



City Research Online

City, University of London Institutional Repository

Citation: Bonadio, E. (2011). Supplementary Protection certificates for Plant Protection Products and Provisional Marketing Authorisation: The ECJ's Decision in Lovells v. Bayer. *The European Journal of Risk Regulation*, 2(1), pp. 115-118.

This is the unspecified version of the paper.

This version of the publication may differ from the final published version.

Permanent repository link: <http://openaccess.city.ac.uk/3656/>

Link to published version:

Copyright and reuse: City Research Online aims to make research outputs of City, University of London available to a wider audience. Copyright and Moral Rights remain with the author(s) and/or copyright holders. URLs from City Research Online may be freely distributed and linked to.

City Research Online:

<http://openaccess.city.ac.uk/>

publications@city.ac.uk

Supplementary Protection Certificates for Plant Protection Products and Provisional Marketing Authorization: The ECJ's Decision in *Lovells v. Bayer*

Enrico Bonadio*

Case C-229/09 Hogan Lovells International LLP v. Bayer CropScience AG

The European Court of Justice (ECJ) rendered a decision regarding supplementary protection certificates (SPCs) for plant protection products and provisional marketing authorisation. The ECJ clarified that SPCs for patented plant protection products may also be based on provisional marketing authorizations pursuant to Article 8(1) Directive 91/114 (author's headnote).

I. Introduction: Plant protection products, marketing authorization and supplementary protection certificates

On 11 November 2010 the European Court of Justice (ECJ) rendered an interesting decision regarding supplementary protection certificates (SPCs) for plant protection products and provisional marketing authorisation (*Case C-229/09, Hogan Lovells International LLP v. Bayer CropScience AG*).

Plant protection products, such as agricultural and horticultural pesticides, fungicides and insecticides, are nowadays more and more necessary because plant yields are often affected by destructive organisms, including weeds, pests of plants, viruses, bacteria, mycoplasmas and other pathogens. They are therefore useful to (i) protect plants against such risks, (ii) contribute to the continuing improvement in the production of food of good quality and (iii) help to ensure security of supplies. However, plant protection products may also be detrimental to plant production and also entail risks and hazards for humans, animals and the environment, particularly where they are marketed without any testing or

when they are incorrectly used. That is why Directive 91/414 concerning the placing of plant protection products on the market was adopted: its aim is to subject these products to marketing authorizations with a view to ensuring “a high standard of protection, which, in particular, must prevent the authorization of plant protection products whose risks to health, groundwater and the environment and human and animal health should take priority over the objective of improving plant production”¹. Indeed a plant protection product cannot be marketed and used in the EU unless the competent authorities of the Member State in question have granted the relevant marketing authorization pursuant to Directive 91/414².

Requirements for obtaining this administrative approval are stringent. First of all, the active substances of the products must be included in a specific list (Annex I to Directive 91/414). Substances are listed in Annex I if in the light of current scientific and technical knowledge their residues and use do not have any harmful effects on human or animal health or on groundwater or exert any unacceptable influence on the environment³. Similar requirements are provided with reference to final (plant protection)

* Enrico Bonadio, City University London. Comments are welcome and should be sent to <enrico.bonadio.1@city.ac.uk>.

1 Recital 9 Directive 91/414 of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1), as amended by Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 (OJ 2005 L 70, p. 1) (“Directive 91/414”). The general purpose of Directive 91/414 is to harmonise across EU Member States the rules on conditions and procedures for the authorization of plant protection products.

2 Article 3 Directive 91/414.

3 Article 5(1) Directive 91/414. When deciding the insertion of active substances in Annex I, the following factors should be taken into consideration: (i) an acceptable daily intake (ADI) for man, if relevant; (ii) an acceptable operator exposure level, if necessary; and (iii) an estimate of its fate and distribution in the environment and its impact on non-target species (Article 5(2) Directive 91/414). Authorizations in relation to active substances are issued at EU level. An active substance is included in Annex I for a period not exceeding 10 years, and the inclusion is renewable once or more for additional periods not exceeding 10 years (Article 5(5) Directive 91/414).

products: they should not be authorized unless it is established that *inter alia* (i) they are sufficiently effective, (ii) they have no unacceptable effect on plants or plant products, (iii) they do not cause unnecessary suffering and pain to vertebrates to be controlled, (iv) they have no harmful effect on human or animal health, directly or indirectly (for example in relation to drinking water, food or feed) and (v) they have no unacceptable influence on the environment⁴.

To guarantee the free circulation of plant production products, Article 10 Directive 91/414 provides for mutual recognition of authorizations granted by EU Member States, as long as the plant health, agricultural and environmental conditions are comparable in the countries concerned. Yet Article 11 sets forth a protective clause allowing countries to provisionally restrict or prohibit the use or sale of the plant protection product in question on its territory if it constitutes a risk to human or animal health or to the environment.

Plant protection research needs strong investment. In particular, manufacturing plant protection products often requires significant financial and human efforts. Patent protection, by offering exclusive exploitation rights to whoever comes up with new and original inventions, is meant to be a solution to stimulate and recoup these investments. Indeed, many plant protection products are covered by patents. In most countries patents last for 20 years from the time the patent application is filed⁵.

Yet, as we have seen above, the products in question must obtain regulatory approval prior to their commercialization. And the ordinary approval process is usually time-consuming and imposes substantial delays prior to the product coming on the market. Thus, where a plant protection product is the subject of a patent, such delay *de facto* reduces the effective term of patent protection, making it much less than 20 years. This clearly makes patent exploitation uneconomic. That is why Regulation 1610/96 created supplementary protection certificates (SPCs) for plant protection products subject to an administrative authorization procedure⁶. SPCs extend the life of the patent for a certain period of time in order to partly set off the above-mentioned loss of the period of patent protection. The extension aims therefore at avoiding a penalization of the competitiveness of the plant protection industry. An analogous system of supplementary protection had already been provided in relation to patented medicinal products, which are also subject to administrative authorization procedures⁷.

According to Article 3(1)(b) Regulation 1610/96, SPCs are granted in relation to plant protection products covered by a patent if *inter alia* a valid authorization to market the product in question has been granted pursuant to Article 4 Directive 91/414.

II. The facts of the case and the referral to the ECJ

The case originated from a German lawsuit.

The well-known company Bayer CropScience AG (“Bayer”) owns a European patent entitled “*aryl urea compounds, a method of preparing them, and their use as herbicides and growth regulators*”. This patent covers *inter alia* a chemical compound called “iodosulfuron”, which acts as a herbicidal substance. On 13 December 1998 an application to the German competent authority to have this substance included in Annex I to Directive 91/414 was filed by a company whose rights were afterwards transferred to Bayer. On 9 March 2000 the German authority granted said company a provisional marketing authorization for a herbicide based on “iodosulfuron” and commercially

4 Article 4(1)(b) Directive 91/414. Moreover, according to Article 4(1)(c)-(f), plant protection products will not be authorized unless: “[...] (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 [...]; (d) its residues, resulting from authorised uses, and which are of toxicological or environmental significance, can be determined by appropriate methods in general use; (e) its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product; (f) where appropriate, the MRLs [maximum residue levels] for the agricultural products affected by the use referred to in the authorisation have been set or modified in accordance with Regulation (EC) No 396/2005”. Authorizations of products containing active substances are within the competence of EU Member States.

5 A term of protection of 20 years is required by Article 33 TRIPS Agreement.

6 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) (“Regulation 1610/96”). Recital 5 Regulation 1610/96 clearly explains the needs for SPCs: “[...] at the moment, the period that elapses between the filing of an application for a patent for a new plant protection product and authorization to place the said plant protection product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research and to generate the resources needed to maintain a high level of research”. For an analysis of Regulation 1610/96 see Alice de Pastors, “Plant Protection product supplementary protection certificates”, 11 *World Patent Information* (2000), pp. 59–61.

7 Regulation (EC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, 2.7.1992, pp. 1–5).

known as “Husar”. Indeed, Member States are able to issue provisional authorizations relying on Article 8(1) Directive 91/114. The rationale of this transitional measure is the following: as the procedure for the inclusion of an active substance in Annex I may take several years, a provisional marketing authorization is needed in order to enable a gradual assessment of properties of new active substances and to make new preparations available for use in agriculture⁸. On 17 July 2003 the German Federal Court for Patents (Bundespatentgericht) granted Bayer a supplementary protection certificate for “*iodosulfuron and its C1 to C12 alkyl esters and salts including iodosulfuron-methyl-sodium salt*”. The calculation of the SPC’s duration was carried out taking into account the issue date of the provisional authorization, which was effectively the first marketing approval related to the product in question.

A third party, namely the law firm Hogan Lovells International LLP, took legal action against Bayer, claiming that the SPC in question was invalid on the ground that it had not been issued in conformity with the above-mentioned Article 3(1)(b) Regulation 1610/96⁹. Bayer argued that this provision allows the granting of SPCs only after a definitive (not provisional) authorization has been issued.

The Bundespatentgericht thus stayed the proceedings and referred the case to the ECJ, which was essentially asked whether SPCs could also be issued on the basis of provisional authorizations granted pursuant to Article 8(1) Directive 91/114.

III. The ECJ’s decision

The ECJ’s decision was straightforward. Departing from the opinion of the Advocate General, the Court held that SPCs for patented plant protection products

may also be based on provisional marketing authorizations.

The ECJ first recognized that Article 3(1)(b) Regulation 1610/96 makes reference only to the administrative authorization issued pursuant to Article 4 Directive 91/414 (*i.e.* the definitive approval); and that the wording of this provision might lead to the *a contrario* finding that SPCs cannot be available for plant protection products authorized on a provisional basis pursuant to Article 8(1) of said directive, as such a possibility has not been expressly envisaged¹⁰.

Yet, the ECJ noted, the above Article 3(1)(b) should not be interpreted exclusively on the basis of its wording, but also taking into account “*the overall scheme and objectives of the system of which it is a part*”¹¹ (“purposive” interpretation). Indeed the ECJ stressed that provisional administrative authorizations granted for plant protection products containing new active substances satisfy the same scientific conditions as to reliability as definitive marketing authorizations: *i.e.* the requirements that in light of current scientific and technical knowledge the products in question be effective and safe¹². Indeed, Article 8(1) (b) Directive 91/414 requires the Member State that grants a provisional authorization to establish that the active substance and the relevant product meet the requirements of the above mentioned Articles 5(1) and 4(1)(b)-(f) of the same directive¹³.

It is on the basis of such “functional equivalence” existing between the conditions required for definitive and provisional authorizations that the ECJ found that Article 3(1)(b) Regulation 1610/96 must be interpreted in such a manner to also allow the granting of SPCs issued on the basis of provisional authorizations¹⁴.

This finding – the ECJ stressed – is buttressed by other provisions of Regulation 1610/96. First, from a combined reading of several provisions of Regulation 1610/96¹⁵ it is clear that SPCs are issued with due account taken of the first administrative approval: and the provisional authorization under Article 8(1) Directive 91/414 is undoubtedly the first administrative approval granted to the products in question. Moreover, Article 13(3) Regulation 1610/96 states that, for the purposes of calculating the duration of SPCs, provisional first marketing authorizations will be taken into account only if they are directly followed by a definitive authorization related to the same product. As the Court put it, this provision means that SPCs can also be issued with reference to products which have only obtained provisional authorization.

8 See also the opinion of Advocate General Verica Trstenjak of 17 June 2010, paras. 46–47. The provisional approval is valid for a period not exceeding three years.

9 Indeed, Article 15(1)(a) Regulation 1610/96 provides that SPCs are invalid if they are granted contrary to the provisions of Article 3.

10 Para. 31 ECJ’s decision.

11 Para. 32 ECJ’s decision.

12 See also para. 44 ECJ’s decision.

13 See *supra* notes 3 and 4.

14 Para. 46 ECJ’s decision.

15 Paras. 47 *et seq.* ECJ’s decision.

Thus, according to the ECJ, a “systematic” interpretation of Regulation 1610/96 also supports the above finding.

IV. Concluding remarks

The ECJ’s finding that Article 3(1)(b) should be interpreted as allowing the granting of SPCs on the basis of provisional authorizations might give rise to criticism. One possible criticism could target the alleged reduced reliability of provisional approvals, given that these authorizations are speedily granted. Even the ECJ admitted that the assessment made by a EU country when dealing with an application for a provisional authorization is by nature “prospective”, and necessarily entails a greater margin of uncertainty than would be the case for an assessment carried out for definitive marketing authorizations¹⁶.

Yet, as we have seen, the Court found that the two procedures, provisional and definitive, must be considered “functionally equivalent” and thus conforming to the general aim of the authorization procedure, *i.e.* ensuring a high standard of protection against the risks to human and animal health, groundwater and the environment, *inter alia*.

What should be carefully pondered are the consequences for owners of SPCs if a definitive marketing authorization is not granted even following the issue of a provisional approval. There is no doubt that under these circumstances the SPC would expire¹⁷. However, this outcome would produce legal and economic uncertainties, to the detriment of (former) SPCs owners. Indeed, how could a company adequately prepare its strategic investments, if it feared

that its SPC – based on a mere provisional authorization – might expire as a consequence of a more thorough examination of its plant protection product?

The “functional equivalence” argument is not the only factor taken into account by the Court. The ECJ’s decision also seems to have been prompted by the general and accepted practice of most EU Member States, including Germany, Belgium, Italy, Spain, UK, France, Austria, the Netherlands and Ireland. In these countries SPCs for plant protection products are usually granted on the basis of provisional approvals issued under Article 8(1) Directive 91/414. Generally speaking, it seems that in the EU 90% of the SPCs issued in relation to these products are based on provisional authorizations¹⁸.

Bearing this widely accepted practice in mind, it is easy to understand why the ECJ has not interpreted Article 3(1)(b) Regulation 1610/96 as prohibiting the issue of SPCs on the basis of provisional authorizations only. Indeed, any such interpretation would have had dangerous spill-over effects, *i.e.* beyond the specific issue of the invalidity of the SPC in *Lovells v. Bayer*. For example, most SPCs in the EU – having been granted on the basis of provisional approvals – could have been invalidated upon the request of anyone: and this would have entailed serious economic consequences for the plant protection industry that relies so heavily on patent protection and particularly on SPCs.

¹⁶ Para. 45 ECJ’s decision.

¹⁷ See also Article 14 Regulation 1610/96.

¹⁸ See the position paper by the European Crop Protection Association of 28 September 2009, quoted in the opinion of Advocate General Verica Trstenjak, para. 84.