JUDGMENT OF THE COURT (Second Chamber)

16 December 2010 *

In Case C-89/09,

ACTION under Article 226 EC for failure to fulfil obligations, brought on 2 March 2009,

European Commission, represented by G. Rozet and E. Traversa, acting as Agents, with an address for service in Luxembourg,

applicant,

v

French Republic, represented by G. de Bergues and B. Messmer, acting as Agents,

defendant,

* Language of the case: French.

THE COURT (Second Chamber),

composed of J.N. Cunha Rodrigues, President of Chamber, A. Arabadjiev, A. Rosas (Rapporteur), A. Ó Caoimh and P. Lindh, Judges,

Advocate General: P. Mengozzi,
Registrar: N. Nanchev, Administrator,

having regard to the written procedure and further to the hearing on 25 March 2010,

after hearing the Opinion of the Advocate General at the sitting on 2 June 2010

gives the following

Judgment

1 By its application, the Commission of the European Communities 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 and by prohibiting the holding of capital in more than two companies formed in order to operate jointly

one or more biomedical analysis laboratories, the French Republic has failed to fulfil its obligations under Article 43 EC.

National law

2 Article 5 of Law No 90-1258 of 31 December 1990 on 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, and on holding companies for liberal professions (*Official Journal of the French Republic* of 5 January 1991, p. 216) provides:

'More than half of the share capital and voting rights must be held, directly or through the company described in point (4) below, by persons currently engaged in their professional activities within the company.

Subject to the provisions of Article 6, the remainder may be held by:

1. Natural or legal persons engaged in the profession or professions that constitute the object of the company;

2. For a period of ten years, natural persons who, having ceased all professional activity, have engaged in that profession or those professions within the company;

3. The successors in title of the natural persons referred to above, for a period of five years following the death of such persons;

4. A company formed in accordance with Article 220 *quater* A of the *Code général des impôts* ["the Tax Code"], where the members of that company engage in their profession within the *société d'exercice libéral*;

5. Persons engaged either in one of the liberal healthcare professions or in one of the liberal legal or judicial professions, or in any of the other liberal professions referred to in the first paragraph of Article 1, provided that the object of the company is to engage in one of those professions.

The number of companies formed to engage in any profession in which a particular natural or legal person in one of the categories listed in points (1) and (5) of the second paragraph is authorised to hold shares may be limited for a particular profession by a decree of the Conseil d'Etat.

Where any of the conditions laid down in this article is no longer met, the company shall have a period of one year in which to comply with the provisions of the present Law. If it does not do so, any interested party may apply to the courts for the company to be wound up. The relevant court may grant that company a maximum period of six months in which to regularise the situation. Winding-up shall not be ordered if, on the day on which a ruling is given on the substance, such regularisation has taken place.

Where, on the expiry of the period of five years provided for in the third paragraph, the successors in title of shareholders or former shareholders have not assigned the shares they hold, the company may, notwithstanding any opposition by such persons, decide to reduce its share capital by the amount of the nominal value of their shares and to buy them back at a price fixed in accordance with the conditions laid down in Article 1843-4 of the Civil Code.'

3 At the end of the period laid down in the reasoned opinion, that article was amended by Law No 2008-776 of 4 August 2008 on the modernisation of the economy (*Official Journal of the French Republic* of 5 August 2008, p. 12471).

4 Article 10 of Decree No 92-545 of 17 June 1992 on *sociétés d'exercice libéral* of managers and assistant managers of biomedical analysis laboratories (*Official Journal of the French Republic* of 21 June 1992, p. 8106) provides:

'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 the above-mentioned Law of 31 December 1990 may, at any given time, hold shares in only two companies formed in order to operate jointly one or more biomedical analysis laboratories covered by Article L. 753 of the Public Health Code.'

5 Article 11 of that decree provides:

'A maximum of 25 % of the capital of a *société d'exercice libéral* of managers and assistant managers of biomedical analysis laboratories may be held by one or more persons who do not meet the conditions laid down in the first paragraph, or in points (1) and (5) of the second paragraph, of Article 5 of the above-mentioned Law of 31 December 1990.

However, if the *société d'exercice libéral* is formed as a limited partnership, the percentage of the capital that may be held by persons other than those referred to in Article 5 of the above-mentioned Law of 31 December 1990 may be higher than that laid down in the first paragraph but may not, however, be so high as to represent 50 % of that capital.'

The pre-litigation procedure

6 In response to a complaint, the Commission sent the French Republic a letter of formal notice on 4 April 2006, in which it stated that certain provisions of the French regulations concerning biomedical analysis laboratories did not appear to be compatible with the principle of freedom of establishment for the purposes of Article 43 EC in that they restrict the possibility for non-biologists to hold shares in a SELARL operating laboratories and limit the number of companies, formed in order to operate jointly one or more laboratories, in which a natural or legal person may hold shares at any given time.

7 As that letter remained unanswered, the Commission sent the French Republic a reasoned opinion on 15 December 2006, calling upon it to take the necessary measures to comply with that reasoned opinion within two months of receipt.

8 In its reply of 14 February 2007, the French Republic stated that the regulations referred to in that reasoned opinion were justified by the objective of protecting public health and that they were necessary and proportionate in relation to that objective.

9 By letter of 11 April 2008, the French Republic stated that its position had changed and that it planned to remove all restrictions on the holding of shares in the laboratories concerned, with the exception of the restrictions arising from certain narrowly defined incompatibilities. According to the French Republic, the law introducing that reform was scheduled for adoption at the end of 2008 or the beginning of the following year, whereupon it was to be implemented immediately.

10 As no information was received on the progress made in the matter, the Commission approached the French Republic, by letter of 20 November 2008, asking for information in that regard.

11 By letter of 27 December 2008, the French Republic informed the Commission that, on 22 October 2008, the National Assembly had been sent a draft law empowering the Government to adopt, by means of an order, legislative provisions for a general reform of medical biology. The French Government stated that the draft law in question was to be considered by the National Assembly in February 2009 and that final adoption of the law had thus been postponed until the following May.

12 Since the French Republic did not forward to the Commission a timetable for the adoption of the order in question, or a copy of the draft law, which would have provided the Commission with specific evidence regarding the measures proposed for remedying the complaints raised, the Commission decided to bring the present action.

Procedure before the Court

13 By order of the President of the Court of 14 September 2009, the Kingdom of Denmark was granted leave to intervene in support of the form of order sought by the French Republic.

14 After the Kingdom of Denmark informed the Court that it was withdrawing its intervention, the President of the Court, by order of 9 November 2009, ordered that Member State to be removed from the register as an intervener in the case.

15 By letter of 5 February 2010, the French Republic was asked, pursuant to Article 54a of the Rules of Procedure of the Court, to comment at the hearing on the statement, made by the Commission for the first time in its reply, that the French authorities approve certain structures allowing access to external capital in excess of the 25% limit authorised by the regulations on biomedical analysis laboratories, where the attendant financial rights are severed from the voting rights relating to decisions on the operation and organisation of the laboratories.

16 By letter of 18 March 2010, the French Republic forwarded to the Court a note it had sent to the Commission on 9 March 2010, under cover of which it had sent the Commission a copy of Order No 2010-49 of 13 January 2010 on medical biology (*Official Journal of the French Republic* of 15 January 2010, p. 819), the draft of which had been referred to by the French Republic during the pre-litigation stage and in its rejoinder.

The action

17 The Commission has raised in substance two complaints in the present proceedings. It claims that the regulations on biomedical analysis laboratories infringe Article 43 EC inasmuch as they provide, first, that a non-biologist cannot hold more than 25% of the shares, hence of the voting rights, in a SELARL operating biomedical analysis laboratories and, second, that a natural or legal person may not, at any given time, hold shares in more than two companies formed in order to operate jointly one or more biomedical analysis laboratories.

18 It should be pointed out that, following the adoption of Order No 2010-49, some amendments were made to the regulations on biomedical analysis laboratories. Given

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 the Court cannot take account of any subsequent changes (see, inter alia, Case C-531/06 *Commission* v *Italy* [2009] ECR I-4103, paragraph 98, and Case C-392/08 *Commission* v *Spain* [2010] ECR I-2537, paragraph 26), those amendments are not taken into account in the present judgment.

The first complaint

Arguments of the parties

19 The Commission claims that the prohibition on a non-biologist holding more than 25 % of the shares, hence of the voting rights, in a SELARL operating biomedical analysis laboratories, which results from the application of Article 5 of Law No 90-1258, read in conjunction with the first paragraph of Article 11 of Decree No 92-545 ('the provisions covered by the first complaint'), constitutes an unjustified restriction on freedom of establishment for the purposes of Article 43 EC. That has the effect of limiting the opportunities for partnerships, in particular with legal persons established in other Member States, as well as limiting the freedom of laboratories established in other Member States to establish themselves in France if they do not meet the criteria laid down in the provisions covered by the first complaint.

20 Admittedly, the protection of public health is one of the reasons that can justify restrictions on the freedom of establishment. However, such restrictions must be appropriate for securing attainment of the objective pursued and must not go beyond what is necessary for attaining it, which — the Commission claims — is not the case as regards the prohibition at issue.

21 In support of its argument, the Commission relies on Case C-140/03 *Commission* v *Greece* [2005] ECR I-3177 concerning opticians' shops. In that judgment, the Court held that, since the measures laid down in the Greek regulations at issue did not permit an optician to operate more than one optician's shop and limited to a maximum of 50% the share of the capital that could be held by natural or legal persons other than the optician operating the shop, they were in breach of Article 43 EC and Article 48 EC. There exists, according to the Commission, an undeniable parallel between the regulations at issue in that case and the provisions covered by the first complaint in the present case.

22 According to the Commission, it seems justifiable to make it a requirement in the legal context of relationships with patients that, for public health reasons, biomedical analyses must be carried out by competent staff with the appropriate professional training. However, in the context of legal relationships concerning the ownership of biomedical laboratories, or the right to operate them, the requirement of such qualifications does not seem proportionate.

23 In its reply, the Commission argues that the approach adopted by the Court in its judgments concerning restrictions on the ownership of capital in pharmacies (Case C-531/06 *Commission* v *Italy* and Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others* [2009] ECR I-4171, delivered after the application and defence had been lodged in the present case, cannot be transposed to biomedical analysis laboratories. In those judgments, the Court adopted a different approach from that adopted in *Commission* v *Greece*. It held that freedom of establishment does not preclude rules, such as those laid down in the Italian and German legislation, which allow only pharmacists to own and operate pharmacies. The explanation for that finding lies in the highly specific nature of medicinal products.

24 Biomedical activities, on the other hand, are carried out solely on the basis of a medical prescription, thus offering a better safeguard, both in terms of the protection of public health and in terms of containing the costs for the health system. The fact of being confined within the terms of medical prescription is justified by both the nature and the number of the tests to be carried out.

25 The Commission maintains, moreover, that the biomedical sector has substantial financing needs, a characteristic which distinguishes it in particular from the pharmacies sector, and that the objective of protecting public health pursued by the provisions covered by the first complaint is not attained because those provisions did not allow amalgamations to take place that would make it possible to achieve the investment needed in order to provide a quality service. Nor did those provisions allow entities to be formed of sufficient size to achieve economies of scale which might have positive effects as regards the cost of analyses and, consequently, as regards the burden on the social security system.

26 Furthermore, measures exist which are less restrictive of freedom of establishment but which would still enable biologists to retain independence in their decision-making, the objective that the provisions covered by the first complaint are intended to achieve.

27 The Commission also maintains that the regulations on biomedical analysis laboratories are inconsistent. Although the arrangements put in place by the provisions covered by the first complaint are based on the part played by the manager of the laboratory in his dual role as manager and as biologist, the actual presence of a biologist on the premises during the laboratory's opening hours is not compulsory. The Commission also states that the French authorities approve structures allowing

access to external capital in excess of the 25 % limit where the attendant financial rights are severed from the voting rights relating to decisions on the operation and organisation of the biomedical analysis laboratory concerned.

28 Although it informed the Commission during the pre-litigation procedure of its intention to bring an end to the restrictions on non-biologists holding shares, the French Republic maintains in its defence that the prohibition on a non-biologist holding more than 25 % of the shares, hence of the voting rights, in a SELARL operating biomedical analysis laboratories is compatible with Article 43 EC.

29 Referring to the central and key role played by medical biology in the healthcare system, the French Republic describes the three stages of biomedical testing: (i) the pre-analysis stage, during which medical staff meet the patient and take samples; (ii) the analysis stage, which is a purely technical stage during which analyses are carried out; and, lastly, (iii) the post-analysis stage, during which the results of the tests are validated in the light of the patient's medical record. The organisation of biomedical analysis in France — by contrast with other Member States, where the biologist's role is essentially purely technical — fully combines those three stages, reflecting the decision of the French authorities to accord a major medical role to biologists. Biologists, who are pharmacists (75 %) or doctors who have supplemented their initial training with specialist training in medical biology, also attend the pre-analysis stage, during which they meet the patient. Similarly, at the post-analysis stage, they validate the results, notify them to the patient and may also be involved, together with the patient's doctor, in the choice of treatment and, if appropriate, carry out further investigations depending on the results obtained.

30 The French Republic also states that, under Article 152(5) EC, action by the European Union in the field of public health must fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

31 Even if the provisions covered by the first complaint did constitute an obstacle to freedom of establishment, that obstacle would in any event be justified, according to the French Republic, on grounds of the overriding public interest in protecting public health. Those provisions apply without discrimination on grounds of nationality and are intended to ensure the independence of biologists by preventing the decisions they take from being motivated by economic considerations rather than by public health considerations. The provisions enable the objective sought to be attained, since the person with the majority shareholding in a laboratory inevitably influences the decisions that the biologists are likely to take regarding patients. The same provisions are also proportionate to that objective. If a biologist employed in a laboratory is required to follow the instructions of an employer who is not a biologist, there is a risk that he will be led to give priority to the economic interest of that laboratory over the requirements of public health.

32 The French Republic contends that the Court's reasoning in *Commission* v *Greece* with regard to the activity of opticians cannot be transposed to biomedical analysis laboratories. Unlike opticians' shops, such laboratories play a part in medical procedures and decision-taking which may involve risks for the health of patients.

33 According to the French Republic, in view of the specific characteristics of medical biology and the way in which that activity is orga nised in France, it is more appropriate in the present case to apply the principles laid down by the Court in Case C-531/06 *Commission* v *Italy* and in *Apothekerkammer des Saarlandes and Others*, relating to the pharmaceutical industry.

34 According to those judgments, a Member State may take the view, in the exercise of its discretion as to the level of protection which it wishes to afford to public health and the way in which that level is to be achieved, that, by contrast with a pharmacy operated by a pharmacist, the operation of a pharmacy by a non-pharmacist may pose a risk to public health, because the pursuit of profit through such an enterprise is not tempered by any moderating factors. By the same token, according to the French Republic, biologists play a part in medical procedures and decision-taking which may, like the dispensing of medicinal products by pharmacies, involve risks for public health.

35 The French Republic also contends that the Commission has not demonstrated how opening up the share capital of SELARLs operating biomedical analysis laboratories would inevitably lead such laboratories to amalgamate, a possibility which is not open under the provisions covered by the first complaint. What is more, the burden to the social security system of the cost of such analyses would not be affected by the structure within which the laboratories operate or by any economies of scale, because the size of that burden depends on the price set by the State for each biomedical test, which is the same for all laboratories, whatever the actual cost of the test carried out.

36 Moreover, the provisions covered by the first complaint are proportionate, since investors who are not biologists may still hold up to 25 % of the capital of a SELARL operating biomedical analysis laboratories. Within such a company, the most important decisions require a majority vote of the shareholders representing at least 75 % of the

shares. Accordingly, that 25 % holding allows a balance to be struck between compliance with freedom of establishment and the objective of preserving the independence of biologists.

37 Furthermore, the measures less restrictive of freedom of establishment to which the Commission refers are not adequate, according to the French Republic, for ensuring the level of protection of public health sought.

38 Lastly, with regard to the consistency of the regulations on biomedical analysis laboratories, the French Republic contends, inter alia, that the obligation on a biologist under Article L. 6221-9 of the Public Health Code to perform his duties in person means that he must be actually present in the laboratory.

39 With regard to the Commission's statement in its reply that the national authorities approve structures allowing access to external capital in excess of the 25 % limit where the attendant financial rights are severed from the voting rights relating to decisions on the operation and organisation of the biomedical analysis laboratory concerned, the French Republic explained at the hearing that that statement relates in reality to situations in which the French authorities treat legal persons managing biomedical analysis laboratories in other Member States in the same way as biologists having the status of a legal person under French law and thus allow them to have a majority shareholding in a SELARL operating laboratories in France.

Findings of the Court

— Preliminary observations

40 First of all, it should be noted that both the case-law of the Court and Article 152(5) EC make it clear that EU law does not detract from the power of the Member States to organise their social security systems and to adopt, in particular, provisions governing the organisation and provision of health services and medical care.

41 In exercising that power, however, the Member States must comply with EU law, in particular with the provisions of primary law relating to the freedoms of movement, including the freedom of establishment for the purposes of Article 43 EC. Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of those freedoms in the healthcare sector (see, to that effect, Case C-169/07 *Hartlauer* [2009] ECR I-1721, paragraph 29; Case C-531/06 *Commission* v *Italy*, paragraph 35; *Apothekerkammer des Saarlandes and Others*, paragraph 18; and Joined Cases C-570/07 and C-571/07 *Blanco Pérez and Chao Gómez* [2010] ECR I-4629, paragraph 43).

42 That being so, for the purposes of assessing whether that obligation has been complied with, account must be taken of the fact that the health and life of humans rank foremost among the assets and interests protected by the EC Treaty and that it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved. Since the level may vary from one Member State to another, Member States should be allowed a measure of discretion (see, to that effect, Case C-141/07 *Commission* v *Germany*

[2008] ECR I-6935, paragraph 51; *Apothekerkammer des Saarlandes and Others*, paragraph 19; and *Blanco Pérez and Chao Gómez*, paragraph 44).

43 It should therefore be considered whether the prohibition on a non-biologist holding more than 25 % of the shares, hence of the voting rights, in a SELARL operating biomedical analysis laboratories constitutes a restriction on freedom of establishment for the purposes of Article 43 EC and, if so, whether such a restriction can be justified.

— The existence of a restriction on freedom of establishment

44 According to settled case-law, Article 43 EC precludes any national measure which, albeit applicable without discrimination on grounds of nationality, is liable to hinder or render less attractive the exercise by citizens of the European Union of the freedom of establishment that is guaranteed by the Treaty (see, inter alia, Case C-299/02 *Commission* v *Netherlands* [2004] ECR I-9761, paragraph 15; *Commission* v *Greece*, paragraph 27; and Case C-531/06 *Commission* v *Italy*, paragraph 43).

45 In that context, it should be noted that the concept of 'restriction' as used in Article 43 EC covers measures taken by a Member State which, although applicable without distinction, affect access to the market for undertakings from other Member States and thereby hinder trade within the European Union (see, to that effect, Case C-442/02 *CaixaBank France* [2004] ECR I-8961, paragraph 12, and Case C-518/06 *Commission* v *Italy* [2009] ECR I-3491, paragraph 64).

46 First, it should be observed that, by prohibiting a non-biologist from holding more than 25 % of the shares, hence of the voting rights, in a SELARL operating biomedical analysis laboratories, the provisions covered by the first complaint restrict the possibility for natural or legal persons who are not biologists and are established in other Member States to hold capital in such a company.

47 Secondly, those provisions discourage — or even prevent — the establishment in France, in the form of SELARLs, of economic operators established in other Member States in which they operate laboratories which do not meet the criteria laid down in those provisions with regard to investment in share capital. The provisions covered by the first complaint thus have the effect of hindering and of rendering less attractive the exercise by those operators of their activities on French territory through a permanent establishment, and impair their access to the market in biomedical analyses.

48 Companies operating biomedical analysis laboratories which are established in other Member States and whose shares are held by non-biologists above the 25 % limit may be compelled, in order to become established in France in the form of SELARLs, to make internal adjustments to the way in which they usually regulate investment in their share capital.

49 It must therefore be held that the provisions covered by the first complaint constitute a restriction on freedom of establishment for the purposes of Article 43 EC.

— The justification for restricting freedom of establishment

50 According to well-established case-law, restrictions on freedom of establishment that are applicable without discrimination on grounds of nationality may be justified

by overriding reasons relating to the general interest, provided that the restrictions are appropriate for securing attainment of the objective pursued and do not go beyond what is necessary for attaining it (*Hartlauer*, paragraph 44; *Apothekerkammer des Saarlandes and Others*, paragraph 25; and *Blanco Pérez and Chao Gómez*, paragraph 61).

51 It should be noted at the outset that the provisions covered by the first complaint are applicable without discrimination on grounds of nationality.

52 In the first place, as the Court has recognised, the protection of public health is one of the reasons which can justify restrictions on the freedoms of movement guaranteed by the Treaty, such as the freedom of establishment (see to that effect, inter alia, *Hartlauer*, paragraph 46, and Case C-531/06 *Commission* v *Italy*, paragraph 51).

53 In that context, it is apparent from case-law that the aim of maintaining the quality of medical services may be covered by one of the exceptions provided for in Article 46 EC, in so far as it contributes to the attainment of a high level of health protection (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).

54 In the second place, it is also necessary that the provisions covered by the first complaint should be appropriate for securing attainment of such an objective.

55 In that regard, it is important to note that, where there is uncertainty as to the existence or extent of risks to human health, a Member State should be able to take

protective measures without having to wait until the reality of those risks becomes fully apparent. Furthermore, a Member State may take the measures which reduce, as far as possible, a risk to public health (see, to that effect, Case C-170/04 *Rosengren and Others* [2007] ECR I-4071, paragraph 49; Case C-531/06 *Commission* v *Italy*, paragraph 54; and *Blanco Pérez and Chao Gómez*, paragraph 74).

56 It is clear from the documents before the Court that the medical biology sector is special and that, as the French Republic maintains, it is at the forefront of healthcare. Likewise, it is common ground that, in France, a medical role has been assigned to biologists at the pre-analysis and post-analysis stages.

57 As the Advocate General stated in points 83 and 84 of his Opinion, just as the supply of the wrong medication to a customer by a pharmacist may have serious consequences, so a biomedical analysis that is performed in an inappropriate manner, or too late, or incorrectly, may result inter alia in wrong diagnosis or treatment. Also, in the same way as excess consumption or incorrect use of medication, the incorrect or inappropriate performance of biomedical analyses, from either the quantitative or qualitative point of view, may generate unnecessary costs for the social security system and, as a consequence, for the State.

58 It is apparent, therefore, that the incorrect or inappropriate performance of biomedical analyses poses a risk to public health comparable with the risk resulting from the inappropriate dispensing of medicinal products, which the Court had occasion to consider in Case C-531/06 *Commission* v *Italy* and in *Apothekerkammer des Saarlandes and Others*. On the other hand, the risk presented by the incorrect or

inappropriate dispensing of optical products, which was at issue in *Commission* v *Greece*, does not appear to be comparable. Although that may undoubtedly have adverse consequences for the patient, the Commission has not demonstrated that those are as serious as the effects liable to be brought about by the incorrect or inappropriate performance of biomedical analyses.

59 Those conclusions cannot be called in question by the Commission's argument that biomedical analyses are performed only on the basis of a medical prescription, which distinguishes them from medicinal products and provides a better safeguard in terms both of the protection of public health and of containing the costs for the health system

60 First, the French Republic stated at the hearing — and the point was not disputed by the Commission — that, like biomedical analyses, a significant majority of medicinal products are sold in pharmacies on medical prescription. Second, in Case C-531/06 *Commission* v *Italy* (paragraph 90) and *Apothekerkammer des Saarlandes and Others* (paragraph 60), the Court held 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. Thus, the existence of a prescription does not appear to prevent the risk for public health stemming from the incorrect or inappropriate dispensing of medicinal products.

61 The same applies in the case of biomedical analyses. It is clear from the explanations provided by the French Republic that, even if such analyses are covered by a medical prescription, the role of the biologist is significant in ensuring that the analysis requested is performed and interpreted correctly and that, accordingly, suitable treatments are chosen by the prescribing doctor on the basis of the results of that analysis. In that regard, it should also be noted that, under Article L. 6211-1 of the Public Health Code, in the version in force on the expiry of the time-limit set in the

reasoned opinion, biomedical analyses were being carried out, in the laboratories, under the responsibility of laboratory managers and assistant laboratory managers, who are biologists with responsibility for supervising the work of the laboratories. The importance of the role of biologists is further increased, first, because of the option open to patients, referred to by the French Republic, of going to a laboratory without a prescription in order to have certain biomedical analyses carried out and, second, by the dialogue which frequently exists in France between the prescribing doctor and the biologist, the latter being able, where necessary, to carry out further examinations to supplement the medical prescription.

62 As for the Commission's arguments, first, that, as compared with the pharmacy sector, the biomedical sector also has substantial financing needs, and, second, that the objective pursued by the provisions covered by the first complaint is not attained because they did not allow amalgamations to take place that would make it possible to achieve the investment needed in order to provide a quality service or economies of scale to be implemented which would have an effect on the cost of biomedical analyses and the ensuing burden on the social security system, are not really supported by the documents on which the Commission relies and are based purely on supposition.

63 The French Republic explained in that regard that the cost borne by the social security system for biomedical analyses depends essentially on the rate which the State decides to pay for each analysis, that rate being the same for all laboratories, irrespective of the actual cost of providing that service. The Commission has not demonstrated that there is a relationship between such payments and the rules on the holding of capital in companies operating biomedical analysis laboratories.

64 Clearly, therefore, the Commission has not demonstrated sufficiently that opening up the capital of such companies to external capital would, so far as the financing of biomedical analysis laboratories is concerned, lead to the positive effects that it claims.

65 Consequently, given the similarities, from the point of view of the risks to public health, between the pharmacy sector and the biomedical analysis sector and the fact that, contrary to the assertions made by the Commission, those two sectors cannot really be distinguished from one another, either from the point of view of the findings with regard to medical prescriptions or in terms of financing needs, the principles laid down in Case C-531/06 *Commission* v *Italy* and *Apothekerkammer des Saarlandes and Others*, concerning restrictions on the holding of capital in pharmacies, would appear to be fully transposable to the present case.

66 Thus, given the power afforded to the Member States to determine the level of protection that they wish to give to public health, it must be accepted that Member States may require that biomedical analyses be carried out by biologists enjoying genuine professional independence. They may also take measures for eliminating or reducing a risk that that independence might be compromised, because that in turn would be liable to have an adverse effect on public health and the quality of medical services (see, to that effect, Case C-531/06 *Commission* v *Italy* paragraph 59 and *Apothekerkammer des Saarlandes and Others*, paragraph 35).

67 By definition, non-biologists have no training, experience or responsibility equivalent to that of biologists. Accordingly, they do not provide the same safeguards as those provided by biologists (see, to that effect, Case C-531/06 *Commission* v *Italy*, paragraph 62, and *Apothekerkammer des Saarlandes and Others*, paragraph 38).

68 Consequently, a Member State may, in the exercise of its discretion as referred to in paragraph 42 above, take the view that non-biologists holding more than 25 % of shares and voting rights in such a company might represent a risk to public health and, in particular, to the quality of medical services. In that regard, it should be noted that, according to the explanations given by the French Republic, which were not challenged by the Commission, the most important decisions taken within a SELARL require a majority vote of the shareholders representing at least 75 % of the shares. It follows that, if more than 25 % of shares and voting rights were held by non-biologists, the latter could have a decisive influence over such decisions.

69 The Commission also maintains that the provisions covered by the first complaint do not allow the objective of protecting public health to be achieved owing to some inconsistencies in the way that objective is pursued. It notes in particular that the regulations on biomedical analysis laboratories do not require the actual presence of a biologist on the laboratory's premises during its opening hours and that the French authorities approve structures which allow access to external capital in excess of the 25 % limit where the attendant financial rights are severed from the voting rights relating to decisions on the operation and organisation of the laboratory.

70 In that regard, it is apparent from the case-law of the Court that national legislation is appropriate for securing attainment of the objective pursued only if it genuinely reflects a concern to attain that objective in a consistent and systematic manner (see Joined Cases C-338/04, C-359/04 and C-360/04 *Placanica and Others* [2007] ECR I-1891, paragraphs 53 and 58; *Hartlauer*, paragraph 55; and Case C-531/06 *Commission* v *Italy*, paragraph 66).

71 In the present case, although the regulations on biomedical analysis laboratories did not, at the date on which the time-limit set in the reasoned opinion expired, require

the constant presence of a biologist on the premises during the laboratory's opening hours, it did contain certain provisions, relied upon by the French Republic, which required *de facto* that the actual supervision of the work of the laboratories be carried out by laboratory managers and deputy managers, who are biologists with responsibility for such work.

72 As was pointed out in paragraph 61 above, Article L. 6211-1 of the Public Health Code provided that biomedical analyses could be carried out only in biomedical analysis laboratories, under the responsibility of the managers and assistant managers. The latter were also required, under Article L. 6221-9 of that code, actually to carry out their duties in person.

73 In view of those requirements, it cannot be held that the regulations on biomedical analysis laboratories do not comply with the declared objective of protecting public health in a consistent and systematic manner solely on the ground that they do not require the constant presence of a biologist on the premises during the laboratory's opening hours.

74 Nor is there support for a finding that the regulations are inconsistent in the argument raised by the Commission in its reply, to the effect that there are situations in which the 25% limit on non-biologists holding capital is *de facto* circumvented by means of mechanisms for severing voting rights from the size of a financial holding.

75 It is apparent from the explanations given by the French Republic at the hearing that these are in reality situations in which the French authorities treat legal persons

managing biomedical analysis laboratories in other Member States in the same way as biologists having the status of a legal person under French law and thus allow them to have a majority shareholding in a SELARL operating laboratories in France. It is also apparent from those explanations that, although at least 75% of the capital of such a SELARL must be held by biologists, those 'biologists' may be either natural persons or legal persons deemed to be biologists. In so far as the regulations on biomedical analysis laboratories also allow companies to engage in the work of biologists, the French authorities, by authorising legal persons managing biomedical analysis laboratories in other Member States to hold more than 25% of the shares and voting rights in a SELARL operating biomedical analysis laboratories, are merely granting such legal persons the same rights as those afforded to biologists with the status of legal persons under French law. As the French Republic explained, it is thus merely complying with EU law.

76 The fact that the majority, or even all, of the capital of legal persons operating biomedical analysis laboratories in other Member States where there are no limits on the shareholding of non-biologists may be held by non-biologists, such as financial investors, is not sufficient for the conclusion to be drawn that the regulations on biomedical analysis laboratories are inconsistent. Such legal persons validly engage in the activity of biologist in those Member States and may therefore be treated as biologists having the status of legal persons under French law.

77 The French Republic also stated at the hearing that although, in certain cases, the regulations on biomedical analysis laboratories allow, in respect of types of company other than SELARLs, the holding of voting rights to be severed from the holding of shares, provision is made for that possibility only in order to enable biologists who do not practise their profession in biomedical analysis laboratories operated by such

companies to hold a majority share in their capital. Consequently that is a rule, specific to other types of companies permitted to operate biomedical analysis laboratories, which concerns the relation between biologists working in those laboratories and those not working in them and which does not call into question the 25 % limit on non-biologists' shareholdings.

78 Lastly, it should be noted that, in response to a question put to it at the hearing, the French Republic stated that the only type of company that may operate biomedical analysis laboratories in which non-biologists are permitted to hold in excess of 25 % of the capital is a limited partnership. Non-biologists may hold up to 49 % of the capital in such an undertaking. That fact, which was not raised by the Commission, does not appear per se to demonstrate that the regulations on biomedical analysis laboratories are inconsistent, and can be explained by the difference between the procedural rules of SELARLs and those of limited partnerships. The French Republic stated — and was not challenged on this point by the Commission — that, in any event, the highly specific procedural rules of limited partnerships make it possible for biologists to retain control over decisions which are important for such undertakings.

79 In the light of all the above, it must be held that the provisions covered by the first complaint are appropriate for securing attainment of the declared objective of protecting public health.

80 Thirdly and lastly, it is necessary to consider whether the restriction on freedom of establishment for the purposes of Article 43 EC does not go beyond what is necessary for attaining that objective, that is to say, whether there are not measures which are less restrictive of that freedom that would permit those objectives to be attained just as effectively.

81 In that regard, the Commission maintains that that objective could be attained by less restrictive measures, such as the requirement that biomedical analyses be carried out by competent staff who have the necessary qualifications and who, by virtue of their code of professional ethics, are bound by the principle of independence of healthcare professionals. It also refers to the provision made in the regulations on biomedical analysis laboratories for: certain activities to be treated as incompatible, in order to prevent conflicts of interest; the requirement for technical and high-quality management; and the requirement for the performance of biomedical analyses to be monitored by doctors and pharmacists who are public health inspectors. Additionally, the Commission mentions the possibility of envisaging the introduction of mechanisms for severing voting rights from financial rights.

82 However, given the discretion which the Member States are allowed, as referred to in paragraph 42 above, a Member State may take the view that there is a risk that rules designed to ensure the professional independence of biologists would not be observed in practice, given that the interest of a non-biologist in making a profit would not be tempered in the same way as that of self-employed biologists and that, if biologists, as employees, were in a subordinate position with respect to a SELARL operating biomedical analysis laboratories in which non-biologists held the majority of shares, that could make it difficult for them to oppose instructions given by those non-biologists (see, to that effect, Case C-531/06 *Commission* v *Italy*, paragraph 84, and *Apothekerkammer des Saarlandes and Others*, paragraph 54). As the French Republic points out, it cannot be excluded, inter alia, that such non-biologists would be tempted to refuse to carry out tests that were less profitable or more complicated to perform, or to cut down on the advice given with regard to patients at the pre-analysis and post-analysis stages, the existence of which is a feature of the organisation of medical biology in France.

83 The Commission has not shown that the risks for the independence of the profession of biologist could be removed with the same degree of effectiveness by incompatibility rules such as the prohibition, laid down in the regulations on biomedical analysis laboratories in order to prevent conflicts of interest, on holding any shares in

the capital of SELARLs operating biomedical analysis laboratories, which applies to specific categories of natural or legal persons, in particular those engaged in another healthcare profession or in supplying equipment for biomedical analyses. As the Advocate General observed in points 178 and 179 of his Opinion, such prohibitions are appropriate for situations in which it is simply a matter of preventing another interest from having an abnormal influence on the activity of a SELARL operating biomedical analysis laboratories. However, such prohibitions do not appear adequate where it is necessary to ensure that decisions taken by the biologists are truly independent in every case, even where there is no conflict of interests of the kind that has already been formally identified as such by the rules on biomedical analysis laboratories.

84 Although technical and high-quality management, as well as the monitoring of the performance of biomedical analyses by doctors and pharmacists who are public health inspectors, are mechanisms designed to ensure that biomedical analysis is carried out by persons with adequate training and technical expertise, and an appropriately high level of experience, the Commission has also not shown that those factors by themselves are likely to ensure the independence of biologists in their decision-making.

85 As regards the possibility, also suggested by the Commission as a less restrictive measure, of envisaging the introduction of mechanisms for severing voting rights from financial rights, which would ensure that decisions on the rules for the operation and organisation of biomedical analysis laboratories were taken by biologists, the French Republic stated at the hearing that it would be wrong to underestimate the pressure that third-party majority shareholders could exert on the biologists practising in laboratories.

86 Given the discretion which the Member States are allowed, as referred to in paragraph 42 above, it does not appear unacceptable for a Member State to consider that the independence in decision-making enjoyed by biologists who held the majority of voting rights in a company operating biomedical analysis laboratories, but not the majority of its capital, would be insufficiently ensured. As the Advocate General noted in point 220 of his Opinion, it is not inconceivable that decisions about financial investment or disinvestment taken by minority shareholders holding no more than 25% of the voting rights could influence, albeit indirectly, decisions taken by the various bodies of a company.

87 Accordingly, it has not been established that less restrictive measures would be sufficient to ensure as effectively the level of protection of public health sought.

88 According to the documents before the Court, moreover, the choice made by the French Republic to restrict to 25% the shares and voting rights that may be held by non-biologists within SELARLs operating biomedical analysis laboratories was based, in particular, on the fact that the most important decisions taken within such companies require a majority vote of the shareholders representing at least 75% of the shares. The holding of capital and voting rights by non-biologists is thus possible only where the latter can have no influence over such decisions. Consequently, the provisions covered by the first complaint also appear proportionate to the objective pursued, since, whilst ensuring that biologists retain independence in their decision-making, they allow SELARLs operating biomedical analysis laboratories to have a degree of access to external capital up to the limit of 25% of their capital.

89 It follows that the provisions covered by the first complaint do not go beyond what is necessary for attaining the objective they pursue. It must therefore be accepted that the restrictions flowing from those provisions can be justified by that objective.

90 In view of all the foregoing, the first complaint in the Commission's application must be rejected as unfounded.

The second complaint

Arguments of the parties

91 The Commission claims that the prohibition on the holding of capital in more than two companies formed for the purpose of operating jointly one or more biomedical analysis laboratories, laid down in Article 10 of Decree No 92-545 ('the provision covered by the second complaint'), constitutes an unjustified restriction on freedom of establishment.

92 Whilst the Commission had stated that that prohibition related both to biologists and to non-biologists, the French Republic stated at the hearing that the prohibition in reality concerned only biologists, since non-biologists could hold shares in an indefinite number of companies formed for the purpose of operating jointly one or more biomedical analysis laboratories, provided it was within the limit of 25 % of the shares and voting rights of each company in the case of SELARLs.

93 The French Republic does not challenge this complaint in its defence, since the provision covered by the second complaint does not appear to it to be justified by the protection of public health.

94 In its rejoinder, the French Republic stated that it had not intended to accept that a prohibition such as that laid down in the provision covered by the second complaint cannot in any circumstances be justified in the light of the objective of protecting public health, since a Member State is entitled to consider that diversity of supply should be ensured in the biomedical field.

95 The French Republic also stated in its rejoinder that it envisaged amending that provision, since it considered the latter to be both inadequate and disproportionate.

96 Thus, the French Republic did not contend that the action should be dismissed in so far as it is based on the second complaint. The French Republic confirmed at the hearing, moreover, that it did not challenge that complaint and stated that that provision was no longer applicable following the adoption of Order No 2010-49.

Findings of the Court

97 First, although the Commission's complaint as originally worded seems to refer to a general prohibition, it appears, in the light of the literal wording of Article 10 of Decree No 92-545, and of the clarifications provided by the French Republic at the hearing,

which were not materially challenged by the Commission, that the prohibition laid down in the provision covered by the second complaint relates only to biologists.

98 Moreover, it is common ground in the present case that, at the end of the period laid down in the reasoned opinion, the prohibition on a biologist holding shares in more than two companies formed for the purpose of operating jointly one or more biomedical analysis laboratories, as laid down in Article 10 of Decree No 92-545, was still applicable.

99 By limiting the number of such companies in which biologists may hold shares, that prohibition has the effect of hindering or rendering less attractive the exercise by biologists of their freedom of establishment.

100 It must therefore be held that the provision covered by the second complaint constitutes a restriction on freedom of establishment for the purposes of Article 43 EC.

101 In the present case, the French Republic has not contended that the provision covered by the second complaint is justified by the objective of protecting public health. It appears that the French Republic regards that provision as inadequate and disproportionate in relation to that objective.

102 In those circumstances, the Commission's second complaint must be held to be well founded.

103 It must therefore be held that, by prohibiting biologists from holding shares in more than two companies formed in order to operate jointly one or more biomedical analysis laboratories, the French Republic has failed to fulfil its obligations under Article 43 EC.

104 The application must be dismissed as to the remainder.

Costs

105 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. Under Article 69(3) of those rules, inter alia where each party succeeds on some and fails on other heads, the Court may order that the costs be shared or that the parties bear their own costs.

106 In the present case, the Commission has applied for an order for costs against the French Republic and the latter has applied for each of the parties to bear its own costs.

107 In those circumstances, since the Commission's application has been upheld only in part, each party must be ordered to bear its own costs.

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

1. **Declares that, by prohibiting biologists from holding shares in more than two companies formed in order to operate jointly one or more biomedical analysis laboratories, the French Republic has failed to fulfil its obligations under Article 43 EC.**

2. **Dismisses the action as to the remainder.**

3. **Orders the French Republic and the European Commission to bear their own costs.**

[Signatures]