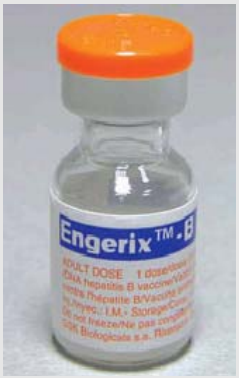
European Court of Justice, 23 January 1997, Biogen



PATENT LAW

One certificate for each basic patent

- **Where a product is protected by a number of basic patents in force, each of those patents may be designated for the purpose of the procedure for the grant of a certificate**

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. 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. 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.

Copy of the marketing authorization

- **The Regulation does not require the holder of the marketing authorization to provide the patent holder with a copy of that authorization**

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. 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. 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.

- **Faillure to provide a copy of the marketing authorization is not as such a ground for refusal**

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.

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European Court of Justice, 23 January 1997
(J.L. Murray, C.N. Kakouris, P.J.G. Kapteyn, G. Hirsch and H. Ragnemalm)
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,
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 un-

able 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.

Opinion of the Advocate-General

1 The Court is asked here to provide for a situation which was not foreseen by the Community legislator and could not have been foreseen by private parties and was not expressly provided for. The 1992 Council Regulation establishing the supplementary protection certificate for medicinal products took no account of the contingency that the basic patent and the marketing authorization for a medicinal product based upon it should be in different hands. In relation to any one medicinal product, can a certificate be granted for more than one patent? Is the holder of the marketing authorization obliged to furnish a copy to the patent holder so that he can obtain a certificate? Alternatively, must the public authority responsible for granting the authorization furnish a copy to the patent holder or to the public authority responsible for granting the certificate? The Regulation is silent on these points.

Legal context

(a) The Regulation

2 The system of supplementary protection is established by Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (hereinafter `the Regulation'). (1) The legal basis of the Regulation is Article 100a of the Treaty establishing the European Community (hereinafter `the Treaty').

3 The third and fourth recitals in the preamble to the Regulation state that the period that elapses between the filing of an application for a patent for a new medicinal product and the 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 pharmaceutical research, a situation which penalizes such research. (2) The sixth recital states that `a uniform solution at Community level should be provided for, thereby preventing the heterogenous 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'. The seventh recital states that it is necessary that the supplementary protection certificate be granted under the same conditions by each of the Member States, thereby justifying legislation by way of a regulation. The eighth recital envisages that `the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains authorization to be placed on the market in the Community'. The ninth recital states that `the protection granted should ... be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product'.

4 Article 1(a) of the Regulation defines a `medicinal product' as `any substance or combination of substances presented for treating or preventing disease in human beings or animals' or `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'. (3) A `product' is defined by Article 1(b) as `the active ingredient or combination of active ingredients of a medicinal product'. Article 1(c) defines a `basic patent' as `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 [supplementary protection] certificate' (hereinafter `certificate').

5 Article 2 of the Regulation states that `[a]ny 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 as laid down in Council Directive 65/65/EEC or Directive 81/851/EEC (4) may, under the terms and conditions provided for in this Regulation, be the subject of a certificate'.

6 Article 3 of the Regulation specifies the conditions for obtaining a certificate:

`A certificate shall 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;

(d) the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product.'

7 Article 6 of the Regulation states that the certificate shall be granted to the holder of the basic patent or his successor in title. Article 4 of the Regulation, reflecting the ninth recital in the preamble, provides that `[w]ithin the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate'. Article 5 of the Regulation states that, subject to Article 4, `the certificate shall confer the same rights as are conferred by the basic patent, and shall be subject to the same limitations and the same obligations'.

8 Article 8(1) of the Regulation, which is central to the instant case, specifies the content of the application for a certificate. Pursuant to Article 8(1)(a), an application for the grant of a certificate must include, inter alia, `(iv) 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'. More significantly, 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.'

9 Article 10 of the Regulation states, in relevant part:

`(1) Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9(1) (5) shall grant the certificate.

(2) The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.

(3) Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.

(4) If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.'

10 Article 13 of the Regulation provides that a 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', but its duration `may not exceed five years from the date on which it takes effect'.

11 A certificate may be granted, under Article 19 of the Regulation, in the case of Belgium, to any product which, on the date of its entry into force (2 January 1993), was protected by a valid basic patent and for which the first authorization to place it on the market as a medicinal product in the Community was obtained after 1 January 1982.

(b) The Directive

12 Article 3 of the Directive states that `[n]o proprietary medicinal product may be placed on the market in a Member State unless an authorization has been issued by the competent authority of that Member State'.

13 Article 4(9) of the Directive (6) requires applications for the grant of an authorization to place a proprietary medicinal product on the market (hereinafter a `marketing authorization') to be accompanied by `[a] summary, in accordance with Article 4a, of the product characteristics'. Article 4a requires this summary to state the product's name, qualitative and quantitative composition in terms of the active ingredients and constituents of the excipient, pharmaceutical form, pharmacological properties, clinical particulars and pharmaceutical particulars, and sets out in detail the information to be provided under each heading. This information is examined by the competent authorities: Article 4b of the Directive states that, when the marketing authorization is issued, `the person responsible for placing that product on the market shall be informed, by the competent authorities of the Member State concerned, of the summary of the product characteristics as approved by them'.

14 Article 4(11) of the Directive states that the particulars and documents accompanying an application for a marketing authorization shall include `[a]ny authorization obtained in another Member State or in a third country to place the relevant proprietary product on the market'.

15 Article 4(8) of the Directive (7) requires applications for the grant of a marketing authorization for a proprietary medicinal product to be accompanied by the results of physico-chemical, biological or microbiological tests, pharmacological and toxicological tests and clinical trials. The provision continues:

`However, and without prejudice to the law relating to the protection of industrial and commercial property:

(a) The applicant shall not be required to provide the results of pharmacological and toxicological tests or the results of clinical trials if he can demonstrate:

...

(iii) ... that the proprietary medicinal product is essentially similar to a product which has been authorized within the Community, in accordance with Community provisions in force, for not less than six years and is marketed in the Member State for which the application is made; this period shall be extended to 10 years in the case of high-technology medicinal products within the meaning of Part A in the Annex to Directive 87/22/EEC (8) or of a medicinal product within the meaning of Part B in the Annex to that Directive for which the procedure laid down in Article 2 thereof has been followed; furthermore, a Member State may also extend this period to 10 years by a single Decision covering all the products marketed on its territory where it considers this necessary in the interest of public health. Member States are at liberty not to apply the above-mentioned six-year period beyond the date of expiry of a patent protecting the original product.'

However, full test and trial results must be presented where the medicinal product in question is intended for a different therapeutic use from that of the medicinal product already authorized or is to be administered differently.

16 Article 12 of the Directive states that `[a]uthorizations to place a proprietary product on the market ... shall be published by each Member State in the appropriate official publication'. In practice, the content of the published decision has not been harmo-

nized. Some Member States set out the summary of product characteristics, while others set out only the name of the applicant and the product, and the authorized dosage.

Factual context

17 The plaintiff in the main proceedings, Biogen Inc. (hereinafter `the plaintiff'), owns two European patents, of 21 December 1979 and 19 November 1985, (9) for DNA (10) sequences and intermediaries used, through recombinant DNA technology, in the production of antigens of the Hepatitis-B virus. The Institut Pasteur and Institut National de la Santé et de la Recherche (hereinafter `the French Institutes') have a number of Belgian and European patents in the same field, dating from between 1979 and 1981. These relate to the production of the DNA of the Hepatitis-B virus itself and to procedures for the production of certain types of antigen to the virus. The defendant in the main proceedings, Smithkline Beecham Biologicals S.A. (formerly Smith Kline-RIT S.A., hereinafter `the defendant'), manufactures and markets a vaccine against Hepatitis-B, called Engerix-B, of which the active ingredient is HBsAG (purified surface antigen of the Hepatitis-B virus). The defendant is licensed by a number of patentees, including the plaintiff and the French Institutes, to use their patented techniques in manufacturing HBsAG. It appears, thus, that Engerix-B is the outcome of the combined application of several of these patents. Pursuant to a licensing agreement of 28 March 1988, the defendant pays the plaintiff royalties for the duration of its patents. The global annual sales of Engerix-B were over US $800 million in 1994.

18 The defendant is, in turn, the holder of four Belgian marketing authorizations for Engerix-B, administered in different forms. The earliest of these, which was granted on 14 November 1986, was the first marketing authorization for the vaccine in the Community. (11) The plaintiff applied in Belgium, on 30 June 1993, for a certificate for its two abovementioned patents. (12) It requested the defendant, on a number of occasions, to provide it with copies of the relevant marketing authorization, which requests were refused. Pursuant to contractual negotiations, the defendant did, however, provide copies of the relevant authorizations to the French Institutes, which were thereby enabled to procure certificates for two of their patents. The Belgian Ministry of Public Health also refused to supply copies of the relevant authorizations to the plaintiff without the permission of the defendant.

19 On 16 September 1994, the plaintiff commenced an action against the defendant before the Tribunal de Commerce (Commercial Court), Nivelles, alleging that the defendant had discriminated against it (relative to the French Institutes), contrary to Article 93 of the Belgian Law of 14 July 1991 on business practice and on consumer protection and information, (13) seeking an order to bring this discriminatory practice to an end and requiring the defendant to provide the plaintiff with certified copies of the relevant marketing authorization. The defendant countered that there could be only one certificate per product, that the plaintiff's patents were of uncertain validity, and that the different treatment of the plaintiff and the French Institutes was financially justified due to the different level of royalties charged by them.

20 The plaintiff sought to obtain certificates in the other Member States of the Community as well. The defendant (or an associated company) resisted everywhere, except in France, where it provided copies of the relevant marketing authorization, and the plaintiff was granted the certificates it sought. The plaintiff succeeded, none the less, in obtaining certificates in Italy, the Netherlands and Sweden, because the national authorities provided copies of the relevant national authorizations. In Sweden, this was done on the basis of constitutional provisions on freedom of information. The plaintiff was also granted certificates in Luxembourg, where the authorities accepted a summary of product characteristics in place of a marketing authorization.

21 The Tribunal de Commerce, Nivelles (hereinafter `the national court') referred four questions to the Court pursuant to Article 177 of the Treaty:

`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 (EEC) 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 (EEC) 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 (EEC) No 1768/92 of 18 June 1992?'

Observations

22 The plaintiff and defendant submitted written observations, as did the Commission, the French Republic, the Italian Republic and the Kingdom of Sweden (the

latter limiting its observations to the fourth question). The plaintiff, the defendant, the Commission and Italy submitted oral observations at a hearing held on 11 July 1996.

23 The second question should logically be addressed first. All of the parties other than the defendant (and Sweden, which is silent on the point) argue that certificates can be awarded in respect of all of the patents to which a single marketing authorization relates. They say that the text of the Regulation does not require exclusivity, and the possibility of multiple certificates in cases where there is a number of patent holders would be consistent with the objective of supporting all aspects of pharmaceutical research. The defendant argues that the certificate regime aims, primarily, to compensate those responsible for developing and marketing medicinal products for the effort, expense and time devoted to seeking a marketing authorization, rather than uniformly to benefit all pharmaceutical research. It also relies on references to the certificate in the singular throughout the text of the Regulation.

24 As regards the first and third questions, read together, the plaintiff argues that the holder of a marketing authorization should be obliged to supply a copy to all concerned patent holders, as Article 6 of the Regulation states that certificates shall be granted to patent holders. The objectives of the Regulation would otherwise be frustrated, as would Community competition rules against abuse of a dominant position, if the holders of marketing authorizations were able to prevent patent holders from exercising their rights. The investment required to obtain a marketing authorization is separately protected by Article 4(8) of the Directive. The other parties (again, with the exception of Sweden) argue against any such obligation: this would disturb existing contractual relations, is not provided for expressly in the Regulation, and should be resolved by contract. The defendant argues that the marketing authorization constitutes a distinct and tradeable item of property, which is as essential as the patent to the supplementary protection regime. If the holder were not in a position to negotiate contractual terms for the provision of a copy of the marketing authorization to the patent holder, the latter would be in a position to withdraw his licence at the end of the patent term or to charge exorbitantly for its extension, contrary to Community competition rules. The defendant points out that the licensing agreement between it and the plaintiff was concluded before even the Commission's proposal for a partially retrospective supplementary protection regime and so did not provide for it.

25 The plaintiff and Italy argue that, as marketing authorizations are issued in the public interest and are not the exclusive property of their holders, and as the right to a certificate is established by law, public authorities must provide copies for the purposes of the Regulation to all patent holders concerned. The purpose of providing a copy of the marketing authorization is to identify the medicinal product in question and its constituents. Precautions can be taken to preserve confidential information while still providing all the information needed for the purposes of the Regulation. France, Sweden and the Commission argue against implying any such obligation from the terms and objectives of the Regulation, although public authorities may be permitted to provide copies if they wish: regard should be had to the applicable national law in this regard. The defendant contends that this question is inadmissible, as the national court failed to explain why it made a reference in relation to the duties of public authorities not represented in the main proceedings. This contention was denied by the plaintiff at the oral hearing. In the alternative, the defendant submits, consistently with its argument that the marketing authorization as such constitutes a distinct property interest for the purposes of the supplementary protection regime, that the provision of copies of the authorization to third parties would unjustly affect income which it would otherwise earn to compensate it for its effort and that this should not be permitted.

Analysis

26 As I have already said, it is logical first to address the second question. If that question is answered in the affirmative, with the effect that only one certificate can be granted in each Member State in respect of any medicinal product authorized to be placed on the market, irrespective of the number of patents on which it is based and of the number of patent holders, some means will have to be devised for choosing which among them should obtain a certificate. In such circumstances, the marketing authorization would indeed be, to borrow the defendant's term, a second pole of the supplementary protection regime (the first being the benefiting patent itself), and thus a tradeable property interest: in the case of competition among patent holders to acquire the right to the sole available certificate, the holder of the marketing authorization would be in a position to decide to reserve it for himself, if he himself had a patent the protection of which he wished to prolong, or to contract to supply a copy to one of the other interested patent holders on the best available terms. In the event of a positive response to the second question, it would not assist matters if the competent public authorities were to supply copies of the marketing authorization to all comers, to enable them to apply for certificates. Those authorities would then have to find a different criterion by which to allocate the sole possible certificate. There is no provision in the Regulation for any qualitative preference of some patents over others, according, for example, to their relative importance to the marketed medicinal product; any such process of selection would be difficult, if not impossible. The alternative approach, that of `first come, first served', is equally unconvincing, not least because it would sit ill with the general principle of legal equality.

27 I will then move on to consider together the first and third questions, which can be combined, and the fourth question. For the reasons just outlined, the respective roles of the holder of a marketing authorization and the competent public authorities under the supplementary protection regime are inextricably linked.

The second question

28 The text of the Regulation does not afford much direct assistance in answering the second question. However, in my view, it should be answered in the negative. To do otherwise would be too much at variance with the objectives of the Regulation and would have too detrimental an effect on the internal market.
29 The text of the Regulation applies simply to a simple situation, in which basic research, product development, production and marketing are vertically integrated: where the holder of the patent or patents relating to a medicinal product, the marketing of which has been authorized in a Member State, is also the holder of the relevant marketing authorization. The Regulation was evidently drafted on the basis of this `classic' model. However, the facts of the instant case do not correspond to this model.
30 The concept of `the product' is central to the legislative scheme. A `product' is defined in Article 1(b) as `the active ingredient or combination of active ingredients of a medicinal product' (emphasis added), indicating that there will be only one `product' corresponding to any one preventative, therapeutic, diagnostic or other medicinal product. Article 1(c) may be thought to assume that, in a case where there are numerous patents, possibly of different kinds (product, process or product-application patents), these will be held by a single holder, who is in a position to choose between them and to designate one as the `basic patent' for the purpose of the procedure for grant of a certificate. (14) The statement in Article 6, that the certificate shall be granted to `the holder of the basic patent' (emphasis added), also seems to be framed in the light of an assumption of integration.
31 This assumption becomes more important in Article 3(c) of the Regulation, which requires, as one of the conditions for obtaining a certificate, that `the product has not already been the subject of a certificate'. As there is only one `product' corresponding to any one medicinal product, this implies that there can be only one certificate for any one marketing authorization for a medicinal product. It could therefore be argued that Article 3(c) is designed to permit a certificate in respect of only one patent, viz. the basic patent chosen by its holder. This, however, does not appear to be its purpose. In my view, the purpose of the provision is to ensure that the right exclusively to market a medicinal product is not multiply extended over time by obtaining a number of certificates in succession. Otherwise, there could be attempts to bypass the calculation of the period of supplementary protection, including the maximum of five years, which represents a key compromise between a number of competing political, social and economic interests. (15) This could occur, in the absence of the condition set out in Article 3(c), if the product - the active ingredient or combination of active ingredients - were, in different dosages or forms, the subject (as in the present case) of a number of different marketing authorizations over time, the first of each of which in the Community could act as the basis for calculating a further period of supplementary protection for associated patents. This explains the centrality of the concept of `the product' in certain parts of the legislative scheme. One product, the composition of which is fixed, can result from many patents and can result in many marketing authorizations in a single Member State. This is because what is essentially the same product may be administered in different ways, or presented in different dosages, each of which must be separately authorized. As the product represents the essential active ingredient or combination of active ingredients of any given therapeutic, diagnostic, preventative or other medicinal invention, it is the fixed point employed to ensure that the patent protection accorded to that invention and its underlying research is supplemented only once.
32 The assumption that for every product, there will be - and there need be - only one corresponding basic patent, designated by its holder, thus entailing the award of a single certificate, underlies the approach adopted in Article 3(c) of the Regulation, but is in no way necessary to the achievement of that provision's objective. On the contrary, the award of a number of certificates in respect of a number of patents associated with a single product, all on the basis of the same marketing authorization, and for which the period of supplementary protection is calculated from the date of award of the first such marketing authorization in the Community, would result in the protection derived from every such patent expiring on the same day. Advocate General Jacobs' statement in Spain v Council (16) about the relative periods of supplementary protection of patents in different Member States, all based on the date of first grant in the Community of a marketing authorization for the relevant product, also holds true in respect of a number of patents granted supplementary protection on the basis of a single marketing authorization in one State:
`Suppose the application for patent protection was lodged in 1990 in Member State A, and in 1991 in Member State B, patent protection expiring respectively in 2010 and in 2011. The authorization to market the product is first given in Member State C, in 1998. That leads to the following calculation of the duration of the certificate. In Member State A that duration is eight (1990-1998) minus five years, the certificate taking effect in 2010 and expiring in 2013. In Member State B the duration is seven (1991-1998) minus five years, the certificate taking effect in 2011 and, again, expiring in 2013.'
This principle of uniformity is subject to an exception, whether the hypothesis involves one or several Member States. Due to the maximum five-year period of supplementary protection, patents applied for more than ten years before the date on which the first marketing authorization was granted in the Community will expire earlier than those applied for less than ten years before that date. However, this exception does not pose problems as regards the objective of Article 3(c) of the Regulation, as there is no extension of the initial maximum period of supplementary protection.
33 A number of problems would arise if Article 3(c) of the Regulation were interpreted as permitting only one

patent to be given the benefit of supplementary protection on the basis of any one product authorized to be marketed as a medicinal product. First of all, contradictions would arise in the text of the Regulation. As was stated above, Article 1(c) appears to provide that the holder of a number of patents shall designate one as his basic patent for the purposes of the award of a certificate. Where there is a number of patent holders, this choice cannot take place unless each is free to designate a patent for supplementary protection. If the other legislative conditions were satisfied, each patent holder could then be granted a certificate in respect of his basic patent, in accordance with Article 6 of the Regulation. In my opinion, and as was, indeed, contended by the defendant, the only effective alternative is that the basic patent (or, at least, the basic patent holder) be designated by the holder of the marketing authorization. This, to my mind, is difficult to reconcile with the patent-oriented express terms of Articles 1(c) and 6 of the Regulation; (17) the issue is discussed further below, in my response to the other questions.

34 More importantly, the automatic limitation of supplementary protection to one patent per product, irrespective of the manner in which the product was developed, would run contrary to two of the fundamental objectives of the Regulation. The first is that of giving additional protection and incentives to all pharmaceutical research. The second is the goal of greater uniformity of patent protection for the purposes of the internal market.

35 As regards the first objective, the first recital in the preamble to the Regulation states that `pharmaceutical research plays a decisive role in the continuing improvement of public health'. Article 1(c) refers indiscriminately to product, process and product-application patents, indicating that patents arising at any stage in the research which ultimately results in a marketable medicinal product can be designated by their holders for supplementary protection. Moreover, the factual perception which motivated the enactment of the Regulation, that pharmaceutical research suffered from reduced returns due to delays in procuring marketing authorization for medicinal products, is valid for all such research, and would imply that all undertakings engaged in such research should be able to benefit from the Regulation. (18)

36 Secondly, a limit of one certificate per product would undermine the objective of the Regulation of achieving greater uniformity of patent protection throughout the Community in order to reduce the obstacles to intra-Community trade in medicinal products. (19) The sixth recital in the preamble to the Regulation attests to this concern to achieve `a uniform solution at Community level'. Article 100a of the Treaty is the legal basis of the Regulation because of the significance of the measure to this aspect of the establishment of the internal market. In Spain v Council, the Court adverted to the trend towards the heterogenous development of national supplementary protection regimes before the adoption of the Regulation, and continued:

`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 would themselves be different in each of the Member States.' (20)

37 The problems posed by such fragmentation are illustrated by the decision in EMI Electrola v Patricia Imund Export & Others, (21) in the related field of copyright protection. Where exclusive rights to market a product persist under the industrial property law of one Member State and where the fact that the product is lawfully marketed in another Member State is due not to an act or the consent of the holder of the industrial property interest or his licensee but to the expiry of the protection period provided for by the legislation of the second Member State, Article 36 of the Treaty permits the interest holder in the first Member State to rely on his exclusive rights in order to prohibit the sale in its territory of imports of the product in question from the second Member State.

38 As Advocate General Jacobs pointed out in Spain v Council, the means by which the period of supplementary protection under the Regulation is calculated in each Member State should result, in the case of any given product, in a uniform point of termination, throughout the Community, of the protection of associated patents which are covered by a certificate (subject to the caveat outlined above about the effect of the five-year maximum). He continued, that this should lead to the free movement of medicinal products which are subject to patent protection. (22) Of course, because patent protection is not fully harmonized or centralized in the Community, obstacles to free movement would remain if equivalent patents associated with a medicinal product were held by different undertakings in different Member States. However, even in a situation in which a number of undertakings hold patents associated with a product, and each such patent is held by the same undertaking throughout the Community, the restriction of supplementary protection to just one patent in each Member State would almost certainly result in the fragmentation of the market. As certificates are awarded on a country-by-country basis, different patent holders could succeed in winning supplementary protection in different Member States, depending, presumably, on the terms they were willing to offer the holder of the marketing authorization or, in the alternative, on the policy of the competent public authorities.

39 In the circumstances just described, the holder of a certificate in respect of patent X in Member State A could then oppose, on the same grounds as in EMI Electrola, the import into that Member State of the medicinal product in question from Member State B, where patent Y benefits from supplementary protection and the equivalent of patent X has expired. The fact that the medicinal product is marketed in Member State B by or with the consent of the company which holds a licence for patent X in Member State A could hardly

permit the invocation of the doctrine of exhaustion against the holder of patent X: (23) he could not be deemed to have consented to marketing in a Member State where he does not himself market the medicinal product and where, his patent having expired, he cannot control the use of his invention in that product. As far as he is concerned, the imported medicinal product is a generic copy rather than a parallel import. While the Court warned in EMI Electrola against the use of such disparities in national periods of protection as a means of arbitrary discrimination or as a disguised measure to restrict trade, (24) it could prove difficult in practice to detect or prevent the award of certificates, with precisely this end, to different patent holders in different Member States, either by public authorities or through the good offices of the holder of the relevant marketing authorization. (25) Even if not deliberately exploited in order to partition the Community market, it is clear that such a system would result in market fragmentation.

40 The Regulation is a legislative enactment of general application, adopted to achieve certain objectives. The text of the Regulation should be interpreted, as far as possible, to facilitate the achievement of those objectives. Where a provision gives rise to more than one possible interpretation, the alternatives should be examined when the most obvious, literal interpretation fails fully to serve the objective of the Regulation because it is based on partially inaccurate assumptions about the pattern of economic relations in the field addressed by the Regulation and gives rise to contradictions in the legislative text. (26) In my view, Article 3(c) of the Regulation should be read as requiring that the product has not already been the subject of a certificate procured on the basis of a different marketing authorization. This implicit condition, unspoken because of the assumptions which guided the draughtsman, is consistent with the structure of Article 3: paragraphs (b) to (d) would then be interpreted as requiring, in logical progression, that there be a valid marketing authorization in respect of the product, that no other marketing authorization relating to that product have been used as the basis for supplementary protection of its associated patents and that the marketing authorization to be used as the basis of such protection be the first granted in respect of the product in that Member State. Such an interpretation would ensure that the stated purpose of Article 3(c) is achieved, viz. the avoidance of multiple extensions of the period of supplementary protection, while the objectives of the Regulation as a whole could then be pursued without impediment. The holder of any patent associated with the product could designate that patent as a basic patent and, subject to compliance with the conditions prescribed in the Regulation, could be granted a certificate in order to compensate more fully his research activities.

41 I conclude, therefore, that the second question referred by the national court should be answered in the negative.

The first, third and fourth questions

42 In my view, the first question referred by the national court should be answered in the negative and the third question, which is effectively its mirror image, should be answered in the affirmative. The fourth question should, subject to qualifications set out below, be answered in the negative.

43 The Regulation is silent on the relationship between the holder of a basic patent and the holder of a related marketing authorization for the Member State in question, due again, I imagine, to the implicit assumption on the part of the draughtsman that they would be concentrated in the hands of a single undertaking. It is, in effect, the legislative failure to advert to the possible divergent ownership of patents and marketing authorizations that creates the problem in the present case. None the less, I would accept the argument that additional obligations should not be imposed on private individuals or bodies by mere implication from the functional needs of legislation which has failed to provide for an unforeseen situation. Thus, in the absence of a contractual obligation to that effect (the parties would have had to be gifted with remarkable prescience to have provided for the event which has arisen under the Regulation), the Regulation should not be interpreted as requiring an undertaking in the position of the defendant to hand over to an undertaking in the position of the plaintiff a copy of the relevant national marketing authorization for the purpose of compliance with Article 8(1)(b). It is impossible even to identify the provision of the Regulation from which such an obligation might be inferred; the most likely contender, Article 6, establishes, at most, the identity of the person who has a right to be granted a certificate by the competent industrial property office and can hardly be interpreted as creating a right to be assisted by private third parties in obtaining any documents which are necessary for that purpose. It would offend gravely against the principle of legal certainty if such an obligation of assistance were to be derived simply from the structure and objectives of the Regulation.

44 The invocation by the plaintiff of Community rules against abuse of a dominant position to support its argument for compulsory provision by its holder of a copy of the marketing authorization can only be relevant, if at all, if an actual copy of the relevant marketing authorization is required for the purposes of an application for a certificate and such a copy is not available from any other source. Demand in the `market' for such copies would be likely speedily to collapse if they were not necessary, while the holder of the marketing authorization would hardly enjoy a dominant position in supplying that market if copies, or an acceptable substitute, were readily available elsewhere. Moreover, a teleological argument for an obligation on private holders of marketing authorizations to supply copies to patent holders, such as that considered and rejected above, would be further weakened if those two conditions of necessity and non-availability were not satisfied. The import of these remarks will become clearer when I come to deal with the substantive nature

of the obligation to produce `a copy of the authorization' to satisfy Article 8(1)(b) of the Regulation.
45 There is, of course, nothing in the Regulation precluding national rules from requiring the provision of a document such as a marketing authorization by one party to a contract to another, in circumstances such as those of the present case. The national court may decide whether such an obligation exists under Belgian law. It may very well be, however, that the applicability of any such national rules would be equally contingent on satisfaction of those conditions of necessity and of non-availability from alternative sources. I now turn, therefore, to examining these two conditions.
46 The defendant argued, on related grounds, that the applicant for a certificate must have a copy of the pertinent national marketing authorization and that this could be provided only by the holder, on the basis of a contractual arrangement. As the substance of its contentions in respect of the first and third questions touches on the freedom of public authorities to undermine the purported property interest of the holder of a marketing authorization by releasing copies of the authorization to patent holders, or by accepting alternative documents, the issues raised by the fourth question need to be addressed in that context, and the defendant's objection of inadmissibility is, thus, demonstrably ill-founded. In any event, the Court has consistently held in that regard that it is solely for the national courts before which actions are brought, and which must bear the responsibility for the subsequent judicial decision, to determine in the light of the special features of each case both the need for a preliminary ruling in order to enable them to deliver judgment and the relevance of the questions which they submit to the Court. A request from a national court may be rejected only if it is quite obvious that the interpretation of Community law or the examination of the validity of a rule of Community law sought bears no relation to the actual nature of the case or to the subject-matter of the main action. (27) In the instant case, the litigation before the national court might be without object if the public authorities were able, or obliged, to supply a copy of the marketing authorization, or to accept an equivalent substitute.
47 The defendant's contention that the patent and the marketing authorization constitute twin poles and distinct property interests in the scheme of the Regulation is unconvincing, for a number of reasons. First, the certificate is granted to the holder of a basic patent and extends the rights held under the patent. The enjoyment of rights granted by Community law is not normally placed at the discretion of private third parties. (28) Just as I cannot read the Regulation so as to oblige the defendant to assist the plaintiff by furnishing a copy of the marketing authorization, equally there is no provision on which to base the suggested interest of the defendant in the supplementary protection certificate sought by the plaintiff.
48 Secondly, the marketing authorization performs some important but, none the less, merely ancillary functions in the scheme of the Regulation. The first authorization granted in the Community determines the period of supplementary protection; the first granted in a particular Member State determines the time-limit for applications for a certificate (six months after the grant of the authorization); (29) the requirement under Article 8(1)(b) of the Regulation that a copy of that national marketing authorization be provided with the application for a certificate serves the further purpose of identifying the product and of assisting the verification of the first two conditions. For that reason, I take the view that it is not necessary to provide a copy of the actual marketing authorization mentioned in that Article, if the information specified therein can be reliably provided from another source - a point upon which I will expand below.
49 Thirdly, a marketing authorization, unlike a patent, need not be exclusive. Its holder enjoys, in many cases, effective exclusivity, but this derives not from the nature of the authorization itself, but from the fact that the person responsible for marketing a medicinal product holds, or has the benefit of exclusive licences under, any applicable patents. The marketing authorization can continue to have effect after the expiry of any associated patent protection, at which point competing producers are free to seek an equivalent authorization; even while patent protection applies, the holder of a marketing authorization may only have a non-exclusive licence under the patent, in which case other licence holders may also apply for a marketing authorization. This type of situation is expressly provided for by Article 4(8)(a)(iii) of the Directive.
50 Fourthly, there is nothing to support the defendant's contention that the Regulation was designed primarily to reward the expense and effort involved in developing marketable medicinal products, rather than pharmaceutical research in general, the results of much of which may require further development before marketing. While it is essential under the scheme of the Regulation that research ultimately result in a marketable medicinal product, the recitals in the preamble to the Regulation (such as the first, second and fourth) speak of pharmaceutical research in general, while Article 1(c) of the Regulation suggests that any patent, including one based on the most elementary research, may be designated as a basic patent for the purposes of applying for a certificate. (30)
51 Fifthly, I would raise again the objective of avoiding, where possible, the fragmentation of the Community market in medicinal products. While the Regulation cannot entirely remedy this problem, it should not be interpreted so as to create new means of raising obstacles to free movement of such products. If the holder of marketing authorizations for a medicinal product in a number of Member States were in a position to determine whether undertakings which held any relevant patents in those countries could obtain certificates and could adopt a different approach in each country dependent on the terms offered, partitioning of the market could ensue even if more than one certificate could, in principle, be granted in respect of the product in each Member State.

52 Finally, I would reject the defendant's argument that it could be unfairly penalized, by virtue of Article 4 of the Regulation, if it did not have a degree of control over the award of certificates. Because the protection conferred by a certificate is stated to be limited to the medicinal product governed by the marketing authorization, the defendant contended that other vaccines against Hepatitis-B could be devised and authorized, with an active ingredient slightly different from Engerix-B but none the less using technology covered by patents such as those of the plaintiff, which would fall outside the scope of the certificate. Thus, it would lose its right exclusively to market vaccines based on those patents, but would be the only undertaking obliged to pay royalties to the holder of the certificate.
53 If the defendant were correct, a variant of this problem would arise even if the certificate and the marketing authorization were held by the same undertaking. Other undertakings could develop slightly different products which, once authorized, they could market without regard to the supplementary period of protection accorded by the certificate. Although this danger may be more apparent than real (because of the five-year maximum period of supplementary protection, the delay involved in obtaining an authorization in most cases and the protection afforded by Article 4(8)(a)(iii) of the Directive), such a situation, whereby the extension of patent protection under the certificate would lose much of its useful effect, would be inconsistent with the objectives of the Regulation. This potential problem could be countered by permitting the holder of a patent either to acquire new certificates in respect of new products which rely on its invention and which are authorized to be marketed as medicinal products, or to extend the protection of an existing certificate to other such new products. It is nowhere stated that a patent can be the subject of only one certificate, or of a certificate only in respect of one medicinal product, as the same patent may be used for widely differing medicinal products (as well as for very similar, competing ones, as in the present hypothesis).
54 However, of these two possibilities, only the second would be consistent with the objective of Article 3(c) of the Regulation: a certificate the material scope of which had been extended by reference to other medicinal products authorized before its expiry would retain its original temporal scope, determined by reference to the date of the first authorization in the Community to market the product initially relied upon in the application for the certificate. Thus, no undue extra advantage would accrue to the holder of the certificate. Furthermore, permitting the material extension of the certificate to other authorized medicinal products would reflect and expand the policy underlying the provision in Article 4 of the Regulation for the extension of the protection of the certificate to any further use of the initial product as a medicinal product that has been authorized before the expiry of the certificate. While such a development would reduce the central role in the legislative scheme, as set out above, of the concept of the product, it would better secure the benefits of the Regulation for the holder of the marketing authorization for the product in relation to which the certificate was first granted, against the competition of fast-followers. Thus, just as every product should be able to give rise, where necessary, to certificates in relation to a number of associated patents in different hands, the material scope of every certificate should be capable of extension to uses of the related patent in a number of different products. In such circumstances, it would be contrary to the interests of the person responsible for marketing the original medicinal product if the holders of marketing authorizations (including that for a later, similar medicinal product) were able to obstruct the obtaining or extension of a certificate.
55 The defendant also submitted an argument, based on the partially retrospective terms of the Regulation, that its interests could be severely prejudiced if the Court did not accept that the holder of a marketing authorization should have a privileged position under the supplementary protection regime. It contended that, if the plaintiff patent holder secured a certificate, it would possess, at the end of the existing period of patent protection, when the licensing agreement was due to expire, greatly increased bargaining power. (31) It could either deny a further licence to the defendant, thus causing its factories, distribution networks and so on to lie idle, or, in the light of that bleak alternative and of the established position of Engerix-B on the market, charge an exorbitant royalty for a new licence. The Regulation, it concluded, should be interpreted in order to avoid placing the plaintiff in a dominant position which it might be able to abuse.
56 I do not accept this argument. First of all, the evidence before the Court is not sufficient to establish that the plaintiff's bargaining power would be greatly enhanced relative to that of the defendant if a certificate were granted. For example, the plaintiff would have little choice but to license its patent to the defendant, if it wished to draw any benefit from its period of supplementary protection under the certificate and if no other company had a marketing authorization for a product involving the patent. Secondly, and more importantly, if, upon grant of a certificate, a sufficiently narrow product market were found to exist - a market for Hepatitis-B antigens, for example - on which the plaintiff enjoyed a dominant position, established remedies exist under the Community competition rules to forestall or rectify an abuse of that position. If, on the other hand, the behaviour of the holder of a certificate were found not to constitute an abuse of a dominant position, within the meaning of that term in Community law, (32) the interpretation of the Regulation which permitted the grant of that certificate could hardly be reproached.
57 If, in the light of the foregoing, the holder of a national marketing authorization for a medicinal product is not entitled effectively to control the application for certificates by patent holders, public authorities must, at the very least, be free, as a matter of Community law, to provide copies of the marketing authorization to the patent holder for the purposes of that application.

(33) France, Sweden and the Commission argue that whether they do so should depend upon national rules relating to such disclosures, as the matter is not provided for in the Regulation. I do not agree. First, however, I will examine whether the provision of such a copy of the marketing certificate is necessary for the grant of a certificate.

58 As I have already briefly outlined, the purpose of the requirement that a copy of the marketing authorization be contained in an application for a certificate is to assist in the identification of the product and in verifying compliance with Article 3(b) and (d) of the Regulation: that it is the first such authorization for the marketing of the product in that Member State (which is important in determining the time-limit for application) and, where applicable, that it is the first such authorization in the Community (the date of which will determine the period of supplementary protection under the certificate). These functions are evident from the stated requirement in Article 8(1)(b) of the Regulation that the copy of the authorization supplied should identify the product and should contain `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'. (34)

59 For that reason, it is my view that the requirement that a copy of the national marketing authorization be produced is not a further substantive condition of award of a certificate; it establishes, rather, a requirement that the applicant be able to show compliance with the actual substantive conditions, set out, chiefly, in Article 3 of the Regulation. A copy of the marketing authorization probably constitutes the easiest means of proof. However, if an applicant who does not possess a copy of the marketing authorization can none the less provide the information specified from a reliable source, which is the real purpose of Article 8(1)(b) of the Regulation, a certificate should not be refused. The competent public authority will, in any event, be in a position to verify that information by reference to information held by the body responsible for granting marketing authorizations. In those circumstances, the conditions referred to in Article 10(1) of the Regulation should be deemed to be satisfied, and the certificate should be granted as a matter of right.

60 I would reject a contrary textual argument made by the defendant. It pointed out that Article 8(1)(b) of the Regulation refers to a copy of the marketing authorization, while Article 8(1)(c) requires only that the applicant provide a copy of the notice publishing the authorization in the appropriate official publication, together with information regarding the identity of the product thus authorized, in cases where the first authorization in the Community was granted in a Member State other than that in which the application is being made. This distinction is all the more important, it contends, because the initial Commission proposal referred to a copy of the authorization in both cases. (35) According to the defendant, the amendment was thus introduced by the Council to preserve the position of the holder of the marketing authorization in the Member State of application and the reason given by the Commission in the Explanatory Memorandum is no longer valid. Furthermore, the fact that the information required will normally be in the public domain shows, in its view, that the requirement of a copy of the marketing authorization itself had a greater purpose, that of making the award of the certificate dependent on the patent holder's actual possession of the authorization or on its contractual relations with the holder of the authorization.

61 I do not find this argument convincing. The fact that the Council amended the equivalent of paragraph (c) of Article 8(1) of the present Regulation before enactment of the proposal need not in itself determine the interpretation of paragraph (b). Furthermore, the objective of paragraph (b) in the original proposal, viz. the obtaining of information about the identity of the product in question, was reinforced by the Council, which added the requirement that a summary of product characteristics be included. (36) The requirement in Article 8(1)(c) that a copy of the notice of the authorization in the appropriate official publication of another Member State be provided, rather than a copy of the authorization itself, probably reflects a realization on the part of the Council that such an authorization to market the product in a different country would not necessarily be held by the applicant patent holder. The fact that it failed to realize that the same might be true within a single Member State should not be held, on its own, to raise a simple procedural requirement into a substantive condition for obtaining a certificate, any more than the requirement in Article 4(11) of the Directive that applications for a marketing authorization include `[a]ny [marketing] authorization obtained in another Member State or in a third country' should be construed as precluding grant of an authorization where such foreign authorizations are held by undertakings other than the applicant.

62 The evidence before the Court suggests that a patent holder will normally be able to supply the information required by Article 8(1)(b) of the Regulation from sources in the public domain. Both of the parties to the main proceedings seem to accept, either expressly or implicitly, that all of the pertinent information in the instant case is available to the plaintiff. This, of course, is a matter of fact for the competent national industrial property office and, in the case of a dispute, the national court to decide. Thus, in order to answer in full the fourth question referred by the national court, and to provide for all possible circumstances, I will now turn to the residual issue of those cases, if any, where the necessary information is not publicly available. In such cases, it is my view that the relevant public authorities should assist the applicant. The public body responsible for awarding marketing authorizations should either supply a copy of the authorization to the applicant or directly to the competent industrial property office of the Member State in question, depending on practical considerations and on the need to protect confidential information. (37) While no such obligation

is directly provided for in the Regulation, leaving the matter to be determined by national rules would lead to inconsistent application of the Regulation as between the different Member States. This would lead to fragmentation of the Community market in medicinal products, for the same reasons already outlined more than once above. It would also be inconsistent with the fact that the certificate, although awarded by national authorities to supplement the varying national systems of patent protection, is established by virtue of Community law. In the words of the seventh recital in the preamble to the Regulation, the certificate is to be granted `under the same conditions, by each of the Member States at the request of the holder of a national or European patent'. (38)

63 The Commission envisaged, in its Explanatory Memorandum, that the administration of the supplementary protection regime might require coordination between national health and industrial property authorities. (39) No significant additional burden would be imposed in practice by such coordination in exceptional cases. Furthermore, Article 10(3) of the Regulation provides for a degree of flexibility on the part of the competent national industrial property office, to ensure that applications are not needlessly obstructed by procedural difficulties. In these circumstances, I consider that it would be contrary to the objectives and scheme of the Regulation if patent holders were prevented from availing of their right to supplementary protection, where all substantive conditions are satisfied, simply because they are not part of a vertically integrated pharmaceutical undertaking which also markets medicinal products and because they are unable to produce published evidence of information already in possession of the authorities of the Member State in question. The right accorded to patent holders by Article 6 of the Regulation would otherwise be deprived of its useful effect in such circumstances. (40) In my view, the duty of the Member States to implement the Regulation includes an obligation to ensure that such applicants are facilitated to enjoy the rights conferred by it. (41)

Conclusion

64 In the light of the foregoing analysis, I would answer the questions referred by the national court as follows:

(1) Where a medicinal product is covered by several patents held by different undertakings, 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 in respect of a basic patent designated by each patent holder.

(2) Where the holder of a basic patent is a person other than the holder of the authorization to place the medicinal product concerned on the market, the latter is not obliged, as a matter of Community law, to provide to the patent holder on request, for the purpose of an application for a supplementary protection certificate, the copy of that authorization referred to in Article 8(1)(b) of Council Regulation (EEC) No 1768/92.

(3) The competent national industrial property office shall deem Article 8(1)(b) of Council Regulation (EEC) No 1768/92 to have been complied with where an applicant for a supplementary protection certificate who is unable to produce a copy of the authorization to place the medicinal product concerned on the market provides with his application, from a reliable source, the information which is specified in that provision.

(4) Where the applicant for a supplementary protection certificate is unable to produce a copy of the authorization to place the medicinal product concerned on the market and the information which is specified in Article 8(1)(b) of Regulation (EEC) No 1768/92 is not in the public domain, the national public body responsible for the grant of the authorization to place the medicinal product on the market must provide a copy of that authorization, or, in the alternative, of the information in question, either to the applicant or to the competent national industrial property office, as the case may be. Whether the relevant material is provided to the applicant or directly to the competent industrial property office, and the manner in which it is provided, will depend on considerations of practicality and on the need to safeguard confidential information.

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(1) - OJ 1992 L 182, p. 1.

(2) - The Commission states in its Explanatory Memorandum (COM(90) 101 final - SYN 255, paragraph 2; hereinafter `Explanatory Memorandum') regarding its proposal for a Regulation concerning the creation of a supplementary protection certificate for medicinal products (OJ 1990 C 114, p. 10; hereinafter `the Commission proposal'), that the average length of that period is 12 years. This leaves an average period of exclusive marketing rights of just eight years.

(3) - This reproduces the definition in Article 1.2 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, OJ, English Special Edition 1965-66 (I), p. 20 (hereinafter `the Directive').

(4) - Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, OJ 1981 L 317, p. 1.

(5) - `[T]he competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorization referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.'

(6) - As amended by Council Directive 83/570/EEC of 26 October 1983 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, OJ 1983 L 332, p. 1.

(7) - As amended by Council Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law,

regulation or administrative action relating to proprietary medicinal products, OJ 1987 L 15, p. 36.

(8) - OJ 1987 L 15, p. 38.

(9) - B-013 828 and B-182 442, respectively.

(10) - Deoxyribo nucleic acid.

(11) - Marketing authorization No 18 S 354 F 17.

(12) - The plaintiff states that two earlier applications deposited on 23 February 1993 were rejected by the Office of Industrial Property of the Belgian Ministry of Economic Affairs because they did not include copies of the relevant marketing authorization.

(13) - Moniteur Belge/Belgisch Staatsblad, 29 August 1991.

(14) - This is evident from paragraph 33 of the Explanatory Memorandum.

(15) - See, to this effect, Case C-350/92 Spain v Council [1995] ECR I-1985, paragraphs 38 and 39 of the judgment. See also the ninth recital in the preamble to the Regulation and paragraphs 34 to 36 of the Explanatory Memorandum.

(16) - Cited in footnote 15 above, paragraph 44 of his Opinion.

(17) - See the Commission's remark in paragraph 37 of the Explanatory Memorandum, relative to the equivalent in the proposal of Article 6 of the Regulation, that the decision as to whether it was opportune to apply for a certificate should be reserved to the patent holder.

(18) - The fact that the Regulation applies to all levels of pharmaceutical research, without discrimination, and not just those final stages in which a marketable medicinal product is developed, is also evidenced by statements by the Commission to that effect in the Explanatory Memorandum, paragraphs 12 and 29.

(19) - Greater uniformity in patent protection would also assist in harmonizing the conditions of competition in the various Member States.

(20) - Cited in footnote 15 above, paragraph 36 of the judgment.

(21) - Case 341/87 [1989] ECR 79; the case is referred to by Advocate General Jacobs at paragraph 44 of his Opinion in Spain v Council, cited in footnote 15 above.

(22) - Spain v Council, cited in footnote 15 above, paragraphs 44 and 45 of his Opinion.

(23) - See, on the doctrine of exhaustion, Case 78/70 Deutsche Grammophon v Metro [1971] ECR 487; Case 15/74 Centrafarm v Sterling Drug [1974] ECR 1147; Case 187/80 Merck v Stephar and Exler [1981] ECR 2063.

(24) - Cited in footnote 21 above, paragraph 13 of the judgment.

(25) - In such circumstances, it would be difficult to accuse the holder of a certificate in Member State A, who has been denied one in Member State B, and who seeks to protect his surviving rights, of having entered into `a restrictive agreement between traders', or of a `concerted practice' or `coordination' giving rise to a restrictive practice, contrary to Article 85(1) of the Treaty, even if the situation has been manipulated by the holder of the marketing authorization to achieve the partitioning of the market. See Case 51/75 EMI Records v CBS United Kingdom [1976] ECR 811, paragraphs 27 to 31 of the judgment; see also Case 40/70 Sirena v Eda [1971] ECR 69, paragraphs 9 to 11; Joined Cases 56/64 and 58/64 Consten and Grundig v Commission [1966] ECR 299, p. 345.

(26) - See, for example, Case 187/87 Saarland v Minister for Industry [1988] ECR 5013, paragraph 19 of the judgment; Case 52/77 Cayrol v Rivoira [1977] ECR 2261, paragraph 14; Case 292/82 Merck v Hauptzollamt Hamburg-Jonas [1983] ECR 3781, paragraph 12.

(27) - See, for example, Case C-186/90 Durighello [1991] ECR I-5773, paragraphs 8 and 9 of the judgment; Case C-415/93 Union Royale Belge des Sociétés de Football Association and Others v Bosman and Others [1995] ECR I-4921, paragraph 59.

(28) - See, for example, Case 61/81 Commission v United Kingdom [1982] ECR 2601, paragraphs 6 to 9 of the judgment.

(29) - Article 7(1) of the Regulation, read in conjunction with Article 3(b) and (d); see further paragraph 35 of the Explanatory Memorandum.

(30) - The Commission remarked, furthermore, in paragraph 2 of the Explanatory Memorandum, that, while the obtaining of a marketing authorization requires considerable scientific, technical and financial efforts, it was primarily the ever-lengthening delays involved in the procedure which resulted in an effective diminution of the period of protection under a patent - delays which affect all patent holders.

(31) - It is, of course, for the national court to interpret the terms of the original licensing agreement. It appears from the order for reference that the national court concluded that the provision for prolongation of a patent in the 1988 licensing agreement does not apply to the period of supplementary protection under a certificate.

(32) - The behaviour would presumably have to fall within one of the exceptions, identified in Case 238/87 Volvo v Veng [1988] ECR 6211, to the general rule that the exercise of exclusive industrial property rights does not constitute, in itself, an abuse of a dominant position. For an elaboration of these exceptions, see Joined Cases C-241/91 P and C-242/91 P RTE and ITP v Commission [1995] ECR I-743. On the charging of patent licence fees greatly in excess of the norm, see also Case T-30/89 Hilti v Commission [1991] ECR II-1439.

(33) - The exercise of such a freedom might remain subject to certain conditions, imposed, for example, by the need to protect confidential information, discussed further below.

(34) - See also paragraph 48 of the Explanatory Memorandum.

(35) - Article 6(3)(b), (c) and (e) of the Commission proposal.

(36) - This was originally a separate requirement, under Article 6(3)(e) of the Commission proposal.

(37) - Article 12(4) of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, OJ 1993 L 214, p. 1, provides a

precedent for such precautions. It states that `[u]pon request from any interested person, the Agency shall make available the assessment report of the medicinal product by the Committee for Proprietary Medicinal Products and the reasons for its opinion in favour of granting authorization, after deletion of any information of a commercially confidential nature'. The need for such measures would be reduced, of course, if documents were provided directly by one public body to another.

(38) - See also paragraph 9 of the Explanatory Memorandum.

(39) - Paragraph 16.

(40) - See, for example, the remarks of Advocate General Van Gerven in Case 362/89 D'Urso and Others [1991] ECR I-4105, paragraphs 33 and 34 of his Opinion, that the useful effect of Council Directive 77/187/EEC on the safeguarding of employees' rights in the event of transfers of undertakings would be undermined if third parties could determine who benefited from it. Advocate General Mischo concluded, in Case 22/86 Rindone v Allgemeine Ortskrankenkasse Bad Urach-Münsingen [1987] ECR 1339, p. 1354, that the need to give useful effect to Council Regulation (EEC) No 574/72 required Member State authorities, in certain circumstances, to accept the conclusions of an examining doctor in the country of residence of a worker regarding his incapacity for work, even if their own national rules did not impose such an obligation.

(41) - See Article 5 of the Treaty, as applied, for example, in Case 93/71 Leonesio v Italian Ministry for Agriculture and Forestry [1972] ECR 287, paragraph 21 of the judgment.