ECLI:EU:C:2022:534

JUDGMENT OF THE COURT (Ninth Chamber)

7 July 2022 (*)

(Reference for a preliminary ruling – Second subparagraph of Article 19(1) TEU – Obligation on Member States to provide remedies sufficient to ensure effective legal protection in the fields covered by EU law – Article 267 TFEU – Obligation on the referring court to give full effect to the interpretation of EU law provided by the Court of Justice – Charter of Fundamental Rights of the European Union – Article 47 – Access to an independent and impartial tribunal previously established by law – Judgment of a national court of last instance after a preliminary ruling by the Court – Alleged non-conformity of that judgment with the interpretation of EU law provided by the Court – National legislation preventing the bringing of an action for revision of that judgment)

In Case C-261/21,

REQUEST for a preliminary ruling under Article 267 TFEU from the Consiglio di Stato (Council of State, Italy), made by decision of 18 March 2021, received at the Court on 21 April 2021, in the proceedings

F. Hoffmann-La Roche Ltd,

Novartis AG,

Novartis Farma SpA,

Roche SpA

v

Autorità Garante della Concorrenza e del Mercato,

interveners:

Società Oftalmologica Italiana (SOI) – Associazione Medici Oculisti Italiani (AMOI),

Regione Emilia-Romagna,

Regione Lombardia,

Altroconsumo,

Novartis Farma SpA,

Roche SpA,

Novartis AG,

F. Hoffmann-La Roche Ltd,

Associazione Italiana delle Unità Dedicate Autonome Private di Day Surgery e dei Centri di Chirurgia Ambulatoriale (Aiudapds),

Coordinamento delle associazioni per la tutela dell'ambiente e dei diritti degli utenti e consumatori (Codacons),

Ministero della Salute – Agenzia Italiana del Farmaco,

THE COURT (Ninth Chamber),

composed of S. Rodin, President of the Chamber, C. Lycourgos (Rapporteur) and O. Spineanu-Matei, Judges,

Advocate General: A.M. Collins,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– F. Hoffmann-La Roche Ltd, by P. Merlino, M. Siragusa and M. Zotta, avvocati,

– Novartis AG and Novartis Farma SpA, by P. Bertolini, L. D'Amario and A. Villani, avvocati,

– Roche SpA, by F. Elefante and E. Raffaelli, avvocati,

– l'Autorità Garante della Concorrenza e del Mercato, by G. Galluzzo and P. Gentili, avvocati dello Stato,

– Società Oftalmologica Italiana (SOI) – Associazione Medici Oculisti Italiani (AMOI), by R. La Placa, avvocato,

– Regione Emilia-Romagna, by R. Bonatti and R. Russo Valentini, avvocati,

– Regione Lombardia, by M.L. Tamborino, avvocata,

– the Italian Government, by G. Palmieri, acting as Agent, and by M. Cherubini, procuratore dello Stato, C. Colelli and M. Russo, avvocati dello Stato,

– the European Commission, by G. Conte and C. Sjödin, acting as Agents,

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

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 4(3) and Article 19(1) TEU, and of Article 2(1) and (2), and Article 267 TFEU, read in the light of Article 47 of the Charter of Fundamental Rights of the European Union ('the Charter').

2 The request has been made in four sets of proceedings between, respectively, F. Hoffmann-La Roche Ltd, Roche SpA (together 'the Roche group'), Novartis AG and Novartis Farma SpA (together 'the Novartis group') and the Autorità Garante della Concorrenza e del Mercato (Competition Authority, Italy) ('the AGCM') concerning the request of the Roche group and the Novartis group for the revision of a judgment of the Consiglio di Stato (Council of State, Italy) on the ground that that judgment is not consistent with the interpretation of EU law provided by the Court of Justice in a judgment given following a reference for a preliminary ruling from the Consiglio di Stato (Council of State).

Legal context

3 Article 6(1) of the codice del processo amministrativo (Italian Code of Administrative Procedure) provides:

'[The Consiglio di Stato (Council of State)] is the court of final instance in administrative cases.'

4 Article 91 of that code provides:

'Means of redress against judgments [of the administrative courts] are appeals, revisions, third-party proceedings and appeals in cassation only for reasons of jurisdiction.'

5 Article 106(1) of that code provides:

'… Judgments … of the Consiglio di Stato [(Council of State)] may be challenged by application for revision, in the cases and according to the procedures laid down in Articles 395 and 396 of the [codice di procedura civile (Italian Code of Civil Procedure)].'

6 Article 395 of the Code of Civil Procedure provides:

'Judgments given on appeal or at first and last instance may be challenged by application for revision:

(1) if the judgments result from intentional fault on the part of one of the parties to the detriment of the other;

(2) if the judgments were given on the basis of evidence found to be false or even declared to be false after the judgment, or where the unsuccessful party was unaware that that evidence had been found to be false or held as such before the judgment was delivered;

(3) if, after delivery of the judgment, one or more decisive documents emerge which the party had been unable to put before the court on account of *force majeure* or because of the other party;

(4) if the judgment is the result of an error of fact arising from the acts and documents submitted in the case. Such an error occurs where the decision is based on the assumption of a fact where that fact is found to be irrefutably untrue, or where a fact is assumed to be untrue but is positively established as true, and, in both cases, if the fact does not constitute a point of contention on the basis of which the judgment was given;

(5) if the judgment is contrary to a previous judgment that has acquired the force of *res judicata*, unless a ruling has been given on the corresponding objection.

(6) if the judgment is the effect of intentional fault on the part of the court, found by a judgment that has acquired the force of *res judicata*.'

7 Under Article 396 of the Code of Civil Procedure:

'Judgments in respect of which the period for bringing an appeal has expired may be challenged by way of revision in the cases referred to in paragraphs 1, 2, 3 and 6 of the preceding article, provided that the discovery of intentional fault, or the falsity or recovery of the documents, or the delivery of the judgment referred to in paragraph 6 occurred after the expiry of that period.

If the facts referred to in the preceding paragraph occur during the period for bringing an appeal, that period shall be extended by 30 days from the day on which the event occurred.'

The dispute in the main proceedings and the questions referred for a preliminary ruling

8 The AGCM, by decision of 27 February 2014 ('the decision of the AGCM'), imposed two fines, one on the Roche group, amounting to approximately EUR 90.6 million, and the other on the Novartis group, amounting to approximately EUR 92 million, on the ground that those undertakings had concluded an agreement contrary to Article 101 TFEU, designed to achieve an artificial differentiation between the medicinal products Avastin and Lucentis by manipulating the perception of the risks of using Avastin in the field of ophthalmology.

9 Those medicinal products were both developed by a company established in the United States of America, whose activities are limited to the territory of that third country. That company entrusted the commercial exploitation of Avastin outside that territory to the Roche group, and the commercial exploitation of Lucentis to the Novartis group.

10 On 12 January 2005, a marketing authorisation ('MA') in respect of the European Union was granted in respect of Avastin, for the treatment of certain tumorous diseases. On 22 January 2007, a MA was granted in respect of Lucentis, for the treatment of ocular diseases.

11 Prior to the placing on the market of Lucentis, some doctors had started prescribing Avastin to their patients suffering from ocular diseases, that is to say for indications which did not correspond to those referred to in the MA for Avastin ('off-label use'). That practice continued after Lucentis, which was more expensive, was placed on the market.

12 According to the decision of the AGCM, the Roche group and the Novartis group entered into a market-sharing agreement that constitutes a restriction of competition by object. Avastin and Lucentis are two equivalent medicinal products for the treatment of ocular diseases. As a result of the widespread off-label use of Avastin for the treatment of that type of disease, Avastin was the main competitor of Lucentis. The agreement between the Roche group and the Novartis group consisted of circulating opinions of such a kind as to give rise to concerns on the part of the public as to the safety of using Avastin in ophthalmology. That resulted in a fall in sales of Avastin and a shift in demand to Lucentis.

13 After the Tribunale amministrativo regionale per il Lazio (Regional Administrative Court, Lazio, Italy) dismissed their actions brought against that decision, the Roche group and the Novartis group brought an appeal before the referring court, the Consiglio di Stato (Council of State), which referred several questions to the Court of Justice for a preliminary ruling on the interpretation of Article 101 TFEU.

14 In response to those questions, the Court, in paragraph 67 of the judgment of 23 January 2018, *F. Hoffmann-La Roche and Others* (C-179/16, 'the judgment in *Hoffmann-La Roche*', EU:C:2018:25) held that for the purposes of the application of Article 101 TFEU, a national competition authority may include in the relevant market, in addition to the medicinal products authorised for the treatment of the diseases concerned, another medicinal product whose MA does not cover that treatment but which is used for that purpose and is thus actually substitutable with the former. In order to determine whether such a relationship of substitutability exists, the competition authority must, in so far as conformity of the product at issue with the applicable provisions governing the manufacture or the marketing of that product has been examined by the competent authorities or courts, take account of the outcome of that examination by assessing any effects it may have on the structure of supply and demand.

15 The Court also stated, in paragraph 95 of the judgment in *Hoffmann-La Roche*, that an arrangement put in place between two undertakings marketing two competing products, which concerns the dissemination, in a context of scientific uncertainty, to the European Medicines Agency (EMA), healthcare professionals and the general public of misleading information relating to adverse reactions resulting from the off-label use of one of those medicinal products, with a view to reducing the competitive pressure resulting from such use on the use of the other medicinal product, constitutes a restriction of competition 'by object' prohibited by Article 101 TFEU.

16 Following that preliminary ruling, the referring court, by judgment No 4990/2019, dismissed the appeals ('judgment No 4990/2019').

17 The Roche group and the Novartis group request the referring court, under Article 106 of the Code of Administrative Procedure, to review that judgment, arguing that it is vitiated by an error of fact within the meaning of Article 395(4) of the Code of Civil Procedure.

18 Those groups submit, inter alia, that the reasoning in judgment No 4990/2019, according to which, 'in the present case, at the time the AGCM applied Article 101 TFEU, any unlawfulness of the conditions under which Avastin was repackaged and prescribed with a view to its off-label use had not been established by the authorities which had competence to review compliance with the rules governing pharmaceutical matters or by the national courts', is factually incorrect, since the unlawfulness of the supply of Avastin for indications which did not correspond to those mentioned in the MA for Avastin had been established, according to the Roche group and the Novartis group, in many official positions adopted by the competent authorities and courts. By failing to take account of the conformity examinations thus carried out, judgment No 4990/2019 disregards the

interpretation provided by the Court in the judgment in *Hoffmann-La Roche*, according to which account must be taken of the outcome of such examinations.

19 Those groups also submit that judgment No 4990/2019 contains no assessment of the misleading nature of the information disseminated by the undertakings concerned. It follows from the judgment in *Hoffmann-La Roche* that it is necessary to carry out such an assessment. The interpretation provided by the Court means that, in a situation such as that at issue in the main proceedings, a restriction of competition by object can exist only if the information disseminated by the undertakings concerned was misleading. The Court stated that it was for the referring court to examine that aspect.

20 The Roche group also submits that the system of judicial review established by Article 106 of the Code of Administrative Procedure, read in conjunction with Articles 395 and 396 of the Code of Civil Procedure, is incomplete, since it does not provide for the possibility of seeking revision of a judgment of a national administrative court where that judgment contains a manifest breach of the principles of law established by the Court in the context of a reference for a preliminary ruling. The consequence of that omission is that judicial decisions that are contrary to EU law may acquire the force of *res judicata*. Such a situation undermines the binding nature and *erga omnes* effect of the Court's preliminary rulings and could lead to an action for failure to fulfil obligations being brought by the European Commission against the Italian Republic.

21 The referring court states that there is no legal remedy under Italian law which makes it possible to verify that a decision given by a national court adjudicating at last instance is not contrary to EU law and, in particular, to the case-law of the Court.

22 It asks whether such a situation is compatible with Article 4(3) and Article 19(1) TEU, and with Article 2(1) and (2), and Article 267 TFEU, read in particular in the light of Article 47 of the Charter.

23 It is true that the Court held, in particular in paragraphs 22 to 24 of the judgment of 3 September 2009, *Fallimento Olimpiclub* (C-2/08, EU:C:2009:506), that the rules implementing the principle of *res judicata* are a matter for the national legal order, in accordance with the principle of the procedural autonomy of the Member States, subject only to compliance with the principles of equivalence and effectiveness, since EU law does not require a national court to disapply domestic rules of procedure conferring finality on a decision, even if to do so would make it possible to remedy an infringement of EU law.

24 However, the referring court has doubts as to the relevance of that case-law in a situation where a litigant claims that the national court which gave a decision at last instance disregarded the Court's preliminary ruling in the case which gave rise to that national decision which is no longer open to challenge.

25 In that regard, the referring court considers that the possibility of influencing a decision before it acquires the force of *res judicata*, in order to avoid giving effect to an infringement of EU law, seems preferable to a remedy a posteriori whereby, in accordance with the case-law arising from the judgment of 30 September 2003, *Köbler* (C-224/01, EU:C:2003:513), the person who has suffered damage as a result of that situation obtains compensation for that damage. That remedy a posteriori would oblige that person to initiate new proceedings in which he or she would have to prove not only the existence of an infringement of EU law but also the manifest nature of that infringement.

26 That said, that court considers that, in the present case, judgment No 4990/2019 respects the interpretation of EU law resulting from the judgment in *Hoffmann-La Roche*. Thus, in its view, there is no conflict between judgment No 4990/2019 and EU law. At the very most, the Consiglio di Stato (Council of State) could be criticised for having misapplied that law to the facts of the case in the main proceedings. Such an error, even if it were established, would not constitute a breach of the binding nature of the judgment in *Hoffmann-La Roche.* The mechanism provided for in Article 267 TFEU leaves intact the judicial function, reserved to the national court, of applying the interpretation of EU law provided by the Court to the facts of the case in the main proceedings.

27 However, the referring court considers that it cannot be ruled out that it is not for it but for the Court to rule on the compatibility of judgment No 4990/2019 with the judgment in *Hoffmann-La Roche*. In that regard, the referring court notes that Article 267 TFEU gives the Court jurisdiction to give preliminary rulings on the validity and interpretation of 'acts of the institutions, bodies, offices or agencies of the Union'. It is possible that the Court's decisions are among those acts and there is therefore, at this stage, no definitive certainty as to whether judgment No 4990/2019 is compatible with the judgment in *Hoffmann-La Roche.*

28 In those circumstances, the Consiglio di Stato (Council of State) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) In a case where a party's application seeks directly to assert an infringement of the principles expressed by the Court of Justice in that case in order to secure the setting-aside of the judgment under appeal, can the national court, against whose decisions there is no judicial remedy under national law, determine whether the principles expressed by the Court of Justice in the same case have been applied correctly in that specific case, or is that determination a matter for the Court of Justice?

(2) Has judgment No 4990/2019 of the Consiglio di Stato (Council of State) infringed, in the sense asserted by the parties, the principles expressed by the Court of Justice in the [judgment in *Hoffmann-La Roche*] in relation (a) to the inclusion in the same relevant market of the two medicinal products without taking account of the views of authorities which had held that the off-label demand and supply of Avastin was unlawful and (b) to the failure to verify the allegedly misleading nature of the information disseminated by the undertakings?

(3) Do [Article 4(3) and Article 19(1) TEU], and [Article 2(1) and (2) and Article 267 TFEU], read also in the light of Article 47 of the [Charter], preclude a system such as that concerning Article 106 of the [Code of Administrative Procedure] and Articles 395 and 396 of the [Code of Civil Procedure], inasmuch as that system does not permit the use of the remedy of an application for revision to challenge judgments of the [Consiglio di Stato (Council of State)] that conflict with judgments of the Court of Justice, and in particular with the legal principles asserted by the Court of Justice in a preliminary ruling on questions referred to it?'

The requests to open the oral part of the procedure

29 By applications submitted on 16 and 17 March 2022, the Roche group requested the opening of the oral part of the procedure under Article 83 of the Rules of Procedure of the Court of Justice, claiming that there was a new fact of such a nature as to be a decisive factor for the decision of the Court.

30 That new fact consists of the definitive adoption, on 24 February 2022, by the EMA of a negative opinion on the use of the substance 'bevacizumab' for the treatment of an ocular disease, on the ground that the risks associated with such use outweigh therapeutic benefits.

31 The Roche group submits that bevacizumab is the active ingredient of Avastin. The EMA's negative opinion on the use of bevacizumab for the treatment of an ocular disease demonstrates, according to that group, that Avastin cannot be a substitute for Lucentis and that those two medicinal products do not therefore belong to the same market. That opinion of the EMA also supports the fact that the information disseminated by the Roche group and the Novartis group, concerning the risks of using Avastin in ophthalmology, was not misleading.

32 The AGCM's decision is therefore vitiated by errors. According to the Roche group, the referring court would have found those errors if, in accordance with the conclusions arising from the judgment in *Hoffmann-La Roche*, it had examined the available data on the risks associated with the use of Avastin in ophthalmology. According to that group, that court should have found, inter alia, that the alleged therapeutic equivalence between Avastin and Lucentis, on which the AGCM relied, had never been established by any authority with competence in that field. The referring court should therefore have concluded that the AGCM had not duly established the existence of anticompetitive conduct.

33 The EMA's negative opinion is decisive, in particular, for the answer to the second question, which seeks to ascertain whether judgment No 4990/2019 disregards the principles set out by the Court in the judgment in *Hoffmann-La Roche*.

34 In that regard, it should be noted that, in accordance with Article 83 of its Rules of Procedure, the Court may at any time, after hearing the Advocate General, order the opening or reopening of the oral part of the procedure, in particular if it considers that it lacks sufficient information or where a party has, after the close of that part of the procedure, submitted a new fact which is of such a nature as to be a decisive factor for the decision of the Court, or where the case must be decided on the basis of an argument which has not yet been debated.

35 The fact relied on by the Roche group in support of the requests to open the oral part of the procedure, consisting of the EMA's negative opinion of 24 February 2022 concerning the use of the substance bevacizumab for the treatment of the ocular disease described in that opinion, is not of such a nature as to be a decisive factor for the Court's decision in the present case.

36 It is not for the Court to assess whether the content of that opinion issued by the EMA demonstrates the presence of errors in the decision of the AGCM which the referring court should have found in its judgment No 4990/2019. It is sufficient to note, in that regard, that the national court or tribunal alone has jurisdiction to find and assess the facts in the case before it (judgment of 6 October 2021, *Consorzio Italian Management and Catania Multiservizi*, C-561/19, EU:C:2021:799, paragraph 35 and the case-law cited).

37 In the present case, the Court, after hearing the Advocate General, considers, on the basis of the request for a preliminary ruling and the documents in the written procedure, that it has all the information necessary to deal with the present reference for a preliminary ruling. Accordingly, there is no need to order the opening of the oral part of the procedure.

Consideration of the questions referred for a preliminary ruling

The third question

38 As a preliminary point, it should be borne in mind that, according to settled case-law, in the procedure laid down by Article 267 TFEU, providing for cooperation between national courts and the Court, it is for the latter to provide the national court with an answer which will be of use to it and enable it to determine the case before it. To that end, the Court may have to reformulate the questions referred to it (judgment of 15 July 2021, *The Department for Communities in Northern Ireland*, C-709/20, EU:C:2021:602, paragraph 61 and the case-law cited).

39 The third question, which it is appropriate to examine first, concerns, inter alia, Article 2(1) and (2) TFEU. Those provisions are, however, irrelevant for the purpose of answering that question.

40 Article 2 TFEU concerns the division, between the European Union and its Member States, of the competence to legislate and adopt legally binding acts. The rules set out in that respect in paragraphs 1 and 2 of that article are unrelated to the question concerning the existence of legal remedies within a Member State raised by the referring court (see, by analogy, judgment of 21 December 2021, *Randstad Italia*, C-497/20, EU:C:2021:1037, paragraph 45).

41 Accordingly, the third question must be reformulated by removing Article 2(1) and (2) TFEU from the substance of that question.

42 That question seeks, in essence, to ascertain whether Article 4(3) and Article 19(1) TEU, and Article 267 TFEU, read in the light of Article 47 of the Charter, must be interpreted as precluding provisions of procedural law of a Member State which have the effect that, where the supreme court of the administrative system of that Member State gives a decision settling a dispute in which it had made a request to the Court for a preliminary ruling under Article 267 TFEU, the parties to that dispute may not seek a revision of that decision of the national court based on the contention that the latter disregarded the interpretation of EU law provided by the Court in response to that request.

43 In that regard, it must be noted at the outset that the second subparagraph of Article 19(1) TEU obliges Member States to provide remedies sufficient to ensure effective judicial protection for individual parties in the fields covered by EU law (see, to that effect, judgment of 26 March 2020, *Miasto Łowicz and Prokurator Generalny*, C-558/18 and C-563/18, EU:C:2020:234, paragraph 32 and the case-law cited).

44 Provided there are EU rules on the matter, it is, in accordance with the principle of procedural autonomy, for the national legal order of each Member State to establish procedural rules for those remedies, on condition, however, that those rules are not, in situations governed by EU law, less favourable than in similar domestic situations (principle of equivalence) and that they do not make it impossible in practice or excessively difficult to exercise the rights conferred by EU law (principle of effectiveness) (judgment of 21 December 2021, *Randstad Italia*, C-497/20, EU:C:2021:1037, paragraph 58).

45 As regards observance of the principle of equivalence, it appears, in the light of the information provided in the request for a preliminary ruling and subject to verification by the referring court, that Article 106(1) of the Code of Administrative Procedure, read in conjunction with Articles 395 and 396 of the Code of Civil Procedure, limits, in accordance with the same rules, the possibility for individuals to seek revision of a judgment of the Consiglio di Stato (Council of State), whether the application for revision is based on provisions of national law or on provisions of EU law.

46 In those circumstances, it must be held that the procedural rules of national law do not breach the principle of equivalence.

47 So far as the principle of effectiveness is concerned, it must be borne in mind that EU law does not have the effect of requiring Member States to establish remedies other than those established by national law, unless it is apparent from the overall scheme of the national legal system in question that no legal remedy exists that would make it possible to ensure, even indirectly, respect for the rights that individuals derive from EU law, or that the sole means of obtaining access to a court is effectively for individuals to break the law (see, inter alia, judgments of 14 May 2020, *Országos Idegenrendészeti Főigazgatóság Dél-alföldi Regionális Igazgatóság*, C-924/19 PPU and C-925/19 PPU, EU:C:2020:367, paragraph 143, and of 21 December 2021, *Randstad Italia*, C-497/20, EU:C:2021:1037, paragraph 62).

48 In the present case, there is nothing in the request for a preliminary ruling or in the observations submitted to the Court to suggest that Italian procedural law has, in itself, the effect of making it impossible or excessively difficult to exercise, in the field of competition law, the rights conferred on individuals by EU law. In those circumstances, a provision such as Article 106(1) of the Code of Administrative Procedure, read in conjunction with Articles 395 and 396 of the Code of Civil Procedure, also does not infringe the principle of effectiveness and does not therefore appear to be contrary to the second subparagraph of Article 19(1) TEU.

49 In circumstances in which a legal remedy does exist, making it possible to ensure respect for the rights that individual parties derive from EU law, it is, as is apparent from the case-law referred to in paragraph 47 of the present judgment, entirely open, under EU law, to the Member State concerned to confer jurisdiction on the highest court in its administrative order to adjudicate on the dispute at last instance, in relation both to the facts and to points of law (judgment of 21 December 2021, *Randstad Italia*, C-497/20, EU:C:2021:1037, paragraph 64).

50 Where, as in the present case, provisions of EU law are relied on before a national court, which gives its decision after receiving the answer to the questions which it had put to the Court concerning the interpretation of those provisions, the condition relating to the existence of a legal remedy within the Member State concerned which makes it possible to ensure respect for the rights that individuals derive from EU law, is necessarily satisfied. That Member State may, consequently, restrict the possibility of seeking revision of a judgment of its supreme administrative court to exceptional and strictly limited situations, which do not include a situation where, according to the litigant who has been unsuccessful before that supreme administrative court, the latter has infringed the interpretation of EU law provided by the Court in response to its request for a preliminary ruling.

51 It follows from the foregoing that the second subparagraph of Article 19(1) TEU does not require Member States to allow individuals to seek revision of a judicial decision given at last instance on the ground that, according to those individuals, that decision disregards the interpretation of EU law provided by the Court in response to a request for a preliminary ruling that had been made in the same case.

52 That conclusion cannot be called into question on the basis of Article 4(3) TEU, which requires the Member States to take any appropriate measure, general or particular, to ensure fulfilment of the obligations arising out of the Treaties or resulting from the acts of the institutions of the European Union. As regards the system of remedies sufficient to ensure effective judicial review in the fields covered by EU law, Article 4(3) TEU cannot be interpreted as meaning that the Member States are required to provide new legal remedies, which they are not however required to do under the second subparagraph of Article 19(1) TEU (judgment of 21 December 2021, *Randstad Italia*, C-497/20, EU:C:2021:1037, paragraph 66).

53 Nor can that conclusion be called into question in the light of Article 267 TFEU.

54 It is true that that provision requires referring courts to give full effect to the interpretation of EU law provided by the Court in judgments in preliminary ruling proceedings (judgment of 12 February 2020, *Kolev and Others*, C-704/18, EU:C:2020:92, paragraph 37 and the case-law cited). Therefore, when it gave judgment No 4990/2019, the Consiglio di Stato (Council of State) was required to ensure that that judgment was consistent with the interpretation of Article 101 TFEU which the Court had just given, at the request of that national court, in the judgment in *Hoffmann-La Roche*.

55 However, as has been pointed out in paragraph 36 of the present judgment, it is for the national court alone to find and assess the facts of the dispute in the main proceedings. It follows that it is not for the Court, in the context of a new reference for a preliminary ruling, to carry out a review designed to ensure that that national court, after making a request to the Court for a preliminary ruling on the interpretation of provisions of EU law applicable to the dispute before it, has applied those provisions in a manner consistent with the interpretation of those provisions given by the Court. Although, under the cooperation between the national courts and the Court established in Article 267 TFEU, it is permissible for the national courts to make a further reference to the Court before settling the dispute before them, in order to obtain further clarifications on the interpretation of EU law provided by the Court (see, to that effect, judgment of 6 October 2021, *Consorzio Italian Management and Catania Multiservizi*, C-561/19, EU:C:2021:799, paragraph 38 and the case-law cited), that provision cannot, however, be interpreted as meaning that a national court could make a request to the Court for a preliminary ruling on whether that national court correctly applied, to the case in the main proceedings, the interpretation provided by the Court in response to a request for a preliminary ruling which the national court had previously made to the Court in the same case.

56 Accordingly, the mechanism of cooperation between national courts and the Court, established by that provision of the FEU Treaty, in no way requires Member States to provide for a legal remedy allowing individuals to bring actions for revision of a judicial decision given at last instance by a national court in a given dispute, for the purposes of compelling that court to make a request to the Court to ascertain whether that decision is consistent with the interpretation provided by the Court in response to a request for a preliminary ruling which that national court had previously made to it in the same case.

57 Nor can the conclusion reached in paragraph 51 of the present judgment be called into question in the light of Article 47 of the Charter. In that regard, it is sufficient to observe that, where, in the field of EU law concerned, individuals have access to an independent and impartial tribunal previously established by law, which appears to be the case, subject to verification by the referring court, in the Italian legal system, the right of access to such a tribunal, enshrined in the Charter, is respected, and the rule of national law which restricts the possibility of seeking revision of judgments of the supreme court of the administrative system to exceptional and strictly defined situations cannot be regarded as a limitation, within the meaning of Article 52(1) of the Charter, of that right laid down in Article 47 thereof (see, by analogy, judgment of 21 December 2021, *Randstad Italia*, C-497/20, EU:C:2021:1037, paragraph 69).

58 Notwithstanding the foregoing, it is important to note that individuals who, due to a decision of a court adjudicating at last instance, may have suffered damage as a result of an infringement of rights which are conferred on them by EU law, may hold that Member State liable, provided that the conditions relating to the sufficiently serious nature of the breach and to the existence of a direct causal link between that breach and the loss or damage sustained by those individuals are satisfied

(see, to that effect, in particular, judgments of 30 September 2003, *Köbler*, C‑224/01, EU:C:2003:513, paragraph 59, and of 21 December 2021, *Randstad Italia*, C‑497/20, EU:C:2021:1037, paragraph 80).

59 The principle of liability on the part of a Member State for damage caused to individuals as a result of breaches of EU law for which the State is responsible is inherent in the system of the Treaty, irrespective of whether the origin of the damage is attributable to the legislature, the judicature or the executive. In the light of the essential role played by the judiciary in the protection of the rights derived by individuals from EU rules, the full effectiveness of those rules would be called in question and the protection of those rights would be weakened if individuals were precluded from being able, under certain conditions, to obtain reparation when their rights are affected by an infringement of EU law attributable to a decision of a court of a Member State adjudicating at last instance (judgment of 4 March 2020, *Telecom Italia*, C‑34/19, EU:C:2020:148, paragraphs 67 and 68).

60 In the light of all of the foregoing, the answer to the third question is that Article 4(3) and Article 19(1) TEU and Article 267 TFEU, read in the light of Article 47 of the Charter, must be interpreted as not precluding provisions of procedural law of a Member State which, while observing the principle of equivalence, have the effect that, where the supreme court of the administrative system of that Member State gives a decision settling a dispute in which it had made a request to the Court of Justice for a preliminary ruling under Article 267 TFEU, the parties to that dispute may not seek a revision of that decision of the national court based on the contention that the latter disregarded the interpretation of EU law provided by the Court of Justice in response to that request.

The first and second questions

61 In view of the answer given to the third question, there is no need to answer the first and second questions.

Costs

62 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Ninth Chamber) hereby rules:

Article 4(3) and Article 19(1) TEU and Article 267 TFEU, read in the light of Article 47 of the Charter of Fundamental Rights of the European Union, must be interpreted as not precluding provisions of procedural law of a Member State which, while observing the principle of equivalence, have the effect that, where the supreme court of the administrative system of that Member State gives a decision settling a dispute in which it had made a request to the Court of Justice for a preliminary ruling under Article 267 TFEU, the parties to that dispute may not seek a revision of that decision of the national court based on the contention that the latter disregarded the interpretation of EU law provided by the Court of Justice in response to that request.

[Signatures]

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[*] Language of the case: Italian.