Court of Justice EU, 17 October 2013, Sumitomo v Patent und Markenamt

PATENT LAW - SPC

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 an emergency MA has been issued under Article 8(4) of Directive 91/414

- **Accordingly, the answer to the first question is that 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 an emergency MA has been issued under Article 8(4) of Directive 91/414.**
- 34 Article 3(1)(b) of Regulation No 1610/96 refers to a MA granted 'in accordance with Article 4 of Directive 91/414'. It is true that, it has been held that there is no need to interpret that provision of that regulation 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 (***Hogan Lovells International***, paragraph 46).
- 35 However, that interpretation rests on the link of functional equivalence which exists between the criteria set out in Article 8(1) of Directive 91/414 as transitional measures and those laid down in Article 4 of that directive (***Hogan Lovells International***, paragraphs 33 to 46). There is no such link of functional equivalence between the criteria laid down in Article 8(4) of Directive 91/414 and those in Article 4 thereof.
- 36 It is apparent from the very definition of the emergency MA laid down in Article 8(4) of Directive 91/414 that it concerns '*plant protection products not complying with Article 4*'. That type of MA is therefore not intended to ensure that plant protection products thus authorised meet the same scientific requirements as to reliability as those granted an MA on the basis of Article 4 of Directive 91/414. Thus, Article 8(4) of that directive does not require the Member States to carry out scientific risk evaluations prior to issuing such an MA. That derogating provision does, however, strictly limit the use of that type of MA, stating that it applies only to 'special circumstances', and the issue of an emergency MA for a period not exceeding 120 days must appear '*necessary because of an unforeseeable danger which cannot be contained by other means*'.
- 37 In those circumstances, it is not possible to apply Article 3(1)(b) of Regulation No 1610/96 to an emergency MA, which is restricted to products which do not comply with the requirements of Article 4 of Directive 91/414 and in respect of which that directive does not require a prior scientific evaluation of the risks.

No application for SPC before the date on which the plant protection product has obtained the MA

- **Accordingly, the answer to the third question is that Articles 3(1)(b) and 7(1) of Regulation No 1610/96 must be interpreted as precluding an application for a supplementary protection certificate being lodged before the date on which the plant protection product has obtained the MA referred to in Article 3(1)(b) of that regulation.**

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Court of Justice EU, 31 March 2010
(C.G. Fernlund, A. Ó Caoimh and E. Jarašiūnas)
JUDGMENT OF THE COURT (Eighth Chamber)
17 October 2013 (*)
(Patent law – Plant protection products – Supplementary protection certificate – Regulation (EC) No 1610/96 – Directive 91/414/EEC – Emergency marketing authorisation under Article 8(4) of that directive)
In Case C‑210/12,
REQUEST for a preliminary ruling under Article 267 TFEU from the Bundespatentgericht (Germany), made by decision of 23 February 2012, received at the Court on 3 May 2012, in the proceedings
Sumitomo Chemical Co. Ltd
v
Deutsches Patent- und Markenamt,
THE COURT (Eighth Chamber),
composed of C.G. Fernlund (Rapporteur), President of the Eighth Chamber, acting as President of the Chamber, A. Ó Caoimh and E. Jarašiūnas, Judges,
Advocate General: E. Sharpston,
Registrar: A. Calot Escobar,
having regard to the written procedure,
after considering the observations submitted on behalf of:
– the Italian Government, by G. Palmieri, acting as Agent, and by S. Varone, avvocato dello Stato,
– the European Commission, by F.W. Bulst and P. Ondrůšek, acting as Agents,
having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,
gives the following
Judgment
1 This request for a preliminary ruling concerns the interpretation of Articles 3(1)(b) and 7(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 request has been made in a dispute between Sumitomo Chemical Co. Ltd ('Sumitomo') and the Deutsches Patent- und Markenamt (German Patent and Trade Mark Office; 'the DPM') concerning the validity of the decision of 20 January 2006 by which the DPM refused to grant a supplementary protection certificate to Sumitomo.

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 Commission Directive 2005/58/EC of 21 September 2005 (OJ 2005 L 246, p. 17; 'Directive 91/414') state:

'Whereas 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;

...

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

5 Article 4 of that directive 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 shall not have any unacceptable effects 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 these 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 of Directive 91/414, concerning transitional measures and derogations, is worded as follows:

'1. 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.
...
4. By way of further derogation from Article 4, in special circumstances a Member State may authorise for a period not exceeding 120 days the placing on the market of plant protection products not complying with Article 4 for a limited and controlled use if such a measure appears necessary because of an unforeseeable danger which cannot be contained by other means. In this case, the Member State concerned shall immediately inform the other Member States and the Commission of its action. It shall be decided without delay, in accordance with the procedure laid down in Article 19, whether and under which conditions the action taken by the Member State may be extended for a given period, repeated, or revoked.'

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. That regulation 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) Whereas the duration of the protection granted by the certificate should be such as to provide adequate, effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen 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) Whereas 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 states:

'For the purpose of this Regulation
...
"certificates" shall mean: Supplementary protection certificates.'

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] 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] 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 and 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] 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 that regulation, entitled 'Effects of the certificate', provides:

'Subject to the provisions of 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 7 of the regulation, entitled 'Duration of the certificate', is drafted 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.'

15 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.'

16 Article 15 of that regulation provides:

'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 institution responsible under national law for the revocation of the corresponding basic patent.'

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

17 Sumitomo is the proprietor of European patent EP 0 376 279, DE 689 06 668 issued for Germany and concerning, in particular, the active substance clothianidin, used for insecticide products.

18 On 19 February 2003, the United Kingdom authorities issued a marketing authorisation ('MA') to a company in the Bayer group, in accordance with Article 8(1) of Directive 91/414, for a product containing clothianidin. That 'provisional' MA was the first issued in the European Union for a product containing that active substance.

19 On 2 December 2003, the German authorities, on the basis of the national provisions transposing Article 8(4) of Directive 91/414, issued an emergency MA to a company in the Bayer group for a plant protection product containing the active substance clothianidin. That emergency MA was valid for 120 days, from 15 January to 13 May 2004.

20 On 14 May 2004, Sumitomo applied to the DPM for a supplementary protection certificate for plant protection products. In its application, Sumitomo referred, first, to the provisional MA granted in the United Kingdom on 19 February 2003, as the first MA granted in the European Union, and, secondly, to the emergency MA issued in Germany on 2 December 2003.

21 On 8 September 2004, the German authorities granted, on the basis of the national provisions transposing Article 8(1) of Directive 91/414, a provisional MA to a company in the Bayer group for a product based on clothianidin. The period of validity of that provisional MA was from 8 September 2004 until 7 September 2007.

22 By letter of 25 November 2004, Sumitomo informed the DPM of the existence of the provisional MA of 8 September 2004.

23 The DPM dismissed the application for a supplementary protection certificate made by Sumitomo on 14 May 2004 by decision of 20 January 2006. Although the application had been lodged within the period set out in Article 7(1) of Regulation No 1610/96, the DPM took the view that the certificate could not be granted as the MA was no longer valid within the meaning of Article 3(1)(b) of Regulation No 1610/96 since the emergency MA had already expired. It is this decision which is contested in the main proceedings.

24 First, the referring court asks whether the decision of 20 January 2006 was not, in any event, justified by the fact that the MA on which Sumitomo relied was an emergency MA. In that regard, it points out that Article 3(1)(b) of Regulation No 1610/96 requires, as a condition for grant of a supplementary protection certificate, that a valid MA was issued *'in accordance with Article 4 of Directive 91/414'*. It notes that, in accordance with the judgment in Case C-229/09 ***Hogan Lovells International*** [2010] ECR I-11335, Article 3(1)(b) of that regulation is to be interpreted as not precluding a supplementary protection certificate from being issued for a plant protection product if a provisional MA had been granted in accordance with Article 8(1) of Directive 91/414. That interpretation rests on the link of functional equivalence between definitive MAs, provided for in Article 4 of Directive 91/414, and provisional MAs, provided for in Article 8(1) of that directive.

25 On the basis of that reasoning, the referring court is doubtful whether the view can be taken that an emergency MA meets that functional equivalence requirement. It therefore points out that emergency MAs are not required to fulfil the criteria laid down in Article 4 of Directive 91/414. In an emergency procedure, neither the plant protection product nor the active substance undergoes tests equivalent to those necessary for the issue of a definitive MA.

26 In addition, the referring court notes that the purpose of the emergency MAs is to respond to an unforeseeable danger which cannot be countered by other means.

27 Secondly, the referring court asks what consequences are to follow from the answer to that question as regards the time-limit for lodging the application for a supplementary protection certificate.

28 If the Court were to hold that a supplementary protection certificate can be based on an emergency MA, the referring court asks whether, in the present case, Sumitomo's application was not, in any event, time-barred. Article 3(1)(b) of Regulation No 1610/96 requires that the MA be valid at the date of the application for a certificate. In the present case, the emergency MA, restricted to 120 days, expired on 13 May 2004. Sumitomo's application, lodged on the following day, is therefore out of time.

29 While pointing out that the majority view favours that interpretation, the referring court notes that such an interpretation may lead to reducing the six-month time-limit laid down for the lodging of applications for certificates under Article 7(1) of Regulation No 1610/96. In the present case, Sumitomo had only four months instead of six within which to lodge its application.

30 If, however, the Court were to take the view that an emergency MA cannot form the basis of an application for a supplementary protection certificate, the referring court asks whether it is possible even so to grant a certificate relying not on the emergency MA which is no longer valid, but on a provisional MA issued more recently.

31 When the DPM rejected Sumitomo's application, it would have known that, since 8 September 2004, the German authorities had granted a provisional MA to a company in the Bayer group for a product containing the active substance at issue in the main proceedings.

At that time, the DPM's practice was to issue supplementary protection certificates, including on the basis of provisional MAs. Having regard to those factors, the referring court asks whether it is appropriate, on the basis of Sumitomo's initial application, to take the view that it is possible to issue a supplementary protection certificate on the basis of the provisional MA issued on 8 September 2004. That would amount to accepting that an application for a supplementary protection certificate can be made before the period for lodging such an application has even begun to run. Even if such a solution could be envisaged in law, the referring court asks, further, whether Sumitomo's letter of 25 November 2004, informing the DPM of the provisional MA, can be deemed to be an application for a certificate. If so, it would then have been lodged within the six-month time-limit laid down in Article 7(1) of Regulation No 1610/96. That court considers that it would be unjust to reject an application for a certificate lodged after the issue of a provisional MA on the ground that that was not the first MA within the meaning of Article 3(1)(d) of Regulation No 1610/96.

32 In those circumstances, the Bundespatentgericht has decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'1. Is Article 3(1)(b) of [Regulation No 1610/96] to be interpreted as not precluding the grant of a supplementary protection certificate for a plant protection product if a valid marketing authorisation was granted in accordance with Article 8(4) of [Directive 91/414]?

2. If Question 1 is answered in the affirmative:

Is it necessary under Article 3(1)(b) of [Regulation No 1610/96] for the marketing authorisation to be still in force at the time of application for the certificate?

3. If the answer to Question 1 is in the negative:

Is Article 7(1) of [Regulation No 1610/96] to be interpreted as meaning that an application can be lodged even before the period mentioned in that provision starts to run?'

Consideration of the questions referred

The first question

33 By its first question, the referring 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 an emergency MA has been issued under Article 8(4) of Directive 91/414.

34 Article 3(1)(b) of Regulation No 1610/96 refers to a MA granted 'in accordance with Article 4 of Directive 91/414'. It is true that, it has been held that there is no need to interpret that provision of that regulation 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 (***Hogan Lovells International***, paragraph 46).

35 However, that interpretation rests on the link of functional equivalence which exists between the criteria set out in Article 8(1) of Directive 91/414 as transitional measures and those laid down in Article 4 of that directive (***Hogan Lovells International***, paragraphs 33 to 46). There is no such link of functional equivalence between the criteria laid down in Article 8(4) of Directive 91/414 and those in Article 4 thereof.

36 It is apparent from the very definition of the emergency MA laid down in Article 8(4) of Directive 91/414 that it concerns '*plant protection products not complying with Article 4*'. That type of MA is therefore not intended to ensure that plant protection products thus authorised meet the same scientific requirements as to reliability as those granted an MA on the basis of Article 4 of Directive 91/414. Thus, Article 8(4) of that directive does not require the Member States to carry out scientific risk evaluations prior to issuing such an MA. That derogating provision does, however, strictly limit the use of that type of MA, stating that it applies only to 'special circumstances', and the issue of an emergency MA for a period not exceeding 120 days must appear '*necessary because of an unforeseeable danger which cannot be contained by other means*'.

37 In those circumstances, it is not possible to apply Article 3(1)(b) of Regulation No 1610/96 to an emergency MA, which is restricted to products which do not comply with the requirements of Article 4 of Directive 91/414 and in respect of which that directive does not require a prior scientific evaluation of the risks.

38 Accordingly, the answer to the first question is that 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 an emergency MA has been issued under Article 8(4) of Directive 91/414.

The second question

39 Having regard to the reply given to the first question, there is no need to reply to the second question referred.

The third question

40 By its third question, the referring court asks, in essence, whether Articles 3(1)(b) and 7(1) of Regulation No 1610/96 must be interpreted as precluding an application for a supplementary protection certificate being lodged before the date on which the plant protection product has obtained the MA referred to in Article 3(1)(b) of that regulation.

41 In order to answer that question, it must be recalled that 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 lodged and the date on which the first MA

in the European Union was granted (***Hogan Lovells International***, paragraph 50).

42 In accordance with that purpose, 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 (***Hogan Lovells International***, paragraph 51).

43 Since Article 3(1) of Regulation No 1610/96 expressly requires each of those conditions to be met on the date at which the application for a supplementary protection certificate is lodged, an application for such a certificate can validly be made only after a valid MA has come into being.

44 That interpretation is supported by the terms of Article 7(1) of Regulation No 1610/96, from which it is clear that the application for a certificate is to be lodged within six months of the date on which the authorisation referred to in Article 3(1)(b) of that regulation to place the product on the market as a plant protection product was granted.

45 Accordingly, the answer to the third question is that Articles 3(1)(b) and 7(1) of Regulation No 1610/96 must be interpreted as precluding an application for a supplementary protection certificate being lodged before the date on which the plant protection product has obtained the MA referred to in Article 3(1)(b) of that regulation.

Costs

46 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 (Eighth Chamber) hereby rules:

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 precluding the issue of a supplementary protection certificate for a plant protection product in respect of which an emergency marketing authorisation has been issued under Article 8(4) of Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, as amended by Commission Directive 2005/58/EC of 21 September 2005.

2. Articles 3(1)(b) and 7(1) of Regulation No 1610/96 must be interpreted as precluding an application for a supplementary protection certificate being lodged before the date on which the plant protection product has obtained the marketing authorisation referred to in Article 3(1)(b) of that regulation.

[Signatures]

*Language of the case: German