

Comparative Quantitative Analysis of Supplementary Protection Certificates (SPCs) in Europe

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This article is an attempt to quantify and compare number of SPCs granted, filed and invalidated in five important European Countries UK, France, Germany, Italy and Spain. The data is collected for those patents having expiry in between 1 January 1995 till 31 December 2025. The article further focuses on recent case laws evolved in Europe and its impact on SPC filings. The analysis reveals that patentees are inclined to file more SPCs on product patents as lesser percentage of SPCs for product patent got invalidated. There is a decline in SPCs for patents on combination product. In contrast patents on composition seems to drive highest number of SPC applications as patent holders are trying to extend the life cycle of the product through follow on products, improved articles. It will be interesting to see how the trend of SPC filing will change in future after rise of Unitary Patents.

Keywords: Medeva, Actavis, SPC, combination patent, Sanofi, Lilly, CJEU, carrier protein, markush claims

Quantitative Analysis

The Supplementary Protection Certificate (SPC) is a valuable intellectual property which allows its holder to maintain monopoly in the European Economic Area. The recent rulings by Court of Justice for European Union (CJEU) have considerably changed the understanding of the Article 3 of Regulation No 469/2009 which governs SPC provisions.¹ This article analyzes the SPC data for the three types of patent *viz* combination, -product and composition. We have quantified the data for SPCs filed, granted and invalidated for above three types of patents in five different European countries UK, France, Italy, Germany and Spain. The data was collected for the Patents, having their expiry between 1 January 1995 and 31 December 2025. Based on the data collected we analyzed the trends of SPC filings in the respective countries and correlated it with the recent case laws in Europe involving SPCs.

The term “product patent” as referred herein includes patents claiming the drug as a new chemical compound or biological entity, irrespective of how it is made.

Polymorphs, stereo- isomers and salts, etc of drugs can be covered by compound claims. This also includes patents claiming the compound but only when made by the claimed novel process. These include patents which are granted by national patent offices of respective European country as well as European Patents which are nationalized in the respective European country after grant. It is to be understood that product patent can also be termed as compound patent.

The term “Combination Patent” as referred herein includes patents claiming the drug in a fixed combination with another drug. These patents will only protect the fixed combination and not the individual components. This also includes patents which do not claim the drug as a fixed combination but only as a single molecule; however SPC for the fixed combination granted to such patents.

The term “Composition Patent” as referred herein includes patents claiming novel the therapeutic formulations containing the active ingredient(s) e.g. capsules, tablets, injections, etc. This also includes patents claiming a delivery of a drug which optimizes the therapeutic/ prophylactic bio effectiveness of the drug by overcoming physiological and/or

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biochemical disadvantages encountered by the existing routes of administration of the drug. These include patents which are granted by national patent offices of respective European country as well as European Patents which are nationalized in the respective European country after grant.

Patents on Combination Products

There are very few SPCs granted on patents claiming combination products as shown in Fig. 1. However, there are higher percentages of SPCs invalidated by the patent office or European Courts in comparison to the one which are granted. Even the rulings which were recently given by the CJEU highlight the difficulty in defending the combination patents in a SPC challenge.

In *Medeva* Case,^{2, 17-18} European patent 1666057, covering method of preparation of vaccine against whopping cough agent, consisting of a combination of two antigens, as active ingredient. Medeva filed five SPC applications with UK patent office citing Marketing Authorizations (MAs) for medicinal products, each of which contained additional active ingredients in addition to the two antigens for which SPC sought. CJEU held that Article 3(a) of Regulation (EC) No 469/2009 concerning the SPC precludes grant of SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent. In *Georgetown* Case³, CJEU held that the Article 3(b) of Regulation (EC) No 469/2009 concerning the SPC does not preclude from granting SPC for an active ingredient 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 SPC application contains not only that active ingredient but also other active ingredients. The interpretation of *Medeva* and *Georgetown* decision is shown in Table 1. In *Novartis* case, European patent no 0443983 was claiming *Valsartan* (an antihypertensive drug) and compositions containing *Valsartan*. Novartis obtained SPC for product containing only *Valsartan* as active ingredient. Actavis obtained the MA for combination of *Valsartan* and Hydrochlorothiazide (HCTZ). Novartis filed immediately for injunction prohibiting *Actavis* from marketing the combination product containing *Valsartan*. UK Court stayed the proceeding and referred the question to the CJEU. Based on *Medeva* decision, CJEU ruled that Articles 4 and 5 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of May 6, 2009 must be interpreted as meaning where a ‘product’ consisting of an active ingredient ‘A’ was protected by a basic patent and the holder of that patent was able to rely on the protection conferred by that patent for that product ‘A’ in order to oppose the marketing of a medicinal product containing that active ingredient in combination with one or more other active ingredients (A+ B), a SPC granted for that ‘product’ ‘A’ enables its holder, after the basic patent has expired, to oppose the marketing by a third party of a medicinal product (A+B) containing that product for a use of the product ‘A’, as a medicinal product, which was authorized before that certificate expired (Table 1).

However, in another case, *Yeda* owned the European patent claiming the administration of two active ingredients separately. *Yeda* applied for two SPCs, one claiming combination of two actives and other claiming only one active, the supporting MA covers only one active whose approved indication was the co-administration of the active ingredients. UK office refused to grant both SPCs and referred the question to CJEU. The CJEU also cautioned in the case of *Yeda*⁴ stating that SPC cannot be granted where the active ingredient is specified in the SPC

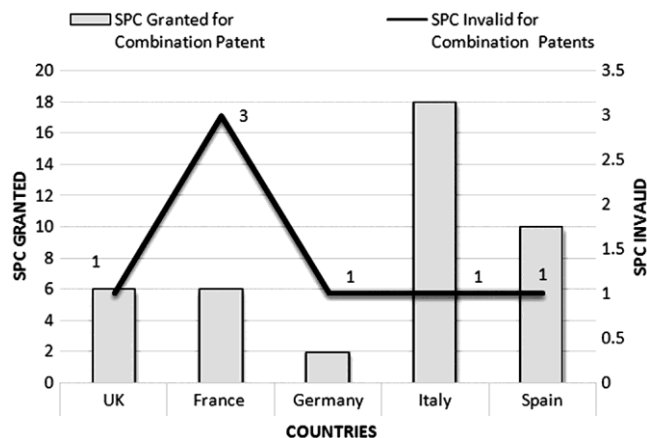


Figure 1—SPC Granted v SPC Invalid in the UK, France, Germany, Italy and Spain for Patents involving combination products*

Table 1— Interpretation of Medeva and Georgetown Decisions¹⁷⁻¹⁸

Basic Patent Claims For	Marketing authorization granted for	SPC applied for	Based on <i>Medeva</i> and <i>Georgetown</i> Rulings SPC
A	A + B	A	Allowable
A + B	A	A	Not Allowable
A	A	A + B	Not Allowable
A + B	A + B	A	Not Allowable

application, even though identified in the wording of the claims of the basic patent as an active ingredient forming a combination in conjunction with another active ingredients, is not the subject of any claim relating to that active ingredient alone. *Daiichi* case⁵ has significant effect on the SPCs relating to combination products in pharmaceutical industry as follow on products or improvement products are common in this field. *Daiichi* owned European patent claiming *Olmесartan* and obtained SPC for MA containing *Olmесartan* as sole active ingredient. *Daiichi* later got approval for combination of *Olmесartan* and *HCTZ* and applied for SPC on same basic patent. UK IPO refused the grant of SPC. The CJEU affirmed the UK IPOs decision in light of *Medeva* ruling. After the *Daiichi* ruling, SPC protection for combination product will only be possible if the basic patent covers the combination product and is properly disclosed in the wordings of the claim of the basic patent.

In *Actavis* case,^{6-7, 15} Boehringer owned European Patent 0502324 claiming *Telmisartan* as a single active ingredient and obtained SPC for MA covering *Telmisartan* as a sole active. Later, Boehringer obtained approval for combination of *Telmisartan* and *HCTZ* and obtained second SPC for combination on the basis of same patent. *Actavis* wanted to market the combination product and claimed that the combination SPC for *Telmisartan* was invalid. The CJEU invalidated the SPC for combination product containing *Telmisartan* citing that the second SPC for combination product was found to violate Article 3(a) and (c) of the SPC Regulation. Similarly, in *Sanofi* case,^{8,15} the CJEU made disclosure requirement for combination product more stringent, as in *Sanofi* case CJEU found that it is not sufficient to describe the invention generically in the claims. The Sanofi patent claims *HCTZ* generically as a ‘diuretic’ in combination with *Irbesartan*. CJEU ruled that under Article 3(c) of the regulation, it is not possible for patent holder to obtain SPC on the basis of same patent but a subsequent Market Authorization (MA) for different medicinal product containing that active ingredient specified in the wording of the claims (*Irbesartan*) in conjunction with another active ingredient hydrochlorothiazide (*HCTZ*) which is not protected as such by the patent.

However, in *Lilly* case,^{13,16} Human Genome Sciences (HSG) owned patent relating to new protein and antibody that bind specifically to new protein and

pharmaceutical composition comprising that antibody. Lilly obtained MA or composition of *Tabalumab*. Lilly sought declaration from UK Court that no SPC should be granted for HSG patent based on MA for *Tabalumab* as according to Lilly, HSG patent failed to meet the requirement under Article 3(a) in that *Tabalumab* antibody was not covered in HSG patent. In short, there was no structural definition of active ingredient *Tabalumab* in the HSG patent. However the CJEU ruled that, in order to satisfy the Article 3(a) requirement, it is not necessary for the active ingredient to be identified in the claims of the patent issued by European Patent Office. The CJEU further stated that Article 3(a) of the regulation did not preclude the grant of SPC for the active ingredient on the condition that the claims cover that active ingredient when interpreted in light of the description. Further, according to the Article 69 of Convention of the Grant of European Patents and the Protocol on the interpretation of that provision, CJEU further left the question of the interpretation of meaning of ‘necessarily and specifically’ concerning the active ingredient to the national courts.

In France, 3 SPCs were invalidated out of 6 SPCs granted for patents on combination products which accounts for 50 % of total SPCs invalidated. In Germany also the success of getting SPC for combination product is 50 %.

As there is higher percentage of SPCs getting invalidated there is lesser inclination of patentees to file SPCs for patents on combination products. There is fewer number of SPC applications filed for combination patents as evident from Fig. 2. In Spain, there is no SPC application filed for combination product patent. Italy has highest number of SPCs granted for combination product patents. Germany leads the highest number of SPC applications filed for combination products.

Composition Patents

The patentee files SPC for composition patents when follow on products are invented long after product patents. Patentee often develops new

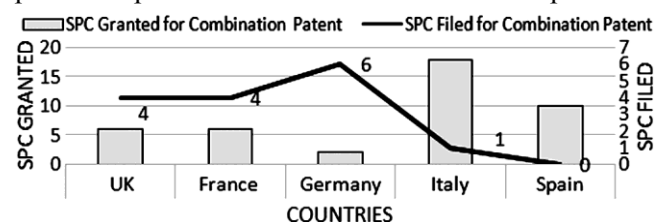


Figure 2—SPC Granted v SPC Filed for Combination Patents in UK, France, Germany, Italy and Spain*

composition, device or improved product after discovery of original compound. There are a significant number of SPCs filed and granted for composition patents. Further, the percentage of getting the SPC for composition products invalidated is quite low. In Spain, the percentage of composition products getting invalidated is 12%, in France it is 13%. Italy has highest number of SPCs granted for composition patents and as expected highest number of SPCs invalidated is in Spain as evident from Fig. 3.

The recent case laws highlight SPC regulation around composition patents. In case of *Forsgren*⁹, the CJEU noted under Article 1(b) that a substance is considered an active ingredient when it has a pharmacological, immunological or metabolic effect on its own. Whether the active ingredient is bound to another active ingredient is in itself immaterial to this test; the test simply requires the active ingredient to have an independent pharmacological, immunological or metabolic effect. Accordingly, the CJEU found that the SPC regulation does not preclude the grant of an SPC where the active ingredient is covalently bound to other active ingredients.

The second part of the question asked in *Forsgren* to the CJEU was whether Article 3(b) precludes the grant of an SPC where the MA describes the substance as a “carrier protein”. The CJEU had established in *GlaxoSmithKline Biologicals*¹⁰ that excipients (which facilitate the formulation of a pharmaceutical product) and adjuvants (which enhance or modify the action of other active ingredients in a medication) may not be regarded as “products” under the SPC regulation, since they have no therapeutic effect.

However, the CJEU concluded on the basis of the wording of the Synflorix MA that protein D is neither an excipient nor an adjuvant, and that accordingly the CJEU’s restriction in *Glaxo Smith Kline Biologicals* did not apply. *Forsgren* drew an analogy with *Bayer CropScience*,¹¹ where the CJEU held that a ‘safener’ in a plant protection product

might have a protective activity in its own right, either directly or indirectly, meaning it could be classified as an active substance.

The CJEU accepted *Forsgren*’s argument and therefore proposed that a carrier protein might also be characterised as an ‘active ingredient’ to the extent that it produces a pharmacological, immunological or therapeutic effect of its own. The CJEU’s answer to this question expressly left it to the referring tribunal to determine whether, under the circumstances, protein D would meet this criterion.

As already, evident from the Fig. 4, high number of SPC applications were filed for composition patents except in Spain and Italy. Surprisingly, Spain has least number of SPC application filed for composition patents which is only 4, while Italy has only 15 SPCs applications filed. At the same time Italy has highest numbers of SPCs granted for composition patents. Germany has highest numbers of SPC application filed for composition patents.

Product Patents

Figure 5 clearly indicates that Product patents or basic patents are the strongest patents having SPCs granted. The numbers are highest among all types of patents to which SPC is granted. As the product patents claim basic invention it is not getting challenged frequently. UK has highest number of SPCs granted for product patent. In Spain, there is no SPC challenged for product patent. In France and Germany highest numbers of SPCs were invalidated for product patent.

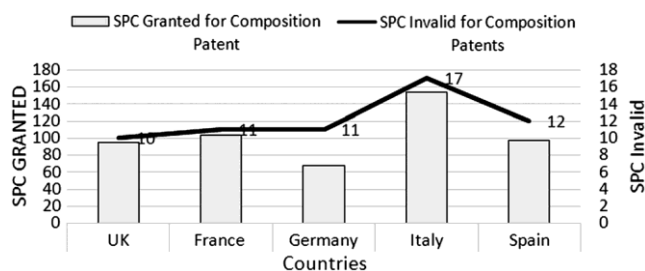


Figure 3—SPC Granted v SPC Invalid for Composition Patents in UK, France, Germany, Italy and Spain*

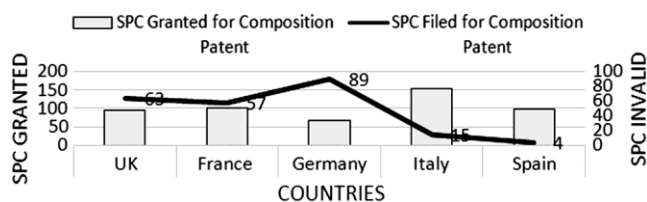


Figure 4—SPC Granted v SPC filed for composition patents in UK, France, Germany, Italy and Spain*

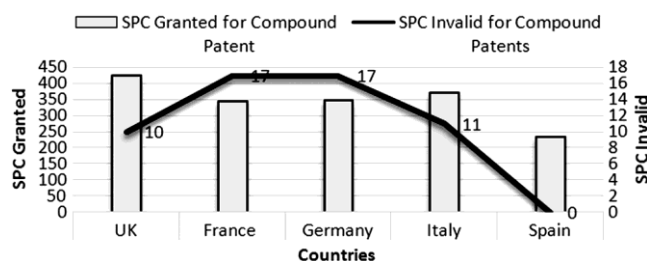


Figure 5—SPC Granted v SPC invalid for product patents in UK, France, Germany, Italy and Spain*

The case law also provides some idea about how much disclosure is required. In *Queensland* case¹² CJEU ruled that it is irrelevant whether the product is derived directly from the process, but that Article 3(a) SPC regulation precludes an SPC being granted for a product other than the one identified in the wording of the claims of the patent as the product deriving from the process in question.

In *Lilly* case¹³, CJEU ruled that in order to satisfy Article 3(a) requirement, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula in the claims of the patent issued by European patent office. The CJEU further stated that Article 3(a) of the regulation does not preclude the grant of SPC for the active ingredient

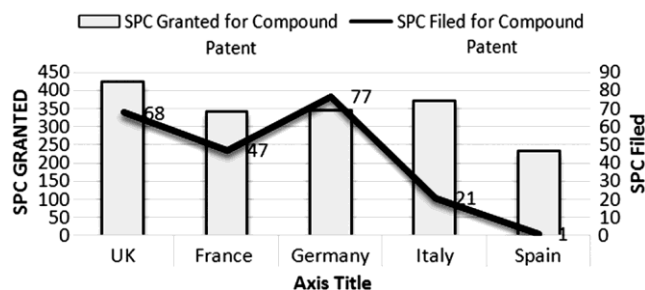


Figure 6—SPCs Granted v SPCs filed for product patents in UK, France, Germany, Italy and Spain*

on the condition that claims cover that active ingredient when interpreted in light of description of the patent. As per Article 69 of Convention of the Grant of European Patents and the Protocol on the interpretation of that provision, CJEU further left the question of interpretation of meaning of ‘necessarily and specifically’ regarding the active ingredient to the National Courts.¹³

In comparison to SPCs granted to product patents there are very few SPC applications filed for product patents. In Spain there is only 1 application filed. One reason for such lesser number of applications filed is due to decline in discovery of new molecules (Table 2).

Conclusion

Based on review of the SPC data for combination products, the number of SPCs filed for combination products are decreasing in all five countries. Further, the percentage of SPCs invalidated is very high. As a result, patentee is not inclined to rely on combination patents as a means of protection for their follow on products. Although, *Actavis* case clarified Article 3 (a) and (c) of Regulation (EC) 469/2009, the CJEU should have answered the questions relating to patent amendments after grant of patent to cover incremental

Table 2—Summary of recent rulings based on CJEU decisions

Case (decision date)	Basic patent claims	MA in place for	SPC possible for
<i>Medeva</i> (24 November 2011)	Combination A+B	A+B+C+D	A+B
<i>Yeda</i> (24 November 2011)	Combination A+B	A	No SPC possible for A + B
<i>Queensland</i>	1. A+B	A+B+C+D	1. A+B (based on patent 1)
Several basic patents (25 November 2011)	2. C		2. C (based on patent 2)
	3. D		3. D (based on patent 3)
	(three different proteins)		
<i>Queensland</i>	A claimed in the wording as (in) direct product of the process claim	A (+B+C)	A
Product through process (25 November 2011)			
<i>Queensland</i>	Process Claim. A = product of process but not specified in the wording	A (+B+C)	No SPC possible
Product through process (25 November 2011)			
<i>Daiichi</i> (25 November 2011)	A (Olmesartan & Olmesartan/HCTZ)	A+B combination therapy	A
<i>Georgetown</i> (12 December 2013)	A, B, C, A+B, B+C	A+B+C+D A+B	Innovator request to surrender SPC for A+B+C+D & to apply SPC for A+B
<i>Actavis v Sanofi</i> (12 December 2013)	A; A+ (B = Generic) (<i>Irbesartan/HCTZ</i>)	A + B	A+ B not possible
<i>Eli Lilly vs HSG/GSK</i> (12 December 2013)	Markush (<i>Belimumab/Tabalumab</i>)	<i>Belimumab & Tabalumab</i> (in clinical trials)	Specified/Identified Functional definition acceptable. Open to National Court (Article 69)
<i>GlaxoSmithKline</i> (14 November 2013)	A + Adjuvants (composition) (<i>Prepandrix</i>)	A + Adjuvants	Not possible for (A + Adjuvants) even though Adjuvants improves efficacy of A.

inventions like in case of combination product. CJEU shall clarify more questions on issues involving patent amendments and SPC for combination products. The more clarity by CJEU will help patent holders to craft their strategies well in advance right from the drafting basic patent which effectively cover all possible combination products.

For composition patents as of now, the case law is clear that SPC would not be possible if active ingredient is not claimed in the basic patent and no SPC is possible for active ingredients in combination with adjuvants like pharmaceutical excipients. The patent holders see composition patents as better candidates to protect their follow on product in comparison to combination patents. The reason is less number of SPCs for composition patents found invalid by patent offices and Courts. Rise in number of SPC application for composition patents in future is expected.

For product patents, the CJEU rulings in *Sanofi* and *Lilly* however pose questions in case of patents with Markush claims. Patents with Markush claims have clinical data for a limited number of compounds, but the claims themselves cover thousands of compounds. Is the ruling in *Lilly* or the *Sanofi* case applicable to Markush claims?

The *Sanofi* case highlights the fact that the compound should be identified and specified in the wording of the claim, but *Lilly* case law implies that functional language of claim is sufficient; hence SPC for compounds based on Markush claims are under question. Questions to the CJEU regarding such cases cannot be ruled out in future.

Another question is about the expiry of a Markush claim including compounds for which a number of SPCs are granted. Like in the *Lilly* case, HSG had its own SPC for Belimumab but based on Lilly's invention of Tabalumab, an additional SPC could be granted to same patent. As a result, patents can be revived multiple times by filing application for compounds covered in Markush claims. What will be life term of such patents?

Despite the above question, product patents remains to be first choice for patentee to file SPC application as they provide strong protection against competitors. Even the least percentage of SPCs for product patents found invalid over time in Courts and patent office. However, the number of SPCs filed for the product patents are also less compare to the one which are granted. One reason authors believe is

scarcity of new compounds, biologics, devices or article which results into such decline in number. Authors expect these numbers to rise in the future if new molecules get discovered and marketed.

The rise of the 'Unitary Patent System' (UPC) in Europe wherein one patent can be granted throughout Europe are likely to pose additional questions. For instance, in case of patents granted under UPC where SPCs have been granted, which ruling shall apply (*Lilly* or *Sanofi*); since the CJEU left the interpretation of 'identified and specified' to discretion of national courts. This is surely going to increase the number of appeals in future.

Finally, the patentee needs to keep an eye on the decisions relating to SPC as well as any amendment in regulation of SPC to find out which patents are best suited for protecting their invention.

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