Court of Justice EU, 11 November 2010, Lovells v Bayer

SUPPLEMENTARY PROTECTION CERTIFICATE –
PLANT PROTECTION PRODUCTS

SPC possible in case of a provisional market authorization for plant protection product

- **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.**

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

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Court of Justice EU, 11 November 2010
(J. N. Cunha Rodrigues, A. Arabadjiev, A. Rosas, A. Ó Caoimh en P. Lindh (rapporteur))
JUDGMENT OF THE COURT (Second Chamber)
11 November 2010 (*)
(Patent law – Plant-protection products – Regulation (EC) No 1610/96 – Directive 91/414/EEC – Supplementary protection certificate for plant protection products – Grant of a certificate for a product which had obtained a provisional marketing authorisation)
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,
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).

In 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 reference 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 sub-

stance 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 unacceptable 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.

* Language of the case: German.

Opinion Advocate General Trstenjak

delivered on 17 June 2010 1(1)
Case C-229/09
Rechtsanwaltssozietät Lovells
v
Bayer CropScience AG
(Reference for a preliminary ruling from the Bundespatentgericht (Germany))

(Regulation EC No 1610/96 – Article 3 – Conditions for the grant of a supplementary protection certificate for plant protection products – Directive 91/414/EEC – Article 4 – Article 8 – Marketing authorisation – Temporal limitation on the effects of the judgment on the reference for a preliminary ruling)

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I – Introduction

. In the present reference for a preliminary ruling under Article 234 EC, (2) the Bundespatentgericht (Federal Patent Court, Germany) ('the referring court') has referred to the Court a question on the interpretation 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. (3) The referring court seeks, in essence, to establish whether a supplementary protection certificate under Article 3 of Regulation No 1610/96 may be applied for and granted following the receipt of a provisional authorisation in accordance with Article 8(1) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (4) or only following the receipt of a definitive authorisation to place that plant protection product on the market in accordance with Article 4 of that directive.

II – Legal framework

A – Community law

1. Directive 91/414

2. In accordance with Article 3(1) of Directive 91/414, Member States must prescribe that plant protection products may not be placed on the market and used in their territory unless they have authorised the product in accordance with that directive, except where the intended use is research and development within the meaning of Article 22.

3. Article 4(1) of Directive 91/414 provides:

'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.'

4. Article 5(1) of Directive 91/414 provides:

'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).'

5. Article 8(1) of Directive 91/414 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).

…'

2. Regulation No 1610/96

6. Article 2 of Regulation No 1610/96 is worded as follows:

'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. Article 3(1) of Regulation No 1610/96 provides:

'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.'

8. In accordance with Article 4 of Regulation No 1610/96, within the limits of the protection conferred by the basic patent, the protection conferred by the certificate extends 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. Under Article 5 the certificate confers, subject to Article 4, the same rights as are conferred by the basic patent and is subject to the same limitations and the same obligations.

9. Article 7 of Regulation No 1610/96 governs applications for supplementary protection certificates in the following terms:

'(1) The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(1)(b) to place the product on the market as a plant protection product was granted.

(2) Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.'

10. Under Article 9(1) of Regulation No 1610/96, the application for a certificate must be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorisation referred to in Article 3(1)(b) to place the product on the market was obtained, unless the Member State designates another authority for that purpose.

11. Article 10 of Regulation No 1610/96 is worded as follows:

'(1) Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9(1) shall grant the certificate.

(2) The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.

…'

12. The duration of the supplementary protection certificate is governed by Article 13 of Regulation No 1610/96 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.'

13. Under Article 15(1)(a) of Regulation No 1610/96, a supplementary protection certificate is deemed invalid if it was granted contrary to the provisions of Article 3. In accordance with Article 15(2) of that regulation, 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.

B – National law

14. Paragraph 15 of the Gesetz zum Schutz der Kulturpflanzen (Law on the protection of cultivated plants) ('PflSchG') (5) governs the authorisation of plant protection products by the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Federal

Office for Consumer Protection and Food Safety) in accordance with the criteria established in Article 4 of Directive 91/414.

15. Paragraph 15c of the PflSchG governs the authorisation of plant protection products for a provisional period by the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit in accordance with the criteria established in Article 8 of Directive 91/414.

III – Facts of the case and question referred

16. The defendant in the main proceedings ('the defendant') is the owner of European patent 0 574 418 (basic patent) granted on 11 November 1998 having validity for, inter alia, the Federal Republic of Germany, for which application was filed at the European Patent Office on 12 February 1992, with the title 'aryl sulphonyl urea compounds, a method of preparing them, and their use as herbicides and growth regulators'. The basic patent covers, inter alia, a chemical compound commonly known as iodosulfuron. Iodosulfuron acts as a herbicidal substance.

17. In 1998, the defendant filed an application with the competent German authorities for the inclusion of the active substance iodosulfuron-methyl-sodium in Annex I to Directive 91/414. On 13 December 1998, the defendant filed, in addition, an application for the provisional authorisation of the plant protection product 'Husar' containing the active substance iodosulfuron in accordance with Paragraph 15c of the PflSchG.

18. By a decision of 31 May 1999, (6) the Commission confirmed that the dossiers submitted in accordance with Article 6(2) of Directive 91/414 were complete and satisfied, in principle, the data and information requirements of Annexes II and III to that directive. Thereupon, by a decision of 9 March 2000, the Biologische Bundesanstalt für Land- und Forstwirtschaft (German Federal Biological Institute for Agriculture and Forestry) granted an authorisation (Authorisation No 4727-00) under Paragraph 15c of the PflSchG for the plant protection product 'Husar' which was valid up to 8 March 2003.

19. By a decision of 21 May 2003, (7) the Commission noted that the examination of the dossiers for the purposes of evaluating the application for the inclusion of the active substance iodosulfuron-methyl-sodium in Annex I to Directive 91/414 was still ongoing. As there were no reasons for immediate concern, the Member States were authorised to prolong provisional authorisations for plant protection products containing iodosulfuron-methyl-sodium for a period of 24 months. Following an application by the defendant, the provisional authorisation granted by decision of 9 March 2000 was extended to 21 May 2005.

20. Inclusion of the active substance iodosulfuron in Annex I to Directive 91/414 was effected by Commission Directive 2003/84/EC of 25 September 2003 amending Council Directive 91/414/EEC to include flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate and silthiofam as active substances. (8)

21. By decision of 13 January 2005, the plant protection product 'Husar' containing the active substance iodosulfuron was authorised under Paragraph 15 of the PflSchG for 10 years up to 31 December 2015.

22. On the basis of the authorisation granted on 9 March 2000 under Paragraph 15c of the PflSchG, constituting also the first authorisation to place the active substance iodosulfuron on the market in the Community as a plant protection product, the defendant had already applied on 8 September 2000 to the Deutsches Patent- und Markenamt (German Patent and Trade Mark Office (DPMA)) for the grant of a supplementary protection certificate for iodosulfuron and the esters and salts thereof, including non-salt form iodosulfuron-methyl. By decision of 5 October 2001, the DPMA rejected in part the defendant's application. Following an appeal by the defendant against that decision, by decision of 17 July 2003 the referring court granted the supplementary protection certificate for plant protection products No 100 75 026 for 'iodosulfuron and its C1 to C12 alykl esters and salts including iodosulfuron-methyl-sodium salt' covering the period from 13 February 2012 to 9 March 2015. The calculation of the certificate's duration took as its basis the authorisation of 9 March 2000 as being the first authorisation for placing the product on the market in the Community.

23. The claimant in the main proceedings ('the claimant') has brought proceedings to have supplementary protection certificate No 100 75 026 set aside as being void. That certificate, it submits, is void under Article 15(1)(a) of Regulation No 1610/96 on the ground that it was granted contrary to Article 3(1)(b) of that regulation. Authorisation No 4727-00 of 9 March 2000 granted under Paragraph 15c of the PflSchG, on which the certificate is based, corresponds to a provisional authorisation for placing the product on the market in accordance with Article 8(1) of Directive 91/414 and, accordingly, does not satisfy the condition set out in Article 3(1)(b) of Regulation No 1610/96.

24. As the referring court has doubts regarding the interpretation of Article 3(1)(b) of Regulation No 1610/96, it has referred to the Court the following question 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 marketing authorisation under Article 4 of Directive 91/414, or can a certificate also be issued pursuant to a marketing authorisation which has been granted on the basis of Article 8(1) of Directive 91/414?

IV – Procedure before the Court

25. The reference for a preliminary ruling dated 28 April 2009 was received at the Registry of the Court on 24 June 2009. In the written procedure, the claimant, the defendant, the Government of the Italian Republic and the Commission submitted observations. At the hearing of 22 April 2010, representatives of the claimant and defendant and the Commission participated.

V – Arguments of the parties

26. According to the claimant and the Commission, the grant of a supplementary protection certificate under Art 3(1)(b) of Regulation No 1610/96 necessarily requires a marketing authorisation granted pursuant to

Article 4 of Directive 91/414. By contrast, the defendant and the Government of the Italian Republic take the view that the reference in Article 3(1)(b) of Regulation No 1610/96 may not be restricted to definitive authorisations in accordance with Article 4 of Directive 91/414 but must be extended to cover provisional authorisations issued under Article 8(1) of that directive.

27. The defendant stresses, first, the considerable economic significance of the question referred. In that context, it emphasises in particular that the DPMA has altered its practice regarding the grant of supplementary protection certificates for plant protection products. As, hitherto, the established practice of the DPMA and most of the bodies in other Member States was to grant those protection certificates on the basis of an authorisation in accordance with Article 8(1) of Directive 91/414, the majority of supplementary protection certificates for plant protection products granted in Germany and other Member States would be rendered void if the Court were to deem that practice to be incompatible with the regulation. The harm to the industry would be immense and irreparable, particularly as in the cases in which authorisations pursuant to Article 4 of Directive 91/414 have in the interim been granted the application period under Article 7 of Regulation No 1610/96 has expired and, as a result, ultimately, no applications could be made for new protection certificates.

28. In the defendant's view, to restrict Article 3(1)(b) of Regulation No 1610/96 exclusively to authorisations in accordance with Article 4 of Directive 91/414 would in practice lead to outcomes – relevant not only to the past but also to the future – which would be at variance with the declared meaning and purpose of the regulation. That follows, inter alia, from the fact that the authorisation procedure in accordance with Article 4 of Directive 91/414 may require such a lengthy period that the basic patent may have expired before an authorisation in accordance with Article 4 of Directive 91/414 has been granted. In that context, for the most part, the applicant is not responsible for the length of time taken by the authorisation process. The owner of an expired basic patent, precisely in the case of such particularly lengthy authorisation processes, would no longer have the possibility to obtain a protection certificate and, more particularly, not through any fault of its own.

29. In the defendant's view, the wording of Article 3(1)(b) of Regulation No 1610/96 can extend to authorisations in accordance with Article 8 of Directive 91/414. Such an interpretation would correspond to the spirit and purpose of Regulation No 1610/96. This, it argues, follows from the fact that, ultimately, authorisations in accordance with Article 4 and authorisations in accordance with Article 8(1) of Directive 91/414 are equivalent. In substantive terms, an authorisation in accordance with Article 8(1) of Directive 91/414 constitutes an authorisation in accordance with Article 4 of that directive.

30. In addition, the defendant stresses that under Article 3(1)(b) of Regulation No 1610/96, for the purposes of issuing a protection certificate, an authorisation granted in accordance with an equivalent provision of national law also suffices. If such a marketing authorisation for a plant protection product granted pursuant to an application for authorisation submitted prior to the transposition of Directive 91/414 suffices of itself for the purposes of granting the protection certificate, then, a fortiori, an application for authorisation in accordance with Article 8(1) of Directive 91/414 submitted after transposition suffices.

31. Finally, the defendant advances an argument also on the basis of Article 13(3) of Regulation No 1610/96. According to that provision, for the purposes of calculating the duration of the certificate, account is to be taken of a provisional first authorisation only if it is directly followed by a definitive authorisation concerning the same product. In the defendant's view, 'provisional authorisations' within the terms of Article 13(3) of Regulation No 1610/96 means both provisional authorisations in accordance with Article 8(1) of Directive 91/414 and 'emergency authorisations' under Article 8(4) of that directive. The rule established in Article 13(3) of Regulation No 1610/96 can be explained by the fact that emergency authorisations under Article 8(4) of Directive 91/414 generally are not directly followed by authorisations pursuant to Article 4 or Article 8(1) of that directive.

32. The Italian Government stresses the fact that the supplementary protection certificate under Regulation No 1610/96 is intended to grant the patent holder effective protection in excess of what the patent itself guarantees. In addition, according to recital 8 in the preamble to Regulation No 1610/96, the grant of such a certificate may be regarded as a positive measure for the protection of the environment. As, in accordance with Article 2 EC, protection of the environment constitutes a primary objective, the requirements for the grant of a protection certificate should not be applied vis-à-vis an applicant in an overly restrictive or disadvantageous manner.

33. The Italian Government emphasises from a schematic perspective that, according to Article 13 of Regulation No 1610/96, for the purposes of calculating the duration of the protective certificate, account is to be taken of a provisional first authorisation in accordance with Article 8(1) of Directive 91/414. Against that background, it would be contrary to the Regulation's scheme if a provisional authorisation could not be invoked as the basis for the grant of a protection certificate. In addition, the protection inherent in the supplementary protection certificate would not be effective if it was not ensured from the date of the first commercial market exploitation but only from the grant of a definitive authorisation at a later date. In the latter case, there would be the risk, too, that the basic patent might have expired during the period of the authorisation process.

34. In the view of the claimant, the clear wording itself of Article 3(1)(b) of Regulation No 1610/96 militates against the grant of a supplementary protection certificate on the basis of a provisional authorisation in accordance with Article 8(1) of Directive 91/414. Such

provisional authorisation, it argues, is not even mentioned in Article 3(1)(b) of Regulation No 1610/96. Moreover, such provisional authorisation cannot be interpreted either as an 'authorisation in accordance with Article 4' or as an 'authorisation in accordance with an equivalent provision of national law'.

35. According to the claimant, from the scheme of Regulation No 1610/96, it follows also that supplementary protection certificates may be granted only on the basis of definitive authorisations in accordance with Article 4 of Directive 91/414. In its view, that interpretation of Article 3(1)(b) of Regulation No 1610/96 is not precluded by the purpose of that regulation. Its primary purpose is to compensate – through the grant of certificates – for the period lost as a result of the lengthy authorisation process, thereby allowing the patent owner to recoup its investment in the research and development of the plant protection product. However, that purpose is not prejudiced by the fact that a patent owner may apply for a certificate only at a later date, that is, only on definitive authorisation. The duration of the certificate is thereby unaffected.

36. In the view of the Commission also, Article 3(1)(b) of Regulation No 1610/96 must be interpreted as meaning that an authorisation for the marketing of a plant protection product in accordance with Article 8(1) of Directive 91/414 may not constitute the basis for the grant of a supplementary protection certificate.

37. In the Commission's view, that interpretation is supported, first, by the wording of Article 3(1)(b) of Regulation No 1610/96. A schematic perspective confirms that interpretation, given the fact that Article 13(3) is the only provision of that regulation which expressly employs the terms 'provisional' and 'definitive' in relation to a marketing authorisation. In that connection, so it argues, account must be taken of a provisional marketing authorisation for the purposes only of calculating the duration of the certificate.

38. In the Commission's view, its interpretation is also more effective than the contrary interpretation in satisfying the demands of legal certainty. It is obvious, it claims, that an interpretation of Article 3(1)(b) of Regulation No 1610/96 which goes beyond the wording of that provision raises consequential problems which, in the interests of legal certainty, ought to be avoided.

39. Finally, according to the Commission, it is also not evident that an interpretation which implies that a protection certificate may be granted only on the basis of a definitive, and not on the basis of a provisional, marketing authorisation within the meaning of Directive 91/414 would interfere with the legitimate interests of the patent owner. The risk – raised in argument in the main proceedings – that the definitive marketing authorisation might be granted only after the expiry of the term of protection of the basic patent is, in its view, simply theoretical. If the application for the marketing authorisation is lodged at a time closely connected to the grant of the basic patent, it is extremely unlikely that such a risk would materialise.

40. At the hearing, in response to questioning, the parties to the main proceedings and the Commission advanced arguments on the question whether, in the event that the Court were to conclude in the present case that supplementary protection certificates may not be granted on the basis of provisional authorisations in accordance with Article 8(1) of Directive 91/414, the temporal effects of the preliminary ruling should be limited to the future.

41. In the defendant's view, a temporal limitation on the effects of such a judgment would establish, in principle, legal certainty in relation to the past. As regards the future, however, the problem of the lengthy authorisation process under Article 4 of Directive 91/414 would remain. On the other hand, the Commission, supported on this point by the claimant, considers that it would be unnecessary to issue such a ruling on an ex nunc basis. In the Commission's view, consideration of the legal consequences of such a judgment in relation to supplementary protection certificates already granted should be reserved for future cases in which applications are made to have such certificates set aside as being void on the basis of Article 15 of Regulation No 1610/96. Having regard to the general principles of legal certainty and protection of legitimate expectations inherent in the legal order of the European Union, it would be a matter for determination in those future cases whether, in relation to infringements of Article 3(1)(b) which arose prior to the handing-down of judgment in the present proceedings, the penalty of invalidity provided for in Article 15 of Regulation No 1610/96 would have to be suspended.

VI – Legal appraisal

42. The main question to be answered in the present proceedings is whether a supplementary protection certificate pursuant to Regulation No 1610/96 may be applied for and granted simply following the receipt of a provisional marketing authorisation for a plant protection product in accordance with Article 8(1) of Directive 91/414 or only following the receipt of a definitive marketing authorisation in accordance with Article 4 of that directive.

43. As the answer to that question results from the interplay of Directive 91/414 and Regulation No 1610/96, first of all, I shall briefly examine the provisions included in that directive and regulation and how they interlink. On the basis of those clarifications, I shall then analyse and answer the question referred. Finally, I shall consider the economic effects of my proposed answer and, in that connection, examine whether the temporal effects of the judgment on the reference for a preliminary ruling ought to be limited.

A – The provisions of Directive 91/414 and Regulation No 1610/96 and how they interlink

1. The authorisation to place plant protection products on the market under Directive 91/414

44. The objective of Directive 91/414 is to harmonise national rules on the grant of authorisations (9) to place plant protection products on the market. That harmonised scheme is intended primarily to ensure a high standard of protection for human and animal health and for the environment. (10) Against that background, au-

thorisation to place plant protection products on the market in accordance with Directive 91/414 must, in principle, be limited to certain plant protection products containing certain active substances specified at European Union level on the basis of their toxicological and ecotoxicological properties. (11)

45. For those purposes, Directive 91/414 provides for the compilation of a European Union list of authorised active substances which plant protection products are permitted to include. That list is attached as Annex I to Directive 91/414 and is updated at regular intervals. The procedure for the inclusion of active substances in Annex I is set out in Articles 5 and 6 of that directive. The inclusion of an active substance in Annex I to Directive 91/414 applies for an initial period not exceeding 10 years; (12) on request, however, it may be renewed once or more for periods not exceeding 10 years. However, that inclusion may be reviewed at any time. (13)

46. In order to ensure that only plant protection products which include the active substances mentioned in Annex I are placed on the market, Article 4(1)(a) of Directive 91/414 provides as a basic rule that a plant protection product may not be authorised in an individual Member State unless its active substances are listed in Annex I and any conditions laid down therein are fulfilled. In addition, the requirements laid down in Article 4(1)(b) to (f) on the effectiveness and safety of the plant protection product concerned must also be satisfied.

47. As the procedure for the inclusion of an active substance in Annex I may take several years, Article 8(1) of Directive 91/414 provides for a derogation under which a Member State may 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 that directive. Such a provisional authorisation presupposes, however, that the applicant has requested the inclusion of the active substance in Annex I and has submitted a dossier in accordance with the requirements of European Union law and that the Member State concerned has established that the active substance and the plant protection product are likely to satisfy the requirements on effectiveness and safety laid down in Article 5(1) and Article 4(1)(b) to (f). If, on expiry of the three-year period, a decision has not been taken on the inclusion of the active substance in Annex I, a further period may be authorised in accordance with the fourth subparagraph of Article 8(1).

48. In addition to that provisional authorisation in anticipation of the inclusion of an active substance in Annex I to Directive 91/414, Article 8(4) provides for the possibility of an emergency authorisation. According to that provision, in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, the active substances of which are not listed in Annex I and which do not satisfy the requirements regarding effectiveness and safety laid down in Article 4(1)(b) to (f), for a limited and controlled use if such a measure appears necessary because of an unforeseeable danger which cannot be contained by other means.

2. Grant of a supplementary protection certificate for plant protection products under Regulation No 1610/96

49. The primary objective of the supplementary protection certificate for plant protection products introduced by Regulation No 1610/96 is to extend the period of patent protection for active substances used in plant protection products.

50. The regular term of patent protection is 20 years, calculated from the date of application for registration of the invention. If an authorisation to place plant protection products on the market in accordance with Directive 91/414 is granted only following the filing of an application to have the patent registered, manufacturers of plant protection products will be unable commercially to exploit their position of exclusivity in relation to the active substances protected under the patent during the period which elapses between the application to have the patent registered and authorisation to place the plant protection product concerned on the market. Since, in the view of the legislature, this makes the period of effective protection under the patent insufficient to cover the investment in research and to generate the resources needed to maintain a high level of research, (14) Regulation No 1610/96 grants those manufacturers the possibility to extend their rights to exclusivity by applying for a supplementary protection certificate to cover a period not exceeding 15 years from the time at which the plant protection product first obtains authorisation to be placed on the market within the European Union. (15)

51. Against that background, the scope of Regulation No 1610/96 is circumscribed in Article 2 on the basis of two principal criteria, that is, (1) the existence of a product protected by a patent, which (2) prior to being placed on the market as a plant protection product was subject to an administrative authorisation procedure in accordance with Article 4 of Directive 91/414. If, in relation to the plant protection product concerned, the application for authorisation was lodged before Directive 91/414 was implemented by the Member State at issue, Regulation No 1610/96, according to Article 2 thereof, applies on condition that the product protected by the patent was subject to a national procedure equivalent to that provided for in Article 4 of Directive 91/414.

52. The principal criteria laid down in Article 2 of Regulation No 1610/96 governing the regulation's scope are repeated in Article 3 as conditions for the grant of a supplementary protection certificate. Under Article 3(1), a protection certificate will be granted if, in the Member State in which the application is submitted, at the date of that application the product is protected by a basic patent in force (subparagraph (a)) and 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 or an

equivalent provision of national law (subparagraph (b)). According to that provision, the grant of a protection certificate is subject to further conditions, namely, that the product has not already been the subject of a certificate (subparagraph (c)) and that the authorisation referred to in subparagraph (b) is the first authorisation to place the product on the market as a plant protection product (subparagraph (d)).

3. The interlinking of Regulation No 1610/96 and Directive 91/414

53. It follows from the above observations that the purpose of Regulation No 1610/96 is to confer on the owner of a patent for a product intended to be used as a plant protection product an additional period for exclusive commercial exploitation of that product. The economic motivation for that preferential treatment for manufacturers of plant protection products with patented active substances is the fact that, although patent protection applies following a successful application to register a patent in relation to an active substance used in plant protection products, such protection cannot be exploited commercially as long as there is no authorisation to place the plant protection product on the market in accordance with Directive 91/414. As the processing of the application for authorisation may take a long time, there is a risk that the period of effective protection under the patent may be reduced to an insufficient duration. The supplementary protection certificate for plant protection products is designed to counteract that risk.

54. Against that background, the scope of Regulation No 1610/96 is defined by reference to the authorisation for placing plant protection products on the market governed by Directive 91/414. If the plant protection product at issue is one for which an application for a marketing authorisation was lodged following the implementation of Directive 91/414 in the Member State concerned, Regulation No 1610/96 applies where an active substance used in that plant protection product is protected by a basic patent and a marketing authorisation for the plant protection product in that Member State has been granted in accordance with Article 4 of Directive 91/414.

B – A supplementary protection certificate for plant protection products may not be granted on the basis of a provisional marketing authorisation within the meaning of Article 8(1) of Directive 91/414

55. By its question, the referring court seeks ultimately to ascertain whether a supplementary protection certificate for plant protection products under Regulation No 1610/96 may be applied for and granted on the basis of a provisional authorisation to place the plant protection product on the market which was issued pursuant to Article 8(1) of Directive 91/414.

56. In my view, that question must be answered in the negative.

57. According to the clear wording of Article 3(1)(b) of Regulation No 1610/96, a supplementary protection certificate may be granted only if, in the Member State in which the application for the certificate is submitted, a valid authorisation to place the product on the market as a plant protection product has, at the date of that application, been granted in accordance with Article 4 of Directive 91/414 or an equivalent provision of national law. It follows from Article 2 of Regulation No 1610/96 that the criterion of an authorisation pursuant to an equivalent provision of national law applies only to cases in which the application for the marketing authorisation was lodged before Directive 91/414 was implemented in the Member State concerned.

58. Therefore, according to its wording, Article 3(1)(b) of Regulation No 1610/96 does not allow a supplementary protection certificate to be granted on the basis of a provisional authorisation to place the plant protection product on the market within the meaning of Article 8(1) of Directive 91/414.

59. In the view of the defendant and the Italian Government, on a schematic and teleological interpretation, and contrary to its clear wording, Article 3(1)(b) of Regulation No 1610/96 ought to be construed to mean that a supplementary protection certificate may be granted also on the basis of a provisional marketing authorisation issued pursuant to Article 8(1) of Directive 91/414.

60. I cannot identify any schematic or teleological arguments which might permit or justify such an interpretation.

61. From a schematic perspective, it must be emphasised that Directive 91/414 distinguishes between three separate categories of authorisation to place plant protection products on the market, (16) that is, definitive authorisations in accordance with Article 4, provisional authorisations in accordance with Article 8(1) and emergency authorisations in accordance with Article 8(4). That distinction between the separate categories of authorisations is reflected systematically and very clearly in Regulation No 1610/96.

62. In relation simply to its material scope, Article 2 of Regulation No 1610/96 makes clear that the regulation applies only in so far as a marketing authorisation in accordance with Article 4 of Directive 91/414 has been granted, that is, of course, presupposing that the application for authorisation was lodged after Directive 91/414 had been implemented. (17) Therefore, the possibility to obtain a certificate on the basis of a provisional authorisation in accordance with Article 8(1) of Directive 91/414 or on the basis of an emergency authorisation in accordance with Article 8(4) of that directive is ruled out simply in terms of the scope of Regulation No 1610/96.

63. In establishing the conditions for the grant of a supplementary protection certificate, Article 3(1)(b) of Regulation No 1610/96 refers expressly also to the authorisation in accordance in Article 4 of Directive 91/414. The same applies with regard to Article 7 of Regulation No 1610/96, according to which an application for a supplementary protection certificate must be lodged within six months of the date on which the marketing authorisation referred to in Article 3(1)(b) was granted, if at that date the basic patent has already been granted.

64. The only context in which Regulation No 1610/96

refers substantively to the category of provisional authorisations within the meaning of Article 8(1) of Directive 91/414 is in the determination of the duration of the protection certificate.

65. According to Article 13(1) of Regulation No 1610/96, the certificate takes 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 European Union, reduced by a period of five years. According to Article 13(2), the duration of the certificate may not exceed five years from the date on which it takes effect. Article 13(3) then makes clear that account may be taken of a provisional first marketing authorisation only if it is directly followed by a definitive authorisation concerning the same product.

66. Having regard to the purpose of Article 13 of Regulation No 1610/96, that reference to provisional authorisations under Article 8(1) of Directive 91/414 is wholly unsuitable as an argument that the grant of such provisional authorisation suffices in itself to trigger the application of Regulation No 1610/96. Rather, it is evident from the recitals in the preamble that the objective underlying the supplementary protection certificate is to grant the patent owner the period of protection of exclusivity required to cover the investment put into research, without losing sight, nevertheless, of all the other interests at stake. (18) Against that background, Article 13(3) of Regulation No 1610/96 essentially provides that, for the purposes of calculating the duration of the certificate, regard must be had also to the opportunities for recoupment enjoyed by the patent owner resulting from the grant of a provisional authorisation within the terms of Article 8(1) of Directive 91/414. However, that consideration given to a provisional authorisation under Article 8(1) of Directive 91/414 for the purposes of determining a fair period during which patent owners may recoup their investments does not permit any conclusions to be reached in relation to the scope of Regulation No 1610/96 or in relation to the conditions established in Article 3(1) of that regulation governing the grant of supplementary protection certificates.

67. In that connection, it should also be noted that Article 13 of Regulation No 1610/96 refers to authorisations to place the product on the market in the Community, whereas Article 3 of that regulation requires a valid authorisation, in accordance with Article 4 of Directive 91/414, to place the product on the market in the Member State in which the application for a certificate is submitted. Thus, in terms of their geographical scope, the references in Article 3 and in Article 13 of Regulation No 1610/96 to 'marketing authorisations' are certainly not identical. (19) That distinction is reflected, for example, in Article 8(1)(a)(iv) of Regulation No 1610/96. According to that provision, the application for a certificate must include the number and date of the first authorisation to place the product on the market, as referred to in Article 3(1)(b) of that regulation, and, if that authorisation is not the first authorisation to place the product on the market within the European Union, the number and date of such authorisation.

68. Having regard to the need – confirmed in consistent case-law (20) – for an interpretation of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (21) and Regulation No 1610/96 which is coherent, it must be emphasised in that connection also that the possibility of granting provisional authorisations to place a product on the market constitutes a specific feature of Directive 91/414. In those circumstances, the reference to such provisional authorisations in Article 13(3) of Regulation No 1610/96 constitutes also a specific feature of that regulation. Thus, on that point, Regulation No 1610/96 differs from Regulation No 1768/92, which, for the remainder, shares almost identical wording. (22)

69. If one were to interpret Regulation No 1610/96 as meaning that regard could be had to a provisional marketing authorisation in accordance with Article 8(1) of Directive 91/414 not only for the purposes of calculating the duration of the certificate in accordance with Article 13 but also as a criterion for the grant of a protection certificate in accordance with Article 3(1)(b), that would result, ultimately, in the abandonment of the structural symmetry between Regulation No 1610/96 and Regulation 1768/92 in relation to their scope and the conditions governing their application. That would scarcely be compatible with the need to ensure a coherent interpretation of both regulations.

70. In the light of the foregoing, I conclude that a schematic and teleological interpretation of Regulation No 1610/96 confirms the literal interpretation of Article 3(1)(b), namely, that a supplementary protection certificate may not be granted on the basis of provisional marketing authorisation under Article 8(1) of Directive 91/414.

71. In the view of the defendant, such an interpretation of Article 3(1)(b) of Regulation No 1610/96 would result in an unacceptable outcome. Having regard to the potentially extremely lengthy authorisation process under Article 4 of Directive 91/414, a patent owner could never be sure that it will obtain the authorisation in accordance with Article 4 prior to the expiry of the patent's term. If it were to obtain that authorisation only after expiry of the basic patent, it would no longer be in a position to apply for certificate protection, an outcome which would be contrary to the purpose of Regulation No 1610/96. In the light of the resulting gap in the law, the defendant invites the Court to close that gap with a contra legem interpretation of Article 3(1)(b) of Regulation No 1610/96.

72. In my view, the alleged gap in the law identified by the defendant does not exist.

73. From my observations above, it follows that the grant of a supplementary protection certificate in accordance with Regulation No 1610/96 presupposes, inter alia, that, at the date of the application for the certificate, the product concerned is protected by a basic patent in force (23) and that at that date an authorisa-

tion to place the plant protection product concerned on the market has been granted in accordance with Article 4 of Directive 91/414.

74. As the regular term of patent protection lasts for 20 years from the date of application to have the invention registered, the alleged gap in the law identified by the defendant would arise only if those 20 years were to constitute an insufficient period in which to obtain, first, the registered patent and an authorisation to place the product under patent on the market as a plant protection product in accordance with Article 4 of Directive 91/414 and, subsequently, on that basis, to apply for a supplementary protection certificate in accordance with Regulation No 1610/96.

75. No information has been provided in the present proceedings which might lead one to conclude that the patent term of 20 years from the date of application to have the invention registered is insufficient to obtain, first, the registered patent and the authorisation to place the product under patent on the market as a plant protection product in accordance with Article 4 of Directive 91/414 and, on that basis, to apply for a supplementary protection certificate in accordance with Regulation No 1610/96. (24)

76. Even if, in an exceptional case, the process of obtaining the authorisation under Article 4 of Directive 91/414 were to be excessively lengthy, such that the patent term of 20 years from the date of application to have the invention registered is insufficient for the purposes of applying for a supplementary protection certificate, that most likely would result from an error or inattention on the part of one or more of the parties concerned. To the extent to which the lengthiness of the process were to result from an error or a lapse by the applicant, it would hardly be appropriate to refer to this as constituting a gap in the law. However, even if the excessive duration of the process were to result from an error or a lapse by the national authorities or the Commission, this would not, in my view, amount to a gap in the system established by Regulation No 1610/96. Instead, such a situation would reflect a failing by the authorities for which compensation would have to be sought in proceedings brought against those authorities with a view to establishing liability.

77. Finally, I should like to add that the interpretation favoured by the defendant, according to which a supplementary protection certificate could be granted also on the basis of a provisional marketing authorisation under Article 8(1) of Directive 91/414, would result in many consequential problems in the interpretation of Regulation No 1610/96. The main reason for that is the fact that, in terms of its wording and scheme, Regulation No 1610/96 is drafted and constructed in such a way that only an authorisation granted in the Member State concerned in accordance with Article 4 of Directive 91/414 may operate as the basis for the grant of a supplementary protection certificate. If it were possible for a supplementary protection certificate to be granted additionally on the basis of a provisional marketing authorisation granted in that Member State under Article 8(1) of Directive 91/414, every provision of Regulation No 1610/96 referring directly or indirectly to a marketing authorisation under Article 4 of Directive 91/414 would have to be examined in order to determine whether it also covers an authorisation granted in the Member State concerned under Article 8(1) of Directive 91/414.

78. A good example in this respect is Article 7 of Regulation No 1610/96, which establishes a six-month period in which to apply for a certificate. If the authorisation to place the product on the market is granted after the basic patent has been granted, in accordance with Article 7(1), that six-month period begins on the date on which the authorisation referred to in Article 3(1)(b) to place the product on the market as a plant protection product was granted. If, however, a provisional authorisation in accordance with Article 8(1) of Directive 91/414 is to be categorised as an authorisation to place the product on the market in accordance with Article 3(1)(b) of Regulation No 1610/96, the question will necessarily arise as to whether the owner of the basic patent now has two six-month periods in which to apply for the certificate, that is, one following the authorisation in accordance with Article 8(1) and another following the authorisation in accordance with Article 4 of Directive 91/414. If a patent owner were granted two six-month periods, that would not only be at variance with the wording of Article 7(1) of Regulation No 1610/96 but would also eliminate in that area the coherence between the rules on certificate applications in accordance with that regulation and with Regulation No 1768/92. (25) If, on the other hand, only one six-month period were granted, that would logically preclude a certificate application after the expiry of the 'first' six-month period starting from the grant of the marketing authorisation in accordance with Article 8(1) of Directive 91/414, which, in turn, would be contrary to the Regulation's scheme and seriously affect the interests of a patent owner which had awaited the grant of an authorisation in accordance with Article 4 of Directive 91/414 before lodging its application.

79. A similar problem would arise in the interpretation of Article 3(1)(d) of Regulation No 1610/96. According to that provision, a supplementary protection certificate may be granted only if the authorisation referred to in subparagraph (b) of that paragraph is the first authorisation to place that product on the market as a plant protection product. (26) If, however, a provisional authorisation under Article 8(1) of Directive 91/414 is also to be categorised as an authorisation to place the product on the market under Article 3(1)(b) of Regulation No 1610/96, that would mean that the authorisation in accordance with Article 4 of that directive to place the same product on the market would have to be regarded – in so far as a provisional authorisation had already been granted – as a 'second' authorisation. If, in that scenario, the owner of the basic patent did not apply for the supplementary protection certificate following receipt of the preliminary authorisation, Article 3(1)(d) of Regulation No 1610/96 would, in principle, preclude such an application following receipt of the definitive authorisation. In this

case, too, the outcome would be contrary to the Regulation's scheme and would constitute a grave interference with the interests of patent owners which had awaited the grant of an authorisation under Article 4 of Directive 91/414 before applying for a supplementary protection certificate.

80. In summary, therefore, I conclude that, on a literal, schematic and purposive interpretation of Article 3(1)(b) of Regulation No 1610/96, a supplementary protection certificate for plant protection products cannot be granted on the basis of a marketing authorisation issued pursuant to Article 8(1) of Directive 91/414.

C – Temporal limitation on the effects of the judgment on the reference for a preliminary ruling

81. If, in giving its judgment on this reference for a preliminary ruling, the Court should hold – as I have proposed – that a supplementary protection certificate for plant protection products may not be granted on the basis of a marketing authorisation under Article 8(1) of Directive 91/414, in the main proceedings, the referring court must, ultimately, set aside as void the supplementary protection certificate No 100 75 026 for 'iodosulfuron and its C1 to C12 alykl esters and salts including iodosulfuron-methyl-sodium salt'. In that case, it would be clear that the certificate had been granted contrary to the provisions of Article 3 of Regulation No 1610/96 and, as a result, in accordance with Article 15(1) of that regulation, must be regarded as invalid.

82. However, the legal consequences of such a ruling would not be limited to the main proceedings.

83. Regard must be had in that connection to the settled case-law of the Court to the effect that the interpretation which, in the exercise of the jurisdiction conferred on it by Article 267 TFEU, the Court gives to a rule of European Union law clarifies and defines the meaning and scope of that rule as it must be or ought to have been understood and applied from the time of its entry into force. It follows that the rule as thus interpreted may, and must, be applied by the courts even to legal relationships which arose and were established before the judgment ruling on the request for interpretation, provided that in other respects the conditions for bringing a dispute relating to the application of that rule before the competent courts are satisfied. (27) In other words, a judgment on a reference for a preliminary ruling does not create or alter the law, but is purely declaratory, with the consequence that in principle it takes effect from the date on which the rule interpreted entered into force. (28)

84. In that connection, in its reference, the Bundespatentgericht notes that the well-established practice of the DPMA was to grant supplementary protection certificates for plant protection products on the basis of authorisations under Article 8(1) of Directive 91/414. In addition, it would appear – according to that court – that in other Member States, too, such certificates were granted on the basis of provisional authorisations. That was the case, for example, in Belgium, Italy and the United Kingdom. (29) The defendant, too, asserts that in other Member States of the European Union protection certificates were, and continue to be, granted regularly on the basis of authorisations in accordance with Article 8(1) of Directive 91/414. It claims that in its portfolio of protective rights at a European level some 75% of all its protection certificates were granted on the basis of such provisional authorisations. As proof to support those assertions, the defendant has submitted several protection certificates for plant protection products granted in Spain, Italy, the United Kingdom, France, Austria, the Netherlands and Ireland on the basis of provisional authorisations in accordance with Article 8(1) of Directive 91/414. (30) In addition, the defendant has submitted a position paper by the European Crop Protection Association of 28 September 2009. (31) According to the position paper, prior to the reversal in the decision-making practice of the DPMA in 2007, it was the uncontested practice of national patent authorities in all the Member States to grant supplementary protection certificates for plant protection products on the basis of marketing authorisations under Article 8(1) of Directive 91/414. As a result, at a European Union level some 90% of protection certificates granted were based on a provisional authorisation to place on the market the plant protection product concerned. (32)

85. If, in the present proceedings, the Court should rule that supplementary protection certificates for plant protection products may not be granted on the basis of an authorisation to place the product on the market in accordance with Article 8(1) of Directive 91/414, the legal consequences of that ruling would extend significantly beyond the question concerning the invalidity of the protection certificate granted to the defendant. The consequence of such a ruling would be that all supplementary protection certificates for plant protection products granted on the basis of provisional authorisations in accordance with Article 8(1) of Directive 91/414 would have to be regarded as void under the terms of Article 15(1) of Regulation No 1610/96. Thus, in accordance with Article 15(2) of that regulation, any person could submit an application or bring an action to have those certificates set aside as void.

86. Although a determination that a supplementary protection certificate is void does not exclude of itself the possibility that the owner of the basic patent may make a new application for a supplementary protection certificate for the plant protection product concerned, such an application must satisfy the requirements of Regulation No 1610/96. The most problematic issue in that connection is likely to be the period in which applications must be lodged, which, under Article 7(1), is six months from the date of the first authorisation to place the product on the market. In all cases in which that period has already expired and the possibility to reopen such no longer applies, a determination that protection certificates granted on the basis of provisional authorisations are void would result in the irrevocable extinction of the exclusivity rights of the certificate owners established therein.

87. Against that background, it appears to me appropriate to examine the possibilities of a temporal limitation

on the effects of the judgment on the reference for a preliminary ruling in the present case.
88. Although Article 264 TFEU grants the Court of Justice express authority to limit the temporal effects of its judgments only in relation to actions for annulment, in consistent case-law, the Court has drawn upon the legal notion inherent in that provision also in proceedings for a preliminary ruling. The Court does that not only in the context of proceedings for a preliminary ruling, in which it must determine the validity of a provision of European Union law or an act of a European Union institution, (33) but also in the context of proceedings for a preliminary ruling in which it is asked to rule on the interpretation of a provision of European Union law. (34)
89. According to that case-law, in exceptional cases, in application of a general principle of legal certainty inherent in the legal order of the European Union, the Court may decide to restrict the right to rely upon a provision, which it has interpreted, with a view to calling into question legal relations established in good faith. (35)
90. The determination that a preliminary ruling on a new legal issue takes effect ex nunc allows for subsequent preliminary rulings on the same legal issue to rely on that temporal limitation. That is, if in an earlier preliminary ruling on a legal issue the Court ordered its judgment to apply ex nunc, in subsequent preliminary rulings on the same issue, too, the Court may limit the temporal effects of its reply to the date on which judgment was handed down in that earlier case. (36) If, on the other hand, the Court first replied to a question by way of a judgment on a reference for a preliminary ruling and did not order that judgment to apply ex nunc, in the context of a subsequent preliminary ruling on the same question, it has refused in consistent case-law to impose any temporal limitation on the effects of its judgment. (37)
91. As a general rule, the Court, in application of the general principle of legal certainty inherent in the legal order of the European Union, limits the temporal effects of its preliminary rulings only where, first, there is a risk of serious economic repercussions owing in particular to the large number of legal relationships entered into in good faith on the basis of rules considered to be validly in force and, second, where it appears that both individuals and national authorities have been led to adopt practices which do not comply with European Union legislation by reason of objective and significant uncertainty regarding the implications of provisions of European Union law, to which the conduct of other Member States or the Commission may even have contributed. (38)
92. In the present case, it should be observed, first, that the Court has not hitherto interpreted Article 3(1)(b) of Regulation No 1610/96.
93. Moreover, as I have already indicated, it must be presumed that a judgment on a reference for a preliminary ruling which establishes that a supplementary protection certificate for plant protection products may not be granted on the basis of a provisional authorisation to place the product on the market pursuant to Article 8(1) of Directive 91/414 will risk having serious economic repercussions. (39)
94. However, the question as to whether there was objective and significant uncertainty regarding the implications of the condition laid down in Article 3(1)(b) of Regulation No 1610/96 for the grant of a supplementary protection certificate which led basic patent owners and national authorities to adopt unlawful practices concerning the grant of protection certificates cannot easily be answered.
95. As I have already argued, on a literal, schematic and purposive interpretation of Article 3(1)(b) of Regulation No 1610/96, the grant of a supplementary protection certificate for plant protection products on the basis of a marketing authorisation issued pursuant to Article 8(1) of Directive 91/414 is precluded.
96. However, it is apparent from information provided to the Court that the established practice of numerous Member-State authorities competent to grant supplementary protection certificates for plant protection products was to grant such certificates on the basis of provisional marketing authorisations issued in accordance with Article 8(1) of Directive 91/414. In addition, it follows from the decision to refer in the present case that the referring court, too, in its capacity as a court dealing with appeals brought against decisions taken by the DPMA, approved that practice and quashed the decision of the DPMA to abandon that practice. (40)
97. It follows, further, from the decision making the reference in the present case that the practice of granting supplementary protection certificates on the basis of provisional authorisations must be understood as resulting from an extensive interpretation of Article 3(1)(b) of Regulation No 1610/96 which was intended to ensure as far as possible that the objectives of that regulation could be realised. (41)
98. According to the referring court, the development of that practice results, inter alia, from the fact that a provisional authorisation to place an active substance on the market as a plant protection product under Article 8(1) of Directive 91/414, as a general rule, will lead in practice to the inclusion of that active substance in Annex I and, immediately following the provisional authorisation, to a definitive authorisation under Article 4(1) of that directive. In its view, that follows from the strict requirements which, under Article 8(1)(a) and (b), in conjunction with Article 6(2) and (3), of Directive 91/414, are applicable to provisional authorisations in order to ensure the high level of protection required by the directive. The comprehensive dossier on the active substance and one or more preparations containing that active substance compiled in accordance with the requirements of Annexes II and III at considerable expense and involving considerable time investment on the part of the applicant allows Member States, for the purposes of a provisional authorisation, to establish in accordance with Article 8(1)(b) of Directive 91/414 that, from a toxicological and ecotoxicological perspective, the plant protection product is not expected to have harmful effects. Further detailed evaluation under

the European Union procedure, in practice, confirms, as a rule, that projection and leads – where necessary, subject to the imposition of conditions – to the inclusion of the active substance in Annex I and to the definitive authorisation to place the product on the market in accordance with Article 4(1) of Directive 91/414. (42)

99. According to the referring court, in practice, the first provisional authorisation to place the product on the market in the Community is followed immediately by a definitive authorisation concerning the same product in accordance with Article 13(3) of Regulation No 1610/96. In its view, the legal basis to ensure that a definitive authorisation immediately follows the first provisional authorisation to place the product on the market in the European Union is provided by the fourth subparagraph of Article 8(1) of Directive 91/414. According to that provision, by way of derogation from Article 6, if, on expiry of the period, not exceeding three years, established in Article 8(1), a decision has not been taken concerning the inclusion of an active substance in Annex I, a further period may be ordered 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). In the light of such further period, Member States have the power to extend the period of provisional authorisation originally granted. In the present case, too, in relation to the active substance iodosulfuron protected by the certificate at issue, by decision of 21 May 2003, in accordance with the fourth subparagraph of Article 8(1) of Directive 91/414, the Commission provided for a further period limited to 21 May 2005 to enable a full examination to be made of the dossier relating to that active substance. Thereupon, in Germany, the authorisation of 9 March 2000 originally limited to 8 March 2003, in accordance with Paragraph 15c(3) of the PflSchG, was extended to 21 May 2005. The definitive authorisation in accordance with Paragraph 15 of the PflSchG was granted on 13 January 2005, thus factually satisfying the requirement of Article 13(3) of Regulation No 1610/96, and, ultimately, the certificate at issue in the proceedings was granted for the correct period. (43)

100. It follows from those observations of the referring court that the practice, in contravention of the regulation, whereby supplementary protection certificates were granted on the basis of provisional authorisations in accordance with Article 8(1) of Directive 91/414, was in essence based on experience gained in everyday procedural practice in conjunction with specific provisions of Directive 91/414 and Regulation No 1610/96. In my view, those – primarily practical – considerations do not suffice to rebut the interpretation of Article 3(1)(b) of Regulation No 1610/96 which I propose, namely, that supplementary protection certificates for plant protection products may not be granted on the basis of provisional authorisations. However, in my view, having regard to the particular circumstances of the present case, those considerations allow the conclusion that objective and significant uncertainty existed as to the implications of the criterion for the grant of a supplementary protection certificate established in Article 3(1)(b) of Regulation No 1610/96, and that this uncertainty led applicants and national authorities to adopt the unlawful practice by which supplementary protection certificates were granted on the basis of provisional authorisations issued pursuant to Article 8(1) of Directive 91/414.

101. Therefore, having regard to the particular circumstances of the present case, I conclude that the interpretation of Article 3(1)(b) of Regulation No 1610/96 which I propose risks causing serious economic repercussions for the industry for plant protection products. In addition, it may be presumed that the practice of granting supplementary protection certificates on the basis of provisional authorisations in accordance with Article 8(1) of Directive 91/414 results from objective and significant uncertainty regarding the implications of the provisions concerned. Thus, both basic conditions are satisfied which, according to established case-law, are required for the purposes of a temporal limit on the effects of a preliminary ruling.

102. In that connection, it should be mentioned that, in cases in which it imposes a temporal limitation on the effects of a preliminary ruling, the Court generally provides for an exception from those ex nunc effects in favour of the parties to the main proceedings and others who have sought legal remedies in the broadest sense prior to the handing-down of the judgment. That exception generally applies in those cases in which the applicant in the main proceedings seeks to assert pecuniary or other claims and the Court has upheld the legal view on that point taken by the applicant. (44) The motive which essentially underlies such exceptions to the ex nunc effect is that it would be unjust to deny to those parties which have particularly sought to assert their rights prior to the handing-down of judgment the ex tunc effects of the judgment on the reference for a preliminary ruling. (45)

103. However, that is not the factual situation which obtains in the main proceedings here. If the claimant's action to have the certificate set aside as void is upheld, that does not mean that the claimant could assert any rights of its own without retroactively weakening the legal position of the defendant in relation to others. Instead, the defendant would lose retroactively and erga omnes its position of exclusivity granted by the supplementary protection certificate. Thus, having regard to the particular circumstances of the present case, to exempt the claimant from the ex nunc effects of the ruling would impose a disproportionate burden on the defendant. In my view, therefore, in the present case, to include such an exception would be also unreasonable.

104. Finally, I should like to observe that I am not persuaded by the Commission's argument that, in the present case, Article 3(1)(b) of Regulation No 1610/96 should be interpreted ex tunc in the manner I have proposed on the basis that the legal consequences of the judgment in this case could be temporally limited, if necessary, in further references for a preliminary ruling on the application of Article 15 of Regulation No 1610/96 to supplementary protection certificates which

were granted in contravention of Article 3(1)(b) of Regulation No 1610/96. First, such a solution would result in extreme legal uncertainty as to the validity of supplementary protection certificates for plant protection products previously granted on the basis of provisional authorisations in accordance with Article 8(1) of Directive 91/414. In addition, such a solution would be incompatible with established case-law, according to which a limitation on the temporal effects of an interpretation handed down in a preliminary ruling may be imposed only in the case itself which delivers a ruling on the interpretation sought. (46)

105. If, in its ruling on the preliminary reference in this case, the Court should rule along the lines which I have proposed, namely, to the effect that a supplementary protection certificate for plant protection products may not be granted on the basis of an authorisation to place the product on the market issued pursuant to Article 8(1) of Directive 91/414, in the light of the foregoing, it appears to me reasonable and justified to limit the effects of that judgment to the future.

VII – Conclusion

106. On the basis of the foregoing, I propose that the Court should reply to the Bundespatentgericht as follows:

(1) 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 meaning that a supplementary protection certificate for plant protection products may not be granted on the basis of a marketing authorisation for that product which was issued 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.

(2) This interpretation of Article 3(1)(b) of Regulation No 1610/96 may not be relied upon for the purpose of any application to have set aside, as being void, supplementary protection certificates for plant protection products which were applied for, prior to the handing-down of the judgment in the present case, on the basis of provisional marketing authorisations issued pursuant to Article 8(1) of Directive 91/414.

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1 – Original language: German.

2 – In accordance with the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community of 13 December 2007 (OJ 2007 C 306, p. 1), the preliminary-reference procedure is now governed by Article 267 TFEU.

3 – OJ 1996 L 198, p. 30.

4 – 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 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ 2005 L 70, p. 1).

5 – Gesetz zum Schutz der Kulturpflanzen of 15 September 1986, in the amended version of 14 May 1998 (BGBl. I p. 971, 1527, 3512), most recently amended by Article 13 of the Law of 29 July 2009 (BGBl. I p. 2542).

6 – Commission Decision 1999/392/EC of 31 May 1999 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of ZA 1296 (mesotrione), Iodosulfuron-methyl-sodium (AEF 115008) Silthiopham (MON 65500) and Gliocladium catenulatum in Annex I to Council Directive 91/414/EEC concerning the placing of plant- protection products on the market (OJ 1999 L 148, p. 44).

7 – 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).

8 – OJ 2003 L 247, p. 20.

9 – The German version of Directive 91/414 does not use the term ‘Genehmigung’ to mean authorisation but refers systematically by means of the term ‘Zulassung’ to the authorisation of plant protection products. In Article 2(11) of the Directive the ‘authorisation of a plant protection product’ [in German: ‘Zulassung eines Pflanzenschutzmittels’] is defined as an ‘administrative act by which the competent authority of a Member State authorises, following an application submitted by an applicant, the placing on the market of a plant protection product in its territory or in a part thereof’. The German version of Regulation No 1610/96 refers to authorisations [‘Zulassungen’] in accordance with Directive 91/414 as authorisations [‘Genehmigungen’] to place plant protection products on the market. In the light of that, hereinafter, in German, I will use the term ‘Genehmigung’ uniformly to mean authorisation both when referring to Directive 91/414 and to Regulation No 1610/96.

10 – See the ninth recital in the preamble to Directive 91/414, in which, in addition, protection of human and animal health and of the environment is mentioned as taking priority in that connection over the objective of improving plant production.

11 – See the eleventh recital in the preamble to Directive 91/414.

12 – Article 5(1) of Directive 91/414.

13 – Article 5(5) of Directive 91/414.

14 – See recital 5 in the preamble to Regulation No 1610/96.

15 – See recital 11 in the preamble to Regulation No 1610/96.

16 – See point 46 et seq. of this Opinion.

17 – See point 51 of this Opinion.

18 – See recitals 5 to 12 in the preamble to Regulation No 1610/96.

19 – On that point, see Case C-127/00 Hässle [2003] ECR I-14781, paragraph 77, and the Opinion of Advocate General Stix-Hackl in that case, point 85 et seq., concerning the interpretation of the identically worded Article 13(1) of Regulation No 1768/92.

20 – See, for example, Case C-482/07 AHP Manufacturing [2009] ECR I-7295, paragraph 23 et seq., Case C-431/04 Massachusetts Institute of Technology [2006] ECR I-4089, paragraph 22 et seq., and Case C-392/97 Farmitalia [1999] ECR I-5553, paragraph 20.
21 – OJ 1992 L 182, p. 1.
22 – On that point, see, for example, Schennen, D., 'Auf dem Weg zum Schutzzertifikat für Pflanzenschutzmittel', GRUR Int. 1996, p. 102 et seq. See also Galloux, J.-C., 'Le certificat complémentaire de protection pour les produits phytopharmaceutiques', JCP 1996 Ed. E, p. 499, point 1. Differences between Regulation No 1610/96 and Regulation No 1768/92 generally stem from provisions included in Regulation No 1610/96 as a result of experiences encountered with Regulation No 1768/92. To ensure a coherent interpretation of both regulations even on those points, recital 17 in the preamble to Regulation No 1610/96 indicates essentially that the innovations introduced by Regulation No 1610/96 apply also in the interpretation of Regulation No 1768/96. That recital is based on a proposal by the Council; see Common Position (EC) No 30/95 adopted by the Council on 27 November 1995 with a view to adopting Regulation (EC) No 1610/96 of the European Parliament and the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ 1995 C 353, p. 36; the second paragraph of point 9 of the Council's statement of reasons). However, in point 13 of the statement of reasons accompanying Common Position No 30/95 the Council stressed also that the consideration given to provisional authorisations in Article 13 of Regulation No 1610/96 constitutes an aspect which is specific to the procedure for the placing on the market of plant protection products and, hence, that the coherence with Regulation No 1768/92 does not extend to that specific aspect of the calculation of the certificate's duration.
23 – On the other hand, it is irrelevant whether at the date of the grant of the supplementary protection certificate the basic patent remains in force; see, for example, S. Jones and G. Cole, (eds), CIPA Guide to the Patents Acts, London, 6th edition, 2009, p. 1214.
24 – In that connection, reference may also be made to point 1.3 of the Opinion of the Economic and Social Committee of 27 April 1995 on the 'Proposal for a European Parliament and Council Regulation (EC) concerning the creation of a supplementary protection certificate for plant protection products' (OJ 1995 C 155, p. 14). It is emphasised there that the period between authorisation to market the product and patent expiry is approximately nine years in the European Union.
25 – On that coherence see, for example, D. Schennen, cited above in footnote 22, p. 108, who emphasises that the procedure for application for and grant of the certificate under Regulation No 1610/96 does not differ from the scheme established by Regulation No 1768/92.
26 – On that point, see Case C-258/99 BASF [2001] ECR I-3643. In that case, the manufacturer of a pesticide had refined its production process, primarily by raising the level of purity of the active substance. In 1967, the Netherlands authorities granted the first marketing authorisation for the plant protection product and in 1987 they granted a new authorisation for the improved plant protection product. In relation to the new process for the manufacture of the purer form of the active substance a European process patent had been granted. It was questionable whether, on the basis of the process patent, a supplementary protection certificate could be applied for in relation to the improved plant protection product. In the Court's view, both plant protection products were based on the same product within the meaning of Regulation No 1610/96. Accordingly, the authorisations granted in 1967 and 1987, which for the purposes of Article 3(1)(b) of Regulation No 1610/96 were regarded as having been granted in accordance with an equivalent provision of national law, also concerned the same product. Against that background, the Court held that the conditions laid down in Article 3(1)(a) and (d) of Regulation No 1610/96 for the grant of a new supplementary protection certificate had not been satisfied.
27 – Case C-292/04 Meilicke and Others [2007] ECR I-1835, paragraph 34; Case C-209/03 Bidar [2005] ECR I-2119, paragraph 66; Joined Cases C-367/93 to C-377/93 Roders and Others [1995] ECR I-2229, paragraph 42; and Case 61/79 Denkavit italiana [1980] ECR 1205, paragraph 16.
28 – See Case C-2/06 Kempter [2008] ECR I-411, paragraph 35.
29 – Paragraph 34 of the reference for a preliminary ruling of 28 April 2009.
30 – Annex 2 to the written observations of the defendant of 13 October 2009.
31 – 'ECPA's position – on the relationship between Supplementary Protection Certificates and National Provisional Authorizations', attached as Annex 1 to the written observations of the defendant of 13 October 2009.
32 – ECPA position paper (cited in footnote 31), p. 3.
33 – Case C-333/07 Régie Networks [2008] ECR I-10807, paragraph 118 et seq.; Case C-228/92 Roquette Frères [1994] ECR I-1445, paragraph 17 et seq.; Joined Cases C-38/90 and C-151/90 Lomas and Others [1992] ECR I-1781, paragraph 23 et seq.; and Case 300/86 Van Landschoot [1988] ECR 3443, paragraph 22 et seq.
34 – The authoritative judgment on that point is Case 43/75 Defrenne [1976] ECR 455, paragraph 69 et seq.
35 – Case C-426/07 Krawczyński [2008] ECR I-6021, paragraph 42; Meilicke and Others, cited above in footnote 27, paragraph 35; Bidar, cited above in footnote 27, paragraph 67; Case C-184/99 Grzelczyk [2001] ECR I-6193, paragraph 51; Case C-104/98 Buchner and Others [2000] ECR I-3625, paragraph 39; and Case C-262/96 Sürül [1999] ECR I-2685, paragraph 108.
36 – See, for example, Case C-262/88 Barber [1990] ECR I-1889, paragraph 40 et seq., limiting the temporal effects of the judgment to the date on which judgment was handed down, and Case C-109/91 Ten Oever

[1993] ECR I-4879, paragraph 15 et seq., limiting the temporal effects of the judgment to the date of the Barber judgment. On that point, see also Kokott, J. and Henze, T., 'Die Beschränkung der zeitlichen Wirkung von EuGH-Urteilen in Steuersachen', NJW 2006, p. 177, at p. 181.

37 – See, for example, Krawczyński, cited above in footnote 35, paragraph 43 et seq. and Meilicke and Others cited above in footnote 27, paragraph 35 et seq.

38 – See Bidar, cited above in footnote 27, paragraph 69, Grzelczyk, cited above in footnote 35, paragraph 53, and Roders and Others, cited above in footnote 27, paragraph 43.

39 – See point 84 et seq. of this Opinion.

40 – See point 22 of this Opinion.

41 – See paragraph 37 of the reference for a preliminary ruling of 28 April 2009.

42 – See paragraph 38 of the reference for a preliminary ruling of 28 April 2009.

43 – See paragraph 39 et seq. of the reference for a preliminary ruling of 28 April 2009.

44 – See, for example, Régie Networks, cited above in footnote 33; Sürül, cited above in footnote 35; Roquette Frères, cited above in footnote 33; Ten Oever, cited above in footnote 36; Barber, cited above in footnote 36; and Defrenne, cited above in footnote 34.

45 – See Kokott, J. and Henze, T., cited above in footnote 36, p. 182.

46 – See, for example, Krawczyński, cited above in footnote 35, paragraph 43, and Meilicke and Others, cited above in footnote 27, paragraph 36.