JUDGMENT OF THE COURT (Second Chamber)

21 April 2005 *

In Joined Cases C-207/03 and C-252/03,

References for preliminary rulings under Article 234 EC, from the High Court of Justice of England and Wales, Chancery Division (Patents Court) (United Kingdom, C-207/03), and from the Cour administrative (Luxembourg, C-252/03), by decisions of 6 May and 3 June 2003, received at the Court on 14 May and 13 June 2003, in the proceedings

Novartis AG (C-207/03),

University College London,

Institute of Microbiology and Epidemiology,

v

Comptroller-General of Patents, Designs and Trade Marks for the United Kingdom,

* Languages of the case: English and French

and

Ministre de l'Économie (C-252/03)

v

Millennium Pharmaceuticals Inc., formerly Cor Therapeutics Inc.,

THE COURT (Second Chamber),

composed of C.W.A. Timmermans, President of the Chamber, C. Gulmann (Rapporteur), J.-P. Puissochet, R. Schintgen and J.N. Cunha Rodrigues, Judges,

Advocate General: D. Ruiz-Jarabo Colomer,
Registrar: M. Múgica Arzamendi, Principal Administrator,

having regard to the written procedure and further to the hearing on 8 July 2004,

after considering the observations submitted on behalf of:

— Novartis AG, University College London and the Institute of Microbiology and Epidemiology, by M. Utges Manley, lawyer, T. Powell, Solicitor, D. Anderson QC, and K. Bacon, Barrister,

— the Ministre de l'Économie, by P. Reuter, avocat,

— the Comptroller-General of Patents, Designs and Trade Marks for the United Kingdom and the United Kingdom Government, by K. Manji and M. Berthell, acting as Agents, and C. Birss and J. Turner, Barristers,

— Millennium Pharmaceuticals Inc., by R. Subiotto, Solicitor, and C. Feddersen, Rechtsanwalt,

— the Netherlands Government, by H.G. Sevenster, acting as Agent,

— the Icelandic Government, par E. Gunnarsson and F.T. Birgisson, acting as Agents,

— the Government of the Principality of Liechtenstein, by A. Entner-Koch, M. Blaas and C. Büchel, acting as Agents,

— the Norwegian Government, by I. Holten, F. Platou Amble and K. Waage, acting as Agents,

— the EFTA Surveillance Authority, by E. Wright and M. Sánchez Rydelski, acting as Agents,

— the Commission of the European Communities, by J. Forman and K. Banks, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 7 September 2004,

gives the following

Judgment

1 The references for preliminary rulings concern the interpretation of Article 13 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).

Relevant provisions

2 The purpose of Regulation No 1768/92 is to compensate for the long period which elapses between the filing of a patent application in respect of a medicinal product and the granting of authorisation to place that product on the market by providing, in certain circumstances, for a supplementary period of patent protection.

3 The eighth and ninth recitals in the preamble to that regulation, concerning the duration of a supplementary protection certificate (hereinafter 'the SPC'), read as follows:

'... the duration of the protection granted by the certificate should be such as to provide adequate effective protection; ... for this purpose, 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 authorisation to be placed on the market in the Community;

... all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector must ... be taken into account; ... for this purpose, the certificate cannot be granted for a period exceeding five years; ...'

4 Article 3 of Regulation No 1768/92 provides:

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

...'

5 Point 6 of Annex XVII to the Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3, 482; hereinafter 'the EEA Agreement'), as amended by Annex 15 to Decision No 7/94 of the EEA Joint Committee of 21 March 1994 (OJ 1994 L 160, p. 1), states that, for the purposes of that Agreement, the following is to be added in Article 3(b) of Regulation No 1768/92:

'for the purpose of this subparagraph and the Articles which refer to it, an authorisation to place the product on the market granted in accordance with the national legislation of the EFTA State shall be treated as an authorisation granted in accordance with Directive 65/65/EEC ...'.

6 Article 7 of the EEA Agreement provides that acts referred to or contained in the annexes to that Agreement are binding upon the Contracting Parties and are, or are to be made, part of their internal legal order.

7 Chapter XIII of Annex II to the EEA Agreement refers to Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ, English Special Edition 1965-1966, p. 20).

8 Under Article 13 of Regulation No 1768/92, the SPC 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 authorisation to place the product on the market in the Community, reduced by a period of five years.

9 Point 8 of Protocol 1 to the EEA Agreement provides: '[w]henever the acts referred to contain references to the territory of the "Community" or of the "common market" the references shall for the purposes of the Agreement be understood to be references to the territories of the Contracting Parties as defined in Article 126 of the Agreement.'

10 Article 126 of the Agreement states:

'[t]he Agreement shall apply to the territories to which the Treaty establishing the European Economic Community ... is applied ... and to the territories of ... the Principality of Liechtenstein ...'.

11 Annex II to the EEA Agreement, as amended by Annex 2 to the Decision of the EEA Council No 1/95 of 10 March 1995 on the entry into force of the Agreement on the European Economic Area for the Principality of Liechtenstein (OJ 1995 L 86, p. 58), provides:

'For products covered by the acts referred to in this Annex, Liechtenstein may apply Swiss technical regulations and standards deriving from its regional union with Switzerland on the Liechtenstein market in parallel with the legislation implementing the acts referred to in this Annex. Provisions on free movement of goods

contained in this Agreement or in acts referred to shall be applicable to exports from Liechtenstein to the other Contracting Parties only [for] products in conformity with the acts referred to in this Annex.'

The main proceedings and the questions referred for a preliminary ruling

Case C-207/03

12 Novartis AG, University College London and the Institute of Microbiology and Epidemiology (hereinafter 'Novartis and Others') applied to the Comptroller-General of Patents, Designs and Trade Marks for the United Kingdom (hereinafter 'the Patent Office') for two SPCs, one for Basiliximab, an immunosuppressant, and the other for an antimalarial combination of Artemether and Lumefantrin.

13 On 7 April 1998 and 22 January 1999 respectively, the Swiss authorities granted marketing authorisations for Basiliximab and for the combination of Artemether and Lumefantrin. Those authorisations were automatically recognised in Liechtenstein, by operation of Liechtenstein law.

14 Basiliximab and the combination of Artemether and Lumefantrin were granted marketing authorisations within the Community on 9 October 1998 and 30 November 1999 respectively.

15 The Patent Office considered that the duration of the SPCs should be calculated by taking into account the dates when the Swiss marketing authorisations were granted and, by decision of 12 February 2003, granted SPCs for durations determined by reference to those dates.

16 Novartis and Others took the view that the duration of the SPCs should have been calculated by reference to the first marketing authorisations granted within the EEA and appealed against that decision to the High Court of Justice of England and Wales, Chancery Division (Patents Court).

17 It was in those circumstances that that court decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'1. Is the date of the granting of a marketing authorisation in Switzerland, which is automatically recognised in Liechtenstein, to be considered as the first authorisation to place a medicinal product on the market, for the purpose of calculating the duration of a supplementary protection certificate as provided in Article 13 of Regulation No 1768/92 (as amended by the EEA Agreement)?

2. Is a competent authority within the EEA obliged to rectify any existing supplementary protection certificates, the duration of which has been erroneously calculated?'

Case C-252/03

18 On 15 December 1999, Cor Therapeutics Inc., which was subsequently taken over by Millennium Pharmaceuticals Inc. (hereinafter 'Millennium'), both being United States companies, applied to the Luxembourg Ministre de l'Économie (Minister for the Economy, hereinafter 'the Minister') for an SPC under Regulation No 1768/92 for the medicinal product 'Eptifibatide', for which the date of the first marketing authorisation in the Community was 1 July 1999. Millennium had stated in its application that a marketing authorisation had been issued for that medicinal product by the Swiss authorities on 27 February 1997.

19 On the ground that, under the legislation in force in Liechtenstein, Swiss marketing authorisations are automatically recognised in that State, which is a member of the EEA, the Minister issued an SPC on 15 February 2000 fixing its date of commencement as the date of the Swiss marketing authorisation, that is 27 February 1997.

20 Millennium brought an action before the Tribunal administratif de Luxembourg (Administrative Court, Luxembourg), claiming that that date, referred to as the date of the first marketing authorisation, should be replaced by 1 July 1999. That court upheld Millennium's claim.

21 The Minister appealed against that court's judgment to the Cour administrative (Higher Administrative Court).

22 He argued that, under Liechtenstein law, marketing authorisations for medicinal products granted by a Swiss authority are valid in Liechtenstein, which is a party to

the EEA Agreement, and that the Commission of the European Communities concluded therefrom that a first marketing authorisation issued by a Swiss authority must be used for the calculation of the duration of SPCs in respect of medicinal products.

23 Millennium contended that it follows from both textual and teleological examination of Regulation No 1768/92, of the EEA Agreement and of the Agreements between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, of 21 June 1999 (OJ 2002 L 114, p. 6), that a Swiss marketing authorisation cannot be regarded as 'the first authorisation to place the product on the market in the Community' within the meaning of Article 13 of that regulation.

24 The Cour administrative therefore decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Does a marketing authorisation issued by the Swiss authorities constitute the first authorisation to place a product on the market in the Community within the meaning of Article 13 of ... Regulation (EEC) No 1768/92 ... ?'

The joinder of Cases C-207/03 and C-252/03

25 In view of the connection between these two cases, it is appropriate to join them for the purposes of the judgment in accordance with Article 43 of the Rules of Procedure, in conjunction with Article 103 thereof.

On the questions referred for a preliminary ruling

The first question referred, in the context of both cases

26 For the purposes of the application of the EEA Agreement, Article 13 of Regulation No 1768/92 is to be read as providing that the SPC 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 authorisation to place the product on the market in the territory of one of the States covered by the EEA Agreement, reduced by a period of five years.

27 It must therefore be considered whether a marketing authorisation issued by the Swiss authorities and automatically recognised by the Principality of Liechtenstein under that State's legislation really constitutes a first marketing authorisation for the purposes of Article 13 of Regulation No 1768/92.

28 In that regard, it is clear from Annex II to the EEA Agreement, as amended by Annex 2 to the Decision of the EEA Council No 1/95, that Liechtenstein may, as regards inter alia the medicinal products to which Directive 65/65 refers, apply Swiss technical regulations and standards deriving from its regional union with Switzerland on the Liechtenstein market in parallel with the legislation implementing that directive.

29 The EEA Agreement recognises therefore that two types of marketing authorisation may co-exist in the principality of Liechtenstein, namely marketing authorisations issued by the Swiss authorities, which because of the regional union between Switzerland and that State are automatically recognised in the latter, and marketing authorisations issued in Liechtenstein in accordance with Directive 65/65.

30 Thus, under Article 13 of Regulation No 1768/92, in conjunction with Annex II to the EEA Agreement, as amended by Annex 2 to the Decision of the EEA Council No 1/95, a marketing authorisation issued by the Swiss authorities and automatically recognised in Liechtenstein in the context of its regional union with Switzerland must be regarded as a first marketing authorisation for the purposes of the said Article 13.

31 Such an interpretation of that provision is, moreover, consistent with the purpose of Regulation No 1768/92, set out in the eighth recital in the preamble thereto, as it is to be read for the purposes of the application of the EEA Agreement and according to which the holder of both a patent and an SPC should not be able to enjoy more than 15 years of exclusivity from the time the medicinal product concerned first obtains authorisation to be placed on the market in the EEA. Indeed, if a marketing authorisation issued by the Swiss authorities and automatically recognised by the Principality of Liechtenstein under that State's legislation were precluded from constituting a first marketing authorisation for the purposes of Article 13 of Regulation No 1768/92, the duration of SPCs would have to be calculated by reference to a marketing authorisation issued subsequently in the EEA. Thus, there would be a risk of the period of 15 years of exclusivity being exceeded in the EEA.

32 Furthermore, the fact that marketing authorisations granted in Switzerland do not permit the free movement of the medicinal products to which they relate within the territory of the EEA, with the exception of Liechtenstein, is not, contrary to the submissions of Novartis and Others, Millennium, the Netherlands and Icelandic Governments, the Government of the Principality of Liechtenstein, the Norwegian Government and the EFTA Surveillance Authority, relevant to the interpretation of Article 13 of Regulation No 1768/92, as it is to be read for the purposes of the application of the EEA Agreement. In that regard, it is sufficient to point out, as did the Advocate General in point 43 of his Opinion, that marketing authorisations granted by a Member State under Directive 65/65 also do not permit the product to be freely distributed on the market of the other Member States.

33 It follows that, in so far as a marketing authorisation issued for a medicinal product by the Swiss authorities and automatically recognised by the Principality of Liechtenstein under that State's legislation is the first authorisation to place that product on the market in one of the States of the EEA, it constitutes the first authorisation to place the product on the market within the meaning of Article 13 of Regulation No 1768/92, as it is to be read for the purposes of the application of the EEA Agreement.

The second question referred in Case C-207/03

34 Since the interpretation of Article 13 of Regulation No 1768/92, as it is to be read for the purposes of the application of the EEA Agreement, given by the Court in its reply to the first question referred was adopted by the Patent Office in the decision which is the subject-matter of the main proceedings in Case C-207/03, there is no need to reply to the second question.

Costs

35 Since these proceedings are, for the parties to the main proceedings, a step in the actions before the national courts, the decisions on costs are a matter for those courts. 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) rules as follows:

In so far as an authorisation to place a medicinal product on the market issued by the Swiss authorities and automatically recognised by the Principality of Liechtenstein under that State's legislation is the first authorisation to place that product on the market in one of the States of the European Economic Area, it constitutes the first authorisation to place the product on the market within the meaning of Article 13 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, as it is to be read for the purposes of the application of the Agreement on the European Economic Area.

[Signatures]