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**“The Supplementary Protection Certificate as
an example for special IP regimes in the
pharmaceutical sector”**

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ABSTRACT

The present thesis is an overview of the Supplementary Protection Certificate ('SPC') regime in the European Union ('EU') and its application in the pharmaceutical industry. During the past years the Court of Justice of the European Union ('CJEU') has been particularly active and has clarified a number of highly controversial legal ambiguities with respect to SPCs including paediatric extensions. In the light of the CJEU case-law, this thesis analyses the relevant legal provisions and discusses their rationale.

A. INTRODUCTION

Companies across Europe are meeting health challenges head on by investing in time, talent, and materials. European law has long protected these endeavors through the intellectual property (IP) regime. This legislation has been very important in creating and sustaining the technological sectors, especially those where innovation is very costly, such as the pharmaceutical sector. The investment in the research and development ('R&D') of pharmaceutical products, which play a decisive role in the continuing improvement of public health, is protectable by means of patents. The patent regime in the pharmaceutical sector is complemented by a special IP regime which provides for supplementary patent protection on a timely basis under specific circumstances, i.e. the SPC regime.

This special IP regime has direct effect in the Member States of the European Union ('EU'), which means that the decisive forum for its interpretation and ultimate arbiter is the CJEU¹. The latter is presented with the increasingly challenging task of interpreting the present legislation in a clear, coherent and fair manner. Its judgments provide patent offices and national courts with important guidance on the application of the SPC regime. The number of questions referred to the CJEU for interpretation of the SPC regime indicates its practical significance for applicants, who wish to make use of the possibilities for obtaining extended patent protection for their pharmaceutical products. Therefore, the following analysis is based on the legislation, along with the respective CJEU judgments interpreting it.

More concretely, a basic overview of the patent system in general, and the pharmaceutical patents in particular, at a EU level, is a beginning point to explore the special IP regime in the pharmaceutical industry. In this context, the first part presents the European patent system and the peculiarity of patents on pharmaceutical products. Then, the next chapter provides an overview of the SPC regime and its rationale, whilst presenting the core provisions of this regime. Reference is made to the products concerned, the extent of the SPC protection, the way of obtaining a SPC, with focus on the conditions and the application procedure, the duration of the SPC, and the relevant

¹ **Westerlund L.**, Preliminary Ruling of the Court of Justice of the European Union in *Neurim Pharmaceuticals (1991) Ltd. v. Comptroller of Patents on Supplementary Protection Certificates in Europe*, 31 Biotechnology Law Report, Number 6, 2012, 566.

transitional provisions. Finally, the last part of the present thesis recapitulates the core CJEU judgments dealing with the SPC regime and includes a few final remarks.

B. EUROPEAN PATENT LAW AND THE PHARMACEUTICAL SECTOR

I. PATENTS AND THEIR RATIONALE

There are two distinct rationales that might be given for patents²: the one justifies patents as recognition of the inventor's creativity and the other justifies patents as means to enhance innovation. In either case, patent rights can be understood as a definition of property rights with regard to new technological knowledge for a limited time span³. During the life of the patent, its proprietor has the right to exclusively exploit the protected specific knowledge economically, whilst other market participants can only gain access to the protected technical knowledge on the condition of approval of the owner, usually obtained by means of license agreements⁴.

II. LEGAL INSTRUMENTS

A first legal instrument is the Paris Convention for the protection of industrial property ('PC')⁵ which is a multilateral treaty, applying not only to patents, but also to industrial property in the widest sense. It provides protection based on national treatment and international property rights. National treatment requires that each Contracting State must grant the same protection to nationals of other Contracting States that it grants to its own nationals⁶. The priority right⁷ means that, on the basis of a regular first application filed in one of the Contracting States, the applicant may, within a certain period of time, apply for protection in any of the other Contracting States. These subsequent applications will be regarded as if they had been filed on the same day as the first application. In other words, they will have priority over applications filed by

² **Barton J.H./Ezekie J.E.**, The patents-Based Pharmaceutical Development Process, JAMA, October 26, 2005, Vol. 294, No. 16, 2076.

³ **Seckelmann M.**, From the Paris Convention (1883) to the TRIPS Agreement (1994): the history of the international patent agreements as a history of propertisation?, Journal der Juristischen Zeitgeschichte. Volume 14, Issue 1, 41.

⁴ **Seckelmann M.**, (n 3) 41.

⁵ The PC, concluded in 1883, was revised at Brussels in 1900, at Washington in 1911, at The Hague in 1925, at London in 1934, at Lisbon in 1958 and at Stockholm in 1967, and was amended in 1979.

⁶ Article 2(1) PC.

⁷ Article 4 PC.

others during the said period of time for the same invention, utility model, mark or industrial design. However, the PC does not provide for centralized filing or registration and concomitantly, the registrant must use the judicial system of the alleged infringer's country to enforce his rights⁸.

In 1967, Members of the PC created the World Intellectual Property Organization ('WIPO Convention'), which aims to promote the international protection of IP and to administer various international agreements through cooperation among States⁹. During its first 20 years, WIPO was a strong force for administration of international conventions, but ineffective as a catalyst in the movement towards harmonization¹⁰. Dissatisfied with the progress being made by WIPO on substantive and enforcement issues for international IP, the U.S. and other nations turned to the 1994 negotiations regarding the General Agreement on Tariffs and Trade ('GATT') for the purpose, the result of which was the Trade Related Aspects of IPRs agreement ('TRIPS')¹¹. TRIPS, which is an integral part of the Agreement establishing the World Trade Organization ('WTO'), covers not only patents, but also all the other main areas of IP rights ('IPRs'). It lays down the minimum substantive standards of protection that should be provided for in each of these areas of IP as well as the procedures and remedies available, so that right holders can enforce their rights effectively¹². The crucial point that distinguishes TRIPS from the PC is that the former set out a mere moral obligation to set up a patent legislation in accordance with its principles, whereas TRIPS departed from this principle and set out a basic reciprocity¹³.

Based on the PC¹⁴, several agreements were concluded. One of them is the European Patent Convention ('EPC'). The latter is a regional international convention outside the EU legal order with 38 Member States, harmonising the requirements to get a patent and granting a bundle of national rights¹⁵ designated by the applicant¹⁶. More concretely, Article 64(1) EPC states that a European patent shall confer from the date

⁸ **Bravo G.**, From Paris Convention to TRIPS: A Brief History, 12 J. Contemp. Legal Issues, 2001-2002, 446.

⁹ Article 3 WIPO Convention.

¹⁰ **Bravo G.**, (n 8) 447.

¹¹ **Bravo G.**, (n 8) 448.

¹² **Otten A.**, WHO Drug Information, 1998, Vol. 12, No. 4, 211.

¹³ **Seckelmann M.**, (n 3) 56.

¹⁴ Special agreement under Article 19 PC.

¹⁵ Article 2(2) EPC.

¹⁶ Article 79 EPC.

of publication of the mention of its grant, in each Contracting State in respect of which it is granted, the same rights as would be conferred by a national patent granted in that State. In addition, Article 64(3) EPC notes that any infringement of a European patent shall be dealt with by national law. Further, Article 138(1) EPC states that a European patent may only be revoked under the law of a Contracting State, with effect for its territory. Another agreement introduces, based on PC, the Patent Cooperation Treaty ('PCT')¹⁷. The PCT makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an "international" patent application. Such an application may be filed by anyone who is a national or resident of a Contracting State. It may generally be filed with the national patent office of the Contracting State of which the applicant is a national or resident or, at the applicant's option, with the International Bureau of WIPO in Geneva. If the applicant is a national or resident of a Contracting State which is party to the EPC the international application may also be filed with the EPO. In addition, the Patent Law Treaty (PLT) was adopted in 2000 with the aim of harmonizing and streamlining formal procedures with respect to national and regional patent applications and patents and making such procedures more user friendly. With the significant exception of filing date requirements, the PLT provides the maximum sets of requirements the office of a Contracting Party may apply.

Aside from the above, there are also several legal instruments at EU level, e.g. Directive 98/44 on biotechnological inventions¹⁸, Regulation 469/2009 concerning the supplementary protection certificate for medicinal products¹⁹, Regulation 1610/96 concerning the creation of a supplementary protection certificate for plant protection products²⁰, Regulation 1901/2006 on medicinal products for paediatric use²¹, Regulation 2100/94 on plant variety protection²², Regulations 1257/2012 implementing

¹⁷ The PCT was concluded in 1970, amended in 1979, and modified in 1984 and 2001.

¹⁸ DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213/13, 30.7.98.

¹⁹ REGULATION (EC) No 469/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152/1, 16.6.2009.

²⁰ REGULATION (EC) No 1610/96 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products, OJ L 198/30, 8.8.96.

²¹ REGULATION (EC) No 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ L 378/1, 27.12.2006.

²² COUNCIL REGULATION (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, OJ L 227/1, 1.1.94.

enhanced cooperation in the area of the creation of unitary patent protection²³ and 1260/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements²⁴. As for the enforcement of patents, while there is no European-wide patent, and thus, no ability to obtain a judgment enforceable across all of the EU, there is reciprocal enforcement of judgments within the EU²⁵, by virtue of Regulation 1215/2012 on jurisdiction and recognition and enforcement of judgments in civil and commercial matters²⁶.

III. PATENT PROTECTION

1. Conditions

In order for an invention to be patentable, four requirements should be fulfilled, namely invention, novelty, inventive step, and industrial applicability²⁷. Further requirement is that the applicant discloses the invention in a manner sufficiently clear and complete for the invention to be carried out as well as that the applicant indicates the best mode for carrying it out²⁸. Disclosure is a key part of the social contract that the grant of a patent constitutes, since it makes publically available important technical information which may be of use to others in advancing technology in the area, even during the patent term, and ensures that, after expiry of the patent term, the invention truly falls into the public domain, because others have the necessary information to carry it out²⁹.

2. Subject matter

European patents shall be granted for any inventions, in all fields of technology, provided that they meet the aforementioned patentability requirements³⁰. In order to avoid monopolization of specific matters, the EPC provides for non-exhaustive list of

²³ REGULATION (EU) No 1257/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, OJ L 361/1, 31.12.2012.

²⁴ COUNCIL REGULATION (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, OJ L 361/89, 31.12.2012.

²⁵ **Blanchard A.M./Grill K./Steinberg J.**, A Practical Guide to IP Issues in the Pharmaceutical Industry, EIPR Practice Series, Book 2, 2007, 30-31.

²⁶ REGULATION (EU) No 1215/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, OJ L 351/1, 20.12.2012.

²⁷ Articles 52-57 EPC, 27(1) TRIPS.

²⁸ Article 83 EPC, 29(1) TRIPS.

²⁹ **Otten A.**, (n 12) 211.

³⁰ Article 52(1) EPC, 27(1) TRIPS.

things which are not regarded as inventions³¹. Items on this list are all either abstract (eg discoveries, theories) and/or non-technical (ie address only human mind without using forces of nature) (eg aesthetic creations or presentations of information or computer programs). Thus, subject matter of patent protection are technical inventions with proven applicability to either products or processes³².

3. Exceptions

Patents may not be granted in respect of i) inventions, the prevention of the commercial exploitation of which is necessary to protect *ordre public* or morality, ii) diagnostic, therapeutic and surgical methods for the treatment of humans or animals, and iii) certain plant and animal inventions³³.

4. Scope

The scope of patent protection is determined by the claims which should be interpreted on the basis of the description and the drawings³⁴. By the patent is protected any product or process in which the characteristics of the claim are embodied. Patent claims comprise technical features and measures which can be interpreted in different ways, i.e. narrowly or broadly. The extent of the patent protection should not be defined in a strict, literal meaning of the wording used in the claims, nor should the claims serve only as a guideline and the actual protection conferred may extend to what the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties³⁵.

IV. PATENT PROTECTION FOR PHARMACEUTICALS

1. Pharmaceutical industry and innovation

The development of a medicinal product is an enormously expensive process because of the high attrition rate of potential products as they proceed through laboratory, animal, and various human trials, as well as the high costs of trials needed for regulatory approval³⁶. Current R&D costs in pharmaceutical industry are, namely, much higher

³¹ Article 52(2) EPC.

³² EPO Cases T 1538/05, 28.08.2006, at [4]; T 154/04, 15.11.2006, at [8]; **Seckelmann M.**, (n 3) 42.

³³ Article 53 EPC, 27(2),(3) TRIPS.

³⁴ EPC 69(1).

³⁵ Protocol on the Interpretation of Article 69 EPC.

³⁶ **Barton J.H./Ezekie J.E.**, (n 2) 2076.

than most, if not all, other industries. As a Judge of the Court of Appeal of England and Wales states³⁷: “It is no good finding a potential suitable molecule. Unless you spend the money and time to find out if it really works and is safe, it is no use”. Even higher than R&D costs is the promotional expenditure³⁸. Along with the high costs, the investment in pharmaceutical innovation entails high risk, since it is often the case that the research leads nowhere. Because of the high risk, pharmaceutical innovation does not only include products with new active pharmaceutical ingredients (APIs), but it includes also a large number of improvements or minor changes to existing drugs and the identification of new uses of known medicinal products³⁹. Incremental innovation is often motivated by the objective of extending the commercial benefits derived from existing products, particularly when original patents expire and new patents may be used to prolong market exclusivity⁴⁰.

2. Pharmaceutical Patents

A pharmaceutical invention is patentable, if it meets the aforementioned patentability criteria, which are the same in all technical fields. Given the nature of pharmaceutical industry’s research activities, which are dominated by profit-making objectives, they rely heavily on the acquisition and enforcement of patents⁴¹. It is a common ground that the higher the risk the more reward is needed to persuade the investors to put their money up⁴², and, as stated above, the nature of such an investment is risky. This means that without a reliable patent monopoly there is no incentive to invest⁴³. If there is no IP protection for a new drug produced, companies essentially lose all economic incentive to further innovation and discovery because competitors can easily replicate the compounds for the same profit without the heavy financial investment. The EU Member States should provide such incentives, especially when it comes to pharmaceuticals, since they are responsible for providing health services and medical

³⁷ **Jacob R.**, Patents and Pharmaceuticals – a Paper given on 29th November at the Presentation of the Directorate-General of Competition’s Preliminary Report of the Pharma-sector inquiry, 3.

³⁸ **Jacob R.**, (n 37) 4.

³⁹ **Correa C.M.**, Ownership of knowledge – the role of patents in pharmaceutical R&D, Bulletin of the World Health Organization, October 2004, 82 (10), 785.

⁴⁰ **Correa C.M.**, (n 42) 785.

⁴¹ **Correa C.M.**, (n 42) 786.

⁴² **Jacob R.**, (n 37) 4.

⁴³ **Jacob R.**, (n 37) 3.

care within their territories⁴⁴. It is the patent system, which provides such incentives, making thus, the advances in medicines possible.

Indeed, pharmaceutical patents are a fundamental component to the success of the pharmaceutical industry. They play a crucial role in terms of stimulating developments of new drugs. In this sense, the pharmaceutical industry is very R&D-intensive⁴⁵. A patent is granted for a drug's novel chemical composition rather than its therapeutic properties⁴⁶. Many pharmaceuticals receive patents despite their being functionally similar to existing drugs⁴⁷. Patents are so valuable to the pharmaceutical industry, because in most cases the value of the patent is equivalent to the value of the product⁴⁸. The pharmaceutical industry recovers its expenses through charging a high price for the drug based on exclusivity rights under a patent⁴⁹. When the patent expires, the price normally decreases through competition with generic drugs⁵⁰. Therefore, it is essential for pharmaceutical companies to maintain their patent rights.

It should be noted, however, that a patent only gives an inventor the right to prevent others from using the patented invention. It says nothing about whether the product is safe for consumers and whether it can be supplied⁵¹. Patented pharmaceuticals still have to go through rigorous testing and approval before they can be put on the market. The effective length of the patent monopoly is not the same as the normal 20 years from the date of the application stated in patent law. In particular, although the term of all patents is the same, i.e. 20 years from the application, in reality a new drug is unlikely to get this much as an effective patent term⁵². Reason for this is that companies, in order to

⁴⁴ Article 152 of the Treaty on the Functioning of the European Union, OJ C 326/47, 26.10.2012.

⁴⁵ **Brekke K.R./Straume O.R.**, Pharmaceutical Patents: Incentives for R&D or Marketing?, Discussion Paper 22/2005, 2, <http://www.nhh.no/Admin/Public/DWSDownload.aspx?File=%2FFiles%2FFiler%2Finstitutter%2Fsam%2FDiscussion+papers%2F2005%2F22.pdf>

⁴⁶ **Brekke K.R./Straume O.R.**, (n 39) 3-4.

⁴⁷ **Brekke K.R./Straume O.R.**, (n 39) 3-4.

⁴⁸ **Bernler K.J.**, Obviating the obvious? An appraisal of pharmaceutical patents, 10 J High Tech. L. 208 2009-2010, 239-240.

⁴⁹ **Barton J.H./Ezekie J.E.**, (n 2) 2076.

⁵⁰ **Barton J.H./Ezekie J.E.**, (n 2) 2076.

⁵¹ WTO OMC Factsheet, September 2006, 2,

https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf

⁵² **Delcourt D.**, Public Health and preservation of economic competitiveness, Journal of Intellectual Property Law & Practice, 2009, Vol. 4, No. 6, 441.

preempt competitors, must apply for patents early in the development process, while marketing exclusivity occurs only after trials lead to regulatory approval⁵³.

C. THE SUPPLEMENTARY PROTECTION CERTIFICATE REGIME

I. INTRODUCTION TO THE SUPPLEMENTARY PROTECTION CERTIFICATE REGULATION

On average 9 and 11 years elapse between the patent application date and the day when a pharmaceutical is put on the market. This leaves an effective patent term of between 9 and 11 years⁵⁴. The relatively short effective patent term for pharmaceuticals began to be noticed during the 1980s, i.e. about 10 years after the authorities granting permits for the sale of pharmaceuticals began to make more and more exacting demands for clinical trials, which led to a reduction of the effective patent term⁵⁵. Many areas around the world introduced statutes extending the patent term and providing supplementary protection for pharmaceuticals: the USA⁵⁶ in 1984, Japan⁵⁷ in 1987, Europe during the 1990s, France⁵⁸ and Italy⁵⁹ in 1991. The interplay of the exclusive right conferred by patents to innovative pharmaceutical products and the regulatory rules for their marketing approval seemed to be solved in EU Member States which started to regulate this matter independently. This practice though, would lead the same pharmaceutical to be protected for different lengths of time in different EU countries⁶⁰.

This situation, which would be contrary to the basic principle of a common market, led the Commission to introduce Regulation (EEC) No 1768/92⁶¹ providing for supplementary protection which came into force on 2 January 1993⁶². The purpose behind this Regulation is to improve the protection of innovation in the pharmaceutical sector by ensuring that research based industry has market exclusivity of sufficient

⁵³ **Barton J.H./Ezekie J.E.**, (n 2) 2076.

⁵⁴ **Domeij B.**, *Pharmaceutical Patents in Europe*, 2000, 196.

⁵⁵ **Domeij B.**, (n 54) 196.

⁵⁶ Drug Price Competition and Patent Term Restoration Act of 1984.

⁵⁷ Japanese Statute No. 27/1987, which came into force on 1st January 1988.

⁵⁸ French Statute No. 91-1180/1991.

⁵⁹ Italian Statute No. 349/1991.

⁶⁰ **Domeij B.**, (n 54) 196.

⁶¹ COUNCIL REGULATION (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ L 182/1, 2.7.92.

⁶² Article 23.

length to permit recovery of the investments put into research⁶³. Its content has been refined by CJEU case-law. More concretely, in *Spain v Council*⁶⁴ the Regulation survived a challenge to its validity. The CJEU declared that neither Article 222 nor Article 36 of the Treaty reserves a power to regulate substantive patent law to the national legislature, to the exclusion of any Community action in the matter⁶⁵. It follows that the Regulation was validly adopted⁶⁶. In order for the effects of supplementary protection not to be delayed by many years, it was judged necessary for supplementary protection to be obtainable for pharmaceuticals which were already on the market when the Regulation came into force⁶⁷.

This Regulation was followed by Regulation (EC) 1610/1996 concerning SPCs for plant protection ('PPR')⁶⁸, some rules of which are also valid, *mutatis mutandis*, for its interpretation. Furthermore, Regulation (EC) 1901/2006 concerning medicinal products for paediatric use ('PUR')⁶⁹ introduced an extension of the SPC duration in specific cases. Regulation (EEC) No 1768/92 was repealed by Regulation (EC) No 469/2009 ('SPCR')⁷⁰ which forms a new legal framework for SPCs, whilst encompassing the amendments by the PUR.

II. ROLE

The SPC regime allows patent owners to extend on a timely basis their exclusive rights upon expiration of the patent, thus mitigating the negative effects of lengthy administrative MAs⁷¹. The creation of the SPC does not in any way affect the substance of the rights of the holder of the basic patent, but it is rather a mechanism for correcting the shortcomings of the system for protecting pharmaceutical research, which arise from the need to obtain MA in order to make use of the innovation⁷². The SPC, therefore, delays the date from which the product in question comes into the public

⁶³ Explanatory Memorandum on the Proposal for a COUNCIL REGULATION (EEC) concerning the creation of a supplementary protection certificate for medicinal products (COM (90) 101 final) at [2], [25].

⁶⁴ C-350/92.

⁶⁵ C-350/92 at [22].

⁶⁶ C-350/92 at [40].

⁶⁷ Article 19 SPCR.

⁶⁸ (n 20).

⁶⁹ (n 21).

⁷⁰ (n 19).

⁷¹ **Porcuna de la Rosa F.**, "The extension of the exclusive right to pharmaceuticals under the European law: The Supplementary Protection Certificate", *Pharmaceuticals Policy and Law* 13 (2011), 62.

⁷² C-350/92 at [15].

domain and may be competitively marketed⁷³. Since the SPCR establishes a system of protection supplementary to that granted by a basic patent, the SPC is ancillary to a previously granted national or European patent⁷⁴. Based on this, it has been supported that the SPC is the natural extension of the basic patent⁷⁵ and it does not create a new IPR⁷⁶. Some take, also, the view that the SPC regime does not extend the patent term, but instead, it confers on patentees, by virtue of the SPCR and PPR, a separate right, the SPC⁷⁷. The latter approach finds grounds on the Explanatory Memorandum for the SPCR which states that a SPC is a unique *sui generis* IPR conferring additional exclusivity for specific products covered by a patent upon expiry of that patent⁷⁸. The reason for this approach lays in the fact that the SPC regime is a creature of the EU law, in contrast to patents, which in general are not, but are instead subject to the EPC, which is not an EU measure⁷⁹, and which did not at the time of drafting the first SPCR admit the possibility of patent term extension⁸⁰.

III. PRODUCTS QUALIFYING FOR SUPPLEMENTARY PROTECTION

1. Medicinal products

Pursuant to Article 1 SPCR, the term ‘medicinal product’ is defined as any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals, and the term ‘product’ is defined as the active ingredient or combination of active ingredients of a medicinal product. A distinction is thus, made between ‘medicinal product’ and ‘product’. The latter term refers to the API or to the combination of APIs

⁷³ Advocate General’s Opinion in C-431/04 at [35].

⁷⁴ Advocate General’s Opinion in C-431/04 at [4]; Advocate General’s Opinion in C-66/09 at [19].

⁷⁵ Advocate General’s Opinion in C-431/04 at [40]-[44].

⁷⁶ C-350/92 at [27].

⁷⁷ **Cook T.**, The Court of Justice Recasts the EU Patent Term Extension System, *Journal of Intellectual Property Rights*, Vol 19, March 2014, 141; **Storz U.**, *Biopatent Law: Patent Strategies and Patent Management*, Hübeler A./Schmelcher T./Storz U., 2012, 28; **Gassner U.M.**, Recent developments in the area of supplementary protection certificates, *Pharmaceutical Policy and Law* 16 (2014), 45.

⁷⁸ Explanatory Memorandum (n 63) at [9], [20], [31].

⁷⁹ **Cook T.**, (n 77) 141.

⁸⁰ The EPC was amended to permit patent terms of more than 20 years by the Act Revising Article 63 EPC of 17.12.1991 which entered into force on 04.07.1997 (OJ EPO 1992, 1 ff).

of the pharmaceutical to which the first term refers⁸¹. More concretely, medicinal products include products which are used therapeutically or prophylactically in animals or human beings⁸². In the case of diagnostic products, however, the provision requires that they are administered to animals or human beings⁸³. This means that diagnostic equipment used *in vitro*, e.g. tests used for blood sampling, are not eligible for supplementary protection, whereas diagnostic products administered *in vivo*, e.g. X-ray contrast media, are eligible for SPC protection⁸⁴. Whilst the categories of medicinal products that are eligible in principle for SPC protection are determined in the SPCR, the terms ‘active ingredient’ and ‘combination of active ingredients’ that form a ‘product’ are not defined in the SPCR. Thus, the issue of what types of invention constitute a product within the meaning of the SPCR serving as a basis for a SPC, entails a little controversy.

A first question which arises is whether an excipient which changes the behavior of an API can be considered itself as an API. The Explanatory Memorandum accompanying the European Commission’s ‘Proposal for a Council Regulation on the Creation of a Supplementary Certificate for the protection of Medicinal Products’ (‘Explanatory Memorandum’) clarifies that the term ‘product’ is to be understood in a narrow sense of product which means the active ingredient when applied to the chemical and pharmaceutical field⁸⁵. The Advocate General (‘AG’) in *MIT*⁸⁶ case answered the above question in the negative, staying in line with the strict interpretation of the term ‘product’ that the Explanatory Memorandum suggests. More concretely, the AG stated that the concept of ‘active ingredient’ designates a substance, such as a chemical compound or a natural solution, with pharmacological or physiological properties on which the therapeutic effect is based⁸⁷, arguing that this concept must be distinguished from ‘excipient’. According to the list of reference terms in the European Pharmacopoeia, drawn up under the aegis of the Council of Europe, an excipient is an auxiliary substance generally therapeutically inert, and needed for the manufacture,

⁸¹ **Domeij B.**, (n 54) 199.

⁸² **Domeij B.**, (n 54) 199.

⁸³ **Domeij B.**, (n 54) 199.

⁸⁴ **Domeij B.**, (n 54) 199; **Morze’ H./Peter H.**, Critical and Practical Observations regarding Pharmaceutical Patent Term Restoration in the European Communities, 77 J. Pat. & Trademark Off., 1995, 481.

⁸⁵ Explanatory Memorandum (n 63) at [28].

⁸⁶ C-431/04.

⁸⁷ Advocate General’s Opinion in C- 431/04 at [10].

administration or conservation of the active ingredient. Its function is to act as a vector or carrier for the active ingredient, thereby contributing to certain properties of the product, such as its stability, its galenical form or its acceptability for the patient⁸⁸. The Court basically adopted this Opinion, holding that a substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of a medicinal product is not covered by the concept of ‘active ingredient’, which, in turn, is used to define the term ‘product’⁸⁹. According to this interpretation, the excipient itself does not constitute an API.

Having precluded the possibility of the excipient being an API, the question becomes whether it can be regarded as ‘combination of active ingredients’, i.e. whether the concept ‘combination of active ingredients’ requires that each of the components of this combination is an API with its own therapeutic effects, or the combination of a new excipient with a known API suffices, if this combination results in a new medicinal product in which the therapeutic effects of the API are defined and controlled by the additional substance (i.e. the excipient). In support of the first interpretation, one could argue that the distinction between these two expressions (APIs and combination of APIs) could be evidence that only APIs or combinations of two or more APIs making up a medicinal product come under the term ‘product’. The second interpretation can find ground on the Explanatory Memorandum for the proposal for a SPCR; it is stated there⁹⁰ that all pharmaceutical research which may be patented, whether it concerns a new product, a new process for obtaining a new or known product, a new application of a product or a new combination of substances containing a new or known product, must be encouraged. According to the first interpretation, where one of the components of the combination does not itself have any therapeutic effect, the grant of the SPC would not be possible, whereas according to the second one such a grant would be possible.

In *MIT* case the Court had to choose between those two interpretations⁹¹. The AG took the view that, where the effective treatment of certain illnesses requires an active ingredient to be combined with a substance which, whilst not having any

⁸⁸ Advocate General’s Opinion in C-431/04 at [11].

⁸⁹ C-431/04 at [25].

⁹⁰ Explanatory Memorandum (n 63) at [29].

⁹¹ Advocate General’s Opinion in C-431/04 at [27]-[30].

pharmacological properties of its own, allows the biologically active substance effectively to release its therapeutic effects, such a combination must fall within the scope of 'combination of active ingredients of a medicinal product' within the meaning of Article 1(b) of the SPCR⁹². According to his opinion, it is the necessity of the excipient for ensuring the therapeutic efficacy of the active ingredient that must be the determining factor in ascertaining whether a combination of these two substances is covered by 'combination of active ingredients of a medicinal product'. Unlike the AG, the Court adopted a purely literal interpretation of Article 1(b), concluding that the alliance of an API with a substance which does have therapeutic effects of its own cannot give rise to a 'combination of active ingredients'⁹³. Again the Court justified its judgment, inter alia, on the basis of the strict interpretation given to the term 'product' in the Explanatory Memorandum⁹⁴. The recent judgment in *Forsgren* case points out that this founding is not altered by the fact that the API is covalently bound to other APIs which are part of the medicinal product⁹⁵.

When both of the above questions were addressed later in *GSK* case to the CJEU, the latter ruled by reasoned order, since the issues at stake were clarified by its judgment in *MIT*⁹⁶. Aside from the above core judgments, there are also earlier decisions which dealt with this matter in the same manner, i.e. stating that the concept of 'product' referred to in Article 1(b) SPCR must be interpreted strictly to mean 'active substance' or 'active ingredient'⁹⁷. More concretely, the Court in *BASF* case held that a greater purity of an API does not give rise to a different 'product'⁹⁸. In *Farmitalia*, the Court stated that minor variations do not make the 'product' different⁹⁹. Furthermore, in *Yissum*¹⁰⁰, the Court stated that in a case where a basic patent protects a second medical use of an API, that use does not form an integral part of the definition of the product¹⁰¹.

⁹² Advocate General's Opinion in C-431/04 at [40] *et seq.*

⁹³ C-431/04 at [26].

⁹⁴ C-431/04 at [19], [21]; Explanatory Memorandum (n 63) at [11].

⁹⁵ C-631/13 at [27].

⁹⁶ C-431/04.

⁹⁷ C-258/99 at [29]; C-392/97 at [18]; C-202/05 at [17]; C-31/03 at [20].

⁹⁸ C-258/99 at [29].

⁹⁹ C-392/97 at [18].

¹⁰⁰ C-202/05.

¹⁰¹ C-202/05 at [20].

The Court, further, clarified in *Pharmacia Italia* that it is irrelevant in this respect whether the product subject to SPC protection is for use in humans or in animals¹⁰².

It should be noted though, that, as opposed to the two latter judgments, according to the more recent judgment in *Neurim* case - which was not handed down on the question of the interpretation of Article 1(b) SPCR, but rather on Article 3(d) SPCR - the SPC grant is possible for second medical uses¹⁰³. It has been supported that this broader definition of the term ‘product’ is most likely in line with the definition under Article 1(b) SPCR¹⁰⁴. This opinion, which finds ground on Recital 14 PPR, which under Recital 17 PPR also has to be applied to the interpretation of SPCR, indicates that the strict definition of the term ‘product’ has to be broadened for second medical indications¹⁰⁵.

2. Subject to a marketing authorization procedure

Article 2 SPCR seeks to determine in a general manner which products may be the subject of a SPC. Under this Article any product protected by a patent in the territory of a Member State and subject to a marketing authorization (‘MA’) procedure may be the subject of a SPC. It is specified that the MA concerned is that provided for in Directives legislating the issue of MA (‘MAD), i.e. Directives 2001/83/EC¹⁰⁶ and 2001/82/EC¹⁰⁷, thereby making it clear that the SPCR applies only to medicinal products for human or veterinary use¹⁰⁸. It is also clarified that the word ‘market’ in Article 2 SPCR does not refer to the market of a Member State, but to the Community market as another interpretation would deprive Article 2 of any *raison d’être*¹⁰⁹.

¹⁰² C-31/03 at [20].

¹⁰³ C-130/11 at [25].

¹⁰⁴ **Schell J.**, *Neurim: a new definition of “product” in supplementary protection certificates?*, from GRUR Int., Journal of Intellectual Property Law & Practice, 2013, Vol. 8, No. 9, 728.

¹⁰⁵ **Schell J.**, (n 104) 727.

¹⁰⁶ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311/67, 28.11.2001.

¹⁰⁷ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, OJ L 311/1, 28.11.2001.

¹⁰⁸ Explanatory Memorandum (n 63) at [30]; **Miles J.**, *Supplementary Protection Certificates for medicinal products: where are we now and what challenges lay ahead?*, Pharmaceutical Patent Analyst, 2012, 1(3), 275; Although logic would dictate that any MA obtained pursuant to MAD can be the basis for a SPC, regardless of whether the API was marketed for another purpose before the MA for marketing the API in a medicinal product was obtained (e.g. the API had been marketed as a dye-stuff for non-medicinal purposes), this situation would seem to be at cross-purposes with the objectives of the SPCR. **Morze’ H./Hanna P.**, (n 84) 487.

¹⁰⁹ C-195/09 at [40].

The question that arises at this point is whether MA granted before entry into effect MAD could be considered as MA within the meaning of the above Article. The CJEU answered this question in the negative. More concretely, the CJEU ruled in *Synthon* that a product, which was placed on the market in the Community as a medicinal product for human use before obtaining a MA in accordance with the MAD and, in particular, without undergoing safety and efficacy testing, is not within the scope of the SPCR, and may not, therefore, be the subject of a SPC¹¹⁰. The Court justified its decision by stating that it would be contrary to the objective of offsetting the time taken to obtain a MA – which requires long and demanding testing of the safety and efficacy of the medicinal product concerned – if an SPC, which amounts to an extension of exclusivity, could be granted for a product which has already been sold on the Community market as a medicinal product before being subject to a MA procedure as laid down in MAD, including safety and efficacy testing¹¹¹. In addition, the Court stated that issuing a SPC for a product which does not fall within the scope of the SPCR disregards the meaning of ‘product’ and thus, such a SPC is invalid pursuant to Article 15 SPCR¹¹². The same approach was followed by the Court in *Generics*¹¹³. Thus, it is clear that a SPC for a medicinal product is valid, only if the first MA in the EU is in line with Europe-wide regulatory rules, i.e. with the MAD¹¹⁴.

IV. THE EXTENT OF THE PROTECTION GRANTED

As mentioned above, supplementary protection is intended for the API or the combination of APIs of a medicinal product. The question, however, is how extensive that protection will be. At first, it was proposed that the supplementary protection should have the same effect as a patent, i.e. include all medicinal use of the API. The Commission adopted a narrower protection though¹¹⁵. More concretely, pursuant to Article 4 SPCR, the protection conferred by a SPC does not extend to the scope of the patent as a whole, but it extends only to the product covered by the MA and for any use of the product authorized before the expiry of the SPC. As a result, protection under a

¹¹⁰ C-195/09 at [51].

¹¹¹ C-195/09 at [46], [47].

¹¹² C-195/09 at [53] *et seq.*

¹¹³ C-427/09 at [33].

¹¹⁴ **Sciaudone R.**, Court of Justice rules on material scope of supplementary protection certificate regime, *Journal of Intellectual Property Law & Practice*, 2011, Vol. 6, No. 12, 849.

¹¹⁵ **Porcuna de la Rosa F.**, (n 71) 63; **Domeij B.**, (n 54) 201; **Westerlund L.**, (n 1) 566.

SPC is limited by¹¹⁶: (i) the scope of the basic patent, (ii) the uses authorized prior to the expiry of the basic patent, and (iii) the uses in the pharmaceutical field as defined by MAD. The delimitation of the subject protected by the SPC can be well understood in cases where a patent protects a series of products based on the same formula. In such cases, usually only some of these products are subsequently developed and possibly only one may be put on the market. Thus, the SPC will only protect the product covered by the MA and not all of the products protected by the patent¹¹⁷. A further example is *GSK*¹¹⁸ case, where the CJEU stated that, where a patent protects an adjuvant as such, an SPC cannot be granted in respect of that adjuvant, since it cannot be regarded as a 'product' within the meaning of Article 1(b) SPCR¹¹⁹.

This delimitation of the subject matter gave rise to the issue of whether the SPC holder can oppose to a product comprising the API, which is protected by his SPC, with other APIs. Two reasoned orders relating both to disputes between *Novartis v Actavis*¹²⁰ dealt with this matter. In essence, the Court had to decide between a regulatory approach, which limits the protection to the product covered by the MA¹²¹, and a patent law approach, which confers on the SPC the same rights as the basic patent¹²². Staying in line with its previous case-law¹²³, the Court supported the second approach, holding that during the period in which the patent was valid, the patent holder could oppose, on the basis of his patent, all uses of his product and that the SPC granted in relation to that product would confer on the holder the same rights for all of its uses which were authorized before the expiry of the SPC¹²⁴. As a result, if a SPC is granted for product A, the SPC holder has the right to launch infringement proceedings concerning a medicinal product containing A+B provided that this would have been possible under the basic patent¹²⁵.

The terms of this provision also gave rise to the question of whether the SPC can only be granted for the specific chemical form mentioned in the MA or whether the

¹¹⁶ **Marks D.**, Life beyond the patent, *Managing Intellectual Property*, Jan/Feb 1994, 15.

¹¹⁷ Explanatory Memorandum (n 63) at [39].

¹¹⁸ C-210/13.

¹¹⁹ C-210/13 at [39].

¹²⁰ C-442/11 and C-574/11.

¹²¹ Article 4 SPCR.

¹²² Article 5 SPCR.

¹²³ C-322/10 at [39]; C-422/10 at [32]; C-630/10 at [34]; C-6/11 at [29].

¹²⁴ C-442/11 at [20]; C-574/11 at [18].

¹²⁵ **Gassner U.M.**, (n 77) 61.

protection conferred by the SPC can be broader, extending also to simple derivatives, salts or products of the product¹²⁶. In *Farmitalia*¹²⁷ the Court stated that if the SPC could protect only a specific API whereas the basic patent protects the specific API and its various derivatives, any competitor would be able, after the expiry of the basic patent, to obtain a MA for a derivative of the same API, formerly protected by the patent, enabling thus, medicinal products therapeutically equivalent to that protected by the SPC to compete with the latter¹²⁸. As a result, the fundamental objective of the SPCR, which is to provide for sufficient protection to encourage research in the pharmaceutical field, could not be attained¹²⁹. Besides, the Court stated that the SPC confers the same rights as those conferred by the basic patent, with the result that, where the basic patent covers an API and its various derivatives, the SPC confers the same protection¹³⁰. Therefore, the Court concluded that, where a product in the form referred to in the MA is protected by a basic patent in force, the SPC is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent¹³¹.

A different aspect of the scope of protection concerns which actions are to constitute infringement and what restrictions are made concerning acts of infringement. Pursuant to Article 5 SPCR, the SPC confers the same rights as conferred by the basic patent and is subject to the same limitation and obligations. National patent law determine which actions constitute infringements, the possibilities of granting interlocutory prohibitions and the sanctions available to the patentee¹³².

V. OBTAINING A SUPPLEMENTARY PROTECTION CERTIFICATE

1. Conditions

a. Introduction

Having determined the products which may be the subject of a SPC, the SPCR sets out in Article 3 SPCR the conditions under which those products may be granted a SPC¹³³

¹²⁶ *Morze' H./Hanna P.*, (n 84) 492.

¹²⁷ C-392/97.

¹²⁸ C-392/97 at [18].

¹²⁹ C-392/97 at [19].

¹³⁰ C-392/97 at [20], [21].

¹³¹ C-392/97 at [22].

¹³² *Domeij B.*, (n 54) 205; *Cook T.*, (n 77) 141; *Morze' H./Hanna P.*, (n 84) 499.

¹³³ C-195/09 at [41]; C-130/11 at [20].

and which are the same for all Member States¹³⁴. As the SPC is a national document, compliance with these conditions must be examined with respect to the Member State in which the SPC application is submitted and to the application date¹³⁵. The first three conditions set out in Article 3 of the SPCR for the grant of an SPC concern the relevant product and require it to be protected by a basic patent in force, to have obtained a valid MA as a medicinal product, and to have not already been the subject of a SPC¹³⁶, whilst, the fourth condition requires that this MA must be the first MA to place the product on the market as a medicinal product.

b. Basic patent in force [Articles 1(c), 3(a)]

Having confirmed the existence of a product, it should be now examined whether it is covered by a basic patent in force in the Member State in which the SPC application is submitted. A ‘basic patent’ is defined in the SPCR as a patent which protects a product, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a SPC¹³⁷. It is supported that this list of ‘basic patent’ categories is not enumerative, but it should be rather treated as illustrative, since the proposal for SPCR does not provide for any exclusion from SPC protection and all pharmaceutical research should be encouraged without discrimination, as the Explanatory Memorandum points out¹³⁸. A basic patent may either be a national patent or a European patent. A product may be protected by different patents, e.g. a product patent or a process patent to obtain such product¹³⁹. The SPCR does not limit a patentee’s choice to select his ‘basic patent’ from a product, process or use patent for SPC protection. However, a patentee must select one patent, if there is a choice between different patents¹⁴⁰. It is not clear whether the patentee has an open choice, i.e. whether he can select whichever patent other than the first or earliest patent claiming that product, but it is supported that such a choice is not precluded¹⁴¹.

¹³⁴ Recital 8 SPCR.

¹³⁵ Explanatory Memorandum (n 63) at [32].

¹³⁶ C-130/11 at [21].

¹³⁷ Article 1(c) SPCR.

¹³⁸ Explanatory Memorandum (n 63) at [29].

¹³⁹ Explanatory Memorandum (n 63) at [33].

¹⁴⁰ **Morze’ H./Hanna P.**, (n 84) 483-484; **Porcuna de la Rosa F.**, (n 71) 64; **Domeij B.**, (n 54) 205; Explanatory Memorandum (n 63) at [33], [36].

¹⁴¹ **Morze’ H./Hanna P.**, (n 84) 484; **Domeij B.**, (n 54) 205.

It comes from the above that the SPC is closely connected with the patent and concomitantly, with its claims which, as mentioned above, determine the extent of the patent protection. That being so, the question of whether a SPC can be granted in respect of APIs which are not specified in the wording of the claims of the basic patent comes into play. The CJEU answered in the negative, and, although it did not foster R&D, it went for a uniform application of the SPCR throughout the EU¹⁴². More concretely, in *Medeva*¹⁴³, the CJEU held that a SPC should not be granted when the APIs are not specified in the wording of the claims of the basic patent relied on in support of the SPC application¹⁴⁴. Therefore, whether a product is protected by the basic patent within the meaning of Article 3(a) of the SPCR is determined by examining the patent claims to establish whether the APIs of the product are specified in the wording of the claims¹⁴⁵. In *Aventis*¹⁴⁶, the Court clarified, by means of reasoned order due to its previous judgment in *Medeva* case, that a SPC should not be granted, if the API specified in the application is not the subject of any claim relating to that API alone, even though it is identified in the wording of the claims of the basic patent as an API forming part of a combination in conjunction with another API¹⁴⁷. Accordingly, if a patent claims a product comprising two APIs which are not specified alone in the patent application, a SPC cannot be granted based on such a patent for products having only one API¹⁴⁸. Concomitantly, *Aventis* case further narrows the test applied in *Medeva* case: if the patent claims A+B, a SPC cannot be granted for just A¹⁴⁹. Further, in *Queensland* case¹⁵⁰ the Court clarified that, where the basic patent relates to the process by which a product is obtained, a SPC cannot be granted for a product other than that identified in the wording of the claims of that patent as the product deriving from that process.

However, the above mentioned decisions did not clarify the crucial issue of the level of specification in the claims required to obtain a SPC for active ingredients¹⁵¹. A first insight into this black-box element was given by the *Eli Lilly* case¹⁵². There the Court

¹⁴² **Gassner U.M.**, (n 77) 57.

¹⁴³ C-322/10.

¹⁴⁴ C-322/10 at [28].

¹⁴⁵ **Gassner U.M.**, (n 77) 56.

¹⁴⁶ C-518/10.

¹⁴⁷ C-518/10 at [39].

¹⁴⁸ **Gassner U.M.**, (n 77) 57; **Westerlund L.**, (n 1) 568.

¹⁴⁹ **Gassner U.M.**, (n 77) 57.

¹⁵⁰ C-630/10 at [38] *et seq.*

¹⁵¹ **Gassner U.M.**, (n 77) 58.

¹⁵² C-493/12.

held that it is not necessary for the API to be identified in the claims of the patent by a structural formula; a functional description in the claims of a patent issued by the European Patent Office (EPO) may suffice for identification purposes, on condition that the claims of the basic patent relate, ‘implicitly but necessarily and specifically’, to the API in question¹⁵³. The formula ‘implicitly but necessarily and specifically’ seems to contain no further guidance on the appropriate level of specification in the claims¹⁵⁴, and the onus of its correct interpretation of lies with the national courts¹⁵⁵.

c. Valid marketing authorization [Articles 2, 3(b)]

A further condition for the grant of a SPC is the existence of a valid MA to place the product on the market in the Member State in which the SPC application is submitted as a medicinal product. As already mentioned, the MA must be valid at the time of filing the application for a SPC¹⁵⁶. However a valid counter-argument is that a SPC has no legal effect whatsoever until it takes effect at the end of the lawful term of the basic patent and it should only be decisive whether from that time onwards the MA for the product in the country concerned is valid¹⁵⁷.

The question which arises is whether it is possible to obtain an SPC for an API or combination of APIs, where the MA submitted in support of the SPC application was not only for that API or combination of APIs, but also for other APIs. In *Medeva*¹⁵⁸ and *Georgetown I*¹⁵⁹ the Court answered in the affirmative, stating that a valid MA to place the product on the market can exist even where the MA relates to a medicinal product which also comprises, in addition to the patented API or in addition to the patented combination of APIs, in respect of which a SPC is applied for, one or more other APIs¹⁶⁰. Therefore, the Court held that it should be possible to obtain a SPC for A on the basis of a MA for A+B¹⁶¹. By this interpretation of Article 3(b), manufacturers of medicinal products were permitted, in principle, to apply for a SPC for individual

¹⁵³ C-493/12 at [39].

¹⁵⁴ **Gassner U.M.**, (n 77) 59; **Snodin M.**, Three CJEU decisions that answer some questions but pose many more, *Journal of Intellectual Property Law & Practice*, 2014, Vol. 9, No. 7, 603.

¹⁵⁵ C-493/12 at [44].

¹⁵⁶ Explanatory Memorandum (n 63) at [32]: “[...] compliance with these conditions must be examined with respect to [...] the application date”.

¹⁵⁷ **Morze’ H./Hanna P.**, (n 84) 490.

¹⁵⁸ C-322/10.

¹⁵⁹ C-422/10.

¹⁶⁰ C-322/10 at [42]; C-422/10 at [35].

¹⁶¹ **Gassner U.M.**, (n 77) 60.

patented APIs, even where those APIs have been placed on the market together with other unpatented APIs in a combination medicinal product¹⁶². In this respect, as opposed to its restrictive approach on Article 3(a) SPCR, the Court chose a broad interpretation of Article 3(b) SPCR¹⁶³.

Another issue is whether a SPC can be granted in respect of an API whose therapeutic effect does not fall within the therapeutic indications covered by the wording of the MA. In *Forsgren* the CJEU stated that Article 4 SPCR implies that a use of a product which has not been authorized as a medicinal product may not be covered by a SPC. Therefore, the Court concluded that an API whose therapeutic effects do not fall within the therapeutic indications for which a MA was granted may not give rise to the grant of a SPC¹⁶⁴.

d. No previous SPC granted [Article 3(c)]

Article 3(c) SPCR requires that the product has not already been the subject of a SPC in the Member State where the SPC application is submitted.

The question which comes into consideration is whether, where a medicinal product is covered by several basic patents in force, the grant of a SPC to each holder of a basic patent is precluded. As stated above, pursuant to Article 1(c) SPCR, a patentee must select a basic patent covering the product on which a SPC application is based and cannot obtain two SPCs for the same product. However, several SPCs each relating to distinct products covered by different MAs but all say in a related class covered by the same patent, are possible¹⁶⁵. That means that, if a product involves more than one inventive concept that results in patents owned by separate legal entities, each entity should be entitled to SPC protection, because each entity should be entitled to designate a patent as the basic patent for a SPC application¹⁶⁶. If only one SPC is to be granted between two patentees, it is unclear to whom it should be awarded: to the party first to file its SPC application or to the party whose SPC happens to be the first to be

¹⁶² Advocate General's Opinion in C-130/11.

¹⁶³ **Gassner U.M.**, (n 77) 60; **Westerlund L.**, (n 1) 568.

¹⁶⁴ C-631/13 at [35].

¹⁶⁵ **Morze' H./Hanna P.**, (n 84) 485, 491; The situation can be explained as follows: when there are 1 basic patent, >1 proprietors → then >1 SPCs can be granted ≠ when there are >1 basic patents, 1 proprietor → then only 1 SPC can be granted.

¹⁶⁶ **Morze' H./Hanna P.**, (n 84) 485.

granted¹⁶⁷. Besides, the SPCR does not explicitly provide for the ‘first-to-file’ principle with regards to SPC applications¹⁶⁸. This approach was adopted by the CJEU in *Biogen*¹⁶⁹ case, where various patent holders had applied for SPCs simultaneously; that is, all applications were pending. The Court there, namely, held that, where a product is protected by a number of basic patents in force, which may belong to a number of patent holders, each of those patents may be designated for the purpose of the procedure for the grant of a SPC¹⁷⁰.

Resolved though it may seemed, the issue arose again, when the PPR came into force, the provisions of which referred to this matter. More concretely, under Article 3(2) of the PPR where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders. Further, according to the Recital 17 of the PPR the detailed rules in Article 3(2) of the PPR are also valid, *mutatis mutandis*, for the interpretation of Article 3 of the SPCR.

Despite the new provisions, the CJEU stayed in line with its previous case-law. In *AHP Manufacturing*¹⁷¹, the Court held that the holder of a basic patent may be granted a SPC for a product for which, at the time the SPC application is submitted, one or more SPCs have already been granted to one or more holders of one or more other basic patents. This founding is not altered by the fact that the application for SPCs were not ‘pending’ in the *AHP Manufacturing* case, within the meaning of Article 3(2) PPR, like it was the case in the *Biogen* case, but the SPC application was filed at a time when the SPCs relating to the other patents had already been granted and were no longer pending. The simultaneity of the applications was namely not considered to be essential for the grant of a SPC, since the strict textual interpretation of the word ‘pending’ would effectively deprive the latter applicant of the benefit provided for by SPCs which would run contrary to the fundamental objective of the SPCR to ensure sufficient protection and to encourage pharmaceutical research¹⁷². In this context, the Court stated that the SPCR seeks also to confer supplementary protection on the holders of national or European

¹⁶⁷ *Morze’ H./Hanna P.*, (n 84) 491.

¹⁶⁸ *Morze’ H./Hanna P.*, (n 84) 492.

¹⁶⁹ C-181/95.

¹⁷⁰ C-181/95 at [28].

¹⁷¹ C-482/07.

¹⁷² *Gassner U.M.*, (n 77) 51; C-482/07 at [30].

patents without instituting any preferential ranking amongst them¹⁷³. Moreover, the CJEU stated that a literal interpretation of Article 3(2) PPR would lead to a situation where the grant of an SPC could depend on an event which was uncertain and, as a rule, outside the control of the applicant, namely the date of the office's decision on the grant of one or more SPCs¹⁷⁴. Such a solution would thus, risk considerably reducing the possibility, provided for in Article 3(2) of PPR, for two or more holders of different patents for the same product to obtain an SPC for that product¹⁷⁵.

To sum up, the rule is that where a product is protected by a number of basic patents in force, each of those patents may be designated for the purpose of the procedure for the grant of a SPC, but only one SPC may be granted for each basic patent. Concomitantly, an applicant may be granted a SPC, if at time of application a third patent proprietor has already obtained a SPC or has applied for a SPC for the same product. As a consequence, the scope of application of Article 3(c) SPCR is restricted to cases where the same applicant has already received a SPC¹⁷⁶. This scope becomes even narrower by the judgment in *Neurim*¹⁷⁷ case. There the Court noted that its decision does not depend upon the identity of the proprietors of the MAs¹⁷⁸, patents or SPC application, which suggests that it should be possible for the same company to obtain SPCs for different medical uses of the same API, on condition that they are the subject of different patents¹⁷⁹. Therefore, a previous SPC is considered to exist, precluding thus the grant of another SPC, where the same applicant has already received a SPC for the same medical use of the same API.

The above rule though gave rise to some ambiguities in its applicability to combination products. More concretely, when it comes to combination products, the same patent may be regarded as protecting a number of products, thus raising a different question from those referred in, inter alia, the cases which gave rise to the decisions in *Biogen* and *AHP Manufacturing*, namely whether such a patent may permit its holder to obtain

¹⁷³ C-181/95 at [26], [27]; C-482/07 at [30].

¹⁷⁴ C-482/07 at [32].

¹⁷⁵ C-482/07 at [33].

¹⁷⁶ *Gassner U.M.*, (n 77) 51.

¹⁷⁷ C-130/11.

¹⁷⁸ C-130/11 at [35].

¹⁷⁹ *Reynolds L./Cordery B.*, Additional protection for second medical uses of known drugs?, *Pharm. Pat. Analyst* (2012) 1 (5), 517-518.

more than one SPC¹⁸⁰. The CJEU clarified this issue in *Actavis*¹⁸¹ and *Georgetown II*¹⁸² case.

In *Actavis*, the CJEU stated it is possible, in principle, on the basis of a patent which protects several different ‘products’, to obtain several SPCs in relation to each of those different products, provided, inter alia, that each of those products is ‘protected’ as such by that ‘basic patent’ and is contained in a medicinal product with an MA¹⁸³. The Court noted though, that it cannot be accepted that the holder of a basic patent in force may obtain a new SPC, potentially for a longer period of protection, each time he places on the market in a Member State a medicinal product containing, on the one hand, the principle API, protected as such by the holder’s basic patent, and, on the other, another API which is not protected as such by that patent¹⁸⁴. The Court added that the SPC is designed simply to re-establish a sufficient period of effective protection of the basic patent which is intended to compensate for the delay to the commercial exploitation of his invention by reason of the time which has elapsed between the date on which the application for the patent was filed and the date on which the first MA in the EU was granted¹⁸⁵. The Court concluded that, where a patent protecting a medicinal product containing an API has already enabled its holder to obtain a SPC relating to that API, a second SPC relating to a combination of that API with other APIs cannot be issued on the basis of the same patent¹⁸⁶. That is, a SPC granted for ingredient A, precludes the grant of a second SPC for the combination of ingredients A+B

As opposed to this judgment where the patented medicinal product consisted of an API, the Court ruled in *Georgetown II* on a case where the patented medicinal product consisted of a combination of several APIs. The CJEU held that, where a patent protecting a medicinal product consisting of a combination of several APIs has already enabled its holder to obtain a SPC relating to that combination of APIs, a second SPC relating to one of those APIs may be issued on the basis of the same patent, provided that that API, individually, is also protected as such by that patent¹⁸⁷. On the contrary,

¹⁸⁰ C-443/12 at [28].

¹⁸¹ C-443/12.

¹⁸² C-484/12.

¹⁸³ C-443/12 at [29].

¹⁸⁴ C-443/12 at [30].

¹⁸⁵ C-443/12 at [31].

¹⁸⁶ C-443/12 at [32], [37], [43].

¹⁸⁷ C-484/12 at [41].

the AG did not distinguish this case from *Actavis*; in his Opinion, he did not explicitly comment on the number of SPCs allowed per patent under Article 3(c) SPCR and proceeded from the assumption of a preclusion of more than one SPC¹⁸⁸. That is, a SPC granted for the combination of ingredients A+B, does not preclude the grant of a second SPC for ingredient A as such.

Although the above decisions clarify some issues, they still leave some queries unanswered¹⁸⁹. For example, in *Georgetown II*, the second to fifth questions were not answered¹⁹⁰, and thus it remained unclear whether a SPC can be granted for a product protected by a basic patent, if an SPC has already been granted for another product protected by the same basic patent, but where the applicant surrenders the latter SPC, with a view to obtaining a new SPC on the basis of the same basic patent.

e. First marketing authorization [Article 3(d)]

Article 3(d) of SPCR provides that a SPC for a product may be applied for only on the basis of the first MA to place that product on the market of the Member State in which the SPC application is submitted as a medicinal product for human use or as a veterinary medicinal product. It follows directly from a purely literal interpretation of this provision that any further MA to place that product on the market as a medicinal product is to be regarded as a later MA, on the basis of which — according to the wording of Article 3(d) — an application for a new SPC cannot be made¹⁹¹. This approach was confirmed by the judgments in *Yissum*¹⁹², *Pharmacia Italia*¹⁹³ and *Medeva*¹⁹⁴ cases.

However, the CJEU, by handing down in the more recent case *Neurim*¹⁹⁵, eased the limitation imposed on applicants based on the existence of earlier MAs for the same API or combination of APIs. There the Court adopted a new legal approach as to what constitutes ‘a first MA’, paving thus, the way for new SPC grants notwithstanding the existence of earlier MAs for the same API¹⁹⁶. More concretely, the patent holder in this case was seeking to obtain a SPC for the use of a API with a therapeutic application

¹⁸⁸ Advocate General’s Opinion in C-484/12 at [43] *et seq.*

¹⁸⁹ **Gassner U.M.**, (n 77) 63.

¹⁹⁰ C-484/12 at [42], [43].

¹⁹¹ Advocate General’s Opinion in Case C-130/11, at [23], [24].

¹⁹² C-202/05 at [20].

¹⁹³ C-31/03 at [20].

¹⁹⁴ C-322/10 at [40].

¹⁹⁵ C-130/11.

¹⁹⁶ **Reynolds L./Cordery B.**, (n 179) 517; **Westerlund L.**, (n 1) 565.

(treating human sleep disorders), while there was an earlier MA for the use of the same API with another therapeutic application (regulating the seasonal breeding activity of sheep)¹⁹⁷. The Court noted that the placement on the market of a new medicinal product commercially exploiting the new therapeutic application of the same API, as protected by the new patent, may enable its proprietor to obtain a SPC, the scope of which, in any event, could cover, not the API, but only the new use of that product¹⁹⁸. The CJEU reached thus, the conclusion that the mere existence of an earlier MA obtained for a veterinary medicinal product does not preclude the grant of a SPC for a different application of the same product for which a MA has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC¹⁹⁹.

The approach adopted in *Neurim*, to grant SPCs for second medical indications in certain cases via a restrictive interpretation of Article 3(d) SPCR, means that there is no longer a uniform interpretation of the term ‘product’ in the SPCR²⁰⁰. Whereas in case-law on Article 1(b) SPCR the term ‘product’ is defined in relation to the substance, the interpretation in Article 3(d) SPCR relates to the basic patent²⁰¹. Thus, there are *de facto* two juxtaposed definitions of the term ‘product’ as, according to previous case-law of the CJEU on Article 1(b) SPCR, SPC are precluded generally for uses of a known API²⁰², whether for other species²⁰³ or as a second medical indication²⁰⁴. Such an approach is not in line with the logic of the SPCR, according to which Article 1 SPCR contains the definitions of the core terms of the SPCR that are to be applied in the subsequent provisions²⁰⁵. It remains unclear whether *Neurim* is compatible with the previous interpretation of Article 1(b) SPCR as regards second medical indications, since this question was not addressed in the judgment²⁰⁶. It is also doubtful whether such an expansion of the term ‘product’ beyond a narrow interpretation of Article 3(d)

¹⁹⁷ C-130/11 at [15].

¹⁹⁸ C-130/11 at [25].

¹⁹⁹ C-130/11 at [27].

²⁰⁰ Schell J., (n 104) 725.

²⁰¹ Schell J., (n 104) 725.

²⁰² Schell J., (n 104) 725.

²⁰³ C-31/03 at [20].

²⁰⁴ C-202/05 at [20].

²⁰⁵ Schell J., (n 104) 728.

²⁰⁶ Schell J., (n 104) 725.

SPCR is compatible with the logic of the SPCR or whether it does in fact concern an interpretation issue under Article 1(b) SPCR²⁰⁷.

2. The application procedure

The SPC is granted at the request of the holder of a national or European patent²⁰⁸. Even though SPCs are subject to European and not national law, and thus, are regulated at the EU level, applications for SPCs must be filed and approved on a country-by-country basis²⁰⁹. More concretely, competent authority for the filing of the application for a SPC is the industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the MA to place the product on the market was obtained²¹⁰. The application shall be lodged within six months of the date on which the MA to place the product on the market in the State concerned as a medicinal product was granted²¹¹. If, however, the patent is by the issuing of the MA not granted, the six-month term will start as of granting of the patent²¹². Generally, the sixth-month-period takes particular account of the interests involved: those of the patent holder who, after having applied for the SPC, may, if he so wishes, forego the SPC, if his product proves to be unsuccessful on the market; and those of third parties who have interest in knowing as early as possible whether or not the product concerned will be protected by a SPC once the basic patent has expired²¹³.

The applicant must provide the national patent office with some documents²¹⁴. Apart from the request itself, a copy of the first MA to place the product on the market in the State concerned is required as this enables the product to be identified. If this MA is not also the first MA to place the product on the Community market, a copy of the latter also has to be attached, since the duration will be calculated, in all Member States in which a SPC is applied for, by reference to this criterion alone. Information enabling the basic patent to be identified must also be provided. The need to provide with a copy of the first MA was moderated in *Biogen*²¹⁵ case. More concretely, the applicant of the

²⁰⁷ Schell J., (n 104) 725.

²⁰⁸ Recital 8 SPCR.

²⁰⁹ Westerlund L., (n 1) 566.

²¹⁰ Article 9(1) SPCR.

²¹¹ Article 7(1) SPCR.

²¹² Article 7(2) SPCR.

²¹³ Explanatory Memorandum (n 63) at [46].

²¹⁴ Article 8 SPCR; Explanatory Memorandum (n 63) at [48].

²¹⁵ C-181/95.

SPC (owner of the basic patent and licensor) and the holder of the MA (licensee) were different persons, and the owner of the basic patent was unable to provide such copy. Staying in line with its previous case-law²¹⁶, the Court held that in this case a SPC application must not be refused on that ground alone and that the mere cooperation among administrations would suffice²¹⁷.

Where the SPC application and the product to which it relates meet the conditions laid down in the SPCR, the competent authority grants the SPC; otherwise the application is rejected²¹⁸. A notification of the grant or the rejection of the SPC is published in an official bulletin²¹⁹. This is to ensure that third parties are informed as soon as possible²²⁰. This decision is open to administrative appeals pursuant to national legislation²²¹.

VI. TERM OF SPC PROTECTION

1. Normal term

Under the TRIPS agreement²²², patent rights must be “enjoyable without discrimination as to [...] the field of technology [...]”. Before the SPCR came into force though, the practice imposed heavy penalties on pharmaceutical research, which was therefore discriminated as compared with other technological sectors²²³. In order to grant adequate effective protection for medicinal products equivalent to that enjoyed by other technological sectors, the SPCR includes provisions regulating the duration of the exclusive rights enjoyed by the holder of both a patent and a SPC.

More concretely, under Article 13 SPCR the duration of the SPC is subject to two limitations²²⁴. The first limitation constitutes a standard deduction of five years from the time lost between patent filing and the date of the first MA in the Community²²⁵. It should be noted that, unlike Article 3(b), (d) SPCR which refers, in respect of the SPC grant, to a first MA issued in the Member State in which the SPC application is

²¹⁶ C-201/94 at [28].

²¹⁷ C-181/95 at [38], [45], [47].

²¹⁸ Article 10(1)(2) SPCR.

²¹⁹ Article 11(1)(2) SPCR.

²²⁰ Explanatory Memorandum (n 63) at [49].

²²¹ Article 18 SPCR.

²²² Article 27(1) of Annex 1C to the TRIPS agreement.

²²³ Explanatory Memorandum (n 63) at [3], [50].

²²⁴ **Morze’ H./Hanna P.**, (n 84) 513.

²²⁵ Article 13(1) SPCR.

submitted, Article 13(1) SPCR refers, in respect of the SPC duration, to the first MA in the Community²²⁶. Reason for this is that the duration of the SPC covering one and the same medicinal product must be the same throughout the Community in order to facilitate the functioning of a genuine Community market²²⁷. In its recent reasoned order in *Merck Canada* the Court stated that the words ‘first authorization to place a product on the market in the Community’ in Article 13(1) SPCR refer to the first MA issued in any of the Member States and not to the first MA in the Member State in which the SPC application is submitted, as only that interpretation ensures that the SPC will expire at the same time in all of the Member States in which the certificate was granted²²⁸. Second limitation is an upper limit of five years for the duration of the SPC²²⁹. The SPCR only defines the maximum period of the SPC duration, and may be less than this maximum, if the SPC holder opts to pay fees for a lesser period²³⁰.

As a result from the upper limit for the SPC duration at 5 years, there is no benefit in applying for a SPC, where less than five (5) years have elapsed between the date of patent filing and the date of the respective MA, since the resulting SPC would have a nominally negative term²³¹. This may be well understood through the following hypothetical example²³²: A company files a European patent application in 1990, which is subsequently granted. One would expect the patent to expire in 2010. In 1997 the first MA in the Community is granted. Normally, the company would expect a SPC to provide protection until 2012 (2010+[1997-1990]-5 = 2012). However, if the first MA in the Community was first obtained in 1992, there would be no SPC protection. Further, in setting the upper limit for the duration of the SPC at 5 years, the SPCR penalizes medicinal products with a development time exceeding 10 years by awarding shorter effective patent lives to those products²³³. While a product with a development phase of 10 years will enjoy only 15 years of effective patent life²³⁴, the product whose

²²⁶ C-127/00 at [74].

²²⁷ Explanatory Memorandum (n 63) at [50].

²²⁸ C-555/13 at [31].

²²⁹ Article 13(2) SPCR.

²³⁰ Article 12 SPCR; *Porcuna de la Rosa F.*, (n 71) 69.

²³¹ *Gassner U.M.*, (n 77) 67; *Porcuna de la Rosa F.*, (n 71) 69.

²³² EU Case Reports, Journal of Generic Medicines, January 2005, Vol. 2, No 2, 166.

²³³ *Morze’ H./Hanna P.*, (n 84) 518.

²³⁴ Patent duration = 20 years (article 33(1) TRIPS) – 10 years (MA phase) = 10 years. SPC Duration= 10 years (MA phase) – 5 years (Article 13(1) SPCR) = 5 years. Total duration of effective patent life = 10 years (patent life) + 5 years (SPC life) = 15 years.

development takes 12 years, will only enjoy 13 years of effective patent life²³⁵. This reflects a bias against products for the treatment of chronic diseases where longer testing periods and thus longer development times are required²³⁶.

Since determining factor for the SPC duration is the first MA to place a medicinal product on the market in the Community, the question of whether a MA issued by a State of the EEA is regarded as the first MA in the Community came into play. The CJEU answered in the affirmative by a series of decisions. More concretely, in *Novartis and Others*²³⁷ the CJEU held that a MA issued by Switzerland (which did not ratify the SPCR) and automatically recognized by Liechtenstein is the first MA to place the product in one of the States of the EEA and thus, it constitutes the first MA within the meaning of Article 13 SPCR which should be taken into consideration for the purposes of calculating the duration of the SPC²³⁸. In strict legal terms, the SPCR does not apply in Switzerland and a first MA in Switzerland is not a MA in the Community. However, the automatic applicability of the MA in Liechtenstein means that the product concerned is available in part of the EEA. Staying in line with this decision, the CJEU issued a reasoned order in *Astrazeneca*²³⁹. There the Court held that, in the context of the EEA, under Article 13(1) SPCR a MA issued for a medicinal product by a State of the EEA must be regarded as the first MA to place that medicinal product on the market in the EEA, where that MA predates MAs issued for the same medicinal product, either by the European Medicines Agency ('EMA'), or by the competent authorities of EU Member States²⁴⁰.

A further question arising relates to the date in which the MA to place a medicinal product on the market in the Community takes effect. The UK IPO, which dealt with this question, concluded that a MA to place a medicinal product on the market in the Community granted according to the relevant European legislation, takes effect not on the date of decision by the European Commission, but rather, on the date that this

²³⁵ Patent duration = 20 – 12 = 8 years. SPC Duration = 12 – 5 = 7 years → but maximum duration of SPC is 5 years (13(2) SPCR) → ~~7 years~~ 5 years. Total duration of effective patent life = 8 + 5 = 13 years.

²³⁶ **Morze' H./Hanna P.**, (n 84) 518; **Goldberg R.**, *Pharmaceutical Medicine, Biotechnology and European Law*, edited by Goldberg R./Lonbay J., 2000, The development risk defense and the European Court of Justice; increased injury costs and the Supplementary Protection Certificate, 199.

²³⁷ Joined Cases C-207/03 and C-252/03.

²³⁸ Joined Cases C-207/03 and C-252/03 at [33].

²³⁹ C-617/12.

²⁴⁰ C-617/12 at [60].

decision is notified to the applicant for the MA. Thus, the calculation of the duration of an SPC based upon such a European MA should take account of the date of notification of the decision by the European Commission to grant the relevant MA and not the date of the decision itself²⁴¹.

To sum up, the term of SPC protection should be calculated by reference to the first MA to place the medicinal product on the market in the Community, i.e. in a Member State of the EU or of the EEA, thereby avoiding different terms in the Member States²⁴². In any case, the upper limit for the effective patent life of a product – that is the time period between the first MA in the EU or EEA and the date of expiry of the SPC – is 15 years²⁴³, after which the medicinal product enters the public domain²⁴⁴.

2. Extended term

Under Article 13(3) SPCR a SPC can be extended by an additional half year to a maximum of 5 ½ years, if it covers a human medicinal product, and data from clinical trials conducted based on a Paediatric Investment Plan ('PIP'), along with – where necessary - proof of possession of MA to place the product on the market of all Member States, have been submitted pursuant to Article 36 PUR. Such an extension may occur only once. The application for an extension of the duration may be made either when lodging the application for a SPC or when the application for the SPC is pending²⁴⁵. If the SPC is already granted, the application for the extension of its duration shall be lodged not later than two years before its expiry²⁴⁶. The period of the paediatric extension starts to run from the date determined by deducting from the patent expiry date the difference between five years and the duration of the period which elapsed between lodging the patent application and obtaining the first MA²⁴⁷. As a result from this provision, a SPC of negative duration may be attractive for a patent proprietor, since a paediatric extension is potentially available, where a MA application includes

²⁴¹ BL O/418/13 at [64], available at <http://webarchive.nationalarchives.gov.uk/tna/20140603093547/http://www.ipo.gov.uk/o41813.pdf>

²⁴² **Gassner U.M.**, (n 77) 65.

²⁴³ Recital 9 SPCR; **Morze' H./Hanna P.**, (n 84) 513.

²⁴⁴ Explanatory Memorandum (n 63) at [53].

²⁴⁵ Article 7(3) SPCR.

²⁴⁶ Article 7(4) SPCR.

²⁴⁷ C-125/10 at [42].

the results of all studies conducted in compliance with a PIP that has been agreed with the EMA²⁴⁸.

This gave rise to the issue whether a paediatric extension of a SPC could be granted in a situation where the SPC would have a negative term, i.e. it would nominally expire before it took effect at the end of the term of the patent upon which it was based²⁴⁹. The CJEU dealt with this issue in *Merck Sharp*²⁵⁰. At first, the Court stated that nothing in the wording of the provision of Article 13(1) or in any other provision of the SPCR suggests that a SPC of negative duration is necessarily precluded²⁵¹. The Court continued, stating that, if a SPC was refused for having a negative or zero duration, the aim of the paediatric extension - which is to reward the evaluation of paediatric effects of the medicinal product concerned - would be jeopardized²⁵². Thus, while a SPC of negative or zero duration serves no purpose of itself, the fact remains that such an SPC may be of use to the holder of the basic patent wishing to obtain the paediatric extension²⁵³. It has been supported that the Merck judgment deserves to be approved, since, by holding that an application for an extension of six (6) months can be filed, even if the SPC duration is negative or zero²⁵⁴, it may support the development and the accessibility of medicines for children²⁵⁵. Moreover, by adopting this approach the undesirable situation of potential applicants for a SPC deliberately delaying the grant of a MA in order to obtain a positive term is avoided²⁵⁶.

Further problems relate to Article 8(1)(d) SPCR which establishes the necessary points to be included in an application for an extension of the SPC duration. A first issue concerns Article 8(1)(d)(i) SPCR and is that PUR fails to specify the means through which the applicant might demonstrate compliance with an agreed completed PIP. It has been supported that, since Community legislation has not drawn up a closed list of means whereby the applicant may prove compliance, the means available for the applicant to evidence the existence of this requisite will depend on the reliability and

²⁴⁸ Gassner U.M., (n 77) 68.

²⁴⁹ Gassner U.M., (n 77) 68.

²⁵⁰ C-125/10.

²⁵¹ C-125/10 at [28].

²⁵² C-125/10 at [34].

²⁵³ C-125/10 at [35].

²⁵⁴ C-125/10; Gassner U.M., (n 77) 67-69; Porcuna de la Rosa F., (n 71) 69.

²⁵⁵ Gassner U.M., (n 77) 68-69.

²⁵⁶ Gassner U.M., (n 77) 69; Müller S./Brückner C., Supplementary Protection Certificate with Negative Duration?, IIC 2011, beck-online, 639-640.

probative efficacy of the information it contributes²⁵⁷. Another issue relates to Article 8(1)(d)(ii) SPCR and is what constitutes “proof of possession of authorisations to place the product on the market of all Member States”. At the Paediatric Forum, pharmaceutical innovators proposed that a statement by the applicant indicating that it was prosecuting the MA in all Member States should be considered as valid proof²⁵⁸. A further question lies in determining whether the MA are MA as such or if they should be qualified, in the sense of including the studies carried out to the agreed PIP. While the European Commission has supported the need for qualified authorisations, the opposite opinion has also been supported²⁵⁹. In any case, beyond any legal consideration, due to the requirement of MA in ‘all Member States’, inadequate operation of Member States’ medicines authorities will have a direct adverse impact beyond their territories, precluding applicants from obtaining their legitimate rights in the entire Internal Market²⁶⁰.

3. End of protection

a. Expiry

Pursuant to Article 14 SPCR the SPC lapses at the end of its effective period, or if its holder surrenders it, or if the annual fee is not paid in time, or if the product covered by the SPC may no longer be marketed following the withdrawal of the MA. In the latter case, the authority, which is competent for granting the SPC, may decide on its lapse either of its own motion or at the request of a third party²⁶¹. The SPC efficacy may be restored, if the decision of invalidity of the MA is eventually reversed²⁶².

b. Invalidity

Although issued SPCs are given the presumption of validity, they are not immune from invalidation. Pursuant to Article 15 SPCR, a claim of invalidity can be brought by any person. Invalidity can result from the following reasons: if the SPC was granted despite the non fulfilment of the respective legal prerequisites, or the basic patent has lapsed

²⁵⁷ **López-Bellosta M./Santa Cruz A.B.**, Fostering paediatric research and the right to extend supplementary protection certificates, *Journal of Intellectual Property Law & Practice*, 2010, Vol. 5, No. 1, 50.

²⁵⁸ **Sánchez A.C.**, Implementing paediatric extensions to SPCs: marketing authorization in ‘all Member States’, *Journal of Intellectual Property Law & Practice*, 2009, Vol. 4 No. 5, 306.

²⁵⁹ **López-Bellosta M./Santa Cruz A.B.**, (n 257) 51 *et seq.*

²⁶⁰ **Sánchez A.C.**, (n 258) 306.

²⁶¹ Article 14(d) SPCR.

²⁶² **Porcuna de la Rosa F.**, (n 71) 69.

before its lawful term expires, or the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

It should be noted that Article 2 SPCR is not included in the above list of grounds on which a SPC is deemed to be invalid. Since it is not included in that list, the question of whether a SPC issued for a product outside the scope of the SPCR is invalid came into play. In *Synthon*²⁶³ the CJEU answered in the affirmative. More concretely, the Court stated that, even if it is not possible to infer from the wording or the origin of Article 15(1) SPCR that the list of grounds of invalidity of an SPC set out therein is not exhaustive, the infringement of an article of SPCR not referred to in Article 15(1) can render an SPC invalid owing to the connection between the provision in question and Article 3 SPCR²⁶⁴. The Court noted that the concept of ‘product’ in Article 3 SPCR refers necessarily to a product within the scope of the SPCR, as defined in Article 2 thereof, and thus, issuing a SPC for a product outside the scope of the SPCR disregards the meaning of ‘product’²⁶⁵. Therefore, a SPC granted for a product outside the scope of SPCR, as that scope is defined in Article 2 SPCR, is invalid²⁶⁶.

VII. TRANSITIONAL PROVISIONS

According to the legal theory, the transitional provisions of a legislative act regulate the applicability of its rules to facts that have occurred before its entry into force or to pending legal actions²⁶⁷. Likewise, the transitional provisions of the SPCR set out the conditions for obtaining a SPC for a product, where, at the date of entry into force of the SPCR on the territory of a Member State, the product had already been placed on the relevant national market as a medicinal product²⁶⁸. The SPCR contains 3 groups of transitional provisions²⁶⁹: on its initial entry into force in Article 19, on accession of new EU Member States in Article 20, and on the existing national regimes for extended patent protection in Articles 21 and 13(4). More concretely, the transitional provisions

²⁶³ C-195/09.

²⁶⁴ C-195/09 at [55].

²⁶⁵ C-195/09 at [56].

²⁶⁶ C-195/09 at [57].

²⁶⁷ **Batakliiev D.**, Supplementary Protection Certificates in Europe – Transitional Regime, 2013, 752.

²⁶⁸ **Batakliiev D.**, (n 267) 750-751.

²⁶⁹ **Batakliiev D.**, (n 267) 751.

of Article 20 SPCR function in two ways²⁷⁰: on the one hand, they extend the scope of the new regime to products for which MA had been issued before the initial entry into force of the SPCR or before its entry into force for the newly acceding Member States, and on the other hand, the transitional regime only applies to products marketed as medicinal products after a certain date.

A question that came into consideration was whether a valid MA within the meaning of Article 3(b) SPCR is still required, even though not included in the transitional provisions. In *Yamanouchi Pharmaceutical*²⁷¹, it was discussed whether the transitional provisions²⁷² derogate from the general requirements²⁷³ regarding the grant of a SPC²⁷⁴. The Court held that a SPC can be granted under the transitional provisions only where the conditions set out in the general requirements of Article 3 SPCR are also fulfilled²⁷⁵. As the Court underlined, this approach is in line with the wording of these general requirements (the SPC ‘shall be granted’) and the transitional provisions (‘may be granted’), which makes clear that the latter provisions do not in any way preclude the requirements set out in the former provisions²⁷⁶. Besides, it is the MA referred to in the general requirements of Article 3 SPCR which confers entitlement to the SPC, since the protection extends only to the product covered by the MA in respect of the corresponding medicinal product²⁷⁷. The question in the mentioned case derived from the fact that the condition of a ‘valid authorization’ was not included in the transitional provisions of the pSPCR. This is also the case in the current SPCR. However, the phrase “without prejudice to the other provisions of this Regulation” at the beginning of the transitional provisions²⁷⁸ of the current SPCR has probably made clear that the transitional provisions only complement the general requirements and do not replace them.

In addition, the fact that for different Member States the transitional provisions have varying requirements as to the date of issue of the first MA has raised the question of

²⁷⁰ *Batakliiev D.*, (n 267) 752-753.

²⁷¹ C-110/95

²⁷² Article 19 previous SPCR.

²⁷³ Article 3 previous SPCR.

²⁷⁴ C-110/95 at [18].

²⁷⁵ C-110/95 at [28].

²⁷⁶ C-110/95 at [20].

²⁷⁷ Article 4 SPCR; C-110/95 at [26].

²⁷⁸ Article 20 SPCR.

their compliance with the principle of equality of treatment under Community law and their validity. In *Hässle* the CJEU stated that the setting of different relevant dates for different Member States appears to be justified insofar as each of those dates reflects the assessment made by each Member State in the light, in particular, of its health system, the organisation and financing of which varies from one Member State to the next, confirming thus the validity of the transitional provisions and their conformity with the principles of Community law²⁷⁹.

Further issues arose relating to the applicability of the transitional provisions of the SPCR. In *Kirin Amgen*²⁸⁰ it was discussed whether the holder of a European patent for a medicinal product can apply with the competent national (Lithuanian) authorities for the grant of a SPC on the basis of its Community MA under the transitional provisions of the SPCR. There was a transitional provision which was specifically referring to Lithuania, stating that a SPC shall be granted, if, amongst others, the first MA was national²⁸¹. Having pointed out that the transitional provisions had been specifically negotiate and they should be interpreted narrowly, the Court held that the above provision was not applicable, because the above requirement was not fulfilled, since the MA at issue was a Community and not a national one²⁸². Furthermore, the Court stated that, although the Community MA (granted on 08.06.2001) entered into force in Lithuania on 1 May 2004, i.e. when Lithuania accessed the EU, the patent holder cannot waive the time limit²⁸³ for the lodge of the application for a SPC, since the entry into force of the Community MA cannot be equated with the date on which the MA was granted under Article 3(b)²⁸⁴. Therefore, the relevant date for assessment of the applicability of the transitional provisions is the date of the issue of the European MA and not its entry into force, whereas the fact that the European MA comes into force on the territory of a state at the time of its accession is irrelevant.

There are also cases where MA obtained outside the territory of the Community or the EEA become effective on these territories by virtue of bilateral agreements²⁸⁵. In *Novartis and Others*, a regional agreement between Liechtenstein and Switzerland

²⁷⁹ C-127/00 at [40], [47].

²⁸⁰ C-66/09

²⁸¹ Article 19a(e) previous SPCR.

²⁸² C-66/09 at [32], [35], [53].

²⁸³ Article 7(1) SPCR.

²⁸⁴ C-66/09 at [40], [52], [53].

²⁸⁵ **Botakliev D.**, (n 267) 761.

provides that Swiss MA automatically become effective on the territory of Liechtenstein. Thus, the CJEU reached the conclusion that such Swiss MA with effect in Liechtenstein shall be considered as the first MA in the Community for the purposes of Article 13 SPCR²⁸⁶.

All in all, as a derogation from the general rules and because of their limited scope of application only to products placed on the market as medicinal products before entry into force of the SPCR, the transitional provisions have always been interpreted strictly by the CJEU. Therefore, any attempt to use the transitional provisions as a means of avoiding the general requirements of Article 3 SPCR or circumventing the temporal or territorial conditions therein have always been denied²⁸⁷.

D. CONCLUSIONS

I. RECAPITULATE THE CORE CJEU'S FOUNDINGS

- Neither can an excipient which changes the behavior of an API be considered itself as an API, nor can it give rise to a combination of APIs, which, in turn, are used to define the term 'product' under the SPCR (*MIT, GSK, Forsgren*).
- The greater purity of an API (*BASF*) and minor variations (*Farmitalia*) do not make the product different, thus qualifying it for a grant of another SPC.
- The second medical use does not make the product different, thus qualifying it for a grant of another SPC (*Yissum, Pharmacia Italia*) ≠ the mere existence of an earlier MA obtained for a veterinary medicinal product does not preclude the grant of a SPC for a different application of the same product for which a MA has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC (*Neurim*).
- A SPC for a medicinal product is valid, only if the first MA in the Community is in line with the MAD (*Synthon, Generics*).
- If a SPC is granted for product A, the SPC holder has the right to launch infringement proceedings concerning a medicinal product containing A+B provided that this would have been possible under the basic patent (*Novartis v Actavis*).

²⁸⁶ Joined Cases C-207/03 and 252/03 at [30].

²⁸⁷ *Batakliiev D.*, (n 267) 754.

- The protection conferred by the SPC can extend to any of the forms enjoying the protection of the basic patent, e.g. to simple derivatives, salts, or products of the product (*Farmitalia*).
- A SPC cannot be granted when the APIs are not specified alone – either by a structural or by a functional formula - in the wording of the claims of the basic patent relied on in support of the SPC application. That is, if the patent claims A+B, a SPC cannot be granted for just A. (*Medeva, Aventis, Queensland, Eli Lilly*).
- A valid MA to place the product on the market can exist even where the MA relates to a medicinal product which also comprises, in addition to the patented API or in addition to the patented combination of APIs, in respect of which a SPC is applied for, one or more other APIs. That is, if there is a MA for A+B, a SPC can be granted just for A (*Medeva, Georgetown I*).
- An API, whose therapeutic effects do not fall within the therapeutic indications covered by the wording of the MA granted, may not give rise to the grant of a SPC (*Forsgren*).
- The holder of a basic patent may be granted a SPC for a product for which, at the time the SPC application is submitted, one or more SPCs have already been granted to one or more holders of one or more other basic patents. (*Biogen, AHP Manufacturing*).
- Where a patent protecting a medicinal product containing an API has already enabled its holder to obtain a SPC relating to that API, a second SPC relating to a combination of that API with other APIs cannot be issued on the basis of the same patent; that is, a SPC granted for ingredient A, precludes the grant of a second SPC for the combination of ingredients A+B (*Actavis*).
- Where a patent protecting a medicinal product consisting of a combination of several APIs has already enabled its holder to obtain a SPC relating to that combination of APIs, a second SPC relating to one of those APIs may be issued on the basis of the same patent, provided that that API, individually, is also protected as such by that patent; that is, a SPC granted for the combination of ingredients A+B, does not preclude the grant of a second SPC for ingredient A as such (*Georgetown II*).

- Where the applicant of the SPC and the holder of the MA are different persons, with the result that the former cannot provide the competent patent office with the copy of the MA, a SPC application must not be refused on that ground alone and the mere cooperation among administrations would suffice (*Biogen*).
- The term of SPC protection should be calculated by reference to the first MA to place the medicinal product on the market in the Community, i.e. in a Member State of the EU or of the EEA, thereby avoiding different terms in the Member States (*Astrazeneca, Merck Canada*). Even where MA is obtained outside the territory of the Community or the EEA, it can still become effective on these territories by virtue of bilateral agreements (*Novartis and Others*).
- A six-month paediatric extension of a SPC could be granted in a situation where the SPC would have a negative term, i.e. it would nominally expire before it took effect at the end of the term of the patent upon which it was based (*Merck Sharp*).
- A SPC granted for a product outside the scope of SPCR, as that scope is defined in Article 2 SPCR, is invalid, although this Article is not included in the list of grounds of invalidity provided for in Article 15 SPCR (*Synthon*).
- A SPC can be granted under the transitional provisions only where the conditions set out in the general requirements of Article 3 SPCR are also fulfilled (*Yamanouchi Pharmaceutical*).
- The varying requirements as to the date of issue of the first MA between the Member States does not infringe the principle of equality of treatment under Community law (*Hässle*).
- The transitional provisions had been specifically negotiate and they should be interpreted narrowly (*Kirin Amgen*).

II. FINAL REMARKS

Although economists sometimes debate whether the patent system is useful generally²⁸⁸, no one has ever seriously challenged its place for medicines²⁸⁹. Patents are an important way to ensure that the benefits of research are captured by the creator, whilst the SPC has proven an effective instrument in protecting innovation for

²⁸⁸E.g. **Grinlos E.L./Henderson J.W.**, Replace pharmaceutical patents now, *Pharmacoeconomics* 2007, 25 (5), 355-363.

²⁸⁹ **Jacob R.**, (n 37) 3.

medicinal products. Nevertheless, the patent applications in Pharmaceuticals filed with the EPO dropped significantly during the last two years²⁹⁰. This may derive, inter alia, from the uncertainty which still surrounds the SPC regime²⁹¹, although some valuable clarifications have been made by the CJEU. As the AG Trstenjak in *Neurim* case pointed out, there are two lines of case-law regarding SPCs, which are difficult to reconcile²⁹²: i) a line of case-law based upon the idea that the grant of a patent normally confirms the eligibility for protection with the result that it should also be possible to grant a SPC, such as *Medeva*, *Georgetown I* and *AHP Manufacturing*, and ii) a line of case-law where the CJEU takes a stricter interpretation as regards the conditions for obtaining a SPC, such as the judgments in *Synthon* and *Generics*.

Another concern relating to the future interpretation of the SPC regime, aside from the legal uncertainty, is whether the CJEU strikes a fair balance between the various interests at stake in the pharmaceutical sector. According to AG Trstenjak, those interests include, on the one hand, the interests of the undertakings and institutions, some of which pursue very cost-intensive research in the pharmaceutical sector, and on the other hand, the interests of the producers of generic medicines who, as a consequence of the extension of the term of protection of the active ingredients under patent protection, are precluded from producing and marketing generic medicines²⁹³. The SPC regime is also intended in the interests of both patients and national healthcare systems to prevent old APIs from being brought onto the market in slightly modified form under the protection of SPCs, but without genuine innovation and thereby artificially driving up expenditure in the health sector²⁹⁴.

²⁹⁰ <http://www.epo.org/about-us/annual-reports-statistics/statistics/patent-applications.html>

²⁹¹ Gassner U.M., (n 77) 69-72.

²⁹² Advocate General's Opinion in C-130/11 at [59]-[64].

²⁹³ Advocate General's Opinion in C-130/11 at [41].

²⁹⁴ Advocate General's Opinion in C-130/11 at [41].

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