JUDGMENT OF THE COURT (Second Chamber)

4 May 2006 *

In Case C-431/04,

REFERENCE for a preliminary ruling under Article 234 EC from the Bundesgerichtshof (Germany), made by decision of 29 June 2004, received at the Court on 7 October 2004, in the proceedings brought by

Massachusetts Institute of Technology,

THE COURT (Second Chamber),

composed of C.W.A. Timmermans, President of the Chamber, R. Schintgen, R. Silva de Lapuerta, G. Arestis (Rapporteur) and J. Klučka, Judges,

Advocate General: P. Léger,
Registrar: K. Sztranc, Administrator,

* Language of the case: German.

having regard to the written procedure and further to the hearing on 6 October 2005,

after considering the observations submitted on behalf of:

— the Massachusetts Institute of Technology, by T. Bausch, Patentanwalt,

— the French Government, by R. Loosli-Surrans, acting as Agent,

— the Lithuanian Government, by D. Kriaučiūnas, acting as Agent,

— the Netherlands Government, by H.G. Sevenster and C. ten Dam, acting as Agents,

— the Polish Government, by T. Nowakowski, acting as Agent,

— the Finnish Government, by A. Guimaraes-Purokoski, acting as Agent,

— the United Kingdom Government, by D. Beard, barrister,

— the Commission of the European Communities, by G. Braun and W. Wils, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 24 November 2005,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 1(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), in the version resulting from the Act concerning the conditions of accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded (OJ 1994 C 241, p. 21, and OJ 1995 L 1, p. 1; 'Regulation No 1768/92').

2 The reference was submitted in the context of an appeal brought by the Massachusetts Institute of Technology ('the MIT') against the rejection by the Bundespatentgericht (Federal Patent Court) of a complaint brought by the MIT against the decision of the Deutsches Patent- und Markenamt (German Patent and Trade Mark Office) rejecting the application for a supplementary protection certificate ('the SPC') which the MIT had filed for the medicinal product Gliadel 7.7 mg Implant ('Gliadel').

Legal context

Community legislation

3 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 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.'

4 Article 3 of Regulation No 1768/92, which sets out the conditions for obtaining an SPC, 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 or Directive 81/851/EEC, as appropriate ...;

(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.'

National law

5 Paragraph 16a of the Law on Patents (Patentgesetz) of 5 May 1936 (BGBl. 1936, p. 117), in the version applicable to the dispute in the main proceedings, is worded as follows:

'(1) Pursuant to regulations of the European Economic Community on the creation of supplementary protection certificates, which shall be notified in the *Bundesgesetzblatt*, supplementary protection directly linked to the term of the patent under Paragraph 16(1) may be requested in respect of the patent. Annual fees shall be paid for supplementary protection.

(2) Unless Community law provides otherwise, the provisions of the Law on Patents relating to the applicant's entitlement (Paragraphs 6 to 8), the effect of the patent and derogations (Paragraphs 9 to 12), rules of use, compulsory licence and withdrawal (Paragraphs 13 to 24), the scope of protection (Paragraph 14), licences and their registration (Paragraphs 15 and 30), fees (Paragraph 17(2)), lapse of the patent (Paragraph 20), nullity (Paragraph 22), preparedness to grant licences (Paragraph 23), national representative (Paragraph 25), the Patentgericht (Patent Court) and proceedings before that court (Paragraphs 65 to 99), proceedings before the Bundesgerichtshof (Federal Court of Justice) (Paragraphs 100 to 122), reinstatement of the patent (Paragraph 123), the duty to be truthful (Paragraph 124), the electronic document (Paragraph 125a), the official language, service of documents and legal aid (Paragraphs 126 to 128), infringements of the patent (Paragraphs 139 to 141 and 142a), joining of actions and the rights and powers attached to the patent (Paragraphs 145 and 146), shall apply by analogy to supplementary protection.

(3) Licences and declarations under Paragraph 23 of the Law on Patents, which are effective in respect of a patent, shall also apply to supplementary protection.'

The main proceedings and the questions referred for a preliminary ruling

6 The MIT is the holder of a European patent, for which it filed an application on 29 July 1987. That patent covers, inter alia, the alliance of two elements, polifeprosan, a polymeric, biodegradable excipient, and carmustine, an active ingredient already used in intravenous chemotherapy with inert excipients and drug additives for the treatment of brain tumours.

7 Gliadel comes in the form of a device which is implanted into the cranium for the treatment of recurrent brain tumours. The mechanism of its action consists in the carmustine, a highly cytotoxic active ingredient, being released slowly and gradually by the polifeprosan, which acts as a bioerodible matrix.

8 A marketing authorisation for Gliadel was granted in Germany by a decision of 3 August 1999.

9 Relying on that authorisation, the MIT asked the Deutsches Patent- und Markenamt to grant it an SPC for Gliadel. It requested in its main application that an SPC be granted for carmustine in combination with polifeprosan. Its alternative application sought an SPC for carmustine only.

10 The Deutsches Patent- und Markenamt rejected that application for an SPC by a decision of 16 October 2001, on the ground that polifeprosan could not be considered to be an active ingredient within the meaning of Article 1(b) and Article 3 of Regulation No 1768/92. It also held that no SPC could be granted for carmustine on its own on account of the fact that that active ingredient was already covered by a marketing authorisation, and had been for a long time.

11 The MIT lodged a complaint against the decision of the Deutsches Patent- und Markenamt before the Bundespatentgericht. That court rejected the complaint by a decision of 25 November 2002.

12 The MIT then lodged an appeal on a point of law ('Revision') before the Bundesgerichtshof (Federal Court of Justice) against the decision of the Bundespatentgericht. In support of its appeal, it claims that polifeprosan is an essential component of Gliadel since it enables carmustine to be administered in a therapeutically relevant way for the treatment of malignant brain tumours, thereby contributing to the efficacy of the medicinal product. It is consequently not a mere excipient or an ancillary component.

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

'(1) Does the concept of "combination of active ingredients of a medicinal product" within the meaning of Article 1(b) of Regulation [No 1768/92] mean that the components of the combination must all be active ingredients with a therapeutic effect?

(2) Is there a "combination of active ingredients of a medicinal product" also where a combination of substances comprises two components of which one component is a known substance with a therapeutic effect for a specific indication and the other component renders possible a pharmaceutical form of the medicinal product that brings about a changed efficacy of the medicinal product for this indication (in vivo implantation with controlled release of the active ingredient to avoid toxic effects)?'

On the questions referred for a preliminary ruling

14 With these two questions, which should be examined together, the referring court is essentially asking whether Article 1(b) of Regulation No 1768/92 must be interpreted so as to include in the concept of 'combination of active ingredients of a medicinal product', inter alia, a combination of two substances, only one of which has therapeutic effects of its own for a specific indication, the other rendering possible a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy of the first substance for that indication.

15 As set out in Article 1(b) of Regulation No 1768/92, 'product' means the active ingredient or combination of active ingredients of a medicinal product.

16 However, Regulation No 1768/92 does not define the concept of 'active ingredient'.

17 In the absence of any definition of the concept of 'active ingredient' in Regulation No 1768/92, the meaning and scope of those terms must be determined by

considering the general context in which they are used and their usual meaning in everyday language (see, inter alia, Case 349/85 *Denmark* v *Commission* [1988] ECR 169, paragraph 9, and Case C-164/98 P *DIR International Film and Others* v *Commission* [2000] ECR I-447, paragraph 26).

18 In this case, it is important to note that it is common ground, as the file in this case shows, that the expression 'active ingredient' is generally accepted in pharmacology not to include substances forming part of a medicinal product which do not have an effect of their own on the human or animal body.

19 In that regard, attention must be drawn to the fact that in point 11 of the Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final), to which the French Government referred in its oral observations, it is specified that '[t]he proposal for a Regulation therefore concerns only new medicinal products. It does not involve granting a [SPC] for all medicinal products that are authorised to be placed on the market. Only one [SPC] may be granted for any one product, a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new [SPC]'.

20 Therefore, the definition of 'product' in Article 1(b) of Regulation No 1768/92 does not in any way conflict with that referred to by the Commission in point 11 of that explanatory memorandum.

21 In fact, it is apparent from that memorandum that the pharmaceutical form of the medicinal product, to which an excipient may contribute, as noted by the Advocate

General in point 11 of his Opinion and the French Government at the hearing, does not form part of the definition of 'product', which is understood to mean an 'active substance' or 'active ingredient' in the strict sense.

22 In addition, reference can be made to Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ 1996 L 198, p. 30), recital 4 in the preamble to which states that innovation in the plant protection sector requires a level of protection which is equivalent to that granted to medicinal products by Regulation No 1768/92. Under Article 1(8) of Regulation No 1610/96, 'product' is defined as the active substance or combination of active substances of a plant protection product. An active substance, under Article 1(3), is defined as a substance having general or specific action against harmful organisms or on plants.

23 In this connection, in point 68 of the Explanatory Memorandum to the Proposal for a European Parliament and Council Regulation (EC), of 9 December 1994, concerning the creation of a supplementary protection certificate for plant protection products (COM(94) 579 final), it is stated that:

— it would not be acceptable, in view of the balance required between the interests concerned, for the total duration of protection granted by the SPC and the patent for one and the same product to be exceeded;

— that might be the case if one and the same product were able to be the subject of several successive SPCs;

— that calls for a strict definition of the product;

— if an SPC has already been granted for the active substance itself, a new SPC may not be granted for that substance, whatever changes may have been made regarding other features of the plant protection product (use of a different salt, different excipients, different presentation, etc.);

— in conclusion, it should be noted that, although one and the same substance may be the subject of several patents and several marketing authorisations in one and the same Member State, the SPC will be granted for that substance only on the basis of a single patent and a single authorisation, namely the first granted in the Member State concerned.

24 Thus, the first sentence of Article 3(2) of Regulation No 1610/96 itself provides that the holder of more than one patent for the same product is not to be granted more than one SPC for that product. As set out in recital 17 in the preamble to that regulation, the detailed rules in Article 3(2) thereof, in particular, are also valid, mutatis mutandis, for the interpretation of Article 3 of Regulation No 1768/92.

25 In the light of the foregoing, the inevitable conclusion is that a substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of 'active ingredient', which in turn is used to define the term 'product'.

26 Therefore, the alliance of such a substance with a substance which does have therapeutic effects of its own cannot give rise to a 'combination of active ingredients' within the meaning of Article 1(b) of Regulation No 1768/92.

27 The fact that the substance without any therapeutic effect of its own renders possible a pharmaceutical form of the medicinal product necessary for the therapeutic efficacy of the substance which does have therapeutic effects cannot invalidate that interpretation.

28 As shown by paragraphs 6 and 7 of this judgment, carmustine is an active ingredient which must be combined with other substances, in particular inert excipients, to be therapeutically effective. More generally, as observed by the Advocate General in point 11 of his Opinion and by the French and Netherlands Governments, it is apparently not unusual for substances which render possible a certain pharmaceutical form of the medicinal product to influence the therapeutic efficacy of the active ingredient contained in it.

29 Thus, a definition of 'combination of active ingredients of a medicinal product' which includes a combination of two substances, only one of which has therapeutic effects of its own for a specific indication, the other rendering possible a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy of the first substance for that indication, might, on any view, create legal uncertainty in the application of Regulation No 1768/92, as the French Government pointed out at the hearing. Whether a substance without any therapeutic effect of its own is necessary for the therapeutic efficacy of the active ingredient cannot, in this case, be regarded as a sufficiently precise test.

30 Moreover, such a definition is liable to prevent the attainment of the objective referred to in the sixth recital in the preamble to Regulation No 1768/92, in the words of which a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market.

31 In those circumstances, the answer to the questions referred must be that Article 1(b) of Regulation No 1768/92 must be interpreted so as not to include in the concept of 'combination of active ingredients of a medicinal product' a combination of two substances, only one of which has therapeutic effects of its own for a specific indication, the other rendering possible a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy of the first substance for that indication.

Costs

32 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. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Second Chamber) hereby rules:

Article 1(b) of Council Regulation No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, in the version resulting from the Act concerning the conditions of accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded, must be interpreted so as not to include in the concept of 'combination of active ingredients of a medicinal product' a combination of two substances, only one of which has therapeutic effects of its own for a specific indication, the other rendering possible a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy of the first substance for that indication.

[Signatures]