Court of Justice EU, 14 November 2013, Astrazeneca v Patent Office

PATENT LAW – SPC

Administrative authorisation issued for a medicinal product by the Swiss authorities, which is automatically recognized in Liechtenstein, must be regarded as first authorisation to place that product on the market when that authorisation predates marketing authorisations issued for the same medicinal product by EU authorities

- **In the context of the European Economic Area (EEA), Article 13(1) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that an administrative authorisation issued for a medicinal product by the Swiss Institute for Medicinal Products (SwissMedic), which is automatically recognised in Liechtenstein, must be regarded as the first authorisation to place that medicinal product on the market within the meaning of that provision in the European Economic Area where that authorisation predates marketing authorisations issued for the same medicinal product, either by the European Medicines Agency (EMA), or by the competent authorities of European Union Member States in accordance with the requirements laid down in 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, and the authorities of the Republic of Iceland and the Kingdom of Norway.**

The fact that, on the basis of similar clinical data, the European Medicines Agency, unlike the Swiss authority, refused to grant a marketing authorisation for that medicinal product at the conclusion of its examination of those data, or the fact that the Swiss authorisation to place the product on the market was suspended by the Swiss Institute for Medicinal Products and subsequently reinstated by the latter only when the holder of the authorisation submitted additional data to it are irrelevant.

Source: **curia.europa.eu**

Court of Justice EU, 14 November 2013

(…)

ORDER OF THE COURT (Eighth Chamber)

14 November 2013 (*)

(Medicinal products for human use – Supplementary protection certificate – Regulation (EC) No 469/2009 – Article 13(1) – Concept of 'first authorisation to place [a product] on the market in the Community' – Authorisation issued by the Swiss Institute for Medicinal Products (Swissmedic) – Automatic recognition in Liechtenstein – Authorisation issued by the European Medicines Agency – Period of validity of a certificate)

In Case C‑617/12,

REQUEST for a preliminary ruling under Article 267 TFEU from the High Court of Justice (England and Wales), Chancery Division (Patents Court) (United Kingdom), made by decision of 11 December 2012, received at the Court on 18 December 2012, in the proceedings

Astrazeneca AB

v

Comptroller General of Patents, Designs and Trade Marks,

THE COURT (Eighth Chamber),

composed of C.G. Fernlund, acting as President of the Eighth Chamber, C. Toader (Rapporteur) and E. Jarašiūnas, Judges,

Advocate General: N. Jääskinen,

Registrar: A. Calot Escobar,

having decided, after hearing the Advocate General, to give a decision by reasoned order, in accordance with Article 99 of the Rules of Procedure of the Court of Justice,

makes the following

Order

1 This reference for a preliminary ruling concerns the interpretation of Article 13(1) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1).

2 The reference has been made in proceedings between Astrazeneca AB ('Astrazeneca') and the Comptroller General of Patents, Designs and Trade Marks ('the Patent Office') concerning the period of validity of the supplementary protection certificate ('SPC') issued by that office for the medicinal product known as Iressa.

Legal context

Regulation No 469/2009

3 Under Article 22 of Regulation No 469/2009, 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 acts listed in Annex I to Regulation No 469/2009, was repealed. References to the regulation thus appealed are to be construed as references to Regulation No 469/2009 and are to be read in accordance with the correlation table in Annex II to that regulation.

4 Article 2 of Regulation No 469/2009 provides as follows:

'Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in 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] ... may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.'

5 Article 3 of Regulation No 469/2009 provides as follows:

'A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

(b a valid authorisation to place the product on the market ['MA'] as a medicinal product has been granted in accordance with Directive 2001/83/EC ...;

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

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

6 As regards the duration of an SPC, Article 13 of Regulation No 469/2009 is worded as follows:

'1. The certificate 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.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

...'

European Union legislation concerning procedures for administrative authorisation of medicinal products

7 Article 3(1) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1) states that *'[n]o medicinal product appearing in the Annex may be placed on the market within the Community unless a [MA] has been granted by the Community in accordance with the provisions of this Regulation'.*

8 Moreover, it follows from Article 3 of Regulation No 726/2004, in conjunction with Articles 2 and 6 of Directive 2001/83, that industrially produced medicinal products for human use intended to be placed on the market in Member States, other than those included in the annex to Regulation No 726/2004, must as a rule have a MA granted by the authorities of those Member States under that directive. There is an option – in the present case on the terms set out in Article 3(2) of Regulation No 726/2004 – whereby medicinal products not included in the annex thereto may none the less be granted a MA under the centralised procedure before the European Medicines Agency ('EMA'), thereby avoiding the need to submit multiple applications for MAs under the authorisation procedure established by Directive 2001/83.

9 Paragraph 3 of the annex to Regulation No 726/2004 refers to *'[m]edicinal products for human use containing a new active substance which, on the date of entry into force of this Regulation, was not authorised in the Community, for which the therapeutic indication is the treatment of any of the following diseases: ... cancer'.*

The Agreement on the European Economic Area, in conjunction with Regulation No 469/2009

10 Regulation No 1768/92, which was succeeded by Regulation No 469/2009, was amended to take account, inter alia, of the Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3), as adjusted by the Protocol adjusting that agreement (OJ 1994 L 1, p. 572) and amended by Decision No 10/95 of the EEA Joint Committee (OJ 1995 L 47, p. 30) ('the EEA Agreement').

11 Annex XVII of the EEA Agreement sets out the Community intellectual property measures which, in accordance with Article 65(2) of the EEA Agreement, must be applied by all contracting parties, subject to any adaptations included in that annex.

12 Paragraph 6 of that annex refers to Regulation No 1768/92 and provides, inter alia, that the following is to be added to Article 3(b) of the regulation:

'for the purposes of this subparagraph [c] 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 [Council] Directive 65/65/EEC [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. 20). ... '

13 Directive 65/65, as amended, was repealed by Directive 2001/83 and references to Directive 65/65, as repealed, are to be construed as references to Directive 2001/83 and are to be read in accordance with the correlation table in Annex III to that directive.

14 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.

15 Paragraph 8 of Protocol No 1 to the EEA Agreement provides as follows:

'Whenever 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'.

16 Article 126 of the EEA Agreement, as amended after the accession of the Principality of Liechtenstein to the agreement, provides as follows:

The Agreement shall apply to the territories to which the Treaty establishing the European Economic Community and the Treaty establishing the European Coal and Steel Community are applied and under the conditions laid down in those Treaties, and to the territories of the Republic of Austria, the Republic of

Finland, the Republic of Iceland, the Principality of Liechtenstein, the Kingdom of Norway and the Kingdom of Sweden'.

17 Annex II to the EEA Agreement, as amended by Annex 2 to Decision No 1/95 of the EEA Council 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) ('Decision No 1/95'), is worded as follows:

'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.'

18 Annex 10 to Decision No 1/95 provides that Annex XVII (Intellectual Property) to the EEA Agreement, as amended by Decision No 10/95 of the EEA Joint Committee, is to be amended by the insertion of the following text into Regulation No 1768/92:

'(d) In addition, the following apply:

In view of the patent union between Liechtenstein and Switzerland, Liechtenstein shall not deliver any supplementary protection certificates for medicinal products as laid down in ... Regulation [No 1768/92] [now No 469/2009]'.

19 Under Decision No 61/2009 of the EEA Joint Committee of 29 May 2009 amending Annex II and Protocol 37 to the EEA Agreement, Regulation No 726/2004 was incorporated into the EEA Agreement.

The facts of the main proceedings and the questions referred for a preliminary ruling

20 Astrazeneca is the proprietor of a European patent covering the active ingredient gefitinib. That patent is due to expire on 22 April 2016.

The applications to place the medicinal product Iressa on the market

21 In July 2002, Astrazeneca submitted an application to the Swiss Institute for Medicinal Products ('Swissmedic') for authorisation to place the medicinal product Iressa on the market in Switzerland. In support of that application, Astrazeneca submitted clinical data from two Phase II studies. SwissMedic granted that authorisation under a fast-track procedure on 2 March 2004 ('the Swiss authorisation'). That authorisation was, however, conditional on the provision of further clinical data to demonstrate the effects of Iressa.

22 By virtue of the customs union between the Swiss Confederation and the Principality of Liechtenstein, relating, inter alia, to patents, the Swiss authorisation was automatically recognised in Liechtenstein. The referring court points out in that regard that there is, however, no direct evidence that Iressa was actually sold in Liechtenstein during the ensuing period, although indirect sales via wholesalers cannot be ruled out.

23 That authorisation was suspended by SwissMedic on 24 October 2005, with the result that, from that date, it was no longer possible to distribute Iressa in Switzerland or Liechtenstein, save for supply of that medicinal product to individual patients, which had to be specifically approved by SwissMedic.

24 In January 2003, Astrazeneca submitted an application to the EMA for a MA for Iressa 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 (OJ 1993 L 214, p. 1). As is apparent from recital 5 of Regulation No 726/2004, Regulation No 2309/93 was incorporated into Regulation No 726/2004 and repealed by it. The Committee for Proprietary Medicinal Products (now the Committee for Medicinal Products for Human Use ('CHMP') refused to grant an MA on the basis of the Phase II studies for Iressa provided by Astrazeneca. Furthermore, the data generated by the Phase III studies submitted by the Astrazeneca did not enable it to provide satisfactory answers to the questions raised by the CHMP and, accordingly, Astrazeneca withdrew its MA application in January 2005.

25 In May 2008, Astrazeneca resubmitted its application to the EMA with a refined therapeutic indication, supported by further studies undertaken to address the CHMP's concerns with the original application. On the basis of those data, the EMA granted an MA for Iressa on 24 June 2009 ('the European MA'), pursuant to Regulation No 726/2004.

26 In June 2008, Astrazeneca requested SwissMedic to lift the suspension of the Swiss authorisation and to amend the indications for Iressa, submitting further studies in that regard. The suspension was lifted on 8 December 2010.

The SPC application

27 On 11 December 2009, Astrazeneca submitted an SPC application to the Patent Office for the active ingredient gefitinib, on the basis of its European patent and the European MA.

28 The Patent Office granted that application by decision of 2 April 2012. However, as regards the duration of the SPC, calculated in accordance with Article 13(1) of Regulation No 469/2009, the Patent Office considered that the Swiss authorisation was to be regarded as the first MA for the purpose of that provision. The duration of the SPC granted was therefore set at two years and 314 days.

29 Astrazeneca challenged the Patent Office's decision before the referring court, contending, in essence, that the duration of the SPC should be calculated, pursuant to Article 13(1) of Regulation No 469/2009, on the basis that the first MA for the purpose of that provision was the European MA, which would have enabled it to obtain an SCP valid for a period of five years, that is to say, the maximum period that may be granted under that regulation.

30 Notwithstanding the answer provided by the Court in a similar context, in its judgment in Joined Cases C‑207/03 and C‑252/03 *Novartis and Others* [2005] ECR I‑3209, Astrazeneca maintains that it may be inferred from the judgments in **Case C‑195/09 *Synthon* [2011] ECR I‑7011** and **Case C‑427/09 *Generics* (UK) [2011] ECR I‑7099**, read in the light of the judgment in **Case C‑127/00 *Hässle* [2003] ECR I‑14781**, that the Swiss authorisation is valid only in respect of the customs union between the Swiss Confederation and the Principality of Liechtenstein, not the legal order of the European Union and that, for the purposes of granting an SPC on the basis of Regulation No 469/2009, only an MA granted by the EMA in accordance with Regulation No 469/2009 or by the competent authority of an EU Member State in accordance with Directive 2001/83 may be regarded as the first MA for the purpose of Article 13(1) of that regulation. Similarly, paragraphs 28 to 31 of the judgment in **Case C‑130/11 *Neurim Pharmaceuticals* (1991) [2012]** ECR may be construed as reflecting the Court's intention of departing from its earlier decisions, in particular the judgment in *Novartis and Others.*

31 In that regard, the referring court points out that Astrazeneca has argued before it that *Novartis and Others* is wrongly decided or should, at the very least, be confined to its own facts. However, the referring court considers that the answer provided by the Court in that judgment is relevant for the purpose of resolving the dispute in the main proceedings.

32 That said, the High Court of Justice (England and Wales), Chancery Division (Patents Court) observes that there is a divergence of interpretation of that judgment, which has led the competent Czech, Latvian, Portuguese, Swedish and United Kingdom intellectual property offices to grant Astrazeneca SPCs for the active ingredient gefitinib on the basis that the Swiss authorisation is the first MA for the purpose of Article 13(1) of Regulation No 469/2009, while the Bulgarian, Danish, Estonian, Italian, Lithuanian, Luxembourg, Slovenian, Slovakian, Romanian and Norwegian offices have granted Astrazeneca such SPCs on the basis that the European MA is the first MA for the purpose of that provision.

33 In those circumstances, the High Court of Justice (England and Wales), Chancery Division (Patents Court) decided to stay proceedings and refer the following questions to the Court for a preliminary ruling:

'(1) Is a Swiss marketing authorisation not granted pursuant to the administrative authorisation procedure laid down in Directive 2001/83, but automatically recognised by the Principality of Liechtenstein, capable of constituting the "first authorisation to place the product on the market" for the purposes of Article 13(1) of Regulation No 469/2009?

(2) Does it make a difference to the answer to the first question if:

(a) the set of clinical data upon which the Swiss authority granted the marketing authorisation was considered by the [EMA] as not satisfying the conditions for the grant of a [MA] pursuant to Regulation No 726/2004; and/or

(b) the Swiss marketing authorisation was suspended after grant and was reinstated only following the submission of additional data?

(3) If Article 13(1) of Regulation No 469/2009 refers solely to [MAs] granted pursuant to the administrative procedure laid down in Directive 2001/83, does the fact that a medicinal product was first placed on the market within [the European Economic Area (EEA)] pursuant to a Swiss marketing authorisation automatically recognised in Liechtenstein, which was not granted pursuant to Directive 2001/83, render that product ineligible for the grant of a supplementary protection certificate, pursuant to Article 2 of Regulation No 469/2009?'

Consideration of the questions referred

34 Pursuant to Article 99 of the Rules of Procedure, where the answer to a question referred to the Court for a preliminary ruling may be clearly deduced from existing case-law, the Court may at any time, on a proposal from the Judge‑Rapporteur and after hearing the Advocate General, give its decision by reasoned order.

35 The Court considers that that is the case here, as suggested, moreover, by the United Kingdom Government. The answers to the questions referred by the referring court may be clearly deduced from the Court's existing case-law, in particular the judgment in *Novartis and Others*. Furthermore, even though Regulation No 469/2009 has not yet been incorporated into the EEA Agreement, the main proceedings must be examined in the light of that regulation, which repealed Regulation No 1768/92, which was incorporated into that agreement, given that: (i) the SPC application was submitted to the competent authority of an EU Member State on 11 December 2009, when Regulation No 469/2009 was applicable; (ii) references to Regulation No 1768/92 are to be construed as references to Regulation No 469/2009; (iii) the provisions in issue are similar in both those regulations and, in any event; (iv) as mentioned at paragraph 18 above, the Principality of Liechtenstein does not grant SPCs.

Questions 1 and 2

36 By its first two questions, which it is appropriate to consider together, the referring court is asking, in essence, whether, in the context of the EEA Agreement, Article 13(1) of Regulation No 469/2009 is to be interpreted as meaning that an administrative authorisation granted by SwissMedic, which is automatically recognised in Liechtenstein, may be regarded as the first SPC for the medicinal product in question in the EEA, even where, on the basis of similar clinical data, the EMA, unlike the Swiss authority, refused to grant an MA for that medicinal product after examining those data, or where the Swiss authorisation was suspended by the Swiss authority and subsequently reinstated only after the holder of the authorisation had submitted further data to it.

37 Astrazeneca is of the view that, in the main proceedings, the Swiss authorisation cannot be regarded as the first MA for the purpose of Article 13(1) of Regulation No 469/2009. On the other hand, the United Kingdom and Liechtenstein Governments, the European Commission and the EFTA Surveillance Authority take the opposite view and maintain, in essence, that the answer to that question may be clearly deduced from *Novartis and Others*.

38 The Court has already held in that regard that, for the purposes of the application of the EEA Agreement, Article 13 of Regulation No 469/2009 is to be construed as providing that an 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 (see, to that effect, *Novartis and Others*, paragraph 26). That first authorisation to place the product on the market in the EEA is not intended to take the place of the MA provided for in Article 3(b) of Regulation No 469/2009, that is to say, the authorisation granted by the Member State in which the application is submitted; instead, it constitutes a further condition applying in the event that the latter authorisation is not the first authorisation to place the product on the market as a medicinal product in the EEA. The first MA in the European Union therefore serves a purely temporal purpose (see, to that effect, **Case C‑110/95 Yamanouchi Pharmaceutical** [1997] ECR I‑3251, paragraph 24).

39 It is also clear from Annex II to the EEA Agreement, as amended by Annex 2 to Decision No 1/95, that the Principality of Liechtenstein may, as regards inter alia the medicinal products to which Directive 2001/83 refers, apply Swiss technical regulations and standards deriving from its regional union with the Swiss Confederation on the Liechtenstein market in parallel with the legislation implementing that directive (see, to that effect, *Novartis and Others*, paragraph 28).

40 The EEA Agreement recognises, therefore, that two types of MA may co-exist in the Principality of Liechtenstein, namely MAs issued by the Swiss authorities, which, because of the regional union between the Swiss Confederation and that State are automatically recognised in the latter, and MAs issued in Liechtenstein in accordance with Directive 2001/83 (see, to that effect, *Novartis and Others*, paragraph 29).

41 Thus, under Article 13 of Regulation No 469/2009, in conjunction with Annex II to the EEA Agreement, as amended by Annex 2 to Decision No 1/95, an MA issued by the Swiss authorities and automatically recognised in Liechtenstein in the context of its regional union with the Swiss Confederation may be regarded as a first MA for the purpose of Article 13, if it was issued before the MA granted by the EMA pursuant to Regulation No 726/2004 or before the MAs granted by the competent intellectual property authorities of an EU Member State in accordance with Directive 2001/83, or by the competent authorities of the Republic of Iceland or the Kingdom of Norway (see, to that effect, *Novartis and Others*, paragraph 30).

42 [Rectified by order of 17 January 2014] Such an interpretation of that provision is, moreover, consistent with the purpose of Regulation No 469/2009, set out in recital 9 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 MA for the purposes of Article 13 of Regulation No 469/2009, the duration of SPCs would have to be calculated by reference to an MA issued subsequently in the EEA. Thus, there would be a risk of the period of 15 years of exclusivity being exceeded in the EEA (see, to that effect, *Novartis and Others*, paragraph 31).

43 Furthermore, the fact that MAs 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 relevant to the interpretation of Article 13 of Regulation No 469/2009, as it is to be read for the purposes of the application of the EEA Agreement (see, to that effect, *Novartis and Others*, paragraph 32).

44 It follows that, where an MA 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 469/2009, as it is to be read for the purposes of the application of the EEA Agreement (see, to that effect, *Novartis and Others*, paragraph 33).

45 The arguments put forward by Astrazeneca before the referring court and before the Court of Justice have already been the subject of extensive debate in Joined Cases C‑207/03 and C‑252/03, which gave rise to the judgment in *Novartis and Others*. The Court's answer in that judgment, as set out at paragraphs 38 to 43 above, was unequivocal.

46 Moreover, in its subsequent rulings, the Court did not intend to depart from its earlier decisions on the implementation of Regulation No 469/2009 in the specific context of the placing on the market in the territory of a State forming part of the EEA, namely, in the present case, the Principality of Liechtenstein, of a medicinal product which has been authorised by the EMA or by the authorities of an EU Member State and, at the same time, by SwissMedic under an administrative authorisation automatically recognised by the Liechtenstein authorities.

47 As regards the judgments in ***Hässle***, ***Synthon*** and ***Generics*** (UK), relied on by Astrazeneca, it is true that the Court essentially found that, for the purpose of granting an SPC on the basis of what is now Regulation No 469/2009, only a product which is protected by a basic patent that is valid in the territory of the Member State in which an SPC application was submitted and which has obtained an MA after being subject, as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83 or Regulation No 726/2004, including safety and efficacy testing in accordance with the requirements of Directive 2001/83, may be the subject of an SPC (see, to that effect, ***Synthon***, paragraph 44).

48 It is also true that the Court has held that the term 'first authorisation to place [the product] on the market in the Community' in Article 13(1) of Regulation No 469/2009 must be interpreted in the same way, irrespective of the provision of Regulation No 469/2009 in which it appears, so that that term must, in the same way as the term 'authorisation to place [the product] on the market' in Article 3 of that regulation, refer to an MA issued in accordance with Directive 2001/83 and, possibly, at the conclusion of the procedure laid down in Regulation No 726/2004 (see, to that effect, ***Hässle***, paragraphs 57 and 58).

49 As observed by Advocate General Ruiz-Jarabo Colomer at point 53 of his Opinion in the case giving rise to the judgment in *Novartis and Others*, in pointing out that, for the purpose of granting an SPC, it is necessary, under Article 3(b) of Regulation No 469/2009, for an MA to have been issued in accordance with the provisions of Directive 2001/83, the Court simply intended to exclude other types of national authorisations granted by EU Member States, such as authorisations relating to prices of, or reimbursement for, medicinal products, or those issued under national legislation which do not correspond to or do not yet comply with the requirements laid down by Directive 2001/83, in particular in so far as concerns the safety and efficacy testing of medicinal products required under that directive.

50 However, as also observed by Advocate General Ruiz-Jarabo Colomer at the same point of his Opinion, the Member States of the EEA which were involved in the facts of the case before the national courts that gave rise to the judgment in ***Hässle*** and also in the cases which subsequently gave rise to the judgments in ***Synthon*** and ***Generics*** *(UK)* were also Members of the European Union, so that it was unnecessary in those judgments, for the purposes of those cases, to refer to the text of Regulation No 1768/92 – now Regulation No 469/2009 – as varied by the EEA Agreement and the protocols and annexes thereto and by the decisions adopted by the decision-making bodies of the EEA.

51 It follows from the foregoing that, by ruling out in the judgments in ***Hässle***, ***Synthon*** and ***Generics*** (UK) any possibility that an authorisation issued by an EU Member State, other than an authorisation issued in conformity with Directive 2001/83, could constitute a proper legal basis for the grant of an SPC under Regulation No 469/2009, inter alia because such authorisations were not granted at the conclusion of safety and efficacy testing of the medicinal products concerned, as required under Directive 2001/83, the Court did not in any way intend to call into question in those cases, which did not have a specific EEA dimension, the principles outlined in *Novartis and Others.*

52 With regard to the fact that SwissMedic, as the national authority of a State that is not a Member of the European Union, does not issue authorisations in accordance with the requirements laid down in Directive 2001/83, it is clear that, irrespective of whether there may be any functional equivalence between the national Swiss provisions and the requirements laid down in that directive relating to safety and efficacy testing – an equivalence that is called into question by Astrazeneca in support of its argument that the Swiss authorisation cannot constitute the first MA in the EEA for the purpose of Article 13(1) of Regulation No 469/2009 – the Court has already held in *Novartis and Others* that, that situation notwithstanding, an authorisation granted by the Swiss authorities and automatically recognised in Liechtenstein in the context of its regional union with the Swiss Confederation may be regarded as a first marketing authorisation for the purpose of that provision.

53 The decisive factor here is not whether the requirements of Directive 2001/83 have been complied with, since the Swiss Confederation is not a Member of the EU. The rationale for that conclusion is to be found in the fact that paragraph 6 of Annex 10 to Decision No 1/95, which relates to the text added to Article 3(b) of Regulation No 1768/92 – superseded by Regulation No 469/2009 – provides that *'for the purposes 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'*, which was superseded by Directive 2001/83.

54 Accordingly, the fact that, in the main proceedings, SwissMedic granted such an authorisation, whereas, on the basis of similar clinical data, the EMA refused to grant a European Union MA, in the light of the requirements laid down in Directive 2001/83, does not prevent the Swiss authorisation, as a result of its automatic recognition in Liechtenstein, from being treated as an authorisation granted in conformity with Directive 2001/83 and, in the circumstances of the present case, it must be regarded as the first MA in the territory of the EEA for the purposes of the application of Article 13(1) of Regulation No 469/2009.

55 With regard to the fact that SwissMedic granted the initial Swiss authorisation on 2 March 2004 at the conclusion of a fast-track procedure and, subsequently, in view of the failure to submit adequate clinical data, that authorisation was suspended on 24 October 2005, it should be noted, first, that such a procedure also exists under EU law and that, in that context, the grant

of an MA at the conclusion of such a procedure may, in certain circumstances, lead to the grant of an SPC.

56 Moreover, the fact that SwissMedic subsequently suspended the initial authorisation is a reflection of the risk inherent in such fast-track procedures, but that does not alter the fact that the operator concerned has in fact already placed his product on the market by obtaining an authorisation for that purpose. Moreover, the argument that Astrazeneca would appear to have put forward – to the effect that it has not in fact had the time or the opportunity actually to market Iressa in the Principality of Liechtenstein, an EEA State – is clearly irrelevant. Indeed, the requirement to obtain an MA laid down in Articles 3 and 13 of Regulation No 469/2009 is not contingent upon whether the holder of the MA has actually been able to market the medicinal product in question.

57 In any event, in the main proceedings, according to the referring court, there may have been indirect sales of Iressa via wholesalers on the basis of the authorisation of 2 March 2004 issued by SwissMedic and, subsequently, following the suspension of that authorisation, Astrazeneca may have supplied Iressa to individual patients with the specific approval of SwissMedic. It follows that, with the grant of that Swiss authorisation, that company was in a position, in one of the EEA States, to start capitalising on its investments in research that culminated in the grant of its patent, which justifies that authorisation being regarded, as the Court held in *Novartis and Others*, as the first authorisation to place that medicinal product on the market for the purpose of Article 13(1) of Regulation No 469/2009, applied in the context of the EEA Agreement.

58 Moreover, that finding is not called into question by the fact pointed out by Astrazeneca that, on 1 June 2005, the Swiss Confederation and the Principality of Liechtenstein decided, following the judgment in *Novartis and Others*, to amend their bilateral agreement on the legislation applicable to medicinal products by providing, for medicinal products containing new active substances, that authorisations issued by SwissMedic would no longer be recognised automatically and immediately in Liechtenstein, but only after a 12-month period. That agreement, in any event, postdates the grant of the Swiss authorisation.

59 With regard to the reference made by Astrazeneca to the judgment in *Neurim Pharmaceuticals* (1991), it should be noted, first, that that judgment was not delivered in an EEA context and, second, unlike the judgments in ***Synthon*** and ***Generics*** *(UK),* the issue in *Neurim Pharmaceuticals* (1991) was not whether the national authorisation of an EU Member State, granted at the conclusion of a procedure that did not correspond to that laid down in Directive 2001/83, may be regarded as an MA on the basis of which an SPC could be granted. Indeed, in *Neurim Pharmaceuticals* (1991), the Court was asked, in essence, whether it is possible, on the basis of a patent which protects, within the meaning of Article 1(c) of Regulation No 469/2009, a new application of a known active ingredient that has already been lawfully marketed in the European Union, to grant an SPC relating to that new use of the product in conjunction with the MA for the medicinal product in which that use of the product was commercially exploited for the first time.

60 In the light of all the foregoing considerations, the answer to questions 1 and 2 is that, in the context of the EEA, Article 13(1) of Regulation No 469/2009 must be interpreted as meaning that an administrative authorisation issued for a medicinal product by SwissMedic, which is automatically recognised in Liechtenstein, must be regarded as the first authorisation to place that medicinal product on the market within the meaning of that provision in the EEA where that authorisation predates MAs issued for the same medicinal product, either by the EMA, or by the competent authorities of EU Member States in accordance with the requirements laid down in Directive 2001/83 and the authorities of the Republic of Iceland and the Kingdom of Norway. The fact that, on the basis of similar clinical data, the EMA, unlike the Swiss authority, refused to grant an MA for that medicinal product at the conclusion of its examination of those data, or the fact that the Swiss authorisation was suspended by SwissMedic and subsequently reinstated by the latter only when the holder of the authorisation submitted additional data to it are irrelevant.

Question 3

61 In view of the answer given to questions 1 and 2 and of the fact that question 3 was submitted by the referring court only in the event that the Court held that, even in the specific context of the EEA, an SPC may be granted only on the basis of an MA issued in conformity with Directive 2001/83, there is no need to answer question 3.

Costs

62 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 (Eighth Chamber) hereby rules:

In the context of the European Economic Area (EEA), Article 13(1) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that an administrative authorisation issued for a medicinal product by the Swiss Institute for Medicinal Products (SwissMedic), which is automatically recognised in Liechtenstein, must be regarded as the first authorisation to place that medicinal product on the market within the meaning of that provision in the European Economic Area where that authorisation predates marketing authorisations issued for the same medicinal product, either by the European Medicines Agency (EMA), or by the competent authorities of European Union Member States in accordance with the

requirements laid down in 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, and the authorities of the Republic of Iceland and the Kingdom of Norway. The fact that, on the basis of similar clinical data, the European Medicines Agency, unlike the Swiss authority, refused to grant a marketing authorisation for that medicinal product at the conclusion of its examination of those data, or the fact that the Swiss authorisation to place the product on the market was suspended by the Swiss Institute for Medicinal Products and subsequently reinstated by the latter only when the holder of the authorisation submitted additional data to it are irrelevant.

[Signatures]

* Language of the case: English.