

# CJEU referral on SPCs for human and veterinary use

## Comments on the decision of the German Federal Patent Court seeking clarification

The German Federal Patent Court<sup>1</sup> (FPC) has recently referred a question<sup>2</sup> of considerable practical and doctrinal importance concerning Article 3(d) of Regulation (EC) No 469/2009 on Supplementary Protection Certificates (SPC), i.e., the »SPC Regulation«, to the Court of Justice of the European Union (CJEU).

The referral addresses a long-standing and unresolved issue at the intersection of marketing authorization law and the SPC regime: whether a marketing authorization for a veterinary medicinal product can qualify as the »first authorization« where the same active ingredient had previously been authorized as a human medicinal product.



<sup>1</sup> Bundespatentgericht (BPatG)

<sup>2</sup> Order of 12 December 2025 - 14 W (pat) 28/23

The case arises from the development of the veterinary medicinal product Aservo® EquiHaler®, containing the active ingredient ciclesonide. The Applicant held a European basic patent protecting the use of ciclesonide for the treatment of respiratory diseases in horses. Following a full development program, including species-specific clinical trials, a marketing authorization for the veterinary product was granted in January 2020. Notably, this authorization constituted the first approval of ciclesonide as a veterinary medicinal product and, in regulatory terms, the substance was classified as a new active substance within the meaning of EU pharmaceutical law.

Despite this, the German Patent and Trademark Office<sup>3</sup> (GPTO) rejected the application for an SPC. It argued that the requirement of Article 3(d) SPC Regulation was not fulfilled because ciclesonide had already been authorized in 2005 as a human medicinal product for the treatment of asthma. According to the GPTO, this earlier human marketing authorization constituted the »first authorization to place the product on the market as a medicinal product,« thereby precluding the grant of an SPC.

On appeal, the FPC did not decide the matter on the merits but stayed the proceedings and referred the question to the CJEU. The FPC asked, in essence, whether a marketing authorization for a veterinary medicinal product may constitute the relevant »first authorization« within the meaning of Article 3(d) SPC Regulation, notwithstanding the existence of an earlier human marketing authorization for the same active ingredient.

### Diverging case law and the need for clarification

The FPC justified its referral primarily by pointing to divergent approaches across Member States of the EU<sup>4</sup>. While an SPC based on the same constellation had reportedly been granted e.g. in the Czech Republic, courts in France and the Netherlands rejected comparable applications. This fragmentation illustrates the risk of inconsistent application of EU law and underscores the absence of a clear and uniform interpretation of Article 3(d) SPC Regulation in cross-category authorization scenarios.

Against this background, the FPC rightly concluded that the matter cannot be regarded as an *acte éclairé*<sup>5</sup>. The existing case law of the CJEU does not provide a sufficiently clear answer to the question at hand, particularly where different regulatory regimes – human versus veterinary medicinal products – are involved.

### Positioning within the CJEU's case law: Pharmacia, Neurim, and Santen

In its reasoning, the FPC carefully situates the present case within the broader framework of the CJEU's jurisprudence.

In *Pharmacia Italia* (2004)<sup>6</sup>, the CJEU held that an earlier veterinary marketing authorization could preclude an SPC based on a later human medicinal product. This decision is often invoked to support a strictly substance-based interpretation of Article 3(d) SPC Regulation, under which the first authorization of the active ingredient – irrespective of its regulatory context – is decisive. However, as the FPC implicitly recognizes, *Pharmacia* did not engage with the specific implications of distinct regulatory pathways, nor did it address the economic rationale underlying the SPC system in situations involving separate and fully independent development programs.

The later judgment in *Neurim* (2012)<sup>7</sup> introduced a more flexible approach. There, the CJEU held that a prior veterinary marketing authorization did not preclude the grant of an SPC based on a later human authorization, where the latter fell within the scope of a different basic patent and concerned a distinct use. Crucially, *Neurim* linked the concept of the »first authorization« to the first marketing authorization to fall within the limits of the protected therapeutic use of the product conferred by the basic patent. This reasoning opened the door to a more nuanced interpretation of Article 3(d) SPC Regulation, one that takes into account the specific investment and innovation underlying a given authorization.

However, in *Santen* (2020)<sup>8</sup>, the CJEU curtailed this expansive reading. It held that a marketing authorization for a new therapeutic indication cannot qualify as a »first authorization« where the active ingredient had already been authorized for another use. The Court thereby rejected the interpretation based on the scope of a patent restricted to the therapeutic use of the product that corresponds to the later MA developed in *Neurim*, at least in the context of successive indications within the same regulatory framework.

<sup>3</sup> Deutsches Patent- und Markenamt (DPMA)

<sup>4</sup> Marginal no. 17

<sup>5</sup> Marginal no. 19

<sup>6</sup> CJEU Judgment of 9 October 2004 - C-31/03

<sup>7</sup> CJEU Judgment of 19 July 2012- C-130/11

<sup>8</sup> CJEU Judgment of 9 July 2020- C-673/18



Importantly, as the FPC emphasizes, Santen **did not address situations involving different regulatory categories**. The case concerned an extension of use within the human medicinal product regime, where the applicant could rely, at least in part, on existing data and did not need to undertake a full development program. Whether the same restrictive approach should apply where a subsequent authorization requires a complete and independent regulatory dossier – such as in the transition from human to veterinary medicinal products – **remains unresolved**.

### Regulatory autonomy of human and veterinary medicinal products

This distinction lies at the heart of the present case. Human and veterinary medicinal products are governed by separate regulatory frameworks, each with its own requirements for safety, efficacy, and quality. Where an active ingredient is authorized for use in a different species, **the applicant typically cannot rely on the data underlying the earlier authorization**. Instead, it must generate new data through species-specific pre-clinical and clinical studies and submit a comprehensive regulatory dossier.

In such circumstances, the later authorization is not a mere variation or extension of an existing approval, but a stand-alone marketing authorization based on substantial additional investment. From a regulatory perspective, the

product effectively enters the market for the first time in the relevant category and is treated as a *new active substance* for that specific use context.

*This regulatory reality raises a fundamental question: can it be justified, in light of the objectives of the SPC Regulation, to disregard this independent development effort merely because the same active ingredient had previously been authorized in a different regulatory regime?*

### Teleological considerations and the compensatory rationale of the SPC system

The FPC answers this question – at least preliminarily – in the negative. It emphasizes that the SPC regime is designed to compensate pharmaceutical innovators for the time and resources required to obtain marketing authorizations. The period between patent filing and regulatory approval often significantly reduces the effective term of patent protection. SPCs aim to mitigate this effect by granting a period of additional exclusivity<sup>9</sup>.



<sup>9</sup> Marginal no. 20 - 23

According to the FPC's preliminary opinion, if an applicant is required to undergo a full and resource-intensive regulatory procedure to obtain the first veterinary marketing authorization for a given active ingredient, denying SPC eligibility on the basis of an earlier human authorization **risks undermining this compensatory rationale**. In economic terms, it would create a »protection gap« for investments made in distinct regulatory pathways, thereby weakening incentives to develop medicinal products across different species<sup>10</sup>.

This concern is particularly acute in areas such as veterinary medicine, where market sizes are often smaller and the economic viability of research projects is more sensitive to regulatory costs and timelines. A rigid, substance-based interpretation of Article 3(d) SPC Regulation could therefore have unintended consequences for innovation in these fields.

### Systematic and textual arguments

Beyond teleological considerations, the structure and wording of the SPC Regulation also support a differentiated approach. Article 3(b) SPC Regulation refers to the marketing authorization of a veterinary »or« a human medicinal product, suggesting that the Regulation recognizes these categories as distinct. This linguistic distinction indicates that the EU legislature was aware of the dual regulatory framework and did not necessarily intend for authorizations in one category to automatically preclude protection in the other.

Moreover, aligning the interpretation of Article 3(d) SPC Regulation with the regulatory classification of a product as a *new active substance* would enhance coherence between pharmaceutical law and the SPC regime. If a product is treated as »new« for the purposes of obtaining a marketing authorization - triggering a full assessment of safety and efficacy - it appears inconsistent to deny its status as a »first authorization« under the SPC framework.

### Outlook

By referring the question to the CJEU, the FPC has created an opportunity to resolve a long-standing ambiguity in EU law. The forthcoming judgment will have significant implications for pharmaceutical companies pursuing development strategies that span both human and veterinary medicinal products. It will also determine whether the SPC regime can adequately accommodate the regulatory and economic realities of cross-category innovation.

Until such clarification is provided, national authorities and courts are likely to continue adopting divergent approaches. The present referral therefore represents an important step towards restoring legal certainty and ensuring a more uniform application of Article 3(d) SPC Regulation across the European Union.



<sup>10</sup> Marginal no. 23



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