Nepafenac – no SPC for composition medicines

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The Vienna Higher Regional Court (1) recently provided valuable conclusions about the interpretation of Article 3(a) of the Supplementary Protection Certificate (SPC) Regulation(2) – specifically, whether a functional identification of an active ingredient in a basic patent is sufficient to assess whether a product can be considered as "protected by a basic patent in force".

Facts

The applicant applied for an SPC for the product Nepafenac under a basic patent (E 250923 (EP 0999825 B1)) for "Ophthalmic compositions containing galactomannan polymers and borate". The patent comprised 30 claims, of which the following are relevant:

> "*1. A topical ophthalmic liquid composition comprising one or more galactomannan(s) and one or more borate compound(s), with a slightly acidic to neutral pH, and wherein the galactomannan and the borate compound are contained in the composition in concentrations effective to create a clear gel or clear partial gel upon installation to an eye and upon increases in pH and ionic strength...*
>
> *8. A composition of any one of claims 1 to 7, further comprising one or more pharmaceutical active agent(s).*
>
> *9. A composition of claim 8, wherein the pharmaceutical active agent(s) is/are selected from the group consisting of: anti-hypertensive, anti-glaucoma, neuro-protective, anti-allergy, muco-secretagogue, angiostatic, anti-microbial, pain relieving and anti-inflammatory agents.*
>
> *10. A composition of claim 9, wherein the pharmaceutically active agent is selected from the group consisting of: betaxolol, timolol, pilocarpine, carbonic anhydrase inhibitors, prostaglandins, apraclonidine, ciprofloxacin, tobramycin, naproxen, diclofenac, suprofen, ketorolac, tetrahydrocortisol, dexamethasone, proteins and growth factors.*"

According to the applicant, the marketing authorisation for Nepafenac was granted on May 3 2013. This was the first marketing authorisation for the product. On the same day, the first marketing authorisation of the new medicinal product was granted. The same basic patent can protect several products in accordance with Article 3(a) of the SPC Regulation. In *Actavis I*(3) the European Court of Justice (ECJ) accepted the functional description "diuretics'; thus, it follows that in this case the indication "anti-inflammatory agents" in Claim 9 was acceptable.

Decisions

Patent Office

The Patent Office rejected the SPC application. It held that the indication of the function of a group of active agents (eg, anti-inflammatory agents) did not support a conclusion on a specific group of active agents. There were three different types of anti-inflammatory agent (steroidal, non-steroidal

and botanical) and each comprised numerous individual active agents that had no common structure. In addition, the basic patent did not claim anti-inflammatory agents as such but a further ingredient in combination with the subject of the patent. This further ingredient was not protected by the patent. The functional description in Claim 9 that anti-inflammatory agents may be contained in the formulation was insufficient to consider Nepafenac as protected by the basic patent.

Vienna Higher Regional Court decision

In its appeal against this decision, the applicant referred to the *Medeva* requirement(4) and argued that the functional description "anti-inflammatory" in Claim 9 fulfilled the requirement that an agent must be named in the basic patent. The Vienna Higher Regional Court disagreed.

The court held that the basic patent related to an ophthalmic liquid composition, which created a gel over the eye on application. The composition may comprise one or more pharmaceutical ingredients for the treatment or prevention of various eye diseases. As the granting of an SPC requires that the product be protected by a valid basic patent, the scope of protection must be assessed. The scope of protection of a patent is defined by the patent claims, and the description must be considered when interpreting the patent claims.

In light of the above, it had to be assessed whether the basic patent protected Nepafenac in the sense of Article 3(a) of the SPC Regulation.

The applicant referred to three ECJ decisions (*Medeva*,(5) *Actavis I*(6) and *Eli Lilly*(7)) to argue that Nepafenac fell within the scope of the basic patent, since only this medicinal product contained galactomannan and borate, as required by Claim 1. According to Article 1(b) of the SPC Regulation, the 'product' is the active ingredient or composition of active ingredients of a medicinal product – in this case, Nepafenac. Galactomannan and borate were not contained in the medicinal product as active ingredients but only as "other ingredients". Therefore, neither qualified as the product. The SPC was granted only for the product and the protection applied only to the product to which the marketing authorisation related. Therefore, the question was whether the basic patent comprised Nepafenac, which was the subject of the marketing authorisation.

The court held that the Patent Office's assessment complied with *Medeva*, because Article 3(a) of the SPC Regulation prevents an SPC from being granted for ingredients which are not identified in the patent claims.

Further, *Actavis I* did not support the applicant's position. Successive marketing of an ingredient together with other ingredients (the number of which is unlimited and which are not protected by the basic patent as such but are only described in general in the patent claims) does not mean that a multitude of SPCs can be granted; only the core of the inventive advance, which is the subject matter of the basic patent, can be protected under Article 3(c) of the SPC Regulation.(8) The Patent Office was therefore correct in assessing an ophthalmic composition which creates a gel on application to the eye as the subject of the invention and finding that the active agent Nepafenac was not covered by the patent's scope of protection.

Supreme Court decision

The Supreme Court(9) did not accept the applicant's extraordinary appeal and confirmed the Vienna Higher Regional Court's decision.

Comment

The decision in *Medeva* clarified that an SPC can be granted only if the active agents are specified in the wording of the claims. Consequently, claims such as "pharmaceutical composition comprising the pharmaceutically active agent A (and potential other ingredients)" are insufficient. However, the decision left open the requirement of specification in the claims. This question is of practical relevance, because compositions are often superior to preparations with only one active agent. In *Actavis I* and *Eli Lilly* the ECJ specified that a structural formula in the claims is sufficient to define the product. Moreover, a functional definition is sufficient, provided that it implicitly but necessarily relates to the product in question.(10) The appellate court held that the group of active ingredients described as "anti-inflammatory agents" was too broad and inhomogeneous to comprise the substance Nepafenac in this sense. In addition, the subject matter of the basic patent was not a

combination of active agents, but rather a specific ophthalmic liquid composition which creates a gel on application. Therefore, the core of the inventive advance was not the pharmaceutically active agent, but the gel-creating liquid.

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Endnotes

(1) OLG Wien, February 10 2016, 34 R 138/15m – *Nepafenac* – ÖBl 2017/13, 45.

(2) Regulation (EC) 469/2009 of the European Parliament and of the Council of May 6 2009 concerning the supplementary protection certificate for medicinal products.

(3) ECJ judgment of December 12 2013; *Actavis v Sanofi.*

(4) ECJ judgment of November 24 2011 – C-322/10 – *Medeva v Comptroller General of Patents, Designs and Trademarks.*

(5) C-322/10.

(6) C-443/12.

(7) C-493/12.

(8) C-443/12 – *Actavis I* – Margin 41.

(9) OGH judgment, August 30 2016, 4 Ob 104/16x.

(10) ECJ judgment, December 12 2013 – C-493/12 – *Eli Lilly v Human Genome Sciences.*
