JUDGMENT OF THE COURT (Sixth Chamber)
23 January 1997 *

In Case C-181/95,

REFERENCE to the Court under Article 177 of the EC Treaty by the Tribunal de Commerce, Nivelles, Belgium, for a preliminary ruling in the proceedings pending before that court between

Biogen Inc.

and

Smithkline Beecham Biologicals SA

on the interpretation 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),

THE COURT (Sixth Chamber),

composed of: J. L. Murray, President of the Fourth Chamber, acting for the President of the Sixth Chamber, C. N. Kakouris, P. J. G. Kapteyn, G. Hirsch (Rapporteur) and H. Ragnemalm, Judges,

* Language of the case: French.

Advocate General: N. Fennelly,
Registrar: H. A. Rühl, Principal Administrator,

after considering the written observations submitted on behalf of:

— Biogen Inc., by Paul Maeyaert and Thomas De Meese, of the Brussels Bar,

— Smithkline Beecham Biologicals SA, by Ludovic De Gryse and Brigitte Dauwe, of the Brussels Bar,

— the French Government, by Catherine de Salins, Head of a Sub-Directorate in the Legal Affairs Directorate in the Ministry of Foreign Affairs, and Philippe Martinet, Foreign Affairs Secretary in the same Directorate, acting as Agents,

— the Italian Government, by Umberto Leanza, Head of the Legal Service in the Ministry of Foreign Affairs, acting as Agent, and Oscar Fiumara, Avvocato dello Stato,

— the Swedish Government, by Erik Brattgård, Ministerial Adviser, acting as Agent, and

— the Commission of the European Communities, by Michel Nolin and Berend Jan Drijber, of its Legal Service, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Biogen Inc., Smithkline Beecham Biologicals SA, the Italian Government and the Commission at the hearing on 11 July 1996,

after hearing the Opinion of the Advocate General at the sitting on 3 October 1996,

gives the following

Judgment

1 By judgment of 2 June 1995, received at the Court on 12 June 1995, the Tribunal de Commerce (Commercial Court), Nivelles, referred to the Court for a preliminary ruling under Article 177 of the EC Treaty four questions on the interpretation 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, hereinafter 'the Regulation').

2 Those questions were raised in proceedings between Biogen Inc. ('Biogen') and Smithkline Beecham Biologicals SA ('SKB') concerning SKB's refusal to provide Biogen with copies of the Belgian marketing authorizations for a recombinant vaccine against Hepatitis-B, called 'Engerix-B', to enable it to complete an application for a supplementary protection certificate.

3 Biogen holds two European patents, of 21 December 1979 and 19 November 1985, relating to medicinal products or, more specifically, sequences and DNA intermediaries, used in the production of vaccines against Hepatitis-B.

4 SKB produces and markets Engerix-B in a number of forms, varying in presentation and/or indications, the active ingredient of which is 'HBsAG' (purified surface antigen of the Hepatitis-B virus). It does so pursuant to patent licences granted to it by the patent holders (or their successors in title). According to the findings of the national court, Engerix-B is the outcome of the combined application of several patents held, in particular, by Biogen and the Institut Pasteur.

5 Under a licensing agreement dated 28 March 1988, SKB pays Biogen royalties for the duration of its patents.

6 SKB holds four Belgian marketing authorizations for Engerix-B. The earliest of these, which was granted on 14 November 1986, was the first marketing authorization for the vaccine in the Community.

7 On 30 June 1993, Biogen applied to the Office de la Propriété Industrielle du Ministère des Affaires Économiques (Industrial Property Office of the Ministry of Economic Affairs) in Belgium for supplementary protection certificates for its two European patents. Since those applications had to include copies of the marketing authorizations for Engerix-B, Biogen repeatedly asked SKB to provide such copies, which it refused to do. SKB did, however, send a copy of its first marketing authorization to the Institut Pasteur, with which it had entered into its first licensing agreement, and which was thus able to obtain a certificate for its patent.

8 The Belgian Ministry of Public Health also refused to provide Biogen with copies of the marketing authorizations without the consent of SKB.

9 Biogen therefore brought an action against SKB before the Tribunal de Commerce, Nivelles, on 16 September 1994, seeking a ruling that, by refusing to provide it with certified copies of its marketing authorizations for the Engerix-B vaccine, whilst providing them to the Institut Pasteur, SKB had discriminated against it, contrary to fair business practice within the meaning of Article 93 of the Belgian Law of 14 July 1991 on business practice and consumer information and protection. Biogen therefore seeks an order requiring SKB to bring the alleged discriminatory practice to an end and to provide it with certified copies of the relevant marketing authorization, with periodic penalty payments in the event of failure to do so.

10 SKB considers that, on the basis of the Regulation, it is entitled to provide only one certificate per product, that Biogen's patents were of uncertain validity, and that the different treatment of Biogen and the Institut Pasteur is financially justified by the different levels of royalties charged.

11 It appears from the third and fourth recitals in the preamble to the Regulation that, prior to its adoption, the period of effective protection under a patent was insufficient to cover the investment put into the pharmaceutical research. The Regulation seeks to make up for that inadequacy by creating a supplementary protection certificate for medicinal products.

12 Article 1 of the Regulation, which defines certain terms, provides that:

'(a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(b) "product" means the active ingredient or combination of active ingredients of a medicinal product;

(c) "basic patent" means a patent which protects a product as defined in (b) 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;

(d) "certificate" means the supplementary protection certificate.'

13 Under Article 2 of the Regulation, any product protected by a patent in a Member State may be the subject of a certificate, under the terms and conditions provided for therein.

14 Article 3, which lays down the conditions for obtaining a certificate, provides that a certificate is to be granted if, in the Member State in which the application is submitted and at the date of that application, (a) the product is protected by a basic patent in force, (b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate, (c) the product has not already been the subject of a certificate, and (d) the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product.

15 Article 5 of the Regulation provides that the certificate is to confer the same rights as conferred by the basic patent and to be subject to the same limitations and the same obligations.

16 Article 6 provides that the certificate is to be granted to the holder of the basic patent or his successor in title.

17 Article 8(1) specifies the content of the application for a certificate. Under Article 8(1)(a)(iv), a request for the grant of a certificate must state, in particular, 'the number and date of the first authorization to place the product on the market, as referred to in Article 3(b) and, if this authorization is not the first authorization for placing the product on the market in the Community, the number and date of that authorization'. Under Article 8(1)(b) and (c), the application must also contain:

'(b) a copy of the authorization to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 4a of Directive 65/65/EEC or Article 5a of Directive 81/851/EEC;

(c) if the authorization referred to in (b) is not the first authorization for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication.'

18 Finally, Article 13(1) of the Regulation provides that the certificate is to 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.

19 The Tribunal de Commerce considered that the dispute raised a question of interpretation of Regulation No 1768/92 and therefore stayed the proceedings and sought a preliminary ruling from the Court on the following questions:

'1. In the event that the holder of the basic patent or his successor in title is a person other than the holder of the authorization to place the medicinal product concerned on the market, is the latter obliged to provide to the patent

holder on request, or, where appropriate, several patent holders when they so request, the "copy" of that authorization which is referred to in Article 8(1)(b) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products?

2. Where one and the same product is covered by several basic patents belonging to different holders, does Regulation No 1768/92 preclude the grant of a supplementary protection certificate to each holder of a basic patent?

3. Regard being had to the wording of Article 6 of Regulation No 1768/92, may the holder of the authorization to place the medicinal product on the market refuse to give a holder of a basic patent or his successor in title the copy of that authorization referred to in Article 8(1)(b) of the Regulation and thereby deprive him of the possibility of completing his application for a supplementary protection certificate?

4. May the relevant administrative and/or government authority which granted the authorization to place the product on the market or is the depositary of an original or a copy of the said authorization refuse to supply a copy to the holder of the basic patent or patents concerned or to his successor in title or may it decide, arbitrarily or subject to certain conditions, whether it is advisable to provide or communicate such copy with a view to its being used to support an application for a supplementary protection certificate under the provisions of Council Regulation No 1768/92 of 18 June 1992 (OJ 1992 L 182, p. 1)?'

The second question

20 By its second question, which falls to be considered first, the national court wishes in substance to ascertain whether, where a medicinal product is covered by several basic patents, the Regulation precludes the grant of a supplementary protection certificate to each holder of a basic patent.

21 Biogen, the French and Italian Governments and the Commission all consider that the Regulation does not, in a situation such as that in the main proceedings, preclude the grant of a supplementary protection certificate to each holder of a basic patent.

22 Biogen submits in particular that, having regard to the aim pursued by the Regulation, namely to improve protection to cover investment in pharmaceutical research, it is inconceivable that, where a medicinal product is covered by a number of basic patents held by different patentees, the research undertaken by one or another of those basic patent holders should be excluded from protection under the supplementary protection certificate system if, as is the case in the main proceedings, the various lines of research have each separately given rise to patented innovations.

23 The Italian Government and the Commission stress that Article 3 of the Regulation, which prohibits renewal of protection for the same product, that is to say in relation to a single patent, nevertheless does not preclude the grant of two certificates (one for each basic patent), even if they relate to the same medicinal product.

24 In the French Government's submission, to interpret Article 3(c) of the Regulation as reserving the right to a supplementary protection certificate to the first patent holder who applies for one would result in an arbitrary choice of the beneficiary of the extension of the period of protection among companies which, in accordance with the aims and subject-matter of the Regulation, are all equally entitled to such protection.

25 SKB, however, considers that, under the system established, only one certificate may be granted for each product — that is to say, each identical active ingredient — even where the product in question is based on several patents. It considers that

the aim of the Regulation is not to reward all basic patent holders but, much more generally, to safeguard and encourage the development of medicinal products in Europe and more particularly in the Community. Such development of new medicinal products is in fact largely due to the research and investment undertaken by those who have finally obtained marketing authorization. The aim sought by the Regulation is fully achieved if the holder of the marketing authorization is prepared to cooperate with the holder of the individual patent, with whom he negotiates terms of cooperation, involving the provision of a copy of the marketing authorization enabling that patent holder to obtain a supplementary protection certificate.

26 It must be borne in mind in that regard that the third and fourth recitals in the preamble give as a reason for the adoption of the Regulation the insufficient duration of the effective protection under the patent to cover the investment put into the pharmaceutical research. The Regulation thus seeks to make up for that insufficiency by creating a supplementary protection certificate for medicinal products, which may be obtained by the holder of a national or European patent under the same conditions in each Member State.

27 Article 6 of the Regulation confirms that the certificate is to be granted to the holder of the basic patent or his successor in title. Article 1(c) mentions the basic patents which may be designated for the purpose of the procedure for the grant of a certificate, namely those which protect a product as such, a process to obtain a product or an application of a product. The Regulation thus seeks to confer supplementary protection on the holders of such patents, without instituting any preferential ranking amongst them.

28 Consequently, where a product is protected by a number of basic patents in force, which may belong to a number of patent holders, each of those patents may be

designated for the purpose of the procedure for the grant of a certificate. Under Article 3(c) of the Regulation, however, only one certificate may be granted for each basic patent.

29 Furthermore, as is clear from Article 13 of the Regulation, the duration of such certificates is to be calculated uniformly on the basis of the date of the first authorization to place the product on the market in the Community.

30 The answer to the second question must therefore be that, where a medicinal product is covered by several basic patents, the Regulation does not preclude the grant of a supplementary protection certificate to each holder of a basic patent.

The third and fourth questions

31 By its third and fourth questions, which fall to be considered together, the national court wishes to ascertain in substance whether the Regulation requires the holder of the marketing authorization to provide the patent holder with a copy of that authorization, referred to in Article 8(1)(b) of the Regulation.

32 Biogen submits that when a basic patent holder asks the holder of the marketing authorization to provide him with a certified copy of that authorization in order that he may comply with the requirements relating to the submission of an application for a supplementary protection certificate, that request may not be refused. The holder of the marketing authorization may not obstruct the exercise of the right referred to in Article 6 of the Regulation.

33 SKB, the French and Italian Governments and the Commission all consider that the Regulation does not impose any specific obligation on the holder of the marketing authorization to provide the patent holder applying for the certificate with a copy of that authorization.

34 SKB stresses in particular that in the scheme of the certificate, the marketing authorization has the value of a separate right attaching to the medicinal product and forms an essential element in the new protection arrangements set up by the Regulation. It is therefore for the holder of that authorization to decide freely to whom and on what terms to provide copies thereof. An interpretation of the Regulation which imposed on the holder of the authorization obligations in favour of a patent holder which, as in the present case, the parties could not take into account when entering into their licensing agreements (on 28 March 1988), would seriously undermine legal certainty.

35 The French and Italian Governments and the Commission consider that there can be no obligation, other than contractual, on the holder of the marketing authorization to communicate the document unless it is expressly provided for by the legislation in issue. That legislation, however, makes no such provision. The solution to the problem raised must therefore be sought in the contractual relationship between the patent holder and the holder of the authorization.

36 In that regard, it need merely be noted that, whilst under Article 8(1)(b) of the Regulation an application for a certificate must contain a copy of the marketing authorization for the medicinal product, there is nothing in the Regulation requiring the holder of that authorization to provide the basic patent holder with a copy of it. Exercise of the right to obtain a certificate referred to in Article 6 of the Regulation is in no way dependent on a discretionary act on the part of the holder of the marketing authorization.

37 The Regulation does not, however, in the circumstances at issue in the main proceedings, preclude such an obligation from being deemed to be inherent in the contractual relationship between the parties.

38 The answer to the first and third questions must therefore be that the Regulation does not require the holder of the marketing authorization to provide the patent holder with a copy of that authorization, referred to in Article 8(1)(b) of the Regulation.

The fourth question

39 In the light of the scheme and objectives of the Regulation, the fourth question must be understood, in order to provide the national court with a helpful answer, as seeking in substance to ascertain whether, where the basic patent and the marketing authorization are held by different persons and the patent holder is unable to provide a copy of the authorization in accordance with Article 8(1)(b) of the Regulation, an application for a certificate must be refused on that ground alone.

40 Biogen and the Italian Government submit that the administrative authority which issued the marketing authorization cannot simply refuse to provide a copy thereof to a basic patent holder who requests one in order to use it in support of an application for a certificate.

41 Biogen observes in particular that, since it must be for the basic patent holder alone to decide whether to apply for a certificate, the administrative authority may not rely on grounds other than the fact that the marketing authorization is confidential as regards the patent holder. If the marketing authorization were to be

precluded, on account of any hypothetical confidentiality, from being communicated to the basic patent holder, there are other possible ways of reconciling the need to protect the confidentiality of the authorization with the achievement of the aims of the Regulation. The administrative authority having in its possession a certified copy of the authorization could, for example, either provide the basic patent holder with a copy in which any quantitative information is concealed, since such information is not necessary to identify the medicinal product to which the application for a certificate relates, or forward the certified copy of the authorization directly to the authority responsible for dealing with applications for certificates rather than through the intermediary of the basic patent holder. The confidential nature of the information contained in the marketing authorization would thus be respected.

42 In the submission of SKB, the French and Swedish Governments and the Commission, the Regulation does not provide for any obligation on the part of an administrative authority to provide the patent holder with a copy of the authorization.

43 SKB submits in particular that if the administration were permitted to provide a third party holding a basic patent with that document, without any legal basis, the holder of the authorization would be definitively and wrongfully deprived, without consideration or justification, of income which he is entitled to expect in return for the effort and cost incurred with a view to obtaining the authorization.

44 In that regard, it must be borne in mind that the purpose of the requirement imposed by Article 8(1)(b) of the Regulation to include a copy of the marketing authorization with the application for a supplementary protection certificate is to

identify the product and verify that the time-limit for submitting an application and, where applicable, the duration of the supplementary protection are observed. It is therefore a formal requirement whose purpose is to demonstrate the existence of an authorization to place the product on the market as a medicinal product.

45 Where the basic patent and the marketing authorization are held by different persons and the patent holder is unable to provide the competent national authorities with a copy of that authorization, granted by the authorities of a Member State, in accordance with Article 8(1)(b) of the Regulation, the application for a certificate must not be refused on that ground alone. By simple cooperation, the national authority granting the certificate can obtain a copy of the marketing authorization from the national authority which issued it (see, to that effect, Case C-201/94 *The Queen* v *Medicines Control Agency* ex parte *Smith and Nephew* [1996] ECR I-5819, paragraph 28). If that were not the case, the entitlement to the certificate conferred by Article 6 of the Regulation on the basic patent holder would be rendered nugatory.

46 With regard to SKB's arguments, it must, moreover, be pointed out that under Article 5 of the Regulation the certificate confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations.

47 The answer to the fourth question must therefore be that, where the basic patent and the authorization to place the product on the market as a medicinal product are held by different persons and the patent holder is unable to provide a copy of that authorization in accordance with Article 8(1)(b) of the Regulation, the application for a certificate must not be refused on that ground alone.

Costs

48 The costs incurred by the French, Italian and Swedish Governments and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Sixth Chamber),

in answer to the questions referred to it by the Tribunal de Commerce, Nivelles, by judgment of 2 June 1995, hereby rules:

1. **Where a medicinal product is covered by several basic patents, Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products does not preclude the grant of a supplementary protection certificate to each holder of a basic patent.**

2. **Regulation No 1768/92 does not require the holder of the marketing authorization to provide the patent holder with a copy of that authorization, referred to in Article 8(1)(b) of the Regulation.**

3. **Where the basic patent and the authorization to place the product on the market as a medicinal product are held by different persons and the patent holder is unable to provide a copy of that authorization in accordance with Article 8(1)(b) of Regulation No 1768/92, an application for a certificate must not be refused on that ground alone.**

Murray Kakouris Kapteyn

Hirsch Ragnemalm

Delivered in open court in Luxembourg on 23 January 1997.

R. Grass G. F. Mancini

Registrar President of the Sixth Chamber