

JUDGMENT OF THE COURT (Sixth Chamber)
10 May 2001 *

In Case C-258/99,

REFERENCE to the Court under Article 234 EC by the Arrondissementsrechtbank 's-Gravenhage, Netherlands, for a preliminary ruling in the proceedings pending before that court between

BASF AG

and

Bureau voor de Industriële Eigendom (BIE),

on the interpretation of Articles 1 and 3 of 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 (OJ 1996 L 198, p. 30),

* Language of the case: Dutch.

THE COURT (Sixth Chamber),

composed of: C. Gulmann (Rapporteur), President of the Chamber, V. Skouris,
J.-P. Puissechot, R. Schintgen and F. Macken, Judges,

Advocate General: F.G. Jacobs,

Registrar: D. Louberman-Hubeau, Head of Division,

after considering the written observations submitted on behalf of:

- BASF AG, by P. Kuipers and W. VerLoren van Themaat, Advocaten,
- Bureau voor de Industriële Eigendom (BIE), by C. Eskes and R.A. Grootoink, acting as Agents,
- the German Government, by W.-D. Plessing and A. Dittrich, acting as Agents,
- the United Kingdom Government, by R. Magrill, acting as Agent, and D. Alexander, Barrister,
- the Commission of the European Communities, by K. Banks and H.M.H. Speyart, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of BASF AG, represented by P. Kuipers and W. VerLoren, the Netherlands Government, represented by M.A. Fierstra, acting as Agent, the United Kingdom Government, represented by D. Alexander, and the Commission, represented by H.M.H. Speyart, at the hearing on 12 October 2000,

after hearing the Opinion of the Advocate General at the sitting on 30 November 2000,

gives the following

Judgment

- 1 By order of 2 July 1999, received at the Court on 12 July 1999, the Arrondissementsrechtbank 's-Gravenhage (District Court, The Hague) referred to the Court for a preliminary ruling under Article 234 EC two questions on the interpretation of Articles 1 and 3 of 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 (OJ 1996 L 198, p. 30).
- 2 Those questions were raised in proceedings brought by BASF AG against the refusal of the Bureau voor de Industriële Eigendom (BIE) (Industrial Property Office, hereinafter 'the Office') to grant it a supplementary protection certificate (SPC) for the product known as 'chloridazon' as a plant protection product.

Community law background

3 It appears from the fifth and sixth recitals in the preamble to Regulation No 1610/96 that, before it was adopted, the length of effective protection conferred by a patent was insufficient to cover the investment put into plant protection research and to generate the resources needed to maintain a high level of research, thus penalising the competitiveness of that sector. The aim of the regulation is precisely to make good that insufficiency by introducing SPCs for plant protection products.

4 Article 1 of Regulation No 1610/96 states:

‘For the purposes of this Regulation, the following definitions shall apply:

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;

...’.

- 5 Article 3 of Regulation No 1610/96, which defines the conditions for obtaining an SPC, reads as follows:

‘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;
- (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.

2. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.'

The main proceedings

- 6 On 27 February 1967 the Netherlands Minister for Agriculture and Fisheries granted BASF marketing authorisation 3594 N for the pesticide 'Pyramin', containing chloridazon as active substance.
- 7 On 23 June 1982 European patent EP 0 026 847, valid for 10 named States including the Netherlands, was granted to BASF for a process for the manufacture of chloridazon.
- 8 On 19 January 1987 the Netherlands Minister for Agriculture and Fisheries granted BASF marketing authorisation 9582 N for the pesticide 'Pyramin DF', containing chloridazon as active substance.
- 9 Chloridazon is a substance made up of two compounds, 4-amino-5-chloro-1-phenyl-pyridazon-6 and 5-amino-4-chloro-1-phenyl-pyridazon-6. The former is active and the latter, which is an isomer of the former, is inactive or scarcely active, and must in fact be regarded as an impurity.

- 10 It is agreed that the proportion of the active compound to the impurity is 80% maximum to 20% minimum in the case of Pyramin and 90% minimum to 10% maximum in the case of Pyramin DF, and that the change in proportion was achieved by the new manufacturing process described in basic patent EP 0 026 847.
- 11 On 3 March 1997 BASF applied to the Office for an SPC for chloridazon as a plant protection product.
- 12 The Office rejected the application by decision of 26 September 1997. BASF's complaint against that decision was declared unfounded by the Office, by decision of 19 February 1998. BASF therefore, on 31 March 1998, brought proceedings in the Arrondissementsrechtbank 's-Gravenhage against the rejection of its complaint.
- 13 The national court notes that the Office refused BASF's application on the ground that the condition laid down in Article 3(1)(d) of Regulation No 1610/96 was not satisfied. According to the Office, marketing authorisation 9582 N, relied on by BASF, cannot be regarded as a first marketing authorisation within the meaning of that provision, as both it and marketing authorisation 3594 N were granted for plant protection products containing chloridazon as sole active substance. Since impurities such as that mentioned in paragraph 9 above do not form part of the concept of a 'product' as defined in Article 1(8) of Regulation No 1610/96, the two marketing authorisations must be regarded as referring to the same product within the meaning of Article 3 of that regulation.
- 14 BASF submits that the more concentrated chloridazon obtained by the process described in patent EP 0 026 847 of 1982 and sold under the name 'Pyramin DF'

is a different product from the chloridazon previously manufactured and sold under the name 'Pyramin'. The marketing authorisation issued in 1987 for Pyramin DF should consequently be regarded as the first marketing authorisation within the meaning of Article 3(1)(d) of Regulation No 1610/96.

- 15 BASF submits in particular that a product within the meaning of Regulation No 1610/96 includes the active substance and the impurities. There is therefore a different product where the proportion of active substance to impurities is substantially altered. Moreover, the fact that a new marketing authorisation was granted for the chloridazon obtained by using the new patent and known as Pyramin DF proves that it constitutes a new product within the meaning of that regulation. Further, BASF submits that if an SPC could only be granted for products which have a different or new active substance, as the Office essentially submits, patents for a process would not be adequately protected and Regulation No 1610/96 would fail to reach its objective. Such patents generally relate not to entirely new products but to existing products whose composition is different as a result of the new processes which have been discovered.

- 16 The Arrondissementsrechtbank 's-Gravenhage considers that it follows from Regulation No 1610/96 that the regulation was enacted with the purpose of ensuring, by means of the SPC, adequate protection of plant protection research, and that for that purpose no distinction is drawn between product patents and process patents. That court observes that, according to the Office's interpretation of the regulation, an SPC will practically never be obtainable for a process patent, since the application of such a patent generally does not make it possible to obtain an entirely new product — containing new active substances — but only to alter the composition of an existing product. In the majority of cases, a marketing authorisation will already have been granted for the existing product, so that the marketing authorisation subsequently granted cannot be relied on as a first marketing authorisation within the meaning of Article 3(1)(d) of Regulation No 1610/96 for the altered product manufactured according to the patented process.

- 17 The national court is uncertain whether this approach is consistent with the aim and purpose of Regulation No 1610/96, and in particular whether the issue of an SPC for a process patent may depend on the more or less fortuitous circumstance that a marketing authorisation has not yet been granted for the existing product whose composition is altered by the process which has been patented.
- 18 In those circumstances, the Arrondissementsrechtbank 's-Gravenhage stayed proceedings and referred the following questions to the Court for a preliminary ruling:
- ‘1. (a) In the light of the definitions laid down in Article 1(2), (3) and (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 1(b) and, if so, how much of a bearing does it have?

2. 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)?'

Question 1

The first part of Question 1

- 19 By the first part of Question 1, the national court is essentially seeking a definition of the concept of a product within the meaning of Article 3 of Regulation No 1610/96.

- 20 It must be noted that, according to Article 1(8) of Regulation No 1610/96, a product means the active substance as defined in Article 1(3) or combination of active substances of a plant protection product.

- 21 Under Article 1(3) of that regulation, active substances are *inter alia* substances having general or specific action against harmful organisms or on plants, parts of plants or plant products.
- 22 Under Article 1(2) of that regulation, substances are defined as chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process.
- 23 It follows from points 2, 3 and 8 of Article 1 of Regulation No 1610/96, taken together, that the concept of a product covers chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process, which have general or specific action against harmful organisms or on plants, parts of plants or plant products.
- 24 Article 3 of Regulation No 1610/96, which lays down the conditions for obtaining an SPC, is based on the concept of a product. There is no indication that that concept differs from that of a product as defined in Article 1 of the regulation for the purposes of that same regulation.
- 25 The answer to the first part of Question 1 must therefore be that the concept of a product within the meaning of Article 3 of Regulation No 1610/96 covers chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing

process, which have general or specific action against harmful organisms or on plants, parts of plants or plant products.

The second part of Question 1

- 26 By the second part of Question 1, the national court is essentially asking whether two products which differ only in the proportion of the active chemical compound to the impurity they contain, one having a greater percentage of the impurity than the other, must be regarded as the same product within the meaning of Article 3 of Regulation No 1610/96.
- 27 It follows from the answer to the first part of Question 1 that two products which are constituted of the same chemical compound having the same general or specific action against harmful organisms or on plants, parts of plants or plant products, and including any impurity inevitably resulting from the manufacturing process, must be regarded as identical.
- 28 It is therefore apparent that a product may be identified by its chemical compound and its action on the targets mentioned in the preceding paragraph, whatever the impurities it contains. *A fortiori*, the nature of a product cannot change solely because of an alteration in the unit quantity of impurities where both the chemical compound it contains and that compound's action on its targets remain unchanged.

- 29 The answer to the second part of Question 1 must therefore be that two products which differ only in the proportion of the active chemical compound to the impurity they contain, one having a greater percentage of the impurity than the other, must be regarded as the same product within the meaning of Article 3 of Regulation No 1610/96.

The third part of Question 1

- 30 By the third part of Question 1, the national court asks whether the fact that a marketing authorisation must be obtained for the new plant protection product which has a different proportion of active chemical compound to impurity from that of the former plant protection product is relevant for the purposes of establishing whether or not the constituent products of those plant protection products are the same.
- 31 As follows from the foregoing, the marketing authorisation is not among the criteria used by Regulation No 1610/96 for defining the concept of a product.
- 32 The answer to the third part of Question 1 must therefore be that the fact that a marketing authorisation must be obtained for the new plant protection product which has a different proportion of active chemical compound to impurity from that of the former plant protection product is not relevant for the purposes of

establishing whether or not the constituent products of those plant protection products are the same.

Question 2

- 33 By this question the national court is essentially asking whether the conditions laid down in Article 3(1)(a) and (d) of Regulation No 1610/96 are satisfied where a product, as a plant protection product, manufactured according to a patented process and the subject of a marketing authorisation, differs from a previously authorised product, as a plant protection product, only in the proportion of the active chemical compound to the impurity it contains, the percentage of impurity being greater in the older product than in the new one, and where that process patent has been designated as the basic patent.
- 34 It must be recalled that, as found in paragraph 29 above, where two products differ only in the proportion of the active chemical compound to the impurity they contain, one having a higher proportion of impurity than the other, they must be regarded as the same product within the meaning of Article 3 of Regulation No 1610/96.
- 35 Consequently, where a product, as a plant protection product, manufactured according to a patented process and the subject of a marketing authorisation, differs from a previously authorised product, as a plant protection product, only in the proportion of the active chemical compound to the impurity it contains, the percentage of impurity being greater in the older product than in the new one, it must follow that those two plant protection products contain the same product within the meaning of Article 3 of Regulation No 1610/96.

- 36 The marketing authorisation for that product, as a plant protection product, manufactured according to a patented process, cannot be regarded as the first marketing authorisation granted for that product, since the product was already the subject of an earlier authorisation as a plant protection product.
- 37 It follows that, with respect to the product, as a plant protection product, manufactured according to a patented process, the condition in Article 3(1)(d) of Regulation No 1610/96 is not satisfied.
- 38 Consequently, without it being necessary to take a position on whether the condition in Article 3(1)(a) of Regulation No 1610/96 is satisfied, the answer to Question 2 must be that the conditions laid down in Article 3(1)(a) and (d) of Regulation No 1610/96 are, in any event, not all satisfied where a product, as a plant protection product, manufactured according to a patented process and the subject of a marketing authorisation, differs from a previously authorised product, as a plant protection product, only in the proportion of the active chemical compound to the impurity it contains, the percentage of impurity being greater in the older product than in the new one, and where that process patent has been designated as the basic patent.

Costs

- 39 The costs incurred by the Netherlands, German and United Kingdom Governments and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Sixth Chamber),

in answer to the questions referred to it by the Arrondissementsrechtbank 's-Gravenhage by order of 2 July 1999, hereby rules:

1. The concept of a product within the meaning of Article 3 of 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 covers chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process, which have general or specific action against harmful organisms or on plants, parts of plants or plant products.
2. Two products which differ only in the proportion of the active chemical compound to the impurity they contain, one having a greater percentage of the impurity than the other, must be regarded as the same product within the meaning of Article 3 of Regulation No 1610/96.

3. The fact that a marketing authorisation must be obtained for the new plant protection product which has a different proportion of active chemical compound to impurity from that of the former plant protection product is not relevant for the purposes of establishing whether or not the constituent products of those plant protection products are the same.
4. The conditions laid down in Article 3(1)(a) and (d) of Regulation No 1610/96 are, in any event, not all satisfied where a product, as a plant protection product, manufactured according to a patented process and the subject of a marketing authorisation, differs from a previously authorised product, as a plant protection product, only in the proportion of the active chemical compound to the impurity it contains, the percentage of impurity being greater in the older product than in the new one, and where that process patent has been designated as the basic patent.

Gulmann

Skouris

Puissochet

Schintgen

Macken

Delivered in open court in Luxembourg on 10 May 2001.

R. Grass

C. Gulmann

Registrar

President of the Sixth Chamber