JUDGMENT OF THE COURT (Second Chamber)

11 November 2010 *

In Case C-229/09,

REFERENCE for a preliminary ruling under Article 234 EC from the Bundespatentgericht (Germany), made by decision of 28 April 2009, received at the Court on 24 June 2009, in the proceedings

Hogan Lovells International LLP, formerly Rechtsanwaltssozietät Lovells,

v

Bayer CropScience AG,

THE COURT (Second Chamber),

composed of J.N. Cunha Rodrigues, President of the Chamber, A. Arabadjiev, A. Rosas, A. Ó Caoimh and P. Lindh (Rapporteur), Judges,

* Language of the case: German.

Advocate General: V. Trstenjak,
Registrar: K. Malacek, Administrator,

having regard to the written procedure and further to the hearing on 22 April 2010,

after considering the observations submitted on behalf of:

— Hogan Lovells International LLP, formerly Rechtsanwaltssozietät Lovells, by K. Pörnbacher and S. Steininger, Rechtsanwälte,

— Bayer CropScience AG, by D. von Renesse, Patentanwältin,

— the Italian Government, by G. Palmieri, acting as Agent, assisted by M. Russo, avvocato dello Stato,

— the European Commission, by H. Krämer, acting as Agent,

after hearing the Opinion of the Advocate General at the sitting on 17 June 2010,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 3(1) 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 The reference has been made in the course of proceedings between Hogan Lovells International LLP, formerly Rechtsanwaltssozietät Lovells, ('Lovells') and Bayer CropScience AG ('Bayer') concerning the validity of a supplementary protection certificate granted to the latter by the Bundespatentgericht (German Federal Patent Court).

Legal context

Directive 91/414/EEC

3 The 9th and 14th recitals in the preamble to 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), as amended by Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 (OJ 2005 L 70, p. 1), ('Directive 91/414') are worded as follows:

'… the provisions governing authorisation must ensure a high standard of protection, which, in particular, must prevent the authorisation of plant protection products whose risks to health, groundwater and the environment and human and animal health should take priority over the objective of improving plant production;

…

… the Community procedure should not prevent Member States from authorising for use in their territory for a limited period plant protection products containing an active substance not yet entered on the Community list, provided that the interested party has submitted a dossier meeting Community requirements and the Member

State has concluded that the active substance and the plant protection products can be expected to satisfy the Community conditions set in regard to them.'

4 According to Article 3(1) of Directive 91/414, a plant protection product may not be placed on the market and used in the territory of a Member State unless the competent authorities of that Member State have authorised the product in accordance with that directive.

5 Article 4 of Directive 91/414 provides:

'1. Member States shall ensure that a plant protection product is not authorised unless:

(a) its active substances are listed in Annex I and any conditions laid down therein are fulfilled, and, with regard to the following points (b), (c), (d) and (e), pursuant to the uniform principles provided for in Annex VI, unless:

(b) it is established, in the light of current scientific and technical knowledge and shown from appraisal of the dossier provided for in Annex III, that when used in accordance with Article 3(3), and having regard to all normal conditions under which it may be used, and to the consequences of its use:

(i) it is sufficiently effective;

(ii) it has no unacceptable effect on plants or plant products;

(iii) it does not cause unnecessary suffering and pain to vertebrates to be controlled;

(iv) it has no harmful effect on human or animal health, directly or indirectly (e.g. through drinking water, food or feed) or on groundwater;

(v) it has no unacceptable influence on the environment, having particular regard to the following considerations:

— its fate and distribution in the environment, particularly contamination of water including drinking water and groundwater,

— its impact on non-target species;

(c) the nature and quantity of its active substances and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants can be determined by appropriate methods, harmonised according to the procedure provided in Article 21, or, if not, agreed by the authorities responsible for the authorisation;

(d) its residues, resulting from authorised uses, and which are of toxicological or environmental significance, can be determined by appropriate methods in general use;

(e) its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product;

(f) where appropriate, the MRLs [maximum residue levels] for the agricultural products affected by the use referred to in the authorisation have been set or modified in accordance with Regulation (EC) No 396/2005.

2. The authorisation must stipulate the requirements relating to the placing on the market and use of the product or at least those aimed at ensuring compliance with the provisions of paragraph 1(b).

3. Member States shall ensure that compliance with the requirements set out in paragraph 1(b) to (f) is established by official or officially recognised tests and analyses carried out under agricultural, plant health and environmental conditions relevant to use of the plant protection product in question and representative of those prevailing

where the product is intended to be used, within the territory of the Member State concerned.

4. Without prejudice to paragraphs 5 and 6, authorisations shall be granted for a fixed period of up to 10 years only, determined by the Member States; they may be renewed after verification that the conditions imposed in paragraph 1 are still satisfied. Renewal may be granted for the period necessary to the competent authorities of the Member States for such verification, where an application for renewal has been made.

5. Authorisations may be reviewed at any time if there are indications that any of the requirements referred to in paragraph 1 are no longer satisfied. In such instances the Member States may require the applicant for authorisation or party to whom an extension of the field of application was granted in accordance with Article 9 to submit further information necessary for the review. The authorisation may, where necessary, be extended for the period necessary to complete a review and provide such further information.

6. Without prejudice to decisions already taken pursuant to Article 10, an authorisation shall be cancelled if it is established that:

(a) the requirements for obtaining the authorisation are not or are no longer satisfied;

(b) false or misleading particulars were supplied concerning the facts on the basis of which the authorisation was granted;

or modified if it is established that:

(c) on the basis of developments in scientific and technical knowledge the manner of use and amounts used can be modified.

It may also be cancelled or modified at the request of the holder of the authorisation, who shall state the reasons therefor; amendments can be granted only if it is established that the requirements of Article 4(1) continue to be satisfied.

Where a Member State withdraws an authorisation, it shall immediately inform the holder of the authorisation; moreover, it may grant a period of grace for the disposal, storage, placing on the market and use of existing stocks, of a length in accordance with the reason for the withdrawal, without prejudice to any period provided for by decision taken under Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances, as last amended by Directive 90/335/EEC, or Article 6(1) or Article 8(1) or (2) of this Directive.'

6 Article 5 of Directive 91/414 provides:

‘1. In the light of current scientific and technical knowledge, an active substance shall be included in Annex I for an initial period not exceeding 10 years, if it may be expected that plant protection products containing the active substance will fulfil the following conditions:

(a) their residues, consequent on application consistent with good plant protection practice, do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, and the said residues, in so far as they are of toxicological or environmental significance, can be measured by methods in general use;

(b) their use, consequent on application consistent with good plant protection practice, does not have any harmful effects on human or animal health or any unacceptable influence on the environment as provided for in Article 4(1)(b)(iv) and (v).

2. For inclusion of an active substance in Annex I, the following shall be taken into particular account:

(a) where relevant, an acceptable daily intake (ADI) for man;

(b) an acceptable operator exposure level, if necessary;

(c) where relevant, an estimate of its fate and distribution in the environment as well as its impact on non-target species.

3. For the first inclusion of an active substance which was not yet on the market two years after notification of this Directive, the requirements shall be deemed to be satisfied where this has been established for at least one preparation containing the said active substance.

4. Inclusion of an active substance in Annex I may be subject to requirements such as:

— the minimum degree of purity of the active substance,

— the nature and maximum content of certain impurities,

— restrictions arising from evaluation of the information referred to in Article 6, taking account of the agricultural, plant-health and environmental (including climatic) conditions in question,

— type of preparation,

— manner of use.

5. On request, the inclusion of a substance in Annex I may be renewed once or more for periods not exceeding 10 years; such inclusion may be reviewed at any time if there are indications that the criteria referred to in paragraphs 1 and 2 are no longer satisfied. Renewal shall be granted for the period necessary to complete a review, where an application has been made for such renewal in sufficient time, and in any case not less than two years before the entry is due to lapse, and shall be granted for the period necessary to provide information requested in accordance with Article 6(4).'

7 Article 8(1) of Directive 91/414, concerning transitional measures and derogations, is worded as follows:

'By way of derogation from Article 4, a Member State may, to enable a gradual assessment to be made of the properties of new active substances and to make it easier for new preparations to be made available for use in agriculture, authorise, for a provisional period not exceeding three years, the placing on the market of plant protection products containing an active substance not listed in Annex I and not yet available on the market two years after notification of this Directive, provided that:

(a) following application of Article 6(2) and (3) it is found that the dossier on the active substance satisfies the requirements of Annexes II and III in relation to the projected uses;

(b) the Member State establishes that the active substance can satisfy the requirements of Article 5(1) and that the plant protection product may be expected to satisfy the requirements of Article 4(1)(b) to (f).

n such cases the Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorisation, giving at least the information provided for in Article 12(1).

Following the evaluation of the dossier as provided for in Article 6(3), it may be decided, in accordance with the procedure laid down in Article 19, that the active substance does not satisfy the requirements specified in Article 5(1). In such cases the Member States shall ensure that the authorisations must be withdrawn.

By way of derogation from Article 6, if, on expiry of the three-year period, a decision has not been taken concerning the inclusion of an active substance in Annex I, a further period may be ordered by the procedure referred to in Article 19 to enable a full examination to be made of the dossier and, where appropriate, of any additional information requested in accordance with Article 6(3) and (4).

The provisions of Article 4(2), (3), (5) and (6) shall apply to authorisations granted under the terms of this paragraph without prejudice to the foregoing subparagraphs.'

Regulation No 1610/96

8 It is apparent from recitals 5 and 6 in the preamble to Regulation No 1610/96 that, before it was adopted, the duration of the effective protection under a patent was

considered insufficient to cover the investment put into plant protection research and to generate the resources needed to maintain a high level of research, thereby penalising the competitiveness of the sector. Regulation No 1610/96 is designed to overcome that insufficiency by establishing a supplementary protection certificate for plant protection products.

9 Recitals 11 and 16 in the preamble to Regulation No 1610/96 are worded as follows:

'(11) … the duration of the protection granted by the certificate should be such as to provide adequate, effective protection; … for this purpose, 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 plant protection product in question first obtains authorisation to be placed on the market in the Community;

…

(16) … only action at Community level will enable the objective, which consists in ensuring adequate protection for innovation in the field of plant protection, while guaranteeing the proper functioning of the internal market for plant protection products, to be attained effectively'.

10 Article 1 of Regulation No 1610/96 provides that, for the purposes of that regulation, 'certificate' means the supplementary protection certificate.

11 Article 2 of Regulation No 1610/96, entitled 'Scope', provides:

'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.'

12 Article 3 of Regulation No 1610/96, entitled 'Conditions for obtaining a certificate', provides:

'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.

…'

13 Article 5 of Regulation No 1610/96, entitled 'Effects of the certificate', provides:

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

14 Article 13 of Regulation No 1610/96, entitled 'Duration of the certificate', is drafted in the following terms:

'1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years.

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

3. For the purposes of calculating the duration of the certificate, account shall be taken of a provisional first marketing authorisation only if it is directly followed by a definitive authorisation concerning the same product.'

15 According to Article 15 of Regulation No 1610/96:

'1. The certificate shall be invalid if:

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

…

2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent.'

The dispute in the main proceedings and the question referred for a preliminary ruling

16 Bayer is the owner of a European patent covering, inter alia, a herbicide known as iodosulfuron. The application for this patent was filed on 12 February 1992 and the patent was issued on 11 November 1998. It expires on 13 February 2012.

17 On 13 December 1998, an application to have iodosulfuron included in Annex I to Directive 91/414 was lodged with the German authorities by an undertaking the rights of which were subsequently acquired by Bayer.

18 On 9 March 2000, the competent German authority issued a marketing authorisation ('MA') to Bayer for a herbicide based on that substance and marketed under the name 'Husar'. According to the information provided by the national court, this MA was issued on the basis of a provision of national law designed to transpose Article 8(1) of Directive 91/414 (a 'provisional MA'). In order to take account of Commission Decision 2003/370/EC of 21 May 2003 allowing Member States to extend provisional authorisations granted for the new active substances iodosulfuron-methyl-sodium, indoxacarb, S-metolachlor, *Spodoptera exigua* nuclear polyhedrosis virus, tepraloxydim and dimethenamid-P (OJ 2003 L 127, p. 58), the expiry date of that provisional MA, initially fixed at 8 March 2003, was put back to 21 May 2005.

19 On 17 July 2003, the Bundespatentgericht granted Bayer a supplementary protection certificate for iodosulfuron and some of its salts and esters for the period between 13 February 2012, the date on which the European patent expires, and 9 March 2015. In calculating the duration of the certificate, the Bundespatentgericht took the view that the provisional MA of 9 March 2000 was the first MA.

20 On 25 September 2003, the Commission included iodosulfuron in Annex I to Directive 91/414 by means of Commission Directive 2003/84/EC (OJ 2003 L 247, p. 20).

21 On 13 January 2005, the competent German authority issued a MA to Bayer for Husar on the basis of the national provisions transposing Article 4 of Directive 91/414 (a 'definitive MA'). The expiry of that definitive MA is fixed at 31 December 2015.

22 Lovells brought an action before the Bundespatentgericht for annulment of the supplementary protection certificate of 17 July 2003. Lovells argues, essentially, that that certificate is invalid in the light of Regulation No 1610/96. Article 3(1)(b) of that regulation provides for the issue of a supplementary protection certificate only after a definitive MA has been issued under the conditions laid down in Article 4 of Directive 91/414. In the present case, however, the MA of 9 March 2000 is a provisional MA coming under Article 8(1) of that directive.

23 Bayer challenges that interpretation of Article 3(1)(b) of Regulation No 1610/96, which it considers to be contrary to the general scheme of that regulation and to the practice of the competent national authorities.

24 In those circumstances, the Bundespatentgericht decided to stay proceedings and to refer the following question to the Court for a preliminary ruling:

'For the purpose of the application of Article 3(1)(b) of Regulation No 1610/96, must account be taken exclusively of [a MA] under Article 4 of Directive 91/414 … or can a certificate also be issued pursuant to [a MA] which has been granted on the basis of Article 8(1) of Directive 91/414 …?'

The application to have the oral procedure reopened

25 By letter of 14 July 2010, Bayer applied to have the oral procedure reopened, arguing, essentially, that the position adopted by the Advocate General in her Opinion is erroneous. In support of its application, Bayer invokes the adversarial principle inasmuch as the Opinion deals at length with the interpretation of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1), even though that point had not even been raised during the oral procedure.

26 Under the second paragraph of Article 252 TFEU, it is the duty of the Advocate General, acting with complete impartiality and independence, to make, in open court, reasoned submissions on cases which, in accordance with the Statute of the Court of Justice of the European Union, require the Advocate General's involvement. In carrying out that task, the Advocate General may, where appropriate, analyse a refer-

ence for a preliminary ruling by placing it within a context which is broader than that strictly defined by the referring court or by the parties to the main proceedings. The Court is not bound either by the conclusion reached by the Advocate General or by the reasoning which led to that conclusion.

27 Having regard to the very purpose of the adversarial procedure, which is to avoid a situation in which the Court may be influenced by arguments which have not been discussed by the parties, the Court may of its own motion, or on a proposal from the Advocate General, or at the request of the parties, order the reopening of the oral procedure in accordance with Article 61 of its Rules of Procedure if it considers that it lacks sufficient information, or that the case must be dealt with on the basis of an argument which has not been debated between the parties (see, inter alia, order in Case C-17/98 *Emesa Sugar* [2000] ECR I-665, paragraph 18; and Case C-42/07 *Liga Portuguesa de Futebol Profissional and Bwin International* [2009] ECR I-7633, paragraph 31 and the case-law cited).

28 In the present case, the Court considers that it has sufficient information to give a ruling and, as the case does not need to be decided on the basis of arguments which were not debated between the parties, there is no need to grant the application to have the oral procedure reopened.

29 Consequently, the application to have the oral procedure reopened must be rejected.

The question referred for a preliminary ruling

30 By its question, the national court is asking, essentially, whether Article 3(1)(b) of Regulation No 1610/96 must be interpreted as precluding the issue of a supplementary protection certificate for a plant protection product in respect of which a provisional MA has been issued under Article 8(1) of Directive 91/414.

31 Article 3(1)(b) of Regulation No 1610/96 refers to a MA granted 'in accordance with Article 4 of Directive 91/414'. That wording could lead to the *a contrario* conclusion that a supplementary protection certificate cannot be issued in respect of products which have been granted a provisional MA on the legal basis of Article 8(1) of that directive, since that possibility has not been expressly provided for.

32 It must be observed that Article 3 of Regulation No 1610/96 is to be interpreted not solely on the basis of its wording, but also in the light of the overall scheme and objectives of the system of which it is a part (see, to that effect, Case C-482/07 *AHP Manufacturing* [2009] ECR I-7295, paragraph 27).

33 In order to interpret Article 3(1)(b) of Regulation No 1610/96, according to which a plant protection product must have been granted a MA 'in accordance with Article 4 of Directive 91/414', reference must be made, more particularly, to the provisions of that directive which govern the conditions under which a MA may be granted for plant protection products.

34 Those provisions are based on a distinction between, on the one hand, the authorisation of an active substance, which is issued at the level of the European Union, and, on the other, authorisations of products containing active substances, which come within the competence of the Member States, as can be seen, in particular, from Articles 3 to 6 and 8 of Directive 91/414.

35 According to Article 3(1) of Directive 91/414, a plant protection product may not be placed on the market and used in a Member State unless the competent authorities of that Member State have authorised the product in accordance with that directive. Article 4(1)(a) of the directive provides that a Member State may not authorise a plant protection product unless its active substances have been approved at European Union level and are listed in Annex I to the directive. The conditions for inclusion of such substances in the abovementioned annex are laid down in Article 5 of Directive 91/414 and must be the subject of a dossier satisfying the requirements of Annex II thereto.

36 The scientific criteria which a plant protection product must fulfil in order to obtain a MA are set out in Article 4(1)(b) to (f) of Directive 91/414 and the requirements for the dossier to be submitted in order to obtain an authorisation are set out in Annex III to that directive.

37 However, Article 8 of Directive 91/414, entitled 'Transitional measures and derogations', permits the Member States to grant, in three situations, a provisional MA for a plant protection product containing active substances which have not yet been listed in Annex I to that directive. Of those three situations, only that provided for in Article 8(1) is material for the purpose of replying to the national court's question in the present case.

38 That provision concerns the placing on the market of a plant protection product containing an active substance not yet listed in Annex I to Directive 91/414 and not yet available on the market two years after notification of the directive (a 'new active substance'). The reasons for that provision are set out in the 14th recital in the preamble to Directive 91/414, which states that 'the Community procedure should not prevent Member States from authorising for use in their territory for a limited period plant protection products containing an active substance not yet entered on the Community list, provided that the interested party has submitted a dossier meeting Community requirements and the Member State has concluded that the active substance and the plant protection products can be expected to satisfy the Community conditions set in regard to them'.

39 The first subparagraph of Article 8(1) of Directive 91/414 sets out the requirements which must be satisfied in order to obtain a provisional MA, to be granted for a period not exceeding, in principle, three years, for a plant protection product which contains a new active substance.

40 With regard to the assessment of that new active substance, Article 8(1), first subparagraph, point (a), of Directive 91/414 requires, first, that it be 'found that the dossier on the active substance satisfies the requirements of Annexes II and III in relation to the projected uses'. In addition, Article 8(1), first subparagraph, point (b), requires the Member State to establish that the active substance can satisfy the requirements of Article 5(1) of the directive and also that 'the plant protection product may be expected to satisfy the requirements of Article 4(1)(b) to (f)'.

41 Under those latter provisions, the Member State concerned is required to establish, in the light of current scientific and technical knowledge, that the product is effective and safe. That Member State is thus required to establish that there are no unaccep-

table or harmful effects on plants, on human or animal health, on groundwater or on the environment. In addition, that Member State must establish that the product does not cause unnecessary suffering and pain to vertebrates to be controlled.

42 That Member State must also establish:

— whether the nature and quantity of the product's active substances and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants can be determined by appropriate methods which are harmonised or, if not, agreed by the competent national authorities;

— whether its residues, resulting from authorised uses, and which are of toxicological or environmental significance, can be determined by appropriate methods in general use;

— whether its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product; and

— whether, where appropriate, the maximum residue levels for the agricultural products affected by the use referred to in the authorisation have been respected.

43 It must be added that, as is expressly provided in the latter part of Article 8(1) thereof, the provisions of Article 4(2), (3), (5) and (6) of Directive 91/414 also apply to provisional MAs. That reference thus makes it possible to ensure that provisional MAs granted by Member States for products containing new substances meet the same scientific requirements as to reliability, and may be reviewed or cancelled under the same conditions, as definitive MAs granted on the basis of Article 4.

44 Applications for provisional MAs submitted under Article 8(1) of Directive 91/414 must therefore be examined in accordance with the scientific criteria applicable to definitive MAs governed by Article 4 of that directive. The conditions under which a Member State may, pursuant to Article 8(1) of Directive 91/414, authorise the placing on the market, on a provisional basis, of a plant protection product containing a new substance which is still being assessed with a view to its inclusion in Annex I to Directive 91/414 are those set out in Article 4(1)(b) to (f) of that directive (see, to that effect, Case C-306/98 *Monsanto* [2001] ECR I-3279, paragraphs 30 and 32).

45 It is, admittedly, true that the assessment made by a Member State when considering an application for a provisional MA is, by its nature, prospective and necessarily implies a greater margin of uncertainty than in an assessment made with a view to granting a definitive MA. However, the intention of Article 8(1) of Directive 91/414 is that the conditions under which a provisional MA may be granted in respect of a product should be the same as those for the grant of a definitive MA, in accordance with the objective referred to in the ninth recital in the preamble to Directive 91/414 of ensuring 'a high standard of protection, which, in particular, must prevent the authorisation of plant protection products whose risks to health, groundwater and the environment and human and animal health should take priority over the objective of improving plant production'.

46 By reason of that link of functional equivalence which exists between the criteria set out in Article 8(1) of Directive 91/414 and those laid down in Article 4 of that directive, there is thus no need to interpret Article 3(1)(b) of Regulation No 1610/96 in a manner which would have the effect of excluding from the application of that provision products which have been granted a provisional MA under Article 8(1) of Directive 91/414.

47 That interpretation is, moreover, corroborated by the terms and the purpose of Regulation No 1610/96.

48 It must be recalled that, as recital 16 in its preamble emphasises, the objective of Regulation No 1610/96 is to ensure adequate protection for innovation in the field of plant protection, while guaranteeing the proper functioning of the internal market for plant protection products. According to recital 11 in the preamble to that regulation, the supplementary protection certificate should be such as to provide adequate, effective protection of the patent, permitting the patent holder to enjoy an overall maximum of 15 years of exclusivity from the time at which the plant protection product in question first obtains a MA in the European Union.

49 Regulation No 1610/96 seeks to limit the erosion of the effective protection accorded to patented inventions in the area of plant protection by reason, in particular, of the time required to obtain a MA. Recital 5 in the preamble to that regulation states, in that regard, that the period that elapses between the filing of an application for a patent for a new plant protection product and the MA for that plant protection product 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.

50 The supplementary protection certificate is designed to re-establish a sufficient period of effective protection of the patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of the basic patent which is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention by reason of the time which has elapsed between the date on which the application for the patent was filed and the date on which the first MA in the European Union was granted.

51 The supplementary certificate establishes a link between the basic patent and the first MA granted for the plant protection product, with that MA marking the moment at which commercial exploitation of the product can begin. Thus, the grant of that certificate requires that the four cumulative conditions set out in Article 3(1) of Regulation No 1610/96 be met. That provision provides, essentially, that a supplementary protection certificate may be granted only if, at the date of the application, the plant protection product is protected by a basic patent in force and has not already been the subject of a certificate. In addition, the product must have been granted a valid MA 'in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national law' and, finally, that MA must be the first authorisation of the product as a plant protection product.

52 If Article 3(1) of Regulation No 1610/96 were to be interpreted as meaning that a supplementary protection certificate could be granted only on the basis of a definitive MA, such an interpretation could give rise to difficulties once account is taken of other provisions of that regulation and its preamble. It follows from a combined reading of recital 11 in the preamble and Articles 3(1)(c), 13 and 19 of that regulation that, for the purposes of the grant of a supplementary protection certificate, the relevant MA must be the first MA granted to the product in the European Union as a plant protection product.

53 Furthermore, the interpretation of Article 3(1)(b) of Regulation No 1610/96 as meaning that a supplementary protection certificate can be issued for a product in respect of which a provisional MA has been granted under Article 8(1) of Directive 91/414 is supported by the wording of Article 13 of Regulation No 1610/96.

54 Article 13(1) of Regulation No 1610/96 states that the duration of the certificate is to be '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 [MA] in the Community, reduced by a period of five years'. According to Article 13(3), '[f]or the purposes of calculating the duration of the certificate, account shall be taken of a provisional first [MA] only if it is directly followed by a definitive authorisation concerning the same product' Thus, that provision does not allow the possibility to be excluded that a supplementary protection certificate may be granted for a product which had a provisional MA.

55 In the light of all those considerations, the answer to the question referred is that Article 3(1)(b) of Regulation No 1610/96 must be interpreted as not precluding a supplementary protection certificate from being issued for a plant protection product in respect of which a valid MA has been granted pursuant to Article 8(1) of Directive 91/414.

Costs

56 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. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Second Chamber) hereby rules:

Article 3(1)(b) 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 must be interpreted as not precluding a supplementary protection certificate from being issued for a plant protection product in respect of which a valid marketing authorisation has been granted pursuant to Article 8(1) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, as amended by Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005.

[Signatures]