**Court of Justice EU, 12 June 1997, Yamanouchi v Comptroller-General**


**PATENT LAW - SPC**

**Conditions for the grant of supplementary protection certificate**

- **Valid authorization to place the product on the market as a medicinal product required**

The grant of a supplementary protection certificate pursuant to Article 19 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products is, in accordance with Article 3(b) of that regulation, conditional on a valid authorization to place the product on the market as a medicinal product having been granted in the Member State in which the application is submitted and at the date of that application.

Source: **Eur-Lex**

**Court of Justice EU, 8 July 2010**

(G.F. Mancini, C.N. Kakouris, G. Hirsch, H. Ragnemalm, R. Schintgen)

In Case C-110/95,

Reference to the Court under Article 177 of the EC Treaty by the High Court of Justice, Chancery Division, Patents Court, for a preliminary ruling in the proceedings pending before that court between

Yamanouchi Pharmaceutical Co. Ltd

and

Comptroller-General of Patents, Designs and Trade Marks

on the interpretation of Article 19 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: G.F. Mancini, President of the Chamber, C.N. Kakouris, G. Hirsch (Rapporteur),

H. Ragnemalm and R. Schintgen, Judges,

Advocate General: N. Fennelly,

Registrar: D. Louterman-Hubeau, Principal Administrator,

after considering the written observations submitted on behalf of:

- Yamanouchi Pharmaceutical Co. Ltd, by K.P.E. Lasok QC, instructed by Robin Whaite, Solicitor,
- the United Kingdom Government, by Stephen Braviner, of the Treasury Solicitor's Department, acting as Agent, and by Michael Silverleaf, Barrister,
- the Belgian Government, by Jan Devadder, Director of Administration in the Legal Department of the Ministry for Foreign Affairs, acting as Agent,
- the German Government, by Alfred Dittrich, Regierungsdirektor at the Federal Ministry of Justice, and Gereon Thiele, Assessor at the Federal Ministry of Economic Affairs, acting as Agents,
- the Netherlands Government, by Adriaan Bos, Legal Adviser at the Ministry of Foreign Affairs, acting as Agent,
- the Commission of the European Communities, by Berend Jan Drijber and Peter Oliver, of its Legal Service, acting as Agents, having regard to the Report for the Hearing, after hearing the oral observations of Yamanouchi Pharmaceutical Co. Ltd, represented by K.P.E. Lasok and Robin Whaite, of the United Kingdom Government, represented by John E. Collins, Assistant Treasury Solicitor, acting as Agent, and by Michael Silverleaf, and of the

Commission, represented by Berend Jan Drijber and Peter Oliver, at the hearing on 9 January

1997,

after hearing the Opinion of the Advocate General at the sitting on 6 February 1997,

gives the following

**Judgment**

**Grounds**

1 By order of 31 October 1994, received at the Court on 3 April 1995, the High Court of Justice, Chancery Division, Patents Court, referred to the Court for a preliminary ruling under Article 177 of the EC Treaty a question on the interpretation of Article 19 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 That question was raised in proceedings between Yamanouchi Pharmaceutical Co. Ltd (`Yamanouchi') and the Comptroller-General of Patents, Designs and Trade Marks (`the Comptroller-General') concerning the rejection by the latter of an application by Yamanouchi for the grant of a supplementary protection certificate.

3 Yamanouchi is the holder of United Kingdom Patent No 1 415 256 dated 18 January 1973, for the exploitation of which it gave a licence to Ciba-Geigy in 1982. Ciba-Geigy has developed, pursuant to that patent, an anti-asthma drug known as eformoterol. In 1989 Ciba-Geigy applied in a number of countries, including the United Kingdom, for marketing approval for a solution aerosol formulation (an inhaled formulation). While Ciba-Geigy obtained its first marketing authorization in the Community in France on 29 June 1990, the United Kingdom authorities initially refused the marketing authorization sought, by reason of the special storage conditions required for the product, and did not ultimately grant it until 17 August 1995, as a result of further development work on the product by Ciba-Geigy.

4 On 15 January 1993 (two days before the expiry of

the abovementioned patent on 17 January 1993), Yamanouchi lodged with the United Kingdom Patent Office an application under Article 19 of the regulation for a supplementary protection certificate, referring to the United Kingdom patent as the basic patent and to the marketing authorization granted in France in 1990, a copy of which was annexed to the application.

5 On 3 February 1993 the United Kingdom Patent Office informed Yamanouchi that its application did not meet the requirements of Articles 3(b) and 8(1)(b) of the regulation, on the grounds, first, that at the date when the application was lodged no valid authorization to place the product on the market as a medicinal product had been granted in the United Kingdom, and, second, that the application did not contain a copy of such authorization. The Patent Office further stated that, in its view, and contrary to the contention advanced by Yamanouchi, Article 19 did not derogate from the conditions for obtaining a supplementary protection certificate laid down in Article 3 of the regulation or from the content of the application as specified in Article 8.

6 Following a hearing on 24 August 1993 before the Principal Examiner, acting for the Comptroller-General, Yamanouchi's application for a certificate was rejected by decision of 8 September 1993. Yamanouchi consequently brought an appeal against that decision before the referring court, claiming that, on the basis of the regulation, its application should be granted.

7 According to the third and fourth recitals in the preamble to the regulation, the period of effective protection under a patent prior to adoption of the regulation was insufficient to cover the investment put into the pharmaceutical research. The regulation is specifically designed to remedy that insufficiency by the creation of a supplementary protection certificate for medicinal products in respect of which marketing authorization has been granted.

8 Article 3, which lays down the conditions for obtaining a certificate, provides as follows: `A certificate shall be granted if, in the Member State in which the application referred to in Article 7 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.'

9 Pursuant to Article 7(1) of the regulation, the application for a certificate must be lodged within six months of the date on which the authorization referred to in Article 3(b) to place the product on the market as a medicinal product was granted. Article 7(2) provides that, notwithstanding paragraph (1), where the marketing authorization is granted before the basic patent is granted, the application for a certificate must be lodged within six months of the date on which the patent is granted.

10 Article 8(1) of the regulation specifies the content of the application for a certificate. It provides, in subsubparagraph (a)(iv), that 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.'

11 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.

12 Lastly, Article 19, which forms part of the transitional provisions, provides:

`1. Any product which, on the date on which this regulation enters into force, is 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 1985 may be granted a certificate. In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988. In the case of certificates to be granted in Belgium and in Italy, the date of 1 January 1985 shall be replaced by that of 1 January 1982.

2. An application for a certificate as referred to in paragraph (1) shall be submitted within six months of the date on which this regulation enters into force.'

13 According to the tenth recital in the preamble to the regulation, the transitional arrangements `should enable the Community pharmaceutical industry to catch up to some extent with its main competitors who, for a number of years, have been covered by laws guaranteeing them more adequate protection, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the health policies pursued both at national and [at] Community level'.

14 The regulation entered into force on 2 January 1993.

15 The national court considered that the case raised a question as to the interpretation of the regulation and decided to stay proceedings pending delivery by the Court of Justice of a preliminary ruling on the following question:
`In the case of an application for a certificate under Council Regulation (EEC) No 1768/92 in a particular Member State (in casu, the United Kingdom) in circumstances where:
- a medicinal product was (on 2 January 1993) the subject of a first marketing authorization in the Community (in casu, in France) which was obtained pursuant to Directive 65/65/EEC (as amended) after 1 January 1985;
- the medicinal product was (on 2 January 1993) protected by a valid basic patent in the Member State;
- at the date of submission of such application, marketing authorization in the Member State had yet to be obtained;
- application for a certificate as referred to in paragraph 1 of Article 19 was submitted to the relevant national authority (viz. the United Kingdom Patent Office) within 6 months of 2 January 1993, as laid down in paragraph 2 of Article 19; is Council Regulation (EEC) No 1768/92, and in particular Article 19 thereof, to be interpreted so as to allow the grant of a supplementary protection certificate to the patentee in that Member State or must the provisions of Articles 3(b), 8 and 9 concerning a valid marketing authorization in the Member State also be complied with?'
16 The essence of the question referred by the national court is whether the grant of a supplementary protection certificate pursuant to Article 19 of the regulation is, in accordance with Article 3(b) of the regulation, conditional on a valid authorization to place the product on the market as a medicinal product having been granted in the Member State in which the application is submitted and at the date of that application.
17 Yamanouchi submits that Article 19 of the regulation provides for the grant of a certificate where three conditions are fulfilled, namely that the medicinal product in question is protected by a valid basic patent on the date on which the regulation enters into force, that the first authorization to place the product on the market in the Community was obtained after 1 January 1985, and that the application for a certificate was made within six months of the entry into force of the regulation. Since each of those conditions has been satisfied in the present case, the competent national authorities are under an obligation to grant the certificate.
18 According to Yamanouchi, that conclusion is apparent from the general scheme of the regulation. The transitional provisions derogate from the `ordinary' provisions of the regulation, namely Article 3 et seq. Thus, Article 19(1) is the equivalent of Article 3, whilst Article 19(2) must be regarded as corresponding to Article 7. Furthermore, it is apparent from the wording of Article 19(1) that it refers neither expressly nor by implication to the conditions laid down by Article 3. On the contrary, if a certificate could be granted under Article 19 only where the conditions set out in Article 3 were also fulfilled, Article 19 would clearly have been worded differently.
19 It should be noted at the outset that Article 19(2) of the regulation, which forms part of the transitional provisions, operates, in the circumstances provided for in Article 19(1), as a derogation from Article 7, pursuant to which an application for a certificate must be lodged within six months of the date on which the marketing authorization or, as the case may be, the patent is granted. Were it not for Article 19(2), all products covered by a marketing authorization granted more than six months prior to the entry into force of the regulation, that is to say, before 2 July 1992, would have been denied the advantages of the scheme established by the regulation. As it is, the question raised by the national court concerns the interpretation of the conditions laid down in Article 19(1), to which Article 19(2) refers.
20 Unlike Article 3, which provides that the certificate `shall be granted' if the conditions for obtaining it, as set out therein, are fulfilled, the conditions specified in Article 19(1) are not in themselves sufficient to confer entitlement to a certificate. Article 19(1) provides that any product which fulfils those conditions `may be granted' a certificate. It is clear from its very wording that Article 19(1) does not in any way preclude the requirement that, in order for a certificate to be granted, a valid authorization to place the product on the market as a medicinal product must have been granted in the Member State in which the application is submitted and at the date of that application, as provided for in Article 3(b).
21 However, relying on the second condition laid down by Article 19(1), Yamanouchi submits that it is still possible, on the basis of the first marketing authorization granted in the Community, to determine the product for which the certificate is sought and to identify its therapeutic properties, as Article 8(1)(c) of the regulation makes clear.
22 Furthermore, according to Yamanouchi, the grant of a certificate on the basis of the first marketing authorization in the Community does not mean that the product in question can be marketed in the State granting the certificate in the absence of marketing authorization granted by that State. It simply means that, when marketing authorization is finally granted (as it was in the United Kingdom in 1995), the person developing the product (here, Ciba- Geigy) will receive, in accordance with the objectives of the regulation, some degree of protection as compensation for the additional delay and expense incurred in connection with the grant of authorization.
23 As is apparent from Article 13, the condition imposed by Article 19(1) in respect of the first marketing authorization in the Community is necessary only for the purposes of determining the duration of the certificate. Thus, Article 8(1)(a)(iv) and (c) and Article 9(2)(e) of the regulation lay down an obligation to provide information concerning that first marketing authorization in support of an application for a certificate, in order to ensure that the competent industrial

property authority receiving the application has available to it the information needed in order to determine the duration of the certificate. Article 11(1)(e) provides that that information is to appear in the notification of the grant of the certificate which is published for the information of the public.

24 However, the effect of Articles 8(1)(a)(iv) and (b), 9(2)(d) and 11(1)(d) is that the first marketing authorization in the Community is not intended to take the place of the marketing authorization provided for in Article 3(b) of the regulation, that is to say, the authorization granted by the Member State in which the application is submitted; instead, it constitutes a further condition applying in the event that the latter authorization is not the first authorization to place the product on the market as a medicinal product in the Community. The first marketing authorization in the Community therefore serves a purely temporal purpose.

25 By referring to the first marketing authorization in the Community, the regulation is designed to exclude the possibility that, in Member States in which there has been significant delay in the grant of authorization to place a given product on the market, a certificate can still be granted even though that is no longer possible in the other Member States in which the authorization in question has been granted before expiry of the deadline. The regulation is thus intended to prevent the grant of certificates whose duration varies from one Member State to another. In those circumstances, Article 19(1) cannot be construed as meaning that the existence of an authorization in the Member State in which the certificate is sought is of no relevance.

26 On the contrary, it is the authorization referred to in Article 3(b) of the regulation which confers entitlement to the certificate. That principle is borne out by Article 4, according to which the protection conferred by the certificate extends only to the product covered by the marketing authorization in respect of the corresponding medicinal product. Entitlement to the certificate is strictly linked, therefore, to the existence of a marketing authorization granted in the Member State in which the application is submitted and to the date of that application.

27 That interpretation is inconsistent neither with the events leading to the adoption of the regulation nor with Decision No 7/94 of the EEA Joint Committee of 21 March 1994 amending Protocol 47 and certain Annexes to the EEA Agreement (OJ 1994 L 160, p. 1, at p. 138).

28 The answer to the national court's question must therefore be that the grant of a supplementary protection certificate pursuant to Article 19 of the regulation is, in accordance with Article 3(b) of the regulation, conditional on a valid authorization to place the product on the market as a medicinal product having been granted in the Member State in which the application is submitted and at the date of that application.

**Decision on costs**

**Costs**

29 The costs incurred by the United Kingdom, Belgian, German and Netherlands Governments and by 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.

Operative part

On those grounds,

**The Court**

**(Sixth Chamber)**,

in answer to the question referred to it by the High Court of Justice, Chancery Division, Patents Court, by order of 31 October 1994, hereby rules:

The grant of a supplementary protection certificate pursuant to Article 19 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products is, in accordance with Article 3(b) of that regulation, conditional on a valid authorization to place the product on the market as a medicinal product having been granted in the Member State in which the application is submitted and at the date of that application.