Reports of Cases

JUDGMENT OF THE COURT (Eighth Chamber)

30 January 2025 *

(Appeal – Public health – Medicinal products for human use – Marketing authorisation – Spikevax – Comirnaty – Action for annulment – Independence and impartiality of the Courts of the European Union – Failure to comply with procedural rules – Failure to give adequate reasons, and contradictory reasoning – Legal interest in bringing proceedings – *Locus standi* – Fourth paragraph of Article 263 TFEU – Right to effective judicial protection)

In Case C-586/23 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 25 September 2023,

Giovanni Frajese, residing in Rome (Italy), represented by O. Milanese and A. Montanari, avvocati,

appellant,

the other party to the proceedings being:

European Commission, represented by G. Gattinara and A. Sipos, acting as Agents,

defendant at first instance,

THE COURT (Eighth Chamber),

composed of N. Jääskinen, President of the Ninth Chamber, acting as President of the Eighth Chamber, M. Gavalec (Rapporteur) and I. Ziemele, Judges,

Advocate General: L. Medina,

Registrar: A. Calot Escobar,

having regard to the written procedure,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

* Language of the case: Italian.

Judgment

1 By his appeal, Mr Giovanni Frajese asks the Court of Justice to set aside the order of the General Court of the European Union of 27 July 2023, *Frajese* v *Commission* (T-786/22, 'the order under appeal', EU:T:2023:457), by which the General Court dismissed the appellant's action for annulment of (i) Commission Implementing Decision C(2022) 7163 final of 3 October 2022 granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for 'Spikevax – elasomeran', a medicinal product for human use and repealing Decision C(2021) 94(final) and (ii) Commission Implementing Decision C(2022) 7342 final of 10 October 2022 granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for 'Comirnaty – tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)', a medicinal product for human use and repealing Decision C(2020) 9598(final) ('the decisions at issue').

Background to the dispute

2 The facts of the dispute are set out as follows in paragraphs 2 to 7 of the order under appeal:

'2. On 21 December 2020 and 6 January 2021, the European Commission adopted Implementing Decision C(2020) 9598 final and Implementing Decision C(2021) 94 final respectively, by which it granted – on applications submitted by BioNTech Manufacturing GmbH ('BioNTech') and by Moderna Biotech Spain SL ('Moderna') respectively under Article 14a of 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), as amended by Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 (OJ 2019 L 4, p. 24) – marketing authorisations ('MAs'), on a conditional basis, for the medicinal product 'Comirnaty – tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)' and the medicinal product 'Spikevax – elasomeran' (together, 'the vaccines in question').

3. Following the advice of the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA), and noting in recital 2 thereof that the specific obligations to which the conditional MAs granted to the vaccines in question are subject have been fulfilled, the decisions [at issue] repealed and replaced Implementing Decision C(2020) 9598 final and Commission Implementing Decision C(2021) 94 final.

4. As set out in Article 1 of the decisions [at issue], an MA under Article 3 of Regulation No 726/2004, which is not subject to specific obligations, is thereby granted to the vaccines in question, the summary of the characteristics of which is set out in Annex I to the decisions [at issue].

5. Under Article 2 of the decisions [at issue], the MAs granted to the vaccines in questions are to remain subject to compliance with the conditions set out in Annex II of the decisions [at issue], in particular relating to manufacture and importation, control and issue.

6. Under Article 4 of the decisions [at issue], the period of validity of the MAs granted to the vaccines in question is to be five years from the notification of those decisions.

7. Under Article 6 of the decisions [at issue], those decisions are addressed to Moderna and BioNTech.'

Procedure before the General Court and the order under appeal

3 By application lodged at the Registry of the General Court on 18 December 2022, Mr Frajese brought an action under Article 263 TFEU seeking annulment of the decisions at issue.

4 By a separate document, lodged at the Registry of the General Court on 6 March 2023, the Commission raised a plea of inadmissibility, claiming that, in respect of the decisions at issue, Mr Frajese had no legal interest in bringing the action and, moreover, no standing to bring it.

5 By the order under appeal, the General Court declared the action inadmissible by reason of the absence of a legal interest in bringing proceedings and lack of standing of Mr Frajese.

Forms of order sought before the Court of Justice

6 By his appeal, Mr Frajese. claims that the Court should:

– allow the appeal in its entirety;

– set aside the order under appeal;

– in any event, set aside the point of the operative part ordering the appellant to pay the costs; and

– uphold the action brought at first instance.

7 The Commission contends that the Court should dismiss the appeal and order Mr Frajese to pay the costs.

The appeal

8 In support of his appeal, Mr Frajese raises four grounds of appeal alleging: (i) infringement of Article 254 TFEU, Articles 2 to 18 of the Statute of the Court of Justice of the European Union, Article 16 of the Rules of Procedure of the General Court and Article 47 of the Charter of Fundamental Rights of the European Union ('the Charter'); (ii) infringement of Article 81(1) and (3) of the Rules of Procedure of the General Court, read in conjunction with Article 61(1) and Article 62 of those rules; (iii) failure to state reasons, and contradictory reasoning, and errors of law made in the finding of a lack of legal interest in bringing proceedings and a lack of standing, stemming from infringement of the fourth paragraph of Article 263 TFEU; and (iv) infringement of the right to effective judicial protection.

The first ground of appeal

Arguments of the parties

9 By his first ground of appeal, Mr Frajese challenges the validity of the order under appeal in so far as the Judge-Rapporteur in the case giving rise to that order performed various functions within the Commission between 1996 and 2019. He submits that the independence and impartiality of the General Court were compromised by the judge's long career within that institution and by the prospect of his resuming that career in that institution after the end of his term of office as a judge.

10 Referring to Article 254 TFEU, Articles 2, 4 and 18 of the Statute of the Court of Justice of the European Union, Article 16 of the Rules of Procedure of the General Court and Article 47 of the Charter, Mr Frajese states that Article 6(1) of the Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950, provides that the right to be heard by an independent and impartial tribunal forms the basis of a fair trial. He adds that, according to the case-law of the European Court of Human Rights, when assessing the independence of a tribunal, appearances also count, given the importance of preserving citizens' trust in a democratic society and the impartiality of the courts; further, in order to establish whether there is any legitimate doubt as to the independence or impartiality of a judge, account must be taken, in particular, of the point of view of the person concerned, in examining whether his or her concerns are justified. Thus, the independence of a judge is infringed both where the judge is actually influenced and where he or she may be influenced *in abstracto*, since suspicion is in itself liable to undermine citizens' trust.

11 The Commission contends that the first ground of appeal must be rejected.

Findings of the Court

12 It should be noted that, before the General Court, Mr Frajese did not request the recusal of the Judge-Rapporteur in the case which gave rise to the order under appeal, pursuant to the first and fourth paragraphs of Article 18 of the Statute of the Court of Justice of the European Union, applicable to the General Court by virtue of the first paragraph of Article 47 of that statute. Similarly, in his appeal, Mr Frajese does not rely on any of the grounds for recusal provided for in the first paragraph of Article 18 of that statute.

13 In his arguments before the Court of Justice, Mr Frajese merely submits, relying on the doctrine of appearances, that the Judge-Rapporteur's long career within the Commission and the prospect of his resuming that career in that institution after the end of his term of office cast doubt on the independence and impartiality of the formation of the General Court which had to hear the case.

14 In that regard, it must be recalled that the requirement that courts be independent, which is inherent in the task of adjudication, forms part of the essence of the right to effective judicial protection and the fundamental right to a fair hearing, which is of cardinal importance as a guarantee that all the rights which individuals derive from EU law will be protected and that the values common to the Member States set out in Article 2 TEU, in particular the value of the rule of law, will be safeguarded (judgment of 11 July 2024, *Hann-Invest and Others*, C-554/21, C-622/21 and C-727/21, EU:C:2024:594, paragraph 49 and the case-law cited).

15 There are two aspects to that requirement of independence. The first, which is external in nature, requires that the court concerned exercise its functions wholly autonomously, without being subject to any hierarchical constraint or subordinated to any other body and without taking orders or instructions from any source whatsoever, thus being protected against external interventions or pressure liable to impair the independent judgment of its members and to influence their decisions (see, to that effect, judgment of 11 July 2024, *Hann-Invest and Others*, C-554/21, C-622/21 and C-727/21, EU:C:2024:594, paragraph 50 and the case-law cited).

16 The second aspect, which is internal in nature, compliance with which is challenged by Mr Frajese by his ground of appeal referring to the formation of the General Court that adopted the order under appeal, is linked to the requirement of impartiality and seeks to ensure that an equal distance is maintained from the parties to the proceedings and their respective interests with regard to the subject matter of those proceedings (see, to that effect, judgment of 11 July 2024, *Hann-Invest and Others*, C-554/21, C-622/21 and C-727/21, EU:C:2024:594, paragraph 51 and the case-law cited).

17 There are two aspects to that requirement of impartiality. In the first place, that court must be subjectively impartial, that is to say, none of its members must show bias or personal prejudice, there being a presumption of personal impartiality in the absence of evidence to the contrary. In the second place, that court must be objectively impartial, that is to say, it must offer guarantees sufficient to exclude any legitimate doubt in this respect (see, to that effect, judgment of 1 July 2008, *Chronopost and La Poste* v *UFEX and Others*, C-341/06 P and C-342/06 P, EU:C:2008:375, paragraph 54, and order of 15 December 2011, *Altner* v *Commission*, C-411/11 P, EU:C:2011:852, paragraph 15).

18 However, first, Mr Frajese does not substantiate his claim, as regards subjective impartiality, with any evidence. He does not refer to any specific circumstance making it possible to establish personal bias on the part of the Judge-Rapporteur in the case which gave rise to the order under appeal. He does not claim, in particular, either that that member of the formation of the court was involved in the adoption of the decisions at issue or that he contributed to their adoption in any way.

19 Second, Mr Frajese has not produced any evidence to call into question the objective impartiality of the formation of the General Court concerned and does not dispute the validity of any provision of EU law intended to establish guarantees to ensure the impartiality of that court. In particular, he does not claim that the rules relating to the composition of the formation of the General Court to which a case is assigned are not such as to ensure the neutrality of that formation in relation to the interests before it.

20 Consequently, since Mr Frajese has not presented any legal argument specifically supporting the first ground of appeal, that ground of appeal must be rejected as inadmissible (see, to that effect, judgments of 11 September 2014, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraph 215 and of 16 November 2023, *Roos and Others* v *Parliament*, C-458/22 P, EU:C:2023:871, paragraph 90).

The second ground of appeal

Arguments of the parties

21 By his second ground of appeal, Mr Frajese submits that the General Court infringed its Rules of Procedure by holding, in paragraph 14 of the order under appeal, that the plea of inadmissibility had been submitted by the Commission within the two-month period extended by ten days, pursuant to Article 60, Article 81(1) and Article 130(1) of those Rules of Procedure. He argues that the General Court should have held the plea of inadmissibility raised by the Commission on 6 March 2023 to be inadmissible on the ground that it was out of time.

22 The Commission contends that the second ground of appeal must be rejected.

Findings of the Court

23 It is apparent from paragraph 14 of the order under appeal that, in accordance with the second paragraph of Article 6 of the decision of the General Court of 11 July 2018 on the lodging and service of procedural documents by means of e-Curia (OJ 2018 L 240, p. 72), the Commission was notified by email, on 20 December 2023, of the service of the application on it by means of e-Curia, that application having been lodged at first instance by Mr Frajese. As it states, the Commission requested access to that document on 22 December 2023, with the result that, in accordance with the third paragraph of Article 6 of that decision, that application must be regarded as having been served on that institution on that date.

24 It follows that the period of two months and ten days following service of the application within which, pursuant to Article 60 and Article 81(1) in conjunction with Article 130(1) of the Rules of Procedure of the General Court, the Commission could submit an objection of inadmissibility, ended on 4 March 2023. However, since 4 March 2023 was a Saturday, the expiry of the time limit was extended, pursuant to Article 58(2) of those Rules of Procedure, until the end of the next working day, namely Monday 6 March 2023.

25 Since the Commission lodged its objection of inadmissibility in respect of the application at first instance on 6 March 2023, Mr Frajese is not justified in claiming that it was out of time.

26 In those circumstances, the second ground of appeal must be rejected as being unfounded.

The third ground of appeal

27 This ground of appeal is divided into three parts. By the first part, the appellant criticises a failure to state reasons, and contradictory reasoning, vitiating the order under appeal. By the second part, he complains that the General Court held, in breach of the fourth paragraph of Article 263 TFEU, that he had no legal interest in bringing proceedings. By the third part, he criticises the General Court for having concluded, in breach of that provision, that he lacked standing to bring proceedings.

First part of the third ground of appeal

– *Arguments of the parties*

28 First, Mr Frajese complains that the General Court examined the question as to whether he was under a vaccination obligation, even though he never submitted, in order to establish his legal interest in bringing proceedings and his standing to bring proceedings, that he was under such an obligation.

29 Second, he submits that the General Court did not examine his argument that the decisions at issue create an obligation for all doctors administering vaccines to assess the medicinal products placed on the market, in the context of their possible prescription.

30 Third, Mr Frajese complains that the General Court did not explain the reasons why it rejected his argument, put forward at first instance in order to substantiate his legal interest in bringing proceedings, that the choice doctors administering vaccines make as to whether or not to administer medicinal products for which an MA has been granted means that they are responsible for and have a direct interest in ensuring that those medicinal products do not have serious consequences for the patients to whom they are administered. He states that he explained before the General Court, without that court giving any specific reasons in that regard, that his liability as a doctor administering vaccines, a specific profession, is the direct consequence of the decisions at issue and of the mere availability of those medicinal products in the territory of the European Union.

31 Fourth, Mr Frajese submits that the reasoning of the order under appeal is contradictory in that the General Court found, in paragraph 22 thereof, both that the decisions at issue prohibit Member States from opposing the placing of the vaccines in question on the EU market and that those decisions do not create any obligation for doctors to prescribe and administer those vaccines to their patients.

32 The Commission contends that the first part of the third ground of appeal should be rejected.

– *Findings of the Court*

33 In the first place, as regards Mr Frajese's claim that, contrary to what is apparent from paragraph 23 of the order under appeal, he never maintained that he was under a vaccination obligation, that objection must be rejected as ineffective since, even if that claim were established, the General Court would have merely rejected, in that paragraph of the order under appeal, an argument which had not been put forward.

34 In the second place, in so far as Mr Frajese complains that the General Court did not examine his argument that the decisions at issue create an obligation for all doctors administering vaccines to evaluate the medicinal products placed on the market, in the context of their possible prescription, it must be held that that objection must also be rejected. In paragraph 24 of the order under appeal, the General Court gave sufficiently clear reasons for the absence of binding legal effects on doctors administering vaccines, since it stated that 'nothing in the decisions [at issue] or in their annexes confers on doctors willing to administer the vaccines in question the

responsibility, or even the obligation, to verify their safety and efficacy', while adding that 'the verification of the safety and efficacy of the medicinal products is carried out by the EMA, on whose opinion the decisions [at issue] are based in the present case'.

35 In the third place, it must be borne in mind that, according to settled case-law, the obligation to state reasons does not require the General Court to provide an account which follows exhaustively and one by one all the arguments put forward by the parties to the case. The General Court's reasoning may therefore be implicit, on condition that it enables the persons concerned to know the grounds of the General Court's decision and provides the Court of Justice with sufficient material for it to exercise its power of review. Furthermore, the obligation to state reasons is an essential procedural requirement that must be distinguished from the question whether the reasoning is well founded, which goes to the substantive legality of the measure at issue (judgment of 29 April 2021, *Achemos Grupė and Achema* v *Commission*, C-847/19 P, EU:C:2021:343, paragraphs 61 and 62 and the case-law cited).

36 In paragraph 25 of the order under appeal, the General Court noted, first of all, that the decisions at issue are addressed exclusively to the producers of the vaccines in question and do not establish obligations on the part of natural persons. Next, in that paragraph, the General Court stated that those decisions could not give rise to any civil or even criminal liability of Mr Frajese towards his patients, since the incurring of that liability depends on specific circumstances which arise from the individual treatment of patients and which are independent of those decisions. Lastly, in that paragraph, the General Court noted that, in so far as Mr Frajese entertained doubts, in the context of the treatment of a patient, as to the safety or efficacy of the vaccines in question, he was entitled not to recommend or administer those vaccines and that, in any event, he could not incur liability for not having challenged in court the MAs granted to those vaccines.

37 It is thus apparent from paragraph 25 of the order under appeal that the General Court clearly explained there the reasons why it considered that the decisions at issue do not in any way affect the obligations on doctors administering vaccines, including Mr Frajese, and that any liability he may have towards his patients would be independent of those decisions and of the mere availability of those vaccines in the territory of the European Union.

38 Those grounds of the order therefore disclose in a clear and unequivocal manner the reasoning of the General Court with regard to Mr Frajese's lack of legal interest in bringing proceedings, in such a way as to enable him to understand the reasons for the decision taken and the Court of Justice to exercise its power of review, without it being necessary for the General Court to reject more explicitly the argument put forward by Mr Frajese.

39 In the fourth place, contrary to what Mr Frajese claims, paragraph 22 of the order under appeal does not contain contradictory reasoning. The observation according to which the decisions at issue prohibit the Member States from opposing the placing of the vaccines in question on the EU market in no way contradicts the finding that those decisions did not create any obligation for doctors to prescribe and administer those vaccines to their patients.

40 The first part of the third ground of appeal must therefore be rejected as unfounded.

Second part of the third ground of appeal

– *Arguments of the parties*

41 First, Mr Frajese states that the purpose of the decisions at issue is to enable the vaccines in question to be used in the territory of the European Union, in compliance with the requirements set out therein, and, therefore, for them to be administered. Thus, in his view, the General Court erred in law by relying, in order to deny his legal interest in bringing proceedings, on the ground that vaccination does not fall within the subject matter of those decisions but may be decided upon by the national authorities, since that ground is contradicted by the centralised nature of the evaluation and marketing procedure at EU level. Moreover, in Mr Frajese's opinion, as the annexes to the decisions at issue require, for the administration of the vaccines in question, a medical prescription, which is an act reserved to doctors administering vaccines, those annexes are likely to have effects on those doctors administering vaccines.

42 Second, Mr Frajese submits that the provisions of the European Charter of Patient's Rights confirm the existence of a legal, ethical and deontological obligation on doctors administering vaccines to provide EU citizens with comprehensive information on the type of treatment, the risks involved and possible therapeutic alternatives.

43 Third, the direct advantage that Mr Frajese would derive from the annulment of the decisions at issue and the withdrawal of the MAs for the vaccines in question is that he would be released from the obligation to evaluate those vaccines and from his liability in the event of adverse events in patients.

44 Mr Frajese concludes that the General Court was wrong to hold that he did not have a legal interest in bringing proceedings in respect of the decisions at issue in view of his lack of a specific, real and present interest in the annulment of those decisions.

45 The Commission contends that the second part of the third ground of appeal should be rejected.

– *Findings of the Court*

46 By the first part of his third ground of appeal, Mr Frajese submits that the General Court erred in law by holding that he had not established a legal interest in bringing proceedings for the annulment of the decisions at issue.

47 In the first place, it should be noted that, as the General Court stated in paragraphs 16 and 17 of the order under appeal, according to the Court of Justice's settled case-law, a legal interest in bringing proceedings is an essential and fundamental prerequisite for any legal proceedings. An action for annulment brought by a natural or legal person is thus admissible only in so far as the applicant has a legal interest in having the contested act annulled. An applicant's legal interest in bringing proceedings requires that the annulment of the contested act must be capable, in itself, of having legal consequences, that the action is therefore appropriate, through its outcome, to procure an advantage to the party which brought it and that that party can show a vested and current interest in the annulment of that act. Moreover, it is for the applicant to prove that he or she has a legal interest in bringing proceedings. The applicant must, in particular, be able to demonstrate a personal interest in the annulment of the contested act. That interest must be

vested and current and is evaluated as at the date on which the action is brought (see, to that effect, judgment of 17 September 2015, *Mory and Others* v *Commission*, C-33/14 P, EU:C:2015:609, paragraphs 55 to 58 and the case-law cited).

48 The General Court, in paragraphs 21 to 24 of the order under appeal, correctly examined the content and scope of the decisions at issue, taking into consideration, inter alia, their addressees, Moderna and BioNTech, and the existence of any liabilities and obligations created by those decisions with regard to doctors administering vaccines, including Mr Frajese, in order to conclude, in paragraphs 25, 26 and 28 of that order, that since the annulment of those decisions could not procure any advantage for Mr Frajese, he therefore had no legal interest in bringing proceedings with regard to those decisions.

49 Contrary to Mr Frajese's contention, it does not follow from the fact that, by the decisions at issue, the MAs are granted to the vaccines in question, allowing the holders of those MAs to place those vaccines on the market in each Member State, that those decisions require doctors to prescribe those vaccines and administer them to their patients. In that regard, the Court has already held that while the grant of an MA for a vaccine is a precondition for the holder's right to place that vaccine on the market in each Member State, that MA does not, in principle, give rise to any obligation on the part of patients or on the doctors administering vaccines (see, to that effect, judgment of 13 July 2023, *Azienda Ospedale-Università di Padova*, C-765/21, EU:C:2023:566, paragraphs 36 and 42).

50 Similarly, contrary to Mr Frajese's contention, while it follows from the annexes to the decisions at issue that a medical prescription is necessary for the purposes of the administration of the vaccines in question, that fact does not directly create either an obligation or liability for a doctor administering vaccines.

51 Mr Frajese does not, therefore, adduce any evidence capable of establishing that the General Court erred in law when it held, in paragraphs 22 and 23 of the order under appeal, that the decisions at issue do not create any burden or obligation on doctors to administer the vaccines in question to their patients and that an obligation of that nature could have a legal basis only in the national law of the Member State concerned.

52 In the second place, Mr Frajese does not show how the annulment of the decisions at issue would affect his duty to inform his patients about the type of treatment, the risks involved and the possible therapeutic alternatives. Such a duty to provide information has no connection at all with the content of those decisions, which do not contain any requirement in respect of those aspects. Thus, Mr Frajese is not justified in maintaining that the General Court should have taken account of that duty to provide information and, in so doing, found that he had a legal interest in bringing proceedings.

53 In the third place, first, Mr Frajese does not demonstrate how the statement, in paragraph 24 of the order under appeal, that 'nothing in the decisions [at issue] or in their annexes confers on doctors willing to administer the vaccines in question the responsibility, or even the obligation, to verify their safety and efficacy', and the finding, also in paragraph 24, that the verification of the safety and efficacy of those vaccines is carried out by the EMA, on whose opinion those decisions are based, are incorrect. Consequently, Mr Frajese cannot claim that the General Court should have accepted that the annulment of the decisions at issue would release him from his obligation to evaluate those vaccines.

54 Second, as regards his alleged liability in the event of adverse events occurring in patients, Mr Frajese does not explain how the statement, in paragraph 25 of the order under appeal, that a doctor's liability towards his patients depends on specific circumstances which originate in the individual treatment of those patients and which are independent of the decisions at issue, is incorrect. Therefore, Mr Frajese cannot maintain that the General Court should have accepted that the annulment of those decisions would relieve him of liability in the event of adverse events occurring in his patients.

55 The second part of the third ground of appeal must, therefore, be rejected as unfounded.

Third part of the third ground of appeal

– *Arguments of the parties*

56 In order to challenge the grounds of the order under appeal relating to his lack of standing, Mr Frajese submits, first, that the General Court erred in finding that he did not satisfy the two cumulative criteria required for him to be regarded as directly concerned by the decisions at issue, within the meaning of the fourth paragraph of Article 263 TFEU. According to the appellant, given that the procedure for supplying and distributing the vaccines in question was centralised at EU level and that the decisions at issue constitute a necessary and sufficient condition for the sale of the products authorised throughout the European Union, without the national authorities being required to adopt intermediate standards, the General Court should have found that those decisions are of direct concern to him.

57 Second, Mr Frajese submits that the General Court was wrong not to recognise that he meets the criteria for being regarded as individually concerned by the decisions at issue, within the meaning of the fourth paragraph of Article 263 TFEU. He claims that the General Court should have found that the fact that he was part of the select group of doctors active in the field of vaccination is sufficient to distinguish him and that he must be classified as the addressee of the decisions at issue, the material implementation of which he ensures, by proposing, administering or advising his patients against the vaccines in question. In any event, the condition that the act in respect of which annulment is sought be of individual concern to an applicant is satisfied in the present case, since the decisions at issue are of concern to him by reason of certain attributes which are specific to him and a factual situation which distinguishes him from any other person.

58 Third, referring to paragraph 58 of the judgment of 6 November 2018, *Scuola Elementare Maria Montessori* v *Commission, Commission* v *Scuola Elementare Maria Montessori and Commission* v *Ferracci* (C-622/16 P to C-624/16 P, EU:C:2018:873), Mr Frajese states (i) that where a regulatory act directly affects the legal situation of a natural or legal person without requiring implementing measures, that person could be denied effective judicial protection if he or she did not have a legal remedy before the EU judicature for the purpose of challenging the legality of the regulatory act and (ii) that his action before the General Court was the only remedy available to him.

59 The Commission contends that the third part of the third ground of appeal should be rejected.

– *Findings of the Court*

60 Despite the finding that Mr Frajese does not have a legal interest in bringing proceedings and despite the cumulative nature of the distinct conditions as to the applicant's legal interest in bringing proceedings and standing (see, to that effect, judgment of 17 September 2015, *Mory and Others* v *Commission*, C-33/14 P, EU:C:2015:609, paragraph 62 and the case-law cited), the General Court stated, in paragraph 29 of the order under appeal, that it considered it appropriate to examine Mr Frajese's standing to bring proceedings.

61 In that regard, it should be borne in mind that a natural or legal person's standing to bring proceedings, in accordance with the fourth paragraph of Article 263 TFEU, against an act that is not addressed to that person can be established in two situations. First, an action for annulment may be instituted if the act is of direct and individual concern to them. Second, such persons may bring proceedings against a regulatory act not entailing implementing measures if that act is of direct concern to them (judgment of 17 September 2015, *Mory and Others* v *Commission*, C-33/14 P, EU:C:2015:609, paragraph 59 and the case-law cited).

62 It is also apparent from the case-law that where an action for annulment is brought by a natural or legal person against an act which is not addressed to that person, the requirement that the binding legal effects of the contested act must be capable of affecting the interests of the applicant by bringing about a distinct change in his or her legal position may overlap with the conditions set out in the fourth paragraph of Article 263 TFEU concerning legal standing (see, to that effect, judgment of 13 October 2011, *Deutsche Post and Germany* v *Commission*, C-463/10 P and C-475/10 P, EU:C:2011:656, paragraph 38).

63 It is in the light of those preliminary considerations that the arguments put forward by Mr Frajese in support of the third part of his third ground of appeal must be assessed.

64 In the first place, as regards the General Court's assessment concerning the absence of direct concern to the appellant of the decisions at issue, it should be noted that it is in accordance with the case-law of the Court of Justice that the General Court recalled, in paragraph 30 of the order under appeal, that, in order to be regarded as directly concerned by a measure, within the meaning of the fourth paragraph of Article 263 TFEU, the contested measure must directly affect the legal situation of the individual and that measure must leave no discretion to its addressees, who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from EU rules without the application of other intermediate rules (judgment of 13 October 2011, *Deutsche Post and Germany* v *Commission*, C-463/10 P and C-475/10 P, EU:C:2011:656, paragraph 66 and the case-law cited).

65 As regards the first condition, it is in accordance with the case-law of the Court of Justice that the General Court stated, in paragraph 31 of the order under appeal, that the measure in question must directly affect the legal situation of the natural or legal person who intends to bring an action under the fourth paragraph of Article 263 TFEU and that such a condition must be assessed only with regard to the legal effects of the measure (judgment of 3 December 2020, *Région de Bruxelles-Capitale* v *Commission*, C-352/19 P, EU:C:2020:978, paragraph 64).

66 In that regard, in paragraphs 32 to 34 of the order under appeal, the General Court found that the decisions at issue do not have any effect on Mr Frajese's legal situation, since they do not impose any obligation on him to administer the vaccines in question to his patients or to verify, by his own means, their safety and efficacy, while adding that, even assuming that there were an obligation on

the doctors to administer those vaccines under Italian or EU law, they would not be legal effects arising from the decisions at issue, but the consequence of the adoption of other measures at either national or EU level.

67 As regards the second condition, the General Court noted, in paragraph 35 of the order under appeal, that the decisions at issue merely grant an MA for the vaccines in question, without those decisions being addressed to the national authorities of the Member States, and that it follows that those authorities have full discretion as to whether it is appropriate to require doctors to use those medicinal products, if necessary by means of coercive measures.

68 On the basis of those factors, in paragraph 36 of the order under appeal, the General Court concluded that the conditions required in order for Mr Frajese to be regarded as directly concerned by the decisions at issue were not satisfied.

69 In order to argue that the General Court should have recognised that he was directly concerned by the decisions at issue, within the meaning of the fourth paragraph of Article 263 TFEU, Mr Frajese merely asserts, first, in general terms, that the first condition required for him to be regarded as directly concerned is satisfied in the present case, without calling into question the General Court's reasoning on the basis of which it concluded that those decisions do not directly affect his legal situation.

70 Second, as regards the second condition required for him to be regarded as directly concerned, it is to no avail that Mr Frajese claims that the national authorities have no discretion in the centralised procedure for the purchase of vaccines, since the decisions at issue relate not to the purchase of the vaccines in question but to the MAs, granted to two pharmaceutical companies, enabling those vaccines to be marketed.

71 It follows that Mr Frajese has not shown that the General Court erred in law by holding that he was not directly concerned by the decisions at issue.

72 In the second place, as regards the General Court's assessment concerning the fact that the appellant was not individually concerned by the decisions at issue, it should be noted that the appellant does not put forward any argument capable of refuting the General Court's conclusions, in paragraphs 39 and 41 of the order under appeal, according to which 'the mere assertion that the [appellant] is a part of the select group of doctors active in the field of the vaccination of citizens is not sufficient to distinguish him or to differentiate him from all professionals active in the health and care sector' and 'it cannot be considered that the decisions [at issue] affect the [appellant] or his patients by reason of certain attributes which are specific to them or by reason of a factual situation which differentiates them from all the persons concerned and thereby distinguishes them in a manner similar to that of an addressee of the decisions.'

73 Moreover, as regards Mr Frajese's assertion that he should be regarded as an addressee of the decisions at issue, it is sufficient to note that he does not explain how the General Court's finding, in paragraph 21 of the order under appeal, that Moderna and BioNTech are the sole addressees of those decisions, is incorrect.

74 In the third place, as regards, on the one hand, Mr Frajese's argument that the need to ensure effective judicial protection implies that a natural or legal person may challenge a regulatory act that affects the legal situation of that person directly and does not require implementing measures, it must be noted that the General Court found, in paragraphs 42 to 44 of the order

under appeal, that the decisions at issue cannot be considered regulatory acts. However, the appeal contains no information to explain how that finding by the General Court was vitiated by an error of law.

75 As regards, on the other hand, Mr Frajese's claim that the action for annulment brought at first instance was the only remedy available to him, it is sufficient to point out that, as the General Court correctly stated in paragraphs 45 and 46 of the order under appeal, since natural and legal persons cannot, on account of the admissibility conditions for an action for annulment, directly challenge EU acts, they are entitled to challenge before the national courts measures adopted by the Member State linked to those acts, by arguing that those acts are invalid and leading the national courts to make a reference to the Court of Justice for a preliminary ruling on the validity of those acts under Article 267 TFEU.

76 Consequently, the third part of the third ground of appeal and, therefore, that ground of appeal in its entirety must be rejected as unfounded.

The fourth ground of appeal

Arguments of the parties

77 By his fourth ground of appeal, Mr Frajese submits that the General Court wrongly held, in paragraph 46 of the order under appeal, that natural or legal persons, such as himself, who cannot, by reason of the conditions for admissibility of an action for annulment, directly challenge EU acts, are entitled to challenge before the national courts the measures adopted by the Member States in connection with those acts, by pleading the invalidity of those acts and by leading the national courts to refer questions to the Court of Justice for a preliminary ruling on the validity of those acts on the basis of Article 267 TFEU.

78 He maintains that it is not possible to 'lead' the national courts to refer questions to the Court for a preliminary ruling on the validity of Commission acts, since that power falls exclusively within the jurisdiction of the courts adjudicating on the substance, and that, therefore, the possibility for national courts to make a reference to the Court is not a sufficient means of guaranteeing the rights of defence of citizens who suffer the harmful consequences of acts adopted by the Commission.

79 Thus, according to Mr Frajese, since the action provided for in Article 263 TFEU was the only remedy available to him, the General Court denied him any effective judicial protection by dismissing his action as inadmissible, in breach of Article 47 of the Charter.

80 The Commission contends that the fourth ground of appeal must be rejected.

Findings of the Court

81 According to the case-law of the Court, the right to effective judicial protection, enshrined in Article 47 of the Charter, cannot have the effect of setting aside the conditions of admissibility of an action for annulment expressly laid down in the fourth paragraph of Article 263 TFEU (see, to that effect, judgment of 3 October 2013, *Inuit Tapiriit Kanatami and Others* v *Parliament and Council*, C-583/11 P, EU:C:2013:625, paragraphs 97 and 98 and the case-law cited).

82 Accordingly, Mr Frajese is not justified in claiming that the General Court, after finding that the conditions of admissibility of his action for annulment were not satisfied in the present case, should nevertheless, pursuant to Article 47 of the Charter, have ruled on the substance of that action.

83 As regards the argument that Mr Frajese is not in a position to compel a national court to make a reference to the Court for a preliminary ruling, it must be borne in mind that the Court has held that requests for preliminary rulings which seek to ascertain the validity of a measure constitute, like actions for annulment, means for reviewing the legality of EU acts and that, where a national court or tribunal considers that one or more arguments for invalidity of an EU act, put forward by the parties or, as the case may be, raised by it of its own motion, are well founded, it is incumbent upon it to stay proceedings and to make a reference to the Court for a preliminary ruling on the act's validity, the Court alone having jurisdiction to declare an EU act invalid (see, to that effect, judgment of 3 October 2013, *Inuit Tapiriit Kanatami and Others* v *Parliament and Council*, C-583/11 P, EU:C:2013:625, paragraphs 95 and 96 and the case-law cited).

84 In that regard, it should be added, as the Commission has done, that it follows from the system established by Article 267 TFEU, read in the light of the second paragraph of Article 47 of the Charter, that, if a national court or tribunal against whose decisions there is no judicial remedy under national law takes the view that it is relieved of its obligation to make a reference to the Court under the third paragraph of Article 267 TFEU, the statement of reasons for its decision must show either that the question of EU law raised is irrelevant for the resolution of the dispute, or that the interpretation of the EU law provision concerned is based on the Court's case-law or, in the absence of such case-law, that the interpretation of EU law was so obvious to the national court or tribunal of last instance as to leave no scope for any reasonable doubt (judgment of 6 October 2021, *Consorzio Italian Management and Catania Multiservizi*, C-561/19, EU:C:2021:799, paragraph 51). In addition, an applicant may seek compensation for the damage resulting from the breach of the obligation to make a reference for a preliminary ruling under the conditions laid down in the case-law and submit a complaint for infringement proceedings to be initiated by the Commission, relating to the breach by the Member State concerned of the obligation to refer the case (see, to that effect, judgment of 21 December 2021, *Randstad Italia*, C-497/20, EU:C:2021:1037, paragraphs 79 and 80 and the case-law cited).

85 Consequently, Mr Frajese is not justified in claiming that the dismissal of his action as inadmissible deprived him of his right to effective judicial protection, in breach of Article 47 of the Charter.

86 In those circumstances, the fourth ground of appeal must be rejected.

87 As none of the grounds of appeal in the present appeal has been upheld, the appeal must be dismissed in its entirety.

Costs

88 In accordance with Article 184(2) of the Rules of Procedure, where the appeal is unfounded, the Court is to make a decision as to costs. Under Article 138(1) of those Rules, which applies to the procedure on appeal by virtue of Article 184(1), the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

89 Since the Commission has applied for costs against Mr Frajese and he has been unsuccessful, he must be ordered to bear his own costs and to pay those incurred by the Commission.

On those grounds, the Court (Eighth Chamber) hereby:

1. **Dismisses the appeal;**

2. **Orders Mr Giovanni Frajese to bear his own costs and to pay those incurred by the European Commission.**

[Signatures]