

SPC Regulation, Analysis of SPC Case Laws and Roadmap for Pharmaceutical Industry

Omkar Joshi,^{1†} Archana Roy¹ and Manthan Janodia²

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

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

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The purpose of the study is to understand Supplementary Protection Certificate (SPC) regulations associated with pharmaceutical products. In this study the case laws associated with SPC regulation and decisions handed down by national IP courts across Europe have been reviewed. On one hand, this study provided insights into innovator strategies in managing product lifecycles and on the other hand, it also helped in studying perspective of generic drug industry. A survey amongst IP experts about SPC regulation have also been carried out. It is observed that there is a need to amend the SPC regulation to provide better clarity to both innovators and generic drug industry.

Keywords: SPC, Court of Justice for European Union, First Marketing Authorization, European Economic Community, Pediatric Extension, European Free Trade Association, New Chemical Entity, Pediatric Implementation Plan, Patent Term Extension, European Commission, Unitary Patent System, Patent Term Adjustment, Unified Patent Court System, One Product-Multiple Extension, One Patent-Multiple Extension

SPC Regulation for Medicinal Products in Europe

Supplementary Protection Certificate (SPC)¹ is a unique intellectual property (IP). In conventional language, it can also be called Patent Term Extension (PTE). SPCs are granted to innovator pharmaceutical/biotechnology companies or brand companies, universities or researchers in return of significant investments made in the research field especially in pharmaceutical and biotechnology field. The grant of SPC prolongs the life of patent which protects the pharmaceutical or biotechnology products. In short, SPCs are of prime importance to maintain monopoly in the market. On the other hand, SPCs are road blocks to generic products to enter into market immediately after patent expiry. The grant of SPCs can extend the monopoly of innovator pharmaceutical/biotechnology companies or brand companies, universities or researchers and at the same time deprive people of the affordable generic products. There have been always attempts by Court of Justice for European Union (CJEU) (the highest legal authority in Europe) and National Intellectual Property Offices (IPO) across Europe, to maintain the balance between providing medicines to the people at

affordable price (in other words early generic product entry) by refusing SPC and unjustified patent extensions, and at the same time promoting innovation and research by granting SPCs to innovators.

Generally, innovator companies file the basic patent application at very early stage of discovery to protect its intellectual property rights (IPR). After filing the patent application, the discovery progresses through various stages. For pharmaceutical products, molecules are first tested in animals in preclinical trials and then in mammals like rodents, for assessing the potential to develop these products further. Final stage involves human clinical trials, which are essential for any drug molecule to get approved for human use.² This process takes years to complete after patent filing. Once the molecule clears the regulatory process, the pharmaceutical product gets launched into the market as described in Fig. 1. For all these years, innovator companies have to invest significant amount of money and research work in the discovery, clinical trials, and regulatory approvals of new drug products. In order to compensate the cost, European Convention allows PTE which is known as SPC in Europe that extends the expiry of the patent and maintains market exclusivity of Innovator Company.

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

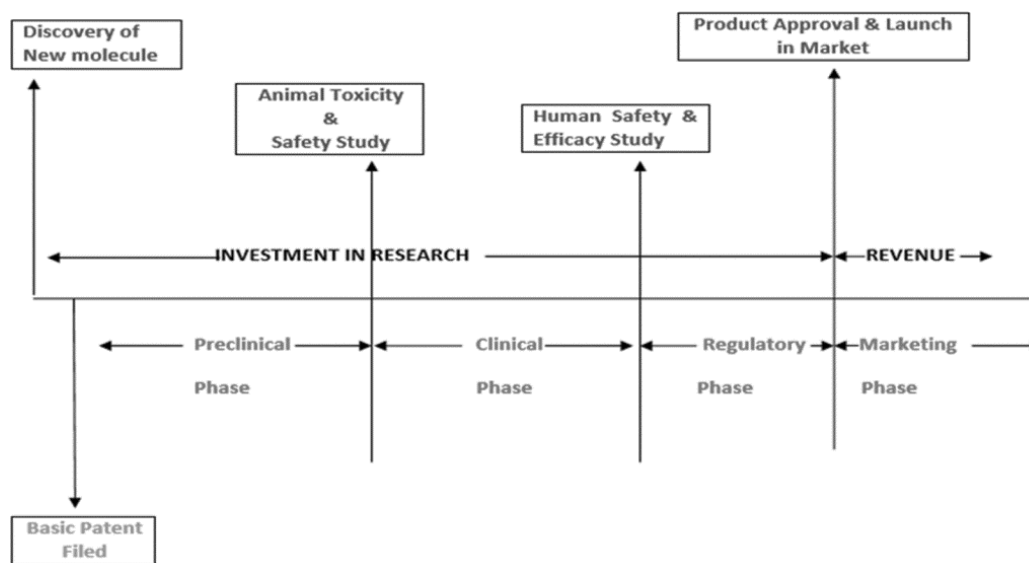


Fig. 1 — Product Approval Process from Discovery of Molecule till Launch

Term of SPC

The maximum term of any SPC is five years which can be added to the normal twenty years expiry of the patent. The following formula is used to calculate the SPC term for any pharmaceutical or biotechnological product:²

$$(X-Y) - 5 \text{ years}$$

Where, 'X' is date of First Marketing Authorization (FMA) meaning the date of first approval of the product in the European Economic Area.

'Y' is the date of application of basic patent protecting that product.

To illustrate the calculation of SPC term, a hypothetical example is provided below:

If, X = Date of FMA, is 1 January 2011; and

Y = Application date of basic patent, is 1 January 2000, then

$$\begin{aligned} \text{SPC term} &= (1 \text{ January } 2011 - 1 \text{ January } 2000) - 5 \text{ years} \\ &= 10 \text{ years} - 5 \text{ years} \\ &= 5 \text{ years} \end{aligned}$$

In 1990, European Economic Community (EEC) concerning the creation of an SPC for medical products presented by the European commission set out a number of objectives (and hypotheses) backing the proposal, *inter alia*: harmonization of the SPC protection in the internal market, increased innovation productivity, limitation of patent erosion and therefore reinforced financial incentives for Research and Development, limited delocalization of research, increased competition, reduction of the price of medicines by extending the investment's payback

period under patent exclusivity and increased transparency.

European Community Regulation (EC) No. 469/2009³ of the European Parliament and of the Council of 6 May 2009 governs the SPCs for medicinal (pharmaceutical and biotechnology) products. A wide range of sectors rely on the European industrial property framework. Some of those sectors develop products that, for health and safety reasons, are subject to lengthy and costly testing to comply with stringent EU regulatory requirements related to safety, efficacy and quality before obtaining marketing authorization. At the time of the adoption of the EU SPC rules, two decades ago, pharmaceutical and agrochemical industry were subject to the lengthiest product testing and market authorization systems. Typically, for these products, marketing authorizations were normally granted several years after the relevant patents were filed leading to a significant reduction of their effective patent protection. To address the concern that innovator companies were no longer given a fair opportunity to recover their research and development efforts and investments, EU introduced the first SPC regime in 1992 with the Council Regulation (EEC) No. 1768/92⁴ concerning the creation of SPC for medicinal products. Four years later, regulation (EC) No 1610/96⁵ of the European Parliament and of the Council was adopted concerning the creation of an SPC for plant protection products.

SPCs are intellectual property rights (IPRs) that serve to compensate patent holders of pharmaceutical

and plant products for the loss of effective patent protection. The certificate does not extend the term of the patent itself, but only extend those claims of the patent which provides protection to product of interest. Article 2 of SPC regulation No 469/2009³ of Europe, entitled ‘Scope’, is worded as follows: ‘Any product protected by a patent in the territory of a member state and subject, prior to being placed on the market as a medicinal product, to an administrative authorization procedure as laid down in Directive 2001/83/EC⁶ of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use or Directive 2001/82/EC⁷ of the European parliament and of the council of November 6, 2001 on the Community code relating to veterinary medicinal products may, under the terms and conditions provided for in this regulation, be the subject of a certificate.’

Article 3 of SPC regulation No 469/2009³ of Europe, entitled ‘Conditions for obtaining a certificate’, mentions: ‘A certificate shall be granted if, in the member state in which the application referred to in Article 7 of SPC regulation is submitted and at the date of that application:

- (a) the product is protected by a basic patent in force;
- (b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC⁶ or Directive 2001/82/EC⁷, as appropriate;
- (c) the product has not already been the subject of a certificate;
- (d) the authorization referred to in point (b) is the first authorization to place the product on the market as a medicinal product.’

Article 4 of SPC regulation No 469/2009³ of Europe, titled ‘Subject matter of protection’, is worded as follows: ‘Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate.’

Article 5 of SPC Regulation No 469/2009³ of Europe, titled ‘Effects of the certificate’ mentions: ‘Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations’. Articles 3, 4 and 5 of SPC Regulation³ are most widely disputed and interpreted differently by national IP Patent Offices and Courts across Europe.

Pediatric Extension Associated with SPC Regulation

The only possible extension to the SPC is pediatric extension. By regulation (EC) No 1901/2006,⁸ additional six months of Pediatric Extension (PED) is available which can be added to the five year term of SPC. So, the maximum period of protection that can be available under SPC regulation is five years and six months as described in Fig. 2 and illustrated further in the below example.

$$\begin{aligned} \text{SPC term} &= [(X-Y) - 5 \text{ years}] + 0.5 \text{ years} \\ &= 5 \text{ years} + 0.5 \text{ year} \\ &= 5.5 \text{ years} \end{aligned}$$

$$\begin{aligned} \text{Final Patent Expiry} &= 1 \text{ January } 2001 + 20 \text{ years} \\ &= (\text{normal patent expiry}) + 5.5 \text{ years} \\ \text{SPC Term} &= 1 \text{ July } 2026 \end{aligned}$$

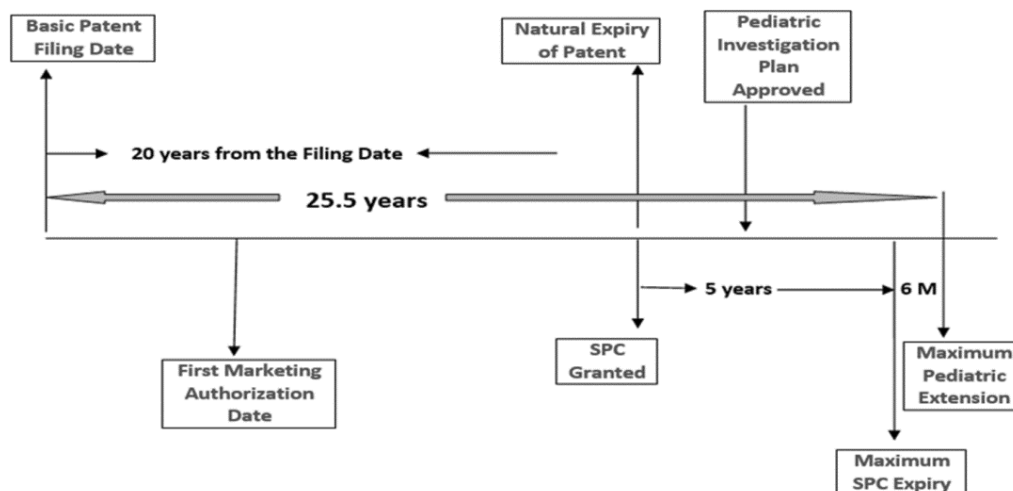


Fig. 2 — Maximum Expiry of European Basic Patent with SPC and PED

The SPC regulation provides for substantive and some procedural requirements for the grant of SPCs at national level; they do not result in a Europe wide SPC protection but instead ensure that SPC protection could be applied across all the EU member states. It should be noted that when these rules were adopted, there was no prospect on a unitary patent title that is currently expected to soon come into force within the EU. The unitary patent was established by regulations EU 1257/2012⁹ and 1260/2012¹⁰ and will be applicable from the date of the entry into force of the Agreement on a Unified Patent Court.

Uncertainty Associated with SPC Regulation and Proposed Solutions

It was the intention of the European Commission's proposal of SPC Regulation in 1990 to provide for a simple, transparent system which can easily be applied by the parties concerned. The current SPC regulation focuses on the substantive requirements for the grant of the title, but leaving most features of the grant procedure to national laws. This has resulted in gaps and divergence in areas of high relevance in practice. Some member states conduct *ex-officio* examination of the substantive requirements stipulated in the SPC regulation, while others only check formal requirements. Some SPC granting authorities consult regulatory agencies in relation to data related to the marketing authorization. Furthermore, the regulations stipulate that the procedure for opposition to the granting of an SPC shall be excluded. Some national patent offices have established a procedure for third party observations to the grant of SPCs.¹¹⁻¹²

The SPC Regulation was adopted two decades ago. Since then, the innovation models of the pharmaceutical and agrochemical sectors have evolved notably. In 2014, of the eight top-selling drug products, seven were biologic medicinal products and their patent protections were expiring within 10 years. Many of the preliminary references referred to the CJEU in the year 2017 are concerned with biologic products. For example, one of the challenges is to determine whether an SPC based on a particular authorized biological product can validly extend protection to an authorized variant of that product. The CJEU has ruled on the SPC eligibility of products consisting of certain combinations of ingredients (MIT¹³ case was perceived as restrictive by relevant stakeholders) and new uses of previously authorized active ingredient (Neurim¹⁴ case).

There are controversies related to the patentability and SPC eligibility of second medical uses that require clinical testing for regulatory approval. Potential infringement of second medical use patents is causing increasing challenges in some EU member states (Germany, Netherlands and France) leading to conflicting rulings by national courts hindering the use of medical indication in public procurement procedures. Conflicting National Court Rulings are taking place in Europe regarding SPC eligibility for products authorized under Directives 93/42/EC¹⁵ for medical devices (a large class of medical devices are drug-device combinations; also some drug-device products can be authorized under Directives 2001/83/EC or 2001/82/EC) and 90/385/EEC¹⁶ for implantable medical devices, or for diagnostics.

It was the intention of the European Commission's proposal of SPC Regulation in 1990 to provide a solution with harmonization of the conditions for the SPC application and the rules governing it and therefore, standardization of the duration of protection of medicinal products has to be established to ensure proper functioning of the internal market. Recent case laws of CJEU have brought some harmonization on the calculation of the SPC term. Other aspects of the SPC regulation might not be fully harmonized in view of the issues discussed earlier. Indeed, the current limited territorially fragmented system of SPCs for medicinal and plant protection products may be at odds with current European trends in the sector and require revision.

The current SPC Regulation, as noted above, foresees SPCs as national rights granted by national authorities. Therefore, there is no SPC protection which provides uniform protection throughout the EU through a centralized authorization, coordination and supervision arrangements. While the current SPC system is widely used by the industry and considered a success, several legal issues have emerged in practice which is reflected in numerous referrals to the CJEU, and in light of further developments in this area (biotechnology), those issues may create obstacles to the full potential that the EU SPC system can deliver. Uncertainty associated with SPC regulation and proposed solutions to those uncertainties are depicted in Fig. 3.

Currently, there is no consolidated comparative analysis or guidance available on country wise SPC provisions in Europe. There is no compiled information available about the court system which has jurisdiction on SPC regulation in each EU

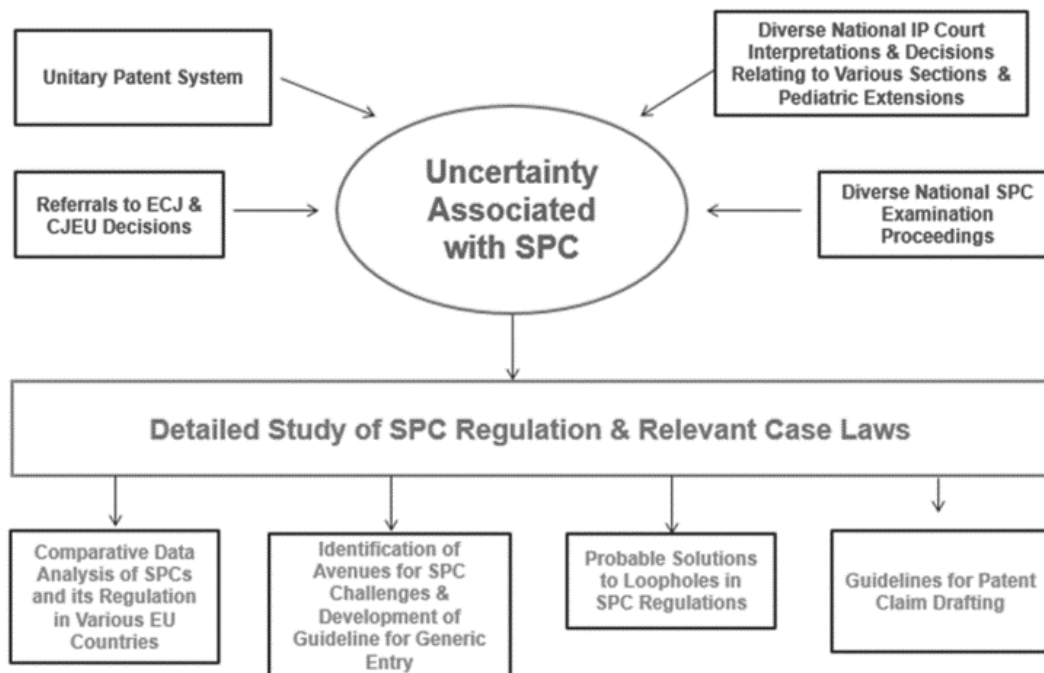


Fig. 3 — Uncertainty Associated with SPC Regulation and Proposed Solutions

country. As a result, the proposed research work aims at comparative analysis for SPC provisions and regulations along with information about court system in each European country. This organized information would be very useful for innovator and generic pharmaceutical industry as well as academicians and academic institutes. Another important aspect of this research work is identifying avenues for challenging SPCs for medicinal products. Indian pharmaceutical industry is a global leader in supplying generic medicines. This research work would help these generic companies to identify opportunities to challenge SPC for medicinal products. Development of generic medicines involves considerable amount of investment.

The recent rulings in CJEU like *Lilly*,¹⁷ *Georgetown*¹⁸ and *Actavis*¹⁹ 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, failure to which patentee might lose the patent right or monopoly in the market. The CJEU and the EFTA (European Free Trade Association) courts 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 (provisional marketing authorizations and marketing authorizations granted by the Swiss medicine agency), or eligibility of the pediatric extension for patented medicinal products not eligible to SPC protection. The scope of the ‘active ingredient’ of bio-similars is an emerging challenge for the scope of protection of the SPC of biomedicines. The proposed research work also aims at analyzing these rulings and proposing guidelines for patent drafting mainly for New Chemical Entity (NCE) patents. This would be particularly useful for brand companies and research institutions which develop innovative products. To sum up, this study of SPC regulation is an attempt to focus on the above mentioned gaps, shortcomings and issues associated with current SPC system and to propose probable solutions to them. Even European Commission has initiated multiple studies through third parties in order to review the SPC regulation.

CJEU Case Laws

Articles 3, 4 and 5 of SPC regulation are most widely disputed and interpreted differently. The below sections focus mainly on the case laws associated with these Articles.

Cases on Article 3 of SPC Regulation

Regarding Article 3(a), CJEU in *Farmitalia*²⁰ case established that it is the issue of claim construction to

determine whether the product is protected by basic patent. Similarly, in Takeda²¹ case, it was held that product in its salt form was protected by basic patent even though the claims did not include salt form *per se*, on the basis that the specification made it clear that the product could be obtained in the salt form. In Centocor²² case, it was found that a product consisting of monoclonal antibody was not protected by claims directed to combination of antibody and anti-microbial agent. Similar decision was reached in Takeda²³ case, wherein products comprising combination of active ingredients were not protected by patent which claimed only one of the actives because the basic patent contained no reference to the combinations specified in the SPC applications. In Daiichi²⁴ case, the Court of appeal upheld the earlier decision of the patent court, which found that the SPC was properly granted despite the existence of earlier marketing authorization for racemate mixture. In Gilead²⁵ case, Patent Court held that although the specific combination was not disclosed in the specification of basic patent, but such a claim did protect the combination within the meaning of Article 3(a) of SPC Regulation. However, in Astellas²⁶ case, Patent Court rejected the SPC as the basic patent did not specifically disclose and claim a combination of active ingredients. In Sankyo²⁷ case, SPC application was rejected for combination of active ingredients on the basis that it did not meet the requirements of Article 3(a) of SPC regulation. On appeal in Sankyo²⁸ case, the CJEU provided the decision similar to its Medeva²⁹ ruling confirming that Article 3(a) of SPC Regulation precludes the grant of SPC to active ingredients which are not identified in the wording of the claims of basic patent. Similar decisions were reached in Georgetown¹⁸ case, University of Queensland³⁰ case and Yeda³¹ case. In Actavis³² case, the patentee tried to amend the claims in granted patent to cover the follow on combination products. The validity of such amendment was questioned in CJEU, but it was not answered.

In Imclone³³ case, it was held that marketing authorization for single active ingredient which additionally specified the clinical use of that active in conjunction with another active ingredient was not, for the purpose of Article 3(b) of SPC regulation, a valid authorization to place such combination product on the market. In Farmitalia²⁰ case, the Court ruled that where an active ingredient, in the form of an individual salt, is referred to in notice of authorization

(under Article 3(b) of SPC Regulation), the SPC is capable of covering the active ingredient both as referred to and in its derived forms as salts and esters, provided that same is also covered in the scope of protection of the basic patent.

Medeva²⁹ and Georgetown¹⁸ cases provide important guidelines for SPC applicants. These decisions by CJEU differentiated between grant of SPC and enforcement of patent right. In order to obtain SPC for A+B (where A = one active ingredient and B = another active ingredient), it is necessary that the combination A+B should be identified/specified in the wordings of the claim of the basic patent. However, if the SPC is granted for 'A' for the basic patent, the holder of such SPC can block others from selling any product which contains 'A' as an active ingredient in combination with other active ingredients like B, C, etc. Based on these decisions, following can be interpreted in terms of SPC protection as summarized in Table 1.

In Queensland³⁰ case, the CJEU reiterated its decisions of Medeva²⁹ and Georgetown¹⁸ cases and clarified that if a basic patent relates to process by which a product is obtained, Article 3(a) of SPC Regulation only permits an SPC to be granted for a product which is identified in the wording of the claims of the basic patent, as the product derived from manufacturing process in question. Applying the decision of Queensland³⁰ in Icahn School of Medicine³⁴ case, it determined that Article 3(a) of SPC Regulation is in compliance if the product identified in the patent claims is the product derived from the process protected by that patent.

The Court also confirmed in Sandoz³⁵ case that Article 3(a) of SPC regulation will be complied if product falls within the scope of Markush claim. In addition, the patent office will determine whether the product specified/identified in the wording of the claims of the basic patent is based on claim interpretation of the product indicated in claim or shown to result from the process protected by basic patent or encompassed by functional definition as decided in Lilly¹¹ case. In Novartis³⁶ case, the UK

Table 1 — Interpretation of Medeva and Georgetown decisions

Basic patent claims	MA granted for	SPC applied for	Based on Medeva Ruling, SPC is
A	A + B	A	Allowed
A + B	A	A	Not allowed
A	A	A + B	Not allowed
A + B	A + B	A	Not allowed

Court noted that the test of whether the product is being adequately identified/specified in the wording of the claims is unclear. However, the Court went on to determine that a claim to a general method of producing a molecule with binding specificity for a particular target did not adequately specify or identify the specific antibody for the purpose of Article 3(a) of SPC Regulation. In Actavis³⁷⁻³⁸ case, a similar question was referred to the CJEU.³⁹ In Lilly¹¹ case, the CJEU answered that functional definition may be sufficient for a product to be protected by a basic patent. In Teva⁴⁰ case, the question was referred to the CJEU for combination products. The question asked was *'what are the criteria for deciding whether the product is protected by a basic patent in force in Article 3(a) of SPC regulation?'*

In Forsgren⁴¹ case, the CJEU ruled that grant of SPC is precluded for product whose effect does not fall within the therapeutic indications covered by the wording of the MAs. In British Technology Group⁴² case, it was determined that a letter from medicines control agency granting permission for a product to be supplied for clinical trial was unacceptable as it was not issued in accordance with the directives. Similarly, in Merck⁴³ case, it was decided that end of procedure communication from a reference member state closing the decentralized approval procedure did not constitute a valid authorization to satisfy the requirement of Article 3(b) of SPC Regulation.

In Novo Nordisk⁴⁴ case, it was concluded that the grant of SPC for product to one holder of basic patent does not provide ground under Article 3(c) for rejecting grant of SPC for second holder for identical product of a different basic patent on the basis of identical marketing authorization. The CJEU has also decided the issue in AHP Manufacturing⁴⁵ case, wherein it was held that Article 3(c) of SPC Regulation does not prevent the grant of a certificate to the holder of a basic patent for a product if, one or more SPCs have already been granted to other holders of other basic patent. However, according to Medeva²⁹ case, only one SPC may be granted for the basic patent. Hence, the question regarding the interpretation of Article 3(c) of SPC Regulation was referred to the CJEU in Actavis³⁹ case and in Georgetown⁴⁶ case. The CJEU determined that it is possible, on the basis of a patent which protects several different products, to obtain several SPCs in relation to each of those products provided that each of those product is protected by the basic patent.

However, Article 3(c) of SPC regulation prevents successive SPCs based on single patent for the same active in combination with another active not itself protected by the patent. In Actavis case³², the CJEU held that where an SPC has already been granted relating to an active ingredient which constitutes the sole subject matter of the invention, the patent holder is precluded from obtaining an SPC for a combination product claimed in a subsequent claim of the same patent comprising that active ingredient and another substance not constituting the subject matter of the invention. In Teva⁴⁷ case, it was held that if the combination represents a distinct invention protected by the patent, it should not matter whether it is protected by the same patent or by a different patent. In other words, it is the active ingredient that is found to represent the subject matter of the invention that are critical in determining what the product is, and not whether the subject matter of the invention is found in one or more patents.

In Yissum⁴⁸ case, the issue was related to Article 3(d) of SPC Regulation, wherein it was held that the MA to place the product on market is not the first for the product, regardless of whether the earlier authorization was for a different medical condition. The CJEU also ruled that when a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product. Similar question was answered in MIT¹⁶ case by the CJEU. In Neurim⁴⁹ case, the CJEU ruled that the mere existence of an earlier MA (for veterinary product) does not preclude grant of SPC for a different application of the same product for which MA has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purpose of SPC. In Abraxis⁵⁰ case, the question was referred to the CJEU, whether Article 3(d) of SPC Regulation permits grant of SPC for new formulations of old active ingredients.

Case on Article 4 and Article 5 of SPC Regulation

In Novartis⁵¹ case, the CJEU provided guidelines for interpretation of Article 4 and Article 5 of SPC Regulation, noting that SPCs provide patent-like infringement protection for the duration of the SPC. Subject to provision of Article 4 of SPC Regulation, the certificate shall confer the same right as conferred by the basic patent and shall be subject to the same limitation and obligation.

Pediatric Extension Associated with SPC Regulation

In Otsuka⁵² case, the application for a six month extension to SPC was just filed before the deadline for doing so, which is 2 years before the expiry date of the SPC. The SPC concerns aripiprazole, the active ingredient in medicinal product, Abilify®, marketed by Otsuka for the treatment of schizophrenia and bipolar disorder. The applicant was carrying out clinical studies concerning the use of Abilify® to treat these two conditions in children. On the date of application, all studies in the agreed Pediatric Implementation Plan (PIP) had not been completed. As a consequence, the application, as acknowledged by the applicant, did not contain MA with an updated Summary of Product Characteristics (SmPC) including the results of the studies in all the pediatric population nor did it contain a statement of compliance according to Article 28(3) of the pediatric regulation of SPC.³ These are necessary requirements for obtaining the six month extension to the SPC under Article 8 of the SPC Regulation and Article 36 of the pediatric regulation of SPC. The applicant argued that they should be entitled to the extension based on all studies in the pediatric population that they had completed so far and because the delay in completing these studies arose from the time taken

to agree the PIP with the EMEA, which was not their fault.⁷

The hearing officer took note of IPO decision BL O/035/09 in Merck⁵³, referred to the UK Court of appeal decision in EI du Pont case Office⁵⁴, and found that the application for the extension did not meet the requirements of Article 8(1)(d) of the SPC Regulation because it did not include an updated MA with the results of the pediatric studies and an Article 28(3) of pediatric Regulation of SPC compliance statement. Although the applicant was given a period of time under Article 10(3) to address the irregularity identified with its application, it was unable to do so within the specified time limit. The hearing officer also considered that, on the balance of probability, this irregularity would not be addressed before the expiry date of the SPC. He rejected the application for an extension to granted SPC/GB04/039 under Article 10(4) of SPC Regulation Pediatric regulation. The summary of key CJEU decisions is provided in Table 2.

Unitary Patent System

The aim of the UPP and UPC⁵⁷⁻⁵⁸ is to offer businesses an alternative to the existing European patent system, and support a cost-effective route to patent protection and dispute settlement. It will still be

Table 2 — Summary of recent rulings based on CJEU decisions

Case (decision date)	Basic patent claims	MA in place for	SPC possible for
Medeva ²⁹ (24 November 2011)	A+B	A+B+C+D	A+B
Yeda ³¹ (24 November 2011)	A+B	A	Not possible
Queensland ⁵⁵ (25 November 2011)	Patent 1. A+B Patent 2. C Patent 3. D A* (*Claimed in the wording as product of the process claim)	A+B+C+D A (+B+C)	1. A+B (based on Patent 1) 2. C (based on Patent 2) 3. D (based on Patent 3) A
	A@ (@Product of process but not specified in the wording)	A (+B+C)	Not possible
Daiichi ²⁸ (25 November 2011)	A, A+B# (#Generically disclosed)	A A+B	A
Georgetown ¹⁸ (12 December 2013)	A, B, C, A+B, B+C	A+B+C+D A+B	A+B
Actavis ³⁹ (12 December 2013)	A, A+B	A+B	Not possible
Eli Lilly ¹¹ (12 December 2013)	A ^S , B ^S (^S Covered by Markush claim)	A B	A [%] , B [%] ([%] Depends upon interpretation by National IP Court)
GlaxoSmithKline ⁵⁶ (14 November 2013)	A+x [†] ([†] Inactive ingredient)	A+x	Not possible (even if x improves efficacy of A)

possible to use the national route for those preferring to seek protection in individual EU member states and to validate a European patent in one or several member states. It will also be possible to combine the new system with the old one and have a European patent with unitary effect and in addition validate the patent as a classical European patent in other contracting states. Consequently, there will be three routes to patent protection in Europe in the future. The Unitary patent protection will make it possible to get unitary effect for a European patent in 25 EU Member States by one request.⁵⁹

Patent Term Extension Provisions in Developed Countries

In order to obtain better understanding of SPC regulation, the comparative study was carried for patent term extension provisions in developed countries USA, Japan, Australia and Europe as summarized in Table 3.⁶⁰ For the purpose of understanding SPC regulation, existing provisions in the regulation were studied along with their new amendments. The pediatric regulation associated with SPC was also studied. The new Unified Patent Court (UPC) system and unitary patent was also reviewed. An attempt was made to predict the future SPC system based on unitary patent related to pharmaceutical products. In order to review regulation, websites of patent offices for various EU countries were referred. The case laws were referred from CJEU website, variety of SPC blog websites and law firm educational materials. For better interpretation of SPC regulation, detailed analysis of key decisions handed down by CJEU and different national IP Courts across Europe was carried out. This analysis further included decisions made by European Patent Office and National Patent Offices across Europe. Attorney opinions available on different website like SPC blog or EP law blog were also referred to.

Based on review of case laws and regulation, it was decided to conduct survey amongst IP experts

from variety of backgrounds like biotechnology, pharmaceutical, new drug discovery, generic, innovators, regulatory, business development and academics. The survey questionnaire was prepared on SPC Regulation, its interpretation, case laws, unitary patent system, pediatric regulation, etc. and administered to 10 IP experts as a sample survey. Based on the findings of the survey, it was decided to conduct a larger survey comprising 100 IP experts. Complete response received from 76 IP experts were analyzed, presented graphically and interpreted to express opinions of IP experts.

Comparative Data Analysis of SPCs and its Regulation in Various EU Countries

In order to carry out comparative data analysis of SPCs and its regulation for EU countries, the data was collected from annual reports of pharmaceutical/biotechnological companies, patent office website, and IMS (Information Management System) Life Sciences. Trend analysis of SPCs granted, filed, invalidated *versus* different types of patents (like compound, composition, process, method of use and combination) was carried out and represented graphically. Bar chart and pie charts were used for presentation of data. The survey questionnaire prepared with multiple choice questions with defined derivatives.

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

Based on review of SPC data for European countries and response provided by IP experts, some loopholes, shortcomings and gaps were identified in the SPC regulation and case laws and avenues for challenging SPCs for medicinal products, in order to expedite the generic entry and reduce the cost of medicine, were proposed.

Probable Solutions to Loopholes in SPC Regulations

The loopholes in the SPC regulations related to pharmaceutical products were identified during

Table 3 — Patent Term Extension provisions in developed countries

Parameter	United States	Europe	Japan	Australia
Length of extension	5 years	5 years	5 years	5 years
Pediatric extension	6 months	6 months	Not available	Not available
PTE for Method of Use Patents	Available	Available	Available	PTE not available
PTE for Enantiomers	Available	Available	Available	Not available
Multiple PTEs per Patent	Not available	Available	Available	Available
Multiple PTEs per Product	Not available	Available	Available	Available
Patent Term Adjustment (PTA) for delay from Patent Office	Yes	No	No	No

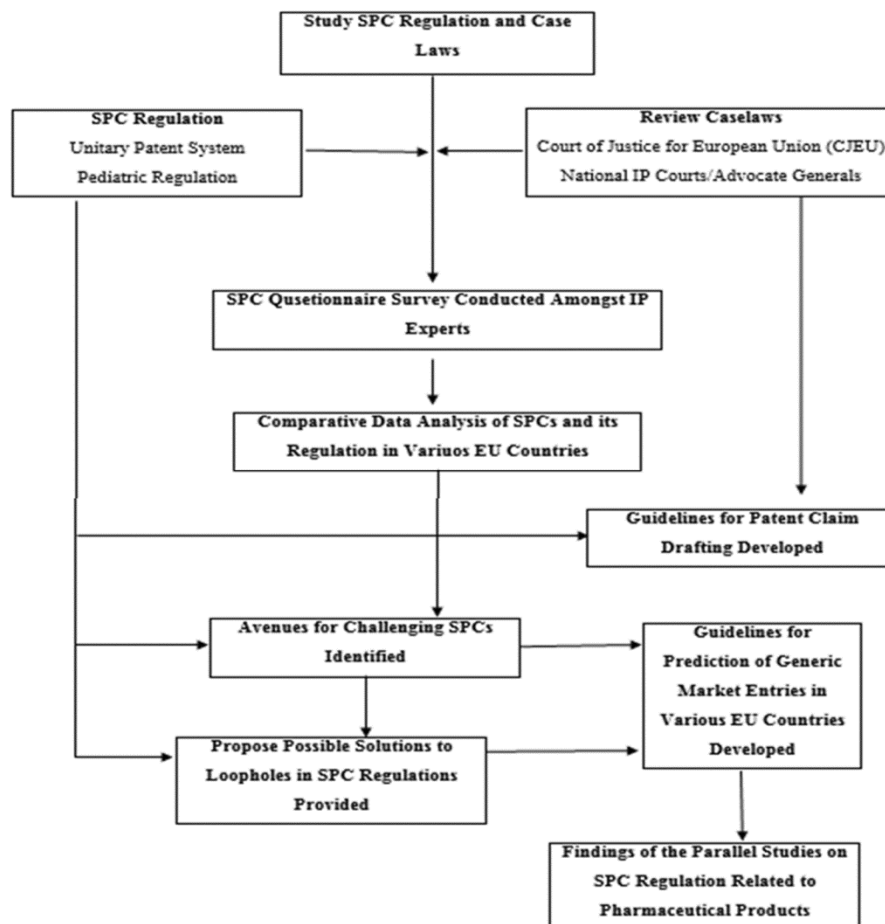


Fig. 4 — Chronology of Study

detailed study of SPC regulation and SPC survey results. Findings of decisions from CJEU and national courts, country wise SPC data analysis and views of IP experts were employed to propose probable solutions to those loopholes.

Guidelines for Patent Claim Drafting

Pharmaceutical patents were also studied and analyzed for understanding the main aspects of patent claim drafting. The decisions of the CJEU were thoroughly analyzed to come up with useful points to be remembered while drafting the patent claims as well as specifications. Based on the review of case laws and SPC regulation, analysis of expert opinions, comparative data analysis of SPCs and its regulation for various EU countries, results obtained have been analysed thoroughly and discussed in the following sections.

SPC Regulation and Case Laws

The study of SPC regulation, decisions related to interpretation for SPC regulation handed down by

CJEU and different national IP courts across Europe was carried out as described in detail in Literature Review section. The upcoming UPC (Unified Patent Court) system and its impact on current SPC regulation was also studied for understanding future of the European patent system. When the current study was ongoing, findings of other parallel studies conducted by European authorities on SPC regulation were also published. Some of the important (especially common) findings of the parallel studies carried out by subject experts and European organizations⁶⁰⁻⁶⁴ and the current research work are discussed below and underlined for emphasis purpose.

The study carried out by Malwina Mejer shows that the scope of protection is not uniform due to availability of the basic patent and differences in examination outcomes across national patent offices. Although, the geographical coverage of the basic patent is expected to increase in the future, efforts to harmonize the scope of SPC protection are needed as for one out of four products SPC applications results

in different outcomes in different EU Member States. Another study conducted by Technopolis-Group shows that, the SPC regulation has failed to incentivize pharmaceutical Research and Development (R&D) in Europe sufficiently to narrow the gap with the US. This is at least partly due to unclear statutory provisions in the SPC regulation on the one hand, and lack of clarity provided by the CJEU in adjudicating referrals for interpretation of those provisions on the other hand. As a result, SPCs can now be granted in areas where this was not originally the case, and/or where it was arguably not intended. This study concludes that the SPC system appears to be in need of a critical review and possibly update, at the level of the EU, as currently SPC system does not fully provide the legal certainty that users and society should be able to expect from the system, to better align the objectives and effects of the regulation and reduce unnecessary ambiguity. Another recommendation is to provide shorter term to the secondary medical use patents, composition patents and derivative patents. EMA should do the assessment of therapeutic value offered by the product to determine the degree of innovativeness of the product to be in line with the size of the compensation provided to the product through SPC.

The third study carried out by focuses on assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe. One of the conclusions was that SPC provides similar protection to that provided by the patent, and therefore under the SPC term the production of the SPC protected medicine is not allowed, even if it is not destined for the domestic SPC protected market. It has been argued that, as a result of this, generic and bio-similar manufacturers located in countries with more relaxed patent protection rules, have a first mover advantage compared to European generic and bio-similar manufacturers. Moreover, during the SPC term, a generic producer cannot manufacture a protected medicine to prepare for day one entry in the domestic market following the SPC expiry (stockpiling), which could place European producers at a disadvantage compared to producers that are located in unprotected countries and can prepare stocks for timely entry. The recommendation provided was allowing manufacturing of SPC protected medicines in protected markets for purposes of exporting to third countries where the corresponding patent or SPC has expired, exporting to

other EU Member States where the corresponding patent or SPC has expired or preparing for timely entry in the domestic market subsequent to patent or SPC expiry (stockpiling).

Fourth study conducted by Margaret Kyle, reveals that in 80% of cases, SPC applications were tied to a single patent, whereas firms had requested SPCs on additional patents in the remaining cases. The most common type of patent associated with an SPC was a compound patent. Almost 44% of SPC applicants were US-based, close to 30% were EU-based, and followed by Japan and Switzerland at roughly 7% and 6%, respectively. There was substantial heterogeneity across member states in the number of SPC applications and in the probability of SPC grants. The study reveals that since SPC applications sometimes have different outcomes in different countries, efforts to harmonize SPCs across member states, either through the use of a unitary SPC or through improved information sharing, would reduce the variation in the intellectual property landscape and the uncertainty for generic entrants. A more complete analysis of the effects of SPCs on entry and prices, as well as on Research and Development incentives, is important for understanding whether SPCs are a valuable policy instrument. Another economic study conducted by European Commission analysed the impact of the SPCs, pharmaceutical incentives and rewards in Europe. One outcome relevant to the current research work is the average duration of protection of all granted SPC is 3.5 years.

Finally, one of the main findings of sixth study of legal aspects of the SPC in the EU conducted by Max Planck Institute for Innovation is that some legal uncertainties have arisen that could jeopardize the smooth functioning of the SPC regime. In particular, inconsistencies and unclear notions resulting from the CJEU's interpretation of central provisions in the SPC regulation make it difficult for the national patent offices to adapt their own practice to the criteria elaborated by case law without causing divergences in relation to their own previous practice or that of other offices. While originator companies tend to be basically confident that the system will correct itself in the long run, generic manufacturers contend that an overhaul is needed in order to strike the right balance. A need for adjusting the balance exists is also specifically emphasized by the generic group in view of the limitations of the SPC rights conferred, which are considered to be too narrowly tailored to respond efficiently to the challenges of enhanced global

competition. Apart from that, all parties agree that a demand for reform exists as far as the creation of a unitary SPC system is concerned. The CJEU has so far failed to deliver a clear test for applying Article 3(a) of SPC regulation. By abandoning the principle of one SPC per new active ingredient and admitting SPCs for products already authorized in the past, it risks undermining the balance of interests on which the SPC legislation was based. If the aim of the SPC regime is to encourage investments in the development of marketable products after an invention is made, then only the patentee that has contributed directly (MA ownership) or indirectly (license agreement; joint development agreement) to developing the product covered by the MA should benefit from the supplementary protection. It is not clear whether the mere manufacturing of the active ingredient protected as such by the basic patent for export or stockpiling purposes would infringe the SPC or not. The Study endorses the view that the unitary patent should be complemented by an SPC of equal dimensions.

In addition to detailed literature review, survey was conducted amongst IP experts to comprehend their views on SPC regulation, recent case laws related to SPC and unitary patent system. The survey also focused on the views of the IP experts on generic industry, innovator industry and interpretation of recent case laws on SPC regulation related to pharmaceutical/biotechnological products. Based on the response received from IP experts, analysis of data was carried out to find out the trends. The questionnaire was administered to 100 IP experts specialized in generics, biotech and new drug discovery development (NDDD), European patent attorneys, and regulatory professionals, out of which a total of 76 respondents successfully completed the questionnaire. The first question posed to the experts was on clarity of SPC regulation. The experts were asked whether SPC regulation is ‘Ambiguous’, ‘Not Clear’, ‘Difficult to Interpret’, ‘Clear’ or ‘Very Clear’.

As shown in Fig. 5, 61% of experts believed that SPC regulation is either not clear or ambiguous. 14% believed that it is difficult to interpret. Only 25% stated that SPC regulation is clear. The second question posed to the experts was related to impact of SPC on entry of generic product. The experts were asked to respond to the statement whether SPC extension creates unwanted delays in launch of generic product. Five options provided to the respondents were ‘Strongly Disagree’, ‘Disagree’, ‘Neutral’, ‘Agree’ or ‘Strongly Agree’.

According to Fig. 6, 64% of experts believed that SPC extension creates unwanted delays in launch of generic products. 25% did not agree with the statement while 11% were neutral on that aspect.

The third question posed to experts was related to generic industry. The experts were asked about their opinion on the statement that SPC extension discourages generic industry from developing generic versions of medicine. Five options provided to the respondents were ‘Strongly Disagree’, ‘Disagree’, ‘Neutral’, ‘Agree’ or ‘Strongly Agree’.

According to Fig. 7, 44% of experts believed that SPC extension does not discourage generic industry whereas 36% believed that it does discourage generic drug industry. 20% showed a neutral response to the question. The fourth question posed to the expert was related to innovator companies. The experts were asked to provide their opinion on the statement that

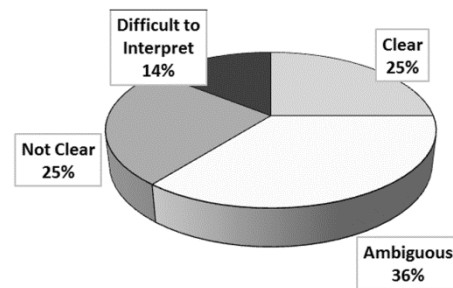


Fig. 5 — IP Experts Response on Clarity of SPC Regulation

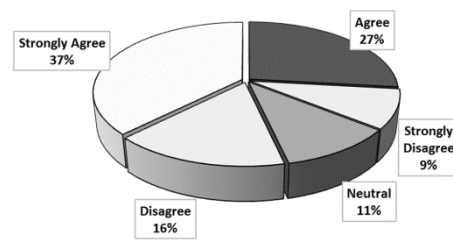


Fig. 6 — IP Experts Response to SPC Extension and Delay in Generic Product Launch

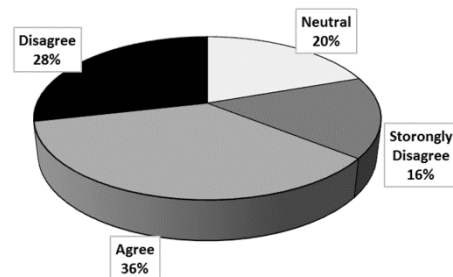


Fig. 7 — IP Experts Response on SPC Extension and Generic Product Development

innovator companies unnecessarily benefit from SPC extension. Five options provided to the respondents were ‘Strongly Disagree’, ‘Disagree’, ‘Neutral’, ‘Agree’ or ‘Strongly Agree’. According to Fig. 8, 50% of experts believed that innovator companies unnecessarily benefit from SPC extension, whereas 36% believed that SPC extension does not unnecessarily benefit the innovator companies. 14% showed a neutral response. The fifth and sixth questions were with reference to multiple SPCs. The experts were asked whether the concept of multiple SPCs per patent is acceptable. Five options provided to the respondents were ‘Strongly Disagree’, ‘Disagree’, ‘Neutral’, ‘Agree’ or ‘Strongly Agree’.

Approximately 61% of experts found the concept of multiple SPCs per patent is not acceptable, whereas 39% found it acceptable (Fig. 9). According to Fig. 10, approximately 63% of experts found the concept of multiple SPCs per product is not acceptable, whereas 37% found that it is acceptable. European PTE system provides ‘One Product-Multiple Extension’ or ‘One Patent-Multiple Extension’. The seventh and eighth questions asked the experts whether this is a pro-patentee policy and against generic pharma industry. Two options provided to the respondents were ‘Yes’ and ‘No’. It was found that 66% of the experts believed it is a pro-patentee policy, while 34% believed that it is not a pro-patentee policy (Fig. 11).

Although majority of the experts believed the policy is not against generic pharma industry, 45% of the

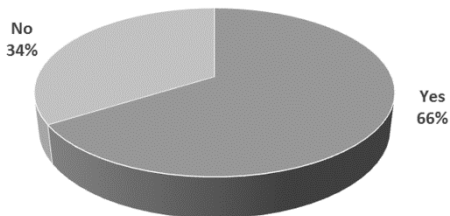


Fig. 8 — IP Experts Response to Whether Innovator Companies Unnecessarily Benefit from SPC Extension

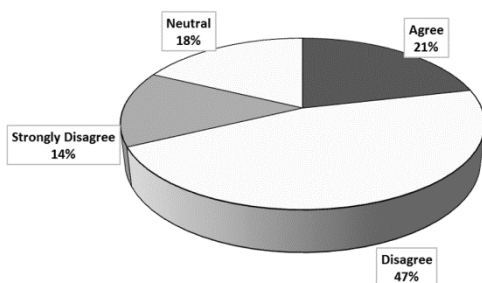


Fig. 9 — IP Experts Response to Whether Concept of Multiple SPCs per Patent is Acceptable

experts still believe it is (Fig. 12). Through the ninth question, the experts were asked whether ‘Pediatric Extension’ should be allowed for SPC applications related to biotechnological/pharmaceutical product. Five options provided to the respondents were ‘Strongly Disagree’, ‘Disagree’, ‘Neutral’, ‘Agree’ or ‘Strongly Agree’.

Fig. 13 shows, 65% of the IP experts believed that granting pediatric extensions to SPC applications or

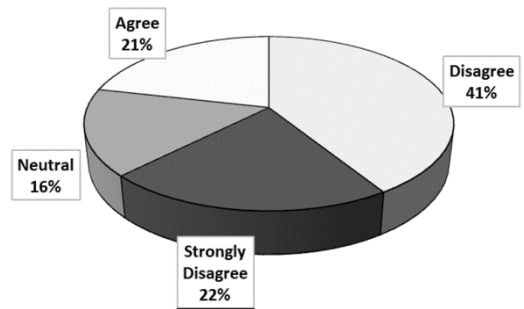


Fig. 10 — IP Experts Response to Whether Concept of Multiple SPCs per Product is Acceptable

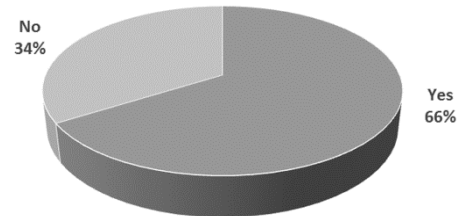


Fig. 11 — IP Experts Response to Whether ‘One Product-Multiple Extension’ Or ‘One Patent-Multiple Extension’ is Pro-Patentee Policy

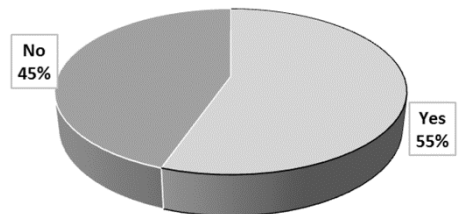


Fig. 12 — IP Experts Response to Whether ‘One Product-Multiple Extension’ Or ‘One Patent-Multiple Extension’ is Against Generic Pharma Industry

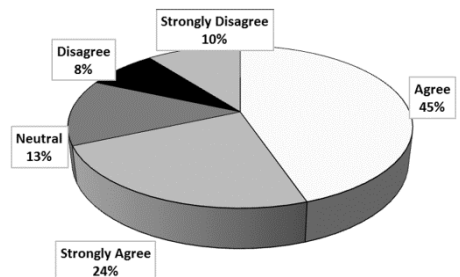


Fig. 13 — IP Experts Response about Pediatric Extension

such extensions are necessary to compensate the expenses incurred by innovator pharma companies. 13% of the IP experts had neutral opinion on this, while 18% believed that pediatric extensions to SPC applications are unnecessary. Through the tenth question, the experts were asked to provide opinion about the statement that negative ‘pediatric extension’ (like sitagliptin molecule in Merck case) for SPC concept is justified. Five options provided to the respondents were ‘Strongly Disagree’, ‘Disagree’, ‘Neutral’, ‘Agree’ or ‘Strongly Agree’. Based on Fig. 14, 53% of the IP experts agreed that negative pediatric extensions (like Sitagliptin)⁴³ for SPCs are necessary. 18% of the IP experts had neutral view on the same, while 29% of them thought that negative pediatric extensions for SPCs are unnecessary. Through the eleventh question, IP experts’ views were collected about the need to amend the SPC regulation. Two options provided to the respondents were ‘Yes’ and ‘No’.

Fig. 15 shows 66% of the IP experts believed that there is a need to amend the SPC regulation provisions in order to avoid ambiguity amongst generic and innovator pharmaceutical companies about SPC provisions. The twelfth question asked to the IP experts was about the definition of ‘active ingredient’ under Article 3 of SPC regulation. Two options provided to the respondents were ‘Yes’ and ‘No’. According to Fig. 16, 80% of IP experts believed that the definition of ‘active ingredient’ under Article 3 of SPC regulation is not adequately defined. The thirteenth question asked to the IP experts was whether the SPC regulation has loopholes

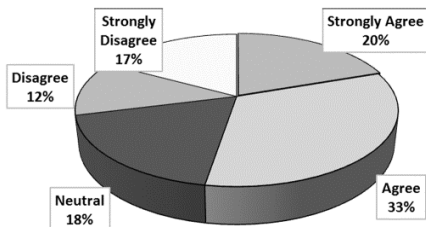


Fig. 14 — IP Experts Response about Negative Pediatric Extension

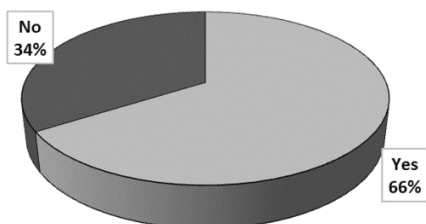


Fig. 15 — IP Experts Response about Need to Amend of SPC Regulation

that benefit generic drug industry. Two options provided to the respondents were ‘Yes’ and ‘No’.

Fig. 17 reflects that 75% of IP experts thought that the SPC regulation has loopholes, which if exploited will benefit the generic industry. The IP experts were asked the fourteenth question about ‘Unitary Patent System’, in anticipation of UPC becoming functional (one patent per product throughout Europe) and what according to them will be the ideal set up for SPCs. Three options provided to the respondents were as enumerated below:

1. There should be only one SPC allowed throughout Europe,
2. Although patent may be one, SPC application should be filed in individual EU member country, or
3. Both above options should be available.

According to Fig. 18, 55% of IP experts believed that under Unitary Patent, there should be only one

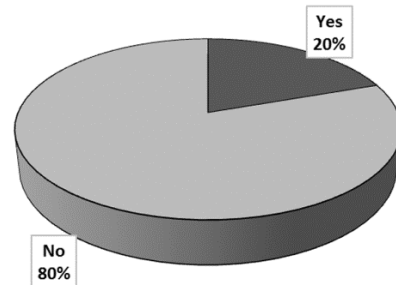


Fig. 16 — IP Experts Response about Definition of Active Ingredient under Article 3 of SPC Regulation is Adequately Defined

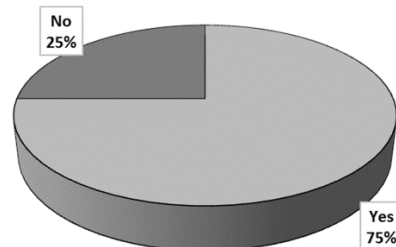


Fig. 17 — IP Experts Response about Loopholes in SPC Regulation Provisions

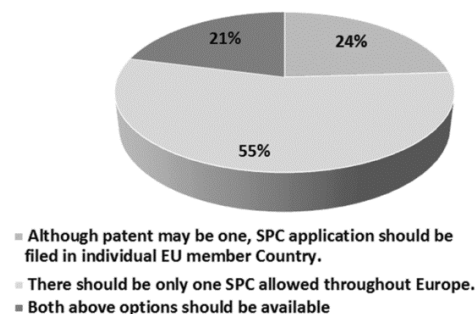


Fig. 18 — IP Experts Response about Unitary Patent System

SPC allowed throughout Europe. However, 24% were of the opinion that SPC application should be filed in individual EU member country, while 21% of experts thought that both the options should be available.

Conclusion

Based on 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 definition of active ingredient under Article 3 of SPC regulation is not adequately defined.
- There is a need to amend the SPC regulation in order to avoid ambiguity amongst generic and innovator pharmaceutical companies about SPC provisions.
- Majority of IP experts found the concept of multiple SPCs per product or concept of multiple SPCs per patent not acceptable.
- Majority of IP experts thought that SPC extension creates unwanted delays but it does not discourage generic industry.

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