Journal of Intellectual Property Rights
Vol 23, November 2018, pp 233-242

Analysis of SPC Regulation Associated with Pharmaceutical Products in Europe

Omkar Joshi,[†1] Archna Roy[1] and Manthan Janodia[2]

[1]Intellectual Property Management Group, Lupin Limited, Nande Village, Pune 412 115, Maharashtra, India

[2]Department of Pharmacy Management, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, 576 104, Karnataka, India

Received: 26 February 2018; accepted: 14 December 2018

The purpose of the study is to understand SPC regulations associated with pharmaceutical products. The study focuses on the case laws associated with SPC regulation and decisions handed down by national IP courts across Europe. The study also provides some guidelines for patent claim drafting with improved chances of getting and identifying avenues for challenging SPCs, as well as possible solutions and loopholes in SPC regulation. The guidelines for predictions of generic drug entry into market are discussed. The data collected and analyzed for individual European Country provides useful insight into pattern of SPC filing, grant and SPC invalidity. It is observed that there is a need to amend SPC regulation to provide better clarity to both innovators and generic drug industry.

Keywords: Supplementary Protection Certificate, Patent Term Extension, Court of Justice for European Union, New Chemical Entity, European Free Trade Agreement, EMA, generic drug industry

Supplementary Protection Certificate (SPC)[1] is a unique form of intellectual property (IP). In conventional language, it can also be called Patent Term Extension (PTE). SPCs are granted to innovator pharmaceutical/ biotechnology companies, universities or researchers in return of significant investments made in the research field, including pharmaceutical and biotechnology fields. The grant of SPC prolongs the life of patent. In short, SPCs are of prime importance to maintain monopoly of products in the market.[2]

While the current SPC system is widely used by the pharmaceutical industry and considered a success, several legal issues have emerged in practice which is reflected in numerous referrals to the (Court of Justice for European Union) CJEU[3-5], and in the light of further developments in this area (e.g., biotechnology), those issues may create obstacles to the full potential that the EU SPC system can deliver. Currently, there is no database or guidance available on countrywide SPC provisions in Europe. There is no organized information available about the court system which has jurisdiction on SPC regulation in each EU country. The recent rulings in CJEU (like Lilly[6], Georgetown[7], and Actavis[8]) highlight the importance of patent drafting, especially claims. If an effective SPC protection is required, then careful drafting of patent claims is of paramount importance; failing to do so might lead to lossof patent right or monopoly in the market. Indian pharmaceutical industry has focused on new drug discovery in recent years. Hence, these rulings and their analysis would help in developing guidelines for patent drafting - mainly for New Chemical Entity (NCE) patents.

The Court of Justice of the EU (CJEU) and the European Free Trade Agreement (EFTA) Court have dealt with numerous preliminary references referred by national courts in matters related to, *inter alia*, the definition of "product" to be protected, SPC eligibility of certain products, scope of protection of the SPC, duration of the SPC term, certain procedural matters, types of marketing authorizations that count for the purposes foreseen in the SPC regulation (e.g., provisional marketing authorizations and marketing authorizations granted by the Swiss medicine agency), or eligibility of the paediatric extension for patented medicinal products not eligible to SPC protection. The issue/scope of the "active ingredient" of biosimilars is an emerging challenge for the scope of protection of the SPC for biomedicines. There are indications that this created a significant degree of legal uncertainty and lack of predictability for users of the system.

For the present study, the SPC data was collected for 27 European Countries from IMS database. The

[†]Corresponding author: Email: omkarjoshi@lupin.com

data was also collected from individual patent office of European countries mentioned in this study. The data includes SPCs granted, filed and invalided which pertain to pharmaceutical patents. The types of patents include method of use, composition, combination, product, drug delivery, device and process. The SPC data was collected for those patents, which would be losing protection during 1 January 1995 and 31 December 2025.

SPC Database for European Countries

UK, France, Germany, Italy and Spain[9]

The top five countries in Europe for pharmaceutical industry are United Kingdom (UK), France, Germany, Italy and Spain. Therefore, analysis of the SPC data collected for the above five countries was carried out first. The analysis includes attempt to quantify and compare number of SPCs granted, filed and invalidated in these five important European Countries. The analysis further focused on recent case laws evolved in Europe and its impact on SPC filings. The analysis revealed that patentees are inclined to file more SPCs on compound patents as SPCs for compound patent invalidated were much lesser. There is a decline in SPCs for combination product. In contrast, patents on composition seem to drive highest number of SPC applications as patent holders are trying to extend the life cycle of the product through follow-on products. It will be interesting to see how the trend of SPC filing will change in future.The results of this study have been published in our earlier papers.[10-12]

Rest of Europe, Including Major Five EU Countries

Apart from above five countries, the SPC data for other countries were also analyzed. Table 1 reflects that maximum number of SPCs were granted for product patents. Most of the SPCs granted to process patents were before 2005, probable reason being decrease in number of process patents being filed. After 2005, there was a sharp rise in SPCs for composition patents. Similarly, there was increase

Table — 1: *Number of SPCs granted* v *Type of patents in various EU countries*

Number of SPCs granted in various EU countries, classified by patent type

Country	Type of Patent				
	Product	Process	Composition	Combination	Method of use
Austria	249	218	117	4	40
Belgium	381	49	98	14	22
Bulgaria	44	5	17	0	3
Croatia	8	0	2	0	0
Czek	262	106	82	2	27
Cyprus	0	0	0	0	0
Denmark	249	95	78	1	14
Estonia	61	4	51	1	6
Finland	92	188	45	1	10
France	343	42	103	6	46
Germany	345	35	68	1	31
Greece	194	51	98	9	33
Hungary	87	18	24	0	0
Ireland	453	37	127	2	14
Italy	370	61	154	18	57
Luxembourg	383	47	146	20	48
Lithunia	76	4	28	1	8
Latvia	96	4	34	5	10
Netherlands	399	63	106	6	35
Portugal	158	73	80	5	25
Poland	39	8	6	0	0
Romania	56	4	20	2	5
Sweden	404	89	128	3	35
Slovenia	117	16	49	7	20
Slovakia	52	0	91	1	3
Spain	233	114	98	10	42
UK	424	59	95	6	33
Total No. of SPCs granted	5575	1390	1945	125	567

in grant of SPCs for combination and method of use patents also, indicating rise in follow on products for original products, like new formulation, new method of use or new route of administration. Very few SPCs were granted for process patents after 2010. In Slovakia, more SPCs were granted to composition patents than product patents. In Finland, more SPCs are granted for process patents than product patents.

Table 2 reflects that product patent remained first choice for filing SPC applications, followed by composition patent in most of the European countries. No SPCs were filed for process patents. Intermediate number of SPCs were filed for method use patent as second use of already approved products. Very few SPC applications were filed for device patents. SPC applications filed for combination patents declined from 2010 due to their vulnerable nature for invalidity. However, Method of use patents was considered as a better option to file SPC applications. SPC applications for product patents were on decline compared to before 2000 due to lower number of new molecule discovery. Due to limitation on availability of data in Cyprus, the analysis was not carried out for such countries. The data for countries like Czek, Estonia, Italy, Slovenia, Luxembourg, Latvia and Spain may be incomplete as no adequate SPC database was available for such countries.

Table 3 reflects that the number of SPCs invalidated were very less when compared to the number of SPCs granted. There was a limitation on availability of data related to invalidity of SPC in European countries. So, only the data available from IMS database was used for analysis.

Table 4 reflects that 25% of SPCs for combination patents were invalidated compared to SPCs granted for combination patents. Only 3 % of SPCs for product patent were found invalid. This explains why innovator companies filed more SPCs for product patent. About 10 % of SPCs for composition patents were invalidated.

National SPC and European SPC Data Analysis

There are two different types of SPCs granted, one by European patent office and other by national patent

Table — 2: *Number of SPCs filed* v *Type of patents in various EU countries*

	Number of SPCs filed in various EU countries, classified by patent type					
Country	Product	Device	Drug delivery	Composition	Combination	Method of use
Austria	49	0	4	23	9	11
Belgium	95	0	9	64	4	32
Bulgaria	26	0	3	11	3	3
Croatia	37	0	4	15	4	2
Czek	9	0	0	3	3	2
Cyprus	0	0	0	0	0	0
Denmark	36	0	9	37	6	23
Estonia	9	0	2	6	3	3
Finland	67	0	9	45	6	28
France	43	0	10	47	4	21
Germany	77	4	15	74	6	41
Greece	16	0	6	9	1	7
Hungary	33	0	0	19	2	7
Ireland	51	1	8	46	5	29
Italy	21	2	2	13	1	10
Netherlands	33	0	9	36	5	21
Luxembourg	2	0	0	0	0	0
Lithunia	21	0	2	11	2	8
Latvia	14	0	6	6	1	7
Portugal	25	0	3	23	1	11
Poland	51	0	1	17	4	4
Romania	38	0	4	29	2	13
Sweden	20	0	6	23	3	15
Slovenia	6	0	1	4	0	0
Slovakia	24	0	2	10	1	7
Spain	1	0	0	4	0	1
UK	68	3	11	52	4	33
Total No. of SPCs filed	872	10	126	627	80	339

Table — 3: *Number of SPCs invalidated* v *Type of patents in various EU countries*

Number of SPCs invalidated in various EU countries, classified by patent type						
Country	Product	Drug delivery	Composition	Device	Combination	Method of use
Austria	13	1	14	0	2	5
Belgium	15	3	19	0	1	5
Bulgaria	0	0	1	0	0	0
Croatia	0	0	0	0	0	0
Czek	1	0	4	0	0	0
Cyprus	0	0	0	0	0	0
Denmark	8	1	15	0	2	5
Estonia	1	0	2	0	0	1
Finland	3	1	3	0	1	3
France	17	1	10	0	3	4
Germany	17	1	10	0	1	7
Greece	11	3	6	0	5	6
Hungary	0	0	1	0	0	0
Ireland	3	1	8	0	1	3
Italy	11	0	17	0	1	3
Luxembourg	8	3	16	0	2	10
Lithunia	1	0	0	0	1	1
Latvia	0	0	1	0	2	0
Netherlands	13	3	16	0	2	5
Portugal	0	0	0	0	0	0
Poland	1	2	1	0	0	0
Romania	2	0	3	0	1	0
Sweden	13	2	16	0	3	4
Slovenia	3	0	3	0	1	2
Slovakia	0	0	1	0	0	0
Spain	5	1	11	0	1	3
UK	10	2	10	0	1	8
Total No. of SPCs invalidated	156	25	188	0	31	75

Table — 4: Number of SPCs granted v SPCs invalidated percentage analysis

SPCs granted/Invalidated	Type of patent			
	Product	Composition	Combination	Method of use
Number of SPCs granted	5575	1945	125	567
Number of SPCs invalidated	188	188	31	75
Percentage of SPCs granted	3	10	25	13

office of respective EU country. Table 5 represents the data for SPCs that were granted to national patents versus SPCs granted to European patents. The data for SPCs granted in Cyprus was not available and excluded from analysis. For the top 5 countries (France, Germany, Italy, Spain and UK), Austria, Belgium, Denmark, Lithunia, Latvia, Netherlands and Sweden number of SPCs granted for national patents were significantly less as compared to number of SPCs granted for European patents. The probable reason could be higher concentration of Innovator companies in these countries, which prefer protection across Europe rather than single country. On the other hand, in countries like Bulgaria, Croatia, Czek, Finland, Hungary, Ireland, Luxemburg, Poland and Slovakia SPCs granted to national patents were higher than those to European patents. One of the reasons could be that these countries joined SPC regulation recently. Another reason could be lack of harmonization of national legal framework with Europe, which prompted Innovator companies to file SPCs to national patents for these countries.

Avenues for Challenging SPCs and Guidelines for Prediction of Generic Market Entries in EU Countries

Pharmaceutical Product Life Cycle

Pharmaceutical companies have two business models.[14] First one encompasses large multinational companies that invest significantly in research and

Table — 5: *Number of National SPCs granted* v *European SPCs granted*

Country	Number of National SPCs granted	Number of European SPCs granted
Austria	76	552
Belgium	86	478
Bulgaria	36	33
Croatia	10	0
Czek	108	40
Cyprus	NA	NA
Denmark	161	318
Estonia	48	75
Finland	215	121
France	23	517
Germany	20	461
Greece	8	377
Italy	23	637
Hungary	113	16
Ireland	412	221
Luxembourg	15	629
Lithunia	3	114
Latvia	32	117
Netherlands	52	557
Portugal	66	275
Poland	51	2
Romania	9	78
Spain	31	466
Sweden	64	595
Slovenia	20	189
Slovakia	99	48
UK	80	537

development to bring new molecules in market. These companies have potential to market their own products. Second model encompasses generic companies, developing biotechnology or large molecules that entered into partnership with large multinational companies in final stages of development as they did not have sufficient resources to market products. Table 6 represents top innovator companies selling their products according to market share.

In order to maintain the monopoly in the market or to maintain market share, patent holders always try to file blocking patents to hinder the generic development and entry. Once patents are granted, SPC applications can be filed for the patents covering approved products. Based on detailed literature search and in-depth analysis of SPC data collected for various European countries, there are various aspects worth highlighting. There are numerous examples, wherein a single patent covers multiple products like A, B, C, etc. Innovator companies develop products according to research on each of the product. For example, first they develop product A which becomes

Table — 6: List of companies by market share of innovator products in Europe[13]

Company Name	Percentage Market Share
Novartis	13.92
Sanofi	13.71
Pfizer	11.49
GlaxoSmithKline	9.30
Teva	6.36
Merck	6.33
Bayer	5.05
Johnson and Johnson	3.91
AstraZeneca	3.77
Boehringer Ingelheim	2.97
Bristol-Myers Squibb	2.92
Roche	2.77
Stada	2.69
Krka	2.68
Lilly	2.63
Allergan	2.55
Novo Nordisk	2.50
Menarini	2.28
Merck KGaA	2.18
Total	100

Source: Margaret Kyle. Economic Analysis of Supplementary Protection Certificates in Europe. MINES ParisTech; 2017.

commercially successful. They file SPC for product A for basic patent. Later, the company develops product B, launches product B into the market and files SPC application for the same.

In some instances, after successful launch of product A, companies find that combination of A with B is better than product 'A' alone. Under such circumstances, companies filed SPC application for A+B for same basic patent near to expiry of SPC for product A. In case of patents having Markush claims, a claim which covers thousands of compounds would provide advantage as any compound out of these thousands compound covered by the claims can form the basis for new SPC application. In some cases, if the product B is found to be more therapeutically effective than product A, then in such cases after launch of product B, the entire market is likely to shift to product B. The commercial sales of product A would reduce and deter other companies from developing and launching product A. At the same time, the new SPC for product B will block the entry of less expensive products.

Multiple SPCs per patent is common in biotechnology field, wherein single basic patent can be basis for number of products. In some instances,

product covered by basic patent is approved for use in condition X. However, after further research, pharmaceutical manufacturers find that product A can also be used for condition Y. In such cases, companies file new patents and once such patents get granted, they will file SPC for use for condition Y. SPC regulation also allows multiple SPC applications per product, wherein the product is covered by multiple basic patents owned by different patentees. In some cases, this approach is useful to deter competition. The patents that can be used for filing SPC applications in such instances are composition patents, drug delivery patents, device patents, method of use patents, etc.

In some instances, patent holder initially does not foresee and understand multiple inventions covered by basic patent and therefore fails to claim the invention. In such cases, there are attempts made by patent holders to amend the claims of granted patents so that the additional inventions can be covered. In some other instances, innovators deliberately file national patents as well as European patent. After product approval, SPC filed for national patents in some of the countries is to create additional barrier incase European patent is successfully challenged by the competitors. The SPC for national patents needs to be invalidated to launch the competing product. Some pharmaceutical companies, referred to as generic companies, invest little in research and development of new molecules, but they focus on developing bioequivalent versions of old drugs or off patent drugs. Such companies need to establish only that their products are substantially similar to reference product. They rely on the safety and efficacy of originator products and are able to sell products at lesser price while maintaining profits. Table 7 represents top companies selling generic products.

Table — 7: List of companies by market share of generic products in Europe[13]

Company Name	Percentage Market Share
Teva	24.41
Novartis	17.64
Stada	10.28
Mylan	6.23
Aurobindo	4.74
Sanofi	4.58
Allergan	4.06
Pfizer	4.04
Intas	3.99
Merck KGaA	3.70
Fresenius	3.03
Sun Pharma	2.93
Krka	1.99
Orion	1.60
Bluefish	1.52
Apotex	1.47
Alter	1.38
Servier	1.31
Esteve	1.10
Total	100

Source: Margaret Kyle. Economic Analysis of Supplementary Protection Certificates in Europe. MINES ParisTech; 2017.

Avenues for Challenging SPCs

In-depth analysis of case laws relating to SPC regulations and comparative country wise SPC data provided useful insights for identifying avenues for challenging SPCs in various EU countries. SPC rulings help generic companies to find out whether the scope of claims of basic patent covers the combination for which SPC is applied, then grant of SPC is not possible. Medeva [15] and Georgetown 1[16] rulings are applicable to previously granted SPCs too and thus, provide opportunities for generic companies to find out avenues for challenging SPC for obtaining early market entries. Further, interpretation of Article 3 of SPC regulation is helpful for generic companies in order to successfully launch generic products in the European market. Table 8 explains the possible avenues for SPC challenges based on the current case laws.

Guidelines for Prediction of Generic Market Entries

Following points may be considered while predicting generic market entries.

Data Exclusivity: For every new approval of product, innovator usually gets 10 years of data protection starting from date of notification of MA, if that product is first to be approved by EMA. This automatically shields the product from generic competition for at least 10 years.

Patent Protection: Other than data exclusivity, any unexpired patent protection blocks the generic product launch, unless the generic company decides to either design around the patent or to challenge its validity.

SPC/Pediatric Extension: Further if SPC/pediatric extensions exist for the patents, they block the generic entry, unless the generic company successfully challenges such extension in national court or designs around such blocking patent with SPC.

Based on the above guidelines, it would be possible to predict the timeline for generic product launch in the market.

Table — 8: Avenues for challenging SPCs

Case (Decision date)	Basic patent claims	MA in place for	Possible avenues challenge to SPCs if granted for
Medeva[15] (24 November 2011)	A+B	A+B+C+D	A or B; A+B+ (C or D); A+B+C+D
Yeda[17] (24 November 2011)	A+B	A	A or B; A+B
Queensland[18] (25 November 2011)	Patent 1. A+B Patent 2. C Patent 3. D	A+B+C+D	A+B+C+D
	A*	A (+B+C)	A+B; A+B+C
	A[@]	A (+B+C)	A; A+B; A+B+C
Daiichi[19] (25 November 2011)	A, A+B[#]	A A+B	A+B
Georgetown 1[16] (12 December 2013)	A, B, C, A+B, B+C	A+B+C+D A+B	A+B+C+D
Actavis[20] (12 December 2013)	A, A+B	A+B	A+B [in circumstances where the SPC was already granted to A for the basic patent & Article 3(d) of SPC regulation is violated]
Eli Lilly[21] (12 December 2013)	A[$], B[$]	A B	A[$], B[$]
GlaxoSmithKline[22] (14 November 2013)	A+x[+]	A+x	A+x[+]

*Claimed in the wording as product of the process claim; [@]Product of process but not specified in the wording; [#]Generically disclosed; [$]Covered by Markush claim; [+]Inactive ingredient

Probable Solutions to Loopholes in SPC Regulations

There is a significant impact of Medeva[15] and Georgetown 1[16] rulings on the SPC regulation in Europe. From Losartan[19] and Valsartan[23] rulings, it is apparent that innovator pharmaceutical companies would be benefited, in blocking others from selling any products containing 'A' in combination with additional active agents even if SPC is granted only for 'A'. At the same time, Daichii[19] case clarifies that no SPC would be possible for the combination product, A+B, if claims of basic patent fail to identify them. Innovator companies should be vary of Sanofi[20] ruling, wherein CJEU even went on to invalidate the SPC for combination product where basic patent claimed the combination generically. These rulings are eye-openers for biotechnology companies as well, especially those involved in research for vaccines in Europe as the vaccines are always complex products or mixture of multiple active ingredients.

For grant of an SPC, the Medeva[15] ruling allows presence of additional active ingredients in the approved product than the one for which SPC is applied and which is claimed by the basic patent. Lilly case highlights the fact that it is not necessary for the product under Article 3(a) to be identified or specified in the wording of the claims; the functional language of the claim can also provide support for the generic claims of product. In addition, there is no case taken up by CJEU regarding Markush claims where the compound is disclosed by Markush structure but not specifically in the claims. CJEU ruling on Lilly[21] case has created more confusion than providing clarification as it has left the outcome of the interpretation to the individual national courts. More appeals may be possible in future.

The referrals made to CJEU in Telmisartan case are equally important for innovator companies as they deal with amendment in the claims of granted patent made after MA granted for the product. The answers to the questions raised in the Actavis case[24] are somewhat clear in light of Sanofi ruling by CJEU. The CJEU failed to answer whether the amendment to claims is possible after patent and SPC is granted.

Based on review of SPC data for combination products, the number of SPCs filed for combination products are decreasing in all European 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[24] case clarified Article 3 (a) and (c) of Regulation (EC) 469/2009, the CJEU shall have to answer the questions relating to patent amendments after grant of patent to cover incremental inventions like combination products. CJEU shall have to clarify more questions on issues involving patent amendments and SPC for combination products. Better clarity by CJEU will help patent holders craft their strategies well in advance right from the drafting basic patent which effectively may 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 were found to be invalid by patent offices and courts. Rise in number of SPC applications for composition patents in future may be expected.

For product patents, the CJEU rulings in Sanofi [20] and Lilly[21] remain unanswered in case of patents with Markush claims. Patents with Markush claims could be applicable for a limited number of compounds, but the claims themselves cover thousands of compounds. Whether the ruling in Lilly[21] or Sanofi[20] case would be applicable to Markush claims still needs to be clarified. The Sanofi case highlights the fact that the compound should be identified and specified in the wording of the claims, but Lilly case implies that functional language of claim is sufficient; hence SPC for compounds based on Markush claims remain questionable. One probable solution would be more proactive approach by regulatory bodies and CJEU in taking up questions relating to SPC regulation and interpreting them explicitly.

Another question is about the expiry of a Markush claim including compounds for which a number of SPCs are granted. In the Lilly case, Human Genome Sciences Inc.[21] (HSG) had its own SPC for Belimumab but based on Lilly's invention of Tabalumab, an additional SPC could be granted to same patent. This suggests that patents can be revived multiple times by filing application for compounds covered in Markush claims. In such instances, for how long a patent could remain enforceable is still unclear. A probable solution to this loophole would be coordinated efforts from European patent offices, courts and national medicinal regulatory bodies to harmonize the interpretation of SPC regulation.

Despite of above questions, product patents remain first choice for patentee to file SPC application as they provide strong protection against competitors. However, the number of SPCs filed for the product patents are also less compared to the one which are granted. One probable reason could be scarcity of new compounds, biologics, devices or article which results into such decline in number. One can expect these number to rise in the future if new molecules get discovered and marketed at a faster rate. The rise of the UPC in Europe wherein one patent can be granted throughout Europe are likely to pose additional questions regarding SPC. 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.

Guidelines for Patent Claim Drafting

Based on the review of the CJEU case laws and decisions handed down by the national courts or IP offices, following points should be considered while drafting patent claims.

1 In case of molecule patents in pharmaceutical field, the compounds intended to be covered in the scope of Markush claims should be identified and specified in the wordings of the claims of molecule patents.
2 The Markush claims should have adequate disclosure in the specification of the patent and enablement.
3 In case of biotechnology based products such as, the antibody/proteins etc., the product of interest should be covered in the scope of Markush claims of patent or at least be defined by the functional language of the claims.
4 In case of combination products, the combination products should be clearly disclosed in the wordings of the claims.
5 If the main invention of patent is compound 'A' and the specification also disclose generically combination of compound 'A' with other chemical/ therapeutic class of compounds, then care should be taken to identify and specify the existing compounds of each chemical/therapeutic class in the specification as well as the claim.

6 If the patent discloses multiple inventions which separately qualifies for SPC, then each invention should be claimed in separate patents (by filing divisional applications).
7 A generic disclosure of the invention may not be sufficient for support of SPC application.
8 Composition claims containing active ingredient along with excipients may not be eligible for SPC, if the active ingredient is already subject of SPC application.
9 Claims directed to the carrier system or excipients, which themselves are not therapeutically effective unless combined with active ingredient, are not eligible for SPC application.
10 Second method of use claims may be eligible for SPC application, if they are not overlapping with the first method of use for which SPC is already been granted.

Conclusion

Based on in-depth study of SPC regulation, review of case laws, survey of SPC related to questionnaire amongst IP experts and SPC country wise data analysis, following conclusions have been drawn:

- The most common type of patent associated with SPC was a compound patent.
- Higher percentage of SPCs were invalidated for patents on combination products, hence there was lesser inclination of patentees to file SPCs for those patents.
- There was significant number of SPCs filed and granted for composition patents.
- The percentage of getting the SPCs for composition products invalidated was quite low.
- SPC regulation has loopholes which if exploited will benefit generic industry.
- Medeva and Georgetown rulings provide opportunities for generic companies to find out avenues for challenging SPC for obtaining early market entries.
- A more proactive approach by regulatory bodies and CJEU in taking up questions relating to Markush claims and interpreting them explicitly is required.
- Coordinated efforts from European patent offices, courts and national medicinal regulatory bodies would be required to harmonize the interpretation of SPC regulation.
- In case of biotechnology based products, the product of interest should be covered in the scope of Markush claims of patent or at least be defined by the functional language of the claims.
- To ensure adequate patent claim drafting for combination products, the combination products should be clearly disclosed in the wordings of the claims.

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