JUDGMENT OF THE COURT (Second Chamber)

2 September 2010 *

In Case C-66/09,

REFERENCE for a preliminary ruling under Article 234 EC from the Lietuvos Aukščiausiasis Teismas (Lithuania), made by decision of 10 February 2009, received at the Court on 16 February 2009, in the proceedings

Kirin Amgen Inc.

v

Lietuvos Respublikos valstybinis patentų biuras,

intervener:

Amgen Europe BV,

* Language of the case: Lithuanian.

THE COURT (Second Chamber),

composed of J.N. Cunha Rodrigues, President of the Chamber, P. Lindh, A. Rosas, U. Lõhmus (Rapporteur) and A. Ó Caoimh, Judges,

Advocate General: Y. Bot,
Registrar: C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing on 3 February 2010,

after considering the observations submitted on behalf of:

— Kirin Amgen Inc., by D. Ušinskaitė-Filonovienė, advokatė, A. Pakėnienė, patentinė patikėtinė, and C. Birss QC,

— the Lithuanian Government, by D. Kriaučiūnas, I. Jarukaitis and L. Mickienė, acting as Agents,

— the Czech Government, by M. Smolek, acting as Agent,

— the Latvian Government, by K. Drēviņa and E. Eihmane, acting as Agents,

— the Hungarian Government, by R. Somssich, K. Szíjjártó, M. Ficsor and M. Fehér, acting as Agents,

— the European Commission, by A. Steiblytė and H. Krämer, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 25 February 2010,

gives the following

Judgment

1 This reference for a preliminary ruling relates to the interpretation of Articles 7 and 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), as amended by the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland,

the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ 2003 L 236, p. 33) ('Regulation No 1768/92' and 'the 2003 Act of Accession' respectively).

2 The reference was made in proceedings between Kirin Amgen Inc. ('Kirin Amgen') and the Lietuvos Respublikos valstybinis patentų biuras (State Patent Bureau of the Republic of Lithuania) concerning the latter's refusal to grant that company a supplementary protection certificate ('SPC') for its medicinal product Aranesp.

Legal context

2003 Act of Accession

3 Article 2 of the 2003 Act of Accession provides:

'From the date of accession, the provisions of the original Treaties and the acts adopted by the institutions and the European Central Bank before accession shall be binding on the new Member States and shall apply in those States under the conditions laid down in those Treaties and in this Act.'

4 Article 20 of the 2003 Act of Accession provides that 'the acts listed in Annex II to this Act shall be adapted as specified in that Annex'.

5 Chapter 4, C, II, headed 'Supplementary protection certificates', which is in Annex II to the 2003 Act of Accession, itself headed 'List referred to in Article 20 of the [2003] Act of Accession', inserts Article 19a into Regulation No 1768/92.

Regulation No 1768/92

6 The 6th, 7th and 10th recitals in the preamble to Regulation No 1768/92 state:

'… 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;

… therefore, the creation of [an SPC] granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted is necessary; …

…

… a fair balance should also be struck with regard to the determination of the transitional arrangements; … such 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 Community level'.

7 Article 3 of Regulation No 1768/92 lays down the conditions for obtaining an SPC as follows:

'[An SPC] 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 [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), as amended by Council Directive 89/341/EEC of 3 May 1989 (OJ 1989 L 142, p. 11)] or [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), as amended by Council Directive 90/676/EEC of 13 December 1990 (OJ 1990 L 373, p. 15)], as appropriate. …

(c) the product has not already been the subject of [an SPC];

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

8 Article 7(1) of Regulation No 1768/92 provides:

'The application for [an SPC] shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted.'

9 Article 13(1) of Regulation No 1768/92 states:

'The [SPC] 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 authorisation to place the product on the market in the Community reduced by a period of five years.'

10 Articles 19 to 22 of Regulation No 1768/92 contain transitional provisions. Article 19 is worded as follows:

'1. Any product which on the date of accession is protected by a valid patent and for which the first authorisation to place it on the market as a medicinal product in the Community or within the territories of Austria, Finland or Sweden was obtained after 1 January 1985 may be granted [an SPC].

In the case of [SPCs] to be granted in Denmark, in Germany and in Finland, the date of 1 January 1985 shall be replaced by that of 1 January 1988.

In the case of [SPCs] to be granted in Belgium, in Italy and in Austria, the date of 1 January 1985 shall be replaced by that of 1 January 1982.

2. An application for [an SPC] as referred to in paragraph 1 shall be submitted within six months of the date on which this Regulation enters into force.'

11 Article 19a, headed 'Additional provisions relating to the enlargement of the Community', provides:

'Without prejudice to the other provisions of this Regulation the following shall apply:

(a) (i) any medicinal product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a medicinal product was obtained in the Czech Republic after 10 November 1999 may be granted [an SPC], provided that the application for [an SPC] was lodged within six months of the date on which the first market authorisation was obtained,

(ii) any medicinal product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a medicinal product was obtained in the Community not earlier than six months prior to the date of accession may be granted [an SPC], provided that the application for [an SPC] was lodged within six months of the date on which the first market authorisation was obtained;

...

(e) any medicinal product protected by a valid basic patent applied for after 1 February 1994 and for which the first authorisation to place it on the market as a medicinal product was obtained in Lithuania prior to the date of accession may be granted [an SPC], provided that the application for [an SPC] is lodged within six months of the date of accession.'

Regulation (EEC) No 2309/93

12 The first subparagraph of Article 12(1) of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation 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:

'Without prejudice to Article 6 of Directive 65/65/EEC, a marketing authorisation which has been granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community. It shall confer the same rights and obligations in each of the Member States as a marketing authorisation granted by that Member State in accordance with Article 3 of Directive 65/65/EEC.'

13 Article 3 of Directive 65/65 has been replaced by Articles 4(3) and 6(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67).

The dispute in the main proceedings and the questions referred for a preliminary ruling

14 Kirin Amgen is the holder of a European patent for the medicinal product Aranesp. The patent was applied for on 16 August 1994 and its effects have been extended to Lithuania. On 8 June 2001 Kirin Amgen obtained for that medicinal product a marketing authorisation under Regulation No 2309/93 ('the Community marketing authorisation'). On 29 October 2004 it lodged an application for an SPC with the Lietuvos Respublikos valstybinis patentų biuras, accompanying the application with the Community marketing authorisation. The SPC was refused by decision of that body and successive appeals contesting its decision before various national courts were unsuccessful.

15 In its appeal before the referring court, Kirin Amgen asserts that the fact that it holds a Community marketing authorisation is sufficient to obtain an SPC in Lithuania and that it did not exceed the six-month period, referred to in Article 7 or 19 of Regulation No 1768/92, for lodging its application, because that period must be calculated from 1 May 2004, the date upon which the Republic of Lithuania acceded to the European Union.

16 In those circumstances, the Lietuvos Aukščiausiasis Teismas (Supreme Court of Lithuania) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Is the date, referred to in Article 19(2) of Regulation No 1768/92, upon which that regulation enters into force to be understood for [the Republic of] Lithuania as the date of its accession to the European Union?

(2) Should the answer to the first question be in the affirmative, what is the relationship between Article 19 and Article 7 of Regulation No 1768/92 when calculating the six-month period and which of those articles is it necessary to apply in a case?

(3) Did an authorisation to place a product on the market in the European Community enter into force unconditionally in the Republic of Lithuania from the date of its accession to the European Union?

(4) Should the answer to the third question be in the affirmative, can the entry into force of the authorisation to place the product on the market be equated to its grant for the purposes of Article 3(b) of Regulation No 1768/92?'

Request that the oral procedure be reopened

17 By letter of 30 June 2010, Kirin Amgen requested the reopening of the oral procedure, stating essentially that the view taken in the Advocate General's Opinion is incorrect and that new arguments relating to Articles 3, 7 and 13 of Regulation No 1768/92,

in particular regarding Article 3(d), have been expounded there. In support of its request, Kirin Amgen pleads the right to adversarial proceedings, in accordance with Article 6 of the European Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950.

18 Bearing in mind the very purpose of an adversarial procedure, which is to prevent the Court from being influenced by arguments which the parties have been unable to discuss, the Court may of its own motion, on a proposal from the Advocate General or at the request of the parties, order that the oral procedure be reopened, in accordance with Article 61 of its Rules of Procedure, if it considers that it lacks sufficient information or that the case must be dealt with on the basis of an argument which has not been debated between the parties (see, inter alia, the order in Case C-17/98 *Emesa Sugar* [2000] ECR I-665, paragraph 18, and Case C-42/07 *Liga Portuguesa de Futebol Profissional and Bwin International* [2009] ECR I-7633, paragraph 31 and the case-law cited).

19 In the present case, however, the Court, having heard the Advocate General, takes the view that it has all the material necessary to answer the questions referred and that the observations submitted before it related to that material.

20 Consequently, the request that the oral procedure be reopened must be rejected.

Consideration of the questions referred

Preliminary observations

21 It is apparent from the order for reference and, in particular, from the first two questions asked by the national court that the latter considers that the outcome of the main proceedings depends essentially on the interpretation of Article 19 of Regulation No 1768/92. The Court has already held that the European Union legislature included that article in the regulation's transitional provisions in order to limit the adverse consequences of the expiry or reduction of the six-month period laid down in Article 7(1) of the regulation and to make it possible for products which had already obtained authorisation to be placed on the market as medicinal products on the date on which the regulation entered into force to take advantage of the scheme established by the regulation. Article 19(2) operates, in the circumstances provided for in Article 19(1), as a derogation from Article 7 of the regulation (see, to this effect, Case C-110/95 *Yamanouchi Pharmaceutical* [1997] ECR I-3251, paragraph 19, and Case C-127/00 *Hässle* [2003] ECR I-14781, paragraph 29).

22 The Court has also held that it was in order to take account of differences in Member States' assessments that Article 19 of Regulation No 1768/92 set, as a transitional measure, different relevant dates for different Member States as regards the obtaining of the first marketing authorisation, the setting of such dates thus appearing to be justified inasmuch as each of them reflects the assessment made by each Member State in the light, in particular, of its health system, the organisation and financing of which vary from one Member State to the next (see, to this effect, *Hässle*, paragraphs 39 and 40). That provision therefore reflects the result of negotiations and establishes specific mechanisms for different Member States.

23 Thus, Article 19 of Regulation No 1768/92 laid down, for the 12 Member States of the Community on the date of the regulation's entry into force and the three Member States which acceded to the Community on 1 January 1995, a transitional rule, derogating from Article 7 of the regulation, for any product which, on the date of the regulation's entry into force, had obtained its first marketing authorisation in the Community after a date specified in Article 19.

24 Just like Article 19, Article 19a of the regulation, which also forms part of the transitional provisions, must be regarded as expressing the result of the negotiations conducted with the Member States which acceded to the European Union on 1 May 2004.

25 Consequently, it follows that Article 19a of Regulation No 1768/92 applies to those new Member States, in particular Article 19a(e) which concerns the Republic of Lithuania. On the other hand, Article 19 of the regulation relates only to the States which were members of the Community on the date on which the regulation entered into force and to the States which acceded upon the enlargement on 1 January 1995.

26 If Article 19 of Regulation No 1768/92 had to be read as also concerning the Member States which acceded on 1 May 2004, the results of the negotiations with those Member States, expressed in the various paragraphs of Article 19a of the regulation, could prove meaningless.

27 In the procedure laid down by Article 267 TFEU providing for cooperation between national courts and the Court of Justice, it is for the latter to provide the national court with an answer which will be of use to it and enable it to determine the case

before it. To that end, the Court may have to reformulate the questions referred to it. The Court has a duty to interpret all provisions of Community law which national courts need in order to decide the actions pending before them, even if those provisions are not expressly indicated in the questions referred to the Court of Justice by those courts (see Joined Cases C-329/06 and C-343/06 *Wiedemann and Funk* [2008] ECR I-4635, paragraph 45 and the case-law cited).

28 Accordingly, and having regard to the facts of the main proceedings, the national court's questions, which it is appropriate to examine together, should be understood to be asking, in essence, whether one or other of Article 7 and Article 19a(e) of Regulation No 1768/92 must be interpreted as allowing the holder of a valid basic patent in respect of a product to apply to the competent Lithuanian authorities, within six months of the date upon which the Republic of Lithuania acceded to the European Union, that is to say, 1 May 2004, for the grant of an SPC where a Community authorisation to place that product on the market as a medicinal product was obtained more than six months before that date, but not a national marketing authorisation in Lithuania.

The possibility of obtaining the SPC on the basis of Article 19a(e) of Regulation No 1768/92

29 Under Article 19a(e) of Regulation No 1768/92, an SPC may be granted in Lithuania for a medicinal product which is protected by a valid basic patent applied for after 1 February 1994 and for which the first national authorisation in Lithuania to place it on the market as a medicinal product was obtained prior to 1 May 2004, provided that the application for an SPC is lodged within six months of 1 May 2004.

30 As a transitional provision derogating from Article 7 of Regulation No 1768/92, Article 19a(e) of that regulation, just like Article 19, is intended to limit the adverse consequences of the expiry or reduction of the period referred to in Article 7 for applying for an SPC in Lithuania and makes it possible for products which had already obtained a national authorisation to be placed on the market as medicinal products on the date on which the regulation entered into force to take advantage of the scheme established by the regulation (see, by analogy, *Hässle*, paragraph 29).

31 It is settled case-law that derogations laid down by acts of accession must be interpreted strictly (see, to this effect, Joined Cases C-267/95 and C-268/95 *Merck and Beecham* [1996] ECR I-6285, paragraph 23, and Case C-233/97 *KappAhl* [1998] ECR I-8069, paragraph 18).

32 In the main proceedings, the marketing authorisation at issue, which was granted to Kirin Amgen on 8 June 2001, is a Community marketing authorisation and not a national marketing authorisation obtained in Lithuania.

33 Under Article 19a(e) of Regulation No 1768/92, an SPC may be granted only in respect of a product for which a first authorisation to place it on the market as a medicinal product has been obtained in Lithuania. This provision does not lay down any derogation concerning products which have been the subject of a Community marketing authorisation. Since the provision is couched in clear and unambiguous terms, it must, in accordance with the rule that transitional provisions are to be interpreted strictly, be construed in a manner which accords with its wording and which reflects the will of the European Union legislature as resulting from the negotiations which led to the 2003 Act of Accession.

34 In the context of the transitional provisions, this conclusion cannot be called into question by the first subparagraph of Article 12(1) of Regulation No 2309/93, under which a Community marketing authorisation confers the same rights and obligations in each of the Member States as a national marketing authorisation granted by that Member State.

35 It follows that, since Article 19a(e) of Regulation No 1768/92 lays down an exception to the period prescribed in Article 7 of that regulation only for the holder of a national marketing authorisation, the holder of a Community marketing authorisation obtained before 1 May 2004 cannot rely on Article 19a(e) to obtain an SPC in Lithuania.

The possibility of obtaining an SPC on the basis of Article 7 of Regulation No 1768/92

36 According to Article 7(1) of Regulation No 1768/92, read in conjunction with Article 3(b) and (d) thereof, an application for an SPC must be lodged within six months of the date on which the first authorisation to place the product on the market as a medicinal product is granted in the Member State for which the application is made (see *Hässle*, paragraph 26).

37 Pursuant to the first subparagraph of Article 12(1) of Regulation No 2309/93, a Community marketing authorisation confers the same rights and obligations in each of the Member States as a national marketing authorisation granted by that Member State in accordance with Articles 4(3) and 6(1) of Directive 2001/83, which have replaced Article 3 of Directive 65/65 as amended by Directive 89/341.

38 Kirin Amgen contends, as does the European Commission, that the holder of a Community marketing authorisation such as that at issue in the main proceedings may, on the basis of Article 7 of Regulation No 1768/92, lodge his application for an SPC within six months of that regulation's entry into force in Lithuania. For that purpose, the grant, within the meaning of Article 3(b) of that regulation, of the Community marketing authorisation must, in their submission, be equated to that authorisation's entry into force, so that it must be considered to have been granted on 1 May 2004.

39 It is true that, as is asserted by Kirin Amgen, the Member States which have submitted written observations to the Court and the Commission, a decision by the Commission granting a Community marketing authorisation has effect, by virtue of Article 2 of the 2003 Act of Accession, in the new Member State of the European Union from the date of its accession, so that the Community marketing authorisation granted to Kirin Amgen on 8 June 2001 entered into force in Lithuania on 1 May 2004.

40 However, the latter date cannot be equated to the date of grant of the marketing authorisation, within the meaning of Article 3(b) of Regulation No 1768/92.

41 In the absence of a definition of 'grant' in Regulation No 1768/92, it follows from the Court's settled case-law that, in interpreting a provision of European Union law, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part (see, inter alia, Case 292/82 *Merck* [1983] ECR 3781, paragraph 12; Case C-34/05 *Schouten* [2007] ECR I-1687, paragraph 25; Case C-466/07 *Klarenberg* [2009] ECR I-803, paragraph 37; and Case C-433/08 *Yaesu Europe* [2009] ECR I-11487, paragraph 24).

42 In that regard, it is clear from the wording of Articles 19 and 19a of Regulation No 1768/92 that the concept of 'obtaining' the marketing authorisation is distinguished from that of 'entry into force' since the obtaining of the authorisation precedes the accession of the Member States concerned. In the majority of the language versions of that regulation existing on the date on which it was adopted, the concept of 'obtaining' a marketing authorisation is used both in Article 19 and in Articles 3(b) and 7 of that regulation and there is nothing to indicate that a different interpretation should be placed on that concept according to the provision in which it is used. On the contrary, it is used in the same context in all those articles. Admittedly, certain language versions of that regulation, in particular the English version, use a different expression in Articles 3(b) and 7 of Regulation No 1768/92, namely 'granted'. The fact, however, remains that the obtaining of a marketing authorisation occurs at the time when it is granted.

43 Kirin Amgen nevertheless submits that the objective pursued by Regulation No 1768/92 of ensuring a uniform duration of protection for a medicinal product necessarily means that the grant of a Community marketing authorisation, within the meaning of Article 3(b) of that regulation, should be equated to that authorisation's entry into force in Lithuania. Any other interpretation would give rise to a two-tier system for the legal protection of intellectual property, according to whether that protection is implemented in the States acceding to the European Union or in its existing Member States. If it were impossible for holders of a Community marketing authorisation to obtain an SPC in a new Member State, parallel imports from that Member State would become possible, thereby threatening the proper functioning of the internal market.

44 This line of argument cannot be upheld.

45 As regards the objective pursued by Regulation No 1768/92, it is admittedly true that the regulation establishes a uniform solution at European Union level by creating an SPC which may be obtained by the holder of a national or European patent under the same conditions in each Member State and by providing, in particular, for a uniform duration of protection (see, by analogy, Case C-350/92 *Spain* v *Council* [1995] ECR

I-1985, paragraph 34, and *Hässle*, paragraph 37). As is apparent from the sixth recital in its preamble, that regulation seeks thereby to prevent the heterogeneous development of national laws leading to disparities 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.

46 Nevertheless, certain Member States wished, in accordance with the 10th recital in the preamble to that regulation, to safeguard for a longer period the achievement of other legitimate objectives, concerning their public-health policies, and, in particular, ensure the financial stability of their health system by supporting the generic medicinal product manufacturing industry (see, to this effect, *Hässle*, paragraph 38).

47 In order to take account of those differences in assessment, Articles 19 and 19a of Regulation No 1768/92 contain different relevant dates as a transitional measure. The setting of those dates according to the Member State thus appears to be justified inasmuch as each of them shows the assessment made by each Member State in the light, in particular, of its health system, the organisation and financing of which vary from one Member State to the next (see, by analogy, *Hässle*, paragraphs 39 and 40).

48 It follows from the foregoing that the objective pursued by Regulation No 1768/92 of according uniform protection for a medicinal product throughout the European Union does not preclude transitional provisions, resulting from the accession negotiations, which may mean that it is not possible to apply for an SPC for certain medicinal products in certain Member States. This outcome, which may impede, even if only temporarily, that objective and the functioning of the internal market, is justified by the legitimate objectives concerning health policies, including, as the case may be, the financial stability of the health systems of the Member States (see, to this effect, *Hässle*, paragraph 46).

49 In the circumstances of the main proceedings, it would run counter to the outcome of the negotiations which led to the accession of the Republic of Lithuania to the European Union to accept that a holder of a Community marketing authorisation such as the holder in the main proceedings can rely on Article 7 of Regulation No 1768/92 to obtain an SPC in Lithuania. Article 19a(e) of that regulation provides for the possibility of applying to the competent Lithuanian authorities for grant of such an SPC only on the basis of a first marketing authorisation obtained in Lithuania before the accession of that State. As has been stated in paragraph 33 of the present judgment, that provision does not lay down any derogation concerning products which have been the subject of a Community marketing authorisation.

50 Furthermore, if the entry into force of a Community marketing authorisation in a new Member State could be equated to its grant there, every Community marketing authorisation would confer entitlement to the grant of an SPC if it were applied for within six months of the accession of such a Member State to the European Union, even if the date of grant of that marketing authorisation were prior to the dates for the obtaining of an authorisation that are referred to in the transitional provisions of Regulation No 1768/92. This would also run counter to the outcome of the accession negotiations.

51 To give an example concerning another Member State, it would be possible, if the grant of a marketing authorisation were equated to its entry into force, for the holder of a Community marketing authorisation obtained before 1 May 2004 to apply in the Czech Republic for an SPC until 30 November 2004, although Article 19a(a)(ii) of Regulation No 1768/92 provides for the lodging of such an application, so far as concerns that Member State, only within six months of the date on which the first marketing authorisation was obtained.

52 Consequently, the wording and the context of Articles 3(b), 7 and 19a(e) of Regulation No 1768/92 as well as the objective of the latter, and in particular the objective pursued by its transitional provisions, preclude the entry into force of the Community marketing authorisation from being equated to its grant within the meaning of Article 3(b).

53 Having regard to all the foregoing considerations, the answer to the questions referred is that Articles 7 and 19a(e) of Regulation No 1768/92 must be interpreted as not allowing the holder of a valid basic patent in respect of a product to apply to the competent Lithuanian authorities, within six months of the date upon which the Republic of Lithuania acceded to the European Union, for the grant of an SPC where a Community authorisation to place that product on the market as a medicinal product was obtained more than six months before accession under Regulation No 2309/93, but the product did not obtain a marketing authorisation in Lithuania.

Costs

54 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:

Articles 7 and 19a(e) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, as amended by the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded, must be interpreted as not allowing the holder of a valid basic patent in respect of a product to apply to the competent Lithuanian authorities, within six months

of the date upon which the Republic of Lithuania acceded to the European Union, for the grant of a supplementary protection certificate where an authorisation to place that product on the market as a medicinal product was obtained more than six months before accession under Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, but the product did not obtain a marketing authorisation in Lithuania.

[Signatures]