ORDER OF THE COURT OF FIRST INSTANCE
(Fifth Chamber, Extended Composition)
3 June 1997 *

In Case T-60/96,

Merck & Co. Inc., a company governed by the law of the State of New Jersey, established at Whitehouse Station, New Jersey (United States of America),

NV Organon, a company governed by Netherlands law, established at Oss (Netherlands),

Glaxo Wellcome plc, a company governed by English law, established at Greenford (United Kingdom),

represented by Romano Subiotto, Solicitor, and Mario Siragusa, of the Rome Bar, with an address for service in Luxembourg at the Chambers of Elvinger & Hoss, 15 Côte d'Eich,

applicants,

v

Commission of the European Communities, represented by Richard Wainwright and Fernando Castillo de la Torre, of its Legal Service, acting as Agents, with an address for service in Luxembourg at the office of Carlos Gómez de la Cruz, of its Legal Service, Wagner Centre, Kirchberg,

defendant,

* Language of the case: English.

APPLICATION for annulment of Commission Decisions C(95)3316 final/1, C(95)3316 final/2 and C(95)3316 def./2, K(95)3316 endg./3, K(95)3316 endg./4, K(95)3316 endelig. udg./5, C(95)3316 final/6 and C(95)3316 final/7 of 20 December 1995 refusing the authorization sought, respectively, by France, Belgium, Germany, Austria, Denmark, Ireland and the United Kingdom to take protective measures with regard to pharmaceutical products coming from Spain,

THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES
(Fifth Chamber, Extended Composition),

composed of: R. García-Valdecasas, President, V. Tiili, J. Azizi, R. M. Moura Ramos and M. Jaeger, Judges,

Registrar: H. Jung,

makes the following

Order

Facts

1 This application is for annulment of Commission Decisions C(95)3316 final/1, C(95)3316 final/2 and C(95)3316 def./2, K(95)3316 endg./3, K(95)3316 endg./4, K(95)3316 endelig. udg./5, C(95)3316 final/6 and C(95)3316 final/7 of 20 December 1995 refusing the authorization sought, respectively, by France, Belgium, Germany, Austria, Denmark, Ireland and the United Kingdom to take protective

measures with regard to pharmaceutical products coming from Spain (hereinafter 'the contested Decisions') pursuant to Article 379 of the Act concerning the conditions of accession of the Kingdom of Spain and the Portuguese Republic, annexed to the Treaty concerning the accession of the Kingdom of Spain and the Portuguese Republic to the European Economic Community, signed on 12 June 1985 (OJ 1985 L 302, p. 9, hereinafter 'the Act of Accession of Spain and Portugal').

2 The addressees of the seven contested Decisions are the Member States listed above. They applied for authorization to take protective measures pursuant to Article 379 of the Act of Accession of Spain and Portugal following the expiry, on 6 October 1995, of the transitional period laid down by Article 47 of that Act.

3 The applicants are three manufacturers of pharmaceutical products, Merck & Co. Inc., a company governed by the law of the State of New Jersey, NV Organon, a company governed by Netherlands law, and Glaxo Wellcome plc, a company governed by English law.

4 On 22 February 1996 Merck & Co. Inc. received a copy of the contested Decisions in the course of a reference to the Court of Justice for a preliminary ruling (Case C-267/95 *Merck and Others*).

5 In addition to a question relating to the expiry date of the transitional period laid down in Article 47 of the Act of Accession of Spain and Portugal, that case concerned — like the parallel Case C-268/95 *Beecham* — the question whether, in view of altered circumstances or other considerations, the Court of Justice should reconsider or amend the principles it had laid down in its judgment of 14 July 1981 in Case 187/80 *Merck* v *Stephar and Exler* [1981] ECR 2063 (hereinafter '*Merck* v *Stephar*'). Thus the national court asked whether Articles 30 and 36 of the Treaty preclude application of national legislation which grants the holder of a patent for a pharmaceutical product the right to oppose importation by a third party of that product from another Member State in circumstances where the holder first put

the product on the market in that State after the latter's accession to the European Community, but before the product could be protected by a patent in that State.

Legislative background

6 Article 47(1) of the Act of Accession of Spain and Portugal provides that 'notwithstanding Article 42, the holder, or his beneficiary, of a patent for a chemical or pharmaceutical product or a product relating to plant health, filed in a Member State at a time when a product patent could not be obtained in Spain for that product may rely upon the rights granted by that patent in order to prevent the import and marketing of that product in the present Member State or States where that product enjoys patent protection even if that product was put on the market in Spain for the first time by him or with his consent'.

7 Under Article 47(2), that right may be invoked until the end of the third year after Spain has made those products patentable.

8 Thus Article 47 of the Act of Accession of Spain and Portugal essentially provides, by way of derogation from Article 42 thereof, that the rule laid down in *Merck* v *Stephar* does not apply to pharmaceutical products during a particular transitional period. Article 42 of that Act, by implied reference to Articles 30 and 34 of the Treaty, abolishes with effect from 1 January 1986 quantitative restrictions on imports and exports and any measures having equivalent effect existing between the Community and Spain.

9 Protocol No 8 to the Act of Accession of Spain and Portugal, on Spanish patents, requires the Kingdom of Spain to adjust its patent law so as to make it compatible with the level of protection of industrial property attained in the Community. For that purpose, it provides that Spain must, by 7 October 1992 at the latest, accede to the Munich Convention of 5 October 1973 on the European patent and make provision in its domestic legislation for pharmaceutical products to be patentable. By Law No 11/1986 of 20 March 1986 on patents, Spain made pharmaceutical products patentable as from 7 October 1992. By judgment of 5 December 1996 in Joined Cases C-267/95 and C-268/95 *Merck and Others* [1996] ECR I-6285, the Court of Justice confirmed that the transitional period provided for in Article 47(2) of the Act of Accession expired on 6 October 1995.

10 Article 379 of the Act of Accession of Spain and Portugal provides as follows:

'1. If, before 31 December 1992, difficulties arise which are serious and liable to persist in any sector of the economy or which could bring about serious deterioration in the economic situation of a given area, a new Member State may apply for authorization to take protective measures in order to rectify the situation and adjust the sector concerned to the economy of the common market.

In the same circumstances, any present Member State may apply for authorization to take protective measures with regard to one or both of the new Member States.

This provision shall apply until 31 December 1995 for products or sectors in respect of which this Act allows transitional derogations of equivalent duration.

2. On application by the State concerned, the Commission shall, by emergency procedures, determine the protective measures which it considers necessary specifying the circumstances and the manner in which they are to be put into effect.

In the event of serious economic difficulties and at the express request of the Member State concerned, the Commission shall act within five working days of the receipt of the request, accompanied by the relevant background information. The measures thus decided on shall be applicable forthwith.

[...]

3. The measures authorized under paragraph 2 may involve derogations from the rules of the EEC Treaty [...] and of this Act to such an extent and for such periods as are strictly necessary in order to attain the objectives referred to in paragraph 1. Priority shall be given to such measures as will least disturb the functioning of the common market.

[...]'

11 In each of the contested Decisions (see paragraph 1 above), the first recital in the preamble states that the Member State concerned has sought from the Commission authorization to apply Article 379 of the Act of Accession of Spain and Portugal in order to take protective measures prohibiting the importation to that Member State of pharmaceutical products from Spain, which are protected by a product patent in the Member State concerned but not in Spain.

12 According to the contested Decisions (fourth recital in each preamble), Article 379 of the Act of Accession derogates from a fundamental principle of the Treaty, namely the free movement of goods and, therefore, in accordance with the well-established case-law of the Court of Justice, it must be strictly construed. The contested Decisions (fifth recital in each preamble) state that, consequently, in accordance with that case-law and with the established practice of the Commission in the past, Article 379 cannot apply.

13 The Commission states in the contested Decisions (sixth recital in each preamble) that the purpose of Article 379 is to rectify and adjust to the economy of the common market a given economic sector experiencing economic difficulties which are serious and liable to persist, and it concludes (seventh recital in each preamble) that an analysis of the economic data provided in support of the applications for protective measures shows that the conditions for the application of Article 379 are not fulfilled.

14 Article 1 of the Decisions addressed to France and Belgium rejects the application for protective measures made by the addressee Member State in the following words: 'The application for safeguard measures made by [the Member State concerned] under Article 379 of the Act of Accession, aimed at refusing the importation [to the Member State concerned] of pharmaceutical products from Spain which are protected by patent [in the Member State concerned] but not in Spain, is rejected.' Article 1 of the Decisions addressed to Denmark, Ireland and the United Kingdom rejects the application for protective measures in similar terms, specifying that the measures sought aimed at 'solving the problem caused by the expiry of the transitional period provided for by Article 47 of the Act of Accession'. Article 1 of the Decisions addressed to Germany and Austria is similarly framed, but specifies that the measures sought were 'to extend the transitional period prescribed by Article 47 of the Act of Accession'.

15 The applicants effectively submit that, since on average ten years elapse between the moment when the molecules are patented and the date on which the pharmaceutical product containing the molecules is put on the market, products patented

in Spain are not expected to be put on the market until about the year 2002. Consequently, so far as concerns pharmaceutical products from Spain, there is a need to adopt protective measures in derogation from the principle of the free movement of goods, until 2002.

Procedure and forms of order sought

16 The application was registered at the Court of First Instance on 29 April 1996. On 3 July 1996 the Commission raised an objection as to admissibility pursuant to Article 114(1) of the Rules of Procedure. The applicants lodged their observations on 19 August 1996.

17 In their application, the applicants claim that the Court should:

— annul the contested Decisions;

— declare that the Commission must fulfil its obligations under Article 176 of the Treaty, in particular by replacing the contested Decisions with effect from the date on which they were adopted, despite the expiry of the transitional period provided for in Article 379 of the Act of Accession of Spain and Portugal;

— order the Commission to pay the costs.

18 The Commission, in its objection as to admissibility, claims that the Court should:

— declare the application inadmissible;

— order the applicants to pay the costs.

19 On 6 September 1996, 3 October 1996 and 9 October 1996, three associations of importers of pharmaceutical products — the Bundesverband der Arzneimittel-Importeure e. V., the Asociación de Exportadores Españoles de Productos Farmacéuticos and the Vereniging Euro Specialités — applied for leave to intervene in support of the form of order sought by the Commission. The parties raised no objections in respect of those applications.

Admissibility

Arguments of the parties

20 The applicants do not deny that the contested Decisions were of general application. Nevertheless, they maintain that a measure of general application may also be of individual concern to certain traders (see Case C-309/89 *Codorniu* v *Council* [1994] ECR I-1853, paragraph 19).

21 The applicants maintain that the contested Decisions adversely affect their economic position, given the scale on which they are engaged in the research and development of new products. As a result of the contested Decisions, the effective patent life of their products will be considerably reduced. They point out that in Community case-law the seriousness of the consequences which a measure has for

a particular undertaking is considered to distinguish that undertaking individually (*Codorniu*, cited above, and Case C-358/89 *Extramet Industrie* v *Council* [1991] ECR I-2501, paragraph 17).

22 The applicants argue that it is possible to distinguish a restricted category of pharmaceuticals manufacturers to whom the contested Decisions are of individual concern, namely those who sell their products in Spain and in other Member States, and whose products sold in Spain are protected by patent in other Member States, in particular in the States to which the contested Decisions are addressed. The fact that these manufacturers are not in a position to withdraw their products from the Spanish market further identifies them as a 'restricted category'. The applicants refer to paragraphs 112 and 113 of the Opinion of Advocate General Fennelly in the *Merck and Beecham* cases, cited above, in which he describes the significant commercial damage which a decision of this nature can entail for manufacturers similarly placed.

23 The applicants maintain that, before taking a decision as to whether the adoption of protective measures was appropriate, the Commission was under a duty to take their interests into account, a fact which distinguishes them individually in relation to the contested Decisions (Case 11/82 *Piraiki-Patraiki and Others* v *Commission* [1985] ECR 207 and Joined Cases T-480/93 and T-483/93 *Antillean Rice Mills and Others* v *Commission* [1995] ECR II-2305). They argue that the wording and purpose of Article 379(3) of the Act of Accession of Spain and Portugal are identical to those of Article 130(3) of the Act concerning the conditions of accession of the Hellenic Republic, annexed to the Treaty concerning the accession of the Hellenic Republic to the European Economic Community, signed on 28 May 1979 (OJ 1979 L 291, p. 9, hereinafter 'the Act of Accession of Greece'), and that in its judgment in *Piraiki-Patraiki*, the Court of Justice interpreted the latter provision as requiring the Commission to take account also of the interests and particular situation of undertakings likely to be affected by protective measures adopted on the basis of Article 130(3).

24 The applicants also argue that a further distinguishing factor is to be found in their contacts, both direct and indirect — via the European Federation of Pharmaceutical Industries Associations (EFPIA) — with the Commission, their participation in the administrative procedure leading to the adoption of the contested Decisions, and the fact that the economic information provided by the United Kingdom and Ireland in support of their applications for protective measures included data on the applicant companies, in particular their names, turnover, and the patents which they hold, thus enabling the Commission to ascertain their economic position and identity. In the applicants' view, although this may not serve to distinguish particular undertakings in the context of the adoption of a regulation, it is enough to distinguish them in the context of the adoption of a decision.

25 One of the applicants, Merck, also claims to have been differentiated from all other manufacturers of pharmaceutical products by virtue of its participation in the proceedings before the national court which raised the questions on which the Court of Justice gave a preliminary ruling in the *Merck and Beecham* cases, cited above.

26 The applicants maintain that, even supposing that none of the factors cited above, considered in isolation, is sufficient to distinguish the applicant companies individually in relation to the Decisions, that is nevertheless the effect produced if all those factors are taken together.

27 Lastly, the applicants deny that a finding that their application is admissible would be tantamount to granting a virtually unlimited number of undertakings the right to contest a decision of general application, thus setting a precedent inviting abuse of procedure of the kind alluded to by the Court of First Instance in Case T-398/94 *Kahn Scheepvaart* v *Commission* [1996] ECR II-477, paragraph 50.

28 The Commission contends that the contested Decisions are of general application in relation to all persons other than the Member States addressed.

29 The contested Decisions entail legal effects for categories of persons viewed in a general and abstract manner. The Court of Justice has consistently held (Case 231/82 *Spijker* v *Commission* [1983] ECR 2559, paragraph 9) that such measures are not of individual concern to the persons affected.

30 However, should the Court consider that the general nature of a measure does not preclude the possibility that it may be of individual concern to persons affected, the Commission contends that, in any event, the contested Decisions are not of individual concern to the applicants.

31 The Commission challenges the applicants' argument based on the judgments in the *Codorniu* and *Extramet Industrie* cases, cited above. In contrast with the situation in those two cases, the adoption of the contested Decisions did not prevent the performance of certain contracts or the enforcement of certain previous specific rights. Nor were the applicants deprived of any specific right whatsoever, since they are not entitled to an extension of the derogation provided for by Article 47 of the Act of Accession of Spain and Portugal, and the expiry of the transitional period laid down therein will not deprive them of their patent rights in the other Member States of the European Communities.

32 The Commission contends that the applicants base their assertion as to the existence of a limited class of pharmaceuticals manufacturers on the fact that the contested Decisions are likely to have an adverse effect on their economic position. That cannot suffice to allow traders to be regarded as individually and directly concerned, in the absence of specific circumstances which distinguish them individually (Case T-32/93 *Ladbroke* v *Commission* [1994] ECR II-1015, paragraph 41).

33 As regards the applicants' argument based on the judgments in the *Piraiki-Patraiki* and *Antillean Rice Mills* cases, cited above, and the fact that the wording of Article 379 of the Act of Accession of Spain and Portugal is identical to that of Article 130 of the Act of Accession of Greece, the Commission points out that, according to those judgments, its duty to take into account the interests of the undertakings concerned in those cases was predicated on the existence of circumstances which differentiated those undertakings from all other traders.

34 The Commission also challenges the applicants' arguments based on their participation in the procedure leading to the adoption of the contested Decisions. Such participation would have distinguished them individually in relation to those Decisions only if the Commission had been required to hear their views. According to the Commission, none of the relevant provisions in the Act of Accession of Spain and Portugal requires the Commission, prior to the adoption of a measure such as the contested Decisions, to follow a procedure in which persons in a category corresponding to that of the applicants have the right to be heard.

35 Lastly, the Commission rejects the argument drawn by Merck from the fact that it was party to the proceedings before the national courts which gave rise to the ruling of 5 December 1996 in the *Merck and Beecham* cases. According to the Commission, for Merck thereby to be distinguished individually in relation to the contested Decisions, that circumstance would have to have some relevance in the context of the adoption of those decisions, that is to say, there would have to be a link between the contested measures and the fact that Merck was party to those domestic proceedings.

36 The Commission concludes that the applicants are not individually concerned by the contested Decisions; those Decisions concern them merely in their objective capacity as manufacturers of pharmaceutical products, in the same way as any other trader on the same market.

Findings of the Court

37 Article 114 of the Rules of Procedure provides that, at the request of one of the parties, the Court may, in accordance with the conditions laid down in Article 114(3) and (4), rule on the admissibility of an application without considering the substance of the case. In the present case the Court considers that, since it has sufficient information from an examination of the documents before it, it is not necessary to open the oral procedure.

38 The fourth paragraph of Article 173 of the Treaty provides that 'any natural or legal person may [...] institute proceedings against [...] a decision which, although in the form of a regulation or a decision addressed to another person, is of direct and individual concern to the former'.

39 It is settled law that the adoption of protective measures in the form of decisions addressed to the Member States is a legislative measure in relation to the undertakings concerned (order of the Court of First Instance of 21 February 1995 in Case T-117/94 *Associazione Agricoltori della Provincia di Rovigo and Others* v *Commission* [1995] ECR II-455, paragraphs 23 to 25, *Antillean Rice Mills*, cited above, paragraphs 180 to 186, Joined Cases T-481/93 and T-484/93 *Exporteurs in Levende Varkens and Others* v *Commission* [1995] ECR II-2941, paragraphs 87 and 88, and *Kahn Scheepvaart*, cited above, paragraph 39). A decision refusing to allow the adoption of such measures is equally of general application in relation to the undertakings concerned.

40 Both the Court of Justice and the Court of First Instance have consistently held that, in certain circumstances, even a measure which is legislative in character by virtue of its being generally applicable to the traders concerned, may nevertheless be of individual concern to some of them (*Extramet Industrie*, cited above, paragraphs 13 and 14, and *Codorniu*, cited above, paragraph 19; order of the Court of First Instance of 11 January 1995 in Case T-116/94 *Cassa Nazionale di Previdenza ed Assistenza a favore degli Avvocati e Procuratori* v *Council* [1995] ECR II-1, paragraph 26; *Exporteurs in Levende Varkens*, cited above, paragraph 50). Thus it

is possible in such cases for a Community measure to be of a legislative character while at the same time being in the nature of a decision *vis-à-vis* some of the traders affected.

41 However, natural or legal persons cannot claim to be individually concerned unless they are adversely affected by the measure in question by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons (Case 25/62 *Plaumann* v *Commission* [1963] ECR 95, 107, and *Cordorniu*, cited above, paragraph 20; Case T-12/93 *CCE de Vittel and Others* v *Commission* [1995] ECR II-1247, paragraph 36, and *Exporteurs in Levende Varkens*, cited above, paragraph 51).

42 Consequently, it is necessary to determine whether the applicants in the present case are affected by the contested Decisions by reason of certain attributes which are peculiar to them, or whether circumstances exist by reason of which they are differentiated from all other traders in relation to the contested Decisions.

43 The applicants maintain that the contested Decisions adversely affect their economic position in that they will bring about a considerable reduction in the effective patent life of their products, a circumstance which differentiates the applicants from all other traders in relation to the contested Decisions.

44 The first point to note in this regard is that although the contested Decisions, in so far as they reject the adoption of protective measures, have the effect of maintaining the existing situation regarding a possible reduction in the patent life of the applicants' products, it is equally certain that they do not alter any pre-existing right of the patent holder.

45 The extent of the protection conferred on patent holders is determined by the combined application of Articles 30 and 36 of the Treaty, as interpreted by the Court of Justice, notably in *Merck* v *Stephar*, cited above. According to that case-law, the substance of the right on which the patent holder may rely lies essentially in according him an exclusive right to put the product on the market for the first time, including the possibility of releasing it in a Member State where the law does not provide patent protection for the product in question (*Merck* v *Stephar*, cited above, paragraphs 9 and 10). If the patent holder decides to do this, he must then accept the consequences of his choice as regards the free movement of the product within the common market and, in particular, the fact that he cannot rely on a patent held in one Member State in order to prevent the importation of the product marketed freely by him in another Member State where that product was not patentable (*Merck* v *Stephar*, cited above, paragraphs 11 and 13). As the Court of Justice pointed out in paragraph 38 of the judgment in the *Merck and Beecham* cases, cited above, it is in the light of this case-law that the transitional measures provided for by Article 47 of the Act of Accession of Spain and Portugal were adopted.

46 Accordingly, the right which the applicants derive from their status of patent holders does not include an entitlement to rely on the patent in order to prevent the importation of pharmaceutical products from Spain after the transitional period has expired.

47 It is important to bear in mind that Article 47 of the Act of Accession of Spain and Portugal introduces a derogation from the principle of the free movement of goods and that it is settled case-law that such derogations must be strictly construed (see Case C-191/90 *Generics and Harris Pharmaceuticals* v *Smith Kline and French Laboratories* [1992] ECR I-5335, paragraph 41, and *Merck and Beecham*, cited above, paragraph 23).

48 This provision must therefore be interpreted to the effect that the transitional period provided for therein expires on the date which ensures the earliest application, in the field concerned, of the principle of the free movement of goods in Spain (*Merck and Beecham*, cited above, paragraph 24).

49 It should also be remembered that by 26 March 1986 — the date of promulgation of Spanish Law No 11/86 of 20 March 1986 on patents, which provides that pharmaceutical products are to be patentable as from 7 October 1992 — the traders concerned were well aware that the transitional period would expire at the end of the third year after that last date.

50 In those circumstances, the applicants' argument based on *Codorniu*, cited above, cannot be accepted. The applicants may not claim any right to the prolongation of a situation which is limited in time in that it is linked to the expiry of a specific time-limit and based on a transitional derogation from a fundamental principle of the internal market, such as the free movement of goods.

51 Consequently, the fact that the applicants' economic position has been impaired because the situation brought about by the transitional period provided for in Article 47 of the Act of Accession of Spain and Portugal has come to an end is not enough to differentiate them, in relation to the contested Decisions, from all other traders.

52 Furthermore, the applicants have not established that their actual position is analogous to that of the applicant in *Extramet Industrie*, cited above, which was the main importer, end user and principal competitor of the sole Community producer of the product covered by the anti-dumping Regulation contested in that case. Accordingly, the applicants' argument based on that judgment cannot be accepted either.

53 Merck argues that the fact that it was party to the proceedings before the national courts which led to the ruling of 5 December 1996 in *Merck and Beecham*, distinguishes it individually in relation to the contested Decisions.

54 It should be borne in mind that the questions on which the Court of Justice was asked to give a preliminary ruling concerned not only the duration of the transitional arrangement provided for in the Act of Accession of Spain and Portugal but also the question whether the principle of the exhaustion of patent rights, as laid down by the Court of Justice in *Merck* v *Stephar*, cited above, had to be reconsidered in view of the particular circumstances referred to in the order for reference (*Merck and Beecham*, cited above, paragraph 14).

55 Apart from the fact that, in the present case, the subject-matter and purpose of the domestic proceedings leading to the ruling in *Merck and Beecham*, cited above, are different from those of the contested Decisions, the Court considers that the status of being a party to proceedings before the national courts in the course of which questions are raised which are linked to those concerning the validity of a measure contested before the Community judicature, is not sufficient in itself to distinguish the applicant individually in relation to that measure, since all traders in the same category as the applicant are entitled to bring an action before the national courts raising the same questions.

56 That argument must therefore be rejected.

57 The applicants maintain that they belong to a restricted category of pharmaceuticals manufacturers — those who sell their products in Spain and in other Member States, and whose products sold in Spain are protected by patent in other Member States, in particular in the States to which the contested Decisions are addressed — to whom the contested Decisions are of individual concern.

58 In Community law, in order for it to be possible for the existence of a limited class of traders to be of relevance as a factor distinguishing the traders in question individually in relation to a contested act, three cumulative conditions must be satisfied (see, for example, Case 97/85 *Union Deutsche Lebensmittelwerke and Others* v *Commission* [1987] ECR 2265, paragraphs 10 and 11, Case C-209/94 P *Buralux*

and Others v *Council* [1996] ECR I-615, paragraphs 33 and 34, and Case T-489/93 *Unifruit Hellas* v *Commission* [1994] ECR II-1201, paragraphs 25 to 27, *Antillean Rice Mills*, cited above, paragraphs 73 to 76, Case T-482/93 *Weber and Others* v *Commission* [1996] ECR II-609, paragraphs 63 to 65, and 69, Case T-298/94 *Roquette Frères* v *Council* [1996] ECR II-1531, paragraphs 41 to 43). First, the traders in question must be in a situation which distinguishes them from all other traders concerned by the contested act. Secondly, the change in their situation — the factor which defines them by closing the limited class — must have its origin in the adoption of the contested measure. Thirdly, the institution adopting the contested act must have been under an obligation to take account, at the time of the measure's adoption, of the particular circumstances of those traders (see *Piraiki-Patraiki*, cited above, paragraph 31, and Case C-152/88 *Sofrimport* v *Commission* [1990] ECR I-2477, paragraph 11).

59 Thus, in paragraph 31 of its judgment in *Piraiki-Patraiki*, cited above, the Court of Justice held that the applicants could be regarded as individually concerned as members of a limited class of traders particularly affected by the decision at issue authorizing the adoption of protective measures, for three reasons: first, the existence of contracts the terms of which had already been agreed and which were to be performed during the period of the decision's application; secondly, the fact that performance of those contracts had been prevented by the decision at issue; and, thirdly, the fact that those traders were identified or identifiable by the Commission, having regard to the stipulation in Article 130(3) of the Act of Accession of Greece of the need to make a prior evaluation.

60 Similarly, in paragraph 11 of its judgment in *Sofrimport*, cited above, the Court of Justice held that the importers whose goods were in transit to the Community at the time when the regulation at issue entered into force were individually concerned by that regulation for two reasons: first, they constituted a limited class, which was sufficiently well defined in relation to all other importers of the same product and could not be widened after the regulation at issue took effect; secondly, the basic regulation underlying the regulation at issue, which defined the

conditions for the application of protective measures in the relevant product sector, required the Commission to take account of the special circumstances of products in transit when adopting such measures.

61 It is therefore necessary to ascertain whether those three conditions are satisfied in the present case.

62 First, so far as concerns the existence of special circumstances, membership of a limited category of pharmaceuticals manufacturers is not sufficient *per se* to differentiate the applicants' situation from that of all other producers of pharmaceutical products in the same category. It follows from all the foregoing that the applicants have failed to show that they are in a situation different from that of all other traders concerned by the contested Decisions, namely those who sell their products in Spain and in other Member States, and whose products sold in Spain are protected by patents in the other Member States, in particular in the States to which the contested Decisions are addressed.

63 Secondly, the change in the factual situation in which the applicants found themselves prior to the expiry of the transitional period provided for in Article 47 of the Act of Accession of Spain and Portugal is not a result of the adoption of the contested Decisions but of the expiry of the transitional period and the subsequent application of Articles 30 and 36 of the Treaty.

64 Thirdly, so far as concerns any obligation incumbent on the Commission to take into account the applicants' particular circumstances, it should be borne in mind, above all, that the applicants have failed to establish the existence of any such special circumstances. Nevertheless, since the applicants have also maintained that the Commission was under a duty to take into account their interests when adopting the contested Decisions, the merits of this argument should be examined.

65 The applicants base that argument on *Piraiki-Patraiki*, cited above, and on the fact that the wording and purpose of Article 130(3) of the Act of Accession of Greece are identical to those of Article 379(3) of the Act of Accession of Spain and Portugal.

66 Although the wording and purpose of those two articles are indeed identical, both the facts giving rise to the Piraiki-Patraiki case and the nature and content of the act adopted by the Commission are radically different from the circumstances of the present case.

67 The differences in relation to the facts of *Piraiki-Patraiki* lie principally in the existence of certain contracts entered into before the adoption of the decision at issue, and which could not be performed because of its adoption. In the present case, however, the existing circumstances in which the applicants found themselves — in common with all other traders belonging to the same category — before the adoption of the contested Decisions have remained unchanged following the Decisions' adoption.

68 At this stage in the argument it should be emphasized that, in relation to the institution's obligation to take into account the particular situation of traders affected by the decision in question, there are important differences between the adoption of a decision granting authorization to take protective measures and the adoption of a decision refusing such authorization.

69 It is reasonable to require an institution which plans to authorize the adoption of a protective measure first to evaluate in detail the existing market situation, which its action will alter. The impact on the market concerned will be sudden and

disturbing; hence the institution is under a duty to give priority to such measures as will least disturb the functioning of the common market (Article 130(3) of the Act of Accession of Greece, and Article 379(3) of the Act of Accession of Spain and Portugal). It is in the course of making such an evaluation that the institution adopting the measure will find whether some traders are in a special situation, which it is obliged to take into account when adopting the act in question.

70 On the other hand, the adoption of a decision refusing authorization to take protective measures does not have a sudden impact on market conditions and does not provoke disturbances on the market which are inherent in all protective measures. Therefore, the evaluation for the purposes of choosing the measures which least disturb the functioning of the common market — in which the obligation incumbent on the institution to take account of the particular situation of traders triggers all its distinguishing effects — does not have to be carried out.

71 It follows that, in the absence of any such obligation on the part of the Commission, and of the other circumstances required by the settled case-law of the Court of Justice and this Court, the applicants do not form part of a limited class of traders individually concerned by the contested Decisions.

72 The applicants further maintain that, by reason of their contacts, both direct and indirect, with the Commission and their participation in the procedure leading to the adoption of the contested Decisions, they are differentiated from all other traders in relation to those Decisions.

73 It is settled case-law of this Court that the fact that a person participates in one way or another in the process leading to the adoption of a Community act does not distinguish that person individually in relation to the act in question unless the relevant Comunity legislation has laid down specific procedural guarantees for such a person (order of the Court of First Instance of 9 August 1995 in Case T-585/93 *Greenpeace and Others* v *Commission* [1995] ECR II-2205, paragraphs 56 and 63; *Exporteurs in Levende Varkens*, cited above, paragraph 55, and *Kahn Scheepvaart*, cited above, paragraphs 48 and 49, and the case-law cited therein).

74 In the context of the relevant provisions of the Act of Accession of Spain and Portugal, there is no provision requiring the Commission, before adopting a decision refusing authorization to take protective measures pursuant to Article 379 of that Act, to follow a procedure during which persons in the category to which the applicants belong would have the right to assert any rights or even to be heard.

75 The applicants' argument to that effect must therefore be rejected.

76 It follows from all the foregoing that the applicants have not shown that they are affected by the contested Decisions by reason of certain attributes which are peculiar to them or that factual circumstances exist which differentiate them in relation to the contested Decisions from all other traders. Consequently, they are not individually concerned by the contested Decisions.

77 In those circumstances, it is unnecessary to consider whether the applicants are directly concerned by the contested Decisions, a question which the parties have not in fact addressed.

78 The application must therefore be dismissed as inadmissible.

79 In the light of the foregoing, there is no need to rule on the applications to intervene made by the Bundesverband der Arzneimittel-Importeure e. V., the Asociación de Exportadores Españoles de Productos Farmacéuticos and the Vereniging Euro Specialités in support of the form of order sought by the Commission.

Costs

80 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs, if they have been asked for in the successful party's pleadings. Since the applicants have been unsuccessful, they must, having regard to the form of order sought by the Commission, be ordered jointly and severally to pay the costs.

81 Under Article 87(6) of the Rules of Procedure, where a case does not proceed to judgment, the awarding of costs is at the discretion of the Court. The Court considers that, in the circumstances of the present case, the parties seeking to intervene must bear their own costs.

On those grounds,

THE COURT OF FIRST INSTANCE (Fifth Chamber, Extended Composition)

hereby orders:

1. The application is dismissed as inadmissible.

2. The applicants are ordered jointly and severally to pay the costs.

3. The applications to intervene need not be considered.

4. The Bundesverband der Arzneimittel-Importeure e. V., the Asociación de Exportadores Españoles de Productos Farmacéuticos and the Vereniging Euro Specialités are to bear their own costs.

Luxembourg, 3 June 1997.

H. Jung — Registrar

R. García-Valdecasas — President