

| MARCO STIEF*

If you say A, you must also say B – The first authorization pursuant to Art. 3 lit. d SPC Regulation – Comments on BPatG, decision of December 12, 2025 – 14 W (pat) 28/23

According to Art. 3 lit. d SPC Regulation, the supplementary protection certificate (SPC) requires that the underlying market authorization is the first authorization for the product in question. The Federal Patent Court (BPatG) referred the question to the ECJ as to whether a first-time veterinary drug approval fulfills this requirement, even though an approval under human drug law already existed for the same active ingredient. This article analyzes and endorses the BPatG's tendency to consider both approval regimes as independent "first approvals."

Article 3(d) of the SPC Regulation requires that the underlying marketing authorization constitutes the first authorization for the product concerned. The Federal Patent Court has asked the CJEU whether a first veterinary marketing authorization satisfies this condition even where a prior human medicinal product authorization had already been granted for the same active substance. The article endorses the court's tendency to treat both regulatory regimes as giving rise to independent "first authorizations."

I. Introduction and facts

[1] Regulation (EC) No. 469/2009 of the European Parliament and of the Council of May 6, 2009, on the supplementary protection certificate for medicinal products (hereinafter: "SPC Regulation") represents the response of the EU legislature to the finding that the period between the filing of a patent application for a new medicinal product and the granting of a marketing authorization shortens the effective patent protection in such a way that it often does not allow for an adequate return on the substantial investment in research and development (see Recital 4 SPC Regulation).

[2] The supplementary protection certificate for medicinal products created a *sui generis* exclusive right that effectively extends the patent protection for human and veterinary medicinal products, subject to the restrictions of Article 4 of the SPC Regulation. It serves to at least partially compensate for the economically unprofitable period between patent application and marketing authorization.

[3] The practical significance of this instrument for research and development can hardly be overestimated.

The development of a new drug regularly involves years of preclinical and clinical trials, significant regulatory requirements, and considerable financial investment. Although patent protection formally exists during this phase, commercial exploitation is impossible due to the lack of marketing authorization. Without the possibility of extending protection, the period of effective market exclusivity would in many cases be reduced to just a few years. The supplementary protection certificate therefore creates a decisive investment incentive by securing the refinancing of risky innovation projects and thus promoting the willingness to research new active ingredients.

[4] Art. 3 SPC Regulation regulates the conditions for the granting of a supplementary protection certificate (hereinafter: "SPC"). According to this, the product must be protected by a basic patent in force at the time of application; for the product as a medicinal product, a valid marketing authorization must have been granted in accordance with Directive 2001/83/EC (human medicinal products) or Directive 2001/82/EC (veterinary medicinal products); no SPC may have been granted for the product; and finally, the authorization in question must be the first marketing authorization for this product as a medicinal product.

[5] The Federal Patent Court (BPatG) recently had to deal with this latter requirement in the context of appeal proceedings based on the following facts:

[6] A pharmaceutical company (applicant) is the owner of a European patent (basic patent) filed on December 18, 2013, and granted with effect for the Federal Republic of Germany, among other countries. The patent protects the use of the active ingredient ciclesonide for the treatment of respiratory diseases in equines, in particular horses. The applicant conducted clinical studies on the use of ciclesonide in horses with asthma and, on this basis, received January 30, 2020, the veterinary drug approval for the marketing of the product Aser-

* Dr. iur., LL.M. (Chicago), attorney and partner, representative before the EPG, Maiwald, Munich.

¹ Ackermann PharmR 2019, 429.

vo® EquiHaler®. This was the first approved veterinary medicinal product containing the active ingredient ciclesonide; the European Medicines Agency therefore classified ciclesonide as a new active ingredient within the meaning of Article 3(2)(a) of Regulation (EC) No. 726/2004 during the approval process. Ciclesonide had already been approved in 2005 for use in humans for the treatment of asthma by another company. On June 30, 2020, the applicant filed an application with the German Patent and Trademark Office (DPMA) for the grant of an SPC for the invention protected by the basic patent. The DPMA rejected the application in a decision dated May 22, 2023. It stated as grounds that the veterinary drug approval granted on January 30, 2020, did not constitute the first approval for the marketing of the active ingredient ciclesonide as a medicinal product within the meaning of Art. 3(d) SPC Regulation due to the human drug approval already granted in 2005. The applicant lodged an appeal against this decision with the Federal Patent Court.

II. Decision of the Federal Patent Court and analysis

[7] The Federal Patent Court discontinued the proceedings by order of December 12, 2025, and referred the question to the Court of Justice of the European Union (CJEU) for a preliminary ruling on whether Article 3(d) of the SPC Regulation is to be interpreted as meaning that the marketing authorization for a product as a veterinary medicinal product constitutes the first marketing authorization for that product as a medicinal product, even if an authorization as a human medicinal product had previously been granted for the same active ingredient.

[8] In its reasoning, the Federal Patent Court states that the European case law, which deviates from the decision of the DPMA and the case law of the Federal Court of Justice, shows that the correct application of EU law is not so obvious that reasonable doubt can be ruled out. In particular, the BPatG points out that the applicant was granted an SPC in the Czech Republic, while in France and the Netherlands, the granting of an SPC was refused by court decision. The resulting risk of inconsistent interpretation and application of EU law justifies the referral question. This assessment is convincing in view of the diverging decisions.

[9] In this case, the BPatG expressly tends to regard the marketing authorization for a product as a veterinary medicinal product as the first authorization, even if an authorization under human medicinal product law had previously been granted for the same active ingredient.

[10] The previous case law of the ECJ does not provide a clear answer. The Federal Patent Court refers in particular to the decisions in *Pharmacia Italia*

Neurim, and *Santen*. It seems plausible to follow the line developed in *Neurim* for the present case.

[11] Unlike the DPMA, the ^{Paris} Court of Appeal, and the District Court of The ^{Hague}, the Federal Patent Court assumes that the ECJ did not completely abandon the *Neurim* case law with the *Santen* decision, but only partially. Since *Santen*, it has been clarified that a subsequent authorization cannot be considered a "first authorization" if it concerns the same active ingredient but has a different therapeutic indication. The constellation to be assessed here—initially approval under human medicine law, later initial approval under veterinary medicine law—is in any case not necessarily covered by this case law.

[12] This is correct. In *Pharmacia*, the ECJ ruled that the granting of an SPC based on an authorized human medicinal product is precluded if the same product had previously been authorized as a veterinary medicinal product.⁷ However, this ruling dates from 2004, while *Neurim* dates from 2012. According to the *Neurim* case law, the "first authorization" is to be understood as the first authorization that falls within the scope of protection of the basic patent specified in the SPC application.⁸ According to this, any new authorization of a patented therapeutic use of an active ingredient could justify an SPC, provided that earlier authorizations are not covered by the scope of protection of the basic patent. This broad interpretation was at odds with the older *Pharmacia* case law.

[13] With *Santen*, the ECJ expressly corrected this interpretation based on the scope of protection. However, the distinction between the first human medicinal product authorization and the first veterinary medicinal product authorization was not the subject of the *Santen* decision. This concerned exclusively the question of multiple therapeutic indications within the same regulatory regime. It therefore remains unclear whether the ECJ wanted to return completely to the *Pharmacia* line with *Santen* or merely abandoned the overstretched part of the *Neurim* case law.

² ECJ GRUR 2005, 139 – *Pharmacia Italia SpA*.

³ ECJ GRUR Int 2012, 910 – *Neurim Pharmaceuticals*.

⁴ ECJ GRUR 2020, 1071 – *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*.

⁵ Court of Appeal of Paris, decision of January 17, 2025 – RG No. 23/13461.

⁶ District Court of The Hague, judgment of May 14, 2025 – SGR 24/4927 OCT95.

⁷ ECJ GRUR 2005, 139 para. 24 – *Pharmacia Italia SpA*.

⁸ ECJ GRUR Int 2012, 910 para. 25-27 – *Neurim Pharmaceuticals*.

⁹ ECJ GRUR 2020, 1071 paras. 51-53 – *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*.

[14] The Federal Patent Court also refers to the different legal and factual requirements of the approval procedures for human and veterinary medicinal products. If an active ingredient is approved for the first time, the data already collected can typically be used for further approval within the same regulatory regime, i.e., either in human or veterinary medicinal product law. However, this is generally not possible if a human medicinal product authorization is followed by a veterinary medicinal product authorization for the first time, or vice versa, as the respective regulatory requirements differ considerably. In such cases, an independent, complete examination is usually required, which involves considerable time and expense.

[15] This difference justifies a differentiated approach. In order to take into account the purpose of the SPC Regulation—the creation of appropriate incentives for research and development—there is much to be said for classifying first-time marketing authorizations for human or veterinary medicinal products as first authorizations within the meaning of Article 3(d) of the SPC Regulation.

III. Assessment

[16] The decision of the Federal Patent Court is to be welcomed for two reasons. On the one hand, a referral to the ECJ and thus an in-depth examination of the scope of the Santen decision is overdue. On the other hand, the Federal Patent Court's tendency to differentiate between human and veterinary drug approvals is convincing.

[17] At present, the unclear legal situation is leading to divergent decisions within the European Union and thus not only to inconsistent application of EU law, but also to considerable legal uncertainty for research companies. This situation is unsatisfactory in view of the objectives of the SPC Regulation.

[18] Even the ECJ's case law to date does not in itself justify the assumption of an *acte éclairé*. Neurim has shown that Art. 3(d) SPC Regulation does not necessarily have to be understood in a strictly substance-related manner. Santen merely corrects the

, but does not rule out every conceivable differentiation.

[19] In this case, the economic dimension addressed by the Federal Patent Court should also be emphasized. If companies had no prospect of obtaining an SPC, even though they would have to conduct costly and lengthy studies again for initial approval under a different regulatory regime—for example, from human to veterinary medicine law—this could significantly impair their willingness to undertake such research programs. Such a "protection gap" would run counter to the amortization concept of the SPC Regulation.

[20] In addition, an active substance that is approved for the first time as a human or veterinary medicinal product is explicitly classified as "new" in the respective approval procedure

This classification entails a full procedure for "first authorization in the Community," including an independent assessment of safety and efficacy.¹⁰ It therefore seems systematic to take this regulatory classification into account when interpreting the term "first authorization."

[21] It seems inconsistent to first impose high regulatory hurdles on a patent holder in the context of a full initial approval procedure, but then deny them the qualification of this approval as "first approval" within the meaning of the SPC Regulation. "If you say A, you must also say B." Transferring the regulatory classification as new to the term "first authorization" could also contribute to a more uniform application across the EU, as national authorities could refer to the assessment of the European Medicines Agency.

[22] It remains to be seen how the ECJ will answer the question referred. However, the fact that clarification of this previously open and practically significant question is to be expected in the foreseeable future and that there will be a differentiated examination of the scope of Santen is to be welcomed.

¹⁰ For more details, see Stief GRUR 2025, 1343 (1346).