OPINION OF ADVOCATE GENERAL RUIZ-JARABO COLOMER delivered on 7 September 2004 [1]

I — Introduction

1. There has been a customs union between Switzerland and Liechtenstein since 1924, [2] which, since 1 April 1980, has extended to patents, a sphere in which a single patent office (the Swiss one) operates, which grants patents effective in both territories: [3] consequently, marketing authorisations for medicinal products granted by one country are automatically recognised in the other. [4]

2. Liechtenstein is part of the European Economic Area ('EEA'), in which Council Regulation (EC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products applies. [5]

1 — Original language: Spanish

2 — Treaty (Zollvertrag) of 29 March 1923 between Switzerland and Liechtenstein on the integration of the Principality into Swiss customs territory (*Liechtenstein Landesgesetzblatt*, — 'LGBl.' — 1923, No 24). As the title of this international treaty suggests, it is not that both countries actually form a customs union with a common tariff but rather that Liechtenstein was integrated into the Swiss regime.

3 — Treaty (Patentschutzvertrag) of 22 December 1978 on patent protection (LGBl. 1980 No 31), as amended by the Additional Agreement (Erganzungsvereinbarung) of 2 November 1994 (LGBl. 1995 No 80), which entered into force on 1 May 1995. Under those provisions, the two members form a single area for the purposes of patent protection (Article 1), so that a single patent produces legal effects throughout the entire area (Article 4(1)). Administrative duties are the responsibility of the Swiss authorities (Article 7) and are carried out by the Eidgenossisches Amt fur geistiges Eigentum (Federal Office for the Protection of Intellectual Property). In the report which he produced in the proceedings before the High Court, Mr Frick, Prime Minister of Liechtenstein between December 1993 and April 2001, explained that, as a consequence of the Treaty, his country does not have a patent office and has no power to grant patents, so patents obtained in Switzerland have immediate effect in Liechtenstein: therefore, patents restricted to one or other of the States do not exist (paragraphs 29 to 32).

4 — Since 1973, by virtue of an exchange of notes (LGBl. 1973 No 20/1), Liechtenstein has automatically recognised authorisations granted by the Interkantonale Kontrollstelle (Swiss Institute for the Control of Medicinal Products), a body which is regulated in the Interkantonale Vereinbarung (*Amtliche Sammlung des Bundesrechts* — 'AS' — 1972, 1026; LGBl. 1973 No 20/2). Between 1990 and 2001, it applied the Heilmittelgesetz (Law on medicinal products) of 24 October 1990 (LGBl. 1990, No 75), Article 7(2) of which merely provided that a medicinal product could be marketed once it was registered at the abovementioned Swiss body. By virtue of the Arzneimittelgesetz-EEE (Law on the marketing of pharmaceutical products in the EEA), of 18 December 1997 (LGBl. 1998 No 45), Liechtenstein established, with effect from 1 May 1998, a system of authorisations in keeping with Community requirements, as a result of the obligations deriving from its membership of the EEA. On 15 December 2000, in order for it to enter into force on 1 January 2001, Switzerland adopted the Heilmittelgesetz (*Systematische Sammlung des Bundesrechts* — 'SR' — 812.21), which replaced the Interkantonale Vereinbarung and set up a new body (the Schweizerisches Heilmittelinstitut — Swiss Institute for Medicinal Products), which was the successor to the Interkantonale Kontrollstelle. The result of these two pieces of legislation and the exchange of notes of 11 December 2001 (AS 2002, 2788) is that two sets of rules on authorisation coexist in Liechtenstein: the Swiss rules, which are effective in the customs union with Switzerland, and Liechtenstein's own rules, which comply with the requirements of the EEA.

5 — OJ 1992 L 182, p. 1

3. The courts which have made these references for a preliminary ruling wish to know whether a marketing authorisation for a medicinal product, which is issued by the Swiss authorities, may constitute 'the first authorisation ... in the Community' and, accordingly, whether the date on which it was granted is to be taken into account for the purpose of calculating the duration of the supplementary protection certificate. In addition to that basic question, the High Court of Justice also asks whether the authorities of the EEA Member States are obliged to rectify certificates, the duration of which has been erroneously calculated.

II — Legal background

A — *Regulation (EEC) No 1768/92*

4. This regulation creates a new intellectual property right, which is ancillary to a previously granted patent, [6] with the aim of extending the period of protection conferred by the patent.

5. It was adopted in order to encourage pharmaceutical research and to prevent research centres in the Member States relocating to countries which offer better protection (second and fifth recitals). Such research calls for major investment, [7] which can be profitable only if the person undertaking the research manages to secure exclusive use of the results of the research over a sufficient period of time. However, in order to protect the right to health, [8] the marketing of a medicinal product is conditional upon obtaining an authorisation, a slow and complex process, [9] and the period

6 — Galloux, J.-C. is responsible for that description, 'Le certificat complémentaire de protection pour les produits phytopharmaceutiques (Règlement (CE) nº 1610/96 du Parlement européen et du Conseil', in *La semaine juridique*, nº 49, 1996, I 609, pp. 499-504. Although his work focussed on certificates for plant protection products, the description is also apt for the certificate provided for in respect of medicinal products. In fact, both sets of Community provisions were adopted on the same grounds and their form and substance are almost identical.

7 — In my Opinion in Case C-368/96 *Generics (UK) and Others* [1998] ECR I-7967, I stressed the innovative drive of firms, which is vital if there is to be a sound pharmaceutical industry in the Community (point 50).

8 — The protection of public health is the fundamental purpose of the directives which I summarise below in notes 14 and 15, as I pointed out in the Opinion cited in note 7 above and as the Court of Justice itself emphasised in paragraph 22 of its judgment in that case. Some years previously, the Court also made the same finding in Case C-83/92 *Pierrel and Others* [1993] ECR I-6419, whilst making clear that at the same time it was necessary to ensure the free movement of medicinal products within the Community (paragraph 7). The fact that protection of that collective right is the primary objective of Community legislation in this sphere has recently been restated in the judgments in Case C-112/02 *Kohlpharma* [2004] ECR I-3369, paragraph 14, and Case C-106/01 *Novartis and Others* [2004] ECR I-4403, paragraph 30.

9 — When the proposal for the regulation was put forward (COM (1990), OJ 1990 C 114, p. 10), the Commission estimated that the average time needed to obtain a marketing authorisation for a pharmaceutical product was four years (point 51 of the preamble to the proposal). However, J.F Bloch and P. Schmitt suggest that it could be 10 years ('Le certificat complémentaire de protection institué par le Règlement nº 1768-92 du 18 juin 1992', in *Gazette du Palais*, 1993, pp. 1280-1283).

which elapses between filing an application for a patent and obtaining an authorisation to place the product on the market markedly reduces the period of exclusive use, [10] deters investors and is prejudicial to scientific work in this sector (third and fourth recitals). [11]

6. France and Italy addressed the situation by introducing supplementary protection certificates. [12] In order to prevent a risk of heterogeneous development in the various Member States of the Union, likely to create obstacles to the free movement of medicinal products in the internal market, Regulation No 1768/92 provided a uniform solution at Community level by introducing a certificate for products in respect of which a marketing authorisation has been obtained, granted under the same conditions in all the Member States, for the owner of a national or European patent (sixth and seventh recitals). [13]

7. Medicinal products which are protected in one Member State and which are subject to a prior authorisation procedure under Directive 65/65/EEC [14] or Directive 81/851/EEC [15] (Article 2) can also benefit from the certificate, which confers the same rights as are conferred by the basic patent and are subject to the same limitations and the same obligations.

10 — The Convention on the Grant of European Patents, signed in Munich on 5 October 1973 and to which Switzerland and Liechtenstein are parties, provides for a term of 20 years as from the date of filing of the application (Article 63(1)).

11 — Galloux., J.-C., op. cit., points out that that is why owners of patents over products which may be marketed only where an authorisation is obtained are treated less favourably than owners of 'common' patents

12 — Laws of 25 June 1990 (France) and 19 October 1991 (Italy), which laid down maximum periods of protection of 7 and 18 years respectively.

13 — Concerning the reasons why the regulation was adopted and the objectives which it pursues, see the Opinions of Advocates General Jacobs and Fennelly of 9 March 1995 and 3 October 1996, respectively, in Case C-350/92 *Spain* v *Council* [1995] ECR I-1985 and Case C-181/95 *Biogen* [1997] ECR I-357. Recently, Advocate General Jacobs has emphasised the aim of preventing disparities in the way the various national laws evolve (see paragraph 44 of his Opinion of 29 April 2004 in Case C-31/03 *Pharmacia Italia*, in which judgment has not yet been delivered.

14 — Council Directive of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ, English Special Edition, 1965-1966 p. 24), as amended and completed by the Second Council Directive of 20 May 1975 of the same name (OJ 1975 L 147, p. 13). These texts were replaced by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67); the second paragraph of Article 128 of Directive 2001/83 provides that references to the repealed legislative provisions are to be construed as references to the new legislation. Directive 2001/83 has, in turn, been amended by Directives 2004/27/EC and 2004/24/EC, both of the European Parliament and the Council, adopted on 31 March 2004 (OJ 2004 L 136, pp. 34 and 85).

15 — Council Directive of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ 1982 L 317, p. 1), repealed and replaced by Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1). Article 96 of which makes the same provision as the second paragraph of Article 128 of Directive 2001/83. Directive 2001/82 has been amended by Directive 2004/28/EC of the European Parliament and the Council of 31 March 2004 (OJ 2004 L 136, p. 58).

8. For a certificate to be granted: the product (i) must be protected by a basic patent in force, (ii) must have, as a medicinal product, a valid marketing authorisation in accordance with the directives referred to above, and (iii) must not already have been the subject of a certificate (Article 3 of Regulation No 1768/92).

9. The application must be made within six months of the date on which the authorisation to place the product on the market as a medicinal product was obtained, unless the authorisation has been obtained before the patent has been granted, in which case the period is calculated from the date on which the patent is granted (Article 7).

10. For the Community legislature, the aim is that the holder of a patent should enjoy, as a maximum, 15 years of exclusivity from the time when the medicinal product first obtains authorisation to be placed on the market in the Community (8th recital). To that end, Article 13 makes the following provision about duration of the certificate:

'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. [16]

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.' [17]

11. A decision on an application for a certificate and a decision on an action for a declaration of invalidity of a certificate, are open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents (Article 17, in conjunction with Articles 10 and 15, of Regulation No 1768/92).

B — *Agreement on the European Economic Area* [18]

12. The aim of the Agreement on the European Economic Area, which was signed

16 — At paragraph 8 of his Opinion in *Spain* v *Council*, cited above, Advocate General Jacobs gave an example of the scope of the provision: '... Suppose an application for a basic patent was lodged in 1990, the patent expiring in 2010. If the marketing authorisation is given in 1997, the certificate takes effect in 2010 for a period of seven minus five years, and will therefore lapse in 2012'.

17 — The aim of this temporal limitation is to protect the other interests at stake, such as public health, referred to in the ninth recital in the preamble to the regulation, which, with the same end in view, also states that the protection is strictly confined to the product covered by the authorisation to place it on the market as a medicinal product.

18 — OJ 1994 L 1, p. 3.

in Porto on 2 May 1992 and which has been in force since 1 January 1994, is to create a homogeneous economic area, in which free movement is ensured in the territory defined in Article 126(1), namely that of the then European Communities and of the Member States of the European Free Trade Association. Consequently, the definition included, in principle, Liechtenstein and Switzerland, which were members of EFTA, but Switzerland, following a referendum in December 1992, decided not to ratify the EEA Agreement.

13. In order to ensure that the good functioning of the EEA Agreement was not impaired by the regional union between Switzerland and Liechtenstein, the agreement did not enter into force in relation to Liechtenstein until 1 May 1995. [19]

14. Under Article 7(a) of the EEA Agreement, Community regulations are binding on the Contracting Parties and are incorporated into their respective legal orders in their entirety and, according to Article 65(2), Protocol 28 [20] and Annex XVII [21] to the Agreement contain, for those purposes, specific provisions and arrangements concerning intellectual, industrial and commercial property.

15. The list in Annex XVII, as amended by Decision No 7/94 of the EEA Joint Committee, [22] includes Regulation No 1768/92. In accordance with the introduction to Annex XVII itself, which refers to Protocol 1 on horizontal adaptations, [23] references in the Community legislation concerned to territories are to be taken as references to the territories of the Contracting Parties as defined in Article 126 of the EEA Agreement.

16. For its part, Annex II to the EEA Agreement, [24] as amended by Council Decision No 1/95 cited above, enunciates the 'principle of parallel marketability' providing that, for products covered by the acts to which it refers, Liechtenstein may apply, in addition to the EEA legislation, Swiss technical regulations and standards deriving from its regional union with Switzerland. The provisions on free movement of goods

19 — See Article 1(2) of the Protocol of 17 March 1993 adjusting the Agreement (OJ 1994 L 1, p. 572), in conjunction with Article 121(a) of the Agreement and Article 7(1) of Decision of the EEA Council No 1/95 of 10 March 1995 (OJ 1995 L 86, p. 58)

20 — OJ 1994 L 1, p. 194. Article 1(1) of the protocol provides that the term 'intellectual property' includes the protection of industrial and commercial property.

21 — OJ 1994 L 1, p. 482.

22 — Decision of 21 March 1994 (OJ 1994 L 160, p. 1).

23 — OJ 1994 L 1, p. 37.

24 — OJ 1994 L 1, p. 263.

apply to exports from Liechtenstein to other signatories to the Agreement only if the products comply with requirements laid down by EEA law. Paragraph XIII of Annex II lists the Community legislation on medicinal products, mentioning Directives 65/65 and 81/851.

C — *Variations to Regulation No 1768/92 deriving from the EEA Agreement and relevant to these cases*

17. Article 3(b) of the regulation provides that: 'for the purpose of this subparagraph and the Articles which refer to it, an authorisation to place the product on the market granted in accordance with the national legislation of the EFTA State shall be treated as an authorisation granted in accordance with Directive 65/65/EEC or Directive 81/851/EC, as appropriate.' [25]

18. The first subparagraph of Article 19(1) reads '[a]ny product which on 2 January 1993 is protected by a valid patent and for which the first authorisation to place it on the market as a medicinal product within the territories of the Contracting Parties was obtained after 1 January 1985 may be granted a certificate'. [26]

19. In accordance with the introduction to Annex XVII, in conjunction with point 8 of Protocol 1, the reference made by Article 13 (1) of Regulation No 1768/92 to the date of the first authorisation to place the product on the market in Community must be construed as referring to the date on which that authorisation was first granted in one of the EEA States.

20. Finally, Decision No 1/95 of the EEA Council amended Annex XVII to the EEA Agreement, referred to above, by adding subparagraph (d) to point 6 thereof, which provides: '[i]n view of the patent union between Liechtenstein and Switzerland, Liechtenstein shall not deliver any supplementary protection certificates for medicinal products as laid down in this regulation' (Annex 10).

III — Facts, main proceedings and the questions referred for a preliminary ruling

A — *Case C-207/03*

21. Novartis AG, University College London and the Institute of Microbiology and

25 — Following the amendments made by Annex XVII (point 6), as amended by Decision No 7/94 of the EEA Joint Committee.

26 — The wording deriving from the legislation referred to in the preceding footnote.

Epidemiology ('Novartis and Others') are holders of the rights in two medicinal products in respect of which valid patents exist: an immunosuppressant used following organ transplant surgery, basiliximab, and an antimalarial combination of artemether and lumefantrin. [27]

22. On 7 April 1998 and 22 January 1999 the Swiss authorities granted authorisations for both products, which were automatically recognised in Liechtenstein.

23. In addition, basiliximab obtained an authorisation granted on 9 October 1998 by the Commission of the European Communities using the procedure established by Regulation (EEC) No 2309/93, [28] whilst the antimalarial combination obtained a national marketing authorisation from the United Kingdom Medicines Control Agency on 30 November 1999.

24. The Deputy Director of the United Kingdom Patent Office, acting on behalf of the examiner, decided on 12 February 2003 that the duration of the supplementary protection certificate should be calculated by reference to the dates on which the Swiss authorisations were granted. Novartis and others challenged that decision arguing that the duration should be calculated by reference to the date on which the first EEA authorisation was granted. [29]

25. With the issues framed in those terms, the High Court of Justice asked the following questions:

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

27 — Basiliximab: patent EP 0 449 769, an application for which was lodged on 13 March 1991. Combination of artemether and lumefantrin: patent EP 0 500 823, applied for on 5 June 1991.

28 — 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).

29 — Following the Patent Office's criterion, the certificate for basiliximab (SPC/GB/00/012) would expire on 6 April 2013 and the certificate for the combination of artemether and lumefantrin (SPC/GB/00/13) on 21 January 2014. The applicants' basis of calculation would delay the expiry dates until 8 October 2013 and 29 November 2014.

(2) Is a competent authority within the European Economic Area obliged to rectify any existing supplementary protection certificates, the duration of which has been erroneously calculated?'

B — *Case C-252/03*

26. When it took over Cor Therapeutics Inc., Millenium Pharmaceuticals Inc. ('Millenium') acquired the rights to the medicinal product eptifibatide (used by patients with cardiovascular illness), which is protected by a valid patent. [30]

27. The Swiss authorities granted an authorisation to place the product on the market for the first time on 27 February 1997, whilst the Commission, applying Regulation No 2309/93, issued another certificate on 1 July 1999.

28. On 15 December 1999 Millenium applied to the Ministry of the Economy, Luxembourg, for a supplementary protection certificate, which was granted on 15 February 2000, its period of validity being determined by reference to the date of the Swiss authorisation.

30 — Patent EP 0 477 295 B1, applied for on 15 June 1990.

29. Millenium did not agree with that decision and challenged it before the Tribunal administratif (Administrative Court), Luxembourg, which, by judgment of 18 December 2002, upheld the application, amended the document at issue and ordered that in the certificate 27 February 1997 be replaced by 1 July 1999 as the date of the first authorisation to place the product on the market.

30. On appeal, the Cour administrative (Administrative Court) stayed the proceedings and referred the following question to the Court of Justice:

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

IV — Procedure before the Court

31. In Case C-207/03 written observations have been submitted, within the period prescribed by Article 20 of the EC Statute of the Court of Justice, by Novartis and Others, the Governments of Iceland, Liech-

tenstein, Norway, the Netherlands and the United Kingdom and by the Commission and the EFTA Surveillance Authority. In Case C-252/03, those governments (with the exception of Norway and the United Kingdom) have intervened, as have the Luxembourg Government, the two abovementioned institutions and Millenium.

32. A hearing was held for both cases on 8 July 2004, which was attended, for the purpose of presenting oral argument, by the representatives of all those, other than the Netherlands Government, to have taken part in the written procedure.

V — Analysis of the questions referred for a preliminary ruling

A — *Swiss marketing authorisations and supplementary protection certificates in the EEA (first question)*

33. The doubts entertained by the Luxembourg administrative court, which coincide with the High Court's first question, concern the status to be accorded to marketing authorisations issued in Switzerland, which, because of the union between Liechtenstein and Switzerland, are automatically effective in Liechtenstein. More particularly, the question is whether such authorisations may constitute the first authorisation within the EEA and be used for calculating the term of validity of the supplementary protection certificate under Article 13 of the regulation.

34. The positions taken in the preliminary ruling proceedings are well defined and irreconcilable. The applicant pharmaceutical companies, the EFTA Surveillance Authority and the Icelandic, Liechtenstein, Netherlands and Norwegian Governments maintain that authorisations issued in Switzerland should not be regarded as the first authorisation, whilst the United Kingdom and Luxembourg Governments and the Commission take the opposite view.

35. The latter base their view on a literal and purposive interpretation of Regulation No 1768/92 and on the fact that, in their opinion, the very act of marketing under an authorisation constitutes the key to the question, irrespective of whether the authorisation can actually facilitate the medicinal product's access to the EEA. However, the other participants in the proceedings emphasise the last point, on the basis that an

authorisation granted in Switzerland does not satisfy the legal requirements laid down in the territory defined by the Agreement and that, accordingly, it does not allow the product to move freely within the internal market: therefore, in their submission, the date on which it was issued cannot be used as the reference point for calculating the period for which the supplementary certificate will be valid. Surprisingly, they also purport to derive their argument from an interpretation based on both the wording and the objectives of the regulation.

36. Thus, the participants in these preliminary-ruling proceedings advocate different solutions on the basis of the same material.

37. The one point on which all the parties concerned, without exception, are agreed is the fact that authorisations granted in Switzerland do not open the EEA to the medicinal products covered by them. Apart from that, there is disagreement about everything, with entirely different conclusions being drawn from that fact: for some it shows that the Swiss authorisations do not mark the point by reference to which the supplementary period of protection is calculated, whilst for others it is of no relevance.

38. In order to mediate in the dispute and put forward a sound answer, it is necessary to examine the so-called principle of parallel marketability, which exists in the Liechtenstein market.

1. Medicinal products on the parallel Liechtenstein markets

39. The principle of parallel marketability, enunciated in Annex II to the EEA Agreement, derives from Liechtenstein's involvement in distinct economic areas, which are governed by different, irreconcilable sets of rules. Two legal systems meet in one place: one governs relations between Switzerland and Liechtenstein, the other regulates the latter's membership of the EEA. If there is no conflict between the systems, they are permeable; as a general rule, nothing prevents a product from Switzerland moving from the territory of its partner to that of another EEA member, and *vice versa*. If, on the other hand, there is conflict, the barriers are raised and the markets are sealed, so that goods authorised in Liechtenstein can be exported to the other Contracting Parties to the Agreement only if they comply with EAA rules.[31] In conclusion, goods which enjoy

31 — The Liechtenstein Government explains in its written observations that there is systematic control, the aim of which is to monitor trade in goods within the country and prevent one market being infiltrated by goods which do not comply with the rules which regulate it (point 34 of its observations).

unimpeded freedom of movement within the customs union do not, merely because of that, enjoy the same freedom within the EEA.

40. As a consequence, both medicinal products authorised under EEA law and others covered by the Swiss system are found on the Liechtenstein market but, because of the principle of parallel marketability referred to above, the Swiss authorisations, which are automatically effective in the framework of the agreement with Liechtenstein, only allow the medicine to enter other States party to the Agreement if it satisfies the requirements laid down by the applicable legislation: Directives 65/65 and 81/851 (now Directive 2001/83, as amended by Directives 2004/27 and 2004/24). Therefore, it is quite clear that medicinal products originating in Switzerland cannot be automatically marketed within the EEA. As I explained in note 4, since 1 May 1998 and as a result of the Arzneimittelgesetz-EEE, Liechtenstein has been granting marketing authorisations in accordance with Community law, which confirms that the authorisations granted by Switzerland are of no relevance outside the boundaries of the customs union between the two countries.

41. However, does this non-conformity, on which all the parties submitting observations are agreed, make it possible to disregard the authorisations when calculating how long supplementary protection is to last? The answer must be sought in the objectives of the regulation.

2. The purpose of Regulation No 1768/92

42. An analysis of the preamble to the regulation shows that the legislature's main motivation in adopting the legislation was not to guarantee the free movement of medicinal products but to create the conditions necessary to ensure that pharmaceutical research is profitable and to deter firms in that industry from leaving the Union, without failing to have regard to other interests worthy of legal protection, such as public health, the interests of consumers and those of the generic medicines industry. [32] The unimpeded trade in medicinal products within the Community is an indirect result of that main objective, so, with the aim of preventing the internal market from being partitioned as a result of divergent national laws, a uniform set of rules has been imposed. It is true that primary importance was attributed to those secondary reasons in order to provide justification for the Community's competence and to situate its legal basis in Article 100a of the EC Treaty (now, after amendment, Article 95 EC), but that

32 — In the judgment in *Spain* v *Council*, cited above, the Court took those interests into account (paragraphs 38 and 39). Advocate General Jacobs, in his Opinion in that case, also pointed out that the purpose of the regulation was not to promote the free movement of medicinal products (paragraphs 44 and 45).

does not mean that the substance and provisions of the rules are to be observed exclusively from the point of view of the establishment and functioning of the common market, whilst any other reasons which were decisive in adoption of the rules are to be disregarded. [33]

43. There can be no question that, for the purpose of replying to the referring courts, it is irrelevant that the marketing authorisations granted in Switzerland do not enable the medicinal products which they protect to be traded within EEA territory, other than Liechtenstein. That is also shown by the fact that authorisations conferred by the Member States under Directives 65/65 and 75/319 and the new Directive 2001/83, as recently amended, do not make it lawful for the product to be freely marketed in other Member States.

44. The purpose of these provisions is to approximate national laws on, inter alia, marketing authorisations for medicinal products, going so far as to create a special committee which has an advisory role and regulates a mutual recognition procedure for the authorisations granted, but, in any event, it is the authorities of a Member State which are competent to allow a product to be marketed within that State and they are not bound by an authorisation granted in another Member State. [34] In my Opinion in *Generics (UK) and Others*, which I have already mentioned, I suggested that 'most medicinal products are marketed after the issue of a national authorisation by the competent authority in a Member State which is valid in that State' (point 5). The Court itself, in its judgment in *Rhône-Poulenc Rorer and May & Baker*, [35] stated that, as a general rule, 'no medicinal product may be placed on the market in a Member State unless a marketing authorisation has been issued in accordance with the Directive by the competent authority of that State' (paragraph 23).

45. Any arguments on this point are thus superfluous, since, as the Commission submits in its observations, there is no functional link between a marketing authorisation and the free movement of goods in the internal market.

46. The key to the answer lies elsewhere.

33 — In any event, as Advocate General Jacobs points out in the Opinion cited in the preceding note, drawing on the judgment in Case C-300/89 *Commission* v *Council* [1991] ECR I-2867, 'measures adopted on the basis of Article 100a of the Treaty need not contribute directly to the free movement of products'.

34 — That is clear from Articles 3, 4 and 5 of Directive 65/65; Articles 9, 10, 11 and 12 of Directive 75/319; and Articles 17 to 39 of Directive 2001/83, as amended by Directive 2004/27.

35 — Case C-94/98 [1999] ECR I-8789.

3. Marketing in a part of the EEA

47. Regulation No 1768/92 extends the protection afforded to new products in the pharmaceutical industry with a view to promoting research within the Union: it does that uniformly in such a way that, as Advocate General Jacobs stated in paragraph 44 of his Opinion in *Spain* v *Council*, the most significant result of the legislation is that protection of products covered by a certificate terminates at the same point in time in all the Member States where a certificate has been granted, even if the application for the basic patent was lodged in different years. [36] The Court endorsed that finding in paragraph 34 of the judgment in the case, stating that Regulation No 1768/92 provided for 'a uniform duration of protection'. In its judgment in *Yamanouchi Pharmaceutical*, [37] the Court alluded to the same idea when it explained, referring to the first authorisation in the Community, that the regulation prevents, in Member States in which there has been significant delay in the grant of authorisation to place a given product on the market, an extension still being granted even though that is no longer possible in the other Member States. 'The regulation is thus intended to prevent the grant of certificates whose duration varies from one Member State to another' (paragraph 25).

48. This specific point, which is where the rules inject uniformity, is the justification for the system, which means those persons are right who maintain, as do the Commission and the Luxembourg and United Kingdom Governments, that Swiss authorisations, which are automatically effective in Liechtenstein, must be taken into account when calculating how long the supplementary protection is to last.

49. The purpose of the regulation is not to standardise marketing authorisations but to set up a single system of extended protection and, as regards ensuring that the period of exclusive use lasts for the same time throughout the EEA, the decisive factor is the date on which that use commences, namely the date from which the drug can be

36 — Advocate General Jacobs illustrates that assertion with the following example: '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 (1990-1998) minus five years, the certificate taking effect in 2010 and expiring in 2013. In Member State B the duration is seven (1991-1998) minus five years, the certificate taking effect in 2011 and, again, expiring in 2013' (paragraph 44 *in fine*). Similar observations may be found in point 85 of the Opinion delivered by Advocate General Stix-Hackl on 26 February 2002 in Case C-127/00 *Hassle* [2003] ECR I-14781.

37 — Case C-110/95 [1997] ECR I-3251.

lawfully marketed in a part of the EEA, [38] regardless of where, [39] and regardless of the enabling document — it could be a national authorisation issued by a Member State under the directives referred to above, it could be a centralised authorisation granted under Council Regulation No 2309/93 (now Regulation (EC) No 726/2004 [40]), or it could be another document which, under the legislation in force, enables it to be lawfully marketed.

50. The latter category includes, as I have explained in points 17 to 19 above, both authorisations granted by the EFTA States under their various national laws, which are not in conformity with the sectoral directives, and authorisations granted by the Swiss authorities, which clearly do not comply with the requirements of Community law either, because both types of authorisation allow the medicinal products to be marketed in a part of the EEA. The comparison which some of the interveners have drawn in an argument *ad absurdum* between authorisations granted in Switzerland and those issued by the Japanese or United States authorities is misplaced, because the latter authorisations, unlike the former, do not allow a pharmaceutical product to be marketed in any part of the internal market. The reference point is the fact — the legally relevant fact — that the medicines can lawfully be marketed in a part of the EEA, [41] and it is irrelevant whether that occurs by virtue of a document which permits free movement throughout the EEA. [42]

51. The risk, mentioned by one of the interveners, of the consequences of an agreement — the customs union between Liechtenstein and Switzerland — being

38 — In his Opinion in *Pharmacia Italia*, to which I have already referred, Advocate General Jacobs explains that the regulation seeks to extend patent protection, that is to say, its intention is to extend the period of exclusivity in order to compensate for time which has been wasted in the absence of an authorisation to market the product. So for him the key point is the first marketing of the medicinal products, which is when the commercial return starts to flow (paragraph 45). The above considerations lead the Advocate General to assert that, for such purposes, no distinction can be drawn by reference to whether the first authorisation was for human or veterinary use. The argument may be applied to this case to conclude that the place within the EEA where that event took place is irrelevant: the central premiss is that the medicinal product may be marketed, making it possible for its owner to recoup its investment in developing the product.

39 — In her Opinion in *Hässle*, Advocate General Stix-Hackl mentions this idea, suggesting that the first authorisation is not the one granted by the Member State in which the certificate is applied for, but the authorisation which results in the product being placed on the market for the first time in one of the Member States (points 84 and 85).

40 — Regulation 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), which, in Article 88, repeals Regulation No 2309/93.

41 — The Court drew attention to this feature in its judgment in *Yamanouchi Pharmaceutical*, when it stated that the condition in respect of the first marketing authorisation is necessary only for the purposes of determining the duration of the certificate (paragraph 23) and made clear that it serves a purely temporal purpose (paragraph 24).

42 — A good indication that this is the case is that the wording of Article 13(1) refers to 'the date of the first authorisation to place the product on the market *in the Community*' (emphasis added). Therefore, the provision refers to an actual event, determined by a legal document which entitles the product to be marketed in one part of the internal market, without any requirement that that authorisation entitles the product to be marketed throughout the internal market in its entirety. For that reason, Decision No 7/94 of the Joint Committee was able to vary Article 3(b) and treat authorisations granted in accordance with national legislation by the EFTA States as authorisations granted by the Member States in accordance with the harmonised rules under Directives 65/65 and 81/851.

extended beyond its strict limits — to the other EEA States — in breach of the principles which prevail in international law, is thereby avoided, because it is not a rule of an external legal order which is rendered effective but rather an event with legal significance which occurs in its own legal order.

52. Accordingly, I propose that the Court, in response to the questions referred to it by the national courts, should declare that a marketing authorisation granted by the Swiss authorities, which is automatically effective in Liechtenstein, can constitute the first authorisation in the EEA for the purposes of Article 13 of Regulation No 1768/92 and that the duration of the supplementary protection certificates should be calculated by reference to the date on which it was issued.

4. Why the arguments to the contrary fail

53. The Court of Justice acknowledged in its judgment in *Hässle* that the 'first authorisation to place [a product] on the market as a medicinal product in the Community' must be a marketing authorisation issued in accordance with Directive 65/65 in any of the Member States (paragraphs 58 and 78 and the second paragraph of the operative part). However, this finding must not be taken out of context: it shows, first, that the intention was to exclude other types of authorisations from the matters covered, such as authorisations relating to prices of, or reimbursement for, medicinal products; second, in *Hässle*, no Member State of the EEA which was not also a Member of the European Union was involved in the facts of the case before the national courts and consequently it was not necessary to refer to the text of Regulation No 1768/92, 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.

54. As the Court observed in its judgment in *Hässle* (paragraph 72), the terms 'first authorisation to place ... on the market' or 'first authorisation to place ... on the market as a medicinal product in the Community' must not be interpreted differently depending on the provision of Regulation No 1768/92 in which they appear. In conclusion, when Article 13 refers to that notion, it also includes authorisations granted under the national law of the EFTA States because that is how Article 3(b) and Article 19(1) read in the wording attributed to them by Annex XVII (point 6) to the EEA Agreement, as adopted by Decision No 7/94 of the Joint Committee (see points 17 and 18 above).

55. Further, Liechtenstein cannot issue supplementary protection certificates, something which, as the Commission reasons, is the logical consequence of not awarding patents and which has no significance for the purpose of answering the question referred, since the cardinal point, as I have already stated, is the time from when a medicinal product can be lawfully marketed in a part of the EEA, a fact which allows the final day of

the period to be fixed when calculating the extended protection. Therefore, if the owner of a patent applicable in Liechtenstein is not entitled to a certificate under Regulation No 1768/92, there will never be a need on the Liechtenstein market for the protection to be extended in the same way as it is in the other member States of the EEA; [43] this difference, however, which is dictated by Liechtenstein's special situation, is the condition imposed on the EEA for the admission of a special member, which maintains a union in this field with a third country: consequently, it cannot serve as an argument for disregarding the purpose of the regulation, which is intended to compensate for the period of time which elapses between the date on which a patent is applied for in the country in which an application is subsequently made for a certificate and the date on which it has actually become possible to place the product on the market for the first time in the internal market.

56. The answer advocated by Novartis and others (which is to discount the Swiss authorisations) ignores that purpose without resolving the anomaly complained of, since, in any event, the Liechtenstein authorities would continue to have no competence to issue certificates.

57. What is more, their approach would disregard Regulation No 1768/92's objective of recognising that the holder of a patent and a certificate should be able to enjoy a maximum of 15 years of exclusivity in the Community (8th recital). Following the scheme of the regulation for basiliximab, for example, Novartis and others would enjoy that exclusivity until 8 October 2013 (see note 29), having been able to market the product in the EEA since 7 April 1998 by virtue of the authorisation granted on that date by the Swiss authorities, which was valid in Liechtenstein.

58. The recognition of the Swiss authorisations means that for the pharmaceutical firms account is taken of periods in which they are marketing the product on the small Liechtenstein market, which has only 32 000 potential consumers. However, quite apart from the fact that that consequence could also ensue where an authorisation is issued by other Member States with small populations, [44] it should be recalled that the Community legislature had in mind, when

43 — The supplementary protection certificates issued by the Swiss authorities are automatically effective in Liechtenstein (Articles 2 to 4 of the *Ergänzungsvereinbarung*). The Swiss system is identical to that provided for in Regulation No 1768/92: the extension, which begins on expiry of the period of patent protection, is equal to the period which elapses 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, reduced by a period of five years, with a maximum duration of five years (Article 140e of the Bundesgesetz über die Erfindungspatente — Federal law on patents, SR 232.14).

44 — It must be borne in mind that the authorisation granted by one Member State does not automatically open the markets of the other members of the EEA.

it adopted Regulation No 1768/92, the protection of other legitimate interests, in particular those of public health, that is — according to the finding of the Court in its judgment in *Spain* v *Council* – the interests of consumers and those of the generic medicines industry. The position adopted by the appellants in the main proceedings reflects the fact that they have proceeded on the wrong basis, incorrectly attributing to Regulation No 1768/92 an objective which focuses on the free movement of medicinal products.

59. Those who disagree with the solution which I propose maintain that the wording of both Article 3(b) and Article 19(1), deriving from Decision No 7/94 of the EEA Joint Committee, was intended to provide a transitional arrangement so that authorisations granted by Austria, Finland, Iceland, Norway and Sweden before their integration into the EEA could serve as a basis for calculating the validity of supplementary protection certificates. That assertion in fact amounts to an admission since, apart from the fact that there is nothing to prevent Liechtenstein's situation from also being regarded as provisional — at least in part — until 1998,[45] the year in which Liechtenstein established the Kontrollstelle für Arzneimitteln (Medicines Control Agency), the body competent to grant marketing authorisations, and adapted its legislation to the Community system, it is posited on a tacit acknowledgement that Regulation No 1768/92 seeks not to harmonise the conditions for approval but to render uniform throughout the EEA the duration of the exclusive protection conferred by a patent on a pharmaceutical product, authorisations issued by the EFTA States before they had adapted their internal legal orders to the requirements of the Community legal system being used for that purpose.

60. The EFTA Surveillance Authority and the Liechtenstein, Iceland and Netherlands Governments argue that, when Decision No 7/94 of the Joint Committee was adopted, which varied Articles 3(b) and 19(1) of Regulation No 1768/92, Liechtenstein was not yet a member of the EEA and therefore those provisions cannot refer to authorisations which, like those issued by Switzerland, a member of EFTA, open Liechtenstein's market to pharmaceutical products. To my mind, however, there are two weak points in the argument. First, it must not be forgotten that at that time Liechtenstein was involved as an observer and had the not too distant prospect of definitive membership of the EEA, once the difficulties deriving from its customs union with Switzerland were overcome: it does not seem reasonable to consider it beyond doubt that in the process

45 — The EEA bodies appreciated and acknowledged that this was the case in Council Decision No 1/95.

leading up to adoption of the decision no regard was paid to the special situation of Liechtenstein.

61. Second, I have already argued that it was clearly the intention of the framers of the decision to take account of authorisations issued by the EFTA States regardless of the Community rules: that is clearly also the case as regards the Swiss authorisations, which, by reason of the agreement with Liechtenstein, are automatically effective in Liechtenstein, an integral part of the EEA. Furthermore, the EEA Council, in its Decision 1/95 (Annex 10), stated, after referring to Decision No 7/94 of the Joint Committee, that Liechtenstein would not issue any supplementary protection certificates but did not deem it necessary to introduce the qualification that, wherever reference was made to authorisations granted in accordance with the national legislation of the EFTA States, authorisations were not to be included which, issued by a member (Switzerland), facilitated the marketing of medicinal products in Liechtenstein.

B — *The rectification of supplementary protection certificates which have been erroneously calculated (second question)*

62. Given that the answer proposed for the first question referred coincides with that advocated by the United Kingdom Patent Office, the second question, raised solely by the High Court of Justice, is hypothetical, since there will not be an error in the calculation of the extended protection applicable to Novartis and others. In those circumstances, there is no need for the Court to give an interpretation.

63. However, considering the possibility of the Luxembourg judgment taking another course and finding the decision giving rise to the main proceedings to be wrong, I shall examine the second question in the following paragraphs, albeit purely as a subsidiary issue.

64. Before continuing, I should make clear that, as it is worded, the question is inadmissible because it bears no relation to the subject-matter of the dispute before the United Kingdom court. The action brought by Novartis and others seeks to rectify the decision of the United Kingdom Patent Office and claims that Swiss marketing authorisations should not be taken into account for the purpose of calculating the duration of supplementary protection certificates and that consequently the duration of those certificates should be extended, the calculation being by reference to the authorisations subsequently granted by the Commission and by the United Kingdom Medicines Control Agency. [46] In order to reach a decision, the High Court has no need to

46 — As is clear from the explanation in point 21 et seq. above.

know whether a competent national authority must rectify the terms of any of those documents, the duration of which has been erroneously calculated, [47] it is sufficient for it to ascertain whether, where a court has confirmed that a calculation was wrong, the competent administrative body is obliged to rectify. Those are the terms in which, in my view, the question of the referring court should be cast.

65. Those of the interveners who have expressed a view on this issue are in agreement, any differences being purely a matter of emphasis.

66. An outline of the answer can be inferred from the wording of Regulation No 1768/92, Article 17 of which provides that decisions taken under the regulation are open to the same appeals as those provided for in national law against similar decisions in respect of patents. Regulation (EC) No 1610/96, [48] concerning plant protection products, takes the same approach, since Article 17(2) thereof admits of an appeal against the grant of a certificate aimed at 'rectifying' [49] the duration of the certificate where the date of the first authorisation to place the product on the market in the Community is incorrect; furthermore, the 17th recital states that Article 17(2) is valid for the interpretation of Article 17 of Regulation No 1768/92.

67. So the national authorities are obliged to rectify the dates by reference to which the duration of the certificate is determined if, when they were set, a mistake was made. In its judgment in *Hässle* the Court made statements to that effect (paragraph 88). [50]

68. Even if those legislative provisions did not exist, the principles governing the Community legal order would bring about the same outcome.

69. If a national authority is mistaken or careless in its interpretation of Regulation No 1768/92 and accordingly an error (by too much or by too little) is made in calculating

47 — As stated in paragraph 44 of the order for reference.

48 — Regulation of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ 1996 L 198, p. 30)

49 — The Spanish version of the regulation uses the term 'reducir' (reduce); however, other language versions use terms equivalent to the Spanish word 'rectificar' (rectify): 'berichtigen' (German), 'rectifier' (French), 'rectifying' (English), 'ottenere la rettifica' (Italian) and 'rectificar' (Portuguese).

50 — In that judgment, the Court interpreted Articles 15 and 19 of the regulation, to the effect that Article 19 is infringed if the certificate contains a mistake regarding the date of the first marketing authorisation and it appears that in fact that date is prior to the date initiating the transitional period: as a result, in such cases the certificate is invalid pursuant to Article 15 (paragraph 89), whereas, if there is a mistake but the correct date is subsequent to the date given in Article 19, the certificate is valid, and it is sufficient to rectify the date of its expiry (paragraph 88). Advocate General Stix-Hackl, in her Opinion cited above (point 105), explained that the rectification to which Article 17(2) of Regulation No 1610/96 refers is intended for the case in which the duration of the certificate has been determined in a manner inconsistent with Article 13 of the regulation, owing to, for example, the fact that the wrong date was given in the application for a certificate.

the duration of the supplementary protection certificate, the uniformity which this rule of Community law pursues is not achieved, leaving it open for the supplementary period of protection to differ from one State to another, a consequence which the legislature quite clearly wished to avoid.

70. That idea goes hand in hand with the primacy of Community law [51] and with the need, in order to ensure that it has full and uniform effect, [52] for national authorities, within the sphere of their competence, to ensure observance of the rules which make up that body of law, in particular its regulations, as interpreted by the Court of Justice. [53] The Court, in exercising its powers under Article 234 EC, clarifies and defines the meaning and scope of a rule of Community law as it must be, or ought to have been, understood and applied from the time of its entry into force. [54]

71. Therefore, as a general rule, any judicial authority must, other than in exceptional cases, apply a rule of Community law in accordance with the parameters set by the Court of Justice, even to legal relationships arising and established before the judgment ruling on the request for interpretation, provided that the conditions enabling an action relating to the application of the rule to be brought before the courts are satisfied. [55] In the same way and for the same reasons, administrative authorities are subject to the same duty. [56]

51 — Enunciated in Case 6/64 *Costa* v *Enel* [1964] ECR 585.

52 — See the judgment in Case 106/77 *Simmenthal* [1978] ECR 629. Kovar, R., in 'Relations between Community law and national law', in *Thirty Years of Community Law*, Ed. Commission of the European Communities, European Perspectives, 1981, p. 118, emphasised that the overriding requirements of unity, uniformity and effectiveness are the legal embodiment of the political objective of European integration on which the principle of primacy is based.

53 — The interpretation given by the Court to a provision of a regulation has effect in all the Member States (Case 59/85 *Netherlands* v *Reed* [1986] ECR 1283, paragraph 13).

54 — That principle, spelled out for the first time in the judgment in Case 61/79 *Denkavit italiana* [1980] ECR 1205, paragraph 16, has been restated, including in the recent judgment in Case C-453/00 *Kühne & Heitz* [2004] ECR I-837, paragraph 21. However, there is a clear precedent in the judgment of 27 March 1963 in Joined Cases 28/62 to 30/62 *Da Costa en Schaake and Others* [1963] ECR 61, in which the Court stated that 'when it gives an interpretation of the Treaty in a specific action pending before a national court, the Court limits itself to deducing the meaning of the Community rules from the wording and spirit of the Treaty, it being left to the national court to apply in the particular case the rules which are thus interpreted. Such an attitude conforms with the function assigned to the Court ... of ensuring unity of interpretation of Community law'. The obligation of national authorities, in particular the courts, to apply the rules in conformity with the Court's interpretation, is thus the corollary of the division of functions which underlies the preliminary ruling procedure, which, as Robert Lecourt pointed out some years ago (*Le juge devant le Marché Commun*, Ed. Institut Universitaire des Hautes Études Internationales, Geneva, 1970, p. 50), when distinguishing between interpretation and application, allows the lawful authority of the court to be reconciled with the requisite uniformity of Community law.

55 — The Court found that to be the case in the judgment in *Denkavit italiana* (paragraph 16 et seq.). In his Opinion of 17 June 2003 in *Kühne & Heitz*, Advocate General Léger points out that that obligation prevents Community law from being distorted over time, to the detriment of its uniform application and full effect, and that the obligation is inherent in the objective pursued by the preliminary ruling procedure, which consists in ensuring, by virtue of judicial cooperation, the uniform interpretation of Community rules (point 39).

56 — In paragraph 22 of the judgment in *Kühne & Heitz* it is stated that national administrative bodies must apply rules of Community law even to legal relationships which arose or were formed before the Court gave its ruling on the interpretation of those rules.

72. Two restrictions can be seen, however. The first is that, in the absence of any Community legislation, it is for the domestic legal systems of the Member States to make provision about the detailed procedural rules for obtaining rectification, by means of rules which, in any event, afford rights deriving from the European legal system the same level of protection as those founded on national law (the principle of equivalence), ensuring that procedures do not render difficult or virtually impossible the exercise of the relevant rights (principle of effectiveness). [57]

73. The second, the counterpart of the first, is to be found in the need for legal certainty, a central principle of the legal order of the European Union, which prevents final non-reviewable decisions being reopened once the ruling on the question is known. By virtue of the judgment in *Kühne & Heitz*, Community law does not, as a general rule, require an administrative body to reopen a decision which is final (because of the exhaustion of legal remedies or because all the reasonable time limits for bringing an appeal have expired), unless national law allows for review, provided that in the latter case the strict requirements laid down in the judgment itself are met. [58]

74. Precedent and the letter of the law hence take us to the same point: any review must comply with the procedures provided for by domestic legislation on national patents, in accordance with the wording of Article 17 of both the regulations cited.

75. Consequently, where, in accordance with the provisions of domestic law, an administrative decision on an application is amenable to review, the national authorities are obliged to rectify, via the procedures laid down in national law, supplementary protection certificates, the duration of which has been erroneously calculated.

57 — The Court's case-law on this point is well known in relation to the exercise of procedural rights to recover charges paid to the State in breach of Community law. The precedent was established in two judgments of 16 December 1976, Case 33/76 *Rewe* [1976] ECR 1989 and Case 45/76 *Comet* [1976] ECR 2043, and has most recently been restated in joined Cases C-216/99 and C-222/99 *Prisco and Caser* [2002] ECR I-6761 and Case C-147/01 *Weber's Wine and Others* [2003] ECR I-11365.

58 — The backdrop to this case is Netherlands law, under which final decisions may be reopened, unless the rights of third parties are adversely affected. The Court stated that in such cases there was, on account of the principle of cooperation arising from Article 10 EC, an obligation to review the decision, if the contested decision (i) had become final as a result of a judgment of a national court ruling at final instance, and (ii) was, in the light of a subsequent judgment of the Court of Justice, based on a misinterpretation of Community law adopted without a question being referred to the Court for a preliminary ruling; provided that the person concerned complained to the administrative body immediately after becoming aware of the Court's judgment.

VI — Conclusion

76. In the light of the foregoing considerations, I propose that the Court, in response to the questions referred to it by the High Court of Justice of England and Wales and the Cour administrative de Luxembourg, should declare that:

(1) Under Article 13 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, marketing authorisations issued in Switzerland which, in the framework of the customs union with Liechtenstein, are automatically effective in Liechtenstein constitute a 'first authorisation to place the product on the market in the Community'.

(2) The authorities of the EEA States are obliged to correct the dates by reference to which the duration of the supplementary protection certificates is determined where, when the dates were set, an error was made, provided that, under the relevant national legal system, the decision is amenable to review.