OPINION OF ADVOCATE GENERAL BOT
delivered on 25 February 2010[1]

1. A pharmaceutical undertaking which is the holder of a patent for a medicinal product and which is also authorised to place that product on the market may benefit from an extension of the period of its exclusive rights as a result of the award of a 'supplementary protection certificate', the grant of which, in each of the Member States, is governed by Regulation (EEC) No 1768/92.[2]

2. In the context of the entry into force of the Regulation in Lithuania, the Community legislature adopted a transitional provision under which supplementary protection is granted, in that State, only to medicinal products which obtained a national marketing authorisation prior to that State's accession to the European Union.

3. It was in application of that provision that the competent Lithuanian authorities refused to grant Kirin Amgen Inc.,[3] a pharmaceutical undertaking, a supplementary protection certificate for the medicinal product Aranesp. Although that medicinal product had been granted a Community marketing authorisation in 2001 by the European Commission, under Regulation (EEC) No 2309/93,[4] those authorities considered that the claimant in the main proceedings did not have the national marketing authorisation required in Lithuania in order to rely on the benefit of supplementary protection.

1 — Original language: French.

2 — Council regulation of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1), as amended, first, by 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 of 29 August 1994 (OJ 1994 C 241, p. 21, and OJ 1995 L 1, p. 1), secondly, 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 of 23 September 2003 (OJ 2003 L 236, p. 33; 'the Act of Accession') and, finally, by the Act concerning the conditions of accession of the Republic of Bulgaria and Romania and the adjustments to the Treaties on which the European Union is founded of 21 June 2005 (OJ 2005 L 157, p. 203) ('the Regulation').

3 — 'The claimant in the main proceedings'.

4 — Council regulation 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).

4. The Lietuvos Aukščiausiasis Teismas (Supreme Court of Lithuania) has therefore asked the Court to interpret that provision in order to determine the legal rules which must be applied quite specifically to that type of situation, in which the holder of the basic patent does not have a national marketing authorisation in Lithuania, but obtained, prior to the accession of that State to the European Union, a Community marketing authorisation granted by the Commission.

5. In this Opinion, I propose that the Court should not interpret the provision at issue broadly, as one might spontaneously be inclined to do since the aim of the legislature is to ensure equivalent protection for medicinal products throughout the European Union, but on the contrary should adopt a strict interpretation which is, moreover, consistent with the case-law established by the Court relating to derogations laid down by acts of accession.

6. That is why, after setting out the context in which the Regulation entered into force in Lithuania, I shall propose that the Court should rule that the transitional and derogating system of rules laid down by Article 19a(e) of the Regulation does not allow the holder of a basic patent such as the claimant in the main proceedings to apply for the grant in Lithuania of a supplementary protection certificate.

I — The Community legal framework

A — *The Treaty of Accession and the Act of Accession*

7. The Treaty concerning the accession to the European Union of 10 new Member States, [5] including the Republic of Lithuania, was signed at Athens on 16 April 2003. [6] It entered into force on 1 May 2004. [7] Under Article 1(2) of that Treaty, the conditions of admission and the adjustments to the Treaties entailed by such admission are set out in the Act of Accession annexed to that Treaty.

8. Article 2 of the Act of Accession provides that, '[f]rom 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'.

5 — 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 ('the new Member States').

6 — OJ 2003 L 236, p. 17 ('the Accession Treaty').

7 — See Article 2(2) of the Accession Treaty.

9. However, under Article 10 of the Act of Accession, the application of those provisions may, as a transitional measure, be subject to the derogations provided for in that act.

10. Thus, Annex II to that act inserted a new Article 19a into the Regulation for the new Member States. [8] That provision lays down the conditions under which products protected by a basic patent which were authorised to be placed on the market in the new Member States before 1 May 2004 may obtain a supplementary protection certificate in those States.

11. The requirements for lodging an application for a supplementary protection certificate in Lithuania are laid down in Article 19a(e) of the Regulation. That provision is worded as follows:

'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 a certificate, provided that the application for a certificate is lodged within six months of the date of accession.'

B — *Marketing authorisation for medicinal products for human use*

12. A medicinal product cannot be placed on the market in a Member State without marketing authorisation, the principal aim of which is to protect public health.

13. The present legislation comprises two bodies of rules.

14. The first is that of Directives 65/65/EEC [9] and 2001/83/EC, [10] which contain provisions

8 — See Annex II, Chapter 4 ('Company law'), Section C ('Industrial property rights'), point II ('Supplementary protection certificates') (OJ 2003 L 236, p. 342).

9 — Council directive of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 24), as amended by Council Directives 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36) and 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22) ('Directive 65/65'). Directive 87/21 laid down the requirements applicable to the grant of marketing authorisations in the specific case of an abridged procedure. Directive 93/39 introduced into existing Community legislation a mutual recognition procedure for national marketing authorisations, together with a Community consultation and arbitration procedure.

10 — Directive 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), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34) ('Directive 2001/83').

specific to national marketing authorisations and to their mutual recognition by the other Member States. Under this national or decentralised procedure, a pharmaceutical laboratory lodges an application dossier for marketing authorisation with the competent national authority which examines that dossier in the light of the harmonised requirements laid down by those directives. If it wishes, that laboratory may subsequently initiate the procedure for recognition of the authorisation by the other Member States.

15. The second body of rules is that of Regulation No 2309/93, which establishes a centralised procedure for authorisation to place a product on the market at Community level, having uniform legal effects throughout the territory of the European Union. This procedure is mandatory where the medicinal product concerned is derived from biotechnology, [11] which is the case with Aranesp.

16. Under Article 12(1) of Regulation No 2309/93, a marketing authorisation which has been granted in accordance with the centralised procedure is to be valid throughout the Community and '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'.

17. Also, under Article 12(3) of Regulation No 2309/93, notification of marketing authorisation is to be published in the *Official Journal of the European Communities*, quoting in particular the date of authorisation.

18. Finally, under Article 13(1) of Regulation No 2309/93, the authorisation is valid for a period of five years and is renewable for five-year periods after consideration by the European Agency of a dossier containing up-to-date information on pharmacovigilance.

C — *The supplementary protection certificate*

19. The Regulation introduces a supplementary protection certificate, which is ancillary to a previously granted national or European patent, with a view to extending the duration of the rights that the patent confers on its holder. [12] Under the patent, the holder thereof

11 — See Article 3 of Regulation No 2309/93.

12 — As the Court stated in Case C-350/92 *Spain* v *Council* [1995] ECR I-1985, paragraph 27, that supplementary protection certificate does not create a new industrial property right.

has the exclusive right to manufacture the patented product and to place it on the market as well as the right to oppose infringements. [13]

20. The Regulation entered into force on 2 January 1993.

21. The aim of the Regulation is to play a role in the continuing improvement in public health by encouraging pharmaceutical research and innovation through the grant of supplementary legal protection to medicinal products that are the result of long, costly research (first and second recitals in the preamble to the Regulation).

22. Pharmaceutical research activities require substantial investment which can be covered only if the undertaking carrying out the research gains a monopoly over the exploitation of its results for a sufficient period of time. In order to protect public health, placing a proprietary medicinal product on the market requires authorisation to be granted, at the end of a lengthy and complex procedure, with the result that the period that elapses between the filing of the application for a patent and the grant of authorisation to place the product on the market reduces significantly the duration of the exclusive exploitation rights, discourages investors and penalises pharmaceutical research [14] (third and fourth recitals in the preamble to the Regulation). Such a situation gives grounds for fears that research centres situated in the Member States might relocate to States that offer greater protection, such as the United States of America or Japan (fifth recital in the preamble to the Regulation).

23. In order to remove the risk of the heterogeneous development of national laws, which would be liable to create obstacles to the free movement of medicinal products in the internal market, the Regulation thus introduces a certificate granted, under the same conditions, by all the Member States at the request of the holder of a national or European patent (sixth and seventh recitals in the preamble to the Regulation).

13 — See Case 15/74 *Sterling Drug* [1974] ECR 1147, paragraph 9.

14 — Article 63(1) of the Convention on the Grant of European Patents, concluded at Munich on 5 October 1973 (*United Nations Treaty Series*, 1978, Vol. 1065, No 16208, p. 199; 'the European Patent Convention'), provides that the term of the European patent is to be 20 years as from the date of filing of the application. When the Commission presented its proposal for a Council regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final), it estimated at four years the average period which elapses in industry in general from the date on which the patent application is filed to the date on which the invention is placed on the market (point 51 of the explanatory memorandum to the proposal). The effective period of exclusivity conferred by a patent is thus in fact reduced to 16 years. In the pharmaceutical sector, however, the need to comply with rigorous additional requirements before authorisation to market a new medicinal product is granted means that considerably more than four years will often elapse before the patent holder can expect to start getting a return on his investment. The effective period of exclusivity will accordingly be correspondingly shorter. This situation is the result of administrative procedures which are moreover recognised and regarded as necessary in order to protect the public in connection with the marketing of medicinal products.

24. Furthermore, in order to grant adequate effective protection for medicinal products equivalent to that enjoyed by other technological sectors, the Regulation sets at 15 years the duration of the exclusive rights which the holder of both a patent and a certificate should be able to enjoy from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community (eighth recital in the preamble to the Regulation).

25. The scope of the Regulation is defined, in Article 2 thereof, as extending to products protected by a patent which are subject, prior to being placed on the market as medicinal products, to an administrative authorisation procedure as laid down in Council Directive 65/65 (replaced by Directive 2001/83).

26. Article 3 of the Regulation sets out the conditions for obtaining a certificate, namely that the product is protected by a basic patent in force in the Member State in which the application is submitted, that a valid marketing authorisation has been granted, that the product has not already been the subject of a certificate and, finally, that the abovementioned authorisation is the first authorisation to place the product on the market as a medicinal product.

27. Under Article 5 of the Regulation, 'the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations'.

28. In accordance with Article 7(1) of the Regulation, the application for a certificate is to be lodged within six months of the date on which the authorisation referred to in Article 3(b) of the Regulation to place the product on the market as a medicinal product was granted.

29. Under Article 13 of the Regulation, the certificate takes effect upon the expiry of the basic patent for a period equal to the period which elapsed between the date on which the application for a 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. However, the duration of the certificate may not exceed five years from the date on which it takes effect.

30. Finally, Articles 19 and 19a of the Regulation provide for transitional measures concerning the grant of supplementary protection certificates in the Member States which acceded in the last three sets of accessions.

31. As regards the Republic of Lithuania, the transitional provisions are laid down by Article 19a(e) of the Regulation in the terms set out above.

II — The facts and the main proceedings

32. The claimant in the main proceedings is the holder of a European patent the application for which was lodged on 16 August 1994 under the European Patent Convention. The European patent was granted in 1997 and protects the medicinal product Aranesp.

33. In accordance with the Agreement implementing Article 3(3) of the Agreement on Cooperation in the Field of Patents between the Government of the Republic of Lithuania and the European Patent Organisation, [15] the effects of that European patent were first extended to the Republic of Lithuania at the request of the applicant. Under Article 1 of the attachment to that agreement, entitled 'Provisions governing the extension of European patents to Lithuania', a European patent extending to the Republic of Lithuania is to have the effect of and be subject to the same conditions as a national patent under Lithuania's Patent Law.

34. The Republic of Lithuania subsequently acceded to the European Patent Convention on 1 December 2004. [16]

35. Since Aranesp is a medicinal product deriving from recombinant DNA technology, the application for marketing authorisation was submitted under the centralised procedure laid down by Regulation No 2309/93. Authorisation was granted on 8 June 2001.

36. Following the accession of the Republic of Lithuania to the European Union on 1 May 2004, the claimant in the main proceedings submitted an application for a supplementary protection certificate to the Lietuvos Respublikos valstybinis patentų biuras (State Patent Bureau of the Republic of Lithuania) on 29 October 2004.

37. The latter rejected that application on 28 September 2005, on the ground that the claimant in the main proceedings did not have the required authorisation to place the product on the market in Lithuania. The claimant in the main proceedings then brought an appeal against that decision, which was dismissed by the Appeal Division of the Lietuvos Respublikos valstybinis patentų biuras. It considered that the claimant in the main proceedings had not, in any event, lodged its application for a supplementary protection

15 — *United Nations Treaty Series*, 1995, Vol. 1885, No I-32085, p. 518. That agreement was signed at Munich on 25 January 1994 and then entered into force on 5 July 1994. Finally, it was terminated on 30 November 2004, as a consequence of the entry into force of the European Patent Convention in Lithuania on 1 December 2004.

16 — On 3 September 2004, the Lithuanian Government submitted its instrument of accession to the European Patent Convention and to the act of 29 November 2000 revising that convention.

certificate within the six-month period laid down in Article 7 of the Regulation.

38. The claimant in the main proceedings then brought further appeals, first before the Vilniaus Apygardos teismas (Regional Court, Vilnius) and then before the Lietuvos Apeliacinis teismas (Court of Appeal). Those appeals were dismissed on grounds essentially similar to those relied on by the Appeal Division of the Lietuvos Respublikos valstybinis patentų biuras. The claimant in the main proceedings then brought proceedings before the Lietuvos Aukščiausiasis Teismas.

II — IThe reference for a preliminary ruling

39. The Lietuvos Aukščiausiasis Teismas decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Is the date, referred to in Article 19(2) of [the] Regulation …, 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 [the] Regulation … 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 [the] Regulation …?'

40. Written and oral observations have been submitted by the claimant in the main proceedings, by the Lithuanian, Czech, Latvian and Hungarian Governments and by the Commission.

IV — Analysis

A – *The issue in the dispute*

41. The issue in the dispute concerns the duration of the exclusive rights which the claimant in the main proceedings is entitled to enjoy in Lithuania under the basic patent which it holds for the medicinal product Aranesp.

42. As I have stated, the claimant in the main proceedings is the holder of a European patent in respect of a medicinal product, for which the application was lodged with the European Patent Office on 16 August 1994. The claimant in the main proceedings then obtained from the Commission its first authorisation to place the product on the market in the Community on 8 June 2001. It was on the basis of that first authorisation that on 29 October 2004 the claimant in the main proceedings lodged its application for a supplementary protection certificate in Lithuania. The Lithuanian authorities refused to grant such supplementary protection on the ground, first, that it had not lodged its application within the six-month period laid down in Article 7 of the Regulation and, secondly, that it did not have the national marketing authorisation required by the transitional provisions laid down by the Act of Accession.

43. The claimant in the main proceedings is therefore in the following situation:

— In the Member States in which it was able to lodge an application for a supplementary protection certificate within the period laid down in Article 7 of the Regulation [17] and was granted a certificate, it will enjoy protection of its rights until August 2016. [18]

— On the other hand, in the absence of a supplementary protection certificate in Lithuania, it will lose the exclusive manufacturing and marketing rights attached to its patent upon the latter's expiry, that is to say, in August 2014. At that time, it will no longer be able to challenge the

17 — That is to say, the States which were members of the European Union on 7 December 2001, since the authorisation was granted on 8 June of that year.

18 — As I have stated, the duration of the European patent is 20 years from the date of lodging the application. The patent held by the claimant in the main proceedings should therefore expire in August 2014. It is also necessary to add the period of the supplementary protection granted by the certificate, laid down in Article 13 of the Regulation. That period, I would recall, is 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 (in this case seven years), reduced by a period of five years. The supplementary protection certificate will therefore be of two years' duration and will take effect at the end of the lawful term of the European patent, that is to say, from August 2014.

placing on the market in Lithuania of a generic version of Aranesp. [19]

44. Such a situation therefore leads to the protection of the medicinal product varying within the Community, a situation whose risks the Court has already referred to in *Spain* v *Council* [20] and *AHP Manufacturing*. [21]

45. According to that case-law, such differences, for one and the same medicinal product, 'would give rise to a fragmentation of the market, whereby the medicinal product would still be protected in some national markets but no longer protected in others'. According to the Community judicature, such differences would mean that the marketing conditions for the medicinal product concerned would themselves differ according to the Member State, 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. [22]

46. In the present case, that case-law is therefore confronted with the specific situation in which a medicinal product a priori cannot enjoy supplementary protection in a new Member State, in the light of the transitional provisions expressly adopted in the context of negotiations for accession to the European Union.

47. By its reference for a preliminary ruling, the Lithuanian court asks the Court to interpret the transitional provisions adopted in respect of the Republic of Lithuania and thereby seeks to ascertain the legal rules which must be applied to a situation such as that at issue in the main proceedings.

19 — The claimant in the main proceedings will therefore be faced with new price-based competition, since the generic medicinal product, which has the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form as the reference medicinal product, will be sold at a far more affordable price. In the course of a recent sectoral inquiry, relating to the pharmaceutical sector, the Commission noted that almost 50% of patented medicinal products are faced with the arrival of generic medicinal products on their market within four to seven months of the expiry of the protection conferred by the patent and the supplementary protection certificate. According to that study, the price of generic medicinal products is, on average, 25% lower than the price of the reference medicinal product as set prior to the loss of exclusivity (see the Commission communication 'Executive Summary of the Pharmaceutical Sector Inquiry Report' of 8 July 2009 (COM(2009) 351 final, pp. 10 and 11)).

20 — Paragraph 36.

21 — Case C-482/07 [2009] ECR I-7295, paragraph 35.

22 — See *Spain* v *Council*, paragraphs 35 and 36, and *AHP Manufacturing*, paragraphs 35 and 36.

B — *The first and second questions referred*

1. Preliminary observations on the scope of the first and second questions referred

48. By its first two questions, the national court asks, in essence, which of Article 7 and Article 19 of the Regulation is applicable to the present case and raises the issue of the relationship between those two provisions.

49. 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. [23]

50. Moreover, the Court has a duty to interpret all provisions of European Union 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. [24]

51. It is clear from the order for reference that the first two questions are based on the premiss that the legal regime applicable in Lithuania to applications for supplementary protection certificates is determined by Articles 7 and 19 of the Regulation. However, such a premiss is, in my view, erroneous.

52. Article 7 of the Regulation lays down the period which is in principle applicable to all applications for supplementary protection certificates, disregarding the transitional provisions which have been expressly adopted with a view to the accession of new Member States to the European Union. Article 19 of the Regulation lays down the transitional rules which were applicable to the Member States of the European Union on 1 January 1993 and to the States acceding as a result of the enlargement of 1 January 1995, namely

23 — Case C-420/06 *Jager* [2008] ECR I-1315, paragraph 46.

24 — Ibid., paragraph 47.

the Republic of Austria, the Republic of Finland and the Kingdom of Sweden. [25]

53. However, in order to determine the legal regime applicable to a situation such as that at issue in the main proceedings, it is necessary to refer to Article 19a(e) of the Regulation, which alone lays down the transitional and derogating rules adopted in respect of the Republic of Lithuania at the time of negotiations for accession to the European Union.

54. In those circumstances, I think that it is unnecessary, for the purposes of settling the dispute in the main proceedings, to answer the first question referred, which is concerned with the interpretation of Article 19(2) of the Regulation.

25 — The relationship between those two provisions has already been explained by the Court in Case C-127/00 *Hässle* [2003] ECR I-14781. As the Court points out, Article 19 of the Regulation is a transitional provision which derogates from Article 7 of the Regulation. Under Article 19(2) of the Regulation, the holder of a basic patent may lodge an application for a supplementary protection certificate within six months of the date on which the Regulation enters into force in the specific cases and circumstances referred to in Article 19(1), namely:
where the product, on the date on which the Regulation enters into force or on the date of the accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden, is already protected by a valid basic patent and has obtained the first authorisation to place it on the market in the Community or in the territory of those three States after 1 January 1985;
if the certificate must be granted in Denmark, in Germany or in Finland, the date of 1 January 1985 is replaced by 1 January 1988;
if the certificate must be granted in Belgium, in Italy or in Austria, the date of 1 January 1985 is replaced by 1 January 1982.

55. Moreover, in order to provide an answer which will be of use to the national court, I propose that the Court of Justice should reformulate the second question and consider that, by that question, the national court seeks to ascertain whether Article 19a(e) of the Regulation must be interpreted as allowing the holder of a basic patent for a medicinal product to apply to the competent Lithuanian authorities for the grant of a supplementary protection certificate where, prior to the accession of the Republic of Lithuania to the European Union, that medicinal product obtained a Community marketing authorisation granted by the Commission under Regulation No 2309/93 but did not obtain a national marketing authorisation.

2. The interpretation of Article 19a(e) of the Regulation

56. Article 19a(e) of the Regulation lays down the three conditions to be met in order to obtain a supplementary protection certificate in Lithuania, namely the medicinal product must be protected by a valid basic patent applied for after 1 February 1994, a first marketing authorisation must have been granted by the competent Lithuanian authorities prior to the accession of the Republic of Lithuania to the European Union and the application for a

certificate must have been lodged within six months of that accession.

57. For the purposes of my analysis, it is necessary to apply the rules of interpretation set out by the Court concerning derogations provided for by acts of accession. As we have seen, it is settled case-law that derogations must be limited to what is strictly necessary and must be expressly laid down. [26] Moreover, they are to be interpreted strictly, in the light of the scheme of the system of which they form part, and must, finally, be interpreted in such a way as to facilitate achievement of the objectives of the Treaty and application in full of its rules. [27]

58. In accordance with Article 2 of the Act of Accession, that act is based on the principle that the provisions of European Union law apply *ab initio* and *in toto* to the new Member States. Moreover, under Article 10 of that act, derogations are allowed only in so far as they are expressly laid down by transitional provisions. [28]

59. Consequently, subject to the application of Article 19a of the Regulation, the provisions of that regulation are fully applicable to the new Member States upon their accession to the European Union.

60. It follows that, if Article 19a of the Regulation did not allow, by way of derogation, the grant of a supplementary protection certificate for medicinal products which obtained a first marketing authorisation in the new Member States prior to their accession, in accordance with Article 7 of the Regulation no supplementary protection certificate could be granted for those medicinal products which obtained marketing authorisation more than six months prior to accession.

61. Under Article 7, the application for a supplementary protection certificate must be lodged *within six months of the date on which the first authorisation to place the product on the market was granted by a Member State under Directive 65/65*. That is also the case where the authorisation is granted by the Commission, under Regulation No 2309/93. [29]

26 — See, in particular, Case 258/81 *Metallurgiki Halyps* v *Commission* [1982] ECR 4261, paragraph 8.

27 — See, in particular, Joined Cases C-267/95 and C-268/95 *Merck and Beecham* [1996] ECR I-6285, paragraph 23 and the case-law cited; Case C-233/97 *KappAhl* [1998] ECR I-8069, paragraph 18 and the case-law cited; and *Hässle*, paragraph 52 et seq.

28 — *KappAhl*, paragraph 15 and the case-law cited.

29 — According to Article 12(1) of Regulation No 2309/93, a marketing authorisation which has been granted in accordance with the centralised procedure is to confer the same rights and obligations in each of the Member States as a marketing authorisation granted by a Member State in accordance with the harmonised requirements laid down by Directive 65/65.

62. Article 19a(e) of the Regulation establishes a twofold derogation from Article 7 thereof.

63. First, it allows an application for a supplementary protection certificate to be lodged for a medicinal product which, prior to its placing on the market, has not been the subject of an administrative authorisation procedure in accordance with Directive 65/65. Article 19a(e) of the Regulation expressly covers the case of medicinal products which have been the subject of a purely national marketing authorisation procedure. [30]

64. Secondly, that provision establishes a derogation from the time-limit referred to in Article 7 of the Regulation, since an application for a supplementary protection certificate based on the grant of a purely national marketing authorisation may be lodged within a period of six months from the date of the entry into force of the Regulation in the new Member State. In the absence of such a transitional measure, the holder of the basic patent would be unable to lodge an application for a certificate on the basis of Article 7 of the Regulation, the six-month period laid down in that article having expired even before the entry into force of the Regulation in that State.

65. It clearly follows from a literal interpretation of Article 19a(e) that it is intended to apply solely to products which have already obtained a first authorisation to be placed on the market as a medicinal product in the Member State where application is made for a certificate, namely the Republic of Lithuania, at the time of the entry into force of the Regulation. Article 19a(e) provides for no derogation concerning products which have obtained a Community marketing authorisation granted by the Commission, under Regulation No 2309/93, and neither the latter nor the Regulation makes any reference, whether express or implied, to that situation.

66. Therefore, in accordance with the rules of interpretation already set out by the Court and having regard to the clarity of the wording of Article 19a(e) of the Regulation, I think it would be difficult to extend the scope of that provision to a product such as that at issue in the main proceedings whose placing on the market has been authorised by the Commission and not by the competent national authorities.

30 — It may be asked whether, like authorisations granted by the Austrian, Finnish and Swedish authorities, authorisations granted by the Republic of Lithuania were equated, under Article 19a of the Regulation, to an authorisation granted in accordance with the requirements of Directive 65/65. In the case of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden, that was expressly laid down in Article 3 of the Regulation. That article provides that an authorisation to place the product on the market granted in accordance with the national legislation of Austria, Finland or Sweden is treated as an authorisation granted in accordance with Directive 65/65. However, there is no similar provision relating to successive accessions to the European Union.

67. This interpretation of Article 19a(e) of the Regulation seems to me to be consistent with the scheme of the system of which it forms part and with the objectives pursued by the Community legislature.

68. Article 19a of the Regulation, like Article 19 thereof, lays down derogating rules which allow products which have already obtained a first authorisation to be placed on the market in the new Member States prior to their accession to benefit from a supplementary protection certificate. Depending on the Member State concerned, the nature of the marketing authorisation required for that purpose and the date on which it must have been granted vary.

69. For example, with regard to the Czech Republic, the marketing authorisation must have been obtained in that State after 10 November 1999 or in the Community not earlier than six months prior to the accession of that State to the European Union. In other Member States, such as the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Malta or the Republic of Slovenia, the marketing authorisation must have been granted by the national authorities before 1 May 2004. On the other hand, in the case of the Republic of Hungary or the Republic of Poland, or in the case of the Republic of Bulgaria or Romania both of which acceded as a result of the last enlargement, it is sufficient that a marketing authorisation was granted after 1 January 2000. In that last case, it is not made clear whether the authorisation must have been granted by the national authorities or simply in the Community.

70. Those mechanisms specific to each of the Member States have been justified by the Court in *Hässle*. In that case, the Court was asked to interpret and assess the validity of Article 19 of the Regulation, which, as we have seen, lays down transitional measures applicable to the Member States of the European Union on 1 January 1993 and to the States which acceded as a result of the enlargement of 1 January 1995, namely the Republic of Austria, the Republic of Finland and the Kingdom of Sweden. As we have seen, that provision lays down relevant dates in respect of the lodging of an application for a supplementary protection certificate which differ depending on the Member State, a situation which, according to the claimant in the main proceedings, was contrary to the objective of harmonisation in the internal market.

71. The Court rejected that line of argument, in view of the particular context of the accession negotiations that provides the framework for Article 19 of the Regulation and of the objectives pursued by each of the parties in the context of the pharmaceutical sector.

72. The Community judicature thus held, in paragraphs 38 to 40 of *Hässle*, that each of the dates laid down by Article 19 of the Regulation reflected the assessment made by each

Member State in the light, in particular, of its health system, the organisation and financing of which, the Court accepted, varied from one Member State to the next. The Court thus acknowledged that although, when the Regulation was adopted, all the Member States wished to protect innovation in the pharmaceutical industry by providing, through grant of a certificate, effective protection for holders of a patent, enabling them to cover the investment put into research, a number of those Member States wished 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.

73. It was in the light of those differences in assessment that the Court justified the laying-down, as a transitional measure, of those different relevant dates, although it noted the existence of a lack of harmonisation as regards products for which a first authorisation to be placed on the market in the Community had been granted between 1 January 1982 and 1 January 1988.

74. That reasoning is, in my view, perfectly capable of being applied to the present case and supports a strict interpretation of Article 19a(e) of the Regulation.

75. Like Article 19 of the Regulation, Article 19a sets out the results of the accession negotiations carried out with the new Member States and establishes mechanisms specific to each of them.

76. As the Court has already pointed out in paragraphs 67 and 68 of *Parliament* v *Council*,[31] accession negotiations are intended to resolve the difficulties which accession entails either for the Community or for the acceding State. By offering opportunities for dialogue and cooperation, they allow each of the future Member States to assert their interest in obtaining the necessary transitional derogations; these might be needed, for example, because it would be impossible to ensure immediate application of new Community acts on accession, or because of major socioeconomic problems to which such application might give rise. In the pharmaceutical sector, there are numerous interests and objectives pursued by each of the parties to the negotiations. They may include not only safeguarding the financial balance of the national health system and ensuring for patients access to medicinal products which are safe,

31 — Case C-413/04 [2006] ECR I-11221, concerning the application of certain provisions of secondary Community legislation to the Republic of Estonia.

effective and affordable (by supporting, for example, the generic products manufacturing industry), [32] but also creating a business environment that stimulates research, boosts innovation and supports the competitiveness of the pharmaceutical sector. [33] It is therefore by means of specific mechanisms, such as those in Article 19a of the Regulation, that the special interests thus invoked can be appropriately balanced against the general interest of the Community.

77. Accordingly, although the interpretation which I propose does leave an absence of harmonisation as regards medicinal products which were not granted marketing authorisation in Lithuania prior to the entry into force of the Regulation, I think that that interpretation is necessary in order to respect such balance and the relevant negotiations.

78. In the light of all those factors, I take the view that Article 19a(e) of the Regulation must be interpreted as not allowing the holder of a valid basic patent for a medicinal product to apply to the competent Lithuanian authorities for the grant of a supplementary protection certificate where, prior to the accession of the Republic of Lithuania to the European Union, that medicinal product obtained a Community marketing authorisation granted by the Commission under Article 3 of Regulation No 2309/93, but did not obtain a national marketing authorisation.

C — *The third and fourth questions referred*

79. By its third question, the national court asks the Court to state whether the date on which the Community marketing authorisation was extended to the Republic of Lithuania does correspond to the date on which that State acceded to the European Union. If that is the case, the national court asks, by its fourth question, whether that first date may be equated to the 'date of grant of authorisation to place the product on the market' for the purposes of Article 3(b) of the Regulation.

80. In essence, the national court seeks to ascertain whether, in a case such as that at issue in the main proceedings, the six-month period laid down in Article 7 of the Regulation for lodging an application for a supplementary protection certificate may start to run from the date on which the Community marketing authorisation was extended to the Republic of Lithuania.

32 — The prices of generic medicinal products are generally much lower than those of originator medicinal products, making it possible to contain the budgets allocated to public health and providing a greater number of patients with access to safe and innovative medicinal products.

33 — See the Commission communication referred to in footnote 19 (p. 2).

81. We know that accession to the European Union entails for new Member States the acceptance *ab initio* and *in toto* of the '*acquis communautaire*' subject to any adjustments accepted by mutual agreement, as shown by the provisions of the accession agreements.

82. Thus, under Article 2 of the Act of Accession, the provisions of the original Treaties and the acts adopted by the institutions before accession are binding on the new Member States from the date of their accession. Consequently, and as all the parties submit, the Community marketing authorisation which was granted by the Commission for Aranesp, under Article 3 of Regulation No 2309/93, was extended to the Republic of Lithuania on the date on which its accession to the European Union became effective, when it acquired the status of a Member State, namely on 1 May 2004.

83. Nevertheless, and contrary to the submissions of the Commission and the claimant in the main proceedings, I do not think that it is possible to equate the date on which an authorisation was extended to a new Member State to the date on which that authorisation was granted, for the purposes of Article 3(b) of the Regulation, even in a situation such as that at issue in the main proceedings.

84. Such an interpretation would be tantamount to establishing a derogation from the rules set out by the Regulation although the derogation has not been expressly laid down by the Community legislature. That interpretation would be contrary to the settled case-law of the Court, according to which derogations must be expressly laid down. [34]

85. In addition, such an interpretation seems to me to be difficult to reconcile with the wording of Articles 3(b) and 7 of the Regulation and with its scheme and the objectives pursued by it.

86. First, it is necessary to read the wording of those articles in conjunction with Article 3(d) of the Regulation. Under that provision, the authorisation to place the product on the market referred to in Articles 3(b) and 7 of the Regulation concerns solely the *first authorisation to place the product on the market* granted under Directive 65/65. A marketing authorisation which is extended to a new territory will therefore never correspond to a *first authorisation to place the product on the market*.

87. Secondly, that interpretation would impair the clarity and coherence of the system put in place by the Regulation.

34 — See, in particular, *Metallurgiki Halyps* v *Commission*, paragraph 8.

88. The date on which the *first authorisation to place the product on the market* has been granted is one of the cornerstones of the Regulation, since it is what makes it possible to ensure a uniform period of patent protection for the medicinal product.

89. I would recall that, under the Regulation, a supplementary protection certificate may be obtained by the holder of a national or European patent under the same conditions in each Member State of the Community. [35] As Advocate General Jacobs pointed out in his Opinion in *Spain* v *Council*, one of the most significant results of the certificate is that patent protection, in the case of products covered by the certificate, will terminate at the same point in time in all the Member States where the certificate was granted, even if the applications for the grant of the basic patents were lodged in different years. [36]

90. That system is based on Article 13 of the Regulation and, in particular, on the mechanism whereby the duration of the certificate depends on a single event, published in the *Official Journal of the European Communities*, [37] namely the grant of the first authorisation to place the product on the market in the Community.

91. A hypothetical example, which was used by Advocate General Jacobs in that case, may clarify this point. [38] The example is based on the method of calculation set out in Article 13 of the Regulation. Suppose the application for patent protection was lodged in 1990 in Member State A, and in 1991 in Member State B, patent protection expiring respectively in 2010 and in 2011. The authorisation to market the product is first given in Member State C, in 1998. That leads to the following calculation of the duration of the certificate. In Member State A that duration is eight years (1990-98) minus five years, the certificate taking effect in 2010 and expiring in 2013. In Member State B the duration is seven years (1991-98) minus five years, the certificate taking effect in 2011 and, in the same way, expiring in 2013. [39]

92. That reasoning applies in a situation such as that at issue in the main proceedings, in which the holder lodged an application for a European patent and obtained Community

35 — *AHP Manufacturing*, paragraph 35.

36 — See point 44 of the Opinion.

37 — Under Article 12(3) of Regulation No 2309/93, the date on which the marketing authorisation is granted by the Commission is to be published in the *Official Journal of the European Communities*.

38 — I would recall that, under Article 13 of the Regulation, the duration of the certificate is 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.

39 — See point 44 of the Opinion.

authorisation to place the product on the market.

93. If the date of grant of the first authorisation to place the product on the market were to be confused with the date on which that authorisation was extended to the new Member States following their accession, that would prejudice the proper functioning of the system put in place by the Regulation. It would mean that there would be as many different dates of grant as of accessions to the European Union for one and the same product. If we were to apply that reasoning to the method of calculation laid down in Article 13 of the Regulation, the duration of protection for the medicinal product would thus not be uniform within the Community, which would be contrary to the objective of standardisation sought by the Regulation.

94. In the light of all those factors, I propose that the Court's answer to the national court should be that the marketing authorisation granted by the Commission for the medicinal product Aranesp under Article 3 of Regulation No 2309/93 was extended to the Republic of Lithuania on 1 May 2004. I also invite it to answer that that date cannot be equated to the date on which that authorisation was granted for the purposes of Article 3(b) of the Regulation.

V — Conclusion

95. In the light of the foregoing considerations, I propose that the Court should answer the questions referred by the Lietuvos Aukščiausiasis Teismas as follows:

'(1) Article 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, first, by 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 of 29 August 1994, secondly, 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 of 23 September 2003 and, finally, by the Act concerning the conditions of accession of the Republic of Bulgaria and Romania and the adjustments to the Treaties on which the European Union is founded of 21 June 2005, must be interpreted as not allowing the holder of a valid basic patent for a medicinal product to apply to the competent Lithuanian authorities for the grant of a supplementary protection certificate where, prior to the accession of the Republic of Lithuania to the European Union, that medicinal product obtained a Community marketing authorisation granted by the European Commission under Article 3 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, but did not obtain a national marketing authorisation.

(2) The marketing authorisation granted by the Commission for the medicinal product Aranesp under Article 3 of Regulation No 2309/93 was extended to the Republic of Lithuania on 1 May 2004. That date cannot be equated to the date on which that authorisation was granted for the purposes of Article 3(b) of Regulation No 1768/92, as amended.'