Supplementary protection certificate for carrier protein?

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Applications for supplementary protection certificates (SPCs) often raise interesting and sometimes difficult questions. Following a preliminary ruling from the European Court of Justice (ECJ),(1) the Supreme Court recently issued a decision in which it provided the Patent Office with supplementary guidance for further proceedings regarding the grant of an SPC.(2)

Facts

Mr Forsgren, the applicant for the SPC, owned a European patent relating to "Protein D – an IgD-binding protein of Haemophilus influenzae". Protein D is present in a pneumococcal vaccine for paediatric use named Synflorix. In March 2009 the European Commission granted marketing authorisation under EU Regulation 726/2004 to "Synflorix – pneumococcal polysaccharide conjugate vaccine (adsorbed)", a medicinal product for human use.

Annex I of the marketing authorisation stated that Synflorix was a vaccine composed of 10 pneumococcal polysaccharide serotypes, which were conjugated to carrier proteins and adsorbed into aluminium phosphate. In eight of those serotypes, Protein D was the carrier protein. The therapeutic indications set out in the marketing authorisation were as follows: "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." Annex I of the marketing authorisation also stated that the excipients of the vaccine were sodium chloride and water for injections.

The Technical Department of the Patent Office refused to grant an SPC on the grounds that Protein D was only an excipient. The Patent Office's Board of Appeal upheld the decision on the grounds that Protein D was not present as such in Synflorix, but instead was covalently bonded to other active ingredients.

Decisions

Forsgren appealed to the Supreme Patent and Trademark Adjudication Tribunal, which referred the following questions to the ECJ:

- Do Articles 1(b) and 3(a) of Regulation 469/2009 preclude the possibility that an active ingredient can give rise to the grant of an SPC solely because the active ingredient is covalently bound to other active ingredients forming part of a medicinal product?
- Does Article 3(b) of Regulation 469/2009 preclude the grant of an SPC for an active ingredient whose therapeutic effect does not fall within the therapeutic indications covered by the marketing authorisation?
- Does Article 3(b) of Regulation 469/2009 preclude the grant of an SPC for a product referred to in the marketing authorisation of a paediatric vaccine as the carrier protein of an active ingredient on the grounds that the protein, as an adjuvant, enhances the effects of an active ingredient without those effects being expressly mentioned in the marketing authorisation?(3)

The ECJ held that, for the purposes of applying Regulation 469/2009, the term 'active ingredient' concerns substances producing a pharmacological, immunological or metabolic action of their own. Since the regulation draws no distinction between whether an active ingredient is covalently bound with other substances, the ECJ held that the grant of an SPC for an active ingredient could not be prohibited on that basis.(4) On the other hand, the ECJ held that a substance which has no therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the term 'active ingredient' and, consequently, cannot give rise to the grant of an SPC.(5) Therefore, the answer to the first question was that, in principle, Articles 1(b) and 3(a) of Regulation 469/2009 do not preclude 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 the medicinal product.

With regard to the second question, the ECJ noted that the grant of an SPC requires the fulfilment of four cumulative conditions set out in Article 3 of Regulation 469/2009. Article 3 provides that an SPC can be granted only if the following conditions are met:

- At the date of application, the product must be protected by a basic patent which is in force.
- The product must not have already been the subject of an SPC.
- The product must have a valid marketing authorisation as a medicinal product.
- The marketing authorisation must be the first in relation to that product as a medicinal product.(6)

Consequently, unless a patented product has been granted marketing authorisation as a medicinal product, it may not give rise to the grant of an SPC.

Moreover, Article 4 of Regulation 469/2009 provides that the protection conferred by an SPC extends only to the use of a product covered under the marketing authorisation as a medicinal product which was authorised before the expiry of the certificate. This implies that the use of a product which has not been authorised as a medicinal product under the marketing authorisation may not be covered by an SPC. Consequently, an active ingredient whose therapeutic effects do not fall within the therapeutic indications for which the marketing authorisation was granted may not give rise to the grant of an SPC.(7) Since no trial or data concerning the therapeutic effects of Protein D on haemophilus influenzae were provided in the marketing authorisation procedure, the commercial use of the basic patent could not be delayed on this basis. This is because the ECJ considers the grant of an SPC to be contrary to Regulation 469/2009 in such circumstances, as the regulation seeks to offset (at least in part) any delay to the commercial use of a patented invention due to the time needed for the first EU marketing authorisation to be granted.

In relation to the third question, the European Commission submitted that the ECJ had already answered the question and confirmed that a substance which has no therapeutic effect – such as an adjuvant – may not be regarded as a 'product' within the meaning of Regulation 469/2009.(8) However, the ECJ noted that aluminium phosphate was used in Synflorix as an adjuvant for adsorption purposes and that sodium chloride and water for injections were used as excipients. Notwithstanding the referring court's verification, according to the marketing authorisation, Protein D was not used as an excipient or adjuvant. Therefore, the ECJ clarified that, in essence, the referring court wanted to know whether a carrier protein conjugated to a pneumococcal polysaccharide used in a vaccine for paediatric use may be regarded as a 'product' within the meaning of Regulation 469/2009 – that is, as an "active ingredient or combination of active ingredients of a medicinal product". Consequently, the ECJ had to determine whether a carrier protein used in a medicinal product which has no immunogenic effect of its own, but is covered by the marketing authorisation, can be categorised as an 'active ingredient' where, conjugated with a polysaccharide antigen by means of a covalent binding, it produces such an effect.

According to the ECJ, Regulation 469/2009 aims to provide sufficient protection in order to encourage pharmaceutical research. The protection conferred by an SPC is largely intended to cover the costs of research leading to the discovery of new products.(9) Therefore, the ECJ held that a carrier protein conjugated with polysaccharide antigen by means of covalent binding can be classified as an 'active ingredient', provided that it produces a pharmacological, immunological or metabolic action of its own, as long as that effect falls within the therapeutic indications covered by the marketing authorisation.

After a review of the ECJ's preliminary ruling, the Supreme Court (which assumed the competence of the Supreme Patent and Trademark Adjudication Tribunal as of January 1 2014) repealed the Board of Appeal's decision and referred the case back to the Technical Department of the Patent Office.

According to the preliminary ruling, the Technical Board must still verify whether Protein D when conjugated with pneumococcal polysaccharides produces a pharmacological, immunological or metabolic action of its own within the therapeutic indications covered by the marketing authorisation. The Technical Board must verify whether the therapeutic effect of Protein D falls within the therapeutic indications set out in the marketing authorisation for Synflorix. According to the marketing authorisation, Synflorix is effective only against the serotypes of streptococcus pneumoniae contained therein (ie, specific pneumococcus). Therefore, an SPC for Protein D can be granted only if it produces a pharmacological, immunological or metabolic effect in relation to these pathogenic germs. This question need not be answered on the basis of whether the ingredient is named as an active ingredient; it is sufficient that it has a pharmacological, immunological or metabolic effect. Since the ECJ based its answer on the effect that Protein D has within Synflorix, the Patent Office must invite the applicant to submit evidence on the pharmacological, immunological or metabolic effect of Protein D in the covalent binding form contained in Synflorix. The Patent Office will evaluate the submitted evidence and make a determination in relation to these effects.

Comment

From the ECJ's (less surprising) answer to the first question, the Supreme Court concluded that the existence of covalent (molecular) binding does not prevent the grant of an SPC.

According to the ECJ's answer to the second question, any possible (or probable) effects that Protein D has on haemophilus influenzae bacterium will not justify the grant of an SPC, as these were not covered by the therapeutic indications of the medicinal product. Consequently, these effects were not

covered in the marketing authorisation.

Whereas the European Commission held that qualification as an active ingredient must be derived only from the wording of the marketing authorisation, the ECJ held that the express mention of the ingredient as an active ingredient is unnecessary; the substance need only have a pharmacological, immunological or metabolic effect. Thus, the Supreme Court held that an SPC for Protein D can be granted only if it has a pharmacological, immunological or metabolic effect of its own in relation to the pathogenic germs (streptococcus pneumoniae). This must be verified on actual conditions.

It remains to be seen whether the applicant can demonstrate these effects.

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Endnotes

(1) January 15 2015, C-631/13 – Forsgren.
(2) April 22 2015, 4 Ob 20/15t (ÖBl 2015/36, 168 – Synflorix II).

(3) August 28 2013, OBp 1/13 (ecolex 2014/139 – Synflorix I).

(4) Decision C-631/13, § 25.

(5) Decision C-631/13, § 26.

(6) Decision C-631/13, § 32.

(7) Decision C-631/13, § 35.

(8) Decision C-762/13 – GlaxoSmithKline.

(9) Decision C-631/13, §§ 51, 52.

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