Court of Justice EU, 19 June 2014, Bayer v Patent und Markenamt

PATENT LAW

Safener must be interpreted as 'product' and 'active substances' in ABC-Vo if the substance has a toxic, phytotoxic or plant protection action of its own.

- **It follows from all the foregoing considerations that the answer to the question referred is that the term 'product' in Article 1.8 and Article 3(1) of Regulation No 1610/96, and the term 'active substances' in Article 1.3 of that regulation, must be interpreted as meaning that those terms may cover a substance intended to be used as a safener, where that substance has a toxic, phytotoxic or plant protection action of its own.**

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Court of Justice EU, 19 June 2014
(M. Ilešič, C.G. Fernlund, A. Ó Caoimh, C. Toader and E. Jarašiūnas)
JUDGMENT OF THE COURT (Third Chamber)
19 June 2014 (*)
(Reference for a preliminary ruling — Patent law — Plant protection products — Supplementary protection certificate — Regulation (EC) No 1610/96 — Articles 1 and 3 — Terms 'product' and 'active substances' — Safener)
In Case C‑11/13,
REQUEST for a preliminary ruling under Article 267 TFEU from the Bundespatentgericht (Germany), made by decision of 6 December 2012, received at the Court on 10 January 2013, in the proceedings
Bayer CropScience AG
v
Deutsches Patent- und Markenamt,
THE COURT (Third Chamber),
composed of M. Ilešič, President of the Chamber, C.G. Fernlund (Rapporteur), A. Ó Caoimh, C. Toader and E. Jarašiūnas, Judges,
Advocate General: N. Jääskinen,
Registrar: K. Malacek, Administrator,
having regard to the written procedure and further to the hearing on 21 November 2013,
after considering the observations submitted on behalf of:
– Bayer CropScience AG, by D. von Renesse, Patentanwältin,
– the Polish Government, by B. Majczyna, acting as Agent,
– the European Commission, by P. Ondrůšek and F.W. Bulst, acting as Agents,
after hearing the **Opinion of the Advocate General** at the sitting on 13 February 2014,
gives the following
Judgment
1 This request for a preliminary ruling concerns the interpretation of Articles 1 and 3 of Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ 1996 L 198, p. 30).
2 The request has been made in proceedings between Bayer CropScience AG ('Bayer') and the Deutsches Patent- und Markenamt (German Patent and Trade Mark Office) concerning the validity of a decision of 12 March 2007 by which that office refused to grant a supplementary protection certificate to Bayer.
Legal context
Directive 91/414
3 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 2006/136/EC of 11 December 2006 (OJ 2006 L 349, p. 42) ('Directive 91/414'), established uniform rules on the conditions and procedures for authorisation to place plant protection products on the market ('MA') and for their review and withdrawal. Its objective was not only to harmonise the rules relating to the conditions and procedures for approval of those products, but also to ensure a high level of protection of human and animal health and also of the environment from the threats and risks posed by unrestricted use of those products. The directive also aimed to eliminate barriers to the free movement of those products.
4 According to Article 3(1) of Directive 91/414, plant protection products could not be placed on the market and used in a Member State unless the competent authorities of that State had authorised the product in accordance with that directive.
5 Article 4 of that directive provided:
'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 [maximum residue levels (MRLs)] 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 [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 Directive 91/414 (OJ 2005 L 70, p. 1)].
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.
...'

Regulation No 1610/96

6 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.

7 Recitals 11 and 16 in the preamble to that regulation 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 [an MA] 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'.

8 Article 1 of Regulation No 1610/96 states:

'For the purposes of this Regulation, the following definitions shall apply:
1. 'plant protection products': active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:
(a) protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;
(b) influence the life processes of plants, other than as a nutrient (e.g. plant growth regulators);
(c) preserve plant products, in so far as such substances or products are not subject to special Council or Commission provisions on preservatives;
(d) destroy undesirable plants; or
(e) destroy parts of plants, check or prevent undesirable growth of plants;
2. 'substances': chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;
3. 'active substances': substances or micro-organisms including viruses, having general or specific action:
(a) against harmful organisms; or
(b) on plants, parts of plants or plant products;
4. 'preparations': mixtures or solutions composed of two or more substances, of which at least one is an active substance, intended for use as plant protection products;
5. 'plants': live plants and live parts of plants, including fresh fruit and seeds;

6. 'plant products': products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves as defined in point 5;
7. 'harmful organisms': pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, bacteria and mycoplasmas and other pathogens;
8. 'product': the active substance as defined in point 3 or combination of active substances of a plant protection product;
9. 'basic patent': a patent which protects a product as defined in point 8 as such, a preparation as defined in point 4, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;
10. 'certificate': the supplementary protection certificate.'

9 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.'

10 Article 3 of that regulation, entitled 'Conditions for obtaining a certificate', provides in paragraph 1 thereof:

'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 [MA for the product] 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 [MA for the product] as a plant protection product.'

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

11 Bayer is the owner of a European patent issued with effect for Germany and titled '*substituted isoxazolines, process for producing them, agents containing them and their use as safeners*'. That patent covers Isoxadifen, a safener.

12 On 10 July 2003, Bayer filed an application with the Deutsches Patent- und Markenamt for a supplementary protection certificate for Isoxadifen and the salts and esters thereof. That application was based on the provisional MA, granted on 21 March 2003 by the German authorities, in accordance with Article 8(1) of Directive 91/414, in respect of a plant protection product to be used as a herbicide, marketed under the name 'MaisTer'. That product is composed of Foramsulfuron, Isoxadifen and Iodosulfuron.

13 In support of its application, Bayer designated as the first MA issued in the European Union that issued by the Italian authorities, on 10 April 2001, in respect of a plant protection product marketed under the name 'Ricestar', composed of Fenoxaprop-P-ethyl and Isoxadifen-ethyl.

14 By decision of 12 March 2007, the Deutsches Patent- und Markenamt refused that application, putting forward, in essence, three grounds. First, the MA granted on 21 March 2003 was a provisional MA; secondly, the application for a supplementary protection certificate was directed at a single active substance, whereas that MA covered a combination of active substances; and, thirdly, it was impossible to rely on the MA issued on 10 April 2001 since that MA had been for a different combination of active substances than that covered by the MA granted on 21 March 2003.

15 Bayer brought an action against that decision, which is the subject of the main proceedings. The referring court notes that, since the adoption of that decision, the Court has delivered several judgments relevant to the case in the main proceedings. According to that court, in **Hogan Lovells International (C‑229/09, EU:C:2010:673)**, the Court held that a supplementary protection certificate may be issued on the basis of a provisional MA. That court adds that, in **Medeva (C‑322/10, EU:C:2011:773)** and **Georgetown University and Others (C‑422/10, EU:C:2011:776),** the Court interpreted Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1) as meaning that an application for a supplementary protection certificate in respect of a single active ingredient cannot be rejected on the ground that that is not the only active ingredient of which the medicinal product at issue is composed.

16 Having regard to those factors, the referring court takes the view that it is now possible to grant a supplementary protection certificate on the basis of the provisional MA granted on 21 March 2003 and to calculate the duration of the supplementary protection certificate taking into consideration the MA issued by the Italian authorities on 10 April 2001 for Ricestar, even though the composition of that product is not identical to that of MaisTer.

17 The referring court nevertheless has doubts as to whether it is possible to issue a supplementary protection certificate for a safener. It points out that Article 2 of Regulation No 1610/96 allows the grant of such a certificate for any product protected by a patent and subject, as a plant protection product, to an MA, in accordance with Article 4 of Directive 91/414. It states that the term 'plant protection products' is defined in Article 1(1)(a) of Regulation No 1610/96 by reference to the active substances which those products contain and whose effect is to protect plants against harmful organisms. According to the referring court, safeners

do not have this effect, but are intended to prevent the harmful effects of a herbicidal active substance, in order to increase its effectiveness.

18 Having regard to the fact that safeners have at the most an indirect effect on plants or harmful organisms, the referring court raises the issue of whether it is possible to consider that type of substance to be covered by the term 'active substances' within the meaning of Regulation No 1610/96.

19 So far as concerns the wording of Article 1 of that regulation, that court is of the opinion that a safener can be considered to be an active substance having regard to its effects on the target organisms. However, it draws attention to several sources of tension with the existing case-law should that interpretation be followed.

20 Thus, in **Massachusetts Institute of Technology (C‑431/04, EU:C:2006:291)** the Court held, concerning medicinal products for human use, that an excipient, that is to say a substance which does not have any therapeutic effect on its own, is not covered by the term 'active ingredient' in 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). That judgment of the Court could, according to the referring court, lead to the term 'active substances' being limited to substances which have a direct plant protection effect of their own. Nevertheless, that court takes the view that the means of action of a safener is not necessarily comparable to that of an excipient in a medicinal product and it points out that a safener is sometimes essential for the use of an active substance.

21 Furthermore, the referring court observes, by reference to *Söll* (C‑420/10, EU:C:2012:111), that the Court has already held that the term 'biocidal products' also covers products that act only indirectly on the target harmful organisms, so long as they contain one or more active substances necessary to the process giving rise to the action sought.

22 Moreover, that court draws attention to the fact that the entry into force of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414 (OJ 2009 L 309, p. 1) could contribute to the clarification of the terms 'product' and 'active substances'. Those terms, as they are used in Regulation No 1610/96, have been reproduced from Directive 91/414. That directive was repealed and replaced by Regulation No 1107/2009. The regulation now distinguishes between the concepts of active substances, safeners, synergists, co-formulants and adjuvants. Article 2(3)(a) of Regulation No 1107/2009 thus defines safeners as 'substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants'.

23 The referring court states that Regulation No 1610/96 was not amended after the adoption of Regulation No 1107/2009. However, on account of the link between those two regulations, the term 'active substances' should be defined in the same way for the purposes of each of them. Consequently, a supplementary protection certificate cannot be granted for a safener.

24 In addition, since 2005, on the Commission's initiative, the Federal Republic of Germany has abandoned its practice of declaring and listing safeners according to the same rules as those relating to active substances. Consequently, the referring court states that it may be impossible in practice for the owner of a patent for a safener, who wishes to obtain a supplementary protection certificate but does not have an MA for a plant protection product, to identify whether a third party has such an MA. According to that court, that may suggest that it was not intended that safeners should be treated in the same way as active substances.

25 The referring court nevertheless observes that this approach is difficult to reconcile with the fact that, under Regulation No 1107/2009, the substantive conditions for approval of a safener are very largely the same as those required for the approval of an active substance. There is a 'link of functional equivalence' between the two procedures concerned within the meaning of **Hogan Lovells International (EU:C:2010:673)**. Therefore, the procedure for obtaining an MA for a safener could last as long as that for an active substance. Having regard to the purpose of Regulation No 1610/96, that could justify the grant of a supplementary protection certificate.

26 In the present case, the referring court points out that Isoxadifen was examined in connection with a procedure for a provisional MA for a product containing two other active substances. The duration of that procedure reduced the effective duration of the protection provided by the patent. Consequently, granting a supplementary protection certificate covering that substance might be justified. However, according to that court, such an interpretation could conflict with the case-law stemming from **BASF (C‑258/99, EU:C:2001:261, paragraph 31)**, in which the Court held that the MA is not among the criteria used by Regulation No 1610/96 to define the term 'product'.

27 In those circumstances, the Federal Patent Court (Bundespatentgericht) decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'*Are the terms 'product' in Article 3(1) and Article 1.8 and 'active substances' in Article 1.3 of [Regulation No 1610/96] to be interpreted as covering a safener?*'

The question referred for a preliminary ruling

28 In order to answer the question asked by the national court, by which that court seeks to establish whether Regulation No 1610/96 allows a supplementary protection certificate to be granted in respect of a patent for a safener, it must be observed that no express provision of that regulation either specifically authorises or excludes such a possibility.

29 Article 2 of Regulation No 1610/96 provides that '*[a]ny 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'.

30 The term 'product' is defined in Article 1.8 of Regulation No 1610/96 as being 'the active substance … or combination of active substances of a plant protection product'.

31 As regards 'active substances', they are themselves defined in Article 1.3 of that regulation as '*substances or micro-organisms including viruses, having general or specific action … against harmful organisms … or … on plants, parts of plants or plant products*'.

32 The term 'active substances' is used in Article 1.1 of that regulation to define the term 'plant protection products'. That provision refers to the uses for which the active substances included in the composition of plant protection products are intended. Under that provision, those uses may be to '*protect plants or plant products against all harmful organisms or prevent the action of such organisms, … [to] influence the life processes of plants, other than as a nutrient (e.g. plant growth regulators), …[to] preserve plant products, …[to] destroy undesirable plants, or [to] destroy parts of plants, [to] check or [to] prevent undesirable growth of plants*'.

33 It follows from the above that the term 'active substances', for the purposes of the application of Regulation No 1610/96, relates to substances which have a toxic, phytotoxic or plant protection action of their own. In this regard, since Regulation No 1610/96 makes no distinction according to whether that action is direct or indirect, there is no need to restrict the term 'active substances' to those whose action may be characterised as direct (see by analogy, so far as concerns pharmaceutical products, **Chemische Fabrik Kreussler, C‑308/11, EU:C:2012:548, paragraph 36**, and, as regards biocidal products, *Söll*, EU:C:2012:111, paragraph 31).

34 Conversely, a substance with no such toxic, phytotoxic or plant protection action cannot be considered to be an 'active substance' within the meaning of Regulation No 1610/96 and, consequently, cannot give rise to the issue of a supplementary protection certificate. That interpretation corresponds to that applied in respect of medicinal products, the Court already having had the opportunity to hold that a substance with no pharmaceutical effects of its own, such as an excipient or an adjuvant, does not constitute an active ingredient and, consequently, cannot give rise to the grant of a supplementary protection certificate (**Massachusetts Institute of Technology, EU:C:2006:291, paragraph 25**, and order in **Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma, C‑210/13, EU:C:2013:762, paragraph 35**).

35 The answer to the question whether a safener is an active substance, within the meaning of Article 1.3 of Regulation No 1610/96, therefore depends on whether that substance has a toxic, phytotoxic or plant protection action of its own. If that is the case, it falls within the concept of a 'product', within the meaning of Article 1.8 of that regulation and may therefore, provided the conditions set out in Article 3 of Regulation No 1610/96 are observed, give rise to the issue of a supplementary protection certificate.

36 It is apparent from the explanations provided by the referring court and the observations submitted by Bayer and the Commission that safeners contained in the composition of plant protection products are intended to reduce the toxic effects of those products on certain plants. Safeners may thereby increase the effectiveness of a plant protection product by improving its selectivity and by limiting its toxic or ecotoxic effects. In this connection, Article 2 of Regulation No 1107/2009, which was not applicable at the date of the facts in the main proceedings, defines safeners as '*substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants'*.

37 It is for the national court before which the case in the main proceedings has been brought to ascertain, in the light of all the relevant factual and scientific evidence, whether the substance at issue in the main proceedings can, on account of its action as a safener, be classified as an 'active substance' within the meaning of Article 1.3 of Regulation No 1610/96.

38 However, it must be observed that, although that classification is a necessary condition for the issuance of a supplementary protection certificate, it is not sufficient in that respect: the four cumulative conditions listed in Article 3(1) of Regulation No 1610/96 must be fulfilled. That provision states, essentially, that a supplementary protection certificate cannot be issued unless, at the date of the application, the product is protected by a basic patent in force and has not already been the subject of a certificate. It is also necessary for that product to have obtained a valid MA 'in accordance with Article 4 of Directive [91/414] or an equivalent provision of national law', that MA being, lastly, the first authorisation of the product as a plant protection product (see, to that effect**, Hogan Lovells International, EU:C:2010:673, paragraph 51**).

39 In this connection, 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 an MA. 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 (**Hogan Lovells International, EU:C:2010:673, paragraphs 49 and 50**).

40 In circumstances such as those at issue in the main proceedings, it is therefore for the national court before which the dispute has been brought to ascertain whether, as provided in Article 3 of Regulation No 1610/96, the product containing the safener at issue in its composition has, on the territory of the Member State concerned, a valid MA as a plant protection product 'in accordance with Article 4 of Directive [91/414] or an equivalent provision of national law'. That latter condition must be read in the light of Article 2 of that regulation, from which it is apparent that the equivalent provision of national law concerned relates to the situation of plant protection products 'in respect of which the application for authorisation was lodged before Directive [91/414] was implemented by [the Member State concerned]'.

41 The referring court, the Polish Government and the Commission have all observed that, under Regulation No 91/414, safeners were not treated in the same way as active substances and, consequently, were not subject to the procedure for registration in Annex I to that directive. According to the Commission, safeners, in the context of the application of Directive 91/414, were regarded at the most merely as 'co-formulants'.

42 However, as the **Advocate General noted in point 39 of his Opinion**, while Directive 91/414 is not without importance for the application of Regulation No 1610/96, the grant of a supplementary protection certificate is still regulated autonomously by that regulation. Thus, although no safener was included in Annex I to Directive 91/414 as an active substance, that fact does not lead to the definitive conclusion that the commercial exploitation of a patent for a safener has not been delayed on account of the time required to obtain an MA 'in accordance with Article 4 of Directive [91/414] or an equivalent provision of national law' within the meaning of Article 3 of Regulation No 1610/96.

43 The procedure for an MA referred to in Article 4 of Directive 91/414 requires the submission of the dossier provided for in Annex III to that directive and intended to demonstrate, in particular, the effectiveness and the effects of a plant protection product. That dossier must include, in particular, data concerning the co-formulants referred to in point 1.4.4 of Part A of Annex III, among which safeners are included. Therefore, it is possible that the submission of a dossier in accordance with the requirements set in Annex III with a view to obtaining an MA for a plant protection product containing a safener has delayed the commercial exploitation of a patent for that safener.

44 In that regard, the referring court stated specifically that Isoxadifen was examined in connection with a procedure for a provisional MA for a product containing two other active substances and that the duration of that procedure reduced the effective duration of protection provided by the patent. Those matters, should they be established by the national court before which the case in the main proceedings has been brought, which alone has jurisdiction in this respect, may enable that court to consider the condition set out in Article 3 of Regulation No 1610/96 and relating to the existence of a valid MA obtained in accordance with Article 4 of Directive 91/414 to be fulfilled.

45 It follows from all the foregoing considerations that the answer to the question referred is that the term 'product' in Article 1.8 and Article 3(1) of Regulation No 1610/96, and the term 'active substances' in Article 1.3 of that regulation, must be interpreted as meaning that those terms may cover a substance intended to be used as a safener, where that substance has a toxic, phytotoxic or plant protection action of its own.

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 (Third Chamber) hereby rules:

The term 'product' in Article 1.8 and 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, and the term 'active substances' in Article 1.3 of that regulation, must be interpreted as meaning that those terms may cover a substance intended to be used as a safener, where that substance has a toxic, phytotoxic or plant protection action of its own.

[Signatures]

*Language of the case: German

OPINION OF ADVOCATE GENERAL

Jääskinen

delivered on 13 February 2014 (1)

Case C‑11/13

Bayer CropScience AG

v

Deutsches Patent- und Markenamt

(Request for a preliminary ruling from the Bundespatentgericht (Germany))

(Plant protection products — Supplementary protection certificate — Regulation (EC) No 1610/96 — Articles 1 and 3 — Terms 'product' and 'active substance' — Possible inclusion of a 'safener')

I – Introduction

1. The present case concerns the interpretation of Articles 1 and 3 of Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products. (2)

2. More specifically, the Bundespatentgericht (Federal Patent Court, Germany; or 'the referring court') asks the Court whether a 'safener' is also covered by the

terms ‘product’ and ‘active substance’ as defined in the above provisions in the case of an application for a supplementary protection certificate for a safener.
3. In EU law, the term ‘safener’ designates ‘substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants’. (3) The Bundespatentgericht describes safeners as antidotes for reducing the phytotoxicity of a herbicide.
4. The point at issue in this case relates to the interaction between two regimes under EU law: (i) the regime governing marketing authorisation for plant protection products; and (ii) the regime for the grant of supplementary protection certificates for such products. In the present case, the grant of marketing authorisations (MAs) is regulated by Directive 91/414/EEC (4) and the grant of supplementary protection certificates by Regulation No 1610/96.
5. The central question is as follows: does the fact that a ‘safener’ has not been treated as an ‘active substance’ in the context of the grant of the MA under Directive 91/414 prevent it from being regarded as an active substance at the next stage, that is to say, for the purposes of an application for a supplementary protection certificate under Regulation No 1610/96? The Polish Government and the Commission consider that to be the case; Bayer CropScience, on the other hand, argues that the two procedures must not be treated as being linked in that way.
6. That question has been raised before the referring court in particular because of an amendment to the legislative framework that is not yet applicable to the situation at issue: the act which replaced Directive 91/414, namely Regulation No 1107/2009, (5) introduced a specific definition of the term ‘safener’ in addition to the definition of the term ‘active substance’.
7. For the purposes of analysing the link referred to above, and in the absence of relevant case-law concerning Regulation No 1610/96, I would note that the EU legislature adopted a similar, albeit distinct, framework for medicinal products for human use: the grant of the MA for those products is regulated by Directive 2001/83/EC (6) and the grant of the supplementary protection certificate initially by Regulation (EEC) No 1768/92 (7) and now by Regulation (EC) No 469/2009. (8) Consequently, the principles identified by the Court in that context may help with the interpretation of Regulation No 1610/96.

II – Legislative framework

8. Directive 91/414 establishes uniform rules governing the authorisation, placing on the market, use and control, within the European Union, of plant protection products in commercial form and of active substances used in their composition. Its objective is not only to harmonise the rules relating to the conditions and procedures for approval of those products, but also to ensure a high level of protection of human and animal health and also of the environment from the threats and risks posed by unrestricted use of those products. The directive is also intended to eliminate barriers to the free movement of those products.
9. Article 4 of Directive 91/414 sets out the conditions for the grant of the MA. Active substances authorised for incorporation in plant protection products are listed in Annex I to Directive 91/414. Annex II to that directive sets out the requirements for a dossier to be submitted for the inclusion of an active substance in Annex I. Annex III to the directive sets out the requirements for the dossier to be submitted for the MA for a plant protection product.
10. Regulation No 1610/96 lays down, inter alia, the circumstances in which a supplementary protection certificate may be obtained for an ‘active substance’ which is already covered by an MA.
11. Under Article 1.1 of Regulation No 1610/96, ‘plant protection products’ means active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended, among other things, to protect plants or plant products against all harmful organisms or prevent the action of such organisms or to influence the life processes of plants, other than as a nutrient (such as plant growth regulators).
12. Under Article 1.2, the term ‘substances’ means chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process. Under Article 1.3, the term ‘active substances’ means substances or micro-organisms including viruses, having general or specific action against harmful organisms (point (a)) or on plants, parts of plants or plant products (point (b)).
13. Article 2 of Regulation No 1610/96 provides that 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 may be the subject of a supplementary protection certificate.
14. The certificate is granted by the Deutsches Patent- und Markenamt (German Patent and Trade Mark Office).
15. Article 3 of Regulation No 1610/96 makes the grant of the certificate subject to four conditions: (i) the product must be protected by a basic patent in force; (ii) it must have been granted an MA as a plant protection product; (iii) it must not already have been covered by a supplementary protection certificate; and (iv) the abovementioned MA must be the first authorisation of the product as a plant protection product.
16. Under Paragraph 15c of the German Law on plant protection (Pflanzenschutzgesetz), (9) in the version published on 14 May 1998, (10) as subsequently amended, (11) the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Federal Office of Consumer Protection and Food Safety; or ‘the Bundesamt’) may authorise a plant protection product for a period of up to three years, in particular where the product contains an active substance whose inclusion in Annex I to Directive 91/414 has not yet been provided

for by a decision taken in accordance with the conditions laid down in that paragraph.

III – The dispute in the main proceedings, the question referred for a preliminary ruling and the procedure before the Court

A – The dispute in the main proceedings

17. Bayer CropScience is the holder of a European patent, filed on 8 September 1994 and granted with effect for Germany, with the title 'substituted isoxazolines, process for producing them, agents containing them and their use as safeners'.

18. On 21 March 2003, Bayer CropScience obtained a provisional MA from the Bundesamt, in accordance with Paragraph 15c of the Law on plant protection, for the plant protection product MaisTer. That authorisation listed the following chemical compounds as the active substances of MaisTer: Foramsulfuron, Iodosulfuron and Isoxadifen. However, in the definitive authorisations of 12 June 2006 and of 19 December 2007, Isoxadifen, the safener at issue in the present case, is no longer listed with those active substances.

19. On 10 July 2003, Bayer CropScience lodged an application for a supplementary protection certificate for Isoxadifen at the Deutsches Patent- und Markenamt.

20. The Deutsches Patent- und Markenamt refused that application by decision of 12 March 2007 on grounds that are not relevant for the purposes of the present reference for a preliminary ruling. (12)

21. Bayer CropScience appealed against that decision. It argued that the Court of Justice had, in the meantime, delivered a number of judgments in consequence of which the grounds given for refusal could no longer be relied upon as justification.

22. In a preliminary legal analysis, the Bundespatentgericht confirmed that this was indeed the position, but pointed out that the application could nevertheless be refused on other grounds. According to the Bundespatentgericht, a safener is not necessarily an active substance and, accordingly, not necessarily a 'product' within the meaning of Regulation No 1610/96, since Regulation No 1107/2009 expressly distinguishes between active substances, safeners and synergists. This could mean that safeners are not eligible for a supplementary protection certificate.

23. The Bundespatentgericht points out that it is still unclear whether it is even possible at all for a certificate to be granted for a safener, given that it may not be a product or an active substance within the meaning of Regulation No 1610/96.

B – The question referred for a preliminary ruling and the procedure before the Court

24. On the view that, in the circumstances, the outcome of the appeal before it hinged on the interpretation of the terms 'product' and 'active substance' as defined in Article 1.8 and Article 1.3, read in conjunction with Articles 2 and 3 of Regulation No 1610/96, the Bundespatentgericht decided, by order of 6 December 2012, lodged on 10 January 2013, to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Are the terms 'product' in Article 3(1) and Article 1.8 and 'active substance' in Article 1.3 of [Regulation No 1610/96] to be interpreted as covering a safener?'

25. Bayer CropScience, the Polish Government and the European Commission have submitted written observations. A hearing was held on 21 November 2013, attended by Bayer CropScience and the Commission.

IV – Analysis

A – Introductory remarks

26. In the exploitation of inventions in the field of plant protection, account should be taken of the fact that there are three stages, which are linked but nevertheless distinct:

– the invention of a chemical compound and/or a process of manufacture or use, and the protection of that invention by a patent, known as a 'basic patent';

– the marketing of the invention, following the grant of an MA, in the form of a 'plant protection product' containing one or more active substances;

– the protection of the active substance contained in a plant protection product, beyond the duration of the patent, by a supplementary protection certificate.

27. Those three stages are governed by different legal instruments. The grant of a patent is regulated by national law or, as in the present case, by the European Patent Convention. (13) Furthermore, in the case before the referring court, the MA is regulated by Directive 91/414, whilst the supplementary protection certificate comes under Regulation No 1610/96.

28. The main proceedings concern Isoxadifen, which is a chemical compound that acts as a safener in this case and which is protected by a basic patent and, in combination with two active substances, has been granted an MA as a 'plant protection product'. In addition, Bayer CropScience has applied for a supplementary protection certificate for Isoxadifen alone.

29. The Polish Government and the Commission argue that Isoxadifen cannot be covered by a supplementary protection certificate under Regulation No 1610/96 because it is not an active substance. (14) Bayer CropScience, on the other hand, argues that a safener is covered both by the term 'product' in Article 3(1) and Article 1.8 and by the term 'active substance' in Article 1.3 of Regulation No 1610/96.

30. It seems to me that this is a significant question of interpretation, since decisions on supplementary protection certificates are taken by national authorities and current practice with regard to 'safeners' differs from one Member State to the next: in some cases, a supplementary protection certificate has been granted for a safener while, in others, as in the case before the referring court, no certificate has been granted.

31. In this Opinion I intend to propose the following interpretation: if a substance satisfies the conditions laid down in Regulation No 1610/96, it may, in my view, be eligible for a supplementary protection certificate, whether or not it is a safener under Directive 91/414 or even under Regulation No 1107/2009. In that regard, one of the key questions is whether or not the

substance at issue in the main proceedings genuinely exerts plant protection action. According to the German Government and the Commission, it does not, whilst Bayer CropScience argues that it does. This, however, is a question of fact which must be determined by the national court.

B – The purpose of the supplementary protection certificate

32. The Court found in ***Hogan Lovells*** (15) that the supplementary protection certificate is designed to establish a sufficient period of effective protection of the patent by permitting the holder to enjoy, upon the expiry of the basic patent, an additional period of exclusivity, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention by reason of the time that has elapsed between the date on which the application for the patent was filed and the date on which the first MA for the European Union was granted.

33. In that regard, the Court has observed that the supplementary protection 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. That is why the four cumulative conditions laid down in Article 3(1) of Regulation No 1610/96 must be satisfied. (16)

34. The supplementary protection certificate is thus governed by Regulation No 1610/96 and, in particular, by Article 3 of that regulation, cited by the referring court. It should be borne in mind in that connection that the Court has ruled 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. (17)

35. For the purposes of construing Article 3(1)(b) of Regulation No 1610/96, under which a plant protection product must have been granted an MA 'in accordance with Article 4 of Directive 91/414', reference must be made, more specifically, to the provisions of that directive which govern the conditions for the grant of an MA for plant protection products. (18)

36. Those provisions are based on a distinction between, on the one hand, the authorisation of an active substance, which is issued at EU level, and, on the other, the authorisation of products containing active substances, which is a matter falling within the competence of the Member States, as can be seen, in particular, from Articles 3 to 6 and Article 8 of Directive 91/414. (19)

37. Under 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 it in accordance with that directive. Article 4(1)(a) of Directive 91/414 provides that a Member State may not authorise a plant protection product unless the active substances in that product have been approved at EU level and are listed in Annex I to the directive. The conditions for the inclusion of such substances in that 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. (20)

38. It should be noted that the provisions applicable in this case — those of Regulation No 1610/96 — do not specifically define the term 'safener'. (21) The fact that such a definition of 'safener' was inserted in Regulation No 1107/2009 (the successor to Directive 91/414), thereby introducing a distinction to be made in connection with the assessment and the grant of the MA, may give rise to reflection on a number of points, but that distinction is not applicable rationae temporis, nor does it directly answer the question referred for a preliminary ruling, which concerns the interpretation of Regulation No 1610/96.

39. It must therefore be concluded that Directive 91/414 is not without importance for the application of Regulation No 1610/96 in general. The objective of that regulation is, precisely, to encourage innovations in products which satisfy the conditions laid down in Directive 91/414 and which have been granted an MA. In my view, however, the grant of a supplementary protection certificate remains separately regulated by Regulation No 1610/96.

C – Obtaining a supplementary protection certificate

40. The Court has favoured a strict approach on the supplementary protection certificate, both for plant protection products and for medicinal products for human use. (22)

41. In ***Massachusetts Institute of Technology*** (23) the Court found, with regard to medicinal products for human use, that an excipient, that is to say, a substance which does not have any therapeutic effect on its own, (24) is not covered by the term 'active ingredient' as used in Regulation No 1768/92.

42. In addition, in the order in Yissum (25) the Court stated with reference to ***Massachusetts Institute of Technology*** that the term 'product' as defined in Article 1(b) of Regulation No 1768/92 should be understood as meaning an 'active substance' or 'active ingredient' in the strict sense.

43. In the order in ***Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma***, (26) the Court found that an adjuvant cannot be regarded as an 'active ingredient' within the meaning of Article 1(b) of Regulation No 469/2009 because, on its own, it has no therapeutic effects.

44. In the present case, the German authorities have relied, inter alia, on the fact that the safener in question does not have any therapeutic effect of its own. This was disputed at the hearing by Bayer CropScience, which argued that a safener is a chemical substance producing a phytotherapic action. According to Bayer CropScience, the safener in question has direct action on the plant's metabolism, even in the absence of other plant protection products, an aspect which distinguishes it fundamentally from the situation of the adjuvant.

45. Whilst these considerations must certainly be taken into account, the fact remains that, in some cases, the Court has undertaken a more in-depth analysis of the

product's effects and has confirmed that the specific mechanism in each case should be taken into account.
46. Accordingly, in ***Chemische Fabrik Kreussler***, (27) the Court took account of specific indirect effects in the field of medicinal products for human use. It ruled that Article 1(2)(b) of Directive 2001/83 has to be interpreted as meaning that, for a substance to be regarded as exerting a 'pharmacological action' within the meaning of that provision, it is not necessary for there to be an interaction between the molecules of which it consists and a cellular constituent of the user's body, as an interaction between that substance and any cellular constituent present within the user's body may be sufficient.
47. In addition, the Court ruled in *Söll* — which concerned biocides and, in particular, the scope of Directive 98/8 (28) — that the concept of 'biocidal products' set out in Article 2(1)(a) of that directive had to be interpreted as including even products which act only by indirect means on the harmful organisms targeted, so long as they contain one or more active substances provoking a chemical or biological action which forms an integral part of a causal chain, the objective of which is to produce an inhibiting effect in relation to those organisms. (29)

D – Application to the present case

48. First, it seems to me that, contrary to the approach taken by the Commission, Regulation No 1610/96 does not distinguish between direct and indirect action, to the effect that only direct action could satisfy the conditions laid down in that regulation with regard to active substances.
49. Secondly, the purpose of the supplementary protection certificate regime is principally economic. The intention of the legislature in granting supplementary protection for plant protection inventions is, in particular, to encourage future innovation. With that in mind, it would be somewhat artificial to distinguish between two or more innovations protected by a patent, contained in the same product and the subject of a single MA, as in the present case. In my view, to grant a supplementary protection certificate for the herbicide component but to refuse it for the safener component does not seem consistent in the light of that aim and given that the safener can enhance the effectiveness of the plant protection product in question. Bayer CropScience has also argued that budgetary considerations connected with public health, which might justify a strict interpretation in the sector of medicinal products for human use, do not carry the same weight in this context.
50. Third, it is clear that Regulation No 1610/96 does not formally exclude applications for supplementary protection certificates for safeners. In addition, Bayer CropScience reported in its observations that in some Member States, such as the Czech Republic, Denmark, France, Italy, Hungary and Austria, the authorities have granted a supplementary protection certificate for the safener in question. (30)
51. That said, I cannot see anything in Regulation No 1610/96 to prevent a supplementary protection certificate from being granted for a safener, provided that that safener satisfies the necessary conditions, particularly those relating to the active substance.
52. Specifically, only a chemical substance, protected by the basic patent, which has general or specific action on plants or parts of plants within the meaning of Article 1.3.b of Regulation No 1610/96 and which, on its own or as part of a preparation containing one or more active substances, is intended to influence the life processes of plants as referred to in Article 1.1.b, may be covered by a supplementary protection certificate. That also holds true where the substance in question is a safener.
53. To my mind, it is sufficient that a chemical substance provokes a chemical or biological action which forms an integral part of a causal chain, the objective of which is to produce a general or specific plant protection action on plants or parts of plants. (31)
54. The grant of a supplementary protection certificate for the substance in question should not be precluded by the fact that that chemical or biological action is categorised as plant protection and the corresponding product as a safener when placed on the market. It seems to me that the antidotal powers of a medicinal product vis-à-vis another medicinal product, which enable it to attenuate the harmful effects of the latter, do not prevent it from being regarded as a medicinal product if it satisfies the relevant conditions. To my way of thinking, the same logic should apply mutatis mutandis to plant protection products.
55. It goes without saying that the national court will have to satisfy itself as to the genuine nature of the purported phytotherapic action.

V – Conclusion

56. In the light of the foregoing considerations, I propose that the Court answer the question referred by the Bundespatentgericht as follows:
The term 'product' in Article 3(1) and Article 1.8 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 and the term 'active substance' in Article 1.3 of that regulation must be interpreted as covering any substance that satisfies the conditions laid down in those provisions, including, as the case may be, a safener.
1 – Original language: French.
2 – OJ 1996 L 198, p. 30.
3 – See the definition given in Article 2(3)(a) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ 2009 L 309, p. 1).
4 – 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). It has been replaced with Regulation No 1107/2009.

5 – See footnote 3.

6 – Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34).

7 – Council Regulation of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1).

8 – Regulation of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1).

9 – In the version in force until 13 February 2012.

10 – BGBl. I, pp. 971, 1527 and 3512.

11 – '[t]he Law on plant protection'. This provision has now been repealed by Article 2(1) of the Law of 6 February 2012, BGBl. I, p. 148.

12 – The refusal was based, in essence, on three considerations: (i) a provisional authorisation under Paragraph 15c of the Law on plant protection was not sufficient for the grant of a certificate; (ii) the application concerned only a single active substance, whereas the authorisation covered a combination of active substances; and, lastly, (iii) it was impossible to rely on the Italian authorisation since that MA had been granted for a different combination of active substances.

13 – Signed in Munich on 5 October 1973.

14 – The present case has a connection with Case C‑229/09 Hogan Lovells International [2010] ECR I‑11335, paragraph 16. That case also concerned an application for a supplementary protection certificate. Unlike the present case, it was clear that the chemical compound at issue in that case (Iodosulfuron) was an active substance, and the point at issue was whether the supplementary protection certificate could be granted on the basis of a provisional MA. The Court answered that question in the affirmative. I note, moreover, that Iodosulfuron is one of two active substances associated with Isoxadifen in the main proceedings, the second being Foramsulfuron.

15 – Hogan Lovells International, paragraph 50.

16 – Hogan Lovells International, paragraph 51.

17 – See, to that effect, Hogan Lovells International, paragraph 32, and Case C‑482/07 AHP Manufacturing [2009] ECR I‑7295, paragraph 27.

18 – Hogan Lovells International, paragraph 33.

19 – Hogan Lovells International, paragraph 34.

20 – Hogan Lovells International, paragraph 35.

21 – It should be noted, however, that the term 'safener' appears in Annex III to Directive 91/414, which is entitled 'Requirements for the dossier to be submitted for the authorisation of a plant protection product' (in Part A, entitled 'Chemical preparations', see point 1.4, entitled 'Detailed quantitative and qualitative information on the composition of the preparation '[active substance(s) and other products]'': points 1.4.1 and 1.4.2 concern active substances and points 1.4.3 and 1.4.4 relate to other products covered by the wording, including safeners).

22 – With regard to the scope of the supplementary protection certificate, see Grubb, P.W. and Thomsen, P.R., Patents for Chemicals, Pharmaceuticals and Biotechnology, Fifth Edition, Oxford, Oxford University Press, 2010, p. 265 and, especially, p. 267.

23 – Case C‑431/04 [2006] ECR I‑4089, paragraph 25.

24 – My italics.

25 – Order of 17 April 2007 in Case C‑202/05 [2007] ECR I‑2839, paragraph 17, and Massachusetts Institute of Technology, especially paragraphs 19, 21, 23 and 24.

26 – Order of 14 November 2013 in Case C‑210/13 [2013] ECR, paragraph 35.

27 – Case C‑308/11 [2012] ECR, paragraph 36. The product in question was chlorhexidine, which reacts with the bacterial cells in the user's mouth.

28 – Directive of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ 1998 L 123, p. 1).

29 – Case C‑420/10 *Söll* [2012] ECR, paragraph 31.

30 – I would nevertheless point out that the grounds of the relevant decisions are not included in the file and that, moreover, Bayer CropScience has not produced, in so far as they may exist, decisions of the competent authorities of other Member States refusing applications.

31 – See, by analogy, *Söll*, paragraph 31.