OPINION OF ADVOCATE GENERAL MENGOZZI
delivered on 2 June 2010[1]

I — Introduction

1. These proceedings relate to an action brought by the Commission of the European Communities against the French Republic under Article 226 EC.

2. The Commission claims that the Court should declare that, by limiting to a maximum of 25% the shares, hence the voting rights, that may be held by non-biologists in a société d'exercice libéral à responsabilité limitée (limited liability company or firm formed by persons practising a profession; 'SELARL') operating biomedical analysis laboratories, the French Republic has failed to fulfil its obligations under Article 43 of the EC Treaty.

3. Similarly, and also on the basis of Article 43 of the EC Treaty, the Commission claims that it was unlawful on the part of the French Republic to bar natural or legal persons without the necessary professional qualifications from holding capital in more than two SELARLs.

II — The national legislation at issue

4. Article 5 of Law No 90-1258 of 31 December 1990,[2] which lays down the general national regulations governing the exercise, in the form of a company or firm, of liberal professions governed by particular legislation or regulations or whose professional title is protected, provides that more than half of the share capital and voting rights must be held by persons currently engaged in their professional activities within the company.

5. The remainder of the share capital and voting rights must, except in certain specific cases — provided for under the second paragraph of Article 5 of Law No 90-1258, and which are of no relevance to the case under consideration — must be held by natural or

1 — Original language: Italian.

2 — *Journal officiel de la République française* No 4 of 5 January 2001, p. 216.

legal persons engaged in the profession or professions which constitute the company's objects.

6. Lastly, again under Article 5 of Law No 90-1258, the number of companies formed to engage in any profession in which a particular natural or legal person in one of the categories referred to above is authorised to hold shares may be limited by a decree issued following an opinion from the Conseil d'Etat (Council of State).

7. With regard more specifically to companies formed to engage jointly in the liberal profession of manager or assistant manager of bio-medical analysis laboratories, Article 11(I) of Decree No 92-545 of 17 June 1992 [3] provides that no more than 25% of the capital of a company of that kind may be held by one or more persons who do not hold the specific professional qualification.

8. The second paragraph of Article 11(I) of Decree No 92-545 lays down that, if the SELARL is established as a limited partnership, the percentage of the capital that may be held by one or more persons without the specific professional qualification may be higher than the limit of 25% indicated above but may not in any event be so high as to represent 50% of the capital.

3 — As amended by Article 60 of Law No 2008-776 modernising the economy (*Journal officiel de la République française* No 181 of 5 August 2008, p. 12471).

9. Lastly, under Article 10 of Decree No 92-545, a natural or legal person in one of the categories referred to in points (1) and (5) of the second paragraph of Article 5 of Law No 90-1258 of 31 December 1990 may, at any given time, hold shares in no more than two companies of the kind described above.

10. As was made clear at the hearing on 25 March 2010, that prohibition essentially relates to biologists and not to persons without that professional qualification, who are unaffected by that provision, apart from the general limit of 25% of the capital in each company.

11. Under Order No 2010-49 of 13 January 2010, which was adopted by the French Republic and notified to the Commission as described below, the national legislation was amended, particularly as regards the provisions of the Public Health Code, which was mentioned several times in the parties' pleadings during the written stage of the present proceedings.

12. Nevertheless, in accordance with the principle repeatedly stated by the Court, and which is not disputed by the parties, that the question whether a Member State has failed to fulfil its obligations must be determined by reference to the situation prevailing in the Member State at the end of the period laid down in the reasoned opinion and that

any subsequent changes cannot be taken into consideration, those changes are not to be taken into account. [4]

III — The pre-litigation procedure

13. Following a complaint, the European Commission sent a first letter of formal notice to the French Republic on 4 April 2006 in which it indicated that there was a problem of compatibility between, on the one hand, the above legislation on companies established for the joint exercise of the liberal profession of manager or assistant manager of bio-medical analysis laboratories and, on the other, the freedom of establishment laid down in Article 43 of the EC Treaty.

14. The French Republic decided not to respond to the formal notice, despite the invitation from the Commission to submit its observations within two months of receiving that notice.

15. On the view that the infringements referred to in the complaint existed, the Commission subsequently served on the French Republic the reasoned opinion of 15 December 2006, calling on that State to comply with the opinion within a period of two months.

16. By letter of 14 February 2007 the French Republic expressed its views, denying that those infringements existed in either of the configurations specified by the Commission; in particular, it maintained that the restrictions introduced by the French legislation had to be regarded as justified by the principles of adequacy and proportionality in relation to the objective pursued by the State administration, which is the protection of public health.

17. However, in a subsequent letter dated 11 April 2008, the Minister for Health stated that the position of the French Republic had changed in view of the intention to overhaul the medical biology sector completely by the beginning of 2009 and in the light of the draft law that was accordingly being prepared; according to the Minister, the planned removal of all restrictions on the holding of capital in companies formed in order jointly to perform bio-medical analyses, with the exception of certain narrowly defined incompatibilities, would adequately satisfy the points raised by the Commission.

4 — See, most recently, Case C-392/08 *Commission* v *Spain* [2010] ECR I-2537, paragraph 26; Case C-531/06 *Commission* v *Italy* [2009] ECR I-4103, paragraph 98; Case C-152/05 *Commission* v *Germany* [2008] ECR I-39, paragraph 15; Case C-456/05 *Commission* v *Germany* [2007] ECR I-10517, paragraph 15; and Case C-103/00 *Commission* v *Greece* [2002] ECR I-1147, paragraph 23.

18. As no further information was received, the Commission wrote to the French Republic on 20 November 2008 to enquire about the progress of the work; by letter of 27 December 2008, the French authorities stated that the adoption of the draft law in question was not scheduled to take place before May 2009.

19. Consequently, on 2 March 2009, the Commission brought the present action under Article 226 EC.

IV — Proceedings before the Court and forms of order sought

20. In the present proceedings, the defence presented by the French Republic changed in the course of the written procedure, especially as compared with the stance adopted during the pre-litigation stage; this came about mainly as a result of the submission of pleas and, subsequently, the publication of a number of judgments (which I describe in detail below) relating to proceedings pending before the Court in which similar issues were addressed.

21. By its statement of defence of 22 May 2009, in which it referred for the first time to the Opinion delivered by Advocate General Bot on 16 December 2008 in Case C-531/06 *Commission* v *Italy*, in which judgment was delivered on 19 May 2009, [5] the French Republic called for the action to be dismissed as regards the first aspect; it did not deny, however, that it was unlawful for the national legislation to bar persons with the necessary professional qualifications from holding capital in more than two companies.

22. By its rejoinder of 15 July 2009, in which it cited the rulings made by the Court of Justice in a number of actions on restrictions on the ownership of capital in pharmacies, the Commission drew attention to the change in the position of the French Republic as compared with its stance during the pre-litigation procedure and maintained the forms of order sought in the application initiating proceedings.

23. In its reply of 5 October 2009, the French Republic made it clear (see paragraph 70) that, although the expression initially used might suggest the opposite, it had not intended to state that a restriction of the kind under examination could not be justified in some cases.

5 — See also Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others* [2009] ECR I-4171.

24. In particular, given the measure of discretion which the Member States are to be permitted as to the level of protection to give to public health and the manner in which to operate, the French Republic contends that as a matter of principle the national decision to ensure diversity of supply in the medical biology field by preventing financial concentration as regards the capital of laboratories and by favouring instead the situation where several laboratories are managed by a single biologist or a single company should be recognised as legitimate.

25. The restrictive measure currently in force in France, which — according to the French Republic — serves that legitimate purpose, is questionable from only two aspects: (a) in that it does not prohibit 'cascade' shareholdings; and (b) in that it is not completely proportionate to its objective, as it applies indiscriminately to shareholdings in companies situated anywhere in the national territory without any assessment as to whether they are close to one another or distant.

26. Accordingly, once those two aspects have been resolved as part of the planned project for reform of the sector, the legislation is to be considered — in the view of the French Republic — compatible with Article 43 of the EC Treaty in that it is adequate and proportionate to the need to protect public health, [6] to be achieved by ensuring diversity of supply as regards medical biology throughout the national territory.

27. According to the French Republic, this safeguards against the risk of financial concentration of the capital of laboratories, as a result of which the withdrawal of a biologist — or of a company to be treated as such — could deprive patients of medical analysis services in some parts of the country.

28. In any event, the French Republic maintained the forms of order sought in its statement of defence, in which it called for the Commission's action to be dismissed only as regards the restrictions, attaching to the person, on the ownership of shares in any given company.

29. By letter of 5 February 2010 pursuant to Article 54a of the Rules of Procedure of

6 — Whereas in its application the Commission had assumed that this prohibition pursued the different objective of preserving the professional independence of biologists; see paragraph 29 of the application initiating proceedings.

the Court, the French Republic was asked to comment on the assertion made by the Commission for the first time in its reply (see paragraph 36) that, by creating a mechanism separating financial rights from voting rights on decisions on the operation and organisation of laboratories, the French authorities permitted certain entities to have access to 'external' capital, held by persons who are not biologists, in excess of the 25 % limit.

30. By letter of 18 March 2010 the French Republic forwarded to the Court the note sent to the Commission on 9 March 2010 accompanying Order No 2010-49 of 13 January 2010 on medical biology, to the draft of which it had referred during the pre-litigation procedure, as indicated in point 17 above, and in its rejoinder (see point 26 above).

31. Upon conclusion of the debate at the hearing on 25 March 2010, which had included discussion of the question submitted beforehand in writing by the Court, the parties reiterated the pleas they had put forward in their respective pleadings.

V — Analysis

A — *The restrictions, attaching to the person, on the ownership of shareholdings in any given company*

1. The alleged failure of the Member State to fulfil its obligations — The existence of a restriction on the freedom of establishment

(a) Arguments of the parties

32. Taking as the frame of reference for the alleged infringement Article 43 of the EC Treaty, now Article 49 TFEU as a result of the entry into force of the Treaty of Lisbon, the Commission claims that the above statutory provisions adopted by the French Republic have the effect of limiting the scope, particularly for legal persons from other Member States, for participating in the operation of one or more bio-medical analysis laboratories.

33. The Commission alleges that, in the same way, the scope for persons from other Member States operating one or more bio-medical analysis laboratories there to establish a centre of activities on French territory is also

limited if they lack the prerequisites, attaching to the person, laid down in the national legislation, especially as regards the personal requirements for holders of share capital.

34. In particular, the Commission points to the principle long upheld by the Court that Article 43 of the Treaty prohibits all national measures which, even though applicable without discrimination on grounds of nationality, are liable to impede or render less attractive the exercise by Community nationals of the freedom of establishment for which the Treaty provides.

35. The French Republic observes in that regard that Article 152(5) of the EC Treaty provides that Community action in the field of public health is to respect in full the responsibilities of the Member States for the organisation and delivery of health services and medical care.

36. The French Republic concedes, however, that the Court has consistently held that, in exercising that power, the Member States must comply with Community law and, in particular, with the Treaty provisions on the freedom of establishment. [7]

37. The French Republic nevertheless maintains that, although in the present case the limitation on the holding of capital which applies to companies of the type indicated above may constitute a restriction on the freedom of establishment, that restriction must be considered justified on grounds of overriding public interest in the form of the objective of protecting public health (see paragraph 34 of the statement of defence).

(b) Assessment

38. It is a general principle consistently upheld by the Court that Article 43 EC precludes any national measure which, even though it is applicable without discrimination on grounds of nationality, is liable to hamper or to render less attractive the exercise by Community nationals of the freedom of establishment guaranteed by the Treaty. [8]

39. Accordingly, a limitation as to the category of person who may own shares in a company operating one or more bio-medical analysis laboratories impedes or at least renders more difficult the holding of shares in such a company by persons from other Member States; the same adverse effect also arises

7 — In that regard, see Case C-169/07 *Hartlauer Handelsgesellschaft* [2009] ECR I-1721, paragraph 29. See also, to that effect, Case 238/82 *Duphar and Others* [1984] ECR 523, paragraph 16; Case C-372/04 *Watts* [2006] ECR I-4325, paragraphs 92 and 146; and Case C-141/07 *Commission* v *Germany* [2008] ECR I-6935, paragraphs 22 and 23.

8 — Case C-299/02 *Commission* v *Netherlands* [2004] ECR I-9761, paragraph 15; Case C-140/03 *Commission* v *Greece* [2005] ECR I-3177, paragraph 27; and *Hartlauer Handelsgesellschaft*, cited in footnote 7 above, paragraph 33.

in relation to the establishment in French territory of companies performing the same activity in another Member State which do not meet the specific requirements laid down in French legislation.

40. The fact that the restrictive effect arises regardless of the nationality of the persons involved does not diminish the conflict with the fundamental freedom of establishment laid down in Article 43 of the EC Treaty.

41. On that premiss, it is therefore necessary to assess whether the restrictions deemed unlawful by the Commission are justified.

2. Possible justifications for the restriction — The assessment as to whether the restrictive measures adopted are adequate and proportionate

(a) Arguments of the parties

42. According to the defensive stance adopted by the French Republic, the purpose of the limitations — introduced by the legislation referred to above — regarding the category of person who may own shares in a company formed to carry out bio-medical analyses is to ensure the quality of care provided to patients and to preserve the decision-making independence of the managers of analysis laboratories.

43. The French Republic claims that, by preventing managers' decisions from being guided by economic rather than health considerations, the overriding general interest in public health is protected.

44. By contrast, the Commission maintains that the measures adopted by the French Republic are not adequate and proportionate in relation to the declared objective.

45. The Commission claims that, given the undeniable parallels in the respective situations, that conclusion is confirmed by an earlier judgment relating to similar restrictions on the holding of capital under Greek legislation, in relation to the operation of an optician's in the form of a company (see paragraphs 35 and 36 of the application).

46. The Commission has pointed out that, in that case, the Court [9] found that the Hellenic Republic had failed to fulfil its obligations under Articles 43 EC and 48 EC by not permitting an optician to operate more than one

9 — Case C-140/03 *Commission* v *Greece*, cited in footnote 8 above.

retail outlet and by limiting to only 50 % of the capital the shareholding that may be acquired by natural or legal persons other than the optician.

47. The Commission draws attention to the Opinion delivered by Advocate General Ruiz-Jarabo Colomer in the case in question, with specific regard to the distinction drawn, so far as commercial activities are concerned, between internal and external spheres of relationship.

48. In particular, the first 'comprises ownership — which includes, for example, the premises or room in which it is situated, the list of customers, the goods or trade name, the labour links with the employees and... proprietorship — which is not the same as ownership, with which it is connected through various legal forms — as well as administration and management. The second comprises relations with third parties, particularly with suppliers and... buyers, customers or, if you prefer, patients.' [10]

49. In that case, according to the approach adopted by the Advocate General, the Member State concerned had introduced restrictions affecting the internal sphere, in that they related to the requirements, attaching to the person, for operating an optician's shop, but justified them by considerations relating to the external field of relationships between the optician providing the service and his customers, including considerations regarding possible liability in the event of error.

50. Lastly, the Commission points out that, in that case, the Court held that the objective of protecting public health upon which the Hellenic Republic relied could *'be achieved by measures which are less restrictive of the freedom of establishment both for natural and legal persons, for example by requiring the presence of qualified, salaried opticians or associates in each optician's shop, rules concerning civil liability for the actions of others, and rules requiring professional indemnity insurance'*. [11]

51. In essence, the mere requirement for a biologist to be present for the laboratory's 'external' activities to be performed and, in particular, actions involving a relationship with the patient, would be sufficient to attain the objective indicated; that requirement would not, however, be justified in the context of

10 — Opinion in Case C-140/03 *Commission* v *Greece*, cited in footnote 8 above, paragraph 34.

11 — Case C-140/03 *Commission* v *Greece*, cited in footnote 8 above, paragraph 35; my italics.

'internal' activities relating to ownership of the laboratory.

52. The French Republic, for its part, maintains that, on the basis of the specific general characteristics of medical biology and the unique way in which these activities are organised in France by comparison with a large number of other Member States as regards, inter alia, university training, the principles applicable in the present case are instead those laid down by the Court for the pharmaceutical sector.

53. In that regard, the French Republic referred in its statement of defence to the Opinion delivered in Case C-531/06 *Commission* v *Italy*, then pending before the Court, in which Advocate General Bot stated (in point 106) that, in the field I have just mentioned, the distinction between the internal aspects and the external aspects of that activity is artificial.

54. According to the French Republic, it would be difficult to ensure that a manager who was not a pharmacist did not interfere in the relationship between the pharmacist and his customers, and that situation is comparable with that of analysis laboratories, which are also at the centre of the health system.

55. In order to support the assertion that the situations are identical, the French Republic states that medical biology is a discipline in the forefront of the health system, that it is continuously evolving and covers extremely wide fields of application, such as microbiology, haematology, biochemistry and immunohaematology; it also requires the use of extremely complex techniques, such as molecular biology.

56. The French Republic adds that, in general, the work of an analysis laboratory comprises a pre-analysis stage (in which trained staff meet the patient and take the necessary samples, which may be 'invasive'); an analytical stage in the true sense, which is highly technical, performed manually or using special apparatus; and a post-analysis stage (validation of the results of the analysis, where appropriate on the basis of the patient's personal characteristics). [12]

57. The special nature of the situation in France (by comparison with the organisation of this sector in other Member States of the European Union) consists, according to the French Republic, in the fact that those three stages are essentially combined on the basis

12 — At present, this distinction is expressly stated in Article L 6211-2 of the Public Health Code, as amended by Order No 2010-49 of 13 January 2010.

of a deliberate choice designed to accord a greater medical role to biologists.

58. Accordingly, under the French system, biologists are not engaged solely in purely technical analytical work but are also present at the pre-analysis stage, through direct contact with patients, and above all they are subsequently responsible for validating the results of the analysis, which they notify to patients; and they may also be involved, together with the doctor, in the choice of therapy.

59. According to the French Republic, France's decision regarding the acquisition of expertise by biologists, who receive an initial training as doctors or pharmacists and then specialise in medical biology, is entirely consistent with this approach, given that it takes a good 10 years to complete the course of study.

60. On the basis of those considerations, according to the French Republic, the approach adopted by the Court with regard to opticians could not be applied to medical analysis laboratories.

61. The French Republic therefore contends that the restriction on the holding of share capital is justified — by analogy with the case of pharmacies — by the need to ensure the complete independence of the laboratory manager in exercising his professional activity, which must be performed solely in accordance with the rules of the profession and without any pressure, especially financial pressure, in order to ensure the greatest possible protection of public health, as has already been stated.

62. The assumption made in the Opinion referred to (see point 121) — that the activity of dispensing medicinal products can be distinguished from the activity of selling optical products owing to the extent of its impact on public health — therefore applies in the same manner, according to the French Republic, if the latter activity is compared with the activity of bio-medical analysis.

63. Lastly, according to the French Republic, the measure adopted can be seen to be proportionate from the fact that the capital of laboratories is not reserved entirely for biologists, since investors without that qualification may in any event acquire a shareholding, although not more than 25 %.

64. That limitation meets the legitimate need to prevent non-professional associates, who are merely investors for profit, from having a decisive weight in corporate decisions, with

a consequent loss of independence for the professionals. [13]

65. In essence, the French Republic argues, although the French legislation allows non-biologists to acquire a shareholding, it also ensures, by limiting the percentage non-biologists may hold, that the power of decision remains with the shareholders who are professionals from the sector, enabling them to preserve their independence in making decisions.

66. In its rejoinder, the Commission disputes the arguments put forward by the French Republic in its statement of defence, pointing out that the approach adopted by the Court in the case of pharmacies, which differs from the precedent on which the French Republic originally relied, can be explained by the unique nature of medicinal products, which distinguishes them from all other goods; in view of the different nature of the sector, that approach cannot, in the opinion of the Commission, be transposed to the case under consideration.

67. In particular, according to the Commission, medical biology activities are carried out solely on the basis of a medical prescription, with a consequently greater guarantee in terms both of the protection of public health and of the control of costs for the health system.

68. Moreover, in its rejoinder the Commission maintains for the first time that the medical biology sector also has substantial financing needs, and the restriction on access to 'external' capital is therefore inappropriate for that purpose.

69. In its reply, the French Republic contests the arguments set out in the Commission's rejoinder and repeats that the precedent cited by the Commission is not in the least relevant, given that, in view of the fact that the circumstances are very similar and that the risks to public health are the same, the principles to be applied should instead be those laid down for pharmacies in the opinions and judgments which were delivered during the written stage and upon which it relied at that point.

70. The French Republic also disputes the assertion that totally open access to the holding of capital in companies operating analysis laboratories would bring about a real improvement in the quality of testing and would generate savings for the social security system.

13 — The French Republic emphasises in particular that the limitation to a 25% share is based on the legal rule under company law — Article L-223-30 of the Code de Commerce (Commercial Code) — under which a vote by the majority of shareholders representing at least 75% of the shares is required for resolutions adopted at an extraordinary general meeting, in particular for capital increases or mergers.

(b) Assessment

71. It is an established principle of case-law that national measures liable to hinder or make less attractive the exercise of fundamental freedoms guaranteed by the Treaty must satisfy four conditions: (i) they must be applied in a non-discriminatory manner; (ii) they must be justified by overriding requirements in the public interest; (iii) they must be suitable for securing the attainment of that objective; and (iv) they must not go beyond what is necessary in order to attain it. [14]

72. That said, there is no dispute between the parties as to the fact that the protection of public health is one of the overriding reasons in the public interest which can, under Article 46(1) EC, justify restrictions of freedom of establishment. [15]

73. Among other things, as regards analysis of the reasons which may justify a restriction on the freedom to provide services in the sector of bio-medical analysis laboratories (which is obviously a principle applicable by analogy to the freedom of establishment), the Court has stated that the aim of maintaining the quality of medical services may be covered by one of the derogations provided for in Article 46 EC if it contributes to the attainment of a high level of health protection. [16]

74. There is no dispute as to the non-discriminatory nature of the restrictive measure under examination; however, the assessment of the adequacy and proportionality of the measure in relation to the objective pursued is a more thorny issue.

(i) The sector affected by the restrictive measure and identification of the relevant case-law

75. The first point to be answered is whether a precise answer to the question, in the terms in which it has been posed, can already be given on the basis of the principles stated by the Court in the abovementioned ruling regarding the Hellenic Republic, which had adopted similar restrictions in the law on the exercise of the profession of optician and on retail outlets selling optical articles, or whether that ruling is not entirely relevant as a precedent.

14 — See Case C-19/92 *Kraus* [1993] ECR I-1663, paragraph 32, and Case C-55/94 *Gebhard* [1995] ECR I-4165, paragraph 37.

15 — See *Hartlauer Handelsgesellschaft*, cited in footnote 7 above, paragraph 46.

16 — See, to that effect, Case C-385/99 *Müller-Fauré and Van Riet* [2003] ECR I-4509, paragraph 67, and Case C-496/01 *Commission* v *France* [2004] ECR I-2351, paragraph 66.

76. It is true that the situation examined by the Court in the case concerning the profession of optician presents a close similarity to that currently pending, as the Commission maintains, and that this gives grounds for examining particularly closely the arguments used and the approaches adopted in that case; nevertheless, to my mind there are a number of fundamental differences.

77. The case now before the Court is especially notable for the nature of the sector involved — bio-medical laboratory analysis — and for its rules, as adopted by the Member State involved, which present particular features from the point of view of the overall organisation of work and the training of the professionals involved, all of which are aimed at achieving services of a particularly high standard.

78. Indeed, if the suppositions on which the French Republic's defence is based are borne in mind and account taken of the true subject of the dispute, it transpires that there are a number of substantive differences as compared with the case-law precedent cited by the Commission, as regards both the sector in question and the grounds justifying the restriction introduced.

79. In essence, I believe that — as the French Republic maintained for the first time in its statement of defence of 22 May 2009 — the references to proceedings in which the Court was asked to consider the exclusive right of persons with the necessary professional qualification to own and operate a pharmacy are more relevant to the present case. [17]

80. The greater relevance of the case-law precedent stems primarily from the much closer similarity between the pharmaceutical sector and the bio-medical analysis sector — albeit regulated in an absolutely unique way in France — than that between the latter and the optical sector.

81. From another — perhaps more important — viewpoint, the question of the independence of decision-making as a specific prerequisite for higher standards of service in order better to protect public health does not appear to have been examined by the Court in the case that led to the precedent cited by the Commission.

82. The characteristics of the profession of biologist in France, as described above, and the way in which bio-medical analysis laboratories

17 — See *Commission* v *Italy* and *Apothekerkammer des Saarlandes and Others*, cited in footnote 5 above.

are actually operated make it possible to equate this sector with that of pharmacies.

83. Unless performed correctly, both activities entail a rather high risk to a primary good, namely health. Just as the supply of the wrong medicament to a customer by a pharmacist may cause the customer serious physical harm, so a bio-medical analysis that is performed in an inappropriate manner, late or incorrectly may cause damage of the same kind (one need only think of possible wrong diagnoses and treatments by the doctor owing to an incorrect diagnostic result).

84. Moreover, there are very close similarities in the means by which these activities are performed, especially as regards the system whereby the cost is borne by the social security system; bio-medical analyses which are performed in an inappropriate way, from either the quantitative or qualitative point of view, may cause unnecessary cost for the social security system, hence for the State, exactly as in the case of the provision of medicaments.

85. According to the Commission, however, there are differences between the two sectors which prevent the application of the same principles of case-law; the Commission points in particular to the fact that analyses can be carried out only on the basis of a medical prescription. The patient could therefore not go to the laboratory direct in order to have an analysis carried out; nor could the biologist decide independently on an analysis without a prescription.

86. In that regard, the Commission adds that, although the results of the analysis are sent both to the doctor who wrote the prescription and to the patient, the patient would not in any case have the technical ability to draw conclusions as to the treatment to be followed, which therefore of necessity requires the involvement of the doctor.

87. In reality, the Commission recognises that, as a general rule, pharmaceutical products also can be supplied and sold only on the basis of a medical prescription, so that in this way they are paid for by the social security system.

88. At the hearing, it emerged that approximately 85 % of medicaments sold in pharmacies are covered by a doctor's prescription, just as the majority of analyses are carried out on the same basis.

89. That being so, the Commission claims that the fact that it is nevertheless possible for

some medicaments to be sold without a doctor's prescription has implicitly been taken into account by the Court in its judgments regarding pharmaceutical activity in order to hold that the restriction laid down in the law is justified; in order to avert the risk to health; that fact makes it necessary for a pharmacist to be present at all times in order to draw the user's attention to any harmful interactions. [18]

90. Those assertions are not decisive, however. First, it does not emerge expressly from the judgments cited that the Court considered that the fact that in some cases medicaments are supplied without a doctor's prescription was a determining factor in justifying the positive approach adopted.

91. That aspect is, in fact, referred to in the Opinion of Advocate General Bot, referred to above, in which he states that a pharmacist's duty to give advice is very important in the case of over-the-counter medicines, the number of which is constantly increasing as a result of decisions taken by States in order to maintain the balance of the welfare budget. [19]

92. That is nevertheless a subsidiary factor by comparison with the fact that, in the same point of that Opinion, the Advocate General expressly states that the work of a pharmacist is not limited to the sale of medicinal products.

93. According to the Advocate General, the activity of dispensing medicinal products also requires a pharmacist to provide other services such as checking medical prescriptions, making up pharmaceutical preparations or providing information and advice to ensure the proper use of the medicinal products.

94. Moreover, in both of the judgments on the pharmaceutical sector, the Court has made it clear that medicinal products '*prescribed or used for therapeutic reasons*' may none the less prove seriously harmful to health if they are consumed unnecessarily or incorrectly. [20]

95. Essentially, the possibility that there may be a medical prescription, expressly

18 — A risk which the Court dismissed in the case of a hospital pharmacy managed by a non-pharmacist since it is inconceivable that medicines would be used incorrectly or abusively by hospitals, which are themselves providers of care; see *Apothekerkammer des Saarlandes and Others*, cited in footnote 5 above, paragraph 48.

19 — See the Opinion in *Commission* v *Italy*, cited in footnote 5 above, paragraph 88.

20 — See *Apothekerkammer des Saarlandes and Others*, cited in footnote 5 above, paragraph 60, and *Commission* v *Italy*, cited in footnote 5 above, paragraph 90.

mentioned by the Court, was not held to rule out the special nature of medicinal products from the point of view of the health risks stemming from their unnecessary or incorrect use.

96. Indeed, the biologist also plays an extremely important role in the case of medical analyses covered by a prescription; this is not intended to downgrade the role and professionalism of the prescribing doctor, as maintained by the Commission at the hearing, virtually subjecting him to a kind of double check, but simply to ensure the correct interpretation, in terms of bio-medical analyses, and execution of the work requested (especially in the case of particularly complex analyses).

97. As the French Republic expressly admitted at the hearing, before changes were introduced in that regard in Order No 2010-49 of 13 January 2010, [21] the analyst could only conduct the tests as specified in the prescription, without being able to diverge from the doctor's requests.

98. However, as the French Republic expressly argued at the hearing, there is nothing to prevent a patient from going to a laboratory without a prescription in order to have certain bio-medical analyses carried out, possibly at his own expense. [22]

99. Also, in the course of dialogue between the prescribing doctor and the biologist, which is now fairly common and which the Commission did not essentially call into question in its reply at the hearing, it is possible that the biologist may carry out certain tests which do not replace those initially planned but simply complement them.

100. Lastly, and again without wishing in any way to diminish the role of the doctor, the risk to public health — as the French Republic correctly states — lies not so much in the conclusions that the patient may draw from wrong results of a bio-medical analysis but rather from the consequences they may have, particularly if incorrectly validated, as regards the treatment decisions that the doctor may possibly make on the basis of those results.

21 — In this regard, see the new version of Article L 6211-8 of the Public Health Code, which expressly mentions that the biologist may carry out tests other than those prescribed or decide not to perform all of the tests indicated by the doctor, albeit subject to the binding condition of approval of the change on the part of the doctor, except in emergencies.

22 — See the specific reference to the campaigns to test for hepatitis C, in paragraph 28 of the rejoinder entered by the French Republic. The same principle is also expressly stated in Article L 6211-10 of the Public Health Code, as amended by Order No 2010-49 of 13 January 2010.

101. It is therefore undeniable that the role of the biologist, independently of the role of the doctor, is of prime importance as regards the level of professionalism required in all of the various stages preceding, accompanying and following the activity of bio-medical analysis.

102. In conclusion, from that point of view, specifically linked to health risks resulting from the performance of a particular professional activity by persons without a specific qualification, it must be found that there is a perfect similarity between the activity of pharmacists and that of analyst-biologists, whereas the activity of opticians is completely different.

103. In the case of opticians, in fact, although it is possible to imagine that a mistake may have adverse consequences, even in physical terms for the user, it is obvious that we are dealing here with a completely different level of seriousness which — contrary to the assertions made by the Commission — makes it difficult to equate the two situations.

104. The Commission then claimed for the first time in its rejoinder that, by comparison with the pharmaceutical sector, the analysis laboratory sector requires substantial financial investment; the rapid pace of technological change and the need to apply technologies to a steadily rising number of ailments requires particularly high injections of capital.

105. According to the Commission, that situation does not apply to pharmacies, which do not require any technical apparatus, since almost all medicaments are prepared elsewhere.

106. The Commission [23] thus demonstrates that barring or limiting injections of capital by investors who are not biologists is a curb on the development of medical biology laboratories by biologists lacking sufficient economic resources.

107. Moreover, it maintains that there is no proof that such a limitation enhances quality; rather, it alleges that inspections show that the most serious errors occur in single-person laboratories, where 100 % of the capital is held by the biologist performing the work.

23 — Referring to the report on the planned reform of medical biology presented by Mr Ballereau and submitted to Ms R. Bachelot Narquin, Minister for Health, on 23 September 2008 and Report No 2006 045 of April 2006, '*The medical biology profession in France: achievements and prospects*', presented by Françoise Lalande, Isabelle Yeni and Christine Lacombe, members of the General Inspectorate of the Ministry of Social Affairs (IGAS) (see footnotes 3 and 5 to the rejoinder).

108. Essentially, in the view of the Commission, the restrictions on share capital, which were designed as a form of protection, have instead caused a deterioration in the standard of service.

109. Among other things, according to the Commission, it has not been possible to achieve the mergers necessary to achieve sufficient size to ensure quality or even to realise economies of scale, which would reduce the cost of analyses, hence the burden on the social security system.

110. In reality — as the French Republic correctly demonstrated in its rejoinder — those assertions are not really supported by the documentation adduced by the Commission; indeed, the Report on the planned reform of the sector of September 2008 (as reported by the Commission in its reply) states, with regard to the average quality of medical biology laboratories in France, that the level is satisfactory, even '*good to excellent*'. [24]

111. The assertions regarding the beneficial effects of complete openness to external capital or possible mergers and economies of scale are also based on mere supposition — not on any genuine actual fact — of which the Commission has not taken the trouble to provide proof. [25]

112. As regards the burden on the social security system, it is clear that this depends on the level of remuneration that the State decides to pay out for each medical analysis, irrespective of the cost of individual tests to the laboratory; it has not been shown that there is any link between the level of remuneration and the form of ownership of laboratories, which means that, once again, the Commission's assertions do not appear to be substantiated.

113. Indeed, the desire for ever higher returns on invested capital would probably drive persons who hold shares in analysis companies purely as a financial investment to seek to increase the number of tests to be carried out or at least those likely to ensure higher remuneration, [26] thus leading to an increase

24 — My italics.

25 — Indeed, as the French Republic argues, the steady overall increase in expenditure on bio-medical analyses may well be explained, at a time of a general increase in health expenditure, by the ageing of the population and an increase in preventive medicine, which entails a larger number of tests.

26 — In this regard, see the document from the French Republic annexed to the rejoinder, which shows that one of the objectives to be pursued by medical visitors employed by the large groups operating analysis laboratories is precisely to increase the number of tests prescribed by comparison with the situation before their visit.

in costs for the State — the opposite effect to that argued for by the Commission.

114. In conclusion, once it has been recognised that there is a similarity between the pharmaceutical sector and the bio-medical analysis sector from the point of view of public health risks and it has been ruled out that the presumed need for greater investment in laboratories truly distinguishes that sector, all that remains is to analyse the justification of the restriction on freedom of establishment in the light of the relevant principles laid down by the Court in the cases which I have already examined.

(ii) The consequent application of the relevant principles

115. In the first of the two parallel actions on which judgment was delivered on 19 May 2009 regarding restrictions on the activities of pharmacists, the Court — in response to the question referred to it for a preliminary ruling — stated that Articles 43 EC and 48 EC do not preclude national legislation, such as that at issue in the main action, which prevents persons not having the status of pharmacist from owning and operating pharmacies. [27]

116. In the second, based on the same arguments, the Court dismissed the action brought by the Commission under Article 226 EC against the Italian Republic, alleging infringement of the same provisions of the Treaty on the ground that it had kept in force legislation under which the right to operate a private retail pharmacy was restricted to natural persons who had graduated in pharmacy and to operating companies and firms composed exclusively of members who were pharmacists. [28]

117. The reconstruction carried out by the Court in that context is based on the premiss that medicinal products are of a markedly special nature, and that their therapeutic effects distinguish them substantially from other goods; [29] if consumed unnecessarily or incorrectly, they may therefore cause serious harm to health, without the patient being in a position to realise this at the time when they are administered. [30]

118. Furthermore, overconsumption or incorrect use of medicinal products leads to a

27 — See *Apothekerkammer des Saarlandes and Others*, cited in footnote 5 above, paragraph 61.

28 — See *Commission* v *Italy*, cited in footnote 5 above.

29 — See, to that effect, Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph4.

30 — See *Commission* v *Italy*, cited in footnote 5 above, paragraphs 55 and 56, and *Apothekerkammer des Saarlandes and Others*, cited in footnote 5 above, paragraphs 31 and 32.

waste of financial resources, which is all the more damaging because the pharmaceutical sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied. [31]

119. Given that the Member States are free to decide the degree of protection of public health, it must be acknowledged that they can require medicinal products to be distributed by pharmacists with genuine professional independence; they may also adopt appropriate measures to eliminate or reduce the risk that that independence will be compromised.

120. In particular, although it cannot be denied that professional pharmacists, like other people, pursue a profit motive, the Court has held that they do not operate pharmacies purely for economic gain but also for professional reasons. Their private interest, which is connected to the profit motive, is therefore moderated by their training, professional experience and the responsibility they bear, considering that any infringement of statutory or professional rules would jeopardise not only the value of their investment but also their professional career.

121. In contrast to pharmacists, non-pharmacists do not, by definition, have training, experience or responsibility comparable with that of pharmacists. Consequently, they do not provide the same guarantees.

122. Accordingly, a Member State may take the view, in the exercise of the discretion to which I have referred, that, unlike the case of a pharmacy operated by a pharmacist, the operation of a pharmacy by a non-pharmacist may represent a risk to public health, in particular to the reliability and quality of the supply of medicinal products at retail level, because the pursuit of profit in the course of such operation does not involve moderating factors. [32]

123. As I have already stated, all those considerations are applicable, *mutatis mutandi*,

31 — See *Commission* v *Italy*, paragraph 57, and *Apothekerkammer des Saarlandes and Others*, paragraph 33. See also, by analogy, with regard to hospital treatment, *Müller-Fauré and van Riet*, cited in footnote 16 above, paragraph 80, and *Watts*, cited in footnote 7 above, paragraph 109.

32 — See *Commission* v *Italy*, cited in footnote 5 above, paragraph 63.

to the bio-medical analysis sector, thereby justifying an identical legal approach.

124. Since the risks to public health, hence the interest being protected, are identical, it can be accepted as a matter of principle that each Member State may also make the operation of bio-medical analysis laboratories subject to similar restrictions linked to the qualifications of the person managing those activities, as occurs in France.

125. It is obviously necessary to assess whether the particular type of restriction adopted, which limits the ownership of shareholdings on the basis of the qualifications of the person involved, can be described as adequate or proportionate in relation to the objective of protecting public health.

126. According to the case-law of the Court, national legislation is appropriate for ensuring attainment of the objective pursued only if it genuinely reflects a concern to attain it in a consistent and systematic manner. [33]

33 — See Joined Cases C-338/04, C-359/04 and C-360/04 *Placanica and Others* [2007] ECR I-1891, paragraphs 53 and 58; Case C-500/06 *Corporación Dermoestética* [2008] ECR I-5785, paragraphs 39 and 40; and *Hartlauer Handelsgesellschaft*, cited in footnote 7 above, paragraph 55.

(iii) The grounds for a positive response; in particular, the decision-making independence of biologists

127. As I have already mentioned, the Commission claims that the type of restriction introduced by the French Republic is inappropriate. In particular, it repeats the arguments set out in the Opinion in the action previously brought before the Court regarding Greek legislation on the exercise of the activities of opticians. [34]

128. In the present case, the Commission maintains that it would have been sufficient to require, in dealings between the laboratory and external users, the presence of a person who had acquired the necessary technical expertise as a result of adequate professional training, an aspect which, by contrast, was irrelevant to the ownership of the company operating a bio-medical analysis laboratory.

129. In reality, as the French Republic rightly points out, in his Opinion presented on 16 December 2008, Advocate General Bot stated with regard to the same line of reasoning put forward by the Commission that the argument that it was necessary to distinguish

34 — See points 45 to 50 of the present Opinion.

between the internal and external aspects did not appear at all convincing.

130. Indeed, in the words of that Opinion, 'a person who has a pharmacy and is both owner and employer inevitably influences the policy followed within the pharmacy in respect of the dispensing of medicinal products. Therefore, the Italian legislature's decision to link professional competence and economic ownership of the pharmacy appears justified in the light of the objective of protection of public health.' [35]

131. In reality, to the extent that a biologist employed in an analysis laboratory is required to follow the instructions of an employer who lacks that professional qualification, there would undoubtedly be a risk that the employer would give priority to the company's economic interests over the real needs of the patient, hence over those of public health.

132. It cannot therefore be excluded that an owner who is not a biologist would be tempted to refuse to carry out tests which were less profitable or more complicated to perform, or would not pay sufficient attention to the necessary equipment, for purely financial reasons.

133. There is no doubt, as the Commission maintains in paragraph 48 of its rejoinder, that a biologist employed by an analysis laboratory managed, at the decision-making level, by owners who are not biologists, would also in any case be required to comply with the code of conduct of the profession.

134. However, this is merely a formal observation, because in fact the interaction between an employment relationship, which in any event entails obligations towards the employer, and professional duties certainly weakens the guarantee that the desirable primary objective — namely the health of the user — will be respected in the performance of the activity for the latter.

135. Nevertheless, it appears that the extremely important added value of the fact that the power of decision is granted to one or more persons who offer greater safeguards for the primary good being protected, by virtue of their specific training and the fact that they are also subject to precise rules of professional conduct, was not taken into account by the Court in the case concerning the

35 — See the Opinion in Case C-531/06 *Commission* v *Italy*, cited in footnote 5 above, point 87, but also, in the same terms, the Opinion in *Apothekerkammer des Saarlandes and Others*, cited in footnote 5 above, point 49.

activities of opticians, to which the Commission refers several times.

136. As I have already pointed out, that circumstance is an extremely important reason for stating that that judgment does not serve as a binding precedent for resolving the issue currently submitted for examination by the Court.

3. The inconsistency of the existing legislation and the protection of the general interest by means of less restrictive measures

(a) Arguments of the parties

137. At this point, it remains for me to verify whether the approach chosen by the French Republic is internally inconsistent, given the general arrangement of the system as regards both the legislation in force and its practical application.

138. In the same way, it must be assessed whether it would be possible to safeguard the same interest by means of one or more measures that were less restrictive of the fundamental freedoms provided for in the EU Treaty, especially the freedom of establishment.

139. In that regard, the Commission maintains first that the failure of the French legislature to provide that a biologist must be on the premises during the opening hours of the laboratory, in contrast to the rules for pharmacies, is a clear inconsistency in the regulations in force for the sector.

140. That assertion is disputed by the French Republic, which states that the presence of a biologist is provided for — if not formally, then at least *de facto* — in express provisions of the Public Health Code; [36] moreover, there is no requirement for pharmacists to be physically present either, as the Court has stated in one of the rulings cited above regarding that sector.

141. From another point of view, in the opinion of the Commission, the objective of preserving the freedom of decision of the manager of a medical analysis laboratory is already pursued by means of other provisions of French legislation which are more appropriate to that purpose.

36 — Articles L 6211-1 and L 6221-9 (paragraph 41 of the statement of defence of the French Republic).

142. The Commission refers to the mechanisms regarding personal incompatibility, to technical and qualitative aspects of staffing and to the consequent mechanisms for supervision by doctors and pharmacists.

143. In addition, the Commission maintains for the first time in its rejoinder (paragraph 36) that a significant number of large laboratories or networks of laboratories are configured in such a way in France that they have access to 'external' capital — held by non-biologists — in excess of 25 %.

144. According to the Commission, this was possible thanks to a mechanism for separating voting rights from financial rights in order to ensure that biologists hold the majority of votes on the board of directors and in other situations in which decisions are taken regarding the operation and organisation of laboratories.

145. The Commission claims that, when such corporate structures are brought to the notice of the order of pharmacists and the French authorities, they are validated and authorised to carry out medical analyses in so far as they are compatible with French legislation.

146. The Commission therefore argues that, from this viewpoint, there is again a clear inconsistency between, on the one hand, the principles proclaimed and, on the other, working practices; as was remarked at the hearing, the French Republic has not ensured respect for a principle which it has itself stated to be fundamental for the purposes of guaranteeing the independence of biologists.

147. From another point of view, in the opinion of the Commission, a separation mechanism of the type indicated above would meet the requirements of EU law from the angle of the proportionality test and, in particular, those raised by the need to guarantee the right of establishment.

148. The Commission states in that regard that this line of thinking figures in the abovementioned plan to reform medical biology, which provides for the adoption of a decision-making mechanism of the kind I have just indicated.

149. According to the Commission, a system of that kind, where it exists, would be proof of patent disregard and inconsistency with the statements of the French Republic; where it is not yet in operation, it would nevertheless be a possible and welcome measure — and certainly less restrictive — that would render the measures relating to access to capital inappropriate.

150. This particular aspect was not contested in the subsequent rejoinder of the French Republic, which remained completely silent on the point; it was only at the hearing on 25 March 2010 that the French Republic provided clarifications on this matter in reply to the question specifically asked by the Court under Article 54a of the Rules of Procedure by letter of 10 February 2010.

151. According to the French Republic, at least 75 % of the capital of a company formed for the joint operation of bio-medical analysis laboratories must be held by biologists, who may be either natural or legal persons.

152. As for the capital of legal persons, which are established mainly in the form of companies to carry on professional activities, the same limit of 75 % operates, and applies both to biologists who are natural persons and, of greater interest here, legal persons equated to such professionals.

153. If those legal persons are from other Member States of the European Union where there are no limits on shareholdings in companies formed for the joint operation of bio-medical analysis laboratories, it may also happen that persons unqualified as biologists hold far more than just 25 % of the share capital.

154. In particular, the French Republic cites Ireland and Spain, where it alleges that more than 25 % of the capital of a legal entity qualified as a biologist and formed for the purpose I have just described could, in the absence of legal limits, be held by non-biologists, for example by certain investment funds.

155. The French Republic asserts that, in essence, this held true in at least two of the cases cited by the Commission in its reply, in particular in the laboratories operated by Biomnis (a company of which more than 50 % of the share capital is held by an Irish legal entity qualified as a biologist, the entire share capital of which, or at least 80 % thereof, is held by an investment fund) and Unilabs (a Swiss company in which the share capital is held by non-biologists and which operates companies owning laboratories in Spain, which in turn operate laboratories in France).

156. According to the French Republic, it is true that this could lead to a risk of circumvention of the law, but it would be an unavoidable consequence of the obligation to comply with the commitments made to the European Union, as they are companies from other Member States.

157. In the view of the French Republic, this creates a kind of 'reverse' discrimination, a phenomenon which emerged relatively recently, which the Commission could certainly not hold against the French Republic, given that it had done no more than allow a company operating a laboratory in Ireland or Spain the right to engage in the same activity in France.

158. In the two other cases cited by the Commission in its reply, that is to say, those of the Cerba and Labco laboratories, the 25% shareholding limit for non-biologists had been fully respected, as was in fact reported, so far as the latter case was concerned, in the newspaper article appended by the Commission.

159. With regard to the possible alternative measure separating financial investment from voting rights, the French Republic stated first and foremost at the hearing that the Commission had raised the argument very late in its reply, and it left the Court to ascertain whether it constituted a new form of order or a new plea which was to be considered out of time.

160. In that regard, the French Republic maintained, in reply to the written question previously submitted, that such a measure would not in any case be adequate in relation to the objective set, given the discretion that the Member State must be allowed in matters of public health.

161. It would be wrong to underestimate the pressure that third party holders of the majority of the capital could in any case exert on biologists carrying out their activities within laboratories, whose independence would be at risk, despite having the majority of voting rights.

162. Lastly, according to the French Republic, this separation mechanism exists in France only and exclusively for certain types of company — and indeed not for limited liability companies — and relates exclusively to relations between biologists carrying on their activities within laboratories and biologists who are 'external' to laboratories; this is therefore a completely different situation and entirely irrelevant as regards the 25% limit, which by contrast applies to non-biologists.

163. At the hearing, the Commission contested the view that what it had stated in its reply about mechanisms for separating financial rights from voting rights constituted a new complaint or a new plea; instead, it was a finding of fact on which the French Republic

had remained silent throughout the pre-litigation stage and also during the written procedure before the Court.

164. In that regard, the Commission emphasised the fact that the principle of compliance with the limit of 25 % of the capital, which the French Republic had adopted as a fundamental means of ensuring the freedom of decision of biologists and thus of safeguarding public health, was in fact not observed in the situations to which it had wished to refer.

165. As to the other less restrictive measures indicated by the Commission (that is to say personal incompatibility, technical and qualitative aspects of staffing and the consequent mechanisms for supervision by doctors and pharmacists), the French Republic argued that, given the level of protection of public health that was sought, they would not in any case be adequate for ensuring the independence of decision-making by biologists.

(b) Assessment

166. In support of its assertions about the inconsistency of the overall structure of the French system, the Commission points out that the legislation in force in France does not formally lay down — even in Articles L 6211-1 and L 6221-9 cited by the French Republic — that a biologist must be present in the laboratory at all times during opening hours, thus enabling the work to be carried out only by the technical staff.

167. Given that the current version of those provisions is different from the one on which the arguments of the parties were based, it must be stated that, according to the wording at that time, the legislation laid down a number of principles which were perfectly consistent with the objective of protecting public health.

168. In particular, Article L 6211-1 lays down (or rather laid down at that time) the principle that analyses may be carried out only in bio-medical analysis laboratories under the responsibility of their managers and assistant managers; Article L 6221-9 provides (or provided) that the managers and assistant managers must perform their functions in person and in actual fact.

169. While it is true that the law does not require the manager-biologist to be present in the laboratory at all times, it is abundantly clear that the national legislation obliges him *de facto* to supervise effectively the entire

activity of the laboratory, for which he assumes direct responsibility, without in any way being able to divest himself of those professional duties by mechanisms for the delegation of powers.

170. On that premiss, it does not appear that those provisions conflict with or are inconsistent with the objective of the highest protection of public health that the defendant Member State has set.

171. Moreover, as the French Republic rightly maintains, the comparative reasoning on which the Commission relies in order to deny the consistency of the rules governing the sector is based on a false assumption, namely the existence of an absolute requirement for the pharmacist to be on the premises in which the related activities are performed.

172. In fact, Article L 5125-21 of the Public Health Code merely provides that a pharmacy may not remain open unless its proprietor has appointed a substitute, whereas under Article R 4235-13 the personal activity which the pharmacist is required to perform consists in his carrying out the acts of the profession or, at the very least, carefully supervising their execution. [37]

173. Those obligations are very similar to those laid down for the manager of a biomedical analysis laboratory, which means that there is no inconsistency of the kind alleged by the Commission, whose observations in this regard miss their mark.

174. As to the possibility of applying less restrictive measures, it is appropriate to state first that, according to the case-law of the Court, it is for the Member States, within the limits imposed by the Treaty, to decide on the degree of protection which they wish to afford to public health and on the way in which that degree of protection is to be achieved. [38]

175. That said, since that degree of protection may vary from one Member State to another, Member States must be allowed discretion when assessing whether the principle

37 — See *Apothekerkammer des Saarlandes and Others*, cited above, paragraph 60, which is cited by the French Republic, at the point where the Court holds the German legislation at issue to be consistent in so far as it provides for a pharmacist to manage up to three branches of the same pharmacy, on his own responsibility and thus determining their commercial policy.

38 — See Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraph 103; Case C-262/02 *Commission* v *France* [2004] ECR I-6569, paragraph 24; Case C-170/04 *Rosengren and Others* [2007] ECR I-4071, paragraph 39; Case C-143/06 *Ludwigs-Apotheke* [2007] ECR I-9623, paragraph 27; and Case C-141/07 *Commission* v *Germany*, cited in footnote 7 above, paragraph 46.

of proportionality has been observed, [39] and consequently the fact that one Member State imposes less strict rules than another does not mean that the latter's rules are disproportionate. [40]

176. In support of its claims as to the assumption that measures already exist in the sector which adequately meet the declared objective pursued by the defendant Member State, the Commission refers first and foremost to Article 12 of Decree No 92-545 of 17 June 1992, which prohibits specific categories of natural or legal persons from holding shares in the capital of the companies in question.

177. That prohibition is linked to the fact that, for reasons which differ from case to case, such persons have interests which may in some way adversely affect the free exercise of laboratory activities. [41]

178. Those prohibitions may be considered appropriate for situations in which it is simply a matter of preventing a different interest from having an abnormal influence on the direction of the company's activities; proof of that interest is not required, since it is linked objectively to the personal characteristics of the potential shareholder.

179. However, they are not adequate where it is a question of ensuring truly independent management of the company by shareholders qualified as biologists, at all times and in every case, even where there is no conflict of interest of the kind that has already been formally held to be such under the existing law.

180. Consequently, given the particularly high degree of protection which the French Republic wishes to provide for public health in the exercise of its specific powers, it must be held that the system of formal incompatibilities provided for under Article 12 of Decree No 92-545 of 17 June 1992 is not sufficient for this purpose.

181. So far as the technical and qualitative aspects of staffing and the consequent mechanisms for inspection by health inspectors from the medical and pharmaceutical professions are concerned, the Commission refers to Articles L 6213-1 to L 6213-5 of the French Public Health Code (in the version in

39 — See, to that effect, Case C-41/02 *Commission* v *Netherlands* [2004] ECR I-11375, paragraphs 46 and 51, and Case C-141/07 *Commission* v *Germany*, cited above, paragraph 51.

40 — See Case C-262/02 *Commission* v *France*, cited in footnote 38 above, paragraph 37; Case C-443/02 *Schreiber* [2004] ECR I-7275, paragraph 48; and Case C-141/07 *Commission* v *Germany*, cited in footnote 38 above, paragraph 51.

41 — For example, it is worth noting that the following are not permitted to hold shares: (a) persons engaging in a different health profession; and (b) suppliers, distributors or manufacturers of materials or reagents needed for medical tests.

force when depositions were made and then amended as a result of Order No 2010-49 of 13 January 2010 on medical biology). [42]

182. Here too, there can be no doubt but that these are mechanisms to ensure that bio-medical analysis is carried out by persons with adequate training and technical expertise, as well as operation at a qualitatively appropriate level.

183. Among other things, according to the case-law of the Court, the need to protect public health referred to in Article 46 EC makes it permissible to maintain the quality of medical services not only by ensuring that the directors and staff of bio-medical analysis laboratories hold the necessary qualifications but also by checking, through periodic inspections, that analyses are at all times carried out in accordance with the rules laid down by the French legislature and the French authorities and, in particular, with the requisite authorisation. [43]

184. Yet again, however, these are systems which are not capable, in themselves, of ensuring achievement of the outcome deemed to be a priority: the protection of public health by guaranteeing the independence of decision-making of the professional performing the work of the laboratory.

185. In conclusion, the less restrictive measures to which the Commission has consistently referred from the outset do not appear apt to render the French measure described above redundant, in terms of limiting shareholdings, if account is taken of the specific objective pursued.

186. At this point, all that remains to be examined is the further aspect, raised by the Commission for the first time in its rejoinder, regarding situations in which the 25% limit for non-biologists is allegedly circumvented *de facto* in France, at least in particular situations, partly by means of mechanisms for separating the size of financial share from voting rights.

187. The French Republic has not formally contended, either in its rejoinder or at the hearing, that this issue is inadmissible; it merely left it to the Court to decide on its legal characterisation and then to consider whether to examine it.

188. I note that, in this case, it is clearly not a question of amendment of the forms of order initially sought, the terms of which have not

42 — Notified to the Commission by note of 9 March 2010, as stated above.

43 — See Case C-496/01 *Commission* v *France*, cited in footnote 16 above, paragraph 67. In that case the Court held, however, that the different requirement for medical biology analysis laboratories to have an operational base in France in order to obtain the necessary administrative authorisation to operate there went further than was necessary to achieve the objective of protecting public health.

been changed in any way from the original pleas entered by the Commission.

189. Nor do I believe that this amounts to a new plea, since from the very outset the Commission raised the question of the proportionality of the measure adopted by the French Republic, albeit without referring specifically to the aspect mentioned above.

190. Instead it is a new argument, based, as the Commission maintains, on a simple finding which forms part of the debate that took place during the written procedure on the general topic of the proportionality and consistency of the French legislation, and does not alter the subject-matter of the dispute.

191. Moreover, it seems to me to be extremely important to emphasise that this conclusion is also reinforced by the fact that no infringement of the rule that the parties should be heard is evident in the present case, given that the French Republic could have used its rejoinder in order fully to exercise its right of the defence on this issue.

192. Instead the French Republic remained completely silent on the subject, so that it was necessary to put a specific written question to it before the hearing, and only on that occasion was there actual discussion of the arguments raised by the Commission in its rejoinder.

193. As to the substance of the Commission's claims, it is my view that, in the light of the clarifications provided by the French Republic at the hearing, the legislation in force in that State, as applied in the circumstances referred to by the Commission — which does not dispute the contrary arguments on this issue — does not contain inconsistencies.

194. Undoubtedly, once it is acknowledged that the work of a biologist may also be performed by a company, without restrictions as to its form (persons, capital, and so on), it becomes perfectly conceivable that the capital of such a company, if formed in Member States where there are no limits of the kind applied in France, may belong, possibly in its entirety, to persons who are not biologists but simply financial investors.

195. Indeed, this happened in at least two of the cases cited by the Commission as examples of inconsistency, specifically Biomnis and Unilabs (in the other cases, by contrast, the factual situation is different and does not

appear problematical from the standpoint that is the subject-matter of these proceedings).

196. It is clear, however, that these are situations in which different conduct on the part of the defendant Member State might have constituted discrimination, hence an infringement of the fundamental freedoms laid down in the Treaty and, specifically, of the freedom of establishment and the freedom to provide services.

197. In that situation, it cannot be considered that the conduct of the French Republic was inconsistent in that it allowed the companies involved to operate bio-medical analysis laboratories on its national territory, regardless of the ownership of the company's capital, since it considered that they had the necessary qualification in biology.

198. At the hearing, the French Republic made it clear, inter alia, that the question of the abovementioned separation between shareholdings and voting rights is different; this issue comes into play in only a small number of cases and not for limited liability companies, in view of the different relations between biologists working for analysis laboratories and 'external' biologists.

199. Hence, in these proceedings the limit of 25 % for non-biologists is not called into question in any way; moreover, the Commission subsequently raised no objection following the clarification of this issue by the defendant.

200. At this point, the only problem that remains to be examined relates to the possibility put forward by the Commission, albeit in hypothetical terms, of applying a separation mechanism of the kind indicated [44] to companies operating analysis laboratories; in that way, according to the Commission, the freedom of decision of biologists would be safeguarded, with only a minor impact on the freedom of establishment.

201. At the hearing, the French Republic replied to those arguments by stating that an approach of this kind could not be considered adequate, since the financial pressure exerted by shareholders should not be underestimated, despite the fact that the majority of votes might be held by biologists.

202. In reply to the question put to it on this point, the French Republic also stated that

44 — At the hearing, however, the French Republic confirmed that the mechanism for separating financial shareholdings from shareholder rights is not alien to national legislation, which has already applied it, albeit to relations between biologists working within companies and biologists who are simply investors.

this assertion did not conflict with the other possibility — which applies only to limited partnerships — in which non-biologists may hold up to 49% of the share capital (see Article 11(II) of Decree No 92-545 of 17 June 1992).

203. In the present case, according to the French Republic, the difference could be explained by the different way in which this type of company operates and especially by the existence of two different classes of shareholder (limited partners and general partners, the latter necessarily being qualified biologists working in the laboratories) and the very rigorous operating rules, which had caused the adoption of this form of corporate organisation to be limited. [45]

204. The general partners, who necessarily hold the professional qualification required, have a general power of decision, which must often be exercised unanimously.

205. Given that this hypothesis is not inconsistent with the general organisation of the sector and is readily explained in the light of the particular nature of that form of company, it is necessary rather to ascertain whether, and to what extent, there is truth in the assertion made by the French Republic that a separation mechanism of the kind under examination is an inadequate means of attaining the general objective of protecting the independence of biologists operating analysis laboratories.

206. It may be considered an established principle of case-law that the burden of proof as to the proportionality and consistency of any restrictions on the fundamental freedoms rests with the Member State concerned.

207. The French Republic considered that it had provided such proof by justifying the restrictions on investment by non-biologist third parties in companies formed by persons carrying on a professional activity on the ground of the objective of safeguarding the decision-making independence of biologists, who must hold the greater part of the share capital.

208. Although that purpose was deemed lawful, in the terms stated above, it was still the responsibility of the French Republic to show that the less restrictive measure envisaged by the Commission — which, according to the Commission, would equally well safeguard that decision-making independence — would not in reality adequately meet the objective set.

45 — According to assertions which the French Republic does not contest, no more than 4% of all analysis laboratories are operated in that form, and the percentage continues to decline.

209. That said, the French Republic did not set out in detail at the hearing the reasons why the separation mechanism would be ineffectual, confining itself to claiming that the ownership of a higher financial stake by non-biologists would give them scope to exert pressure on the biologists, even though in formal terms the latter had the power of decision.

210. Furthermore, the Commission did not even adopt a precise position on that claim; it made no detailed comment on this aspect in its reply at the hearing.

211. I observe first in this regard that recognition that a company operating a bio-medical analysis laboratory may be established as a capital company [46] and that persons without the specific professional qualification may become shareholders in such a company means that a financial shareholding by persons 'external' to the professional category in question is not deemed by the French Republic to be a circumstance which of itself alone is likely to prevent the adequate safeguarding of the independence of the biologist managing the activity, hence the protection of public health.

212. According to the approach adopted by the French Republic, such an 'external' presence becomes an impediment to achieving the set public interest objective only where that shareholding, by exceeding 25 %, makes it possible to influence the more important decisions on the operation of analysis laboratories.

213. In essence, following the line of argument that the French Republic put forward up until the hearing, 'external' capital does not of itself constitute an absolute risk factor but becomes one only when it makes it possible to have a significant influence on the company's operational decisions.

214. In addition, that this was the intention of the legislature of the Member State involved is demonstrated by the fact that where the decision-making independence of the biologist-shareholder is safeguarded in another way, as in the case of bio-medical analysis companies established as limited partnerships, a higher proportion of 'external' capital is deemed acceptable, up to 49 %.

215. As I have already stated, this is justified in that the special rules governing this type

46 — In contrast to Italy and Germany, where the exercise of the profession of pharmacist in corporate form was authorised — under the legislation examined by the Court in the cases that gave rise to the abovementioned rulings on the sector — only for partnerships (and in Italy for limited liability cooperative societies as well) between persons who nevertheless hold the necessary qualification.

of company bestow managerial power on the general partners, who must of necessity be qualified biologists.

216. The decision taken by the French Republic in order to reconcile investment in laboratories by purely investor shareholders with protection of the independence of the biologist-shareholders is undoubtedly of itself an important factor to be assessed positively for the purposes of an overall ruling on the proportionality of the measure adopted.

217. Without jeopardising the decision-making independence of the professional shareholders, this arrangement makes it possible to bring in external financial resources and permits shareholdings by persons aiming to benefit solely from the return constituted by the operating profit, on the basis of common market rules and without any discrimination.

218. It remains to be assessed whether, as the Commission suggests, the presence of 'external' capital in excess of 25 % of the total but not such as to deprive the shareholders with qualifications as biologists of real power of decision within the company — as occurs in limited partnerships — would not be just as effective as the restriction that has been introduced for the purposes of the declared objective of safeguarding the independence of the professional shareholders.

219. From that point of view, it has to be recognised that, despite the fact that voting rights remain subject to the 25 % limit, permitting a larger external financial shareholding entails greater risk to the independence of the biologist-shareholders, as the French Republic maintains.

220. It should not be underestimated that decisions about financial investment or disinvestment by minority shareholders could influence — albeit in a rather indirect way — decisions taken by the corporate bodies, even if they constituted the will of the majority, unless such financial decisions related to a shareholding that was negligible or at least small.

221. In essence, therefore, the assertion made by the French Republic that the mere holding of more than 25 % of the capital could of itself lead to financial pressure, irrespective of the associated voting rights, appears justified.

222. As I have stated, the Commission did not reply in substance to this specific claim at the hearing, and did not offer any concrete refutation.

223. It is therefore my opinion that, given the measure of discretion which, as I have already pointed out, must be granted to a Member State with regard to the protection of public health, it can be stated that the mechanism separating financial shareholdings from voting rights could actually prove to be less effective in attaining the objective pursued.

224. The decision of the French Republic, which in any case created an opening for external capital, albeit a limited one, may therefore be held, of itself, to be proportionate in relation to that objective, for the purposes of which, given the Member State's discretion as to the choice between equally effective instruments and the absence of any argument to the contrary by the Commission, it is the least restrictive measure that can be adopted.

225. That conclusion can be confirmed, moreover, if the assessment of proportionality takes account of the array of measures implemented in the bio-medical analysis sector, with particular regard to the different means of investing external capital in relation to the different forms of company.

226. The more restrictive measure for analysis laboratories established as limited liability companies formed by persons carrying on a professional activity, which are the specific subject of the action by the Commission, is accompanied, in the pertinent law, by a provision for larger investment of 'external' capital (up to 49 % of the total) in laboratories operated by companies established as limited partnerships, which permit such higher external investment because they are governed by much stricter operating rules.

227. The foregoing conclusions enable me to make a positive assessment of the consistency and proportionality of the measure adopted by the French Republic and contested by the Commission in the first of its objections in the application, which I therefore consider to be unfounded in this respect.

228. I therefore propose that the Court dismiss the action in so far as the Commission claims that it should declare that, by limiting to a maximum of 25 % the shares, hence the voting rights, which persons who are not biologists may hold in a SELARL established for the joint operation of one or more biomedical analysis laboratories, the French Republic has failed to fulfil its obligations under Article 43 of the EC Treaty.

B — *The restrictions on the acquisition of shareholdings in different companies*

(a) Arguments of the parties

229. The Commission considers that the prohibition on natural or legal persons from holding shares in more than two companies established for the joint operation of one or more bio-medical laboratories is also unlawful.

230. In contrast to its position during the pre-litigation stage, it is evident from paragraph 64 of the statement of defence that the French Government did not dispute this complaint from the very beginning of the written stage of the proceedings, acknowledging that the restriction in question is not justified by the need to protect public health.

231. Despite the subsequent change in that position in the rejoinder, which I have already reported above, the French Republic has not asked the Court to dismiss the Commission's action on this count. At the hearing on 25 March 2010, the French Republic again declared that it did not contest the action as regards the aspect under examination.

232. In that forum, in reply to a specific question on this issue put by the Court, the Commission claimed in general terms that the prohibition in question related primarily to biologists, but also to non-biologists, then in essence deferred to the French Republic's interpretation in this respect; the French Republic then stated that the contested limitation applied only to biologists.

(b) Assessment

233. First of all, the clarification must be made that, whereas the Commission's initial objection appears to relate to a general prohibition, it is clear — given the literal wording of Article 10 of Decree No 92-545 of 17 June 1992 and the clarifications made by the French Republic at the hearing on 25 March 2010 — that the prohibition that is the subject of the action relates only to qualified biologists.

234. In essence, according to the French Republic, for persons who are not biologists —

and who therefore are not among the persons mentioned in subparagraphs 1 to 5 of Article 5(2) of Law No 90-1258 of 31 December 1990, referred to in Article 11 of Decree No 92-545 of 17 June 1992 — there is no limit on the number of companies in which they may hold shares, subject obviously to the maximum limit of 25% of the capital that they may acquire in each company, as stated above.

235. On that premiss, taking into account the arguments of the parties as they evolved in the course of the proceedings, I am bound to conclude that the Commission's application, which the French Republic has asked the Court to dismiss only as regards the first plea, should be upheld, albeit only in the terms stated more fully above.

236. I therefore propose that the Court declare that, by prohibiting a natural or legal person in one of the categories referred to in subparagraphs 1 to 5 of Article 5(2) of Law No 90-1258 of 31 December 1990 from holding shares in more than two companies established for the joint operation of one or more bio-medical analysis laboratories, the French Republic has failed to fulfil its obligations under Article 43 of the EC Treaty.

VI — Costs

237. Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. In accordance with the first subparagraph of Article 69(3) of the Rules of Procedure, however, where each party succeeds on some and fails on other heads, or where the circumstances are exceptional, the Court may order that the costs be shared or that the parties bear their own costs.

238. In the present case, the Commission applied for the French Republic to be ordered to bear the costs, while the latter asked that each party be ordered to bear its own costs.

239. That being so, since the parties have both failed on some heads, I suggest that the Court order them both to bear their own costs.

VII — Conclusion

240. In the light of all the foregoing considerations, I propose that the Court should:

— declare that, by prohibiting a natural or legal person in one of the categories referred to in subparagraphs 1 to 5 of Article 5(2) of Law No 90-1258 of 31 December 1990 from holding shares in more than two companies established for the joint operation of one or more bio-medical analysis laboratories, the French Republic has failed to fulfil its obligations under Article 43 of the EC Treaty;

— dismiss the remainder of the action;

— order the European Commission and the French Republic each to bear its own costs.