JUDGMENT OF THE COURT
13 July 1995 *

In Case C-350/92,

Kingdom of Spain, represented by Alberto Navarro González, Director General for Community Legal and Institutional Coordination, and by Antonio Hierro Hernández-Mora, Abogado del Estado in the Legal Department for Matters before the Court of Justice, subsequently replaced by Gloria Calvo Díaz, Abogado del Estado, in the same department, acting as Agents, with an address for service in Luxembourg at the Spanish Embassy, 4-6 Boulevard E. Servais,

applicant,

supported by

Hellenic Republic, represented by Vassileios Kontolaimos, Assistant Legal Adviser in the State Legal Service, and by Maria Basdeki, Legal Agent, subsequently replaced by V. Pelekou, Legal Agent, acting as Agents, with an address for service in Luxembourg at the Greek Embassy, 117 Val Sainte Croix,

intervener,

v

Council of the European Union, represented by Antonio Sacchettini, Director in its Legal Service, and by Sophia Kyriacopoulou and Ignacio Díez Parra, of the

* Language of the case: Spanish.

same service, acting as Agents, with an address for service in Luxembourg at the office of Bruno Eynard, Director of Legal Affairs of the European Investment Bank, 100 Boulevard Konrad Adenauer,

defendant,

supported by

French Republic, represented by Philippe Pouzoulet, Deputy Director of Legal Affairs at the Ministry of Foreign Affairs, and by Hélène Duchêne, Secretary for Foreign Affairs at the same ministry, and subsequently by Hubert Renié, also Secretary for Foreign Affairs, acting as Agents, with an address for service in Luxembourg at the French Embassy, 9 Boulevard du Prince Henri,

and by

Commission of the European Communities, represented by Jean Amphoux, Principal Legal Adviser, and Ricardo Gosalbo Bono and Pieter Van Nuffel, of the Legal Service, acting as Agents, with an address for service in Luxembourg at the office of Gomez de la Cruz, also of its Legal Service, Wagner Centre, Kirchberg,

interveners,

APPLICATION for the annulment of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products,

THE COURT,

composed of: G. C. Rodríguez Iglesias, President, F. A. Schockweiler and P. J. G. Kapteyn (Presidents of Chambers), G. F. Mancini, C. N. Kakouris, J. L. Murray, D. A. O. Edward, J.-P. Puissochet, G. Hirsch (Rapporteur), H. Ragnemalm and L. Sevón, Judges,

Advocate General: F. G. Jacobs,
Registrar: R. Grass,

having regard to the report of the Judge-Rapporteur,

after hearing the Opinion of the Advocate General at the sitting on 9 March 1995,

gives the following

Judgment

1 By application lodged at the Court Registry on 4 September 1992, the Kingdom of Spain brought an action pursuant to Article 173(1) of the EEC Treaty for the annulment of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning

the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1), issued on the basis of Article 100a of the Treaty.

2 The second recital in the preamble to that regulation states that medicinal products, especially those that are the result of long, costly research, will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research. The third recital states that, at the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research. That situation leads to a lack of protection which penalizes pharmaceutical research (fourth recital).

3 The sixth recital states that a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market. It is therefore necessary, according to the seventh recital, to create a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorization has been granted; a regulation is therefore the most appropriate legal instrument.

4 Article 1 defines the terms 'basic patent' and 'certificate'. A 'basic patent' is one which protects a product as such, a process to obtain a product or an application

of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate. The term 'certificate' means the supplementary protection certificate.

5 Article 2 of the regulation defines the scope of the latter as follows:

'Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorization procedure ... may ... be the subject of a certificate.'

6 Article 3 lays down four conditions for obtaining a certificate, which must be fulfilled at the date of application:

— the product must be protected by a basic patent in force in the Member State where the application is made,

— a valid authorization to place the product on the market must have been granted,

— it must not already have been the subject of a certificate, and

— the authorization referred to above must be the first authorization to place the product on the market as a medicinal product.

7 Article 4 provides that, within the limits of the protection conferred by the basic patent, the protection conferred by the certificate shall extend only to the product covered by the marketing authorization.

8 Article 5 provides that, subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

9 Under Article 6, the certificate shall be granted to the holder of the basic patent or his successor in title.

10 Article 7 provides that the application for the certificate may be lodged only after the date on which the product obtained marketing authorization.

11 Finally, the regulation provides that the certificate is to have a uniform duration. Under Article 13:

'1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.'

Community powers

12 The Kingdom of Spain, supported by the Hellenic Republic, argues first that, in the allocation of powers between the Community and the Member States, the latter have not surrendered their sovereignty in industrial property matters, as is demonstrated by the combined provisions of Articles 36 and 222 of the Treaty.

13 Citing the case-law of the Court (judgments in Case 56/64 and 58/64 *Consten and Grundig* v *Commission* [1966] ECR 299, especially at p. 345; Case 24/67 *Parke, Davis and Co.* v *Centrafarm* [1968] ECR 55, especially at p. 72; Case 78/70 *Deutsche Grammophon* v *Metro* [1971] ECR 487, paragraph 11; Case 4/73 *Nold* v *Commission* [1974] ECR 491, paragraph 14; and Case C-30/90 *Commission* v *United Kingdom* [1992] ECR I-829, paragraphs 16 and 17), Spain argues that the Community has no power to regulate substantive patent law, and may harmonize only those aspects relating to the exercise of industrial property rights which are capable of having an effect upon the achievement of the general objectives laid down in the Treaty. Such action may not take the form of a new industrial property right which, by its nature, content and effects, alters the basic concept in force under the national legal systems of each of the Member States. The duration of a patent is its most important feature, since it intrinsically affects the balance in time between the rights and obligations of its holder, whether legal or economic in character.

14 The Council, supported by the French Republic and the Commission, argues from the case-law that the purpose of Article 36 of the Treaty is not to reserve certain matters for the exclusive competence of Member States. As for Article 222 of the

Treaty, its purpose is to allow general freedom to Member States in the organization of their property regimes, but it cannot completely prohibit Community intervention in the property rights of individuals, without paralysing the powers of the Community.

15 The case-law has not excluded the possibility of the Community determining by legislation the conditions and rules regarding the protection conferred by industrial property rights, should such action prove necessary in pursuing its objectives. In any event, the creation of the supplementary certificate does not in any way affect the substance of the rights of the holder of the basic patent. It is a mechanism for correcting the shortcomings of the system for protecting pharmaceutical research, which arise from the need to obtain marketing authorization in order to make use of the innovation.

16 In the light of those arguments, the Court must examine whether Articles 222 and 36 of the EEC Treaty reserve the power to regulate substantive patent law for the national legislature, thereby excluding any Community action in the matter.

17 In that respect, the Court held in its judgment in *Commission* v *United Kingdom*, cited above (paragraphs 16 and 17), that, as Community law stands, the provisions on patents have not yet been the subject of unification at Community level or in the context of approximation of laws, and that, in those circumstances, it is for the national legislature to determine the conditions and rules regarding the protection conferred by patents.

18 However, it added that the provisions of the Treaty — and in particular Article 222, which provides that the Treaty does not in any way prejudice the rules in Member States governing the system of property ownership — cannot be

interpreted as reserving to the national legislature, in relation to industrial and commercial property, the power to adopt measures which would adversely affect the principle of free movement of goods within the common market as provided for and regulated by the Treaty (paragraph 18 of the same judgment).

19 Thus, far from endorsing the argument that rules concerning the very existence of industrial property rights fall within the sole jurisdiction of the national legislature, the Court was anticipating the unification of patent provisions or harmonization of the relevant national legislation.

20 The Court followed similar reasoning in relation to Article 36 of the Treaty. That provides, in particular, that the provisions of Articles 30 to 34 shall not preclude prohibitions or restrictions justified on grounds of the protection of industrial and commercial property, but that such prohibitions or restrictions shall not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

21 In its judgment in Case 35/76 *Simmenthal* v *Italian Minister for Finance* [1976] ECR 1871, paragraph 14, the Court held that Article 36 is not designed to reserve certain matters to the exclusive jurisdiction of Member States but permits national laws to derogate from the principle of the free movement of goods to the extent to which such derogation is and continues to be justified for the attainment of the objectives referred to in that article.

22 It follows that neither Article 222 nor Article 36 of the Treaty reserves a power to regulate substantive patent law to the national legislature, to the exclusion of any Community action in the matter.

23 The Court has, moreover, confirmed in Opinion 1/94 ([1994] ECR I-5267, paragraph 59) that, at the level of internal legislation, the Community is competent, in the field of intellectual property, to harmonize national laws pursuant to Articles 100 and 100a and may use Article 235 as the basis for creating new rights superimposed on national rights, as it did in Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark (OJ 1994 L 11, p. 1).

24 The first submission by the Kingdom of Spain must therefore be dismissed.

Legal basis

25 The second argument advanced by the Kingdom of Spain is that if the Court were to hold that the Community has the power to adopt the contested regulation, the only legal bases for such a measure are Articles 235 and 100 of the Treaty, which require the unanimity of all Member States and therefore do not affect their sovereignty. Use of either of those legal bases requires in any event the conferral of a special power upon the Community, without implying a general attribution of jurisdiction in patent matters.

26 It is settled case-law (see Case 45/86 *Commission* v *Council* [1987] ECR 1493, paragraph 13) that Article 235 may be used as the legal basis for a measure only where no other provision of the Treaty gives the Community institutions the necessary power to adopt it.

27 Even if Article 235 may be used to create new rights superimposed on national rights (see paragraph 23 above), it is undisputed that in this case the contested regulation does not create a new right.

28 As for Article 100 of the Treaty, the Kingdom of Spain has not put forward any valid argument that it constitutes the legal basis of the measure taken.

29 In any event, Article 100a, which is the legal basis claimed by the Council, expressly derogates from Article 100. It is thus important to verify whether the Council had the power to issue the contested regulation on the basis of Article 100a of the Treaty.

30 The Kingdom of Spain argues that the regulation does not pursue the objectives set out in Article 8a of the EEC Treaty, to which Article 100a refers. As far as the free movement of goods is concerned, the certificate, by its very nature, tends to extend the compartmentalization of the market beyond the duration of the basic patent, and thus add to the exceptions provided for in Article 36 of the Treaty, without the extension of the scope of that provision being justified by the Community objective.

31 The Kingdom of Spain adds that, by prolonging the monopoly in marketing the product enjoyed by the undertakings which hold the patent or which have obtained the corresponding licences, the supplementary certificate has the effect of preventing the generic medicines industry from competing freely with those

undertakings, to the obvious detriment of consumers, who would be able to obtain the medicines at better prices from the moment the monopoly situation ended.

32 In its judgment in Case C-300/89 *Commission* v *Council* [1991] ECR I-2867, paragraph 15, the Court held that, in order to give effect to the fundamental freedoms mentioned in Article 8a, harmonizing measures are necessary to deal with disparities between the laws of the Member States in areas where such disparities are liable to create or maintain distorted conditions of competition. For that reason, Article 100a empowers the Community to adopt measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States and lays down the procedure to be followed for that purpose.

33 In the same way, harmonizing measures are necessary to deal with disparities between the laws of the Member States in so far as such disparities are liable to hinder the free movement of goods within the Community.

34 In this case, the Council has pointed out that, at the time the contested regulation was adopted, provisions concerning the creation of a supplementary protection certificate for medicinal products existed in two Member States and were at the draft stage in another State. The contested regulation is intended precisely to establish a uniform Community approach by creating a supplementary certificate which may be obtained by the holder of a national or European patent under the same conditions in each Member State, and by providing, in particular, for a uniform duration of protection (Article 13).

35 The regulation thus aims to prevent the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the

free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market (sixth recital).

36 The Council rightly emphasizes that differences in the protection given in the Community to one and the same medicine would give rise to a fragmentation of the market, whereby the medicine would still be protected in some national markets but no longer protected in others. Such differences in protection would mean that the marketing conditions for the medicines would themselves be different in each of the Member States.

37 The Kingdom of Spain rightly argues that the objectives set out in Article 8a of the EEC Treaty require that a balance be struck in this case between the interests of undertakings which hold patents and the interests of undertakings which manufacture generic medicines.

38 Nevertheless, the regulation recognizes the necessity, in a sector as complex as the pharmaceutical sector, to take all the interests at stake into account, including those of public health (ninth recital). In that regard, Article 13(2) of the regulation provides that the certificate may not be issued for a period longer than five years.

39 In those circumstances, it does not appear that the Council has disregarded the interests of consumers or of the generic medicines industry.

40 It follows from the above that the regulation was validly adopted on the basis of Article 100a of the Treaty, and did not therefore have to be adopted on the basis of Article 100 or Article 235.

41 The plea challenging the regulation for lack of a legal basis is therefore without foundation.

42 Since both the applicant's pleas have failed, the action must be dismissed.

Costs

43 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. Since the Council has so applied, and the Kingdom of Spain has been unsuccessful, the latter must be ordered to pay the costs. In accordance with Article 69(4) of the Rules of Procedure, the Hellenic Republic, the French Republic and the Commission, which have intervened in the proceedings, shall bear their own costs.

On those grounds,

THE COURT

hereby:

1. Dismisses the application;

2. Orders the Kingdom of Spain to pay the costs;

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

Rodríguez Iglesias Schockweiler Kapteyn

Mancini Kakouris Murray

Edward Puissochet Hirsch

Ragnemalm Sevón

Delivered in open court in Luxembourg on 13 July 1995.

R. Grass
Registrar

G. C. Rodríguez Iglesias
President