Calculating SPC application period based on variation of existing marketing authorisation

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The period available to apply for a supplementary protection certificate (SPC) commences only once a marketing authorisation has been obtained for a medical indication which corresponds to the relevant patent protection. Earlier marketing authorisations for a medical use outside the scope of the patent are irrelevant.

Facts

The applicant was the owner of European Patent (EP) 0 758 900 for botulinum toxin, which was used to reduce migraine pain. The patent was granted on April 10 2002. The date of application was May 2 1995. Marketing authorisations for the medicinal product Botox, which contains botulinum toxin, were granted on July 10 2000, November 19 2009 and February 3 2011. These marketing authorisations related to the indications blepharospasmus, hemifacial spasm and coexisting focal dystonia, cervical dystonia, focal spasticity and axillary hyperhidrosis. On June 12 2013 the applicant applied for an SPC, claiming that it met the criterion of timeliness, as the original authorisation for Botox did not include chronic migraines. The relevant marketing authorisation for migraines was the December 20 2012 authorisation. This marketing authorisation was considered to be the first authorisation according to Article 3(d) of the EU Regulation (469/2009).

The Patent Office rejected the application as belated, holding that the six-month term set out under Article 7(1) of Regulation 469/2009 had expired, as the amendment to the marketing authorisation did not trigger a separate application period.

In its appeal, the applicant asked that the following questions be referred to the European Court of Justice (ECJ):

- Can an amendment (eg, adding a new medical indication) to a Type II variation of an existing marketing authorisation be considered a valid authorisation under Articles 3(b) and (d) of Regulation 469/2009?
- If so, can an SPC be granted on the basis of an application to amend the marketing authorisation?

Decision

The Vienna Higher Regional Court(1) sustained the appeal and remanded the case to the Patent Office for a decision on the SPC application.

The Vienna Higher Regional Court held that according to Article 2 of Regulation 469/2009, an SPC may be granted for any patented product in a member state which is subject to a marketing authorisation before being put on the market. According to Article 3 of Regulation 469/2009, an SPC will be granted if:

- the product was protected under a basic patent at the time of application;
- a marketing authorisation has been granted;
- no other SPC has been granted for the product; and
- the marketing authorisation is the first marketing authorisation for putting the product on the market as a medicinal product.

The purpose of an SPC is to compensate for the time lost between the granting of the patent and the marketing authorisation. SPCs extend patent protection for a five-year period, which is then reduced by the time between the patent application and the first marketing authorisation (Article 13 of Regulation 469/2009).

Article 7 of Regulation 469/2009 sets out a six-month period for applicants to apply for an SPC. This period starts once marketing authorisation has been obtained. The Patent Office referred to three medicinal products which had been granted marketing authorisations on July 10 2000, November 19 2009 and February 3 2011. The same products had obtained marketing authorisations in the European Economic Area on September 21 2007, May 17 1994 and March 30 2009. The Patent Office considered the SPC application on June 12 2013 as belated, as the December 10 2013 modification to the marketing authorisation did not trigger a new application period.

According to the Vienna Higher Regional Court, the Patent Office did not consider the basic patent (EP 0 758 900 B1 (AT E215 832 T1)) to protect "the use of a botulinum toxin for the production of a medicinal product to reduce pain related to migraine headache... by administration... in... muscles, in the face, cranium or in the neck" (Claim 1). Claims 2 to 13 were construed from this claim and related to the reduction of migraine pain. The marketing authorisations to which the Patent Office referred did not relate to migraines, as the treatment of migraines was first included in the marketing authorisation on December 20 2012.

Further, the court held that the ECJ's decision in *Neurim*(2) was relevant. In *Neurim*, an active ingredient to treat insomnia had been patented. After obtaining marketing authorisation, the patent owner applied for an SPC. The UK Intellectual Property Office denied the application, as there was a prior marketing authorisation for the ingredient concerning the fertility of sheep. The ECJ held that an SPC can be granted for a specific use of a product for which marketing authorisation has already been granted where the earlier authorisation is for another use of the product (eg, a medicinal product for animals), provided that this use falls within the scope of the basic patent to which the application for the SPC relates. The court held that the word 'this' in the sentence above refers to the use according to the latest marketing authorisation – in this case, a treatment for insomnia in humans. The ECJ's decision thus clarifies that the patent and marketing authorisation must correspond to one another, and that prior authorisations do not prevent later authorisations of a patented use from being considered as a first authorisation, as prescribed under Article 3(d) of Regulation 469/2009, as long as the earlier authorisation is not protected by the basic patent. According to the court, it was irrelevant that *Neurim* related to the crossover between medical uses for humans and animals, as the essential point was that the basic patent and marketing authorisation were congruent.

According to the Vienna Higher Regional Court, the ECJ's second answer in *Neurim* supports this finding. The ECJ also clarified that the marketing authorisation of the specific product is paramount and must fall within the scope of the basic patent. In return, any earlier marketing authorisation for a use outside the patent protection is irrelevant, because it does not trigger the start of the six-month period. Therefore, the case had to be remanded back to the Patent Office for a decision on the merits.

Comment

These two cases are comparable, despite the fact that *Neurim* dealt with two basic patents and the case at hand dealt with only one. According to Article 1(c) of Regulation 469/2009, a 'basic patent' is defined as a patent that protects the use of a product which has been determined by the owner in the SPC application. In the case at hand, the basic patent described a new indication for the treatment of migraines which was not covered by previous marketing authorisations. As such, the basic patent protected this medical use of the product.

The applicant's wording – that is, "modification of the marketing authorization" – was imprecise. The

Vienna Higher Regional Court correctly stressed the need for the basic patent and marketing authorisation to be materially congruent. In case of separate protection scopes in the medical use patent, prior marketing authorisations do not prevent a later marketing authorisation from qualifying as a first marketing authorisation. In the case at hand, there was no need for a modified marketing authorisation, as there was nothing to modify. Instead, the applicant had to apply for an SPC based on the December 20 2012 marketing authorisation, which was beyond the scope of the product for which there had been earlier marketing authorisations. Further, as all of these products had separate scopes of protection, it was irrelevant that they were all protected by the same basic patent.

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Endnotes

(1) Vienna Higher Regional Court, January 21 2016 (34 R 104/15m – *Botulinum Toxin* – ÖBl 2016/20, 87).

(2) C-130/11 of July 19 2012, GRUR Int 2012. 910.