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1.001 Health is a universal human right and the attainment by all peoples of the highest possible level of health is enshrined in Article 1 of the Constitution of the World Health Organization. Health is also enshrined in the EU Charter of Fundamental Rights, and good health and well-being is goal number three among the 17 UN Sustainable Development Goals.

1.002 Pharmaceutical research and the introduction of new medicinal products are considered vital for society to support continuing improvements in public health. The pharmaceutical industry is one of the most heavily regulated industries subject to both technological, legal, and financial restraints. The industry is controlled by a variety of different areas of law, such as intellectual property law, regulatory law, competition law, and international and EU law.

1.003 This book will provide a discussion and analysis of some of the legal aspects of intellectual property law of the pharmaceutical industry. Whereas the main legal incentives will be briefly discussed, the focus will be on supplementary
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protection certificates (SPCs) for medicinal products – an incentive for the pharmaceutical industry introduced in 1993 to compensate for the lack of adequate protection against competition provided by the patent system caused by regulatory delay in bringing new medicinal products on the market.

This introductory chapter will provide a background to the book. The first part thereof aims to give an overview of the multi-faceted pharmaceutical industry, its stakeholders and the various legal instruments surrounding and regulating said industry, including intellectual property rights (IPR), regulatory provisions, innovation, and competition etc. This will help set the scene for the narrower aspect explored in detail in the subsequent chapters. Subsequently a more specific background will be presented which describes the particular focus of this book. In this more specific part a brief description of the development of the pharmaceutical industry will also be presented. This will lead to a description of the purpose of this book. An overview of the structure of the book will be presented in the last part of the introduction.

A. BACKGROUND

The pharmaceutical industry is one of the most important industries in the industrialised world – both in terms of value to society as a whole and in terms of size.\(^1\) The pharmaceutical industry is among the most research and development (R&D) intensive industries in the world and is also one of the most intensive users of the patent system.

The patent system was instituted to promote innovation. Patent protection provides a patent owner, such as a pharmaceutical company, a time-limited monopoly during which it can exclude competitors from the market and recover (some of) the costs involved in developing a marketable product. In exchange, the patent owner must divulge the invention, i.e. disclose the invention and make it publicly available and thereby stimulate further innovation. After patent expiry, anyone is free to use the invention, including preparing a copy or generic\(^2\) version thereof.

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1 In 2014, five of the 11 leading global R&D firms were pharmaceutical companies according to the International Federation of Pharmaceutical Manufacturers & Associations, Facts and Figures 2017; https://www.ifpma.org/resource-centre/ifpma-facts-and-figures-report/ (last visit 13 February 2022).
2 See further below at Chapter 2, Section A.
1. Approval of new medicines

Prior authorisation procedures for medicinal products were first introduced in Europe following the tragic experience with the drug thalidomide in the 1950–1960s. Thalidomide was given to pregnant women to prevent morning sickness and was later found to cause birth defects in thousands of newborns. Since then, public authorities have required the pharmaceutical industry to demonstrate the quality, safety and efficacy of new medicinal products before marketing thereof is allowed. In order to safeguard public health extensive rules relating to the safety, efficacy etc. of a medicinal product must be complied with before a marketing authorisation is issued to allow a new medicinal product to be brought to the market.

The development of a new drug is increasingly lengthy and costly due to the necessary pharmacological, toxicological and clinical tests to demonstrate efficiency and tolerability. A relationship exists between – on the one hand – the importance of pharmaceutical innovation and – on the other hand – the costs involved in obtaining an authorisation for the marketing of a medicinal product. For society there is a need for new medicinal products without compromising the requirements for testing thereof prior to the grant of an authorisation to market such products.

As a result of the extensive, costly and time-consuming resources necessary to perform the required clinical tests in order to obtain marketing authorisation for a medicinal product, the effective patent life, i.e. the period of exclusivity where a patent holder is allowed to market his product and recoup (some of) the investments put into research, had during the 1980s decreased to often less than 10 years (compared to the original 20 years patent term). In the early 1990s, an average period of 12 years was required between the discovery of a new medicinal product (at which point in time the patent application is filed) and its being made available to patients, thus leaving only about eight years for exclusive exploitation of the invention to the patentee. These figures still hold true today. According to a report from the European Federation

3 Council Directive (65/65/EEC) was the first EEC wide directive relating to proprietary medicinal products stipulating that a medicinal product may not be placed on the market in a Member State unless an authorisation has been issued by a competent authority. Directive 65/65/EEC has been replaced by Directive 2001/83/EC.

of Pharmaceutical Industries and Associations (efpia), it takes an average of 12–13 years from the first synthesis of a new active substance before the medicinal product reaches the market. Correspondingly, according to a report from the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), facts and figures as of 2017, it takes 10–15 years to develop a medicine or vaccine.

Furthermore, the success rate in pharmaceutical innovation is slim. It was estimated that out of 10,000 substances synthesized by a research laboratory, a few hundred would be selected for the filing of patent applications, of which only one to three would actually be authorised to be placed on the market.

2. Supplementary protection certificates (SPCs)

A system was therefore put in place in Europe in order to allow patent holders for pharmaceutical inventions a longer period of effective protection. This was achieved via a so-called supplementary protection certificate (SPC) providing for up to 15 years of effective protection. An SPC is issued in accordance with Regulation (EC) No 469/2009 of 6 May 2009 (codified version of Regulation (EEC) No 1768/92) (the “SPC regulation”) meaning that the SPC system has existed for more than 25 years.

An SPC extends the protection of a product as a medicinal product provided certain conditions are fulfilled. For a product protected by a patent and for which a marketing authorisation has been issued for the first time, the patent owner (patentee) may apply for an SPC extending the marketing exclusivity for up to five years, provided said product has not already been the subject of a certificate. During said period, the patentee may prohibit any third party from marketing a competing medicinal product falling under the scope of protection of the SPC, however, with an overall maximum period of exclusivity of 15 years.

The text of the SPC regulation is very brief. Still – or maybe as a consequence thereof – the SPC regulation has been the subject of a large number of referrals.

6 See footnote 1 above.
7 See also Chapter 2, Section B.
8 Explanatory Memorandum, par. 5.
9 SPC regulation, Art. 3.
10 Establishing the scope of protection of an SPC and thus what constitutes the subject matter of protection of an SPC is one of the key issues of this book and will be discussed in detail further below.
to the Court of Justice of the European Union (CJEU). This shows that the judicial systems around Europe have struggled with interpreting the individual articles of the SPC regulation. Furthermore, the decisions rendered by the CJEU itself have evolved and at times led to inconclusive or even contradictory interpretations, leading to significant uncertainty and adding to its complexity. Thus, while some issues with regard to the SPC regulation seem to have been resolved, many questions are outstanding.

1.014 In Part II of the book, the most significant issues with regard to the SPC regulation – and the ones subject to the most extensive number of referrals to the CJEU – are discussed in order to establish the law as it is (de lege lata), namely which medicinal products may be eligible for SPC protection, the conditions to be fulfilled in order to obtain an SPC, and the scope of protection and effects of an SPC.

3. Technological development after the introduction of the SPC regulation

1.015 Technological developments in the pharmaceutical industry have presented additional challenges to the system of SPCs.

1.016 At the time the SPC regulation was adopted, the focus of the pharmaceutical industry was on so-called “small molecules”, i.e. well-defined molecules of relatively small molecular weight synthesized chemically or retrieved from nature. The SPC regulation was therefore drafted with a focus on such small-molecule products. However, over the past decades, the biotechnology and life-science industries have become more and more influential on the pharmaceutical industry. Biotechnology and life-science innovation will in the present book be broadly termed “biotechnological innovation”.

1.017 Another part of innovation in the pharmaceutical industry which has undergone a substantial development is based on inventions relating to new applications of known chemical compounds for new indications (diseases), new formulations of known chemical compounds, new dosage regimes of known chemical compounds, and application of combinations of known or unknown chemical compounds for new indications or improved treatments for known...
indications. In the present book such innovation will be broadly termed “second-ary innovation”.

The above two aspects of the development of the pharmaceutical industry are not meant to provide an exhaustive picture of the technological development thereof. However, these aspects play a significant role in the development of this industry and have been shown to present challenges to the present SPC system. They are therefore considered relevant aspects to consider.

(a) Biotechnological innovation

A substantial part of research and development in the pharmaceutical industry of today relies on biology and biotechnology, with new medicines involving large biomolecules, such as proteins, antibodies, and viruses or other vehicles carrying genetic information, as well as microorganisms or cells producing such biomolecules or being therapeutic in themselves. A biological medicinal product is a medicinal product whose active ingredient, the biomolecule, is made by a living organism. Biomolecules are often difficult, if not impossible, to characterise by their chemical structure, but are more typically characterised by how they function, e.g. by their ability to interact with or bind to specific receptors.

While the scope of protection of an SPC for a small-molecule product seems to have been established by case law, the scope of protection of an SPC for a biological medicinal product is – due to the inherent variability of biological medicinal products – unclear. Sparse case law exists in Europe with regard to the scope of protection of a biological medicinal product. It is unclear, whether – or under which conditions – a competitor biological medicinal product falls under the scope of protection of an SPC for the corresponding reference biological medicinal product. It is also unclear, what are the criteria to be applied in order to establish the scope of protection of an SPC for a biological medicinal product.

In this book it is analysed and discussed in the light of the technological development whether the existing legislation and case law enables the establishment of a scope of protection of SPCs for biological medicinal products which provides a reasonable degree of legal certainty and gives a reasonable scope

15 See Part III, Chapter 9.
of protection for the SPC holder, thereby fulfilling some of the fundamental objectives of the SPC regulation of encouraging pharmaceutical research, while also taking into account all interests at stake.\(^\text{16}\)

(b) \textit{Secondary innovation}

\textbf{1.022} The term “secondary innovation” is used in this book in a broad sense to describe inventions based on e.g. improving existing medicinal products or expanding therapeutic coverage to new indications, such as inventions relating to new applications of known chemical compounds for new indications (diseases), new formulations of known chemical compounds and new dosage regimes of known chemical compounds providing e.g. better patient compliance or more efficient treatment, treatment of new patient groups, new routes or modes of administration, new mechanisms of action, as well as application of combinations of known or unknown chemical compounds for new indications or improved treatments for known indications. This type of innovation is also sometimes called “follow-on innovation”, or “incremental innovation”.\(^\text{17}\) The term “secondary innovation” includes innovation termed “second medical use inventions”. The patentability of “second medical use inventions” is expressly recognized under the EPC\(^\text{18}\) provided the usual patentability criteria are fulfilled.

\textbf{1.023} It appears from the Explanatory Memorandum\(^\text{19}\) that it was the intention of the legislators of the SPC regulation that “all pharmaceutical research, provided that it leads to an new invention that can be patented, whether it concerns a new product, a new process for obtaining a new or known product, \textit{a new application of a new or known product or a new combination of substances containing a new or known product}, must be encouraged, without any discrimination, and must be able to be given a supplementary certificate of protection” (emphasis added). However, case law of the CJEU regarding SPC eligibility of products based on secondary innovation has varied greatly over the years leading to major shifts in the possibilities for SPC protection of such products.

\textsuperscript{16} Recital 10 of the SPC regulation.
\textsuperscript{19} Explanatory Memorandum, par. 29.
the latest case law severely restricting availability of SPC protection for products based on secondary innovation.

On the basis of an analysis and discussion of the case law of the CJEU it is analysed and discussed whether the existing legislation and case law has struck a balance with regard to SPC eligibility for products of secondary innovation which provide legal certainty and take into account all interests at stake.

B. AIM OF ANALYSES PERFORMED

The overall aim of this book is to analyse and evaluate whether the SPC system, Regulation (EC) 469/2009 – having a wording practically unchanged since its original inception at the beginning of the 1990s – is (still) fit for purpose. More particularly the aim of this book is to analyse and evaluate whether the SPC system fits into today’s pharmaceutical innovation and, if not, provide recommendations and suggestions on how the SPC system might be improved.

When the SPC system entered into force it was based on a three-way overlap between technology, the regulatory system and the patent system supporting said technology.

The hypothesis, which forms the basis for this book, is that – while the regulatory system and the patent system have evolved as a response to the technological development during the past decades – the SPC system has remained more-or-less unchanged. This may present challenges to the SPC system and lead to an imbalance, thereby potentially increasing the risk of legal uncertainty and over- or under-protection.

One specific aim of this book is to analyse whether the above hypothesis can be affirmed or invalidated. The analysis consists of two parts, each having its specific focus and purpose. The first part of the analysis – Part II of this book – consists of a legal analysis of specific aspects of the SPC regulation and aims to contribute to a clarification of the law as it is or de lege lata and to thereby provide increased clarity and predictability of the present legal situation. This part of the analysis focuses – as mentioned above – on which medicinal products may be eligible for SPC protection as per Art. 1 of the SPC regulation, the conditions to be fulfilled in order to obtain an SPC as per Art. 3 of the SPC regulation, the subject matter of protection as per Art. 4 and the effects of the SPC as per Art. 5 of the SPC regulation. The second part of the analysis – Part III of this book – provides a legal analysis of the SPC regulation with regard
to modern pharmaceutical innovation in the form of an analysis and discussion of whether the SPC regulation as interpreted by the law as it is (still) fulfils its original purpose of improving the protection of innovation in the pharmaceutical sector. The latter involves an analysis and discussion of whether the SPC regulation as interpreted by the CJEU provides the required balance between incentivising research of today (particularly biotechnological innovation and secondary innovation, respectively) and furthering new treatment options, while taking into account all interests at stake, including those of public health, affordability of medicine, and promotion of competition through innovation.

1.029 The analysis and evaluation of whether the SPC regulation fulfils its purpose for modern pharma research is performed as a two-branched analysis, namely as (1) an analysis of the suitability of the SPC regulation for providing SPC protection for biotechnological medicinal products, in particular for determining the scope of protection afforded by supplementary protection certificates for biotechnological medicinal products such as proteins, antibodies and viruses; and (2) an analysis of whether or to which extent medicinal products based on secondary innovation patents are or should be eligible for SPC protection. As noted above these two technological areas do not by any means constitute an exhaustive picture of the modern pharmaceutical industry but have been selected as examples of the changes caused by the technological development of the pharmaceutical industry since the adoption of the SPC regulation, cf. above.

1.030 In summary, the objectives of this book are thus:

- To discuss, analyse and systematise CJEU case law regarding the SPC regulation in the present legal situation (de lege lata) with respect to which medicinal products are eligible for SPC protection, the conditions to be fulfilled in order to obtain an SPC, and the scope of protection of an SPC. This part of the book – Part II thereof – is thus intended to provide a clarification of the law as it currently stands with regard to the SPC regulation.
- To analyse and discuss whether interpretation of the SPC regulation by the CJEU and national courts of Europe has established thresholds or principles with regard to determination of the scope of protection of medicinal products based on biotechnological innovation which might provide legal certainty and strike a fair balance for all interests at stake. This analysis is the subject of Part III, Chapter 9 of this book.

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20 Explanatory Memorandum, par. 1.
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- To analyse and discuss whether interpretation of the SPC regulation by the CJEU and national courts of Europe has struck a balance with regard to SPC eligibility for secondary innovation which provides legal certainty and takes into account all interests at stake. This analysis is the subject of Part III, Chapter 10.

- To provide practical recommendations and/or suggestions for any modifications needed, de lege ferenda. See further in Part IV, Chapter 11 of this book.

1. Delimitations

Delimitations have been carried out with regard to both technology and law. It is not the intention of this book to analyse all aspects of pharmaceutical technology. Rather – and as mentioned above – technological restrictions have been made, so that focus will be on two specific types of pharmaceutical innovation, namely biotechnological and secondary innovation. These have been chosen because they are considered emblematic for the technological development of the pharmaceutical industry and because they have been shown to give rise to significant lack of clarity in terms of the SPC regulation, cf. further below.

Restrictions have also been made in terms of neighbouring fields of technology, so that e.g. SPC eligibility of medical devices will not be discussed per se. The eligibility of medical devices for SPC protection has been the object of a number of national court decisions and has also been the subject of a PhD thesis. However, the CJEU ruled in C-527/17 Boston Scientific that medical devices are not SPC eligible. The question of SPC eligibility of medical devices is therefore not discussed in this book.

A regulation corresponding to the SPC regulation for medicinal products was set up in 1997 for products within the agro-chemical field in the form of Regulation (EC) No 1610/96 concerning the creation of a supplementary protection certificate for plant protection products (PPPs). Since the focus of the present book is SPCs for medicinal products, the regulation on SPCs for plant protection products is only discussed to the extent necessary for an analysis of SPCs for medicinal products.

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21 E.g. the German cases 14 W (pat) 12/07 (Yttrium-90 Glass microspheres) and 15 W (pat) 25/08 (Hylan A and Hylan B).

Other legal incentives for the pharmaceutical industry, such as orphan drug exclusivity and data and marketing exclusivity, are briefly discussed. However, the focus of this book is on SPCs and other incentives are discussed only to the extent necessary or relevant in order to assess the SPC regulation. Thus whether other incentives might be more suitable for the pharmaceutical industry than the SPC system is not evaluated or analysed.

SPC-like incentives exist in a number of countries around the world, including in the USA, Japan, South Korea, Canada, Israel and Australia. However, except for the USA and Japan – whose patent term extensions were an inspiration for the European SPC system – the present book will not concern SPC-like systems outside Europe.

The study of national case law has been primarily limited to decisions from the United Kingdom, Germany, the Netherlands, Denmark, Sweden and Norway.

Lastly, an Agreement on a Unified Patent Court (UPC) was signed in 2013, setting up a court common to the Contracting Member States and ultimately having exclusive competence in respect of European patents and SPCs. The establishment of the UPC might have a significant impact on the interpretation of the SPC regulation and hopefully lead to more harmonisation in the interpretation of the SPC regulation between the Member States or even the establishment of a Unitary SPC. However, the Agreement has not yet entered into force. This is due to both the United Kingdom’s withdrawal from the European Union (“Brexit”) and the UK’s consequent withdrawal of their ratification of the UPC Agreement and a judgment from the German Constitutional Court of 20 March 2020 declaring that the German Parliamentary Act of Approval to the Agreement on a Unified Patent Court was void. Germany has subsequently voted on and approved the legislation for the Agreement on the Unified Patent Court and its Protocol on the provisional application. It is currently estimated that the Agreement may enter into force in 2023.

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force around mid 2022. However, since the UPC Agreement has not as yet entered into force, the UPC Agreement and any impact on the SPC regime is not discussed any further in this book.

Finally, it is noted that the European Commission (EC) in February 2022 has announced a new initiative for a single procedure for the granting of SPCs across the European Union. The initiative is said to put in place a unitary SPC and/or a single (“unified”) procedure for granting national SPCs.

The European Commission has not yet provided details of its proposals or opened a call for evidence, but it would appear that the goal is to provide a new centralised mechanism for obtaining SPC protection across the EU, whether the result of the procedure is a single unitary SPC or a co-granted bundle of national SPCs. Since the initiative is at a very early stage it will not be discussed further in this book.

C. STRUCTURE OF THE BOOK

The structure of the book is outlined in the following.

1. **Introduction to the pharmaceutical industry and its legal and economic environment**

The pharmaceutical industry is briefly described in Chapter 2, including the main stakeholders thereof and the importance and costs of pharmaceutical innovation.

Next, a brief description of the technological development of the pharmaceutical industry over the last few decades is presented. This description is not intended in any way to give a full picture of the development which has taken place. Rather, said description focuses on two aspects of pharmaceutical innovation which have been identified as particularly troublesome – and at the same time relevant with respect to SPC protection – namely biotechnological innovation and secondary innovation.
The legal and economic environment in which the pharmaceutical industry operates is also presented in Chapter 2. The legal and economic environment will focus on the legal instruments surrounding the SPC system, in particular patent law and regulatory law. The rationale of patent protection and how the patent system is supposed to encourage and support innovation broadly and more particularly within the pharmaceutical field is described. The patentability criteria are explained, together with an illustration of how different types of pharmaceutical innovation (such as small-molecule innovation, biotechnological innovation and secondary innovation) are protected by patents according to European patent law.

Regulatory law, i.e. the legal measures controlling the authorisation of medicinal products is likewise briefly described. The description of regulatory law focuses on those measures relevant to the study of the SPC system, i.e. the measures and procedures used for granting marketing authorisations (MAs) for original medicinal products (reference medicinal product) for both small-molecule medicinal products and biological medicinal products.

The description of regulatory law also includes a brief outline of the procedures for obtaining marketing authorisation for competitor medicinal products, in particular for generic medicinal products and for biosimilar medicinal products.

The description of regulatory law also includes an outline of the procedures for obtaining marketing authorisation for products based on secondary innovation. This part of the book includes a description of the conditions for obtaining marketing authorisation in the form of (different forms of) variations of marketing authorisations.

Next, a brief introduction to the SPC system is presented. This introduction sets forth the overall requirements for obtaining an SPC and gives an overview of the SPC system. The analysis and evaluation of the SPC regulation as such takes place in the subsequent part of the book, Part II thereof.

In the last part of Chapter 2 related legal measures surrounding the pharmaceutical industry, such as the orphan medicinal products regulation29 and paediatric drug research protection30 are also briefly described.

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Having set the scene, Part II includes a study and analysis of the law as it is, i.e. how the CJEU and selected European courts have interpreted the SPC regulation.

2. Legal framework

In order to be able to evaluate whether the SPC regulation is (still) fit for purpose it is first necessary to establish the legal framework. This is the subject-matter of Part II of this book.

The intention of the legislators of the SPC regulation is analysed and discussed in the analysis of the law as it is (de lege lata). In this regard, the preparatory documents to the SPC regulation have been studied in order to analyse the reasoning behind the particular wording chosen for the regulation.

In particular, the preparatory documents have been studied to establish which medicinal products were to be the subject of an SPC, which innovation the SPC regulation was intended to protect, and what conditions should be fulfilled for obtaining an SPC.

This part of the book thus includes a description, analysis and systematisation of case law of the CJEU and selected European courts with regard to SPCs in order to establish de lege lata with respect to which medicinal products may be eligible for SPC protection, the conditions to be fulfilled in order to obtain an SPC, and the scope of protection of an SPC. Such a description and analysis are intended to increase clarity and predictability of the law as it is with regard to the above.

The analysis is more particularly based on an analysis of how the CJEU and national courts of Europe have interpreted the term “product” and which products may be eligible for SPC protection, the conditions to be fulfilled in order to obtain an SPC, and the scope of protection obtained by an SPC as well as the effects of an SPC.

(a) The law as it is – conclusion

As a summary of this part of the book a conclusion is drawn as to the law as it is (de lege lata), i.e. which medicinal products may be eligible for SPC protec-

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31 Art. 1 of the SPC regulation.
32 Art. 3 of the SPC regulation.
33 Art. 4 of the SPC regulation.
34 Art. 5 of the SPC regulation.
tion, the conditions to be fulfilled in order to obtain an SPC, and the scope of protection of an SPC.

3. A mismatch between innovation and the SPC system?

Having established *de lege lata* with regard to the SPC regulation, Part III presents an analysis and evaluation of whether or to which degree the SPC system has been challenged by the technological development of the pharmaceutical industry during the past decades exemplified by biotechnological and secondary innovation.

The focus is on (i) innovation in the form of biotechnological products, such as proteins, antibodies, viruses, vaccines etc., and (ii) secondary innovation, i.e. innovation based on e.g. new applications of known chemical compounds for new indications, new formulations and new dosages of known active ingredients, and combinations of known or unknown active ingredients for new indications or improved treatments for known indications.

**(a) Legal analysis of the SPC regulation with regard to biotechnological products**

A part of this book is based on a study of how the CJEU and national courts of Europe have interpreted the term “product” and the scope of protection obtained by an SPC based on a biotechnological product. This is the subject of the first part of Part III, namely Chapter 9. Based on the analysis of the law as it is (*de lege lata*) in Part II, the criteria to be used to establish the scope of protection of an SPC for a biological medicinal product are analysed and discussed.

It is also discussed and evaluated whether the existing legislation and case law enable the establishment of a scope of protection of SPCs for biological medicinal products which provide a reasonable degree of legal certainty and take into account all interests at stake.

**(b) Legal analysis of the SPC regulation with regard to secondary innovation**

Another part of Part III is a study of whether or to which extent innovation in the form of secondary innovation may or should be the subject of SPC protection. This is the subject of Chapter 10. It is analysed and discussed whether the delimitation chosen by the CJEU is in accordance with the aims of the SPC regulation of encouraging pharmaceutical research and seems to strike a fair balance for all interests at stake. This part of the book builds upon the analysis of the case law in relation to in particular Art. 3(d) as presented in Part II. However, whereas Part II presents, systematises and discusses the case law of
the CJEU, Part III, Chapter 10 focuses on what was the background for reaching the individual decisions arrived at and what innovation was – according to the CJEU – to be the subject of SPC protection.

4. Conclusions on the analyses carried out and recommendations and/or guidelines

Part IV of the book is based on the analyses carried out and presents conclusions thereof.

Finally, a number of practical recommendations are provided on how the SPC system might be improved in order to provide enhanced legal certainty while taking into account the technological development of the pharmaceutical industry in the past decades.

Lastly, in the Appendix, a complete list of CJEU decisions on SPCs is presented. For each decision, the central issue discussed is indicated.

D. PRIOR STUDIES OF THE SPC SYSTEM

The SPC regulation has been the focus of several studies in the years 2016–18. A brief description of the studies performed, and the conclusions reached therein is provided below.

1. Charles River Associates

The European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SME (“DG Growth”), commissioned Charles River Associates to conduct a study to assess the economic impacts on the European pharmaceutical industry of a number of changes to exemption provisions during the patent and SPC term in Europe on medicines for human use. The study more particularly assessed the economic impacts of extending the scope of the so-called Bolar exemption and of introducing a so-called SPC export waiver in a number of scenarios.

2. Max Planck Institute for Innovation and Competition (MPI)

Following the adoption of the Single Market Strategy in 2015, the European Commission commissioned the Max Planck Institute for Innovation and Competition (MPI) in Munich, Germany to make a comprehensive evaluation of how the SPC Regulation is functioning.

The “Study on the Legal Aspects of Supplementary Protection Certificates in the EU” by the MPI examined the functioning of the system of SPCs established in the EU by Regulation 1768/92/EEC on SPCs for medicinal products (now: Regulation 469/2009/EC) and Regulation 1610/96/EC on SPCs for plant protection products from a legal perspective. The functioning of the regulations was considered in the context of adjacent legislation concerning marketing authorisation for medicinal products and plant protection products (Directives 82/2001/EC and 83/2001/EC; Regulation 1107/2009/EC).

The MPI study provided a systematic review of the SPC legislation, focusing in particular on three topics: the prerequisites and the scope of SPC protection as interpreted by the CJEU, the breadth of limitations and exceptions, and the creation of a unitary SPC system. The MPI report furthermore presented a number of recommendations for closing the identified gap between written law and case law by either codifying case law, overriding it or adopting it with amendments.

While it was concluded that the SPC system, by and large, fulfils its purposes, some legal uncertainties were identified that could jeopardise the smooth functioning of the SPC regime. In particular, it was found that inconsistencies and unclear notions resulting from the CJEU’s interpretation of central provisions in the SPC regulations make it difficult for the national patent offices (NPOs) to adapt their own practice to the criteria elaborated by case law without causing divergences in relation to their own previous practice or that of other offices. While originator companies tended to be basically confident that the system will correct itself in the long run, generic manufacturers contended that an overhaul was needed in order to strike the right balance.

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37 33 recommendations.
38 MPI report, p. 647ff.
39 Ibid, p. III.
Although a number of recommendations were presented in the report, only one of these has been implemented so far,\textsuperscript{40} namely the introduction of a so-called “Export Manufacturing Waiver”. The introduction of the Export Manufacturing Waiver in the SPC regulation made it possible under specific and limited circumstances for generics and biosimilar companies, while an SPC is in force, to manufacture SPC-protected drugs for export and also – during the last six months of the SPC term – to manufacture for stock-piling in order to be able to enter the market immediately after SPC expiry (“day-one entry”).\textsuperscript{41}

3. Copenhagen Economics

In April 2017 the European Commission awarded Copenhagen Economics the task of carrying out a study entitled “Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe” (call for tender 590/PP/GRO/SME/16/F/121).\textsuperscript{42} The need for the study was based upon the European Commission Single Market Strategy of October 2015 and on Council Conclusions of 17 June 2016, inviting the Commission to prepare an analysis of the impact of the pharmaceutical incentives and rewards on innovation, availability and accessibility of medicinal products. Copenhagen Economics looked at five pharmaceutical incentives and rewards i.e. (1) Supplementary protection certificates, (2) & (3) Data protection (DP) and Market protection (MP), (4) Market exclusivity for orphan medicinal products, and (5) Paediatric investigations of medicinal products.

Copenhagen Economics found that the protection offered by the IP rights and incentives and rewards do stimulate innovation in the EU and abroad. On the other hand, such protection delays entry of generic medicinal products and a subsequent downward push on prices.

Copenhagen Economics concluded that finding the “right” balance between innovation and lower prices of medicinal products through faster availability

\textsuperscript{40} February 2022.


of generics is a political decision and that “it would be ideal to secure a sufficient period of protection and reduce uncertainties associated with developing medicinal products in order to incentivise innovation, while finding other ways of curbing high prices”.

4. Technopolis

1.075 The Technopolis report\(^4\) showed the results of a study performed by the company Technopolis in collaboration with experts from the University of Liverpool and University of Amsterdam. It was commissioned by the Dutch Ministries of Health and Economics. The Technopolis report was based on a study investigating the impacts of the interaction of supplementary protection certificates (SPCs), paediatric extensions, data and market exclusivity as well as orphan drug protection on innovation in pharma and on the healthcare system, i.e. the same incentives as in the Copenhagen Economics study referred to above. The report built on a legal analysis as well as an economic analysis involving an interview programme, secondary data analysis as well as case studies for seven drugs that have used the said supplementary protection instruments.

1.076 The key findings of the Technopolis group were that each incentive was found to have succeeded to a varying degree in achieving their desired objectives and with regard to the SPC Regulation that said Regulation offers innovator companies an adequate compensation for their effective loss of patent term.

1.077 A number of drawbacks of the above incentives were also discussed. The Technopolis report particularly referred to the “evolving, and at times inconclusive – if not contradictory –, interpretations of the SPC Regulation” by the judicial system that have reshaped the system in fundamental ways and added to its complexity. This complexity was said to be at least partly due to unclear statutory provisions in the SPC regulation on the one hand, and a lack of clarity provided by the CJEU in adjudicating referrals for interpretation of those provisions on the other.

1.078 The Technopolis report specifically recommended that, with regard to the SPC regulation, the issue of the extent of protection of basic patents had to be solved, since the issue of defining the scope of protection of the basic patent

remained unresolved. The Technopolis report also discussed the extent to which secondary medical use patents, formulation patents, or patents related to dosages should be protected by SPCs and discussed the possibility of providing a shorter SPC term or some other type of incentive for such kinds of patents.

It was also discussed whether the extent of supplementary protection granted by an SPC could or should be differentiated depending on the “therapeutic added value”44 offered by the product, but also pointed to the complications involved therein, including the fact that there is no agreed definition or metric for what constitutes “therapeutic added value”.

Finally, the Technopolis report recommended to consider eliminating the possibility of “SPC squatting”, i.e. relying on a third-party marketing authorisation when filing an SPC application based on one’s own basic patent.

The Technopolis study concluded that the SPC system appears in need of a critical review and possibly update, at EU level, as it currently does not fully provide the legal certainty that users and society should be able to expect from the system, to better align the objectives and effects of the regulation and reduce unnecessary ambiguity.

5. Conclusion and impact of prior SPC studies on the present book

The above three reports – the MPI report, the Copenhagen Economics Study report, and the Technopolis report – all provide valuable studies of the existing SPC system and the surrounding supplementary protection mechanisms.

However, except for the MPI report, the above reports do not put much, if any, emphasis on the technological developments which have taken place in the pharmaceutical industry over the last decades and the potential consequences thereof on any of the supplementary protection mechanisms studied.

Since the overall aim of the present book is to analyse whether the current SPC system fits into today’s pharmaceutical innovation the present book fills a gap in the understanding of the present state of supplementary protection mechanisms for pharmaceutical innovation in Europe.

44 “Therapeutic added value” understood as “whether a product meets a need in a previously unserved therapeutic area or whether it offers significant benefits over existing products in terms of, for instance, effectiveness, ease of use, or fewer adverse effects”, Technopolis report, p. 88.