

Patent Extension Eligibility in the European Union, its Changes, and its Effects: Evidence from Medeva v. Comptroller General of Patents

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Abstract

Supplementary Protection Certificates (SPCs) restore patent driven effective exclusivity of pharmaceutical products, yet their eligibility rules have shifted repeatedly through the evolution of Court of Justice of the European Union (CJEU) case laws. This chapter examines how the Medeva judgment—a turning point in SPC jurisprudence and its claims-based test translated into examination outcomes, using the universe of SPC decisions issued by the German Patent and Trade Mark Office (DPMA). We classify examiner documents to identify which applications raised Medeva-type eligibility concerns and which CJEU cases examiners invoked. We document that combination products and large-molecule drugs face systematically higher adverse SPC decisions, and these shifted after Medeva, and that the eligibility concerns and CJEU citations are associated with such outcomes. The results show how a single line of jurisprudence “protected by a basic patent” reshaped the exclusivity available to pharmaceutical originators across the European Union.

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I. Introduction

Supplementary Protection Certificates (SPCs) occupy an unusual position in European pharmaceutical law. They are not patents in the strict sense, but they extend the protection conferred by a patent. At the same time, they are closely linked to the regulatory process, as they depend on the grant of a marketing authorization (MA) for a medicinal product. SPCs are designed to compensate pharmaceutical companies for the time lost between filing a patent and obtaining regulatory approval. Under Regulation (EC) No 469/2009, an SPC can extend exclusivity for up to five years beyond patent expiry, with an additional six months for pediatric studies (we henceforth call this the SPC regulation).¹ For high-revenue drugs, this additional period can be worth hundreds of millions of euros, making SPC eligibility a central issue in pharmaceutical intellectual property.

Despite this relatively clear objective, the SPC system has not remained stable over time. In particular, uncertainty emerged around the requirement that a product must be “protected by a basic patent” to qualify for SPC protection.² The Regulation provided limited guidance on how this requirement should be interpreted, and disputes over its meaning have repeatedly reached the Court of Justice of the European Union (CJEU). As a result, national patent offices have had to adapt their examination practices in response to evolving judicial interpretations, contributing to a degree of legal uncertainty within the SPC system.

By contrast, the equivalent system in the United States—the Patent Term Extension (PTE) that came into force with the passage of the Hatch-Waxman Act (1984) has generated far less litigation on conditions relating to its eligibility; although, overall patent litigation, especially relating to secondary patents is much higher in the United States than in Europe.^{3,4} That is partly because of the incentive Paragraph IV certifications provide to generics.

¹ Regulation 469/2009, of the European Parliament and of the Council of 6 May 2009 Concerning the Supplementary Protection Certificate for Medicinal Products, 2009 O.J. (L 152) 1 (EC).

² Frantzeska Papadopoulou, “Twenty Years of SPC Case Law: A Long Way to Go in the Quest for Clarity,” in *Developments and Directions in Intellectual Property Law: 20 Years of The IPKat*, ed. Hayleigh Bosher and Eleonora Rosati (Oxford: Oxford University Press, 2023), <https://doi.org/10.1093/oso/9780192864475.003.0035>.

³ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

⁴ C. Scott Hemphill and Bhaven N. Sampat, “Patents, Innovation, and Competition in Pharmaceuticals: The Hatch-Waxman Act after 40 Years,” *Journal of Economic Perspectives* 39, no. 2 (2025): 27–52.

Both systems, the SPC and the PTE provide extension to one only patent per drug. The US Code defines that the patent should claim either a product, a method of using a product, or a method of manufacturing a product.⁵ Similarly, the SPC regulation's Article 1(c) and Article 4 define the “basic patent” and its scope, and there a basic patent could be a product, a process, or an application of a product. Yet, the evolution of case laws and their interaction with other forms of exclusivity have led to legal uncertainty in Europe, particularly where the relationship between the patented invention and the authorized medicinal product is not straightforward, as we discuss in this chapter.

This uncertainty matters not only from a legal perspective but also from a policy perspective. SPCs play a role in balancing incentives for pharmaceutical innovation against timely access to medicines.^{6,7,8} If protection is too strong, it may delay generic entry; if it is too weak or unpredictable, it may reduce incentives to invest in new drugs. While this broader trade-off has been discussed in the economic literature, much less is known about how changes in SPC rules affect decision-making in practice.

This chapter addresses that gap by examining two related questions. First, how do CJEU rulings shape decision-making at national patent offices in practice? Second, are some types of drugs and firms disproportionately affected by changes in SPC eligibility rules? We focus on the landmark decision *Medeva v. Comptroller General of Patents* and provide an empirical analysis of SPC applications and examination outcomes at the Deutsches Patent- und Markenamt (DPMA). Using a novel dataset of 1,236 SPC applications, we examine how changes in CJEU SPC jurisprudence translated into examination outcomes at the DPMA and how these effects varied across different categories of drugs and applicants. To our knowledge, this is the first quantitative study to trace the effects of CJEU SPC case law on national patent office decision-making.

⁵ 35 U.S.C. § 156 (2018).

⁶ Margaret Kyle, “Economic Analysis of Supplementary Protection Certificates in Europe” (report, European Commission, January 30, 2017), <https://ec.europa.eu/docsroom/documents/25621/attachments/1/translations/en/renditions/native>.

⁷ Malwina Mejer, “25 Years of SPC Protection for Medicinal Products in Europe: Insights and Challenges” (report, European Commission, May 2017), <https://ec.europa.eu/docsroom/documents/26001/attachments/1/translations/en/renditions/native>.

⁸ Copenhagen Economics, “Study on the Economic Impact of Supplementary Protection Certificates, Pharmaceutical Incentives and Rewards in Europe: Final Report” (report prepared for the European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, May 2018), <https://ec.europa.eu/docsroom/documents/29521>.

We further expand our work by linking the evolution of CJEU doctrine to observable changes in examination practice. In doing so, the chapter offers a new perspective on the functioning of the SPC system. It shows not only how legal rules are interpreted at the European level, but also how they are applied, adapted, and sometimes left uncertain at the national level.

The chapter proceeds as follows. Section II introduces the SPC framework, its legislative origins, and its rationale. Section III provides a background to Medeva. Section IV describes the research question and methodology. Section V presents the data and empirical analysis, and Section VI concludes.

II. The SPC Instrument: Design, Rationale, and its History

The SPC was conceived in the late 1980s as a response to a recognized imbalance in pharmaceutical innovation incentives, similar to its US equivalent, the Hatch-Waxman Act (1984). Unlike most patented technologies, pharmaceutical products cannot be commercialized upon patent grant. Before a new drug reaches patients it must clear years of clinical testing and regulatory review. The US Food and Drug Administration (FDA) is responsible for this in the United States, while in Europe the process is more complex. Each European nation has their own national medicines agency that is responsible for reviewing and approving drugs for sale in their respective nations. However, since 1995, post the establishment of the European Medicines Agency (EMA), a parallel, centralized pathway has been created to enable approval of drugs in all EU member states simultaneously. Drug originators have the choice to either file for separate approvals at the respective nations' medicine agencies, or apply once at the central agency. For certain drugs, however, the central pathway is mandatory.

It takes approximately 12 years, from the drug discovery to them reaching the market as an approved product (measured from patent filing to MA). By the time an MA is received, the effective patent term remaining is substantially shorter than the nominal twenty-year term that a patent generally receives, leaving originators with a much shorter window making it difficult to recoup their research and development investments.

Regulation (EEC) No 1768/92, the original SPC regulation, was adopted on June 18, 1992 and entered into force EU wide on January 2, 1993.⁹ It was subsequently codified as Regulation (EC) No 469/2009, which remains as the current regulation. Prior to this, France and Italy were the only two EU states that had an SPC-like regulation in force from 1990 and 1991 respectively.¹⁰ Once a drug product has received its first MA in the European Economic Area (EEA), the holder of a basic patent covering that product may apply for an SPC to the national patent office.¹¹ If granted, the SPC extends exclusivity for a period equal to the time between patent filing and first EEA MA, minus 5 years, and this is capped at a maximum of 5 years. With the pediatric reward under Regulation (EC) No 1901/2006, a further six months may be added.¹²

The eligibility conditions are set out in Article 3 of the SPC regulation. An SPC may be granted only if: 3(a) the product is protected by a basic patent in force; 3(b) a valid MA has been granted; 3(c) the product has not already been the subject of a certificate; and 3(d) the authorization in 3(b) is the first authorization to place the product on the market as a medicinal product. Article 1(b) defines “product” as the active ingredient or combination of active ingredients of a medicinal product.

The source of interpretive difficulty is primarily Article 3(a), though the interpretation happens almost all the time in conjunction with Art. 3(b), and in some cases, including Art. 3(c) and 3(d). In Art. 3(a), the core point of contention is the meaning of a product to be “protected by a basic patent”. Drug products are frequently combinations of active ingredients, and patents are often filed early in development when the eventually authorized combination may not yet be known. In these situations, the question of whether the MA has a “basic patent” requires an interpretive judgment that the Regulation provides no guidance on how to make.

⁹ Council Regulation 1768/92, of 18 June 1992 Concerning the Creation of a Supplementary Protection Certificate for Medicinal Products, 1992 O.J. (L 182) 1 (EEC).

¹⁰ Mejer, “25 Years of SPC Protection,” 8.

¹¹ The first MA date is the first approval in the EEA, even if they are not EU member states. This includes Switzerland, even if it is not part of the EEA. *See* Case C-617/12, AstraZeneca AB v. Comptroller General of Patents, Designs & Trade Marks, ECLI:EU:C:2013:761 (Nov. 14, 2013) (order).

¹² Regulation 1901/2006, of the European Parliament and of the Council of 12 December 2006 on Medicinal Products for Paediatric Use and Amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, 2006 O.J. (L 378) 1 (EC).

We illustrate this by classifying the various drug-patent combinations that occur in practice. In the simplest case, the patent claims an active pharmaceutical ingredient (API) or a molecule and the MA covers the same API alone, i.e. there is no mismatch, having an SPC is straightforward. But, as soon as a patent explicitly claims a combination, let us say, molecules A and B, and the MA covers exactly that combination, eligibility starts entering the space of controversy. The difficulty increases when the patent claims a molecule alone but the MA and the corresponding SPC application cover two molecules where one is a novel formulation that is described in the underlying patent, and the second, a known compound or formulation, whether previously patented (and now that is expired) or not. These scenarios of mismatch and/or combinations, where the patent covers fewer active ingredients than the authorized product, was the central contested terrain of SPC eligibility throughout the 2000s, and it is the scenario that Medeva ultimately tackled, but in the process, raised new sources of ambiguity.

III. The three case law regimes: pre-Medeva, Medeva, and post-Medeva

A. The pre-Medeva “infringement test”

Prior to the Medeva judgment, SPCs were evaluated for eligibility using the “infringement test”. It means that a product is “protected by a basic patent” if such product comes within the scope of protection of the patent and would amount, failing the consent of the patent holder, to an infringement. Therefore, if a patent, that is to be extended using an SPC, claims protection on molecule A, and the MA concerns a drug containing molecule A as one (among others) of its active ingredients as well, then the drug “infringes on the patent”, and hence, the SPC is eligible. There is no actual patent infringement, but this is merely a test; and the drug “infringes” on the patent because, on the one hand, infringement in part also means infringement,¹³ and, on the other, the use of the claimed molecule A, even if together other molecules, interferes with the patent. This is how the interpretation of Articles 3(a) and 3(b) of the SPC regulation prevailed pre-Medeva. An example of its usage verbatim can be found in the Takeda judgement delivered by the Patents Court.^{14,15}

¹³ This goes back to *Wallace v. Holmes*, 29 F. Cas. 74 (C.C.D. Conn. 1871) (No. 17,100).

¹⁴ The Patents Court is a specialist court under the England and Wales High Court.

¹⁵ *Takeda Chem. Indus. Ltd. v. Comptroller General of the Patent Office* [2003] EWHC (Pat) 649 (Eng.), <https://www.bailii.org/ew/cases/EWHC/Patents/2003/649.html>.

Until 2011, there were 13 SPC related cases decided by the CJEU. These were unrelated to the issue raised in *Medeva*, and thus, there was no EU-wide interpretation of Articles 3(a) and 3(b). Rather, it was up to the national offices to interpret them. The closer we come to 2011, the more divergence we see between national courts in using the infringement test. For example, Switzerland still, after *Medeva* used the infringement test.¹⁶

At least three separate instances from national courts prior to *Medeva* interpreted Articles 3(a) and (b), similar to the CJEU's decision that came later in 2011, laying down the limits to the infringement test. These are from the respective courts of the United Kingdom, France, and Sweden relating to *Takeda*, *Abbott*, and *AB Hässle*, respectively.^{17,18,19} Eventually, *Medeva* was decided that we discuss in detail in the following section.

B. The *Medeva* judgment: Establishment of the Claims Test

The CJEU delivered the judgment on the *Medeva* case on November 24, 2011.²⁰ The patent that was in issue is EP1666057, filed by *Medeva BV Holdings* and the MAs linked to this patent are: *Infanrix IPV*, *Infanrix-IPV+Hib*, *Repevax*, and *Pediacel* for which five SPCs were sought.²¹

¹⁶ *Farmitalia* did raise an issue of whether an active ingredient that already had an SPC also covered its different salt forms or not, but the CJEU did not answer this particular question. Thus, it was on the national offices and courts (in case of disputes and appeals) to interpret the SPC regulation in light of the patent law. For a comprehensive description of the prevalence of the infringement test across Europe, see Cour de justice de l'Union européenne, Direction générale de la Bibliothèque, Recherche et Documentation, "Note de recherche: Certificat complémentaire de protection pour les médicaments" [Research Note: Supplementary Protection Certificate for Medicinal Products] (February 2018), https://curia.europa.eu/site/upload/docs/application/pdf/2024-04/ndr_certificat_complementaire_de_protection_pour_les_medicaments_fr.pdf.

¹⁷ See *Takeda*, [2003] EWHC (Pat) 649.

¹⁸ Cour d'appel [CA] Paris, Jan. 19, 2005, No. 04/14435, *Abbott Laboratories c/ Directeur INPI* (Fr.), cited in Cour de justice de l'Union européenne, "Note de recherche," 39.

¹⁹ Regeringsrätten [Supreme Administrative Court] Feb. 2, 2000, Mål nr 3248-1996, RÅ 2000 ref. 9 (Swed.) (*AB Hässle*), <https://rattspraxis.etjanst.domstol.se/sok/publicering/d083bc4f-47ae-4308-befb-31190668d2c9>.

²⁰ Note that the court delivered judgment to four more cases the next day, November 25, 2011: *Georgetown 1*, *Queensland*, *Daiichi Sankyo Company*, and *Yeda*, and we collectively refer to them as *Medeva*, because the central dispute in all of the cases boils down to Regulation 469/2009, art. 3(a)-3(b). For the rest of the cases and their facts, see IPcuria, "SPC for Medicinal Products," accessed September 1, 2026, https://ipcuria.eu/browse.php?id_category=85.

²¹ The two *Infanrix* were marketed by SmithKline Beecham (GSK), and *Repevax* and *Pediacel* were marketed by Aventis Pasteur MSD Ltd (later merged with Sanofi). For a comprehensive discussion on the facts, see the two judgments made by the England and Wales Court of Appeal and the High Court: *Medeva BV v. Comptroller General of Patents, Designs & Trade Marks* [2010] EWCA (Civ) 700 (Eng.), <https://www.bailii.org/ew/cases/EWCA/Civ/2010/700.html>, and *Medeva BV v. Comptroller General of Patents* [2010] EWHC (Pat) 68 (Eng.), <https://www.bailii.org/ew/cases/EWHC/Patents/2010/68.html>.

This patent was granted on February 18, 2009 and this patent contained two APIs.²² The four different MAs as mentioned contained up to 11 ingredients.²³ After the patent's grant in 2009, Medeva filed for five Supplementary Protection Certificates (SPCs) in the United Kingdom, asking for them to be based on the one patent in issue and the four MAs, or the four vaccines.²⁴ All the SPCs were rejected by the Comptroller General of Patents.²⁵ Then, this went to the Patents Court and then to the Court of Appeal.²⁶ The CJEU was referred to by the Court of Appeal, and then the CJEU issued its judgment on November 24, 2011. This decision was adopted throughout the European Union.

The central issue that was discussed in all these was “does this SPC satisfy 3(a) and (b) of the Regulation EC 469/2009, i.e., was the drug product protected by a basic patent”, and concurrently, “did the MA or the drug product(s) satisfy to be a valid MA for the SPC that was being sought?”²⁷ The pre-Medeva infringement test as described previously would mean all the five SPCs would be granted to Medeva BV. However, the CJEU confirming the Court of Appeal's decision ruled the following:

“On those grounds, the Court (Fourth Chamber) hereby rules:

- 1. Article 3(a) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be **interpreted as precluding the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent** relied on in support of the application for such a certificate.*

²² The two APIs are: 69 kDa antigen of *Bordetella pertussis* (commonly known as pertactin) and filamentous haemagglutinin antigen of *Bordetella pertussis*.

²³ For instance, the first MA out of the four, Pediacel, contained purified pertactin 69kDa and Pertussis adsorbed purified filamentous haemagglutinin, the two APIs and nine other ingredients, such as diphtheria toxoid and tetanus toxoid.

²⁴ Pediacel was combined twice, hence five SPCs.

²⁵ Medeva BV's SPC Applications, BL O/357/09 (UK IPO Nov. 16, 2009) (Cullen, Hearing Officer), <https://www.ipo.gov.uk/p-challenge-decision-results/o35709.pdf>.

²⁶ See Medeva, [2010] EWCA (Civ) 700; Medeva, [2010] EWHC (Pat) 68.

²⁷ Regulation 469/2009, *supra* note 1, art. 3(c).

2. *Article 3(b) of Regulation No 469/2009 must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision **does not preclude** the competent industrial property office of a Member State from granting a supplementary protection certificate for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing [authorization] is submitted in support of the application for a supplementary protection certificate contains not only that combination of the two active ingredients but also other active ingredients.”*

The ruling meant that those drugs for which the underlying patent covered fewer molecules (or more molecules) compared to the authorized drug would be under scrutiny from here on. In summary, the CJEU concluded that claims of the basic patent should name all APIs for which SPCs are being sought. Thus, the precedent changed through Medeva, i.e., rather than applying an “infringement test” to define SPC eligibility, the new test to be adopted from now on was “the claims test”.

This is not the first time such interpretation of Articles 3(a) and 3(b) have been applied, as discussed in the previous section. However, the Patent Court’s decision on Takeda came eight years before CJEU’s Medeva.²⁸ The only difference being, Tadeka did not approach the Court of Appeal, and the Court did not refer the case to the CJEU back then, because of several case-level details. Thus, there was no EU-wide conformity in interpreting Articles 3(a) and (b) until Medeva.

C. The post-Medeva cases: Lilly, Teva, Neurim, and Seattle

The Post-Medeva claims based test brought a measure of legal certainty at the European level, as the interpretation of Article 3(a) and (b) no longer needed to depend on the national offices or their courts. However, it was also more restrictive than before, that is, all the molecules in a drug had to be specified in the wording of the claims of the basic patent for the SPC to be eligible. Note that the court did not clarify *how* the molecules had to be specified. For example, in the Gilead patent later at issue in Teva, claim 27 covered “a pharmaceutical composition comprising a compound according to any one of claims 1-25 together with a pharmaceutically acceptable

²⁸ See Takeda, [2003] EWHC (Pat) 649.

carrier and optionally other therapeutic ingredients.”²⁹ Emtricitabine did not appear in the claims of the patent, yet the Gilead drug contained tenofovir and emtricitabine, and the latter molecule hinged on the phrase “optionally other therapeutic ingredients” for the SPC that was sought. Such challenges were anticipated when Medeva was decided, already sowing uncertainty in the case-law’s consistency and longevity.

Post-Medeva, there was a rise in overall SPC related disputes that were eventually taken up by the CJEU. Not all of them were Medeva-related, such as Neurim and Seattle, but were nevertheless, important cases. Thus, it is important to mention them in brief, as they appear later in the chapter’s analyses.

Neurim discussed Article 3(c) of the SPC regulation, while Seattle discussed Article 3(d). In Neurim, an old veterinary drug was repurposed and reauthorized for human use, for which a new SPC was filed, which was eventually granted after CJEU’s decision on Neurim, paving path for repurposed drugs to be considered for SPCs. Seattle, on the other hand deliberated the date of the MA, which is crucial for calculating SPC terms. In the Seattle case, the core dispute revolved around considering the MA notification date as official authorization date of the drug versus its publication in official gazettes as the official date. The CJEU concluded that the publication date has to be considered the official authorization date. This difference amounts to about three days, between the notification of MA and its publication, but this also means three extra days of SPC validity, which could, using the most conservative estimates, amount to tens of thousands of Euros.

There is a crucial difference between Seattle, Neurim, and Medeva-like cases. Seattle was a one-off case, opening and shutting, clarifying the official MA date, which changes the SPC terms by about three days. Neurim, on the other hand, in 2012 started the issue of repurposing of existing drugs which later was overruled and shut using Abraxis, delivered in 2019, and Santen, delivered in 2020. Abraxis and Santen said the first MA of a molecule, regardless its form or the type of the product, would be eligible for an SPC. As opposed to these cases, the Medeva was more uncertain and risked potentially months off of exclusivity terms, especially for combination drugs.

²⁹ European Patent No. 0 915 894 B1, cl. 27 (filed June 25, 1997).

There were specifically five cases that returned to Medeva after 2011: Actavis, Lilly, Teva, Sandoz, and Royalty Pharma, decided in between years 2013 to 2020.³⁰ The core issue in all of them were on clarifying the decision that was left out in Medeva, i.e. on *how* the molecules had to be specified in the claims. The answers evolved from the infringement test to the claims test and as of now, have converged on a two-limb test, as mentioned in Teva in 2018 and Royalty Pharma in 2020.³¹ It is somewhere in the middle of the two previous tests: a molecule not named in the claims would still be protected if a person skilled in the art is able to understand it and to specifically identify that product. Functional definitions and Markush claims or structures could therefore satisfy Article 3(a), but a general catch-all, as in the Gilead patent could not.

IV. The Effect of Medeva on Drug Research and Development

A. The effect of Medeva ruling on effective exclusivity

SPCs are not the only form of exclusivity that a drug can have. Companies routinely exploit multiple routes of exclusivity, as some are susceptible to third-party challenges. A drug receives an exclusivity of its own during its launch, and its length varies according to jurisdictions and the population the drug caters to, among others, such as orphan drug exclusivity, or pediatric extensions. The underlying patent that protects the novel drug's molecule too enjoys its exclusivity, enforced by the patent office of that jurisdiction. In addition to this patent, there are also secondary patents protecting ancillary components of the drug, such as delivery devices (if it has one, like the EpiPen), or the production processes, if those are patentable. These are only a few routes out of multiple others that the originator exploits.

While the intention of SPC is to cover a portion of exclusivity that is lost due to regulatory delays in the European Union, just like the PTE in the United States, it can well be replaced or combined with other forms of exclusivity. Due to its interactions with other exclusivities, the effect of the Medeva ruling is not straightforward to conclude. However, it is likely that Medeva (and the subsequent cases) had heterogeneous effects on drug types.

B. Research Questions and Methodology

³⁰ See IPcuria, "SPC for Medicinal Products." Note that Sandoz was settled before it could be decided by the CJEU.

³¹ See IPcuria, "SPC for Medicinal Products."

Research Questions

The previous sections have shown that the legal framework governing Supplementary Protection Certificates has evolved through a continuous interaction between European legislation, the case law of CJEU, and the examination practices of national patent offices. While Regulation (EC) No. 469/2009 establishes the general conditions under which an SPC may be granted, several of its key concepts, most notably the requirement that a product be “protected by a basic patent”, have progressively been defined through judicial interpretation. As discussed in the previous sections, successive CJEU rulings have substantially modified the interpretation of Article 3 and, consequently, the examination practices adopted by national patent offices.

Although SPCs constitute one of the most important instruments for restoring effective patent protection in the pharmaceutical industry and in the European Union, surprisingly little is known about how this evolving legal framework has affected the practical operation of the SPC system. The existing literature has mainly focused on the legal interpretation of individual judgments³² or on the economic rationale of patent term restoration,³³ while providing limited empirical evidence on how changes in judicial interpretation translate into examination outcomes, how they affect different categories of pharmaceutical innovation, and how they ultimately modify expected effective exclusivity.

This chapter addresses these questions by providing, to our knowledge, the first comprehensive empirical analysis of SPC applications and examination outcomes at the DPMA, the largest SPC-granting authority in Europe. By combining administrative records on drugs, patents and examination documents, we investigate how changes in the interpretation of SPC eligibility have affected examination outcomes and how these effects differ across drug types.

Our empirical analysis is organized around two related research questions:

³² See Papadopoulou, “Twenty Years of SPC Case Law,” 408; Frantzeska Papadopoulou, “Evergreening Exclusive Rights in Pharmaceutical Products: The Case of SPCs, Paediatric Extensions and Orphan Drugs,” in *EU Competition Law and Pharmaceuticals*, ed. Wolf Sauter, Marcel Canoy, and Jotte Mulder (Cheltenham: Edward Elgar Publishing, 2022), 33–47.

³³ The extant discussion focuses on the United States and is not limited to these papers. See Eric Budish, Benjamin N. Roin, and Heidi Williams, “Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials,” *American Economic Review* 105, no. 7 (2015): 2044–85, <https://doi.org/10.1257/aer.20131176>; and Maya Durvasula and Lisa Larrimore Ouellette, “Beyond the Pharmaceutical Patent Arms Race,” *Yale Journal on Regulation* 43 (forthcoming 2026).

1. Which drug types are more exposed to uncertainty in obtaining SPC protection and how does it change over time?

The first question concerns the heterogeneity of SPC examination outcomes. Pharmaceutical innovation encompasses technologies characterized by markedly different scientific complexity, regulatory pathways and patenting strategies. Small-molecule drugs, vaccines, monoclonal antibodies and other biologics differ substantially in the way patents protect the underlying inventions and in the relationship between patents and authorized medicinal products. These differences may generate systematic variation in both the demand for SPC protection and the likelihood of adverse examination outcomes. We therefore ask whether some classes of pharmaceutical products are systematically more exposed to uncertainty in obtaining SPC protection than others, whether this heterogeneity is associated with observable characteristics of drugs, and whether it changes over time. In particular we investigate whether distinct classes of drugs, specifically distinguishing between small and large molecules (we split large molecules into vaccines, monoclonal antibodies, and non-monoclonal antibodies), are disproportionately subjected to adverse decisions, defined as rejections or applicant withdrawals. We also look at the statistics over time, specifically splitting the period into two: pre- and post-Medeva.

2. To what extent did changes in CJEU case law modify the examination practice of the DPMA and contribute to observed SPC outcomes?

The second question concerns the transmission of CJEU jurisprudence into national examination practice. The Medeva judgment and the subsequent line of Article 3 decisions redefined the interpretation of SPC eligibility. We examine whether these judicial developments altered the reasoning adopted by DPMA examiners, whether they changed the probability of adverse examination outcomes, and whether these effects were concentrated in particular classes of pharmaceutical products. Also, we ask how rapidly and to what extent changes in European case law are incorporated into administrative decision-making at the national level. In so doing we also ask whether these adverse events reflect routine administrative

attrition by the DPMA, or if they are directly correlated with structural changes in examination rules triggered by Medeva.

Methodology

To address these research questions, the empirical analysis combines three complementary approaches.

First, we provide a comprehensive descriptive analysis of SPC activity in Germany using a novel database of SPC applications filed at the DPMA. We document the evolution of SPC applications and examination outcomes over time and analyze their heterogeneity across authorization cohorts, and different classes of pharmaceutical products, including small molecules, vaccines, monoclonal antibodies and other biologics. This descriptive evidence allows us to characterize the distribution of grants, rejections and withdrawals and to identify the product categories most exposed to adverse SPC outcomes.

Second, we quantify these differences by estimating econometric models of the probability of an adverse SPC outcome. Specifically, we estimate logit models relating the likelihood of rejection or withdrawal to drug characteristics, authorization cohorts and their interactions. The estimated marginal effects allow us to assess whether particular classes of pharmaceutical products are systematically associated with higher probabilities of adverse examination outcomes, after controlling for cohort effects. These estimates complement the descriptive evidence by providing a statistical assessment of the heterogeneity in SPC examination outcomes.

Third, we examine how changes in CJEU jurisprudence have been incorporated into national examination practice. To do so, we exploit the complete corpus of examination documents produced by the DPMA during the prosecution of each SPC application. We combine conventional text-searches with large language models (LLMs) to identify references to CJEU judgments, classify the legal issues discussed by patent examiners, distinguish examiner reasoning from applicants' arguments, and reconstruct the evolution of the legal doctrines underlying SPC examination. This approach allows us to move beyond simple citation counts and identify the substantive role played by individual CJEU decisions, particularly Medeva and the subsequent Article 3 case law, in shaping administrative decision-making.

Taken together, these complementary approaches allow us to connect changes in European judicial interpretation with observable changes in national examination outcomes. More generally, they provide new empirical evidence on how evolving legal doctrines are translated into administrative practice and how this process affects the effective operation of the SPC system.

More generally, the empirical evidence presented in this chapter contributes to understanding how legal interpretation influences the effective duration of pharmaceutical exclusivity. Rather than viewing SPCs as a static legal instrument, our analysis highlights how changes in judicial doctrine modify the practical availability of patent extensions and, consequently, the incentives facing pharmaceutical innovators.

V. The Empirical Record: German SPC Decisions

A. Data

To conduct our empirical analysis, we construct a novel, comprehensive dataset by exploiting and merging information across three distinct administrative and proprietary databases. Specifically, we integrate patent and Supplementary Protection Certificate (SPC) records from the DPMA with regulatory MA data from the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM)—the regulatory body in Germany responsible for the authorization of medicinal products and medical devices. Finally, we merge these public records with proprietary drug-level data from Synapse’s Patsnap (henceforth Patsnap).

We start with a universe of 2027 SPCs that are linked to patents listed at the DPMA register.³⁴ Upon cleaning, this reduces to 1,236 SPCs that relate to 806 drugs that we use in this chapter.³⁵ We take out 791 SPCs because of the following reasons: 247 are plant SPC (irrelevant to this chapter), 185 are unlinkable to BfArM, 178 were pending at the time of the sample construction, and 181 SPCs cannot be connected to Patsnap.^{36,37} Using Patsnap, we obtain drug-

³⁴ We obtain this universe of SPCs filed at the DPMA by scraping the DPMA register. We explain the scraping pipeline in the Appendix.

³⁵ One drug can have multiple SPCs. In rare cases, one SPC links to multiple drugs.

³⁶ Of the 182 SPCs that do not have authorization numbers in BfArM, 131 are veterinary drugs and 51 have non-German authorization numbers. We hand-check these 51 SPCs to ensure we are not leaving out important drugs. A bulk of these foreign authorization numbers link to medical devices, or are nuclear medicines.

³⁷ The 180 SPCs that do not have drug level data from Patsnap are mostly (132 SPCs) from the pre-2000 era, but these drugs are recorded as authorized drugs in BfArM.

level information, such as drug types (small molecules, vaccines, biologics, etc.), Anatomical Therapeutic Chemical (ATC) code, indications, and drug originator company names.³⁸ We start our analysis with these 1,236 SPCs. In the Appendix, we provide a detailed account of the attrition.

For the drugs authorized on or after 1997, we obtain the examination documents released by the DPMA examiners. If the documents are publicly accessible, we scrape them. Those that are not, we request their disclosure to the DPMA. We obtain 99.4 percent of the examination documents for drugs that are authorized between 1997 to 2021. Using the documents, we go beyond comparing granted and adverse SPCs; we explain why an SPC might receive an adverse decision.

On average, an SPC has 12 to 13 examination documents. Some are administrative files, such as notification of filing of the SPC by the applicant, a follow-up by the same on an approximate decision date, or an appeal to reconsider their application. And, there are about 1 to 2 documents per SPC that are generated by the examiner, pertaining to an interim examination report or a final decision. We use Optical Character Recognition (OCR) on all the available documents, and then categorize them as applicant or examiner-submitted. Then, we search for CJEU case names using a keyword search.³⁹ Then, we pass the OCR'ed text through a Large Language Model (LLM) to extract metadata about the documents.⁴⁰ Specifically, we output the following per examination document: the date on which the file was generated (extracting the embedded dates), the author of the document (examiner, applicant, or others), the examination stage in which the document was generated (interim, final, response, notification, appeal, annex, other), a conclusion at the time of the document's generation (did the examiner concluded for the SPC to be granted, rejected, withdrawn, or was it unclear from that document), a reason for the conclusion (obtained verbatim from the document), whether the SPC examination was halted pertaining to an ongoing and related CJEU case, the cited CJEU cases, a reason for citing the case, and the cited articles from EC-469/2009.

³⁸ We show counts in the Appendix that the 382 SPCs for which we do not have adequate information through either BfArM or Patsnap do not qualitatively change our findings.

³⁹ For example, we count the occurrence of either the word 'Medeva' (and its variations) or the CJEU case number 'C-322/10' in the raw OCR'ed documents.

⁴⁰ We report the results using OpenAI's GPT-4o mini and GPT-5 mini, and we validate them using xAI and Gemini.

Then, we do a second stage of LLM classification: we distinguish routine adverse SPC outcomes with those that invoke Medeva, i.e. we classify each SPC on whether its examination involved a Medeva-type SPC eligibility issue. For each SPC, we pass all examiner-authored interim and final documents together to the LLM and ask it to provide an indicator called the “Medeva-issue indicator”. The model determines whether the DPMA examiner raised an Article 3(a), or 3(b) concern regarding the relationship between the authorized product and the claims of the basic patent—whether the product is identified only generically rather than specifically in the claims. More precisely, the indicator equals one when the examiner questioned whether the relevant active ingredient or combination was sufficiently specified or identifiable in the patent claims. It equals zero when no such concern was raised, including cases in which Medeva or a related judgment was mentioned only incidentally or in connection with a different legal issue. In this way, we separate pure procedural rejections, such as response failures, or disputes in arithmetic SPC term calculations, or fee non-payments with Medeva-like SPCs. We explain this using examples in Table 9.

Using the sample we construct, we provide evidence on the three questions we began with—which drug types are more exposed to uncertainty in obtaining SPC protection? How does the timing of SPC examination interact with the evolution of CJEU jurisprudence? And, to what extent did changes in CJEU case law modify the examination practice of the DPMA and contribute to observed SPC outcomes?

B. What types of drugs face higher adverse rates?

Small and large molecules have different strengths and weaknesses in terms of market capturing capability and holding on to exclusivity. The marginal gain from having a valid SPC, if all other forms of exclusivity are held constant, is much larger for small molecules compared to large molecules. Small molecules generally have shorter overall exclusivity than large molecules, partly because they have relatively fewer secondary patents, but have the ability to capture larger markets, and thus charge higher prices initially, and then as generics enter, their prices drop sharply.⁴¹ The story is opposite for large molecules, where a combination of different forms of

⁴¹ DrugPatentWatch, “Small Molecules: The Pharmaceutical Industry's Most Durable Strategic Asset,” DrugPatentWatch (blog), March 22, 2026, <https://www.drugpatentwatch.com/blog/small-molecules-unsung-heroes-of-pharma/>.

exclusivities ensures market relevance for the originator for a relatively longer period. Large molecules keep adding patents to their portfolio long after they are launched. While revenues for large molecules are much higher than small molecules, the latter allow for a greater market volume and this is one reason why weight loss drugs like Ozempic and Mounjaro have injectable and pill versions.

For combination drugs the economic story is different, and there exists a mismatch between societal benefits and private profits. Two old off-patent molecules can not be provided any form of exclusivity once their patents expire and generics enter, and that is why, even if society can have gains from the combination being in the market, the private market never participates in such clinical trials.⁴² However, new molecules can be combined with older ones, as the new molecule's patent would cover the old molecule's exclusivity, and therefore, private players are interested in investing if such opportunities exist.⁴³ In the latter case, again, SPCs inadvertently start playing an increasingly important role in protecting the new molecule's exclusivity the longer the clinical trial runs. Because the gains to having an SPC are different by drug types, the goal of this section is to look at their heterogeneity in SPC outcomes.

An SPC's outcome is decided in three ways: granted or rejected by the DPMA, or withdrawn by the applicant. To begin with, in Table 1 we report the number of drugs by cohort, their SPCs, and the decisions they received from the DPMA. We follow drug cohort intervals as in Hemphill and Sampat.⁴⁴ A drug's cohort is determined by the year of its first MA, even if a few drugs may be reauthorized or newly authorized as a new combination, or formulation. Table 1 details the distribution of grants, rejections, and withdrawals. Throughout the rest of this chapter, we refer to rejections and withdrawals collectively as 'adverse' decisions. Note that the sum of decisions—granted, rejected, and withdrawn may sum up to a number that is more than the count of SPCs. This is because 103 SPCs are doubly-coded, i.e. granted first and then withdrawn or rejected. From the table, we see that 446 SPCs (31.8 percent) have adverse outcomes out of the

⁴² Eric Budish, Maya M. Durvasula, Benjamin N. Roin, and Heidi L. Williams, "Missing Markets for Innovation: Evidence from New Uses of Existing Drugs" (NBER Working Paper 34222, National Bureau of Economic Research, Cambridge, MA, 2025), <https://doi.org/10.3386/w34222>.

⁴³ Rebekah Dix and Todd Lensman, "Combining Complements: Theory and Evidence from Cancer Treatment Innovation" (job market paper, Department of Economics, Yale University, 2024), https://rebekahanne.github.io/files/dix_lensman_cancer.pdf.

⁴⁴ See Hemphill and Sampat, "Patents, Innovation, and Competition," 35.

1402, and the share of adverse by cohorts reaches 51.2 percent for the cohort 2006-08, the maximum adverse for any cohort in our sample.

Table 1: Distribution of drugs and their SPCs' decisions

Cohort	Drugs	SPCs	Granted	Rejected	Withdrawn	% Adverse
1985-1987	2	2	1	2	0	100.0
1988-1990	42	52	45	6	5	21.2
1991-1993	38	51	43	4	10	27.5
1994-1996	59	73	54	18	4	30.1
1997-1999	79	97	81	13	15	26.8
2000-2002	83	110	84	23	18	36.4
2003-2005	58	84	59	19	19	45.2
2006-2008	84	149	103	15	59	49.0
2009-2011	82	133	89	16	42	42.9
2012-2014	112	161	108	26	38	39.1
2015-2017	110	163	108	24	33	35.0
2018-2020	76	105	82	7	19	23.8
2021+	45	56	45	2	9	19.6
Total	806	1236	902	175	271	35.5

Note: Cohort is defined as the first MA of the API

Beyond cohort-level heterogeneity, Table 2 and 3 show that certain drug types disproportionately contribute to adverse SPC outcomes. While small molecules account for 52 percent of the SPCs in our sample (58 percent of drugs), large molecules represent 57 percent of all adverse SPC outcomes. In large molecules, vaccines account for 54 percent of adverse decisions. We also report the shares of adverse by combination and non-combination drugs, as they go beyond the molecular structure of the drug, and represent an intersection between small and large molecules. Small molecules are responsible for 57.5 percent of combinations, and within combinations, the adverse share is 50.2 percent while within non-combinations, 32.4 percent are adverse.

Table 2: Adverse outcomes by drug type: drugs and SPCs

	Drugs			SPCs		
Drug type	<i>N</i>	<i>N adv.</i>	<i>% adv.</i>	<i>N</i>	<i>N adv.</i>	<i>% adv.</i>
Small molecule	559	153	27.4%	727	195	26.8%
Vaccine	21	14	66.7%	113	68	60.2%
Monoclonal antibody	63	35	55.6%	115	61	53.0%
Biologic (non-mAb)	115	44	38.3%	181	65	35.9%
Other/Unknown	65	31	47.7%	100	50	50.0%
Total	823	277	33.7%	1,236	439	35.5%

Notes: Drug types from Patsnap, consolidated into five broad categories.

Table 3: Adverse outcomes by combination status

Group	<i>N SPCs</i>	<i>N adverse</i>	<i>% adverse</i>
Combination	265	134	50.6%
Non-combination	971	305	31.4%
All	1,236	439	35.5%

Notes: Combination SPCs protect a fixed-dose combination of active ingredients. We label an SPC to be a combination if they have more than one API.

C. How does the timing of SPC decisions interact with the evolving CJEU jurisprudence?

In Section III, we mention a few key CJEU decisions pertaining to SPCs, and discuss specifically Medeva and the interpretation of Article 3. We continue with that discussion and to demonstrate the evolution of jurisprudence, we split our data into two distinct periods, pre- and post-Medeva by defining the period before November 2011 as pre-, and on or after as post-Medeva.

Table 4 reports the mean, median, and standard deviation of lags in granted and adverse SPCs, measured from the date of SPC filing to the date of decision. Grants are relatively straightforward to decide, as can be seen from the median lag of 2.6 years. Adverse decisions take longer, and the median lag is 4.6 years. Note that both distributions are right skewed, showing that there are some outliers that take longer than the median. Because of the long decision lag, from our sample 224 SPCs were filed in pre-Medeva period, and decided in post-Medeva. In Table 5,

where we show the shares of SPCs decided for both periods. Post-Medeva, we observe a doubling of adverse decisions.

Table 4: Filing-to-decision lag by outcome (years)

Outcome	N	Mean	Median	SD
Granted	902	3.44	2.62	2.79
Adverse (rej.+ wdr.)	439	5.07	4.55	3.46
All SPCs	1235	3.92	3.15	3.05

Notes: Lag measured from filing date to decision date in years, where decision date is the date when the SPC was either granted, rejected, or withdrawn.

Table 5: SPC outcomes before and after the Medeva ruling (2011)

Period	N granted	N adverse	N total	% granted	% adverse
Pre-2011	335	92	427	78.5%	21.5%
2011 and later	461	347	808	57.1%	42.9%
<i>Total</i>	796	439	1,235	64.5%	35.5%

Notes: Decision date assigned as withdrawal date (if withdrawn), rejection date (if rejected), or grant date (if granted). Adverse = withdrawn or rejected.

Summing up Tables 1 to 5, we descriptively show that relatively complex drugs—large molecules and combination drugs are responsible for a larger share of adverse SPCs, and these decisions are concentrated in the post-Medeva period. It is not straightforward to categorize drugs based on their complexity, and yet, a formalization of the findings is necessary. We test if large molecules receive statistically different adverse decisions more than small molecules by estimating a logit model where the dependent variable is an indicator for adverse SPCs and the independent variables are dummies for the various cohorts, with 2003-05 as the base cohort and we report the marginal effects of the model in Table 6. Specifically, we estimate the following:

$$adverse_i = \alpha + \Sigma_c \beta_c \times large\ mol \times I(cohort = c) + \Sigma_c \gamma_c \times I(cohort = c) + \varepsilon_i$$

Where $adverse_i$ is an indicator that takes value 1 if SPC_i received an adverse decision, β_c denotes the difference in average of adverse for large molecules and small molecules authorized in cohort c , and γ_c reports for the cohort wise averages. In Table 6, we report the marginal effects derived from β_c . The marginal effect of being an adverse large molecule SPC ranges from 13 to

27 percentage points, and is statistically significant for six of the eleven cohorts, running from cohorts 1997 to 2017. We take cohort 2003-05 as the base cohort for a conservative comparison. From Table 1, we can see that 2003-05 has an overall high adverse share compared to the previous cohorts, and the adverse share of 2006-08 for large molecules remains statistically significant in comparison to the base. The pattern in Table 6 is robust to using combination drugs as a dependent variable instead of large molecules in the above specification, as combinations represent an intersection of complex drugs from both small and large molecules.

Table 6: Large molecule drugs' marginal effects compared to small molecules

Auth cohort	ME of Large molecule	SE
1985-1987	.	.
1988-1990	0.124	(0.119)
1991-1993	0.077	(0.127)
1994-1996	0.334**	(0.136)
1997-1999	0.253**	(0.100)
2000-2002	0.145	(0.093)
2003-2005	0.109	(0.109)
2006-2008	0.197**	(0.080)
2009-2011	0.168**	(0.085)
2012-2014	0.173**	(0.080)
2015-2017	0.210***	(0.074)
2018-2020	0.238***	(0.087)
2021+	0.405***	(0.141)

Notes: Marginal effects of large molecule drugs on probability of adverse outcome, from a pooled logit with robust standard errors. N = 1,236. Base cohort: 2003–2005. Standard errors in parentheses. * p<0.10, ** p<0.05, *** p<0.01.

While we do make a descriptive case showing the disproportionality between adverse SPC decisions for large molecules over small molecules (and combinations over single molecule drugs); the next question that needs detailed evaluation is this—what do these adverse SPC decisions relate to, and why are they adverse? Are they routine SPC rejections and withdrawals by the DPMA, or, are they correlated to certain changes in the SPC examination rules initiated due to Article 3 or Medeva?

C. DPMA examiners' citations to the CJEU decisions and their reasoning

In this section, we use the sample that is restricted to drugs authorized in 1997 and later, as described in Section V.A Data. We begin by reporting the outcomes of SPCs that cite any CJEU case versus those that do not cite any CJEU case in Table 7. The proportion of adverse outcomes if CJEU is cited is double compared to those SPCs for which there are no CJEU citations. Yet, those who do not cite any CJEU case and receive an adverse outcome from the DPMA is not small, and we provide explanations as to why later in this section.

We focus on the SPCs that do cite a CJEU case first. Table 8 shows them in detail. To date there are 43 preliminary rulings (judgments and orders) by the CJEU pertaining to SPCs.⁴⁵ Seven of these are responsible for 81 percent citations in the SPCs (476 out of the 590). Six of those seven are Art. 3 cases, while one is Art. 13.

Article 13 defines the duration of an SPC. The Seattle Genetics case was on what would be considered as the “actual” MA date of the drug for which an SPC is being asked, is it the notification date of the MA, or is it the issue date of the MA. This is cited frequently not to overturn the SPC, but rather, substantiate the duration of SPC. Oftentimes, the examiner (or applicant) cites it in their correspondence to disprove (or prove) their case. This is why, Seattle Genetics' cited SPCs have an adverse rate of 24.7 percent. The rest of the citations all lead to one source of dispute, the interpretation of Article 3.

In Section III, we discussed how a new precedent was set for Article 3(a) and 3(b) with Medeva, tightening the definition of a basic patent in accordance with the corresponding MA when an SPC is being asked for that patent-MA pair, and we argued how this may have led to the subsequent cases. In Table 8 we observe evidence regarding that, i.e. post-Medeva, there are five cases that are either directly or are closely related to Medeva. Note that we double-count an SPC if it has multiple CJEU citations. This is why the sum of the first five rows of Table 8 exceeds its last row. In the Appendix, we provide a matrix of CJEU co-citations to show that in many cases, when one case is cited, it is likely that other cases are cited along with it, as is the case with Medeva and Actavis.

⁴⁵ IPcuria, “SPC for Medicinal Products.”

Table 7: Outcomes by CJEU citation status

Group	N	%	Grants	Grant rate	Adverse	Adv. rate
Citing any CJEU case	464	44.1%	271	58.4%	226	48.7%
Citing no CJEU case	594	56.4%	488	82.2%	164	27.6%
Total	1,053	100%	759	72.1%	390	37.0%

Notes: 1997+ authorization cohorts with examination documents (N = 1,053; full 1997+ sample = 1,058). CJEU citation = at least one document mentions any CJEU case number.

Table 8: Top CJEU cases cited in the SPC examination documents

CJEU case	SPCs	%	Adverse	Adv. rate
Seattle Genetics (C-471/14, 2015)	239	22.7%	66	27.6%
Medeva (C-322/10, 2011)	107	10.2%	68	63.6%
Neurim (C-130/11, 2012)	84	8.0%	74	88.1%
Georgetown (C-422/10 / C-484/12, 2011/13)	67	6.4%	47	70.1%
Actavis I+II (C-443/12 / C-577/13, 2013/15)	70	6.6%	42	60.0%
SPCs citing at least one of the above	379	36.0%	171	45.1%
SPCs citing any CJEU case	464	44.1%	226	48.7%

Notes: Top 7 CJEU cases by number of SPCs citing the case number in at least one document.

The preceding citation analysis shows that DPMA examiners increasingly referred to Medeva and subsequent Article 3 cases in their examination documents. Explicit citations, however, provide an imperfect measure of whether the doctrine developed in these cases was substantively relevant to an application. An examiner may raise a Medeva-type objection without citing Medeva itself, relying instead on a subsequent judgment or directly applying the requirement that the relevant active ingredient or combination be specified in the claims of the basic patent. Conversely, a judgment may be cited only incidentally, while the decisive objection concerns a different eligibility requirement, such as whether the MA is the first authorization for the product under Article 3(d).

Therefore, we raise and address two related sub-questions. First, to what extent do explicit CJEU citations accurately identify applications in which the DPMA substantively considered a

Medeva-type eligibility issue? Second, are such eligibility concerns disproportionately associated with large molecules and with adverse SPC outcomes?

The second question provides a direct link with the preceding descriptive analysis. That analysis documents a higher incidence of rejections and withdrawals among large molecules and combinations. We now investigate whether this difference is associated with the particular Article 3(a) and 3(b) problem addressed by Medeva: whether the active ingredient or combination for which SPC protection is sought is sufficiently specified or identifiable in the claims of the basic patent. To distinguish the substantive application of the Medeva doctrine from the mere citation of a CJEU judgment, we construct an indicator that we explained in Section V.A Data. The analysis also identifies applications in which the underlying doctrine is applied even when the examiner does not explicitly cite Medeva. The indicator we design is conservative, meaning, a Medeva-issue will only be raised if an examiner explicitly mentions it in the document that straightforwardly indicates it to be a Medeva-type eligibility concern. In the Appendix, we provide the prompt that designed the indicator.

We provide four examples in Table 9 to demonstrate the consolidation of various CJEU citations into whether they are Medeva-type eligibility concerns or not, as raised by the examiners. The first row is an example where a Medeva-issue is flagged by the LLM and various CJEU cases are cited by applicants and the examiner. In this case, the examiner explicitly mentions that the basic patent does not name the API “Trastuzumab” in its claims, raising a Medeva-type concern. The second row is an example where a Medeva-issue is flagged but no CJEU cases are cited. The key sentence from the examiner-authored document “... *the designated product is not named in the claims of the basic patent.*” clearly states the underlying Medeva-issue.

The third row is an example where CJEU cases are mentioned (by an applicant in this particular case, a third party) but the underlying issue is not related to Medeva, because the LLM does not find any passage in the examiner-authored documents which negates the issuance of the SPC. This example shows the usefulness of LLM in distinguishing the CJEU citations based on author and the context. This drug is also an example that demonstrates the importance of SPCs in Europe. Sofosbuvir filed four SPCs in Germany, one of which was granted, one rejected, and two were withdrawn. Yet, the one which is granted with an SPC allows the drug to have an exclusivity

of 15.5 years (apart from other patents the drug has in its portfolio, which contribute to an even longer exclusivity). This patent is scheduled to expire in July 2029. In the United States, the same drug has nine patents attached to it, five of which were not filed at the European Patent Office (EPO).^{46,47} But, the originator, Gilead, was challenged by public-interest groups, competitors, and generic manufacturers at various US courts leading to an Abbreviated New Drug Application's approval (ANDA) granted to Teva, a generic company.⁴⁸ Yet, Gilead still has been successful in deterring generic entry to date in the US and in Europe. But, it is important to note the two sources through which the drug has maintained its exclusivity in Europe and in the United States; one being SPC and the other being patent thickets.

The fourth row is an example where the Medeva-issue is not flagged and no CJEU cases are cited in the SPC documents. These are examples of straight grants, as can be understood from the statement by the examiner: "*The conditions for the grant of the certificate pursuant to Article 3 of the EEC Regulation are fulfilled.*"

Using the four examples, we demonstrate how we consolidate the SPC decisions into Medeva-issue versus SPC decisions which do not raise a Medeva-issue for the full sample.

⁴⁶ The nine patents are mentioned in the US Food and Drug Administration's Orange Book.

⁴⁷ This also demonstrates that EPO is on average stricter when it comes to examining secondary drug patents. See Michael D. Frakes and Melissa F. Wasserman, "Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination," *American Economic Journal: Economic Policy* 15, no. 3 (2023): 151–83; Margaret Kyle, "Potential and Effective Exclusivity of New Drugs in Europe," in *Bringing Medicines to Life: How Intellectual Property Enables Innovation in the Life Sciences*, ed. Jonathan M. Barnett and Bowman Heiden (Cambridge: Cambridge University Press, forthcoming 2026).

⁴⁸ Teva never launched the generic version of Sofosbuvir, as shown on Drugs@FDA; U.S. Food and Drug Administration, "ANDA 211353: Sofosbuvir (Teva Pharmaceuticals USA)," Drugs@FDA: FDA-Approved Drugs, approved January 27, 2022, accessed September 1, 2026, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211353>.

Table 9: Illustrative SPC examination passages: Medeva-issue × CJEU citation

Medeva-issue; CJEU cited	SPC number	API name	CJEU cases cited (by whom)	Key passage (examiner, translated)
Yes; Yes	100 75 038.9	Trastuzumab	C-207/03, C-252/03 (applicant); C-617/12 (applicant); C-207/03, C-252/03 (examiner)	<i>“Trastuzumab is not directly named in patent specification EP 451 216 B1. Nor is the Chemical Abstracts Registry Number 180 288-69-1 for trastuzumab mentioned in Chemical Abstracts summary Nr. 114:183735 prepared for this patent. It is therefore assumed that the chemical structure of trastuzumab is not cited as an example in this specification.”</i>
Yes; No	102 99 046.8	Quinoxifen	None	<i>“... the designated product is not named in the claims of the basic patent.”</i>
No; Yes	12 2014 000 079.4	Sofosbuvir	C-493/12 (applicant)	No clear examiner passage recorded (folder classified as “no issue” at folder level i.e. no Medeva issue was raised for all the SPC documents combined; the CJEU case was cited by a third-party applicant).
No; No	197 75 085.0	Cidofovir	None	<i>“The conditions for the grant of the certificate pursuant to Article 3 of the EEC Regulation are fulfilled.”</i>

Notes: Each row shows one randomly drawn SPC from the respective cell of the classification matrix used in Figure A1, Table 10, and Table 11. Key passage is the most informative sentence extracted by the LLM from all examiner documents in the folder (translated from German).

To conclude, we generalize the four examples demonstrated previously to all the SPCs in our sample, and show three sets of evidence. In Figure 1, we show the co-occurrence of the Medeva-

issue flag with any CJEU citations. CJEU citations go up regardless of the Medeva-issue flag, showing that in general, the usage and mentions of CJEU cases went up post-Medeva. But, those that mention a CJEU case in conjunction with a Medeva-type eligibility concern particularly rise post-Medeva. This demonstrates a change in DPMA's examination patterns post-2011. The two dotted lines confirm the statistics we showed earlier; SPCs without any Medeva-issue and CJEU citations are likely to be straight grants. These are the highest in absolute numbers and do not particularly increase post-Medeva. Similarly, those SPCs where the examiners routinely raised a Medeva-type eligibility concern do not change post-Medeva, as shown by the black dotted line. What changes though post-Medeva are CJEU citation intensity and among those that also have a Medeva-issue flag.

Table 10 shows the number and shares of granted and adverse SPCs by the Medeva-issue indicator. On average, Medeva-type eligibility concerns raised by the examiners are associated with 64 percent adverse cases, as opposed to 72 percent grants if the concern was not raised.

In Table 11, we recreate Table 8's rows but with the Medeva-issue indicator. Medeva-issue is raised in 62 out of 299 SPCs that cite Seattle Genetics, the case that is unrelated to the concern this chapter raises. It is possible that an SPC has two CJEU cases that are co-cited in one SPC, as discussed in the previous part and also reported in the Appendix. This is why the 62 SPC are flagged as Medeva-issue by the LLM while the case Seattle Genetics too is explicitly raised in the SPC documents. For the other cases, the Medeva-issue flag is raised (and is co-cited) more often than not, because all the cases relate to Article 3 (such as Medeva, Georgetown, and Actavis).

From Figure 1, Table 10, and Table 11, we descriptively demonstrate that for those SPCs where the Medeva-issue is flagged by the examiner and has CJEU citations are on average more likely to receive adverse decisions.

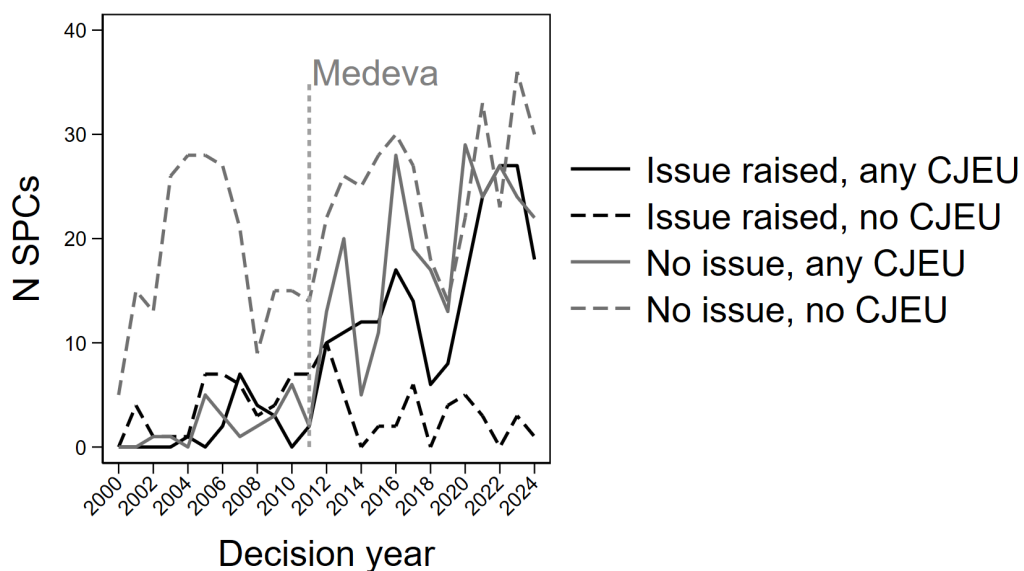


Figure 1: Number of SPCs by Medeva-type eligibility concern and CJEU citations

Table 10: Medeva-type eligibility concern and SPC outcomes

Medeva type elig. raised	N granted	N adverse	% granted	% adverse
No	573	220	72.3	27.7
Yes	95	170	35.8	64.2
Total	668	390	63.1	36.9

Table 11: Correspondence between CJEU citations and substantive Medeva-type eligibility concerns

CJEU case	Issue not raised		Issue raised	
	N	% adverse	N	% adverse
Seattle Genetics (C-471/14, 2015)	177	18.6%	62	53.2%
Medeva (C-322/10, 2011)	27	55.6%	80	66.2%
Neurim (C-130/11, 2012)	38	78.9%	46	95.7%
Georgetown (C-422/10 / C-484/12, 2011/13)	25	60.0%	42	76.2%
Actavis I+II (C-443/12 / C-577/13, 2013/15)	31	29.0%	39	84.6%

	Issue not raised		Issue raised	
CJEU case	N	% adverse	N	% adverse
SPCs citing at least one of the above	232	31.0%	147	67.3%
SPCs citing any CJEU case	271	33.9%	193	69.4%
SPCs citing no CJEU case	522	24.5%	72	50.0%

VI. Conclusion

This chapter has examined how the evolution of CJEU case law on SPC eligibility translated into examination outcomes at the DPMA. Our findings add to the literature on SPCs using two broad threads: one, adverse outcomes differ by drug types. Large molecules, among them vaccines, and combination drugs face substantially higher rejection and withdrawal rates than small molecules, and this gap is pronounced for drugs launched on or after 2006. The timing of SPC decisions matters in this regard, as SPC applications are frequently decided several years after filing. A substantial number of SPCs are filed under one definitional or interpretive regime and are decided under another.

The second strand we focus on is the Medeva ruling which transformed the interpretation of what constitutes a “basic patent” in a substantial way. We distinguish SPCs with Medeva-type eligibility concern from the mere citation of a CJEU decision. Applications in which examiners raised such a concern are more likely to be decided adversely. We show that the occurrence of Medeva-type eligibility concern leads to adverse outcomes and such outcomes are concentrated in large molecules. This reflects a broader structural mismatch between how the drugs and its patents are associated and how the SPC’s basic patent definition interacts with it.

Taken together, the findings of this chapter link back to the interpretive difficulty and ambiguity this chapter started with, that a product is “protected by a basic patent”. This discussion is crucial because of the centrality of SPCs to protecting the exclusivity of a drug in Europe. The evolution of case laws and the intention with which the SPC was designed have diverged in two different directions. The welfare cost of SPC eligibility rules lies not only in their stringency but in their unpredictability, which falls hardest on the complex drugs. Do they also inadvertently affect the incentives to develop and launch the socially valuable classes of innovation, especially in Europe, is a question that remains open for future research to conclude.

Appendix

A1. Attrition of observations and the final sample

Table A1: Sample attrition

Stage	SPCs	Drugs
Raw DPMA records	2,027	—
Less: plant SPCs	– 247	—
Less: unlinkable to BfArM (veterinary, foreign, unresolved)	– 185	—
Less: pending (no decision)	– 178	—
Sample without Patsnap	1,417	923
Less: absent from Patsnap	– 181	—
Sample in chapter	1,236	806

Notes: Plant SPCs are excluded as outside the pharmaceutical scope of this chapter. Pending SPCs are applications with no recorded decision as of the data extraction date. Patsnap is a proprietary database providing drug-level details including drug type, ATC code, indications, and originator.

Table A2: Drugs in BfArM and its linkage to Patsnap

Authorization cohort	Linked	Unlinked	Total
1985-1987	2	1	3
1988-1990	51	28	79
1991-1993	52	20	72
1994-1996	73	22	95
1997-1999	97	24	121
2000-2002	110	8	118
2003-2005	84	12	96
2006-2008	149	20	169
2009-2011	133	13	146
2012-2014	161	18	179
2015-2017	163	11	174
2018-2020	105	3	108

Authorization cohort	Linked	Unlinked	Total
2021+	56	1	57
Total	1,236	181	1,417

Notes: Linked: SPC matched to both BfArM and Patsnap are in the analysis sample. Unlinked: 193 SPCs present in BfArM but absent from Patsnap.

A2. Patsnap drug type classification

Patsnap drug type classification. Patsnap assigns each drug one or more raw type labels from a controlled vocabulary of roughly 60 categories (e.g., Small molecule drug, Chemical drugs, Monoclonal antibody, Prophylactic vaccine, Therapeutic vaccine, Synthetic peptide, Recombinant protein, AAV based gene therapy, CAR-T, siRNA, mRNA, Biosimilar, etc.). We consolidate these into five broad categories used throughout the analysis:

Broad category	Patsnap types included
Small molecule	Small molecule drug; Chemical drugs
Vaccine	Prophylactic vaccine; Therapeutic vaccine; Inactivated vaccine; Live attenuated vaccine; mRNA vaccine
Monoclonal antibody (mAb)	Monoclonal antibody; Bispecific antibody; Nanobody; Antibody drug conjugate (ADC); Antibody fusion proteins; Radiolabeled antibody; BiTE; single-chain Fv; VHH; trispecific; polyclonal antibody
Biologic (non-mAb)	Synthetic peptide; Recombinant protein; Enzyme; Fusion protein; Fc fusion protein; Immunoglobulin; Allergen extract; CAR-T; stem cell; gene therapy; AAV; mRNA (non-vaccine); siRNA; ASO; oncolytic virus; T-lymphocyte; biosimilar (non-mAb); and related
Other/Unknown	All remaining types; drugs with no Patsnap match

Table A3: Overlap of top CJEU citations in SPC examination documents

	Seattle	Medeva	Neurim	Georgetown	Actavis
Seattle	239				
Medeva	33	107			

	Seattle	Medeva	Neurim	Georgetown	Actavis
Neurim	24	19	84		
Georgetown	19	55	9	67	
Actavis	25	40	10	38	70

Notes: Diagonal = SPCs citing that case in at least one document. Off-diagonal = SPCs citing both cases.

Prompt template

"""

You are an expert in EU pharmaceutical patent law, specifically Supplementary Protection Certificates (SPCs) under Regulation (EC) 469/2009.

Below are one or more examiner documents from a DPMA SPC file. Classify this file on ONE binary flag.

DEFINITION

medeva_issue = 1 if ANY examiner document raises a concern that the basic patent does not adequately cover the product as authorized – specifically:

- The product is a combination of active ingredients but the basic patent claims only one or a subset of them
- The product is not specifically named or identified in the patent claims (only defined functionally, generically, or by class)
- The patent claims a different molecule, antibody, or chemical entity than the authorized product

Set to 1 even if the issue was eventually resolved and the SPC was granted.

DO NOT set to 1 for:

- Actavis "core inventive advance" test (C-443/12) invoked without the above
- Prior marketing authorization for a component or related product (Art. 3(d) lineage issue)
- Purely procedural or administrative rejections
- Art. 13 arithmetic, fee non-payment, late filing, procedural default

EXAMPLES

Example 1 – medeva_issue=1:

"The combination Valsartan+Amlodipine is not specifically identified in the claims of EP 443 983, which discloses only Valsartan."

→ Combination not in claims. medeva_issue=1.

Example 2 – medeva_issue=1:

"The vaccine antigens are defined only generically in the patent; the specific combination of six antigens in Infanrix hexa is not identified."

→ Functional/generic claiming. medeva_issue=1.

Example 3 – medeva_issue=0:

"Relying on C-443/12 (Actavis), the combination does not represent the core inventive advance of the patent."

→ Actavis test only – conservative definition excludes this. medeva_issue=0.

Example 4 – medeva_issue=0:

"An earlier marketing authorization existed for the single-component product; the 2004 Duodopa gel MA is not the first MA under Art. 3(d)."

→ Prior-MA lineage issue only – conservative definition excludes this. medeva_issue=0.

Example 5 – medeva_issue=0:

"Rejected. The SPC term under Art. 13 would be zero or negative."

→ Arithmetic rejection. medeva_issue=0.

INSTRUCTIONS

1. Base classification ONLY on the reasoning in the documents – not article numbers alone (Art. 3(a) appears in both Medeva-type and non-Medeva-type cases).

2. When in doubt, default to 0.

3. If documents contain no substantive examiner reasoning, set to 0.

OUTPUT FORMAT (JSON only, no other text):

```
{{
  "medeva_issue": <0 or 1>
}}
```

SPC FILE: {folder_name}

{doc_blocks}

JSON output: ""