Rules of Procedure.

16 As those applications were submitted within the one-month period prescribed in Article 190(2) of the Rules of Procedure, EMA may, in accordance with Article 132(1) of those rules, which is applicable to the appeal procedure under Article 190(1) of those rules, submit a statement in intervention within one month after the communication referred to in the preceding paragraph.

17 Lastly, EMA will be able to submit oral observations if a hearing is organised.

Costs

18 Under Article 137 of the Rules of Procedure, applicable to appeals under Article 184(1) thereof, a decision as to costs is to be given in the judgment or order which closes the proceedings.

19 In the present case, since EMA's application for leave to intervene has been granted, the costs relating to its intervention must be reserved.

On those grounds, the President of the Court hereby orders:

1. **The European Medicines Agency (EMA) is granted leave to intervene in Joined Cases C-6/21 P and C-16/21 P in support of the forms of order sought by the Federal Republic of Germany and the Republic of Estonia.**

2. **A copy of every procedural document shall be served on the European Medicines Agency (EMA) by the Registrar.**

3. **A period shall be prescribed within which the European Medicines Agency (EMA) may submit a statement in intervention.**

4. **Costs relating to the intervention by the European Medicines Agency (EMA) are reserved.**

Luxembourg, 17 September 2021.

A. Calot Escobar
Registrar

K. Lenaerts
President