OPINION OF ADVOCATE GENERAL CRUZ VILLALÓN
delivered on 10 June 2010[1]

1. This case raises important and delicate questions of both procedural and substantive law. On the one hand, the Administrativen sad Sofia-grad (Administrative Court, Sofia) asks the Court of Justice whether European Union law precludes a lower court from complying with a judgment of its supreme court where a case is referred back to it and it has serious doubts as to whether the judgment is compatible with European Union law. On the other hand, the referring court asks in detail about the payment of costs which are incurred in a hospital in another Member State because it is materially impossible for the patient to receive treatment in Bulgaria, when it has been established that there is alternative, but less effective and also more radical, treatment available.

2. It is immediately clear that the replies to both questions may be found in the case-law of the Court. However, it is also true that in recent years there have been significant changes which explain why these questions have been raised again. The relatively recent emergence of important case-law on the relationship between the Court of Justice and national courts (*Köbler*, *Kühne & Heitz* and *Commission* v *Italy*,[2] among others) may explain why the Administrative Court, Sofia, questions whether the statement of the law which the Court laid down in *Rheinmühlen I*[3] in 1974 continues to be valid. In addition, the accession to the European Union of new States with different healthcare systems, both in terms of their organisation and their financial resources, raises uncertainties about the applicability of case-law which was conceived and correspondingly developed in an era preceding that expansion, and which will be examined below.

3. Those changes in the case-law and factual circumstances of the European Union explain why the Court has decided to adjudicate on the case sitting as the Grand Chamber.

1 — Original language: Spanish.

2 — Respectively Case C-224/01 [2003] ECR I-10239; Case C-453/00 [2004] ECR I-837; and Case C-129/00 [2003] ECR I-14637.

3 — Case 166/73 *Rheinmühlen-Düsseldorf* [1974] ECR 33.

I — Legal framework

A — *European Union legislation*

Article 267 TFEU

'The Court of Justice of the European Union shall have jurisdiction to give preliminary rulings concerning:

(a) the interpretation of the Treaties;

(b) the validity and interpretation of acts of the institutions, bodies, offices or agencies of the Union;

Where such a question is raised before any court or tribunal of a Member State, that court or tribunal may, if it considers that a decision on the question is necessary to enable it to give judgment, request the Court to give a ruling thereon.

Where any such question is raised in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal shall bring the matter before the Court.

If such a question is raised in a case pending before a court or tribunal of a Member State with regard to a person in custody, the Court of Justice of the European Union shall act with the minimum of delay.'

Article 56 TFEU

'Within the framework of the provisions set out below, restrictions on freedom to provide services within the Union shall be prohibited in respect of nationals of Member States who are established in a Member State other than that of the person for whom the services are intended.'

4. The secondary law applicable to these proceedings is essentially restricted to Article 22 of Regulation No 1408/71, [4] which sets out the rules concerning medical care provided in a Member State other than that of registration for social security, in the following terms:

'*Article 22*

1. An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to

4 — Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community (OJ, English Special Edition 1971 (II), p. 416), as amended on a number of occasions.

benefits, taking account where appropriate of the provisions of Article 18, and:

…

(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition,

shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay or residence in accordance with the provisions of the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State;

(ii) to cash benefits provided by the competent institution in accordance with the provisions of the legislation which it administers. However, by agreement between the competent institution and the institution of the place of stay or residence, such benefits may be provided by the latter institution on behalf of the former, in accordance with the provisions of the legislation of the competent State.

1a. The Administrative Commission shall establish a list of benefits in kind which, in order to be provided during a stay in another Member State, require, for practical reasons, a prior agreement between the person concerned and the institution providing the care.

2. The authorisation required under paragraph 1(b) may be refused only if it is established that movement of the person concerned would be prejudicial to his state of health or the receipt of medical treatment.

The authorisation required under paragraph 1(c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resided and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease.

…'

B — *National legislation*

5. Article 224 of the Law on administrative procedure ('APK') governs the effects of judgments given by the Supreme Administrative Court of Bulgaria vis-à-vis a lower court in the following terms:

'The directions of the Supreme Administrative Court concerning the interpretation and application of the law shall be binding [on the lower court] when the case is reconsidered.'

6. Article 36(1) of the Law on health insurance establishes the right of everyone insured under the compulsory scheme 'to receive in part or in full the value of the expenses for medical care abroad only if they have received prior authorisation from the National Health [Insurance] Fund ["the Fund"]'.

7. The basic level of cover under the compulsory scheme is set out in Article 45 of that Law, according to which:

'(1) The [Fund] shall pay for the following medical services:

…

3. outpatient and hospital medical care for diagnosis and treatment of a disease;

…

5. emergency medical care;

(2) … The medical care under the first paragraph, with the exception of item 10, shall be determined as a basic package guaranteed out of the budget of the [Fund]. The budget shall be determined by an order from the Minister [for] Health.'

8. The order to which the Law refers is Order No 40 of 2004 establishing the basic package of healthcare services guaranteed to come from the Fund budget, the single article of

which provides: 'The basic package of medical care includes services the type and range of which are set out in Annexes 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10.'

9. Annex 5 to the order sets out the 'List of clinical treatments', which includes the following:

'133. Surgical treatment of glaucoma

134. Ocular surgery using laser or cryogenic techniques

135. Operations on the ocular region

136. Other eyeball operations

…

258. High technology radiotherapy for oncological and non-oncological conditions.'

II — The facts

10. Mr Georgi Ivanov Elchinov, who is resident in Bulgaria and has health insurance cover with the Fund of that country, was diagnosed with a malignant oncological disease of the right eye. On the advice of his doctor, the patient was recommended treatment consisting of the attachment of radioactive plates or proton therapy.

11. On 9 March 2007, Mr Elchinov applied to the Fund under Article 22 of Regulation No 1408/71 for the issue of a Form E 112 (document authorising medical treatment abroad), so that he could receive the prescribed treatment in a special clinic for eye diseases in Berlin with the cost to be covered by his Bulgarian health insurance. The application was based on the fact that it was impossible to receive the prescribed treatment in the State of residence, where he was only offered an alternative treatment consisting of the complete removal of the diseased eye (enucleation).

12. On 15 March 2007, in the light of the seriousness of his medical condition and before the Fund had replied to his application, Mr Elchinov travelled as a matter of urgency to the German clinic where the prescribed treatment was carried out. A few weeks later, after receiving a report from the Ministry of Health which confirmed that the treatment concerned was not provided in Bulgaria, the Fund decided to refuse Mr Elchinov's application on 18 April 2007.

13. Mr Elchinov brought an administrative appeal before the Administrativen sad Sofiagrad which, on 13 August 2007, gave judgment

in his favour, annulling the contested decision and referring the case back to the Fund in order for it to issue Form E 112; in addition, the Administrativen sad Sofia-grad ordered the Fund to pay the costs. The reasoning of the judgment rejected the interpretation of Article 22 of Regulation No 1408/71 given by the Fund and concluded that the treatment prescribed is provided for in the Bulgarian legislation. In the opinion of the Administrativen sad Sofia-grad, the fact that the treatment is provided for in the legislation, even though it cannot actually be carried out in Bulgaria, is sufficient for the application of that article, and therefore it held that it was appropriate to grant authorisation for the treatment to be carried out abroad.

14. The Fund appealed against the judgment at first instance before the Varhoven administrativen sad (Supreme Administrative Court). On 4 April 2008, that court gave judgment allowing the appeal, setting aside the judgment of the Administrativen sad Sofia-grad and referring the case back for a new ruling by a different chamber of the lower court. The higher court found that the interpretation of Article 22 of Regulation No 1408/71 by the lower court was incorrect since the fact that it is impossible to provide the treatment in issue in Bulgaria, even though it is referred to in the national legislation, establishes a presumption that it is not included among the benefits that are lawfully payable.

15. During the reconsideration of the case by the Administrativen sad Sofia-grad, Mr Elchinov requested that a reference for a preliminary ruling be made to the Court of Justice of the European Union.

III — The reference for a preliminary ruling and the procedure before the Court

16. On 14 May 2009, the Court received the reference for a preliminary ruling from the Administrativen sad Sofia-grad, which is drawn up on the basis of the following questions:

'(1) Is the second subparagraph of Article 22(2) of Council Regulation (EEC) No 1408/71 of 14 June 1971 … to be interpreted as meaning that, where it is impossible to give in a Bulgarian healthcare institution the specific treatment that has been the subject of an application for the issue of Form E 112, it is to be assumed that this treatment is not financed from the budget of the National Health Insurance Fund (NZOK) or the Ministry of Health and, conversely, where such treatment is financed from the budget of the NZOK or the Ministry of Health it is to be assumed that it can be given in a Bulgarian healthcare institution?

(2) Is the phrase "the treatment in question cannot be provided for the person concerned within the territory of the Member State in which he resides" in the second [sub]paragraph of Article 22(2) of Regulation (EEC) No 1408/71 to be interpreted as encompassing cases in which the treatment that is given in the territory of the Member State in which the insured person resides is much less effective and more radical than the treatment that is given in another Member State, or does it encompass only those cases in which the person concerned cannot be treated without undue delay?

(3) Having regard to the principle of procedural autonomy: is the national court obliged to take account of binding directions given to it by a higher court when its decision is set aside and the case referred back for reconsideration if there is reason to assume that such directions are inconsistent with Community law?

(4) If the particular treatment concerned cannot be given on the territory of the Member State in which the person with medical insurance resides is it then sufficient, in order for that Member State to be obliged to issue authorisation for treatment in another Member State under Article 22(1)(c) of Regulation (EEC) No 1408/71, for the type of treatment concerned to be included within the benefits provided for under the legislation of the first-mentioned Member State even if that legislation does not expressly stipulate the specific method of treatment?

(5) Are Article 49 EC and Article 22 of Regulation (EEC) No 1408/71 inconsistent with a national provision such as Article 36(1) of the Law on health insurance, according to which persons insured under the compulsory scheme have the right to receive in part or in full the value of the expenses for medical care abroad only if they have received a preliminary permit?

(6) Must the national court oblige the competent institution of the State in which the patient has medical insurance to issue the document for treatment abroad (Form E 112) if it considers the refusal to issue such a document to be unlawful, where the application for the issue of the document has been lodged before the treatment was carried out abroad and the treatment has been completed by the date on which the court decision is pronounced?

(7) If the aforementioned question should be answered in the affirmative and the court should consider the refusal of authorisation for treatment abroad to be unlawful how is the person with medical

insurance to be reimbursed the costs of his treatment:

(a) directly by the State in which he is insured or by the State in which the treatment has been given, following submission of authorisation for treatment abroad;

(b) to what extent, if the range of benefits that are provided for under the legislation of the Member State where he resides should differ from the range of benefits provided for under the legislation of the Member State in which the treatment is given; in the light of Article 49 EC, which prohibits restrictions on freedom to provide services?'

17. Observations were lodged, within the time-limit indicated in Article 23 of the Statute of the Court of Justice, by the applicant in the main proceedings, the Bulgarian, Czech, Spanish, Finnish, Greek and United Kingdom Governments and the Commission. Since none of the parties to the main proceedings, or the Member States or the Commission, requested that a hearing be held, the proceedings became ready for the delivery of this Opinion at the conclusion of the written stage.

IV — Whether the directions given by the Supreme Administrative Court must be complied with

18. As we have just seen, the third of the seven questions submitted by the referring court differs substantially from the others, in that it raises a procedural issue as opposed to the substantive matters with which the remaining questions are concerned. A positive reply to that question will, for reasons set out below, lead to the remaining questions being ruled inadmissible. Accordingly, it is appropriate to begin by addressing that procedural aspect.

19. The third question is whether a Bulgarian procedural provision is compatible with European Union law and with the applicable case-law of the Court. Specifically, the referring court asks whether a national court must apply a national provision such as Article 224 of the APK, pursuant to which it is required to take account of binding directions given to it by a higher court after that court set aside a judgment at first instance from the lower court, when those directions appear to be contrary to European Union law. Thus, as will be seen below, the referring court has requested an examination of the case-law of the Court beginning with *Rheinmühlen I* in 1974 and, in this particular case, its application to

a procedural system such as the Bulgarian administrative system. The fact that the last 36 years have witnessed an important evolution with regard to the application of European Union law by national courts brings with it a need to reflect, at the invitation of the referring court, on how the *Rheinmühlen I* case-law must now be interpreted.

A — *The Rheinmühlen I case-law, its context and its application to the present case*

20. In *Rheinmühlen I*, the Court held that 'a rule of national law whereby a court is bound on points of law by the rulings of a superior court cannot deprive the inferior courts of their power to refer to the Court questions of interpretation of Community law involving such rulings'.[5] That declaration amounted to an important endorsement of the normative force of European Union law, which was thereby endowed, from that moment, with the capacity to take precedence over a judgment of a superior court whose case-law was binding on inferior courts. Although the wording refers only to the right of a lower court to make a reference for a preliminary ruling, it goes without saying that the purpose of so doing is, where necessary, to disregard the directions of the judgment of a higher court. The only exception accepted by the Court was where a lower court submitted questions for a preliminary ruling which 'were substantially the same as questions already put by the superior court'.[6]

21. *Rheinmühlen I* thus introduced a form of decentralised review of the compatibility with Community law not of legislative provisions but of judicial decisions. Indeed, lower courts whose decisions were set aside by a higher court could, relying on that case-law, and when the case was referred back to them, disregard the setting-aside of their judgment by the higher court when, in their opinion, it was contrary to European Union law. In the conflict between national procedural autonomy and the opportunity, which was thus reopened, to assert the primacy of European Union law, priority was given to the latter.[7]

22. The automatic application of *Rheinmühlen I* would mean that it would be necessary to reply to the third question in the

5 — *Rheinmühlen I*, paragraph 4.

6 — Ibid.

7 — That was how the judgment was interpreted when it was given, as is clear from remarks made at the time by Bebr, G., *Europarecht*, 1974, p. 354; Winter, A., *Common Market Law Revew*, 1974, p. 210; and Hartley, T., 'Article 177 EEC: appeals against an order to refer', *European Law Review*, 1975, p. 48.

negative and then move on directly to reply to the other questions. However, *Rheinmühlen I* is a judgment which arose specifically from a number of procedural and historical circumstances that are very different from the ones surrounding the present case. An interpretation which is, so to speak, one-directional and focused solely on primacy runs the risk of ignoring that change of perspective.

B — *National courts of last instance and the redefinition of their place in the application of European Union law and of their responsibility in the context of that task*

23. The growth of European Union law and the devolution to the national courts of the responsibility for interpreting and applying that law have converted the highest courts of the Member States into the keystone of judicial cooperation between the Court of Justice and its national counterparts. Taking that in conjunction with the fact that, after successive amendments of the founding Treaties, the right to bring a direct action before the Court against the decisions of national courts neither exists nor is envisaged, it is clear that the highest courts of the Member States play a decisive role in overseeing the correct application of European Union law. That devolution of powers to the highest national courts has taken place in a context in which their duty to ensure that European Union law is applied correctly and their duty to protect the rights which that law confers on individuals have increased simultaneously.

24. To my mind, that is how the *Köbler* judgment should be interpreted, [8] since it established the financial liability of Member States for judicial acts, even in those States where actions for compensation against courts were unknown. [9] In parallel with that development, in *Commission* v *Italy*, the Court, urged by the Commission, broke the persistent resistance of both institutions to bringing and upholding, respectively, actions for failure to fulfil obligations against Member States based on judgments of national courts. [10] In both *Köbler* and *Commission* v *Italy*, the Court focused on courts of last instance, identifying them as key players which have responsibility for complying with and enforcing European Union law. [11] Further, whether or not those courts have made a reference for a preliminary ruling to the Court of Justice, and the terms in which, where appropriate, the *CILFIT* case-law has been applied, are matters of

8 — Cited above.

9 — In that regard, see the analysis of Advocate General Léger in his Opinion in *Köbler*, concerning the establishment of State liability for judicial acts in the Member States (points 77 to 86).

10 — *Commission* v *Italy*.

11 — *Köbler*, paragraphs 34 and 35, and *Commission* v *Italy*, paragraph 32.

particular significance with regard to the application of those remedies. [12]

25. That said, it should also be noted that Member States have developed guarantees which contribute to ensuring that courts of last instance are not spared when they adopt decisions which overlook the intervention of the Court of Justice. The constitutional courts of a number of Member States have given a new direction in that regard – albeit to different extents – to direct actions for the protection of fundamental rights, beginning with the Federal Republic of Germany, [13] followed by Austria [14] and Spain, [15] and more recently by the Czech Republic [16] and Slovakia. [17] Thus, in some Member States, mechanisms for reviewing the growing responsibility incumbent on supreme courts may be found not only in the Court of Justice but also in the constitutional courts of those States, which increasingly internalise European Union law in order to include it in their criteria for constitutional assessment.

26. As a result, it is also necessary to draw attention to another development in case-law which, at first sight, does not appear to take the same direction as the one described above but which is an outcome that is also consistent with that evolution. In *Kühne & Heitz*, [18] the Court declared that a national administrative act confirmed by a judgment at last instance whose interpretation of European Union law was subsequently shown to be incorrect following a decision of the Court does not, however, need to be reviewed. Thus, the Court gave preference to the European Union principle of legal certainty, which protects the force of *res judicata* of a national judgment. [19] The judgment in *Kapferer* took another step in the same direction, by applying that approach to a judicial decision with the force of *res judicata* which had been given by a lower court. [20] In that case, the Court could not have been clearer when it declared that '[European Union] law does not require a national court

12 — Case 283/81 *CILFIT* [1982] ECR 3415. On the application of that case-law in the context of financial liability and infringements by courts, see, respectively, *Köbler*, paragraph 35, and the judgment of 12 November 2009 in Case C-154/08 *Commission* v *Spain*, paragraphs 64 and 65.

13 — Judgment of the Federal Constitutional Court of 22 October 1986, BVerfGE 73, 339, subsequently confirmed by the judgment of 31 May 1990, BVerfGE 82, 159.

14 — Judgment of the Constitutional Court of 11 December 1995, B 2300/95 WBl 1996, 24.

15 — Judgment 58/2004 of the Constitutional Court, subsequently confirmed by judgment 194/2006.

16 — Orders of the Constitutional Court of 30 June 2008, IV. ÚS 154/08, and of 24 July 2008, III. ÚS 2738/07, subsequently confirmed by the judgment of 8 January 2009, II. ÚS 1009/08.

17 — Orders of the Constitutional Court of 29 May 2007, III. ÚS 151/07, and of 3 July 2008, IV ÚS 206/08.

18 — Cited above.

19 — However, the Court held that European Union law does not preclude the revocation of an act where four conditions are satisfied: (a) under national law, it has the power to reopen that decision; (b) the administrative decision in question has become final as a result of a judgment of a national court ruling at last instance; (c) that judgment is, in the light of a decision given by the Court subsequent to it, based on a misinterpretation of [European Union] law which was adopted without a question being referred to the Court for a preliminary ruling under the third paragraph of Article 234 EC; and (d) the person concerned complained to the administrative body immediately after becoming aware of that decision of the Court.

20 — Case C-234/04 *Kapferer* [2006] ECR I-2585.

to disapply domestic rules of procedure conferring finality on a decision, even if to do so would enable it to remedy an infringement of [European Union] law by the decision at issue'.[21] The passage of time has merely confirmed that case-law, as in, for example, *i-21 Germany and Arcor*, *Kempter* and *Fallimento Olimpiclub*.[22] The only exception to that line of case-law appears to be where the provision of European Union law the primacy of which is invoked was adopted pursuant to an exclusive competence of the European Union.[23]

27. In short, that case-law demonstrates how the European Union principles of legal certainty and institutional autonomy may, where appropriate, place conditions on the effectiveness of the primacy of European Union law. While that assessment may appear to conflict with the case-law arising from judgments such as *Köbler* and *Commission* v *Italy*, in reality they are simply two sides of the same coin. To the extent that courts of last instance begin to be held to account directly for their decisions which are contrary to European Union law, it will become less essential to sacrifice legal certainty and national procedural autonomy in the interests of guaranteeing the effectiveness of European Union law. In particular, it does not appear to be necessary also for a lower court to consider it possible to disregard its internal hierarchical organisation in order to preserve the effectiveness of European Union law, since, inter alia, an individual who holds rights conferred by European Union law may now bring an action for liability for judicial acts (*Köbler*); further, if the national law of that individual permits, he will also have available to him a review, carried out by a court of its own motion, of the act which confirmed the unlawful judgment (*Kühne & Heitz*). Proceedings for failure to fulfil obligations may also now be used to protect an individual who has been the subject of an incorrect interpretation of European Union law by a higher court (*Commission* v *Italy*), particularly in cases in which Member States provide for extraordinary actions for review to set aside final judgments that are declared unlawful by the Court of Justice in the context of a failure to fulfil obligations.[24]

28. Where a national supreme court must be held to account vis-à-vis an individual through the remedies laid down in European Union law, it correspondingly ceases to make sense that a lower court, which is required to apply the decision of a higher court, which, although it might be contrary to European Union law, is final, should retain the right to

21 — Ibid., paragraph 21.

22 — Respectively Joined Cases C-392/04 and C-422/04 [2006] ECR I-8559; Case C-2/06 [2008] ECR I-411; and Case C-2/08 [2009] ECR I-7501.

23 — Case C-119/05 *Lucchini* [2007] ECR I-6199.

24 — See Alemanno, A., 'La responsabilità dello Stato nei confronti dei privati per le violazioni commesse dai giudici di ultima istanza', in Spitalero, F., *Il risarcimento dei danni causati da sentenze definitive, en L'incidenza del Diritto Comunitario e della CEDU sugli atti nazionali definitivi*, Giuffrè, Milan, 2009, pp. 65 to 72.

disregard that decision even where national law does not permit it to do so. In my opinion, the procedural autonomy of the Member States, in particular in relation to matters as sensitive as the ones under discussion, recovers its *raison d'être* when the effectiveness of European Union law begins to be protected decisively by other means.

29. The increased workload facing the Court of Justice warrants a final word in that connection. The high number of references for a preliminary ruling which arrive at the doors of this institution together with the creation of the urgent procedure, which is intended to provide a reply in a much shorter period, make it all the more pressing for the Court to share functions with the national courts. The introduction before national courts of remedies under European Union law, as occurred with State financial liability and the principles of effectiveness and equivalence, is a move which strengthens and promotes cooperation between the Court and its national counterparts. In addition, the increased number of Member States, allied to the ever more frequent and direct contact between individuals and European Union law, make the aim that the Court should deal alone with the task of supplying an authoritative interpretation of European Union law less and less realistic. [25] In that regard, the judgment in *Rheinmühlen I*, which is a product of its time and of a particular context, may, paradoxically, end up impeding rather than safeguarding the effectiveness of European Union law. That is all the more so since, in the circumstances of the present case, Mr Elchinov could use other legal remedies before the national courts, remedies which, moreover, are guaranteed to him under European Union law.

30. The present case draws particular attention to the fact that there are now effective legal remedies other than those resulting from *Rheinmühlen I* for a claim such as that of Mr Elchinov. Thus, after the Supreme Administrative Court had referred the case back to the Administrativen sad Sofia-grad, and that court has given judgment dismissing the action, Mr Elchinov would have the right to bring proceedings for liability against the State for infringement of European Union law. In the course of those proceedings, the competent national court could seek a preliminary ruling from the Court of Justice concerning whether, in accordance with its case-law, there had been a manifest error of

25 — In that connection, see the Opinion of Advocate General Jacobs in Case C-338/95 *Wiener* [1997] ECR I-6495, point 40 et seq., and the Opinion of Advocate General Ruiz-Jarabo Colomer in Case C-461/03 *Gaston-Schul* [2005] ECR I-10513, points 80 to 87.

law. [26] If the infringement were confirmed, the referring court would give judgment and would make reparation to the applicant, in short, in the same terms as it would have done under the *Rheinmühlen I* case-law. Finally, in the event that the court did not uphold the action for liability, it is appropriate to point out that the alternative remedy of an action for failure to fulfil obligations would still be available, which the individual could, by means of a complaint, request the Commission to bring. [27]

31. In contrast to the situation in the 1970s, it is possible to assert today that European Union law has reached a level of maturity which allows it to ensure its own practical effectiveness before the courts of the Member States with a lesser degree of involvement in the autonomy of national courts than that which indubitably results from *Rheinmühlen I*. That is why the time for reconsidering that case-law appears to have arrived.

32. That said, I acknowledge that the proposal which I make to the Court comes at a price. Depriving national courts of the powers derived from the *Rheinmühlen I* case-law is liable to preclude them from furnishing individuals with an immediate solution, thereby making it necessary for the latter to bring long, costly proceedings for compensation which may sometimes have an unfavourable outcome. However, that shortcoming is not significantly different from that faced by a litigant in a purely national case, against whom a court of last instance gives an incorrect and damaging judgment under national law. In those circumstances, an individual who found himself in a situation to which European Union law did not apply would also be required to bring an action for liability, in the same terms as the ones which Mr Elchinov would have to negotiate when claiming the rights conferred on him by European Union law. Provided that the Court acknowledges that the requirements of primacy may occasionally give way to the principle of legal certainty, the solution which I propose is, to my mind, not only more consistent with current case-law but is naturally also more consistent with the national judicial structure of each

26 — See, inter alia, Joined Cases C-6/90 and C-9/90 *Francovich and Others* [1991] ECR I-5357, paragraph 35; Joined Cases C-46/93 and C-48/93 *Brasserie du Pêcheur and Factortame* [1996] ECR I-1029, paragraph 31; Case C-392/93 *British Telecommunications* [1996] ECR I-1631, paragraph 38; Case C-5/94 *Hedley Lomas* [1996] ECR I-2553, paragraph 24; Joined Cases C-178/94, C-179/94 and C-188/94 to C-190/94 *Dillenkofer and Others* [1996] ECR I-4845, paragraph 20; and Case C-127/95 *Norbrook Laboratories* [1998] ECR I-1531, paragraph 106.

27 — See, by way of example and in circumstances similar to those of Mr Elchinov, recent Case C-211/08 *Commission* v *Spain*, pending judgment, proceedings for failure to fulfil obligations arising out of the complaint made by a French national, Mr Chollet, resident in Spain and covered by the Spanish social security system. After he was hospitalised during a stay in France, the competent Spanish institution refused Mr Chollet's claim for the reimbursement of the percentage of the costs charged to him by the institution in the place of stay in accordance with French legislation (what is known as 'the ticket modérateur'), which formed the grounds for his complaint to the Commission which has led to those proceedings.

Member State, whose design and balance ought not to be altered unnecessarily.

33. It might also be possible to counter that, in accordance with the case-law of the Court, the principle of primacy may be derogated from only where a final judgment of a national court acquires the force of *res judicata*, which was the situation in cases such as *Kühne & Heitz* and *Kapferer* but not in the present case. However, that argument makes sense only if *res judicata* is assessed in strictly procedural terms, something which is not compatible with the approach taken by the Court in its most recent case-law. As is clear from the judgments in *Kühne & Heitz*, *Kapferer, Kempter*, *i-21 Germany and Arcor* and, more recently, *Fallimento Olimpiclub*, the assessment made by the Court of the finality of a national judicial decision greatly depends on the specific circumstances of each case. As Advocate General Mazák observed in his Opinion in *Fallimento Olimpiclub*, that case-law reflects the importance of carrying out a case-by-case assessment in the light of the particular factual and legal circumstances. [28] Such an approach, which takes account of the special features of the national framework, is precisely what the *Rheinmühlen I* case-law does not allow. By enabling a national court to disapply the judicial decision of a supreme court which is directly binding on it, *Rheinmühlen I* removes any latitude for taking into account factors such as the stability of legal relationships, the finality of judgments or legal certainty. [29] Accordingly, the principle of *res judicata* provided for in national law and its relationship with European Union law warrant an assessment both detailed and mindful of the procedural autonomy of each Member State.

34. Turning again to the circumstances of the present case, no appeals may be brought against a judgment of the Bulgarian Supreme Administrative Court; however, a case may be referred back to a lower court for a reconsideration in which that court may only carry out a new appraisal of the facts. There can be no doubt that the judgment of the higher court brought an end to the proceedings as far as the law is concerned, and that judgment may not be contested even by means of an extraordinary appeal to the Constitutional Court. [30] Further, it is clear from learned writing in this field that the assessment of the law which the Supreme Court carries out in the case will be binding on it in the future should a further appeal against the judgment of the lower court

28 — Opinion in Case C-2/08, point 54.

29 — The Court took the same approach, focused on the specific features of each legal system, in its case-law on the assessment of European Union law by a court of its own motion. In that regard, see (and compare) the judgments in Joined Cases C-430/93 and C-431/93 *van Schijndel and van Veen* [1995] ECR I-4705; Case C-312/93 *Peterbroeck* [1995] ECR I-4599; and Case C-455/06 *Heemskerk and Schaap* [2008] ECR I-8763.

30 — The Bulgarian Constitutional Court (Article 149 of the Bulgarian Constitution) does not hear direct actions brought by individuals for the protection of fundamental rights.

be brought before it. [31] Accordingly, when the Supreme Court gave the judgment in question in 2008, it is possible to assert that that judgment had the force of substantive, but not procedural, *res judicata*. The substance of the judgment was thus unalterable, and, under Bulgarian procedural law, assessments of the law made in that judgment are afforded all the stability of a final judgment. In short, it is my view that the fact that no appeal may be brought against the legal grounds of a decision such as the one in issue is sufficient to give rise to a legal stability which warrants special protection.

35. Finally, it might, perhaps, be possible to complain that this proposal is not completely consistent with the solution for which the Court opted in *Cartesio*. [32] It should be pointed out, however, that that judgment concerned a different problem and also touched on a totally different procedural issue from the one raised in the present case. It is well known that the *Cartesio* judgment qualified the terms of the *Rheinmühlen II* judgment [33] with regard to the fact that orders for reference may not be contested. [34] It should be recalled that in the latter decision, which was adopted a few weeks after the judgment in *Rheinmühlen I* and in the course of the same national proceedings, the Court held that Article 267 TFEU (then Article 177 of the EEC Treaty) does not preclude a decision of a lower court to refer a question for a preliminary ruling 'from remaining subject to the remedies normally available under national law'. On the other hand, even though it cited the *Rheinmühlen* case-law as authority, the *Cartesio* judgment qualified that outcome by stating that the jurisdiction conferred by Article 267 TFEU to make a reference to the Court 'would be called into question, if – by varying the order for reference, by setting it aside and by ordering the referring court to resume the proceedings – the appellate court could prevent the referring court from exercising the right, conferred on it by the EC Treaty, to make a reference to the Court'. [35] The judgment continues with that line of reasoning and then concludes by declaring that it is for the lower court 'to draw the proper inferences from a judgment delivered on an appeal against its decision to refer and, in particular, to come to a conclusion as to whether it is appropriate to maintain the reference for a preliminary ruling, or to amend it or to withdraw it'. [36]

36. Above all, it is striking that the fact that orders for reference may not be contested, and the consequences that may arise from

31 — К. Пенчев, И. Тодоров, Г. Ангелов и Б. Йорданов, Административнопроцесуален кодекс – Коментар, Първо издание, София 2006, чл. 224, ал. 2.

32 — Case C-210/06 [2008] ECR I-9641.

33 — Case 146/73 *Rheinmühlen-Düsseldorf* [1974] ECR 139.

34 — In that regard, see Alonso García, R., 'Cuestión prejudicial comunitaria y autonomía procesal nacional: a propósito del asunto Cartesio', *Revista Española de Derecho Europeo*, No 30, 2009, pp. 209 to 211, and Barbato, J.-C., 'Le droit communautaire et les recours internes exercés contre les ordonnances de renvoi', *Revue trimestrielle de Droit européen*, No 2, 2009, p. 280 et seq.

35 — *Cartesio*, paragraph 95.

36 — Ibid., paragraph 96.

it, is a problem reflecting certain specific features which are very different from those which have arisen in the present case. The reference framework of each case changes substantially, since *Cartesio* concerns what might be termed the ascending phase of an action, in other words, the natural gestation period running from the time when the proceedings begin in the lower court until the time they conclude in the form of a judgment against which no appeal may be brought. However, the present case concerns what might be termed the descending phase of the action, that is to say, the terminal point of the proceedings after final judgment has been given and the case has been referred back to the lower court simply for the purposes of complying with a decision in law the terms of which may not be called into question.

37. The conclusion proposed in this Opinion does not imply that the *Rheinmühlen I* judgment should lose its whole *raison d'être*. On the contrary, in my view, that judgment will remain fully effective where, in the course of the ascending phase of an action, there is intervention which requires a lower court to disregard the directions of its superior court. A case in point is where an appeal is brought against an order for reference, as occurred in *Cartesio*. In those circumstances, the retention of the *Rheinmühlen I* case-law is justified and it is no coincidence that the Court cited and reproduced that case-law in paragraph 94 of *Cartesio*. In such a case, in the ascending phase of an action in which European Union law is applied, *Rheinmühlen I* must be used as a tool in the hands of the lower court, to which the case-law of the Court of Justice affords special protection at that moment. [37]

38. Consequently, for the reasons set out above, I invite the Court to declare that European Union law must be interpreted as meaning that it does not preclude a lower court, such as the Administrativen sad Sofia-grad in the present case, in proceedings in which it has already given a first judgment, from being required under national law, after the case has been referred back to it, to apply the directions set out in the judgment on appeal given by a higher court in the same proceedings.

39. If the Court agrees with that proposal, the remaining questions concerning the substance will be irrelevant since they are all based on the assumption that the referring court does not necessarily have to follow the ruling of the Bulgarian Supreme Administrative Court. In that case, the Court should

37 — The situation is different where the *Rheinmühlen I* case-law is applied when new proceedings are commenced which are not affected by the force of procedural *res judicata* of the judgment of the higher court. That occurred recently in Case C-378/08 *ERG* [2010] ECR I-1919, where the Court relied on that judgment in a situation in which the parties commenced a new action against administrative acts other than the ones challenged in the action which had previously acquired the force of *res judicata*.

logically declare that those questions are inadmissible, in accordance with its case-law. [38]

40. However, in case the Court does not share that view, it is appropriate to analyse the remaining six questions on the substance, which concern, as stated above, the cross-border medical services received by Mr Elchinov.

V — The substance

41. In order to provide a helpful reply, it is necessary once more to change the order of the questions referred by the Administrativen sad Sofia-grad. First of all, I will examine whether the Bulgarian system of prior authorisation for the receipt of medical treatment abroad is compatible with the Treaties and with Article 22 of Regulation No 1408/71. Second, I will analyse whether the conditions laid down in Article 22 of the regulation are satisfied, focusing on the degree of precision with which the Bulgarian legislation provides for cover for the cost of the treatment, the consequences of it being materially impossible to provide that treatment in Bulgaria, and the possibility of offering alternative, but less effective and more radical, treatment. Third, I will consider the rules on reimbursement which will be applicable in the event that Mr Elchinov satisfies the conditions for reimbursement of the cost of the treatment carried out in Germany. Finally, it will be necessary to give a view on the powers of the national court to declare, where appropriate, that the applicant is entitled to such reimbursement.

A — *Prior authorisation as a condition for reimbursement of the costs of medical treatment provided abroad (fifth question)*

42. By its fifth question, the referring court asks whether a system of prior authorisation for the receipt of medical treatment in another Member State is compatible with European Union law. In view of the fact that Mr Elchinov was treated in Germany *after* applying for authorisation but *before* that authorisation was granted, the question arises whether a system such as the one provided for in Article 36 of the Bulgarian Law on health insurance is compatible with Article 56 TFEU and with Regulation No 1408/71.

43. The Member States which have lodged observations have adopted a partially common position. On the one hand, it is common ground that the case-law of the Court permits States to establish systems of prior

38 — See, inter alia, Case 244/80 *Foglia* [1981] ECR 3045, paragraph 21; Case 149/82 *Robards* [1983] ECR 171, paragraph 19; and Case C-83/91 *Meilicke* [1992] ECR I-4871, paragraph 25.

authorisation for the receipt in another Member State of medical care requiring hospitalisation. However, whereas Spain and Bulgaria maintain that, by specifically excluding any reimbursement where authorisation has not been requested, the Bulgarian system does not conflict with European Union law, the Commission and the Czech and Polish Governments reach the opposite conclusion.

44. The reply to this question is clear from the case-law of the Court.

45. In *Decker* and *Kohll*, [39] the Court held that national rules which 'make reimbursement of the costs incurred in [another] Member State subject to prior authorisation, and deny such reimbursement to insured persons who have not obtained that authorisation' constitute a restriction of freedom to provide services and 'deter insured persons from approaching providers of medical services established in another Member State'. [40] After analysing the arguments put forward in support, the Court held that a system of prior authorisation was not covered by the public health derogation set out in Articles 52 TFEU and 62 TFEU or by an overriding reason in the public interest.

46. That important assertion, which confirmed the development already underlying the two *Pierik* judgments, [41] entailed two significant clarifications. First, in line with the Opinion of Advocate General Tesauro, [42] it confirmed that it was possible to interpret Article 22 of Regulation No 1408/71 in the light of the Treaties and that the Treaties were applicable where the regulation could not be relied on. [43] Second, as a result of the foregoing, it made it clear that public and private medical services are economic activities which are caught in full by the provisions governing freedom of movement. [44]

47. However, it should be borne in mind that both those judgments concerned treatment not requiring hospitalisation, and instead dealt with outpatient treatment the organisation and cost of which were not comparable to treatment necessitating a stay in hospital. It was specifically by reference to that factor that the Court stated in the judgments in *Smits and Peerbooms* and *Müller-Fauré and*

39 — Respectively Case C-120/95 [1998] ECR I-1831 and Case C-158/96 [1998] ECR I-1931.

40 — *Decker*, paragraphs 35 and 36, and *Kohll*, paragraphs 34 and 35.

41 — Case 117/77 [1978] ECR 825 and Case 182/78 [1979] ECR 1977.

42 — Points 17 to 24 and 32 of the Opinion in *Decker* and *Kohll*.

43 — *Decker*, paragraphs 22 to 25, and *Kohll*, paragraphs 20 to 21.

44 — *Kohll*, paragraphs 31 to 35. That point had already been made by the Court in Joined Cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377, but had not been applied to the healthcare sector until the *Kohll* judgment.

van Riet,[45] which were given shortly after *Decker* and *Kohll*, that, 'by comparison with medical services provided by practitioners in their surgeries or at the patient's home, medical services provided in a hospital take place within an infrastructure with, undoubtedly, certain very distinct characteristics'.[46] The Court went on to specify those distinct characteristics and referred to the necessary planning required by such centres, for which purpose information is needed about 'the number of hospitals, their geographical distribution, the mode of their organisation and the equipment with which they are provided, and even the nature of the medical services which they are able to offer'.[47] As a result of all the foregoing, the Court declared that European Union law does not 'in principle' preclude a system of prior authorisation for those who wish to receive hospital treatment in another Member State.[48]

48. The Court reached the same conclusion in *Vanbraekel and Others*,[49] in which it added an important element to the previous judgments: where a request is refused and after it has been established that that refusal was contrary to Article 22 of Regulation No 1408/71, it does not preclude the person making the request from claiming the reimbursement guaranteed to him under the article.[50] In those circumstances, the person entitled to reimbursement may obtain it directly from the institution to which he is affiliated in his State of residence.

49. In the light of all the foregoing, a provision such as Article 36(1) of the Bulgarian Law on health insurance must be applied having regard to the interpretation which the Court has supplied of Article 56 TFEU and Article 22 of Regulation No 1408/71. That means that the requirement of prior authorisation for receiving hospital treatment in another Member State is not 'in principle' incompatible with the provisions of European Union law. It does not mean, as is clear from the judgments in *Smits and Peerbooms* and *Müller-Fauré and van Riet*, that that Bulgarian provision is devoid of any uncertainty. If Bulgarian law were to implement a system which is so strict that it impedes or renders less attractive the freedom to provide services, the case-law cited would necessarily lead to a finding that it is not compatible with European Union law.

50. In view of the wording of the provision in issue, which is somewhat ambiguous, it does not appear that such incompatibility exists.

45 — Respectively Case C-157/99 [2001] ECR I-5473 and Case C-385/99 [2003] ECR I-4509.

46 — *Smits and Peerbooms*, paragraph 76, and *Müller-Fauré and van Riet*, paragraph 77.

47 — Ibid.

48 — *Smits and Peerbooms*, paragraph 82, and *Müller-Fauré and van Riet*, paragraph 83.

49 — Case C-368/98 [2001] ECR I-5363 ('*Vanbraekel*').

50 — *Vanbraekel*, paragraph 34. On that point, see also the judgment in Case C-8/02 *Leichtle* [2004] ECR I-2641, paragraph 55, and the Opinion of Advocate General Ruiz-Jarabo Colomer in that case, point 41.

51. Article 36(1) guarantees the right of all individuals insured under the compulsory scheme 'to receive in part or in full the value of the expenses for medical care abroad only if they have received prior authorisation from the [Fund]'. As the Commission and Mr Elchinov point out, the provision could be interpreted as a specific prohibition on the receipt of any reimbursement, a priori or a posteriori, in the event that authorisation has not been requested. However, the wording could indicate a more subtle interpretation: the provision might also state that reimbursement is possible only where authorisation has been received in advance *on satisfying the conditions laid down in Article 22(2) of Regulation No 1408/71.* Thus, if the article is construed as a derivation of Article 22 of the regulation, it should also be interpreted as meaning that where it is established, by the competent institution itself or by a judicial decision, that a refusal to grant authorisation was unfounded, the authorisation will no longer be necessary.

B — *Satisfaction of the conditions laid down in Article 22(2) of Regulation No 1408/71*

52. It is well known that it is for the referring court alone, rather than the Court of Justice, to interpret national provisions. However, it is the responsibility of the Court to supply the referring court with all the elements necessary to ensure that national law is correctly applied in the light of European Union law. In those circumstances, it is my view that Article 56 TFEU and Article 22 of Regulation No 1408/71 must be interpreted as meaning that they do not preclude a provision such as Article 36(1) of the Bulgarian Law on health insurance, in so far as that provision establishes a system of prior authorisation for the receipt of hospital treatment in another Member State, and, in any event, provided that it does not prevent applicants from claiming reimbursement subsequently in cases where it is established, by the competent institution itself or by a judicial decision, that refusal of their application was unfounded.

53. The referring court has submitted a number of questions concerning the interpretation of Article 22(2) of Regulation No 1408/71, which sets out the conditions to be satisfied as a step prior to obtaining the right to be authorised to receive hospital treatment in another Member State. In this instance too, the reply to those questions may already be found in the case-law of the Court, based exclusively on the regulation, since the Treaty on the Functioning of the European Union should be used only as a criterion for interpretation.

1. The inclusion of the treatment in the legislation of the Member State in whose territory the person concerned resides (fourth question)

54. The referring court harbours uncertainties about the scope of Article 22(2) of Regulation No 1408/71, where it provides in the second subparagraph that authorisation to receive treatment in another Member State 'may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned reside[s]'. Those uncertainties flow from the decision of the Bulgarian legislature to draw up a comprehensive list of treatment covered by the scheme under which Mr Elchinov is insured but to define only in general terms the treatment which he has been prescribed.

55. Once again, the Member States have adopted divergent positions, although they all assert that they have competence to determine the specific benefits available to those who pay social security contributions. Following on from that common position, the Czech and Finnish Governments point out that a list system such as the one established in Bulgaria must not be discriminatory. The Kingdom of Spain states that the categories must be sufficiently specific and must not give rise to legal uncertainty. The Polish Government maintains that Article 22(2) must be interpreted strictly, while the Greek Government and the Commission propose a broader interpretation of the provision and argue that the Bulgarian rules must be applied in such a way that they do not prejudice the recipient of the service.

56. In *Smits and Peerbooms* and *Müller-Fauré and van Riet*, and also in *Inizan* and *Watts*, [51] it was clear that the Court was concerned about the manner in which some Member States apply the system of prior administrative authorisation for obtaining treatment in another Member State. In that connection, those judgments stated that a scheme of prior administrative authorisation cannot legitimise discretionary decisions taken by the national authorities which are liable to negate the effectiveness of provisions of European Union law. On that premiss, the Court held that a scheme of prior administrative authorisation such as the one established for the receipt of hospital treatment in another Member State 'must, in any event, be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily'. [52]

51 — Respectively Case C-56/01 [2003] ECR I-12403 and Case C-372/04 [2006] ECR I-4325.

52 — *Smits and Peerbooms*, paragraph 90; *Müller-Fauré and van Riet*, paragraph 85; *Inizan*, paragraph 57; and *Watts*, paragraph 116.

57. In *Smits and Peerbooms*, the provision of Netherlands law in issue did not set out a list of benefits but rather a general rule which stated that medical treatment would be covered provided that it corresponded to 'what is normal in the professional circles concerned'. The Court held that such an ambiguous provision made it likely that national providers of treatment would always be preferred in practice to those established in other Member States. [53] The *Watts* judgment also drew attention to the difficulty of reconciling with European Union law a system such as that of the United Kingdom which did not set out the criteria for the grant or refusal of prior authorisation for hospital treatment provided in another Member State. [54]

58. Unlike the situation in the cases mentioned above, the Bulgarian legislature opted for a list system which sets out comprehensively and definitively the treatment covered by the compulsory insurance. Accordingly, the uncertainties of the referring court do not concern a discretionary system but rather a system which aims to be objective, transparent and non-discriminatory, but which gives rise to uncertainties about its interpretation.

59. Indeed, Annex 5 to Order No 40 implementing the Law on health insurance sets out the 'List of clinical treatments' covered by the compulsory insurance, including 'surgical treatment of glaucoma', 'ocular surgery using laser or cryogenic techniques', 'operations on the ocular region', 'other eyeball operations' and 'high technology radiotherapy for oncological and non-oncological conditions'. The referring court asks whether, within that group of treatments affecting the ocular region, the use on a tumour of proton particle radiotherapy followed by the resection of the tumour is treatment which is covered by any of the categories listed in Annex 5.

60. As the Commission has rightly stated, a national system consisting of definitive lists which, however, occasionally describes the treatment concerned in broad terms must be coherent and afford the definition of such treatment an interpretation consistent with its wording. In other words, since the Bulgarian system seeks to define exhaustively and very specifically each and every treatment covered by the compulsory insurance, the inclusion of treatment described in general terms as 'high technology radiotherapy for oncological and non-oncological conditions', in point 258 of Annex 5 to the implementing order, cannot be interpreted in a way which renders it devoid of meaning. That finding does not mean that point 258 must be interpreted broadly, as the Greek Government suggests. On the contrary, what it means is that it must be interpreted in a manner consistent with the ultimate aim of both the Bulgarian legislation and European Union law. As far as the Court's

53 — *Smits and Peerbooms*, paragraph 96.
54 — *Watts*, paragraph 118.

interpretation of the latter is concerned, it is clear that for point 258 to be compatible with the principles of objectivity, transparency and non-discrimination, which are repeatedly set out in its case-law, point 258 must be interpreted in the terms proposed in this Opinion.

61. In addition, such an interpretation must be based on technical criteria which, although they are not legal criteria, must form part of the appraisal of the law required under the European Union legal system. As the Commission has pointed out in its observations, the judgment in *Smits and Peerbooms* stated that, when it comes to determining whether a treatment is 'sufficiently tried and tested' in medical practice, the national authorities must take into consideration all the relevant available information, including, in particular, existing scientific literature and studies and the authorised opinions of specialists. [55]

62. The present case does not call for an assessment of whether the treatment concerned is 'sufficiently tried and tested', as Netherlands law required in *Smits and Peerbooms*, but rather of whether it is a 'high technology' treatment. Logically, the definition of that term falls exclusively to the referring court, but in its assessment it must take into consideration the guidelines previously laid down in case-law. Thus when establishing whether or not treatment is high technology, in accordance with the case-law cited, the national court must carry out a prudent appraisal, since there will be techniques of that nature in existence which, owing to their high complexity, are not common in medical practice. A dividing line which marks the boundary between a 'high technology' treatment which is routine and another which is not may be established using the experimental nature of the latter as a criterion. Thus, if the treatment prescribed necessitates the use of 'high technology' techniques, these will fall within the scope of Article 22 of Regulation No 1408/71 provided that they are not experimental. That characteristic must be defined in accordance with the *Smits and Peerbooms* case-law, taking into consideration all the relevant available information, including, in particular, existing scientific literature and studies and the authorised opinions of specialists.

63. On the basis of those criteria for interpretation, it is for the referring court to assess the exact scope of the provisions in issue. That court must also carry out a factual assessment of whether or not the high technology treatment used in this case is experimental. However, that assessment must be reconciled with the European Union law criteria proposed in this Opinion, which leads me to suggest

55 — *Smits and Peerbooms*, paragraph 98.

that Article 22(2) of Regulation No 1408/71 is to be interpreted as meaning that it does not preclude a system such as that provided for in Annex 5 to Order No 40 of 2004, in so far as that annex enables the identification of the treatment set out therein, based on objective, non-discriminatory criteria which are known in advance. Where national law uses a list system and treatment is provided for in general terms by reference to 'high technology' practices, in order not to deprive of substance the right granted by Article 22 of Regulation No 1408/71, the referring court must determine whether or not the treatment received is experimental in the light of the relevant available information including, in particular, existing scientific literature and studies and the authorised opinions of specialists.

2. The presumption that there is no cover for treatment which is not financed from the social security scheme budget (first question)

64. By its first question, the referring court asks whether a presumption, to the effect that where treatment is not financed from the social security scheme budget but is referred to in national legislation it must be regarded as not being covered by the scheme, is compatible with European Union law. That question touches on an important aspect which is still to be developed in the case-law of the Court, namely where there are insufficient resources for providing guaranteed medical treatment and how to reconcile that situation with freedom to provide services.

65. With the exception of Bulgaria and the United Kingdom, all the States which have lodged observations in these proceedings, and the Commission, state that there is no basis for such a presumption in Article 22 of Regulation No 1408/71. In their opinion, such an interpretation would have the effect of depriving of substance the right of all patients to receive hospital treatment in another Member State, thereby leaving the effectiveness of the regulation in the hands of each national authority (and the available funds). However, Bulgaria and the United Kingdom maintain that the presumption is consistent with the availability of funds in each State, something which is beneficial and detrimental to all patients in equal measure, whether or not they wish to exercise freedom of movement.

66. Of all the questions raised in these proceedings, this is the only one for which there is not already a concrete answer in the case-law of the Court. However, the reply to be

given to this question may be inferred from the judgments already cited and from the case-law on freedom to provide services.

67. It is settled case-law that Article 56 TFEU precludes the application of any national rules which have the effect of making the provision of services between Member States more difficult than the provision of services purely within a Member State. [56] Regulation No 1408/71, which is aimed at making freedom of movement fully effective in the context of social security, pursues that same objective and therefore precludes any interpretation of Article 22 which leaves providers of services in other Member States in a worse position than those in the State of residence. [57] On that premiss, any national practice or legislation which, directly or indirectly, gives national providers of services priority over those from other Member States must be treated with extreme caution. The presumption adopted by the Bulgarian Supreme Administrative Court when applying Article 22 of Regulation No 1408/71 must clearly be regarded as a restriction in that sense.

56 — Case C-381/93 *Commission* v *France* [1994] ECR I-5145, paragraph 17; *Kohll*, paragraph 33; *Smits and Peerbooms*, paragraph 61; and *Watts*, paragraph 94.

57 — See the first and second recitals in the preamble to Regulation No 1408/71.

68. Notwithstanding the restrictive nature of that interpretation, it is necessary to take the time to establish whether the presumption in issue allows for any latitude which would allow it to be declared compatible with the regulation. In that connection, Bulgaria has merely repeated that the treatment prescribed is not provided for in its legislation, without, therefore, questioning the harmful potential of the presumption. On the other hand, the United Kingdom has argued that, owing to its complexity and high cost, proton therapy warrants an interpretation of the kind made by the Bulgarian Supreme Administrative Court. That interpretation assumes that the financial integrity of social security systems would be jeopardised if patients were authorised to access such advanced and expensive treatments in another Member State.

69. Those arguments are not persuasive.

70. First of all, it must be noted that the presumption in issue is not expressly referred to in Article 22 of Regulation No 1408/71, or in any other provision of that instrument. It is, therefore, a derogation from a right conferred under European Union law in clear, specific terms. Adding to that the fact that, as I stated in point 67 of this Opinion, the measure creates an advantage for Bulgarian providers of

services vis-à-vis those from other Member States, any approach which entails a presumption like the one in issue must be rejected prima facie.

71. Second, the argument to the effect that this type of presumption does not safeguard the financial integrity of the Fund is also weak. It must be borne in mind that, as all the Member States which have lodged observations in these proceedings point out, it is they which are the competent authorities for determining the treatment in respect of which cover includes authorisation to receive it in another Member State. [58] That means that it is they which are responsible for defining in an objective, transparent and non-discriminatory manner the list of services which are covered by their social security scheme. If the financial resources of a Member State do not allow it to bear the cost of a treatment such as proton therapy, it is for that State not to include it in the list of services covered. In the present case, should the national court conclude that the treatment prescribed is provided for in the Bulgarian legislation (and the expert reports submitted to the national courts appear to indicate that it is), the provision of that treatment in another Member State would be the consequence of a decision freely adopted by the Bulgarian authorities. Under no circumstances would European Union law increase the range of treatment covered by the national social security scheme.

72. Third, it is necessary to put forward an argument relating to efficiency. For the simple reason that Bulgaria is a member of the European Union, a system such as the Bulgarian system, which seeks to offer a very advanced list of treatment that is paid for by the Fund, benefits from the knowledge and technology of other Member States which have the technical resources to which Bulgaria aspires. If a Member State wishes to be at the cutting edge of medical treatment (which naturally requires time), European Union law allows its citizens to receive in another Member State treatment which the former State wishes to make available to them domestically, although not at present in a position to do so. Further, where a State provides for a particular treatment in its national legislation, an attempt to prevent the receipt of that treatment in another Member State is not only contrary to the rules governing the internal market but also contributes to the fragmentation of the healthcare sector, which requires cooperation and the sharing of professional resources, expertise and skills. An approach of the kind maintained by the Bulgarian Government not only adversely affects the efficiency of the system vis-à-vis individuals in the Member State

58 — See, inter alia, *Decker*, paragraphs 21 to 24; *Kohll*, paragraphs 17 to 20; *Smits and Peerbooms*, paragraphs 53 to 58; *Vanbraekel*, paragraphs 40 to 44; *Müller-Fauré and van Riet*, paragraphs 38 to 43; *Inizan*, paragraphs 16 to 18; and *Watts*, paragraphs 90 to 92.

concerned but also the European healthcare sector as a whole, the joint functioning of which, moreover, strengthens the effectiveness, quality and expertise of the health services in each Member State.

73. For all the foregoing reasons, I propose to the Court that the second subparagraph of Article 22(2) of Regulation No 1408/71 is to be interpreted as meaning that it precludes a presumption that a treatment which is provided for in national legislation but which is not financed from the budget is not covered by the social security scheme.

3. The possibility of offering alternative, but less effective and more radical, treatment in the State of residence (second question)

74. By its second question, the referring court raises an uncertainty concerning the interpretation of the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71. According to that provision, the competent authority must give authorisation where 'the person concerned... cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease'. The referring court asks the Court of Justice whether that requirement permits a Member State to refuse authorisation where there is equivalent, but less effective and more radical, treatment available in its territory. Specifically, it is necessary to analyse whether the complete removal of a diseased eye is treatment which is equivalent to proton therapy.

75. Once again, the States which have lodged observations are divided in their views. On the one hand, the Czech Republic, Poland, Finland, Greece and the Commission propose a flexible approach which considers on a case-by-case basis the circumstances of each patient when determining whether there are alternative means available in the State of residence within a reasonable period. On the other hand, Bulgaria, Spain and the United Kingdom adopt a strict interpretation of Article 22 of Regulation No 1408/71, and assert that only where none of the available treatments, including the alternative ones, may be provided without undue delay in the State of residence is it compulsory to grant authorisation.

76. At the outset, it must be recalled that the Court has already ruled on this question in the *Pierik* case-law, declaring that 'when the competent institution acknowledges that the treatment in question constitutes a necessary and effective treatment of the sickness or disease' the condition set out in Regulation

No 1408/71 is satisfied.[59] The Community legislature subsequently rectified the effect of that judgment by including a temporal dimension in the second subparagraph of Article 22(2) of the regulation.[60] However, the case-law of the Court, in particular since *Smits and Peerbooms* and *Müller-Fauré and van Riet*, has once again reduced the scope of the temporal aspect, just as *Pierik* did.

77. Although *Smits and Peerbooms* and *Müller-Fauré and van Riet* were cases where the Court applied Article 56 TFEU directly rather than Regulation No 1408/71, it held in those judgments that a national authority may refuse authorisation to receive treatment in another Member State only 'if treatment which is the same or equally effective for the patient can be obtained without undue delay from an establishment with which the insured person's sickness insurance fund has an agreement'.[61] That statement of the law was repeated in *Inizan*[62] and *Watts*,[63] where Regulation No 1408/71 was applicable, thereby placing the interpretation of the Treaty and the interpretation of secondary law on an equal footing in case-law. The conclusion is that only national treatment with a significant degree of equivalence is capable of justifying a refusal to authorise receipt of the service in another Member State.

78. For the purposes of establishing the degree of equivalence, the Court also supplied in those judgments the criteria to be taken into account. Thus, in order to determine whether medical treatment which is equally effective for the patient can be obtained without undue delay in the Member State of residence, the competent institution is required to have regard to 'all the circumstances of each specific case, taking due account not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, of the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity, but also of his medical history'.[64]

79. Having reached this point, it is for the referring court to apply the criteria set out to the present case. To recapitulate everything that has been stated above, the court must, first, determine whether the treatment prescribed can be carried out in the State of residence without undue delay. If that is not the case, the court must take into consideration whether there are equivalent treatments in that State. In the present case, it appears from the case-file that there is only one such treatment: the complete removal of the diseased eye. At that point, the referring court must establish whether the alternative treatment is equivalent in the light of the criteria supplied

59 — The *Pierik* judgments, paragraph 13.

60 — Council Regulation (EEC) No 2793/81 of 17 September 1981 amending Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons and their families moving within the Community and Regulation (EEC) No 574/72 fixing the procedure for implementing Regulation (EEC) No 1408/71 (OJ 1981 L 275, p. 1).

61 — *Smits and Peerbooms*, paragraph 103, and *Müller-Fauré and van Riet*, paragraph 89.

62 — Paragraph 45.

63 — Paragraph 61.

64 — *Smits and Peerbooms*, paragraph 104; *Müller-Fauré and van Riet*, paragraph 90; *Inizan*, paragraph 46; and *Watts*, paragraph 62.

in *Smits and Peerbooms* and the subsequent judgments cited.

80. For all the foregoing reasons, I propose to the Court that it should reply to the second question, declaring that the second subparagraph of Article 22(2) of Regulation No 1408/71 must be interpreted as meaning that authorisation to receive treatment in another Member State may be refused only where treatment which is the same or equally effective for the patient can be obtained without undue delay from an establishment with which the insured person's sickness insurance fund has concluded an agreement.

C — *Reimbursement of the insured person's costs (seventh question)*

81. By its seventh question, the referring court asks how the insured person's costs should be reimbursed by his health insurance in the event that the refusal of authorisation is considered to be unlawful.

82. In that connection, Mr Elchinov, the States which have lodged observations and the Commission all agree that the case-law set out in *Vanbraekel*, *Inizan* and *Watts* is applicable.

83. According to the settled case-law of the Court cited above, where a competent institution refuses a request for authorisation under Article 22 of Regulation No 1408/71 and it is subsequently established, either by the institution itself or by a judicial decision, that that refusal was unfounded, the insured person 'is entitled to be reimbursed directly by the competent institution by an amount equivalent to that which it would ordinarily have borne if authorisation had been properly granted in the first place'. [65] Accordingly, as explained in points 48 to 52 of this Opinion, Mr Elchinov is entitled to seek reimbursement directly, without having to request authorisation, provided that a national authority has found his claim to be lawful.

84. As concerns the amount to which he is entitled, the Court has repeatedly stated that Article 22 of Regulation No 1408/71 is not intended to regulate the costs incurred in connection with treatment provided in another Member State. [66] However, the Court has also asserted that the amount of the reimbursement is a matter which falls within the scope of the Treaties, specifically Article 56 TFEU. In that connection, the Court held in *Vanbraekel* that 'the fact that a person has a lower level of cover when he receives hospital treatment in another Member State than when he

65 — *Vanbraekel*, paragraph 34.
66 — *Vanbraekel*, paragraph 36.

undergoes the same treatment in the Member State in which he is insured may deter, or even prevent, that person from applying to providers of medical services established in other Member States and constitutes, both for insured persons and for service providers, a barrier to freedom to provide services.' [67] Consequently, pursuant to Article 56 TFEU, the State of residence is required to reimburse the costs incurred as a result of hospital care provided in another Member State, in accordance with the provisions and scales in force (in the State of residence or in the State of treatment) that are most advantageous to the insured person. [68]

85. That outcome is markedly different from the one reached where hospital care is received in another Member State outside the procedure provided for in Article 22(2) of Regulation No 1408/71. In such cases, insured persons are entitled only to the cover provided by the sickness insurance scheme of the Member State of affiliation. [69] However, that does not apply to Mr Elchinov, because he used the procedure laid down in Article 22 and it is on that basis that he is now pursuing an action before the courts of his Member State.

86. Accordingly, I propose to the Court that it should reply to the seventh question referred for a preliminary ruling, declaring that Article 22(2) of Regulation No 1408/71 is not intended to regulate the costs incurred in connection with medical treatment provided in another Member State. However, Article 56 TFEU must be interpreted as meaning that a Member State, in circumstances such as those of the present case, is required to reimburse the costs incurred as a result of hospital care provided in another Member State, in accordance with the provisions and scales in force that are most advantageous to the insured person.

D — *The powers of the national court to guarantee the rights referred to in Article 22(1)(c) of Regulation No 1408/71 (sixth question)*

87. Lastly, the referring court asks about the procedure to be followed in the event that it is established that the refusal of authorisation to

67 — *Vanbraekel*, paragraph 45.

68 — As the Court itself put it: 'the purpose of Article 22... is to confer a right to the services in kind provided, on behalf of the competent institution, by the institution of the place where the treatment is provided, in accordance with the provisions of the legislation of the Member State in which the services are provided as if the person concerned were registered with that institution... The applicability of Article 22... does not mean that the person concerned may not simultaneously have the right under Article 49 EC to have access to healthcare in another Member State under rules on the assumption of costs different from those laid down by Article 22' (*Watts*, paragraph 48).

69 — *Müller-Fauré and van Riet*, paragraph 106. On the differences in the rules on reimbursement by reference to the applicable provision, see the Opinion of Advocate General Tesauro in *Decker* and *Kohll*, points 26 to 34.

Mr Elchinov was unlawful. More specifically, the referring court wishes to know whether, in the event that it finds in favour of the applicant, it may oblige the institution to grant authorisation.

88. As a preliminary point, it is necessary to recall once again that the Court held in *Vanbraekel* that an insured person who is granted the right to obtain authorisation a posteriori 'is entitled to be reimbursed directly by the competent institution by an amount' which that institution should have paid. [70] In other words, in accordance with Article 22 of Regulation No 1408/71, interpreted in the light of Article 56 TFEU, the referring court may require not only the issue of authorisation but also, directly, the amount owed in order to rectify the legal position in issue.

89. However, as the Greek Government and the Commission have pointed out, this matter falls within the remit of the national court and must be resolved by applying the procedures laid down in its domestic legislation. [71] To the extent that the procedures for enforcing the judgment to be given by the referring court are consistent with the European Union principles of effectiveness and equivalence, the court must refer to those procedures. Should the referring court have the power, under domestic law, to require the issue of the authorisation concerned, it would be strange if it did not have the power to demand payment of the amount of the debt which the Fund is required to bear. In that case, the referring court must assess, in the light of the case-law of the Court, whether such a difference in treatment is consistent with the principle of effectiveness. [72]

90. Consequently, I propose to the Court that, where appropriate, it should reply to the sixth question referred for a preliminary ruling, declaring that, in accordance with the European Union principle of institutional autonomy, it is for the referring court to determine the correct procedural remedies, as provided for in national law, for ensuring that the judgment at first instance is enforced. To that end, the referring court must apply national law in accordance with the European Union principles of effectiveness and equivalence.

70 — *Vanbraekel*, paragraph 34.

71 — Inter alia, Joined Cases C-143/88 and C-92/89 *Zuckerfabrik Süderdithmarschen and Zuckerfabrik Soest* [1991] ECR I-415, paragraphs 26 and 27; Case C-465/93 *Atlanta Fruchthandelsgesellschaft and Others* [1995] ECR I-3761, paragraph 39; Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04 *ABNA and Others* [2005] ECR I-10423, paragraph 104; Case C-78/98 *Preston and Others* [2000] ECR I-3201, paragraph 31; Case C-201/02 *Wells* [2004] ECR I-723, paragraph 67; and Case C-432/05 *Unibet* [2007] ECR I-2271, paragraph 79.

72 — See, inter alia, Case 543/79 *Birke* v *Commission and Council* [1981] ECR 2669, paragraph 28; Case 799/79 *Bruckner* v *Commission and Council* [1981] ECR 2697, paragraph 19; Joined Cases C-46/93 and C-48/93 *Brasserie du Pêcheur and Factortame* [1996] ECR I-1029, paragraph 66; Case C-310/97 P *Commission* v *AssiDomän Kraft Products and Others* [1999] ECR I-5363, paragraph 59; and *Köbler*, paragraph 57.

VI — Conclusion

91. In the light of the foregoing considerations, and following the order used in this Opinion, I propose to the Court that it should reply to the questions referred by the Administrativen sad Sofia-grad, declaring as follows:

'European Union law must be interpreted as meaning that it does not preclude a lower court, such as the Administrativen sad Sofia-grad in the present case, in proceedings in which it has already given a first judgment, from being required under national law, after the case has been referred back to it, to apply the directions set out in the judgment on appeal given by a higher court in the same proceedings.'

92. In the event that the Court disagrees with that answer to the third question referred for a preliminary ruling, I propose that it should reply to the remaining questions, declaring as follows:

'(1) Article 56 TFEU and Article 22 of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community must be interpreted as meaning that they do not preclude a provision such as Article 36(1) of the Bulgarian Law on health insurance, in so far as that provision establishes a system of prior authorisation for the receipt of hospital treatment in another Member State, and always provided, in any event, that that provision does not prevent applicants from claiming reimbursement subsequently, once the refusal of the application has been declared unfounded by the competent institution itself or by judicial decision.

(2) Article 22(2) of Regulation No 1408/71 must be interpreted as meaning that:

— it does not preclude a system such as that provided for in Annex 5 to Order No 40 of 2004, in so far as that annex enables the identification of the treatment set out therein, based on objective, non-discriminatory criteria which are known in advance. Where national law uses a list system and treatment is provided for in general terms by reference to "high technology" practices, in order not to deprive of substance the right granted by Article 22 of Regulation No 1408/71, the referring court must determine whether or not the treatment received is experimental in the light of the relevant available information including, in particular, existing scientific literature and studies and the authorised opinions of specialists;

— it precludes a presumption that a treatment which is provided for in national legislation but which is not financed from the budget is not covered by the social security scheme;

— authorisation to receive treatment in another Member State may be refused only where treatment which is the same or equally effective for the patient can be obtained without undue delay from an establishment with which the insured person's sickness insurance fund has concluded an agreement.

(3) Article 22(2) of Regulation No 1408/71 is not intended to regulate the costs incurred in connection with medical treatment provided in another Member State. However, Article 56 TFEU must be interpreted as meaning that a Member State, in circumstances such as those of the present case, is required to reimburse the

costs incurred as a result of hospital care provided in another Member State, in accordance with the provisions and scales in force that are most advantageous to the insured person.

(4) In accordance with the European Union principle of institutional autonomy, it is for the referring court to determine the correct procedural remedies, as provided for in national law, for ensuring that the judgment at first instance is enforced. To that end, the referring court must apply national law in accordance with the European Union principles of effectiveness and equivalence.'