JUDGMENT OF THE COURT (Fifth Chamber)

16 September 1999 *

In Case C-392/97,

REFERENCE to the Court under Article 177 of the EC Treaty (now Article 234 EC) by the Bundesgerichtshof, Germany, for a preliminary ruling in the proceedings brought before that court by

Farmitalia Carlo Erba Srl,

on the interpretation of Article 3(a) and (b) 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 (Fifth Chamber),

composed of: J.-P. Puissochet, President of the Chamber, P. Jann, C. Gulmann (Rapporteur), D.A.O. Edward and L. Sevón, Judges,

Advocate General: N. Fennelly,

Registrar: L. Hewlett, Administrator,

* Language of the case: German.

after considering the written observations submitted on behalf of:

— Farmitalia Carlo Erba Srl, by M. Kindler, Rechtsanwält, Munich,

— the German Government, by A. Dittrich, Ministerialrat in the Federal Ministry of Justice, and E. Röder, Ministerialrat in the Federal Ministry of Economic Affairs, acting as Agents,

— the French Government, by K. Rispal-Bellanger, Head of the Subdirectorate for International Economic Law and Community Law in the Legal Affairs Directorate of the Ministry of Foreign Affairs, and R. Loosli-Surrans, Chargé de Mission in the same Directorate, acting as Agents,

— the Netherlands Government, by J.G. Lammers, Acting Legal Adviser in the Ministry of Foreign Affairs, acting as Agent,

— the United Kingdom Government, by D. Cooper, Treasury Solicitor, acting as Agent,

— the Commission of the European Communities, by K. Banks, of its Legal Service, acting as Agent, assisted by I. Brinker, of the Brussels Bar,

having regard to the Report for the Hearing,

after hearing the oral observations of Farmitalia Carlo Erba Srl, represented by M. Kindler; of the French Government, represented by R. Loosli-Surrans; of the Netherlands Government, represented by J.S. van den Oosterkamp, Deputy Legal Adviser in the Ministry of Foreign Affairs, acting as Agent; and of the Commission, represented by K. Banks, assisted by I. Brinker, at the hearing on 4 March 1999,

after hearing the Opinion of the Advocate General at the sitting on 3 June 1999,

gives the following

Judgment

1 By order of 17 June 1997, received at the Court on 18 November 1997, the Bundesgerichtshof (Federal Supreme Court) referred to the Court for a preliminary ruling under Article 177 of the EC Treaty (now Article 234 EC) two questions on the interpretation of Article 3(a) and (b) 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).

2 Those questions were raised in an appeal brought by Farmitalia Carlo Erba Srl ('Farmitalia') against the rejection by the Bundespatentgericht (Federal Patent

Court) of Farmitalia's application for the grant of a supplementary protection certificate ('the certificate') in the terms used by that company.

3 It is clear from the third and fourth recitals in the preamble to Regulation No 1768/92 that, before the regulation was adopted, the period of effective protection under the patent was insufficient to cover the investment put into pharmaceutical research. The regulation is specifically intended to remedy that insufficiency by creating a certificate for medicinal products.

4 Article 1 of Regulation No 1768/92 provides:

'For the purposes of this regulation:

(a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings or 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.'

5 Article 3 of Regulation No 1768/92, which defines the conditions for obtaining the certificate, provides:

'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 authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC...;

(c) the product has not already been the subject of a certificate;

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

6 Farmitalia was the holder of German patent No 25 25 633, notified on 9 June 1975, the legal period of protection of which has now expired. The patent concerned alpha-anomers of 4-Demethoxy-daunomycin, processes for manufacturing them and medicaments containing those compositions. Claims 1 and 4 of that patent referred respectively to alpha-anomers of 4-Demethoxy-daunomycin

with an indication of the corresponding formula, and the medicaments containing one of the compositions referred to in Claims 1 and 2 and usual additives and/or vehicles.

7 The short designation recommended by the World Health Organisation for chemical compositions structured according to the formula in Claim 1 is 'idarubicin'.

8 In Germany, Farmitalia obtained market authorisation, under the names 'Zavedos 5mg' and 'Zavedos 10mg', for medicinal products for treatment of acute myelitic leukaemias in humans, in which the active ingredient is idarubicin hydrochloride and the ancillary ingredient is dehydrated lactose.

9 By decision of 9 June 1993 the Deutsche Patentamt (German Patent Office) issued to Farmitalia, on the basis of Germany patent 25 25 633, a certificate 'for the medicament Zavedos containing as its active ingredient idarubicin hydrochloride'. It declined, however, to issue the certificate, which was primarily sought, for 'idarubicin and salt thereof including idarubicin hydrochloride'.

10 Farmitalia brought proceedings before the Bundespatentgericht seeking, primarily, to obtain a certificate for 'idarubicin and salts thereof including idarubicin hydrochloride' and, in the alternative, a certificate for 'idarubicin and idarubicin hydrochloride'. That application was rejected.

11 According to the Bundespatentgericht, both the main and the ancillary application fail to satisfy Article 3(b) of Regulation No 1768/92. By virtue of that provision, a certificate can be granted only for a product which is stated to be an 'active ingredient' in the decision to grant marketing authorisation under pharmaceutical legislation. In the present case, that condition is fulfilled only in respect of the active ingredient 'idarubicin hydrochloride' which, at the time of

notification of the application, was the only ingredient to have received marketing authorisation under the pharmaceutical legislation applicable in Germany.

12 According to the Bundespatentgericht, the main application also appears to be unfounded because the conditions specified in Article 3(a) of Regulation No 1768/92 are not satisfied for all idarubicin salts. In order to determine whether the product is 'protected by a basic patent', reference must be made to the subject-matter of the protection conferred by the patent, that is to say, the technical teaching which the basic patent is intended to protect as patentable. The Bundespatentgericht points out that, in addition to the matters set out *verbatim* in the specification, the only further matters required are those which, in the view of an average expert, are self-explanatory or all but indispensable in regard to the patented teaching without the need for special mention, or which the expert, on an attentive reading of the patent specification, can recognise without difficulty and follow at once in his own mind.

13 That is not the case regarding the idarubicin salts for which the claim is made in the proceedings before the national court. To an average expert, it is neither self-explanatory nor immediately evident that, in addition to idarubicin hydrochloride which is mentioned in an embodiment, any other idarubicin salts, not mentioned in the patent itself, could yield the active ingredient of a medicinal substance distinguished by the same properties as those stated in the patent. On the contrary, since their chemical composition is different from that of idarubicin and idarubicin hydrochloride, the expert will be prompted at least to consider it possible that differences exist in the therapeutic effectiveness of those salts.

14 In its appeal brought before the Bundesgerichtshof, Farmitalia maintains its request for the grant of a certificate for 'idarubicin and salts thereof including

idarubicin hydrochloride' and, in the alternative, 'for idarubicin and idarubicin hydrochloride'.

15 Noting that Farmitalia has already obtained a certificate for idarubicin hydrochloride, the Bundesgerichtshof considers that, for the purposes of its decision, an interpretation of Article 3(a) and (b) of Regulation No 1768/92, starting with (b), is needed. According to that court, only if the grant of a certificate is not restricted to the active ingredient indicated in the marketing authorisation granted under the pharmaceutical legislation will the application for a certificate not automatically fail under Article 3(b) of the regulation and will it be necessary to deal with the other question, concerning Article 3(a), to ascertain what criteria determine whether the product 'is protected by a basic patent'. If the wording of the claim for the patent is decisive, then the ancillary application must succeed. If, on the other hand, attention has to be focused on the whole area of protection of the basic patent, the primary application made by the appellant in the main proceedings could be well founded.

16 In those circumstances, the Bundesgerichtshof decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Does Article 3(b) presuppose that the product in respect of which the grant of a protection certificate is sought is described as an "active constituent" in the authorisation for marketing as a medicinal product?

Is, then, Article 3(b) not complied with where a single individual salt of an active ingredient is stated in the notice of authorisation to be an "active

constituent", but the issue of a protection certificate is sought for the free base and/or for other salts of the active ingredient?

(2) If the questions at 1. are answered in the negative:

According to which criteria is it to be determined whether the product, as referred to in Article 3(a), is protected by a basic patent where the issue of a protection certificate is sought for the free base of an active ingredient including any of its salts, but the basic patent in its patent claims mentions only the free base of that ingredient and, moreover, mentions in an embodiment a single salt of this free base? Is the wording of the claim for the basic patent or the latter's scope of protection the determining criterion?'

The first question

17 By its first question, the national court asks, in substance, whether, on a proper construction of Article 3(b) of Regulation No 1768/92, the certificate can protect the product only in the specific form stated in the marketing authorisation.

18 In that regard, all the interested parties who have submitted observations have maintained, in particular, that while the certificate could protect only the particular salt form of the active ingredient mentioned as the active constituent in the marketing authorisation, whereas the basic patent protects the active ingredient as such as well as salts thereof, including the one which is the subject-matter of the marketing authorisation, any competitor would be able,

after the basic patent had expired, to apply for and, in some circumstances, obtain marketing authorisation for a different salt of the same active ingredient, formerly protected by that patent. It would therefore be possible for medicinal products which were, in principle, therapeutically equivalent to that protected by the certificate to compete with the latter. The result would be to frustrate the purpose of Regulation No 1768/92, which is to ensure the holder of the basic patent of exclusivity on the market during a given period extending beyond the period of validity of the basic patent.

19 That line of argument must be accepted. If the certificate did not cover the actual medicinal product, as protected by the basic patent and one of the possible forms of which is the subject-matter of a marketing authorisation, the fundamental objective of Regulation No 1768/92, as set out in the first and second recitals in the preamble thereto, which is to provide for sufficient protection to encourage research in the pharmaceutical field, which plays a decisive role in the continuing improvement in public health, could not, for the reasons set out in paragraph 18 of this judgment, be attained.

20 Moreover, it should be borne in mind that the 13th recital in the preamble to Regulation (EC) 1610/96 of the European Parliament and of the Council of 23 July 1996 which, by virtue of the 17th recital, is also valid, *mutatis mutandis*, for the interpretation *inter alia* of Article 3 of Regulation No 1768/92, states that the certificate confers the same rights as those conferred by the basic patent, with the result that, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection.

21 Accordingly, where an active ingredient in the form of a salt is referred to in the marketing authorisation concerned and is protected by a basic patent in force, the certificate is capable of covering the active ingredient as such and also its various

derived forms such as salts and esters, as medicinal products, in so far as they are covered by the protection of the basic patent.

22 Consequently, the answer to the first question must be that, on a proper construction of Regulation No 1768/92 and, in particular, Article 3(b) thereof, where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, the certificate is capable of covering that product, as a medicinal product, in any of the forms enjoying the protection of the basic patent.

The second question

23 By its second question, the Bundesgerichtshof is, in substance, asking what are the criteria, according to Regulation No 1768/92, and in particular Article 3(a) thereof, for determining whether or not a product is protected by a basic patent.

24 In that connection, it should be noted that one of the conditions for obtaining a certificate is that the product should be protected by a basic patent in force.

25 As indicated in the seventh recital in the preamble to Regulation No 1768/92, the patent concerned may be either national or European.

26 As Community law now stands, the provisions concerning patents have not yet been made the subject of harmonisation at Community level or of an approximation of laws.

27 Accordingly, in the absence of Community harmonisation of patent law, the extent of patent protection can be determined only in the light of the non-Community rules which govern patents.

28 As is clear in particular from paragraph 21 of this judgment, the protection conferred by the certificate cannot exceed the scope of the protection conferred by the basic patent.

29 The answer to be given to the second question must therefore be that, in order to determine, in connection with the application of Regulation No 1768/92 and, in particular, Article 3(a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern that patent.

Costs

30 The costs incurred by the French, German, Netherlands and United Kingdom Governments and by the Commission, 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 (Fifth Chamber),

in answer to the questions referred to it by the Bundesgerichtshof by order of 17 June 1997, hereby rules:

1. **On a proper construction of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products and, in particular, Article 3(b) thereof, where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, the supplementary protection certificate is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent.**

2. **In order to determine, in connection with the application of Regulation No 1768/92 and, in particular, Article 3(a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern that patent.**

Puissochet Jann Gulmann

Edward Sevón

Delivered in open court in Luxembourg on 16 September 1999.

R. Grass J.-P. Puissochet

Registrar President of the Fifth Chamber