OPINION OF ADVOCATE GENERAL STIX-HACKL

delivered on 26 February 2002 [1]

I — Introduction

1. The issue in this case is whether the establishment of relevant dates differing by Member State in the transitional provision in Article 19(1) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, [2] as amended by the Acts of Accession of Austria, Finland and Sweden [3] ('Regulation No 1768/92'), infringes higher-ranking Community law and is consequently invalid. If that is not the case, the referring court (the Bundesgerichtshof (Federal Court of Justice)) (Germany) applies for an interpretation of the notion of 'first authorisation to place... on the market... in the Community' as it appears in the transitional provision and seeks a ruling on the legal consequences of an infringement of that provision.

1 — Original language: German.

2 — OJ 1992 L 182, p. 1.

3 — Act concerning the conditions of accession of the Kingdom of Norway, the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded, Annex I — List referred to in Article 29 of the Act of Accession — XI. Internal market and financial services — F. Intellectual property and product liability — I. Patents (OJ 1994 C 241, p. 233).

II — Facts of the case and main proceedings

2. These questions have arisen in a dispute between Ratiopharm GmbH ('Ratiopharm') and Aktiebolaget Hässle ('Hässle') concerning the grant to Hässle of a supplementary protection certificate for the active substance omeprazol.

3. Hässle was the holder of a European patent for the active substance omeprazol. That patent, valid inter alia in Germany, was granted to Hässle with effect from 3 April 1979 and expired on 3 April 1999 at the end of its 20-year period of validity.

4. In France and Luxembourg authorisations for the purposes of the law on medicinal products were granted in respect of proprietary medicinal products based on omeprazol, in accordance with Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid

down by law, regulation or administrative action relating to medicinal products [4] ('Directive 65/65'), on 15 April 1987 and 11 November 1987 respectively. In Germany the corresponding authorisations were not granted until 6 October 1989.

5. In Luxembourg a price-law authorisation is also required for the marketing of proprietary medicinal products. By letter of 17 December 1987, which was received by the firm concerned on 31 December 1987, the competent ministry granted that authorisation. For a proprietary medicinal product to be placed on the market in Luxembourg, it must further be included in the list of proprietary medicinal products authorised for sale in the Grand Duchy. This was done in the case in question on 21 March 1988. In France the proprietary medicinal product was entered on 22 November 1989 in the list of medicaments eligible for reimbursement to persons insured under the social security scheme.

6. On 9 June 1993 Hässle applied to the Deutsches Patentamt for a protection certificate for the active substance omeprazol. It stated 'March 1988 Luxembourg' as the time and place of the first authorisation to place omeprazol on the market as a medicinal product in the European Community and attached a copy of the abovementioned list containing the entry dated 21 March 1988.

4 — OJ, English Special Edition 1965-1966, p. 20, in the version established by Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products (OJ 1993 L 214, p. 22).

7. The Deutsches Patentamt, by decision of 10 November 1993, issued the protection certificate and fixed as its duration the period until 21 March 2003.

8. Ratiopharm applied to the Bundespatentgericht (Federal Patent Court) for a declaration that the protection certificate was invalid on the ground that it should not have been issued because a first authorisation to place omeprazol on the market as a medicinal product in the Community had already been granted before the relevant date for Germany of 1 January 1988. [5] The Bundespatentgericht upheld the application and declared the certificate invalid. Hässle having taken that ruling to appeal, the Bundesgerichtshof stayed the proceedings and referred a number of questions to the Court of Justice for a preliminary ruling.

III — Community Law

A — *Regulation No 1768/92*

9. The *third and fourth recitals* read:

'Whereas at the moment the period that elapses between the filing of an application

5 — Regulation No 1768/92, Article 19(1), second sentence.

for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research;

Whereas this situation leads to a lack of protection which penalises pharmaceutical research;'.

10. The *sixth and seventh recitals* read, in extract:

'Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community...

Whereas, therefore, the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;'.

11. The *10th recital* reads:

'Whereas a fair balance should also be struck with regard to the determination of the transitional arrangements; whereas such arrangements should enable the Community pharmaceutical industry to catch up to some extent with its main competitors who, for a number of years, have been covered by laws guaranteeing them more adequate protection, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the health policies pursued both at national and Community level;'.

12. *Article 1* reads, in extract:

'For the purposes of this regulation:

(a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings or animals...;

(b) "product" means the active ingredient or combination of active ingredients of a medicinal product;

(c) "basic patent" means a patent which protects a product as defined in (b) as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;

(d) "certificate" means the supplementary protection certificate.'

13. *Article 2* reads:

'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 Council Directive 65/65/EEC or Directive 81/851/EEC may, under the terms and conditions provided for in this regulation, be the subject of a certificate.'

14. *Article 3* reads, in extract:

'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:

...

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate. For the purpose of Article 19(1),[6] an authorisation to place the product on the market granted in accordance with the national legislation of Austria, Finland or Sweden is treated as an authorisation granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;...

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

6 — In what is clearly an editorial error, the German version refers to Article 19(2). All other language versions refer at this point to Article 19(1). The erroneous reference has therefore been corrected hereinafter, without further explicit mention.

15. *Article 5* reads:

'Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.'

16. *Article 7*(1) reads:

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

17. *Article 8*(1) reads, in extract:

'The application for a certificate shall contain:

(a) a request for the grant of a certificate, stating in particular:...

(iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3(b) and, if this authorisation is not the first authorisation for placing the product on the market in the Community, the number and date of that authorisation;

(b) a copy of the authorisation to place the product on the market, as referred to in Article 3(b), ...

(c) if the authorisation referred to in (b) is not the first authorisation for placing the product on the market as a medicinal product in the Community,...'.

18. *Article 13*(1) reads:

'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.'

19. *Article 15*(1) reads:

'The certificate shall be invalid if:

(a) it was granted contrary to the provisions of Article 3;

(b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.'

20. *Article 19*(1) reads:

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

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

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

B — *Directive 65/65*

21. *Article 1* reads, in extract:

'For the purposes of this Directive, the following shall have the meanings hereby assigned to them:

1. Proprietary medicinal product:

Any ready-prepared medicinal product placed on the market under a special name and in a special pack....'

22. *Article 3* reads:

'No proprietary medicinal product may be placed on the market in a Member State unless an authorisation has been issued by the competent authority of that Member State.' [7]

C — Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products [8] *('Regulation No 1610/96')*

23. *Recital 17* reads, in extract:

'Whereas the detailed rules in... Article... 17(2) of this Regulation are also valid, *mutatis mutandis*, for the interpretation in particular of... Article 17 of Council Regulation (EEC) No 1768/92,'.

7 — For the purposes of Directive 65/65, 'medicinal products' requiring authorisation means 'proprietary medicinal products' within the meaning of Article 1(1) thereof and other 'commercially prepared medicinal products...' that do not correspond to the definition of a proprietary medicinal product (see Article 2(2) of Directive 65/65).

8 — OJ 1996 L 198, p. 30.

24. *Article 17*(2) reads:

'The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorisation to place the product on the market in the Community, contained in the application for a certificate as provided for in Article 8, is incorrect.'

IV — Questions referred

1. (a) For the purpose of applying the transitional provision in Article 19(1) of the Regulation, in so far as that provision refers to the 'first authorisation to place... on the market... in the Community' before a specified relevant date, does that refer exclusively to an authorisation within the meaning of Directive 65/65/EEC or Directive 81/851/EEC as the case may be, or may another authorisation granted later (after the relevant date) relating in particular to the prices of the medicinal product also be material in this respect, if

(aa) without such a further authorisation, for example one for price-law purposes, marketing of the medicinal product is not permissible under the law of the Member State concerned, or

(bb) without such a further authorisation the medicinal product may in principle be marketed in the Member State concerned, but effective marketing is nevertheless not possible, in particular because the sickness funds reimburse the costs of the medicinal product only if the further authorisation, in particular for price-law purposes, has been granted or a determination of the price eligible for reimbursement has been made?

(b) Is the material authorisation for this purpose a first authorisation in any Member State of the Community (as with Articles 8 and 13 of the Regulation) or the first authorisation in the Member State for which the grant of the supplementary protection certificate has been applied for?

2. Is there doubt as to the validity of the transitional provision in Article 19(1) of the Regulation in so far as it lays down different relevant dates for different Member States?

3. Is the list of grounds of invalidity in Article 15(1) of the Regulation exhaustive?

If not:

(a) Does it constitute a ground of invalidity that a certificate was granted under the transitional provision in Article 19(1) of the Regulation even though a first authorisation to place the product on the market in the Community was already granted before the relevant date for the Member State in which the certificate was applied for and granted?

(b) In that case is the certificate completely invalid, or should its duration merely be rectified accordingly?

4. If a breach of the transitional provision in Article 19(1) of the Regulation does not constitute a ground of invalidity:

May and must national law provide, as under Article 17(2) of Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 June 1996 concerning the creation of a supplementary protection certificate for plant protection products, for an appeal aimed at rectifying the duration of the protection certificate for a medicinal product in the event of a breach of the transitional provision in Article 19(1) of Regulation No 1768/92?

V — Preliminary remarks on the concepts underlying, and the aims of, patent protection for the purposes of the law on medicinal products and on the underlying reconciliation of interests [9]

25. Patent protection for the purposes of the law on medicinal products affords an exclusive right. It allows the holder of a basic patent [10] to exploit economically the results of its research effort, to the exclusion of other market participants, for a specified period of time. [11] Such research results are active ingredients or combinations of active ingredients (hereinafter 'product') [12] or processes used to obtain them.

26. Medicinal products, [13] based on such active ingredients, for treating or preventing disease in human beings require, in the Community, authorisation for the purposes of the law on medicinal products; [14] authorisation is then granted on successful completion of a national procedure based on the corresponding national measure(s) for implementing Directive 65/65 ('procedure under Directive 65/65'). Such authorisation is not granted in respect of a medicinal product as such but is granted separately for each presentational form, dosage etc. in which the medicinal product concerned is to be placed on the market under a special name and in a special pack (proprietary medicinal product). [15]

27. In the Member States a number of other authorisation procedures are to some extent also in operation which are generally initiated only when the procedure under Directive 65/65 has been completed but which are often also, under national law, a

9 — See also the preamble and the judgments in Case C-350/92 *Commission* v *Spain* [1995] ECR I-1985 and in Case C-181/95 *Biogen* [1997] ECR I-357 and the Opinion of Advocate General Fennelly in the latter case and in Case C-392/97 *Farmitalia* [1999] ECR I-5553.

10 — Article 1(c) of Regulation No 1768/92.

11 — Patent protection generally runs for 20 years.

12 — Terms used in Article 1(b) of Regulation No 1768/92.

13 — Article 1(a) of Regulation No 1768/92.

14 — Article 3 of Directive 65/65.

15 — Article 1(1) of Directive 65/65.

pre-condition for placing on the market and hence for the economic exploitation of the basic patent. These are in the main price-law authorisation procedures.

28. A number of Member States also have social security regulations under which the social security system will bear the cost of a proprietary medicinal product only if the product has been authorised by that system or has been entered in a list of proprietary medicinal products eligible for reimbursement. While placing on the market a proprietary medicinal product that has not been so authorised or listed is not a bar to economic exploitation of the basic patent, its exploitation is a substantially more attractive proposition if reimbursement by social security authorities is possible.

29. All procedures that have to be implemented *after* application for the basic patent in order to place a proprietary medicinal product on the market shorten the period during which economic use can be made of the exclusive right. Procedures which, though not compulsory for the purposes of placing on the market, are necessary for a high-volume turnover shorten the period during which particularly *effective* use can be made of the exclusive right.

30. Creation of a supplementary protection certificate for a medicinal product ('certificate')[16] has the effect of extending the exclusive right concerned beyond the date of expiry of the basic patent. The basic patent itself is not thereby extended; rather the certificate provides protection limited to specific products covered by the basic patent.[17]

31. Extending the exclusive right constitutes, in economic terms,[18] a prolongation of the period during which scientific research results are available for economic exploitation on an exclusive basis. This benefits those firms which, by virtue of their research, are the holders of the certificates concerned. To the extent that the firms concerned reinvest the additional profits so earned in further research, grant of the certificates directly benefits research and hence also contributes to the availability of new products. The grant of certificates is however also of benefit to firms which produce proprietary medicinal products under licence to certificate holders.

32. The award of certificates does, on the other hand, run counter to the interests of firms which, on expiry of the basic patent,

16 — Article 1(d) of Regulation No 1768/92.

17 — The subject-matter of protection by a certificate, provided for in Article 4 of Regulation No 1768/92, is not addressed any more closely here, as such further consideration is not required in order to answer the question referred.

18 — See the third and fourth recitals; Commission proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products COM(90) Final — SYN 255 of 11 April 1990, statement of reasons.

would have been in a position to use products that were no longer protected to, in particular, develop their own medicinal products or to place known medicinal products on the market in the form of proprietary medicinal products. These so-called 'generic' medicines are generally cheaper to produce, if only because, with the use of products that are no longer protected, no or only modest research costs are incurred. It follows that the production of economical generic medicines is of strong interest above all to the national health systems and the Member States that support them financially.

VI — Consideration of the questions referred by the national court

33. Regulation No 1768/92 refers, at a number of points relevant to the present discussion, not only to Directive 65/65 (medicinal products for human use) but also to Directive 81/851/EEC (medicinal products for veterinary use). As the main proceedings concern the procedure for the authorisation of medicinal products, only the procedure under Directive 65/65 is referred to in the following discussion.

34. In the case before the Court, the parties to the main proceedings, Hässle and Ratiopharm, and also the Commission and the Danish, Netherlands, French and Spanish Governments, have stated their positions. In view of the length of those statements, the views expressed will, in what follows, be ordered according to basic lines of argument. [19]

35. As the answers to the other questions depend on the answer to the second question referred, that question will be addressed first in what follows.

A — *The second question: compatibility of Article 19(1) of Regulation No 1768/92 with higher-ranking Community law (varying relevant dates)*

36. Article 19(1) of Regulation No 1768/92 is a transitional provision specifying, in the first subparagraph, a generally applicable relevant date. In the second and third subparagraphs, two relevant dates diverging from that generally applicable date are declared to be applicable in the case of certificates applied for in the Member States referred to in those subparagraphs. Although only the relevant date for Germany (second subparagraph) is essential to the main action, the discussion on this

19 — Submissions pursuing the same aims have thus been combined.

point will turn more generally, in what follows, on the establishment in Article 19(1) of different relevant dates, as the alleged infringement could only arise out of the variation in relevant dates taken as a whole.

Arguments of the parties

37. *Hässle* argues that providing for differing relevant dates by Member States is invalid because it infringes higher-ranking Community law and in particular the principle of equal treatment, the obligation to state reasons and 'harmonisation of the internal market'. There is discrimination because medicinal products for which an authorisation to place on the market in Germany has been obtained could not be granted a certificate for Germany if authorisation occurred prior to 1 January 1988. In contrast, a certificate for other Member States could still be obtained even if an authorisation to place on the market in those countries lay six years further into the past. An objective justification for the differing relevant dates cannot be discerned. The Community legislature has moreover failed fully to comply with the obligation to state reasons, as convincing grounds for the differing relevant dates assigned to Member States are to be found neither in the legislative materials nor in the recitals. The whole of Regulation No 1768/92 is, in *Hässle*'s view, solely concerned with the harmonisation of patent protection in accordance with the legal basis of the Regulation in Article 100a of the EC Treaty (now, after amendment, Article 95 EC). Variations in treatment by Member States cannot however be reconciled with the fundamental concept of harmonisation.

38. *Ratiopharm*, the *Commission* and the *Danish* and *Netherlands Governments* consider the transitional provision in Article 19(1) to be valid. They argue that, according to the principles underlying the Court's decisions, the standards applying to the statement of reasons for a regulation of general application are not very high. The 10th recital can thus be regarded as adequately explaining the purpose of the transitional provision, that of achieving a balance of interests, as considered above. [20] As the question of costs is of varying significance in the public health policies of individual Member States, providing for differing relevant dates is justified in objective terms.

Assessment

39. The question of the validity of the transitional provisions at issue clearly turns on the following points: incompatibility of Article 19(1) of Regulation No 1768/92 with the legal basis of that regulation, namely Article 100a of the EC Treaty (now, after amendment, Article 95 EC);

20 — See point 31 et seq. above.

infringement of the general principle of equality; and at all events — if that principle is ruled to have been observed — non-compliance with the obligation to state reasons for acts of Community law in accordance with Article 190 of the EC Treaty (now Article 253 EC).

40. The Court has already, in its judgment in *Pinna*, [21] addressed the question of the validity of a provision of secondary law that differentiated between Member States. At issue then had been an exemption provision in a regulation, according to which one of the provisions of that regulation would not [22] be applicable in one Member State. The Court, in that judgment, refers to the objective of the primary law concerned (freedom of movement for workers, Articles 48 and 51 of the EEC Treaty (now, after amendment, Articles 39 EC and 42 EC) and finds that '... that objective... will be imperilled... if unnecessary differences in the social security rules are introduced by Community law. It follows that the Community rules on social security introduced pursuant to Article 51 of the Treaty must refrain from adding to the disparities which already stem from the absence of harmonisation of national legislation.'

41. That ruling is not however, in my opinion, of general application. In particular, the present case does not concern a *coordinating provision*, that is to say a provision serving the *realisation* of a fundamental freedom and hence dictated by primary law. Rather, Regulation No 1768/92 rests on Article 100a of the EC Treaty (now, after amendment, Article 95 EC) and is intended to bring about a Community-wide *harmonisation* [23] of particular elements of intangible property law in furtherance of *more effective exercise* of fundamental rights. The Court has already found that harmonisation as an aim of Community secondary law does not in itself conflict with the fact that the application of Community law has varying consequences for those subject to the provisions concerned in the various Member States. [24]

42. It follows that incompatibility can be considered to obtain only if the general principle of equal treatment has been infringed. [25] This is always the case, where provisions of Community law introduce differential treatment, if there is no objective justification for the differentiation so introduced.

43. The entire Regulation serves the reconciliation of interests described earlier. [26] It

21 — Judgment in Case 41/84 *Pinna* [1986] ECR 1.

22 — Regulation No 1408/71 'on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community' contained, at the time of the judgment, a special provision pertaining to particular situations that were subject to French law: the provision concerning family benefits was thereby modified to such an extent, to the detriment of the persons subject to it, that it became to all intents and purposes inapplicable.

23 — See the sixth recital.

24 — This was for example the Court's finding in its judgment in Case C-233/94 *Germany* v *Parliament and Council* [1997] ECR I-2405 concerning a harmonisation provision in the form of a directive on the basis of Article 57 of the EC Treaty (now, after amendment, Article 47 EC).

25 — See the judgment in Case C-309/89 *Codorniu* v *Council* [1994] ECR I-1853 and the recent judgment in Case C-263/98 *Belgium* v *Commission* [2001] ECR I-6063.

26 — See point 31 et seq.

is clear that the extent to which national health policies have an interest in economical generic medicines varies considerably from one Member State to another; the Commission's submission is undisputed on this point. In so far as the competitiveness of the pharmaceutical manufacturers in the Member States concerned may also have a bearing on events, it should be borne in mind that the firms concerned are in part the holders of basic patents or licensees and in part manufacturers of generic medicines.

44. The retrospective provision in Article 19(1) of Regulation No 1768/92 determines, through the time-periods specific to the Member States concerned, the number of 'established' medicines qualifying for conferment of extended exclusive patent rights.[27] A relatively long retrospective period has advantages for undertakings that are holders of the basic patents or are manufacturers under licence to those undertakings. A short retrospective period represents a decision in favour of the availability of more economical generic medicines and in favour of those undertakings that manufacture them. Bearing in mind, as described earlier, the many layers of interests at play in the framework of patent protection for the purposes of the law on medicinal products and given that this constellation of interests is clearly not uniform across the Community but varies from one Member State to another, differentiating in this way would seem fundamentally appropriate.

45. In the light of these considerations it need only be observed, as regards alleged non-compliance with the obligation to state reasons in accordance with Article 190 of the EC Treaty (now Article 253 EC), that the Court has consistently held it to be unnecessary,[28] particularly in the case of regulations, which are of general application, to specify all relevant factual or legal aspects. It is sufficient to present — even succinctly — the overall situation that led to their adoption and to state the overall objective pursued. Regulation No 1768/92 meets these requirements in its preamble.

46. This analysis has thus brought out nothing to indicate that the establishment of varying relevant dates in Article 19(1) of Regulation No 1768/92 is incompatible with higher-ranking Community law.

27 — See also the Opinion of Advocate General Fennelly in Case C-110/95 *Yamanouchi* [1997] ECR I-3251.

28 — See, for example, its judgments in Case 108/81 *Amylum* [1982] ECR 3107, Case 3/83 *Abrias* [1985] ECR 1995, Case C-350/88 *Société Française des biscuits Delacre* v *Commission* [1990] ECR I-395, Case C-122/94 *Commission* v *Council* [1996] ECR I-881, and Case C-183/95 *Affish* [1997] ECR I-4315.

B — *The first question: 'first authorisation to place on the market in the Community' in the first subparagraph of Article 19(1) of Regulation No 1768/92*

1. The question whether the 'authorisation to place on the market' refers exclusively to an authorisation under Directive 65/65 or whether it may also refer to another, later, authorisation under national law

Arguments of the parties

47. *Hässle* argues that, under the terms of the first subparagraph of Article 19(1) of Regulation No 1768/92 and in the absence of any explicit reference therein to Directive 65/65, the 'first authorisation to place on the market' means those national legal or administrative acts on which effective economic exploitation of the product as a medicinal product depends. Such acts include price-law authorisations and authorisations by the social security authorities recognising proprietary medicinal products as eligible for reimbursement. The absence of such authorisations would make effective exploitation more difficult, or even impossible, to achieve. In so arguing, Hässle relies essentially on the wording and purpose of the Regulation.

48. Concerning the wording, Hässle invokes the general principle of interpretation, according to which diverging forms of words within a legal instrument are assumed to express diverging content. Hässle observes that Regulation No 1768/92 dispenses, in Articles 8(1)(c) and 13(1) and in the first subparagraph of Article 19(1), with any explicit reference to Directive 65/65. It concludes from this that other authorisations granted later could also be meant. This interpretation is also, in its view, supported by the amended version of Article 3(b) of Regulation No 1768/92. The legal fiction that for the new Member States the authorisations concerned are, for the purposes of the first subparagraph of Article 19(1) of Regulation No 1768/92, granted in accordance with Directive 65/65 shows that Article 3(b) of the Regulation is necessarily concerned with first 'authorisations' that differ from the authorisations under Directive 65/65.

49. Hässle argues further that this interpretation is consistent with the purpose of Regulation No 1768/92. It follows in particular from the third and seventh recitals, from the Commission's explanations concerning the Regulation when submitted as a proposal, and from the history of the Regulation in general, that its purpose is to extend patent protection to compensate for the time taken up with authorisation procedures of all kinds. In the absence of a certificate, the 'real' duration of the patent protection, that is to say the period of effective exploitation of the basic patent, would be limited to the time remaining between the *last* authorisation required and

expiry of the basic patent. If the first subparagraph of Article 19(1) were taken to refer only to authorisations for the purposes of the law on medicinal products within the meaning of Directive 65/65, the compensation which Regulation No 1768/92 seeks to provide would not be secured.

50. *Hässle* counters the argument that such an interpretation would produce legal uncertainty with the contention that the concern for legal certainty cannot be allowed to call into question the overall purpose of the Regulation as referred to above. Indeed, legal uncertainties could be expected to result precisely from a narrow interpretation, based solely on authorisation within the meaning of Directive 65/65, of the first subparagraph of Article 19(1) of the Regulation.

51. *Ratiopharm*, the *Commission*, and the *Danish*, *Netherlands* and *Spanish Governments* contend that the first subparagraph of Article 19(1) relates solely to authorisation for the purposes of the law on medicinal products, within the meaning of Directive 65/65. They too invoke — relying in part on arguments put forward by the referring court — the wording, purpose and general scheme of Regulation No 1768/92, invoking further a risk that legal uncertainty might otherwise arise when certificates are granted.

52. It can, in their view, be inferred from the wording of the first subparagraph of Article 19(1) that the product obtains authorisation 'as a medicinal product'. This can only mean authorisation for the purposes of the law on medicinal products, within the meaning of Directive 65/65. The additions made to the first subparagraph of Article 19(1) and to Article 3(b) of Regulation No 1768/92 with the accession of the new Member States make no difference in this respect.

53. They argue further that only an exclusive link with authorisations for the purposes of the law on medicinal products, within the meaning of Directive 65/65, would be consistent with the purpose of Regulation No 1768/92. As is clear from the third and fourth recitals and from Article 2 of the Regulation, the certificate is intended as compensation for the time taken up by the procedures laid down in Directive 65/65 and is not granted on other — commercial — grounds, for Regulation No 1768/92 does not seek to guarantee the most economically efficient exploitation of patent rights in respect of medicinal products. This is, in their view, borne out in particular by the historical background to the Regulation.

54. They argue finally that the general scheme of Regulation No 1768/92 supports the view that by 'first authorisation in the Community' can only be meant authorisation within the meaning of Directive 65/65. They observe that Article 8(1)(a)(iv) and (c) of the Regulation employ the same concept and refer expressly, in so doing, to Article 3(b) thereof. The latter in turn refers only, and unequivocally, to authorisations

for the purposes of the law on medicinal products within the meaning of Directive 65/65. It is also argued, with reference to the judgment in the *Yamanouchi* case,[29] that as a transitional provision Article 19 is, technically, modelled on the main body of the Regulation, such that Article 19(2) corresponds to the provision concerning time-limits for application (Article 7) and Article 19(1) to the provision concerning the conditions for obtaining a certificate (Article 3(b)).

55. They are however concerned above all that legal uncertainty might arise were authorisation procedures other than those provided for in Directive 65/65 to be regarded as material. For such procedures would not, unlike those under Directive 65/65, be harmonised under Community law. For those falling within the scope of Regulation No 1768/92, it would thus be unclear whether there exist, in the individual Member States, further obstacles to placing on the market or — only — to 'effective marketing', and, if so, what those obstacles might be. This would run counter to the regulatory uniformity sought by Regulation No 1768/92. Moreover, a reference to authorisations other than authorisation for the purposes of the law on medicinal products, within the meaning of Directive 65/65, would create legal uncertainty as to the duration of the certificate (Article 13 of Regulation No 1768/92) since the same concept is employed in the first subparagraph of Article 19(1) and in Article 13. If it is assumed further — as do all the parties submitting these arguments apart from the Kingdom of Denmark — that, in the first subparagraph of Article 19(1), the 'first authorisation to place on the market' does not always have to be the first authorisation in the Member State of application, a further uncertainty arises. For the authorities of the Member State of application would then have to consider whether, and if so what, other authorisation procedures exist in other Member States, and would have also to assess whether, in individual cases, effective economic exploitation depends on receipt of such authorisation. The possibility could not be ruled out therefore of different authorities arriving at different conclusions.

Assessment

56. The contention that, in the framework of the first subparagraph of Article 19(1) of Regulation No 1768/92, in addition to authorisation for the purposes of the law on medicinal products within the meaning of Directive 65/65, any further authorisation that might be required under national law could also be material, relies essentially on the wording of the provision and on a particular view of what the Regulation seeks to achieve.

57. A first point is that the German language version, where it refers to 'a' first authorisation, cannot be taken as an incontrovertible basis for concluding that in the

29 — Case C-110/95, cited in footnote 27.

first subparagraph of Article 19(1) the Community legislature wished to allow for an authorisation to place on the market other than the authorisation within the meaning of Directive 65/65. It is true that the German and other language versions of this provision are ambiguous on this point because they use the indefinite article 'a'. In the Danish and English language versions, however, the definite article 'the' is used, while other versions (in the Greek and Finnish languages for example) use neither the definite nor the indefinite article.

58. Nor does Article 3(c) of Regulation No 1768/92, in the version — invoked by both sides — amended following the accessions of Austria, Sweden and Finland, provide support for one or other interpretation of the first subparagraph of Article 19(1). For while the fiction implicit in this provision presupposes, logically, that the authorisations hitherto granted in those States were not authorisations within the meaning of Directive 65/65, that fiction is grounded in the fact that an authorisation granted earlier in one of the new Member States could never be 'an authorisation granted in accordance with Directive 65/65/EEC' because of the non-applicability of Community law at that time.

59. Nor again does the fact that the first subparagraph of Article 19(1) does not refer explicitly to authorisation for the purposes of the law on medicinal products within the meaning of Directive 65/65 necessarily provide a basis for concluding that in this context other national authorisations could (also) be material with regard to placing on the market. Neither the recitals nor the legislative materials indicate at any point with sufficient clarity that Regulation No 1768/92, in extending the period during which a product can be marketed under the protection of exclusive patent rights, seeks to provide compensation for delays in placing a product on the market resulting from national authorisation procedures *additional to* the procedure under Directive 65/65, even less do they suggest which authorisations might thereby be referred to.

60. It is also far from clear why within the Regulation the Community legislature should, in the basic norm of Article 3(b) (Conditions for obtaining a certificate), have referred only to authorisation within the meaning of Directive 65/65, while seeking in the transitional provision of Article 19(1) to allow other authorisations to be material in respect of placing on the market, without however making this point explicit.

61. The general scheme of Regulation No 1768/92 again provides no clear indication that an express reference to authorisation for the purposes of the law on medicinal products within the meaning of Directive 65/65 has deliberately been omitted from individual recitals, the provision on duration of the certificate in

Article 13 and the transitional provision in Article 19(1). In any case the position of Article 19 at the end of the Regulation and its — explicit — status as a transitional rule do not suggest a compelling need for such an express reference. This is borne out by the considerations below.

62. Article 19 provides for a deviation from the general principle that a legal provision is applicable only to facts that arise after it has entered into force and where all the operative elements have come into being on that new legal basis. Under Article 19(1), however, a certificate may be granted in cases where one of the operative elements that has to be present for it to be so granted had already come into being *before* Regulation No 1768/92 entered into force. That operative element can however only be authorisation for the purposes of the law on medicinal products within the meaning of Directive 65/65 for no other 'authorisation' is referred to anywhere in the entire Regulation.

63. The reservations concerning legal uncertainty are also convincing. If the transitional provision were taken to refer also to other authorisation procedures that were not harmonised under Community law, then neither the holder of a basic patent nor a competitor interested in exploiting the product could tell from Regulation No 1768/92 whether, in the Member State concerned, a certificate can be, or as the case may be has been wrongfully, granted for 'established' medicines. It would, furthermore, be unclear in those circumstances which authorisations, other than authorisation for the purposes of the law on medicinal products within the meaning of Directive 65/65, were supposed to be material, in the various Member States, to placing on the market. [30]

64. It can be concluded from the foregoing that, in the first subparagraph of Article 19(1) of Regulation No 1768/92, 'authorisation to place... on the market' means exclusively authorisation for the purposes of the law on medicinal products within the meaning of Directive 65/65 (or Directive 81/851/EEC in the case of medicinal products for veterinary use).

2. The question whether the 'first authorisation to place... on the market... in the Community' means the first authorisation in the Member State of application or in any Member State

30 — In addition to the price-law authorisation referred to in the main proceedings and inclusion in the lists of medicaments eligible for reimbursement maintained by the social security authorities — the latter not so much an 'authorisation' perhaps as a measure to boost sales volumes — other national authorisations relevant to placing on the market could also be imagined, in furtherance for example of consumer protection, environmental protection or fair competition.

Arguments of the parties

65. *Hässle* and the *Danish Government* are of the view that the material authorisation is the first authorisation in the Member State of application.

66. Basing their argument essentially on the judgment in *Yamanouchi*,[31] they contend that the Court, in that judgment, interpreted Article 19(2) of Regulation No 1768/92 in such a way that, for the purposes of the transitional provision, a material authorisation is one granted in the Member State of application. Authorisation in any Member State was relevant 'only' in determining the duration of the certificate.

67. Hässle and the Danish Government argue further that Article 19(1) of the Regulation constitutes a special condition attaching to the granting of certificates. As the general condition established in Article 3(b) of the Regulation relates to authorisation in the Member State of application, the same must also hold for the condition of grant in Article 19(1).

68. The words 'in the Community' do not, in their view, conflict with this interpretation, the Community being the sum of all the Member States and one of those States being the Member State of application. They consider it to be clear from the use, in the German and also in other language versions, of the indefinite article in '*a* first authorisation' that there can be more than one 'first' authorisation in the Community. It follows that in Article 19(1), as in Article 3(c), of the Regulation, 'first authorisation' means the first of several authorisations that may be granted in one and the same Member State.

69. A reference to authorisation in any Member State would run counter to the purpose of the transitional provision since authorisations granted by foreign authorities, and in particular authorisations for the purposes of the law on medicinal products within the meaning of Directive 65/65, would never be material in law to the granting of a certificate in the Member State of application. It would thus make no sense for Regulation No 1768/92 to be taken to refer to such authorisations.

70. *Ratiopharm*, the *Commission*, and the *French* and *Spanish Governments* take the view that for the purpose of granting a certificate, the relevant date is the date on which an authorisation was granted in any Member State. They rely essentially on the wording of the first subparagraph of Article 19(1), which speaks of first authorisation 'in the Community'. They observe

31 — Cited in footnote 27.

moreover that, in a number of provisions, Regulation No 1768/92 even uses the concepts 'authorisation in the Member State of application' and 'in the Community' in juxtaposition (in Articles 8(1)(a)(iv), 9(1)(d) and (e) and 11(1)(d) and (e)). It can be concluded from this that Regulation No 1768/92 makes this distinction deliberately. And it follows that, where a provision such as the first subparagraph of Article 19(1) speaks of 'in the Community', this can only be taken to refer to an authorisation in any Member State.

71. The reference to the first authorisation in the Community is important above all in relation to the duration of the certificate. If, in contrast, the reference were to the first authorisation in the Member State of application, the duration of the certificate could, for example, be extended at will.

Assessment

The reference to the judgment in *Yamanouchi*

72. The point must first be made that the arguments developed by the Court in *Yamanouchi*[32] addressed a different question[33] in relation to Article 19 of Regulation No 1768/92. The Court ruled on that occasion that the condition laid down in Article 3(b), namely that for a supplementary protection certificate to be granted in a Member State *an* authorisation for the purposes of the law on medicinal products must previously have been granted for that Member State (the State of application), applies also to 'established' medicines within the scope of Article 19(2).

73. The Court established rather that, as regards the material conditions attaching to the grant of a certificate, Article 3 of Regulation No 1768/92 assumes the procedure concerning authorisation for the purposes of the law on medicinal products *in the Member State of application* and that this must therefore also be the case for the conditions attaching to the grant of certificates within the scope of the transitional provision ('established' medicines).

74. In that case, the Court thus dealt only indirectly with 'first authorisation', namely as a condition attaching to the grant of a

32 — Cited in footnote 27.

33 — It can however be said in the parties' favour that the line of argument in the grounds for the decision is not entirely clear. The points made in paragraphs 24 and 25 in particular suggest that a totally clear distinction has not been drawn between the provision concerning the duration of the certificate in Article 13 and the transitional provision in Article 19 of Regulation No 1768/92. Bearing in mind the specific issues addressed in the main proceedings, it should probably not be assumed either that the Court, in saying that the first authorisation *in the Community* was of importance 'only' in determining the duration of the certificate, really meant that the first authorisation in the Community could be of significance at no other point in the Regulation.

certificate under Article 3 (subparagraph (b) in conjunction with subparagraph (d)) of Regulation No 1768/92. The issue in the present case is not however the conditions attaching to the grant of certificates within the scope of the transitional provision but rather the interpretation of the scope of application itself.

The wording of the first subparagraph of Article 19(1) of Regulation No 1768/92

75. A first point to be made concerning the wording of the first subparagraph of Article 19(1) of Regulation No 1768/92 is that the text refers unequivocally to 'first authorisation *in the Community*' (emphasis added). As regards the line of argument relying on the reference in the German and some other language versions to 'a' first authorisation, I refer to the points developed above [34] concerning the lack of uniformity in the various language versions of this provision.

34 — See point 57.

The use of the concepts 'first authorisation *in the Member State of application*' and 'first authorisation *in the Community*' in their various occurrences in Regulation No 1768/92

76. The concepts 'first authorisation in the Member State of application' and 'first authorisation in the Community' are used not only in the first subparagraph of Article 19(1) but also in a number of other provisions in Regulation No 1768/92. The various references are taken in turn below and the sense in which the concepts are used is analysed in each case. It can be shown that the reference to the first authorisation *in the Member State of application* on the one hand and to the first authorisation *in the Community* on the other, or again the use of *both concepts* in one and the same article, are by no means fortuitous. In each instance particular requirements are attached to, or effects produced on, the grant of certificates and these, taken together, allow a specific overall purpose to be discerned in Regulation No 1768/92. I propose to ascertain that purpose and then proceed, on that basis, to interpret the first subparagraph of Article 19(1) of the Regulation.

77. Article 3(d) of Regulation No 1768/92 refers to the first authorisation *in the Member State of application*. The background to this provision is considered below.

78. Directive 65/65 requires authorisations for the purposes of the law on medicinal products to be obtained for each individual proprietary medicinal product. It follows that, in a Member State, several procedures under Directive 65/65 — in respect of several proprietary medicinal products based on the same [35] product protected by a basic patent — can be initiated simultaneously or consecutively. One of these authorisations is then 'in the Member State... the first authorisation to place the product on the market' within the meaning of Article 3(d) of Regulation No 1768/92.

79. The reference to obtaining such a first authorisation in the Member State of application is of importance for the beginning of the period during which applications may not be lodged for certificates, which — as will be shown — have very restrictive effects for the holders of a basic patent.

80. In accordance with Article 3(d) in conjunction with Article 7(1) of the Regulation, a certificate may be granted only if the application is lodged within six months of the successful completion, in the Member State of application, of the first procedure for authorisation, for the purposes of the law on medicinal products, of a proprietary medicinal product based on a particular product. It is true that a single product can form the basis for different medicinal products. Under the Regulation it is however no longer possible, upon expiry of the above period, to apply for a certificate for a product only when a later authorisation has been granted for a proprietary medicinal product based on another medicinal product. This is a consequence of the association with Article 3(c), according to which only one certificate may ever be granted for a particular product, even if several medicinal products have been developed from it.

81. To sum up, the holder of a basic patent thus has only one opportunity to apply for a certificate for its product. It has only a short period of time in which to do so and that period begins at the earliest possible point in time, namely when it is established that, in the *Member State of application*, the product is eligible for authorisation, for the purposes of the law on medicinal products, in the form of at least one proprietary medicinal product. It can be seen therefore that the reference to the *Member State of application* in Article 3(d) of Regulation No 1768/92 serves a restrictive application of the Regulation.

82. A reference to the first authorisation *in the Community* is to be found — apart from the occurrence in the provision at

35 — It can also occur that medicinal products are produced on the basis of products that are protected by more than one basic patent. Although Regulation No 1768/92 does not offer unequivocal guidance on this point, the Court holds that several certificates (one for each basic patent) may be granted in such cases. This was the tenor of the judgment in Case C-181/95 *Biogen* (cited in footnote 9).

issue, the first subparagraph of Article 19(1) — in the provision concerning the duration of the certificate (Article 13 of Regulation No 1768/92). The background to this provision is considered below.

83. The purpose of Regulation No 1768/92 being to compensate, by means of the certificates, for the shortening of the period of economic exploitation of the exclusive right resulting from the procedures under Directive 65/65, it follows that the duration of a certificate must in principle be calculated by reference to the duration of those procedures. Generally speaking, procedures under Directive 65/65 are set in motion at the same time as the application for the basic patent and come to an end upon successful completion of the process. From that period, five years are deducted as standard and a maximum certificate duration of five years can be obtained from the time remaining.

84. If the duration were calculated solely on the basis of the duration of the first successfully completed procedure *in the Member State of application*, the duration of the national certificate concerned would in principle — because of the standard Community-wide curtailments — be longer, the longer the duration of the procedure itself. That is clearly not the intention, since Article 13(1) of the Regulation takes as the starting point for the calculations the duration of the procedure on whose completion the first authorisation for the purposes of the law on medicinal products was granted *in the Community*. Where the application for the basic patents and the procedures under Directive 65/65 are set in motion at the same time, the basis for calculating the duration of the certificate in the Member State of application thus becomes the shortest procedure in any Member State and hence is not necessarily the duration of the procedure that in practice shortened the period of economic exploitation of the basic patent in the Member State of application. [36]

85. Article 13(1) of Regulation No 1768/92 contains a further restriction of the duration of the certificate, again through a deliberate reference to the 'first authorisation... in the Community'. Calculation thereof is not based on the overall duration of this first procedure to be successfully completed in any Member State of the Community. It is based rather on the period from the time of application for the basic patent in the *State of application* to the date of completion of the first procedure for the purposes of the law on medicinal products in any Member State. [37] The effect of this calculation is that the certificates —

36 — Basis for the Commission proposal (cited in footnote 18).

37 — If for example, in any Member State, the procedure under Directive 65/65 was only successfully completed first because the basic patent was applied for earlier and hence the procedure for the purposes of the law on medicinal products could also be initiated and completed earlier, the basis for calculating the duration of the certificate is limited to the period from expiry of the basic patent to completion of the procedure under Directive 65/65 in any Member State.

regardless of the dates on which the basic patents were applied for in the various Member States — always expire on the same date, [38] which then makes it possible to establish when the patent protection enjoyed by a product lapses in the entire Community.

86. It can be concluded from the foregoing that a certificate under Regulation No 1768/92, because of the limitation placed on its duration by Article 13(1), rarely has the same duration as the corresponding national procedure under Directive 65/65. The primary considerations would seem rather to be acceleration of the procedures under Directive 65/65 and the legal certainty afforded by simultaneously expiring certificates. This outcome is to be obtained by means of the reference to 'the first authorisation to place the product on the market *in the Community*'.

38 — Example: an application for a basic patent was filed in Member State A in 1979. The basic patent in A expired in 1999 after a 20-year life. The procedure under Directive 65/65 was initiated in A in 1979 and lasted, say, 8 years. According to the formula contained in Article 13 of Regulation No 1768/92, the duration of a certificate for Member State A is: 8 years — 5 years = 3 years. In Member State A, the duration of the certificate thus comes to an end *in 2002*. In Member State B the basic patent was applied for a year later, in 1980, and lapsed in 2000. The duration of the certificate for which an application has been made for Member State B is calculated on the basis of the period from expiry of the basic patent in B to completion of the procedure in the first Member State in the Community, i.e. Member State A. The procedure in A, having taken 8 years, was completed in 1987. For the purpose of the calculation account is not however taken of the entire duration of the procedure but only of the residual period as from the application for a basic patent in B, i.e. 1980 — 1987 = 7 years. According to the formula in Article 13 of Regulation No 1768/92, the duration of a certificate for Member State B is thus: 7 years — 5 years = 2 years. The period of validity of the certificate commences on expiry of the basic patent in B, i.e. in 2000. This means that the period of validity in B ends *in 2002* — at the same time then as the certificate in A.

87. In addition to the reference to the first authorisation *in the State of application* (Article 3(d)) and to the first authorisation *in the Community* (Article 13), there are several provisions in Regulation No 1768/92 where *both forms of words occur in juxtaposition*. These are Articles 8 (Content of the application), 9 (Lodging of an application) and 11 (Publication).

88. These occurrences do not in themselves, however, allow any particular conclusions to be drawn in answer to the questions referred. If the two concepts are used in juxtaposition, this is solely because (a) where application for a certificate, and more particularly examination of the associated conditions and time-limits (Articles 3 and 7 of Regulation No 1768/92), are concerned, and for the purposes also of lodging an application and notifying the fact that a certificate has been granted, the relevant date is that of the first authorisation in the Member State of application, while (b) in calculating the duration of the certificate, the relevant date is that of the first authorisation *in the Community*. [39]

Conclusions regarding the use of the concept 'first authorisation in the Community'

39 — See also the Opinion of Advocate General Fennelly in the *Yamanouchi* case (cited in footnote 27).

in the first subparagraph of Article 19(1) of Regulation No 1768/92

89. With the transitional provision in Article 19(1) it becomes possible to apply for certificates for products in respect of which the authorisation procedures for the purposes of the law on medicinal products had already been successfully completed some years before the Regulation entered into force and which, therefore, would not ordinarily have fallen within the scope of that Regulation. As discussed,[40] Article 19(1) constitutes a deviation from the general rules applying to the temporal scope of a Regulation and should, if only for that reason, be interpreted restrictively.

90. But this provision should also, in my opinion, be construed narrowly in keeping with the generally restrictive nature — a point developed earlier[41] — of Regulation No 1768/92. It is not however possible with a restrictive interpretation to establish, on the basis of the corresponding first successfully completed procedure under Directive 65/65 in the Member State of application, the relevant date for determining whether 'established' medicines are eligible for certificates. This assertion is supported by the considerations set out below.

91. In Article 19(1) the relevant date of 'first authorisation' is the date on which a procedure under Directive 65/65 was completed by the grant of an authorisation. That date has to be later than one of the dates specified in the first, second and third subparagraphs (1 January 1982, 1985 and 1988). If the relevant date was determined by the first authorisation *in the Member State of application*, it would be all the more easily exceeded, the longer the duration of the procedure for the purposes of the law on medicinal products in the Member State concerned.

92. In contrast, where relevant dates are governed by uniform, Community-wide provisions hinging on the earliest possible point in time (the 'first' authorisation in the Community), the effect is for Regulation No 1768/92 to be applied to 'established' medicines in a uniform manner across the Community. This is because all products are disqualified where the medicinal products based on them were granted authorisation for the purposes of the law on medicinal products later than the earliest possible point in time. The earliest possible point in time is however the time when it is established that a proprietary medicinal product based on the product qualifying for a certificate is in principle eligible for authorisation — this being the time when an authorisation for the purposes of the law on medicinal products within the meaning of Directive 65/65 was granted in *any Member State*.

93. It can be concluded from the foregoing that, in the first subparagraph of Article 19(1) of Regulation No 1768/92, the 'first authorisation... in the Community' means the first authorisation in any Member State of the Community and not the first authorisation in the Member State of application.

40 — See point 62.

41 — See points 79 et seq. and 82 et seq.

C — *The third and fourth questions: legal consequences of a breach of Article 19(1) of Regulation No 1768/92*

94. The third and fourth questions referred to the Court come down in essence to asking what legal consequences result from the grant of a supplementary protection certificate that, for Article 19(1) to have been applied correctly, ought not to have been granted.

Arguments of the parties

95. *Hässle* and the *Danish* and *Netherlands Governments* take the view that the grant of a certificate in breach of Article 19(1) of Regulation No 1768/92 does not invalidate the certificate. They argue essentially that Article 15(1) of the Regulation gives an exhaustive list of the grounds of invalidity ('shall be invalid if...') but makes no reference to Article 19(1). Article 15(1) contributes in this way to the legal certainty that is necessary in patent law. They observe further that Regulation No 1610/96 concerning the creation of a supplementary protection certificate for plant protection products is to a large extent identical to Regulation No 1768/92 but that here again the Community legislature — in full awareness of the issues — has nowhere provided for breaches of the transitional provision to be treated as a ground of invalidity. Nor, in their view, is a failure on the part of the competent authorities in the State of application to take account of an earlier authorisation, for the purposes of the law on medicinal products, in another Member State so serious a fault as to justify invalidity under Article 15. In support of this view, they point inter alia to Article 10(5), according to which 'Member States may provide that the authority... is to grant certificates without verifying that the conditions laid down in Article 3(c) and (d) are met.'

96. *Hässle* and the *Danish Government* contend that the response to a breach of Article 19(1) should not be invalidation of the certificate but rather a recalculation of its duration. They point out that Article 17(2) of Regulation No 1610/96 provides expressly for such recalculation where the date of the first authorisation to place on the market was incorrectly given. This legal consequence is also, in accordance with Recital 17 in Regulation No 1610/96, applicable in the framework of Regulation No 1768/92. The expression '*mutatis mutandis*' also allows such application in connection with provisions that are not expressly mentioned in that recital.

97. The *Netherlands Government*, without expressly registering a preference for recalculation of duration, takes the general view that the legal consequence of an infringement of Article 19(1) should, in accordance with Article 17 of Regulation No 1768/92, be determined by national law.

98. *Ratiopharm*, the *Commission* and the *French Government* argue — relying in part on the Court's judgment in *Yamanouchi* — that a failure to comply with the provisions on relevant dates in Article 19(1) of Regulation No 1768/92 must result in complete invalidation of the certificate. They consider that Article 19(1), in just the same way as Article 3, is concerned with establishing the conditions for obtaining certificates. If non-compliance with one of the conditions set out in Article 3 results, in accordance with Article 15(1)(a), in the complete invalidity of the certificates, this must also — through further interpretation, or through the application of Article 15, either directly or by analogy — hold for non-compliance with Article 19(1).

99. The *Commission* takes the view in principle that Article 19(1) is concerned with defining the practical scope of application of Regulation No 1768/92 and that a recalculation of duration is inconsistent therefore with the delimiting function of a provision concerning relevant dates. In the alternative, it does however consider — with reference to Recital 17 in Regulation No 1610/96 — recalculation of duration under national law in accordance with Article 17 of that Regulation to be possible.

100. *Ratiopharm* objects to the reference to Article 17(2) of Regulation No 1610/96 on the ground that, while Recital 17 thereof refers to various provisions in Regulation No 1768/92, it fails precisely to refer to Article 19(1) of that regulation. It considers further that rectification of duration is an appropriate legal consequence only where a breach of a provision leads to incorrect determination of duration, which is not the case here.

Assessment

101. As a first point, there is in my opinion no need to consider here whether or not the list of *grounds of invalidity in Article 15 of Regulation No 1768/92* is exhaustive or whether a legal consequence can be derived, by analogy, from Article 15(1)(a).

102. If a supplementary protection certificate is granted pursuant to Article 10(1) of Regulation No 1768/92 even though the conditions laid down in Article 19(1) have not been fulfilled, the certificate has necessarily been granted outside the area of application of the Regulation. That being the case, a ground of invalidity within the meaning of Article 15(1) cannot be envisaged as a legal consequence — whether through further interpretation of, or by analogy to, the grounds of invalidity specified in that article. A certificate granted outside the scope of Regulation No 1768/92 cannot be regarded as a 'supplementary protection certificate' within the meaning of Regulation No 1768/92 and, by the same token, cannot lay claim to the protective effects of Article 5 thereof.

103. In the light of the points just made, there is again, in my view, no need to consider *a recalculation of duration* on the basis of Article 17(2) of Regulation No 1610/96. In case that view is not shared by the Court, I would nevertheless like, with all due brevity, to take a position on the fourth question referred.

104. There is no mention in Regulation No 1768/92 of recalculation of duration as a legal consequence. The Regulation recognises only the grounds of invalidity set out in Article 15(1) and leaves any legal consequences that may arise from other errors to the legal systems of the Member States. Article 17(2) of Regulation No 1610/96 provides for such recalculation of duration in particular circumstances. That detailed rule concerned is then, according to Recital 17 in Regulation No 1610/96, valid '*mutatis mutandis*' for the 'interpretation' of Article 17 of Regulation No 1768/92. [42]

105. The recalculation of duration provided for in Article 17(2) of Regulation No 1610/96 is presumably intended for a situation in which the duration of a certificate has been calculated *incorrectly* in relation to Article 13 of Regulation No 1768/92, say because the relevant date for the purpose of this calculation was given incorrectly in the application for the certificate.

106. This does not however mean that, in the granting of a certificate, all errors relating to an incorrect date must result in recalculation of its duration. 'Certificates' granted despite a failure to comply with the relevant dates specified in Article 19(1) of Regulation No 1768/92 fall into this category. But it does not necessarily follow that the actual duration of a 'certificate' granted in this way has been calculated incorrectly.

107. Finally, the fact that recalculation of duration in the event of a certificate being granted in breach of Article 19(1) of the Regulation can only ever have an effect on the certificate in the Member State of application argues against such recalculation. The duration of the certificates for the same product in other Member States would be unaffected because the authorities in a particular Member State can only correct the duration of certificates in that State. The effect would be that the certificates granted for a product in the Community would no longer all expire on the same date, which would detract from the legal certainty — discussed earlier [43] — that Article 13(1) of Regulation No 1768/92 is meant to ensure.

42 — The question is left open here whether the certainty principle is satisfied where the Community legislature provides for the specific legal consequences of a regulation to be determined by a particular 'interpretation' of that regulation and where that interpretation is itself provided for in another regulation, and even then only in the recitals.

43 — See point 85.

VII — Conclusion

108. In the light of the foregoing, I propose that the questions referred for a preliminary ruling be answered as follows:

(1) Examination of the transitional provision in Article 19(1) of Regulation (EEC) No 1768/92 with regard to its establishment of varying relevant dates has disclosed no factor capable of calling into question its compatibility with higher-ranking Community law.

(2) The concept of 'first authorisation for placing on the market in the Community' as it appears in Article 19(1) of Regulation No 1768/92 must be interpreted as meaning exclusively the first authorisation for the purposes of the law on medicinal products, within the meaning of Directive 65/65/EEC or Directive 81/851/EEC as the case may be, granted in any Member State of the Community.

(3) Where — as in the main proceedings — a certificate is granted in breach of the transitional provision in Article 19(1) of Regulation No 1768/92, the consequence is that no rights can be asserted under Regulation No 1768/92.