Reports of Cases

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.

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. 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).

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).

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.

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.

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;

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.

— 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.

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.

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.

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).

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]

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.

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.

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.

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.