Supplementary Protection Certificates (SPC)

Bearbeitet von
Marco Stief, Dr. Dirk Bühler, Drs. Gabor Abbas, Thierry Caen, Kilian Schärli, Marco Spadaro, Alex Wilson, Dr. Tom Wittop Koning

1. Auflage 2016. Buch. XVIII, 241 S. In Leinen
ISBN 978 3 406 64856 4
Format (B x L): 16,0 x 24,0 cm

XXIII. Referral: AstraZeneca v. Comptroller-General of Patents, Designs and Trademarks, C-617/12 of 18 December 2012

(1) Is a Swiss marketing authorisation not granted pursuant to the administrative authorisation procedure laid down in Directive 2001/83/EC, but automatically recognised by Liechtenstein, capable of constituting the 'first authorisation to place the product on the market' for the purposes of Article 13(1) of Regulation 469/2009/EC?

(2) Does it make a difference to the answer to the first question if:

(a) the set of clinical data upon which the Swiss authority granted the marketing authorisation was considered by the European Medicines Agency as not satisfying the conditions for the grant of a marketing authorisation pursuant to Regulation 726/2004/EC; and/or

(b) the Swiss marketing authorisation was suspended after grant and was only reinstated following the submission of additional data?

(3) If Article 13(1) of Regulation 469/2009 refers solely to marketing authorisations granted pursuant to the administrative authorisation procedure laid down in Directive 2001/83/EC, does the fact that a medicinal product was first placed on the market within the EEA pursuant to a Swiss marketing authorisation automatically recognised in Liechtenstein which was not granted pursuant to Directive 2001/83/EC render that product ineligible for the grant of a supplementary protection certificate pursuant to Article 2 of Regulation 469/2009?

Grounds:

(…)

[57] In any event, in the main proceedings, according to the referring court, there may have been indirect sales of Iressa via wholesalers on the basis of the authorisation of 2 March 2004 issued by SwissMedic and, subsequently, following the suspension of that authorisation, Astrazeneca may have supplied Iressa to individual patients with the specific approval of SwissMedic. It follows that, with the grant of that Swiss authorisation, that company was in a position, in one of the EEA States, to start capitalising on its investments in research that culminated in the grant of its patent, which justifies that authorisation being regarded, as the Court held in *Novartis and Others*, as the first authorisation to place that medicinal product on the market for the purpose of Article 13(1) of Regulation No 469/2009, applied in the context of the EEA Agreement.

(…)

XXIV. Referral: Bayer CropScience v. Deutsches Patent- und Markenamt, C-11/13 of 6 December 2012

Are the terms 'product' in Article 3(1) and Article 1.8 and 'active substance' in Article 1.3 of that regulation to be interpreted as covering a safener?

XXV. Referral: GlaxoSmithKline Biologicals v. Comptroller-General of Patents, Designs and Trademarks, C-210/13 of 21 March 2013

(1) Is an adjuvant which has no therapeutic effect on its own, but which enhances the therapeutic effect of an antigen when combined with that antigen in a vaccine, an 'active ingredient' within the meaning of Article 1(b) of Regulation 469/2009/EC?

(2) If the answer to question 1 is no, can the combination of such an adjuvant with an antigen nevertheless be regarded as a 'combination of active ingredients' within the meaning of Article 1(b) of Regulation 469/2009/EC?

XXVI. Eli Lilly and Company Ltd. V. Human Genome Sciences Inc., C-493/12 of 12 December 2013

Article 3(a) of 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 must be interpreted as meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of that provision, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active ingredient is covered by a functional formula in the claims of a patent issued by the European Patents Office, Article 3(a) of that regulation does not, in principle, preclude the grant of a supplementary protection certificate for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the Convention on the Grant of European Patents and the Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court.

Grounds:

(…)

[43] In the light of the objective of Regulation No 469/2009, the refusal of an SPC application for an active ingredient which is not specifically referred to by a patent issued by the EPO relied on in support of such an application may be justified – in circumstances such as those in the main proceedings and as observed by Eli Lilly – where the holder of the patent in question has failed to take any steps to carry out more in-depth research and identify his invention specifically, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients. In such a situation, if an SPC were granted to the patent holder, even though – since he was not the holder of the MA granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention, that would undermine the objective of Regulation No 469/2009, as referred to in recital 4 in the preamble thereto.

(…)

XXVII. Georgetown University v. Octroicentrum Nederland (referred to as Georgetown II in the text) C-484/12 of 12 December 2013

In circumstances such as those in the main proceedings, where, on the basis of a basic patent and a marketing authorisation for a medicinal product consisting of a combination of several active ingredients, the patent holder has already obtained a supplementary protection certificate for that combination of active ingredients, protected by that patent within the meaning of Article 3(a) of 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, Article 3(c) of that regulation must be interpreted as not precluding the proprietor from also obtaining a supplementary

protection certificate for one of those active ingredients which, individually, is also protected as such by that patent.

XXVIII. Merck Canada Inc. v. Accord Healthcare Ltd. and others, C-555/13 of 13 February 2014

Article 13 of 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, read in conjunction with recital 9 to the same regulation, must be interpreted as meaning that it precludes the holder of both a patent and a supplementary protection certificate from relying on the entire period of validity of such a certificate, calculated in accordance with Article 13, in a situation where, pursuant to such a period, it would enjoy a period of exclusivity as regards an active ingredient, of more than 15 years from the first authorisation to be placed on the market, in the European Union, of a medicinal product consisting of that active ingredient, or containing it.

XXIX. Referral: Seattle Genetics, C-471/14 of 15 October 2014

Is the date of the first authorisation to place the product on the market in the Community pursuant to Article 13(1) of 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 determined according to Community law or does that provision refer to the date on which the authorisation takes effect under the law of the Member State in question?

If the Court's answer is that the date referred to in Question 1 is determined by Community law, which date must be taken into account — the date of authorisation or the date of notification?

XXX. Novartis v. Actavis Deutschland, C-574/11 of 9 February 2012

Articles 4 and 5 of 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 must be interpreted as meaning that, where a 'product' consisting of an active ingredient was protected by a basic patent and the holder of that patent was able to rely on the protection conferred by that patent for that 'product' in order to oppose the marketing of a medicinal product containing that active ingredient in combination with one or more other active ingredients, a supplementary protection certificate granted for that 'product' enables its holder, after the basic patent has expired, to oppose the marketing by a third party of a medicinal product containing that product for a use of the 'product', as a medicinal product, which was authorised before that certificate expired.

XXXI. Actavis v. Boehringer Ingelheim, C-577/13 of 14 November 2013

(1)(a) If a patent does not, upon grant, contain a claim that explicitly identifies two active ingredients in combination, but the patent could be amended so as to include such a claim could this patent, whether or not such an amendment is made, be relied upon as a

"basic patent in force" for a product comprising those ingredients in combination pursuant to Article 3(a) of Regulation No 469/2009/EC ("the Regulation")?

(b) Can a patent that has been amended after the grant of the patent and either (i) before and/or (ii) after grant of the SPC be relied upon as the "basic patent in force" for the purposes of fulfilling the condition set out in Article 3(a) of the Regulation?

(c) Where an applicant applies for an SPC for a product comprised of active ingredients A and B in circumstances where,

(i) after the date of application for the SPC but before the grant of the SPC, the basic patent in force, being a European Patent (UK) (the "Patent") is amended so as to include a claim which explicitly identifies A and B;

and

(ii) the amendment is deemed, as a matter of national law, always to have had effect from the grant of the Patent;

is the applicant for the SPC entitled to rely upon the Patent in its amended form for the purposes of fulfilling the Art 3(a) condition?

2. For the purposes of determining whether the conditions in Article 3 are made out at the date of the application for an SPC for a product comprised of the combination of active ingredients A and B, where (i) the basic patent in force includes a claim to a product comprising active ingredient A and a further claim to a product comprising the combination of active ingredients A and B and (ii) there is already an SPC for a product comprising active ingredient A ("Product X") is it necessary to consider whether the combination of active ingredients A and B is a distinct and separate invention from that of A alone?

3. Where the basic patent in force "protects" pursuant to Article 3(a):

(a) A product comprising active ingredient A ("Product X"); and

(b) A product comprising a combination of active ingredient A and active ingredient B ("Product Y").

And where:

(c) An authorisation to place Product X on the market as a medicinal product has been granted;

(d) An SPC has been granted in respect of Product X; and

(e) A separate authorisation to place Product Y on the market as a medicinal product has subsequently been granted.

Does the Regulation, in particular Articles 3(c), 3(d) and/or 13(1) of the Regulation preclude the proprietor of the patent being issued with an SPC in respect of Product Y? Alternatively, if an SPC can be granted in respect of Product Y, should its duration be assessed by reference to the grant of the authorisation for Product X or the authorisation for Product Y?

4. If the answer to question (1)(a) is in the negative and the answer to question l(b)(i) is positive and the answer to question (l)(b)(ii) is negative, then in circumstances where:

(a) in accordance with Art 7(1) [of the] Regulation, an application for an SPC for a product is lodged within six months of the date on which a valid authorisation to place that product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC;

(b) following the lodging of the application for the SPC, the competent industrial property office raises a potential objection to the grant of the SPC under Article 3(a) of the Regulation;

(c) following and in order to meet the aforesaid potential objection by the competent industrial property office, an application to amend the basic patent in force relied upon by the SPC applicant is made and granted;

(d) upon amendment of the basic patent in force, said amended patent complies with Article 3(a);

does the SPC Regulation prevent the competent industrial property office from applying national procedural provisions to enable (a) suspension of the application for the SPC in order to allow the SPC applicant to apply to amend the basic patent, and (b) recommencement of said application at a later date once the amendment has been granted, the said date of recommencement being

– after six months from the date on which a valid authorisation to place that product on the market as a medicinal product was granted but
– within six months of the date on which the application to amend the basic patent in force was granted?

XXXII. Arne Forsgren v. Comptroller-General of Patents, Designs and Trademarks, C-631/13 of 15 January 2015

(1) Articles 1(b) and 3(a) of 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 must be interpreted as not precluding, in principle, the possibility that an active ingredient can give rise to the grant of a supplementary protection certificate where the active ingredient is covalently bound to other active ingredients which are part of a medicinal product.

(2) Article 3(b) of Regulation No 469/2009 must be interpreted as precluding the grant of a supplementary protection certificate for an active ingredient whose effect does not fall within the therapeutic indications covered by the wording of the marketing authorisation.

Article 1(b) of Regulation No 469/2009 must be interpreted as meaning that a carrier protein conjugated with a polysaccharide antigen by means of a covalent binding may be categorised as an 'active ingredient' within the meaning of that provision only if it is established that it produces a pharmacological, immunological or metabolic action of its own which is covered by the therapeutic indications of the marketing authorisation, a matter which it is for the referring court to determine, in the light of all the facts of the dispute in the main proceedings.

Grounds:

(…)

[25] It follows that the term 'active ingredient', for the purposes of applying Regulation No 469/2009, concerns substances producing a pharmacological, immunological or metabolic action of their own. Since Regulation No 469/2009 does not draw any distinction according to whether an active ingredient is covalently bound with other substances, it is not appropriate to exclude, on that ground, the grant of an SPC for such an active ingredient.

(…)

[28] Accordingly, the answer to Question 1 is that Articles 1(b) and 3(a) of Regulation No 469/2009 must be interpreted as not precluding, in principle, the possibility that an active ingredient can give rise to the grant of an SPC where the active ingredient is covalently bound to other active ingredients which are part of a medicinal product.

(…)

[37] As was pertinently noted by the referring court, the wording of Annex I to the marketing authorisation for Synflorix makes it clear that the therapeutic indications for which Synflorix was authorised are restricted to 'active immunisation against invasive

disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants and children from 6 weeks up to 2 years of age'; that annex further states that 'there is insufficient evidence that Synflorix provides protection against … non-typeable *Haemophilus influenzae*'. It should further be noted that the European Public Assessment Report prepared by the European Medicines Agency ('EMEA') as part of the assessment of the application for a marketing authorisation for Synflorix (Assessment report for Synflorix, procedure No EMEA/H/C/000973; 'the European Public Assessment Report') states in that regard that '[s]ince the claim for protection against [acute otitis media] caused by non-typeable *H. influenzae* at this stage is not supported by clinical data there is no need for an assay of the protein D content in the specification at the level of the drug product.

(…)

A2. German Courts*

Federal Court of Justice (Bundesgerichtshof, BGH)

I. Trioxan,
X ZB 9/70 of 6 July 1971

1. Patent protection of a macromolecular chemical compound is not precluded by the fact alone that the compound cannot be identified by a complete and exact structural formula.

2. In such cases it is required and sufficient to describe the patent claim with as many information as necessary about the characteristics of a macromolecular compound of unknown structure to be able to differ its inventive character by reliably ascertainable (measurable) parameters from other reliably ascertainable parameters of macromolecular compounds not claimed, and to be able to reliably judge the prerequisites for patentability.

3. A product claim that identifies a chemical compound by the manufacturing process (product-by-process-claim), is permitted in cases where neither the structural formula of the compound is known, nor an identification of the compound by means of reliably ascertainable parameters is possible.

II. Idarubicin III,
X ZB 21/00 of 17 July 2001

The application for an SPC for a specifically named substance cannot be refused on the ground alone, a version claimed in the alternative without specification of the active ingredient to be protected would be preferable.

III. Sumatriptan,
X ZB 12/01 of 29 January 2002

1. A granted SPC has to specify precisely the product (active ingredient or combination of active ingredients according to Art. 1 lit. b RegSPC 1992) covered by the SPC.

2. The SPC can also be granted for an active ingredient not specified in the basic patent, if it is covered by the scope of protection of one claim of the basic patent. In this case it is not relevant whether the basic patent could be reduced to this active ingredient or whether this would be, due to lack of disclosure of the specific active ingredient, an inadmissible additional subject matter.

IV. Custodiol II,
X ZR 73/01 of 12 March 2002

The case law saying that the protective effect of a patent whose claim contains numeric expressions or stated measurements cannot be extended to ranges substantially deviating from those in the patent claim if this numeric expressions or stated measurements ground the novelty of the patent (cf. BGH GRUR 1984, 425 [427] – Bierklärmittel), only applies to patents whose scope of protection hasn't already to be judged by means of Art. 69 EPC or § 14 PatG 1981. The binding nature of numeric expressions or

* Headnotes only.

stated measurements within the patent claim has de lege lata not to be judged by the question, what relation they have to the state of the art. Yet this does not preclude to interpret such data also by consideration of indications of the state of the art given in the patent description.

V. Anti-Helicobacter-Präparat, X ZB 1/08 of 8 July 2008

If the marketing authorisation for a medicinal product has been issued for a single active ingredient only, even if an application in combination with the other active ingredients of a substance combination is mentioned in the authorisation, an SPC for the substance combination cannot be granted, even though if the basic patent protects the substance combination.

VI. Doxorubicin, X ZB 4/08 of 14 October 2008

For the judgement of the question, whether an active ingredient is a different one than the one a marketing authorisation has been issued for, enhancing the effectiveness alone is not decisive.

Federal Patent Court (Bundespatentgericht, BPatG)

(Headnotes or keynotes by the authors only)

VII. Abamectin, 15 W (pat) 71/97 of 21 June 1999

1. A supplementary protection certificate for medicinal products can only be granted if all prerequisites mentioned in Art. 3 [RegSPC] are fulfilled in the Member State of application and at the time of application. Therefore, the lack of basic patent in force cannot be healed by restitutio in integrum if in consequence of an overly long approval procedure the marketing authorisation was issued after expiry of the basic patent. Injustice in such cases also is beyond the limits of development of the law by judges and must be for the legislator.

2. In individual cases, due to the obligations of the DPMA to give information and to give opportunity to submit observations in accordance with § 139 ZPO and § 42 para. 3 sentence 2 PatG and § 48 PatG, it may be appropriate to make reference to legal elements or to an intended change of the yet perceptible legal position of the DPMA [with further legal references].

VIII. Porfimer, 15 W (pat) 59/03 of 23 June 2005

Assuming the wording of the [RegSPC] the time of issuance of the marketing authorisation is the time of issuance by the competent authority, i. e. the date to be found on the approval notification. The decisiveness of this date directly results from Art. 8 para. 1 lit. b [RegSPC] requiring the SPC application to contain "a copy of the authorisation to place the product on the market, as referred to in Article 3(b), in which