OPINION OF ADVOCATE GENERAL JACOBS

delivered on 30 November 2000 [1]

1. After ruling on a number of occasions on the validity and interpretation of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, [2] the Court of Justice is in this case asked for the first time to interpret the provisions of Council Regulation (EC) No 1610/96 of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (hereinafter 'the Regulation'). [3]

2. The need for interpretation arises in a situation in which a producer has obtained, at a 20-year interval, marketing authorisations in the Netherlands for two different versions of a herbicide which it manufactures. Both versions contain the same active ingredient but, as a result of an improved manufacturing process for which the producer holds a specific patent, the second of the two contains a greater proportion of that ingredient and a lesser proportion of impurities. The producer now seeks a supplementary protection certificate (hereinafter 'SPC') in respect of the second version of the herbicide, but the competent Netherlands authority considers that to be impossible on the basis that the currently valid marketing authorisation is not the first to have been granted in respect of the product.

3. The issue turns, therefore, on the interpretation of the meaning of the term 'product' in the relevant provisions of the Regulation.

The relevant legal provisions

4. The development of new plant protection products such as pesticides, fungicides, herbicides and plant growth regulators requires considerable research and investment. In order to encourage such research, and to protect the interests of those who invest therein, national laws and the

1 — Original language: English.

2 — OJ 1992 L 182, p. 1. See Case C-350/92 *Spain* v *Council* [1995] ECR I-1985, Case C-110/95 *Yamanouchi Pharmaceutical* v *Comptroller-General of Patents, Designs and Trade Marks* [1997] ECR I-3251, Case C-181/95 *Biogen* v *Smithkline Beecham Biologicals* [1997] ECR I-357, Case C-392/97 *Farmitalia Carlo Erba* v *Patentamt* [1999] ECR I-5553.

3 — OJ 1996 L 198, p. 30.

European Patent Convention [4] have for many years provided for patenting of plant protection products (product patents), the manufacturing processes used to produce those products (process patents), and their distinct uses (product-application patents). The period of validity of such patents is generally 20 years from the day the patent application was submitted. [5]

5. The sale of plant protection products is subject to a requirement of marketing authorisation. Directive 91/414 [6] lays down procedural rules for the grant of such authorisations. The procedure for obtaining marketing authorisation is strict. The applicant is normally required to prepare and carry out a number of tests and analyses, and it may therefore take a number of years to complete the procedure. [7] As a result of that delay, the period in which a patent holder enjoys effective patent protection is shortened considerably, and the opportunity to recover the investment made in research is reduced accordingly. [8]

6. The Regulation is designed to compensate the holder of a 'basic patent', or his successor in title, [9] partially for the delay inherent in the authorisation procedure. [10] Thus, under Article 2:

'Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure as laid down in Article 4 of Directive 91/414/EEC, or pursuant to an equivalent provision of national law if it is a plant protection product in respect of which the application for authorisation was lodged before Directive 91/414/EEC was implemented by the Member State concerned, may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.'

7. The Regulation provides an additional period of protection which takes effect at

4 — The European Patent Convention, done at Munich on 5 October 1973.

5 — See, for example, Article 63(1) of the European Patent Convention, cited in note 4.

6 — Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJ 1991 L 230, p. 1.

7 — The period which elapses between the submission of a patent application and the grant of marketing authorisation for a plant protection product is, on average, more than ten years. See J.-C. Galloux, 'Le certificat complémentaire de protection pour les produits phytopharmaceutiques', *La Semaine Juridique, Edition entreprise*, no 49 (1996), p. 499.

8 — According to figures cited in the Commission's explanatory memorandum annexed to the proposal for the SPC regulation, the duration of effective patent protection had fallen from an average of 12 years in 1978 to just over 9 years in 1992. See COM(94) 579 final, paragraph 15.

9 — See Article 6 of the Regulation.

10 — See the third and seventh recitals in the preamble to the SPC regulation and the discussion below at paragraphs 46 to 56.

the end of the lawful term of the basic patent. Under Article 13(1) of the Regulation, the duration of the supplementary protection certificate is equal to 'the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by five years'. Article 13(2) provides that the duration of the SPC cannot in any event exceed five years.

8. Article 4 of the Regulation describes the subject-matter of the protection conferred by the SPC as follows:

'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 authorisations to place the corresponding plant protection product on the market and for any use of the product as a plant protection product that has been authorised before the expiry of the certificate.'

9. The legal effects of the SPC are set out in Article 5 of the Regulation. During the period covered by the SPC, the holder enjoys the same rights and is subject to the same limitations and obligations as under the basic patent. Thus, although the SPC is described by the Commission as a new and distinct form of intellectual property right, rather than simply an extension of the period of protection of existing patents, [11] it is very closely connected with the national systems under which patent rights are initially granted and protected. [12]

10. The authority to issue SPCs lies with the competent industrial property offices of the Member States. Those offices act in accordance with the procedural and substantive conditions laid down in Articles 3, 6, 7, 8 and 9 of the Regulation. [13]

11. The present case is concerned with the substantive conditions for the award of SPCs. Those conditions are set out in Article 3(1) of the Regulation:

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

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

11 — Explanatory memorandum annexed to the proposal for the SPC regulation, COM(94) 579 final, paragraph 24.

12 — See the Opinion of Advocate General Fennelly in Case C-392/97 *Farmitalia Carlo Erba* v *Patentamt*, cited in note 2, paragraph 21.

13 — On the equivalent procedural provisions of Regulation No 1768/92, see Case C-181/95 *Biogen* v *Smithkline Beecham Biologicals*, cited in note 2.

(b) a valid authorisation to place the product on the market as a plant protection product has been granted in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national law;

(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 plant protection product.'

12. Article 3 of the Regulation must be read in the light of the definitions set out in Article 1:

'1. "plant protection products": active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:

...

(d) destroy undesirable plants;

...

2. "substances": chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;

3. "active substances": substances or micro-organisms including viruses, having general or specific action:

(a) against harmful organisms; or

(b) on plants, parts of plants or plant products;

4. "preparations": mixtures or solutions composed of two or more substances,

of which at least one is an active substance, intended for use as plant protection products;

...

8. "product": the active substance as defined in point 3 or combination of active substances of a plant protection product;

9. "basic patent": a patent which protects a product as defined in point 8 as such, a preparation as defined in point 4, 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;

...'

The facts and questions referred

13. The facts, as set out in the order for reference and the documents annexed thereto, may be summarised as follows.

14. The applicant in the main proceedings, BASF AG, is the producer of a number of plant protection products. The present proceedings concern two herbicides in which the active substance is a chemical compound known as 'chloridazon'. [14]

15. Chloridazon is a compound which appears in different isomeric forms. That is, while all chloridazon consists of molecules with the same chemical formula, $C_{10}H_8ClN_3O$, the physical structure of those molecules varies. There are two isomers in the chloridazon produced by the applicant: 4-amino-5-chloro-1-phenyl-pyridazon-6 ('isomer 1') and 5-amino-4-chloro-1-phenyl-pyridazon-6 ('isomer 2'). Those isomers have different chemical properties. While isomer 1 is an active substance, isomer 2 has little or no effect as a plant protection product. Isomer 2 may therefore be regarded as an impurity which occurs as an unavoidable result of the production of isomer 1.

16. The applicant has sold herbicides based on chloridazon in the Netherlands, and in other Member States, for several years, and

14 — Chloridazon is also known as 'pyrazon'. See C. Tomlin et al., *Pesticide Manual*, 10th edition, British Crop Protection Council, 1999, p. 179.

it has been granted a number of different marketing authorisations for that purpose. Only two of those authorisations are relevant here. First, the applicant obtained, on 27 February 1967, a marketing authorisation in the Netherlands for a product known as 'Pyramin' (Authorisation 3594 N). According to the order for reference, Pyramin contains a maximum of 80% of the active isomer 1 and a minimum of 20% of the inactive isomer 2 of chloridazon. According to the applicant, Pyramin contains on average 65% of isomer 1 and 35% of isomer 2. Second, on 19 January 1987, the applicant obtained a marketing authorisation in the Netherlands for the product 'Pyramin DF' (Authorisation 9582 N). Pyramin DF contains, according to the order for reference, a minimum of 90% of the active isomer 1 and a maximum of 10% of the inactive isomer 2. According to the applicant, Pyramin DF contains in practice more than 95% of isomer 1.[15] Owing to the higher concentration of the active substance in Pyramin DF, that product is more effective as a plant protection product than Pyramin.

17. The higher concentration of the active substance in Pyramin DF was the result of a new process for the preparation of chloridazon which had been developed by the applicant. On 23 June 1982, the applicant was granted a European patent (EP 0 026 847) in respect of that process valid for 10 designated countries, including the Netherlands. The applicant had previously, on 28 December 1961, been granted a (German) product patent in respect of chloridazon. That product patent expired before the Regulation entered into force on 8 February 1997.

18. On 3 March 1997, BASF AG applied to the defendant — the Bureau voor de Industriële Eigendom (Industrial Property Office) — for an SPC for the product chloridazon, pointing out that chloridazon had been approved for marketing as a plant protection product by Authorisation 9582 N of 19 January 1987 and that BASF AG was the proprietor of a valid patent covering the process of production of chloridazon (EP 0 026 847).

19. The defendant refused that application in a decision of 26 September 1997 on the grounds that the conditions set out in Article 3(1)(d) of the Regulation had not been fulfilled. Its decision was based on the following reasoning. The phrase 'product' in Article 3(1) of the Regulation must, in accordance with Article 1(2), 1(3) and 1(8), be understood as a reference to the active substance in the plant protection product. Since the active substance in the plant protection products which were granted marketing authorisations on 19 January 1987 (Authorisation 9582 N) and on 27 February 1967 (Authorisation 3594 N) is isomer 1 of chloridazon, the two plant protection products are identical 'products' for the purposes of Article 3(1) of the Regulation. The fact that the authorisation

15 — The applicant also explained in its written submissions and at the hearing that Pyramin DF contains *other* (inactive) impurities than isomer 2. That information is however not confirmed by the order for reference, and I will therefore proceed on the assumption that the chloridazon produced by the applicant contains no other chemical compounds than isomer 1 and isomer 2 of chloridazon.

granted in 1987 related to a plant protection product with a different, and better, ratio of active substance and impurities is irrelevant in this regard. The authorisation granted on 19 January 1987 cannot, therefore, be considered to be the first marketing authorisation within the meaning of Article 3(1)(d).

20. The applicant appealed against that decision in a letter dated 7 November 1997. Having heard the applicant's oral submissions, the defendant rejected the applicant's objections by a decision of 19 February 1998. The applicant challenged the latter decision in the Arrondissementsrechtbank 's-Gravenhage (District Court, The Hague), claiming that the defendant's refusal to grant it an SPC was based on an incorrect interpretation of the Regulation. According to the applicant, the more concentrated chloridazon, which is manufactured according to the procedure described in the patent from 1982 and sold under the name Pyramin DF, is a different 'product' from the less concentrated chloridazon previously produced and sold under the name Pyramin. The marketing authorisation which was granted in 1987 should therefore be considered to be the first marketing authorisation within the meaning of Article 3(1)(d) of the Regulation.

21. The applicant advanced three main arguments in support of that claim. First, the reference to 'product' in Article 3(1) must be understood as a reference to the active substance (or substances) and impurities taken as a whole. There is therefore a different product whenever the ratio between active substance and impurities changes. Second, the applicant points out that it was required, under Netherlands law, to obtain a separate marketing authorisation for the more concentrated chloridazon (sold as Pyramin DF). That shows, of itself, that a new product is involved. Third, the applicant maintains that process patents would be inadequately protected, and the purpose of the Regulation undermined, if SPCs could be granted only in respect of products which contained a different or new active substance.

22. Having regard to the arguments of the parties, the Arrondissementsrechtbank 's-Gravenhage has sought a preliminary ruling on the following questions:

'I.a. In the light of the definitions laid down in Article 1.2, 1.3 and 1.8 of Regulation (EC) No 1610/96 ("the regulation"), must "product" within the meaning of Article 3 of the regulation be understood as meaning an active substance or the combination of active substances, as described in more detail in Article 1.3, as they occur naturally or by manufacture, *including any impurity inevitably resulting from the manufacturing process*?

b. Are identical products involved, for the purposes of the regulation, in the case where, by means of a new process, a plant protection product is obtained which contains a lower amount of unavoidable impurities than an existing plant protection product with the same active component?

c. Does the issue of whether a new authorisation must be obtained for this new plant protection product have any bearing on the answer to Question I.b. and, if so, how much of a bearing does it have?

II. Are the conditions laid down in Article 3(1)(a) and (d) of the regulation satisfied if a plant protection product has been produced by means of a patented process, as a result of which it contains a lower amount of unavoidable impurities than an existing plant protection product with the same active substance, a new authorisation has been obtained for that new plant protection product, and the patent covering the manufacturing process in question was designated as the basic patent within the meaning of Article 3(1), opening passage and subparagraph (a)?'

Observations

23. Written observations have been presented by BASF AG, the Bureau voor de Industriële Eigendom, the German, Netherlands, and United Kingdom Governments, and the Commission. At the hearing BASF AG, the Netherlands and United Kingdom Governments and the Commission were present.

24. The Commission and the Netherlands and United Kingdom Governments support the interpretation of the Regulation favoured by the defendant in the main proceedings. The German Government argues, essentially, that the interpretation favoured by BASF AG is correct.

Analysis

25. By its questions the referring court seeks to ascertain, essentially, whether two plant protection products, containing the same active substance and the same impurity, must be considered as different 'products' for the purpose of Article 3(1) of the Regulation where the only difference between them is that one contains a higher percentage of the active substance than the other because it is produced according to a new method described in a process patent held by the producer.

26. The answer to that question must, in my opinion, take into account the following preliminary observations.

27. First, the rules contained in the Regulation are practically identical to those of Regulation No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products.[16] It follows that the case-law of the Court of Justice on the interpretation of the term 'product' in Regulation No 1768/92 may provide guidance for the present case,[17] and conversely that the Court's ruling in the present case may affect the interpretation of Regulation No 1768/92 and thus the market in medicinal products.

28. Second, the concept of a 'product' is central both to the conditions for grant of SPCs and to the determination of the scope of the legal protection they confer upon the holders.[18] That concept is defined in Article 1(8) and must, as the defendant stresses, be given a uniform interpretation throughout the Regulation.[19]

29. Third, the definition of 'basic patent' in Article 1(9) of the Regulation includes patents which protect 'a process to obtain a product'. Process patent holders may therefore in principle benefit from the SPC regime in the same way as product patent holders. The question in the present proceedings is what specific conditions must, under Article 3 of the Regulation, be fulfilled for process patents to be eligible for that benefit.

30. Finally, the facts of this case must be distinguished from the situation which occurs where the producer of a plant protection product, consisting of two different *active* isomers of the same compound,[20] adopts a new method of manufacture which changes the ratio between those two isomers. In such a case there would, as the Commission and the defendant contend, appear to be a new 'product' for the purposes of Article 3(1) of the Regulation, because the active substances of the product as defined in Article 1(3) would have changed.

31. With these comments in mind, I will answer the referring court's questions by examining the definition of 'product' in Article 1 of the Regulation, the purpose of the Regulation, and the relationship between the Regulation and the marketing authorisation regime.

16 — Cited in note 2. See the 4th and 17th recitals in the preamble to the SPC regulation.

17 — See, in particular, Case C-392/97 *Farmitalia Carlo Erba* v *Patentamt*, cited in note 2.

18 — See Article 4 of the Regulation, cited in paragraph 8.

19 — See similarly the Opinion of Advocate General Fennelly in Case C-392/97 *Farmitalia Carlo Eba* v *Patentamt*, paragraph 23.

20 — See, for example, the description of 'cyhalothrin' and 'lambda-cyhalothrin' in C. Tomlin et al., *Pesticide Manual*, cited in note 14, pp. 252 to 255.

The definition of 'product' in Article 1 of the Regulation

32. Article 1(8) of the Regulation defines the 'product' as

'the active substance as defined in point 3 or combination of active substances of a plant protection product'.

In Article 1(3), 'active substances' are defined as

'substances... having general or specific action:

...

(b) on plants, parts of plants or plant products'.

'Substances' are defined, in Article 1(2), as

'chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process'.

33. BASF AG argues that the definition of 'substances' in Article 1(2) should be read into the definition of 'active substances' in Article 1(3) and thus into the definition of 'product' in Article 1(8). In so far as Article 1(2) defines substances as chemical compounds *including* impurities resulting from the manufacturing process, the 'product' must be understood as the active substance and impurity in the plant protection product taken as a whole. Two plant protection products containing different levels of the same impurity are, therefore, different products for the purposes of the Regulation.

34. I agree with that argument, but only in part.

35. It is in my view clear from a systematic reading of Article 1 that the notion of 'active substances' mentioned in Article 1(8) — and defined in 1(3) — must be interpreted in the light of the definition of 'substances' set out in Article 1(2). It is furthermore clear that 'substances' must be

interpreted so as to mean the same thing in Article 1(2) and 1(3). The Community legislature cannot have intended to confer a different meaning on the same term in different parts of the same article of the Regulation.

36. I consider, therefore, that the 'product' is to be understood as the active substance including any impurity inevitably resulting from the manufacturing process.

37. The defendant and the United Kingdom Government contest that interpretation. They argue, essentially, that Article 1(8) clearly states that the product is the active substance as defined in Article 1(3), and that the phrase 'active substance' has a natural meaning which excludes impurities. It is therefore irrelevant that the definition of 'substances' in Article 1(2) includes impurities. The defendant also points out that the 14th recital in the preamble states, in so far as is relevant, that 'the issue of a certificate for a *product consisting of an active substance* does not prejudice the issue of other certificates for derivatives'. [21]

38. I find that argument unconvincing.

39. Article 1(4) of the Regulation defines 'preparations' as 'mixtures or solutions composed of two or more substances, of which at least one is an active substance'. That wording indicates that a distinction must be drawn between impurities and non-active substances (which may themselves contain impurities). While impurities occur inevitably as a result of the production of an active substance, non-active substances are substances which are added by the producer in order to dilute or otherwise prepare the active substance for sale to the final consumer. The meaning of the phrase 'active substances' must be interpreted in the light of that distinction. It follows that while the word 'active' in Article 1(3) and 1(8) excludes non-active substances from the notion of 'product', it does not exclude impurities.

40. I am thus unshaken in my view that the 'product' within the meaning of Article 1(8) is the active component including any impurity inevitably resulting from the production process.

41. However, as the Commission rightly points out — and contrary to BASF AG's assertions — it does not follow that plant protection products containing different levels of impurity constitute different 'products' for the purposes of the Regulation.

42. First, BASF AG stresses that Article 1(2) describes substances as chemical

21 — Emphasis added.

components *including* any impurity inevitably resulting from the manufacturing process. In my view, the word 'including' is not decisive. It is more natural to stress the word 'any', in which case Article 1(2) would seem to mean that substances are chemical compounds, including any impurity, *whatever that impurity might be.* That argument applies to all the language versions of the Regulation. For example, in the French version of the Regulation substances include 'toute impureté résultant inévitablement du procédé de fabrication'; in the German version substances include 'einschliesslich jeglicher bei der Herstellung nicht zu vermiedenden Verunreinigung'. Thus, while it is true that 'substances' include impurities resulting from the production process, it does not follow from that premiss that two substances containing different levels of impurity constitute different substances under Article 1(2).

43. Secondly, the explanatory memorandum annexed by the Commission to its proposal for the Regulation provides guidance as to the interpretation of the concept of 'product'. In the comments on Article 3 of the Regulation, which was adopted by the Community legislature without any changes to the wording proposed by the Commission, it is stated: 'It is frequently the case that one and the same product is successively granted several authorisations to place the product on the market, in particular every time a modification is made affecting dose, composition or use, and every time a new use for the product is developed. In such a case, only the first authorisation to place the product on the market in the Member State in which the application is lodged is taken into account for the purposes of the Regulation ...'.[22] It follows that 'if the same active substance is used in different forms (powder, liquid, etc.), only one certificate can be issued... The certificate protects the active substance which is contained in the different forms or presentations of the product ...'[23] and that 'although one and the same substance may be the subject of several patents and several authorisations ..., the supplementary protection certificate will be granted for that substance only on the basis of a single patent and a single authorisation ..., namely the first granted in the State concerned'.[24]

44. Thirdly, the Regulation is, as explained above, intimately linked with the national and European patent rules.[25] The terms of the Regulation must therefore be interpreted in accordance with those rules. According to the Commission's written and oral submissions, there is not — in the field of chemical product patents — a new and patentable 'product' whenever the level of impurity changes. It may also be noted that the Commission stated, in the proposal for Regulation No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products,[26] that 'the term "product" is not understood to mean a proprietary medicinal product or a medicinal product in the

22 — COM(94) 579 final, paragraph 68.
23 — COM(94) 579 final, paragraph 46.
24 — COM(94) 579 final, paragraph 68.
25 — See paragraph 9.
26 — Cited in note 2.

wider sense, but in the narrower sense of product used in patent law which, when applied to the chemical and pharmaceutical field, means the active ingredient'. [27] That statement is relevant for the present case because the Regulation and Regulation No 1768/92 contain virtually identical provisions which should be given a similar interpretation. [28]

45. I consider for those reasons that, on the interpretation of the term 'product', the Commission's interpretation of the Regulation is correct. The product is the active substance including any impurity inevitably resulting from the manufacturing process. Two plant protection products containing the same active substance in different concentrations are however identical products for the purposes of the Regulation.

The purpose of the Regulation

46. BASF AG and the German Government claim that that interpretation of Article 1(8) is contrary to the purpose of the Regulation. Their argument may be summarised as follows.

47. A producer will normally be required, under Directive 91/414 or under provisions of national law, to apply for a new marketing authorisation where the concentration of active substance in a plant protection product changes due to a new patented production process. The authorisation procedure limits the effective period of enjoyment of the process patent in the same way as it limits that period for product patents. In contrast to product patents, however, process patents typically concern processes for the preparation of known active substances which have already been authorised for marketing as plant protection products. It follows that if the 'product' is defined as the active substance including impurities — the level of impurities being immaterial — holders of existing process patents will very rarely be able to benefit from the SPC system because the first marketing authorisation requirement in Article 3(1)(d) of the Regulation will not be fulfilled. That outcome is, according to BASF AG and the German Government, contrary to the wording of Article 1(9) of the Regulation and to the purpose of the Regulation.

48. That argument should, in my view, not be accepted.

49. It is true that process patents are covered by the definition of a 'basic patent' in Article 1(9) of the Regulation and that

27 — COM(90) 101 final, paragraph 28.

28 — See the 3rd and 17th recitals in the preamble to the SPC regulation.

process patent holders may therefore benefit from the SPC regime. However, in order to benefit from that regime, the substantive conditions laid down in Article 3 of the Regulation must be fulfilled. The fact that those conditions — combined with the definition of 'product' in Article 1(8) — may in practice exclude many process patents from the SPC regime is not contrary to the wording of Article 1(9). For, as the Commission points out, process patent holders may still be granted SPCs in cases where the relevant active substance has not been the subject of a previous marketing authorisation. That might happen in a situation in which the proprietor of a product patent decided not to go through the costly process of applying for a marketing authorisation because the relevant product could not be produced and sold with a profit on the basis of the production process known at the time.

50. As regards the purpose of the Regulation, the preamble contains the following statements in the third to seventh recitals:

'(3) Whereas plant protection products, especially those that are the result of long, costly research, will continue to be developed in the Community and in Europe if they are covered by favourable rules that provide for sufficient protection to encourage such research;

(4) Whereas the competitiveness of the plant protection sector, by the very nature of the industry, requires a level of protection for innovation which is equivalent to that granted to medicinal products by Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products;

(5) Whereas, at the moment, the period that elapses between the filing of an application for a patent for a new plant protection product and authorisation to place the said plant protection product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research and to generate the resources needed to maintain a high level of research;

(6) Whereas this situation leads to a lack of protection which penalises plant protection research and the competitiveness of the sector;

(7) Whereas one of the main objectives of the supplementary protection certificate is to place European industry on the same competitive footing as its

North American and Japanese counterparts.'

51. Those recitals must be read in conjunction with the 12th recital which acknowledges that 'all the interests in a sector as complex and sensitive as plant protection must be taken into account' and the Commission's explanatory memorandum which states that the Regulation 'aims to strike a fair balance between what is needed to achieve the [its] objectives and what can reasonably be accepted by society'. [29]

52. It is clear from all of those statements that while the main purpose of the Regulation is to extend patent protection in the field of plant protection products and to prevent distortions of competition resulting from disparate national patent laws, that purpose must be balanced against a number of competing political, social, and economic interests.

53. It may be noted in this context that the holder of a valid patent has a monopoly on the sale of the goods covered by that patent. While the existence of such a monopoly may increase the holder's chances of recovering what has been spent on research and development, it may also inhibit the free movement of goods and increase the price of plant protection products to the detriment of the farmers who use those products and the consumers of agricultural products. [30] The rules concerning the scope, the duration, and the substantive conditions for grant of SPCs represent a delicate balance between those conflicting interests.

54. One of the key elements of that balance is the rule in Article 13(2) which limits the duration of SPCs to five years, and the first authorisation rule in Article 3(1)(d) which aims to prevent attempts at bypassing that five-year limitation. [31] The effectiveness of the five-year rule would, as the Commission and the United Kingdom Government emphasise, be undermined if the same active substance could — in different forms, presentations, or concentrations — be the subject of more than one SPC. [32]

55. I consider, therefore, that the broad definition of 'product' advocated by BASF

29 — COM(94) 579 final, paragraph 52.

30 — For estimates of the effect on prices, see COM(94) 579 final, paragraphs 50 to 54.

31 — See COM(94) 579 final, paragraph 68: 'it would not be acceptable, in view of the balance required between the interests concerned, for this total duration of protection [of five years] to be exceeded'.

32 — See similarly the Opinion of Advocate General Fennelly in Case C-181/95 *Biogen* v *Smithkline Beecham Biologicals*, cited in note 2, paragraph 31.

AG and the German Government would upset the balance on which the Regulation is founded and extend patent protection beyond what was intended by the Community legislator.

56. That view is furthermore supported by the fact that the Commission calculated, in its explanatory memorandum, how many products would qualify for an SPC.[33] It found that 37 products on the European market satisfied the relevant conditions. That number would presumably have been higher if the Commission had taken the view that the Regulation applied to a product which, owing to a new production process, contains a higher concentration of an active substance which has previously been granted marketing authorisation as a plant protection product. It appears that the number of valid process patents relating to existing plant protection products is considerable, and that most patented processes result in changes in the level and nature of impurities.

57. Accordingly I conclude, having regard to the wording and purpose of the Regulation, first, that the 'product' within the meaning of Articles 1 and 3 must be understood as the active substance including any impurity inevitably resulting from the manufacturing process and, secondly, that two plant protection products containing different proportions of active substance and impurity are identical products for the purposes of the Regulation.

The relationship between the Regulation and the marketing authorisation rules

58. In its question I.c, the referring court asks in substance whether the fact that a new marketing authorisation must under Netherlands law be obtained for a plant protection product which is, owing to a new production process, more concentrated than an existing product has any bearing on the interpretation of the term 'product' in the Regulation.

59. The answer to that question follows from what has been said above. The fact that a more concentrated version of a plant protection product requires marketing authorisation does not, in itself, mean that there is a new 'product' within the context of the Regulation. It may be added that the conditions for grant of SPCs cannot depend on requirements of national law. That would jeopardise the uniform interpretation of the Regulation and thus be contrary to the objective — set out in the ninth recital in the preamble to the Regulation — of creating 'a uniform solution at Community level'.

33 — COM(94) 579 final, paragraphs 46 and 51 to 54.

Conclusion

60. In the light of all the foregoing observations, I am of the opinion that the Court of Justice should answer the questions referred by the Arrondissementsrechtbank 's-Gravenhage as follows:

I.a. The term 'product' in Article 3 of Council Regulation (EC) No 1610/96 concerning the creation of a supplementary protection certificate for plant protection products must be understood as the active substance or combination of active substances as they occur naturally or by manufacture. Impurities which occur as the inevitable consequence of the manufacturing process form part of the product.

I.b. Where, by means of a new process, a plant protection product is obtained which contains a smaller proportion of unavoidable impurities than an existing plant protection product with the same active component, the two products are one and the same for the purposes of the Regulation.

I.c. The issue of whether a new authorisation must be obtained for a new plant protection product has no bearing on the answer to Question I.b.

II. The conditions laid down in Article 3(1)(a) and (d) of the regulation are not satisfied if a plant protection product has been produced by means of a

patented process as a result of which it contains a smaller proportion of unavoidable impurities than an existing plant protection product with the same active substance, a new authorisation has been obtained for that new plant protection product, and the patent covering the manufacturing process in question was designated as the basic patent within the meaning of Article 3(1)(a).