OPINION OF ADVOCATE GENERAL JACOBS
delivered on 29 April 2004 [1]

1. In the present case the Bundesgerichtshof (Federal Court, Germany) has referred to the Court a question concerning the grant of a supplementary protection certificate ('a certificate') under Council Regulation No 1768/92. [2]

2. That regulation provides for the grant of a certificate by 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. The certificate is designed to extend patent protection for such products so as to reflect the fact that in the pharmaceutical sector there is normally a considerable delay after the filing of a patent application before the patent holder is authorised to market the product, and hence the normal period of patent protection — usually 20 years from the filing of the application — may be inadequate.

3. The Regulation applies to medicinal products for humans and animals. One of the conditions for obtaining a certificate is that, at the date when and in the Member State where the application is submitted, there should be a valid marketing authorisation for the product under either the Community code relating to veterinary medicinal products [3] or the Community code relating to medicinal products for human use. [4]

1 — Original language: English.

2 — Council Regulation (EEC) of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ 1992 L 182, p. 1. Minor amendments were made to the Regulation by Annex I to the Act concerning the conditions of accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded, OJ 1994 C 241, p. 233, as adjusted by Decision 95/1/EC, Euratom, ECSC of the Council of the European Union of 1 January 1995 adjusting the instruments concerning the accession of new Member States to the European Union, OJ 1995 L 1, p. 1; however, since the material time for the purpose of the present case is 1994 while the amendments applied from 1 January 1995, the relevant provisions of the Regulation are cited in their original version.

3 — 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Council of 6 November 2001 on the Community code relating to veterinary medicinal products, OJ 2001 L 311, p. 1, which repealed and replaced with effect from 18 December 2001 Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary products, OJ 1981 L 317, p. 1, as amended.

4 — 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, which repealed and replaced with effect from 18 December 2001 Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, OJ, English Special Edition, 1965-66 (I), p. 20, as amended.

4. As part of the transitional arrangements laid down by the Regulation, Article 19(1) provides that a certificate may be granted for any product which, when the Regulation enters into force, [5] is protected by a patent and for which the first marketing authorisation in the Community as a medicinal product was obtained after (in the case of Germany) 1 January 1988.

5. The Bundesgerichtshof asks essentially whether that provision precludes the grant of a certificate in Germany for a medicinal product for human use which was protected by a patent when the Regulation entered into force in circumstances where a marketing authorisation had been granted before 1 January 1988 for the same (patent protected) product as a veterinary medicinal product but not as a medicinal product for human use.

6. Put differently, the question is thus whether a distinction should be drawn for the purpose of Article 19(1) between the first marketing authorisation as, on the one hand, a medicinal product for human use and, on the other hand, a veterinary medicinal product. Although in the present case the question referred mentions only the transitional provision in Article 19(1), the issue is, as will be seen, relevant to the whole scheme of the Regulation.

5 — 2 January 1993: see paragraph 22 below.

Background to the Regulation

7. The duration of patent protection is generally 20 years from the date of filing the patent application. The applicant will not however normally be in a position to market the patented invention until some time after the patent has been granted. In 1990, when it presented its Proposal for the Regulation, [6] the Commission estimated at four years the average period which elapses in industry in general from the date on which the patent application is filed to the date on which the invention is placed on the market. [7] The average effective period of exclusivity conferred by a patent is thus in fact reduced to 16 years. In the pharmaceutical sector, however, the need to comply with rigorous additional requirements before authorisation to market a new medicinal product is granted means that considerably more than four years will often elapse before the patent holder can expect to start getting a return on his investment. The effective period of exclusivity will accordingly be correspondingly shorter.

6 — Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, COM(90) 101 final, OJ 1990 C 114, p. 10.

7 — Paragraph 51 of the explanatory memorandum for the Proposal, cited in note 6.

8. The purpose of the certificate is to confer on medicinal products which have been granted a marketing authorisation in the Community effective overall protection equivalent to that pertaining in other sectors of technology. [8] The Regulation seeks to do this, in essence, by providing that a certificate is to be valid for a period equal to that which elapsed between the filing of the patent application and the grant of the marketing authorisation, reduced by five years; it accordingly compensates in effect for a delay of more than five years between filing and market authorisation. The duration of a certificate is moreover subject to a maximum of five years. [9]

Relevant provisions of the Regulation

9. The first five recitals in the preamble to Regulation No 1768/92 refer to the need to provide for sufficient protection for medicinal products to encourage research and preempt the relocation of research centres. In particular the second and third recitals state:

'... medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research;

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

10. The sixth recital suggests a uniform solution at Community level to prevent 'further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market'. The seventh recital points to the need for the creation of a supplementary protection certificate by regulation. The eighth recital concerns the duration of the protection granted by the certificate, which should be 'adequate' and 'effective', and states;

'... the holder of both a patent and a certificate should be able to enjoy an overall

8 — Ibid., paragraph 14.

9 — Article 13, set out in paragraph 19 below.

maximum of 15 years of [exclusivity] [10] from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community'.

11. The 9th and 10th recitals state:

'...all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector must nevertheless be taken into account; ... for this purpose, the certificate cannot be granted for a period exceeding five years; ... the protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product;

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

10 — The English text reads 'exclusively'; however it is clear both from the sense and from the other language versions that that is an error.

12. Article 1(a) defines 'medicinal product' as 'any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals'. Article 1(b) defines 'product' as 'the active ingredient or combination of active ingredients of a medicinal product'. Article 1(c) defines 'basic patent' as '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'.

13. Article 2 states:

'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 sets out the conditions for obtaining a certificate, namely that:

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

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;

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

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

15. Article 4 provides:

'Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.'

16. Article 5 provides that, subject to Article 4, the certificate is to confer the same rights as conferred by the basic patent and to be subject to the same limitations and the same obligations.

17. Article 6 provides that the certificate is to be granted to the holder of the basic patent or his successor in title and Article 7 requires the application for a certificate to be lodged within six months of the grant of a marketing authorisation in the Member State concerned.

18. Article 8 prescribes the content of the application for a certificate, which must include pursuant to Article 8(1)(b) 'a copy of the authorisation to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in

particular the number and date of the authorisation and the summary of the product characteristics listed in Article 4a of Directive 65/65/EEC or Article 5a of Directive 81/851/EEC'.

19. Article 13 concerns the duration of the certificate. It provides:

'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 first authorisation to place the product on the market in the Community reduced by a period of five years.

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

20. Article 14 sets out the circumstances in which the certificate is to lapse, including at (d) 'if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation or authorisations to place on the market in accordance with Directive 65/65/EEC or Directive 81/851/EEC. ...'

21. Article 19(1) states:

'Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product in the Community was obtained after 1 January 1985 may be granted a certificate.

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

22. Article 23 provides that the Regulation is to enter into force six months after publication in the Official Journal. Since that publication took place on 2 July 1992, the Regulation entered into force on 2 January 1993.

The facts and the main proceedings

23. The applicant was the holder of a German patent for which it had applied in 1981 covering (i) ergoline derivatives and their pharmaceutically acceptable additive salts containing organic or inorganic acids and (ii) a compound known by the international non-proprietary name 'Cabergoline' (an ergoline derivative). Although the patent has since expired owing to the passage of time, it was valid when the Regulation came into force.

24. In January 1987, and thus before the deadline of 1 January 1988 referred to in Article 19(1) of the Regulation, the veterinary medicinal product 'Galastop', which contains the active ingredient 'Cabergoline', was authorised in Italy. Within the Community that active ingredient was first authorised as a medicinal product for human beings in the Netherlands in October 1992, and thus after that deadline. In June 1994 the medicinal product 'Dostinex' was first authorised in the Federal Republic of Germany as a medicinal product. The authorisation refers to 'Cabergoline' as the active ingredient of the medicinal product.

25. In December 1994 the applicant applied for a supplementary protection certificate primarily for the active ingredient 'Cabergoline' in the form of the free base or a pharmaceutically acceptable acid additive salt thereof or alternatively for the active ingredient of the medicinal product 'Dostinex' in all forms subject to the protection of the basic patent.

26. The application was rejected by the Deutsches Patent- und Markenamt (German Patent and Trade Mark Office) for both claims. The appeal against that decision was dismissed by the Bundespatentgericht (Federal Patent Court). The applicant further appealed to the Bundesgerichtshof, which considers that the outcome of the proceedings depends on the interpretation of Article 19(1) of the Regulation. It has accordingly referred the following question to the Court for a preliminary ruling:

'Is the grant of a supplementary protection certificate in a Member State of the Community on the basis of a medicinal product for human beings authorised in that Member State precluded by an authorisation to place the same product on the market as a veterinary medicinal product granted in another Member State of the Community before the date specified in Article 19(1) of the Protection Certificate Regulation, or is the sole determining factor the date on which the product was authorised in the Community as a medicinal product for human beings?'

Assessment

27. Written observations have been lodged by the applicant, the United Kingdom Government and the Commission. The applicant considers that where a certificate is sought for a medicinal product for human use, it is the date of the first authorisation to place the product on the market for human use which is alone relevant for the purpose of Article 19(1); the United Kingdom and the Commission submit in contrast that the relevant date is that of the first authorisation to place the product on the market for either human or veterinary use.

28. I agree with the latter interpretation.

29. In support of its view the applicant submits first that the Regulation draws a distinction between medicinal products for human and for veterinary use as is demonstrated by both the definition of 'medicinal product' in Article 1(a) and the references in Articles 2, 3(b), 8(1)(b) and 14(d) to both Directive 65/65 and Directive 81/851. The applicant suggests in particular that it follows from the reference in Article 2 to those two directives that a distinction should be drawn between certificates granted on the basis of an authorisation for medicinal products for human use and those based on an authorisation for veterinary medicinal products and that consequently when a certificate is issued for a product authorised as a human medicinal product any authorisation for veterinary use should be disregarded.

30. Article 2 concerns the scope of the Regulation, Article 3 the conditions for obtaining a certificate, Article 8(1) the content of the application for a certificate and Article 14 expiry of the certificate. The applicant is thus suggesting not only that Article 19(1) draws a distinction for the purpose of the transitional regime which it introduces between the first marketing authorisation in the Community for human use and that for veterinary use, but that the Regulation as a whole draws a general distinction between human and veterinary medical products.

31. Nowhere however either in the preamble or in the substantive text of the Regulation [11] is there any suggestion that the legislation seeks to draw such a distinction.

11 — Or in the Proposal, cited in footnote 6.

32. The wording of the provisions cited by the applicant, moreover, seems to me rather to suggest, as the United Kingdom and the Commission submit, that no general distinction between medicinal products for human and veterinary use is drawn. In particular the definition of 'medicinal product' in Article 1(a) of the Regulation refers without distinction to disease in human beings or animals. Similarly, Articles 2, 3(b), 8(1)(b) and 14(d) do not distinguish between the various procedures for authorising veterinary products on the one hand and medicinal products for humans on the other: those provisions simply refer, in various contexts, to the marketing authorisation procedures 'as laid down in' Directive 65/65 or Directive 81/851 or to the marketing authorisations granted or withdrawn 'in accordance with' those directives.

33. The applicant refers also to Article 4 of the Regulation, submitting that where a certificate is issued on the basis of an authorisation for medicinal products for human use, the protection conferred by that certificate is limited to use of the product as a medicinal product for humans and not to veterinary use.

34. That submission however is in my view based on a misapprehension as to the nature and extent of the protection conferred by a certificate and in particular the effect of and interaction between Articles 4 and 5.

35. As a starting point, the effect of Article 5 is that a certificate covering a given product confers the same rights as the basic patent, namely the patent protecting that product.

36. Article 5, however, is subject to Article 4. That provision specifies that the protection conferred by a certificate extends 'only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate'. Article 4 is expressed as a limitation for the following reason.

37. As indicated above, a given certificate and the basic patent underlying it both protect the same product. Article 1 defines 'product' as 'the active ingredient or combination of active ingredients' of medicinal products for human or veterinary use. In the chemical and pharmaceutical sectors a patent may often be sought and granted for a series of related products: the original patent in the present case, for example, protects both (i) the class of ergoline

derivatives and their pharmaceutically acceptable additive salts containing organic or inorganic acids and (ii) the specific ergoline derivative Cabergoline. Only that latter product in the narrow sense, however, was the subject of a marketing authorisation, first in 1987 for veterinary use and subsequently in 1992 for human use. Article 5 read alone would extend all the protection conferred by the basic patent. Where however, as in the present case, the relevant marketing authorisation covers some only of the products protected by the underlying patent, it would be perverse for the supplementary certificate to be broader. Article 4 therefore has the effect that in such a case the certificate cannot protect products covered by the patent but not by the marketing authorisation.

38. Moreover Article 4 confers protection on a *product*, namely the active ingredient, and not on a *medicinal product*, namely the substance or compound presented for the treatment of humans or animals. The distinction between the two terms is critical to the working of the Regulation. The *product*, as defined, is the subject of patent protection, which the certificate seeks to extend. The *medicinal product*, as defined, is in contrast the subject of the marketing authorisation: it is a substance or combination of substances, including a patent-protected active ingredient or combination thereof, presented for medicinal use. The Regulation operates at the interface between patent protection of products and authorisation to market medicinal products: it seeks to extend the patent protection of products which are constituents of authorised medicinal products. An awareness of that context is essential to a correct understanding of the Regulation.

39. I do not therefore agree with the applicant's view that by virtue of Article 4 the protection conferred by a certificate issued on the basis of an authorisation to market a medicinal product for human use is limited to use of that medicinal product for human purposes alone.

40. There seems thus to be nothing in the tenor of the Regulation to support the view that a distinction should be drawn between the two different types of medicinal product in granting a certificate. [12]

41. The applicant next refers to the objectives of the Regulation. In particular the applicant submits that the purpose of the

12 — See also paragraphs 30 and 31 of the Opinion of Advocate General Fennelly in Case C-181/95 *Biogen* [1997] ECR I-357.

transitional rule in Article 19 demonstrates clearly that in applying that rule a distinction must be drawn between medicinal products for human and for veterinary use. The legislature justified the limitation imposed by Article 19 on the retroactive application of the Regulation by invoking the need to reduce the costs for health systems attributable to medicinal products by enabling generic products to enter the market. The goal of limiting health system costs however is relevant to human and not veterinary medicinal products. The applicant concludes that in cases such as the present the first authorisation for human use is alone to be taken into account for the purpose of Article 19.

42. In my view the preamble to the Regulation, and in particular the second and third recitals taken in their context, stress the importance of compensating research into medicinal products by providing a sufficient period of patent protection. It seems clear from that wording that the principal intention of the Regulation as a whole was to compensate the investment that culminates in a patent. [13] That aim does not require that a distinction be drawn depending on whether the medicinal product was first authorised for human or for veterinary use. It is moreover striking that — as mentioned above — at no point does the preamble itself draw a distinction between the two.

43. Admittedly the 10th recital in the preamble, which concerns the transitional arrangements enacted by Article 19, refers to the need not to compromise the achievement of national health policy objectives. The principal objectives referred to in the 10th recital, however, are striking a fair balance, by implication between all the interests at stake, including public health [14] but also the interests of the pharmaceutical sector, and enabling the Community pharmaceutical industry to catch up to some extent with its main competitors. Thus although public health costs are one factor in the overall equation, the aim of enabling the pharmaceutical industry to recoup investment costs remains paramount. In any event it seems to me that 'health policies' encompass more than merely limiting public health costs; as recent events have demonstrated, animal health frequently has serious implications for human health. Finally, the applicant's argument would, if carried to its logical conclusion, mean that one element of the transitional arrangements (the limit on the retroactive application of the Regulation) could not apply to veterinary medicinal products at all, a proposition which finds no support in the Regulation. The fact that

13 — See also *Biogen*, cited in note 12, paragraph 26 of the judgment, Case C-110/95 *Yamanouchi Pharmaceutical* [1997] ECR I-3251, paragraph 7, and Case C-392/97 *Farmitalia* [1999] ECR I-5553, paragraph 19.

14 — See the ninth recital.

the objectives of the transitional regime established by Article 19 include respect for health policies is not therefore to my mind inconsistent with linking the grant of a certificate to the date of the first marketing authorisation in the Community independently of whether for human or veterinary use.

44. More generally with regard to its objectives, the Regulation seeks to provide a uniform solution at Community level to the problem of insufficient patent protection, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market. [15] It achieves that aim by ensuring that patent protection, in the case of products covered by a certificate, will terminate at the same point in time in all the Member States where the certificate was granted, even if the application for the basic patent was lodged in different years. That follows from Article 13, and in particular from the mechanism by which the duration of the certificate depends on the date of a unique event — namely the first authorisation to place a medicinal product containing the product on the market in the Community. [16] That uniformity, which I have previously described as probably the most significant result of the certificate introduced by the Regulation, [17] would be undermined if, with regard to a given patent-protected product, there could be two certificates each supplementing the same patent but expiring at different times depending on whether the medicinal product of which the patented product was an active ingredient was authorised for human or veterinary use. [18]

45. It is clear moreover that the Regulation is designed to ensure that the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community. [19] The intention there expressed of imposing a maximum period of protection also to my mind shows that the 'first authorisation to place [the product] on the market' for the purpose of Article 19(1) must mean the first authorisation of either kind. That is because the protection which the Regulation seeks to supplement is the

15 — Sixth recital in the preamble.

16 — For an explanation of how Article 13 operates in practice, see paragraph 44 of my Opinion in Case C-350/92 *Spain* v *Council* [1995] ECR I-1985.

17 — Ibid.

18 — See by analogy *Yamanouchi Pharmaceutical*, cited in note 13, paragraph 25 of the judgment; see also paragraph 26 of the Opinion of Advocate General Fennelly.

19 — Eighth recital in the preamble.

patent protection of the product, or active ingredient;[20] the 'exclusivity' is that conferred by the patent and supplemented by the certificate. The principal aim of the Regulation is to extend the period of exclusivity conferred by the patent so as to compensate for the proportion of that period which was commercially fruitless in the absence of an authorisation to market medicinal products containing the patent-protected product. The commercial returns start to flow from the first marketing of such medicinal products, whatever their destination.

46. With specific reference to the present case, an interpretation of Article 19(1) under which the 'first authorisation to place [the product] on the market' for the purpose of that provision referred to the first authorisation whether for human or veterinary use would mean that in the present case the applicant would enjoy 15 years' exclusivity: the certificate granted pursuant to Article 19 (1) would, pursuant to Article 13, take effect in 2001 ('at the end of the lawful term of the basic patent') for one year ('for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged [1981] and the date of the first authorisation to place the product on the market in the Community [1987] reduced by a period of five years'). Protection would thus expire in 2002.

47. The applicant's interpretation of the Regulation, however, would in the present case give the applicant 19 years' exclusivity: the certificate would take effect in 2001 ('at the end of the lawful term of the basic patent') for five years, the maximum permitted pursuant to Article 13(2), since the calculation provided in Article 13(1) would otherwise lead to six years ('for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged [1981] and the date of the first authorisation to place the product on the market in the Community [1992] reduced by a period of five years'). Protection would thus expire in 2006. The applicant's interpretation would accordingly lead to a result which conflicts with an explicit aspiration of the Regulation.[21]

48. Finally the applicant invokes the scheme of the Regulation and in particular the effect of Articles 3(c) and (d).

49. In my view however the scheme of the Regulation also supports the view that the system of supplementary protection certificates which it establishes does not distinguish between medicinal products for, on the

20 — See paragraphs 35 to 38 above.

21 — See the same reasoning in relation to the same product in the decision taken in the United Kingdom Patent Office by Mr L. Lewis in *Farmitalia Carlo Erba Srl's SPC Application* [1996] RPC 111.

one hand, human use and, on the other hand, veterinary use, whether generally or for the specific purpose of Article 19.

50. In particular, the interpretation which I am suggesting appears consistent with Article 3(c) and (d). Article 3(c) includes as a condition for obtaining a certificate that the product has not already been the subject of a certificate and thus precludes the grant of more than one certificate for a product in a Member State even if it has been authorised as a medicinal product more than once. Article 3(d) includes a further condition that the marketing authorisation covering the product in respect of which a certificate is sought is the first authorisation to place that product on the market as a medicinal product and thus precludes the grant of a certificate on the basis of a second marketing authorisation even if an application for a certificate has not been made on the basis of the first marketing authorisation. Those provisions highlight the significance for the system put in place by the Regulation of the notion of one certificate per product without distinction depending on the number of authorisations. [22] Although the authorisation referred to in Article 3(b) and (d) is the first authorisation in the Member State in which the application for the certificate is made whereas that at issue in Article 19 and the question referred is the first Community authorisation, to my mind the principle underlying Article 3 equally suggests that no distinction should be drawn for the purpose of Article 19 depending on whether the relevant authorisation was for human or veterinary use.

51. The answer to the question referred by the Bundesgerichtshof should therefore in my view be that the grant of a supplementary protection certificate in a Member State of the Community on the basis of a medicinal product for human beings authorised in that Member State is precluded by an authorisation to place the same product on the market as a veterinary medicinal product granted in another Member State of the Community before the date specified in Article 19(1) of the Regulation.

52. It may however be more helpful for the ruling to be expressed in more general terms, namely to the effect that where the Regulation refers to the first authorisation to place a product on the market in the Community, that reference is to the first such authorisation whether under the Community code relating to veterinary medicinal products [23] or the Community code relating to medicinal products for human use. [24]

22 — See also paragraph 26 of the Opinion of Advocate General Fennelly in *Yamanouchi Pharmaceutical*, cited in note 13.

23 — Directive 2001/82, formerly Directive 81/851 on the approximation of the laws of the Member States relating to veterinary products, both cited in footnote 3.

24 — Directive 2001/83, formerly Directive 65/65 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, both cited in footnote 4.

Conclusion

53. I accordingly conclude that the Court should give the following ruling in response to the question referred for a preliminary ruling by the Bundesgerichtshof:

References in Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products to the first authorisation to place a product on the market in the Community are to the first authorisation to place that product on the market whether as a veterinary medicinal product or as a medicinal product for human use.