

**PATENT TERM EXTENSION AND THE
SUPPLEMENTARY PROTECTION CERTIFICATE:
Does the current approach to the regulatory regime
provide adequate protection for combination drugs?**



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Abstract

The term of a patent is an essential feature of the patent system. This feature is arguably even more essential in the area of pharmaceutical patents, burdened with inherent formalities delaying a product's arrival on the market. The inability for pharmaceutical patents to exercise their exclusive rights for an effective duration has a negative knock-on effect on the research and development for innovative drugs, which in turn, impinges on public health and society at large. Thus, the European Community has sought to address these issues with a supplementary protection certificate ("SPC"), which essentially prolongs the effective lifespan of a patent. However, recent case law shows that national courts are applying diverging approaches when it comes to combination drugs, leading to heterogeneity within the Community. Most recently, the Court of Justice of the European Union ("CJEU") produced an Opinion on the joined cases of C-322/10 and C-422/10 *Medeva BV and Georgetown et al. v Comptroller-General of Patents* ("*Medeva et al.*") and posed an approach which would make it easier for combination drugs to obtain an SPC. However, it also limited the grant of such to one SPC per patent. The effect of this on combination drugs is potentially damaging as it could serve to undermine the development of combination vaccines and hinder the possibility for immunisation against multiple diseases, particularly for babies.

The CJEU currently has an opportunity in its upcoming preliminary ruling on *Medeva* to create a degree of uniformity in the approach of granting SPCs for combination drugs. Whether they follow the approach presented by the Advocate-General in *Medeva et al.* will be most interesting for those affected by pharmaceutical patents. This thesis explores the policies behind the regime, the competing interests at stake, and the differing approaches by the courts and their effects on different scenarios of combination drugs, in order to examine the current adequacy of the regulatory regime in relation to combination drugs. In particular, it focuses on the recent approach posed by the Advocate-General in *Medeva et al.* and examines the adequacy of such in light of combination drugs.

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1 Introduction

1.1 Overview

This introductory chapter aims to demarcate the legal issues at hand by providing a short, contextualised legal and policy backdrop to the patent system, in relation to pharmaceutical patents. In doing so, it attempts to provide the reader with a concise overview of the issues and interests which lie in the patent system. Such an overview will be drawn only insofar as necessary to inform the reader of where supplementary protection certificates (“SPC”) sit in the wider context of patent law and pharmaceutical drugs.

1.2 Background and problem definition

The pharmaceutical industry is a complex area with many competing interests at stake. Research and development (“R&D”) into innovative medicines to treat or diagnose disease and illness is a high interest area in public health and society at large. Inventions for the products and processes of such can be rewarded with the grant of a patent, procuring monopoly rights to the inventor for a limited time.¹ An essential element in the patent system is the term of the patent itself.² The pharmaceutical industry, being inherent with formality delays, essentially precludes a patent lifespan from being effectively utilised. This in turn, can negatively impinge on R&D for new pharmaceutical drugs, reduce profitability and affect competition.³ Thus, ensuring that a patent can fully exhaust its lifespan is arguably critical to the proper functioning of a patent system, though, not all

¹ Richard Miller, Guy Burkill, Colin Briss and Douglas Campbell, *Terrell on the Laws of Patents* (17th edn Sweet & Maxwell 2011) 1.

² Peter Kolker, ‘The Supplementary Protection Certificate: The European solution to patent term restoration’ (1997) IPQ 249.

³ See Chapter 3.2, ‘Primary interests at stake’.

jurisdictions allow for such.⁴ The ways in which this can be achieved currently varies in each jurisdiction and require different prerequisites to be met. An SPC grants a right prolonging the life of a patent for a medicinal product but does not extend it as such.⁵ SPCs are a European Community (“the Community”) initiative, aiming to create a uniform approach towards the free movement of medicinal products whilst ensuring adequate protection for pharmaceutical R&D.⁶ However, the regulatory framework is not without its ambiguities. Certain criteria must be fulfilled prior to the successful grant of an SPC, such as the need for a ‘basic patent in force’ protecting the product in question.⁷ Furthermore, whether a medicinal product is made up of a combination of partially patented ingredients is an equivocal area giving rise to questions of the purposiveness of the SPC Regulation. This is particularly critical when it comes to multi-purpose, combination drugs, as there are arguably greater interests at stake.⁸

Case law shows that national courts are applying diverging approaches to the SPC Regulation. Namely, these approaches are the ‘infringement test’ and ‘the identification or disclosure test’.⁹ Most recently, however, the Court of Justice of the European Union’s (“CJEU”) Opinion on *Medeva et al.* applied a teleological interpretation to the provisions of the SPC Regulation.¹⁰ This approach made it easier for combination drugs to obtain an SPC; however, it also created a limitation in that only *one* SPC could ever be granted for *one* patent. The *Medeva* case is currently awaiting a preliminary ruling by the CJEU and

⁴ Dr Grace Chan, David Tadgell and Virginia Beniac, ‘Pharmaceutical Patent - Extension of term provisions around the world’ (IP Organisers November 2007) <<http://www.drugterm.com/country/world.htm>> accessed 27 September 2011.

⁵ Catherine Seville, *EU Intellectual Property Law and Policy*, (Edward Elgar Publishing Limited 2009) 158.

⁶ Council Regulation (EC) No 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products (codified version) [2009] OJ L152/1 (SPC Regulation).

⁷ *ibid*, art 3(a).

⁸ Joined cases C-322/10 and C-422/10 *Medeva BV and Georgetown et al v Comptroller-General of Patents* [2011] Opinion of AG Professor Dr Trstenjak (*Medeva et al.*).

⁹ See Chapter 4.7, ‘The product and its corresponding “basic patent in force”’, for a discussion of these approaches and relevant case law.

¹⁰ *Medeva et al.* (n 8), para 74-124. Please note that reference throughout this thesis to ‘*Medeva et al.*’ refers to the CJEU Opinion on the joined cases of *Medeva* and *Georgetown et al* (see n 8), while reference to ‘*Medeva*’ refers to the solo case of *Medeva* (C-322/10 *Medeva BV v The Comptroller-General of Patents*) currently awaiting its CJEU preliminary ruling, due 24 November 2011 (see Chapter 4.8 for more on *Medeva*).

provides the Court with an opportune window in which to set a precedent and create a degree of uniformity within the Community.¹¹ Thus, the author finds it extremely timely to examine the adequacy of the current regulatory regime in light of these competing approaches being applied and to consider how each approach might affect combination drugs differently in the pharmaceutical industry.

1.3 Limitations

This thesis predominantly looks at Community legislation as it applies to the area of patents and SPCs, and will only touch upon domestic legislation where necessary. Such domestic legislation will namely be UK domestic law for the author of this thesis holds a common law background from New Zealand. Furthermore, it is also worth mentioning here that in light of the author's background, this thesis and analysis is written and undertaken with respect to this common law background.

The following areas are considered to be outside the scope of this thesis: multinational drug corporations, compulsory licensing, and price control regulations. Additionally, this thesis will not delve into detailed discussions of ingredients, medical products and biological or chemical compounds and will only mention such to the extent necessary for the purposes of any legal analysis.

1.4 Thesis overview

The first chapter provides a brief overview of the interests at stake in relation to pharmaceutical patents and the pharmaceutical R&D. It aims to provide a concise legal, and contextual backdrop to the issues around combination drugs and why this is currently a topic area. It also provides the reader with the parameters of this thesis.

¹¹ *ibid.*

Chapter two provides a brief historical background to patents, the rationale behind them, and the relevant international legal instruments on intellectual property. It then outlines the law around patentability and the enforcement of such rights.

Chapter three provides an overview of the primary interests of the parties who have an interest at stake in regards to pharmaceutical industry. It then introduces the SPC and where it sits among these interests and the legal effect of obtaining an SPC.

Chapter four expands on how one can obtain an SPC and the hurdles one must jump through to successfully obtain one, particularly in relation to combination drugs. It draws on recent and relevant case law to illustrate the competing approaches by national courts and in particular, highlights the most recent case before the CJEU, the *Medeva* case.

Chapter five provides an analysis of the aforementioned approaches currently being applied and considered by the courts. It specifically considers the effect of each approach on different scenarios of combination drugs which may end up before the court and the possible results which may ensue. It then examines the current approach posed by the CJEU Advocate-General's Opinion on *Medeva et al.* in light of the aims and objectives of the SPC Regulation, in order to determine the adequacy of the current regulatory regime in protecting combination drugs.

2 Patent Law

2.1 Overview

This chapter aims to provide the reader with a brief overview of the patent law system and its historical roots. It begins with a short summary of the history of patents and the rationale behind the system. It then moves on to its regulatory background and the requirements for patentability and infringement. That is, *how do you obtain a patent? And how and when can you enforce your exclusive rights?* This chapter aims to leave the reader with an understanding of the general background to this particular facet of intellectual property law with which, the reader can build an understanding of where pharmaceutical patents fit in.

2.2 Historical background and rationale of patents

A patent is a form of intellectual property granted by a national patent authority and gives a monopoly of 20 years, conferring exclusive rights on a patentee.¹² The term *patent* is derived from the Latin *patere* meaning ‘to be open’ and was used to originally refer to a *letters patent* granted by the sovereign bestowing the privilege of a monopoly.¹³ The first recorded patent in England was given in 1449 by King Henri VI for a method of making stained glass.¹⁴ However, Venice was the first to establish a formal patent system in 1474 in order to draw in more skilled workers and new products and processes.¹⁵ In 1624,

¹² The Convention on the Grant of European Patents of 5 October 1973 (as amended), art 63(1) (EPC); Agreement on Trade-Related Aspects of Intellectual Property Rights 1994, arts 28 and 33 (TRIPS).

¹³ Robert P. Merges, Peter S. Menell, Mark A. Lemley, *Intellectual Property in the New Technological Age* (4th edn Aspen Publishers 2006) 118; Hector MacQueen, Charlotte Waelde, Graeme Laurie & Abbe Brown, *Contemporary Intellectual Property: Law and Policy* (first published 2008, 2nd edn Oxford University Press 2011) 372.

¹⁴ MacQueen (n 13) 372.

¹⁵ *ibid.*

England passed the Statute of Monopolies under James I which stipulated the conditions for bestowing a new invention.¹⁶

The extent to which the exclusive rights conferred by patent protection are justified is the subject of much debate.¹⁷ Since its inception, the patent system has sought to reconcile the interests of innovative individuals with the interests of the wider community. And thus, a monopoly grant is given in return for the benefit procured for the community. Originally, the *new craft* was perceived to be the benefit; however, by the late eighteenth century the perception changed and the benefit to society was seen as the *know-how* behind the new invention. This helped ensure industry growth by allowing for the dissemination and disclosure of the most current technical information whilst concomitantly, providing an effective incentive for inventors to keep inventing.¹⁸

In 1958, a famous report was given to the US Senate by Fritz Machlup identifying four basic justifications for giving inventors such exclusive rights:¹⁹ the moral entitlement of ownership stemming from the natural property rights of ideas; a reward in return for contribution to scientific progress; an incentive for investment; and the encouragement to disclose new ideas to the world. However, one particular criticism to the system was that the reward to induce an incentive need not be a monopoly in itself but could take form as a prize or pay-off.²⁰ Furthermore, a monopoly assumes that the value of innovative activity overrides the cost to consumers and that those consumers are able to bear the costs to support further innovation. Some scholars argue that this is particularly costly to society when it comes to the pharmaceutical sector as it creates an artificial scarcity in a product which would otherwise not be scarce.²¹ Hence, an innate problem with the patent system is

¹⁶ Merges (n 13) 119; MacQueen (n 13) 373.

¹⁷ David T. Keeling, *Intellectual Property Rights in EU Law* (vol 1 Oxford University Press 2003) 243; Merges (n 13) 127; MacQueen (n 13) 377.

¹⁸ Merges (n 13) 120 and 127.

¹⁹ Fritz Machlup, *An Economic Review of the Patent System*, Study No. 15 of the Subcommittee on Patents, Trademarks, and Copyright of the Committee on the Judiciary – United States Senate. As cited in: David T. Keeling (n 17) 243.

²⁰ MacQueen (n 13) 378.

²¹ Michael A. Heller and Rebecca S. Eisenberg, ‘Can Patents Deter Innovation? The Anticommons in

its incessant attempt to deal with the competing interests of multiple parties. Such parties include the state, competitors, consumers, researchers and the inventors themselves.²²

The corollary of a system without patents, however, also comes with costs. Pugatch elucidates such costs as the consequences of treating knowledge as a public good: ‘free-riding’ and ‘secrecy’.²³ An inventor would lose in a market where knowledge was free for all and competitors were able to access such knowledge at no cost of their own; thereby, deterring research and innovation and leading inventors to want to keep knowledge in secrecy from fear of losing claim to it. Society would then lose out and be prevented from reaping any benefits stemming from the new knowledge and innovation. Such a system would lead to underproduction due to a lack of innovation and minimal use of any innovative productions.²⁴ Again, this brings us back to the economic incentive trade-off of having a patent system: the monopoly on a product in the market leads to a higher cost to the consumer. However, because patents are subject to a maximum period of 20 years, the higher prices are not perpetual. This is particularly so for pharmaceutical drugs, as once its patent lifespan is exhausted society can then benefit from the reproduction of the once patented drugs by generic firms, which are marketed at a substantially lower price. This in turn, has a negative effect on the share prices of pharmaceutical corporations.²⁵

2.3 International and European legal instruments

The Paris Convention for the Protection of Industrial Property 1883 (as revised) was one of the first international intellectual property treaties, and the first to protect patents (“The Paris Convention”).²⁶ However, the Convention fails to define the subject matter, criteria and length of patentability of patents.²⁷ Its two main significant features lie in its principle

biomedical Research’ (1998) 280 Science 698; Meir Perez Pugatch, *The International Political Economy Of Intellectual Property Rights* (Edward Elgar Publishing 2004) 16.

²² MacQueen (n 13) 378.

²³ Pugatch (n 21) 19.

²⁴ *ibid* 21.

²⁵ *ibid* 86.

²⁶ The Paris Convention currently has 173 contracting parties as at March 2010.

²⁷ Frederick M. Abbot, ‘Intellectual Property, International Protection’ (2010) Max Planck Encyclopedia of

of national treatment (Article 2), which ensures that each signatory state affords the same rights to foreigners as to its nationals; and its linkage to the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”).²⁸ The significance of the link is due to the Agreement being administered by the World Trade Organisation (“WTO”), which thereby subjects its signatories to intellectual property protection through trade-related privileges and sanctions under the General Agreement on Tariffs and Trade (“GATT”).²⁹

Another international instrument is the Patent Co-operation Treaty 1970 (“PCT”) which provides for a system for applications and examinations, simplifying international patent applications, but not granting patents itself. Applicants benefit from a single procedure when making multiple national applications, an ‘international application’, but whether a patent is granted is the decision of the relevant national patent offices. The PCT application does not result in an ‘international patent’ as such, but a single international route to multi-national patents.³⁰

In the European sphere, the European Patent Convention 1973 (“EPC”, as revised in 2000) provides the legal framework for granting a European patent; however it is not a European Union instrument.³¹ The EPC establishes the European Patent Organisation, who carry the task of granting European patents, and is made up of the European Patent Office (“EPO”) and an Administrative Council.³² A grant does not provide for a unified European patent as its name would suggest, but instead provides for an independent patent under the national jurisdiction of the state/s in which an application is sought for.³³ Thus, it simplifies the process of lodging a patent application in several European states by creating only one point of entry and one examination process.³⁴ One negative aspect of the regime is that it

Public International Law <www.mpepil.com> accessed 2 October 2011.

²⁸ TRIPS (n 12).

²⁹ MacQueen (n 13) 389.

³⁰ Seville (n 5) 75; PCT, art 3.

³¹ MacQueen (n 13) 382.

³² EPC (n 12), art 4.

³³ *ibid*, arts 2-3.

³⁴ MacQueen (n 13) 380.

currently lacks a centralised European judiciary (though, referrals can be made to the CJEU under Article 267 of the Treaty of the Functioning of the EU). The EPO has, however, looked into creating a centralised European judiciary through its Working Party on Litigation, who has subsequently drafted a European Patent Litigation Agreement to set up a European Patent Court.³⁵

The EU Council has recently agreed on two draft regulations for a unified EU patent system, including a unified litigation system proposed by the Commission.³⁶ However, the CJEU recently raised concerns about the compatibility of such a regime under the European Law.³⁷ Following this, amendments to the proposal were made and are currently being discussed under the Polish presidency. The Commission have stated that they aim to have the regime running by 2013.³⁸

2.4 Patentability

As previously mentioned, a patent is subject to a grant by an intellectual property office under an independent national regime.³⁹ Under the EPC, a European patent can be granted for ‘any inventions in all fields of technology’ provided it is: 1) susceptible to industrial application; 2) novel; and 3) involves an inventive step.⁴⁰ The invention must also be disclosed in a sufficiently clear and complete manner.⁴¹ Upon a patent application, the applicant/patent owner is given a right in the form of personal property in which they can exclude everyone else from the market, subject to certain limitations such as its duration and compulsory licensing.⁴²

³⁵ European Patent Office, “EPLA - European Patent Litigation Agreement” (European Patent Office 3 April 2009) <<http://www.epo.org/law-practice/legislative-initiatives/epla.html>> accessed 2 October 2011.

³⁶ European Patent Office, “Unified Patent/EU Patent” (European Patent Office 28 July 2011) <<http://www.epo.org/law-practice/legislative-initiatives/eu-patent.html>> accessed 2 October 2011.

³⁷ Commission Opinion on the compatibility of the 2009 draft agreement on the European and EU Patents Court with the EU Treaties (COM Opinion 1/09).

³⁸ See <<http://www.epo.org/law-practice/legislative-initiatives/eu-patent.html>> for more details.

³⁹ See above Chapter 2.3, ‘International and European legal instruments’.

⁴⁰ EPC (n 12), arts 52-55 and 56.

⁴¹ *ibid*, art 83.

⁴² MacQueen (n 13) 473.

The rationale behind the *novelty* requirement is the aim of preventing a monopoly going to something which is already in the public domain.⁴³ In order to be ‘new’ it must not be part of the *state of the art*.⁴⁴ ‘State of the art’ includes everything available to the public by means of description or any other way before the filing date of the invention.⁴⁵ The EPC takes an objective approach when assessing ‘novelty’, utilising all information available in any form, ensuring a greater degree of certainty than would a subjective approach.⁴⁶ Something is considered part of the state of the art on the day it is made publicly available, no matter the language or whether the public are aware of it but merely by virtue of it being available to them. However, this does not include instances of making something public subject to a confidentiality agreement. Furthermore, if a person who is skilled in the state of the art is able to sufficiently determine the core features and reproduce the invention by merely seeing it, it is then also considered to be part of the state of the art.⁴⁷

An *inventive step*, or ‘non-obviousness’ as it is sometimes referred to as, requires a high level of inventive activity and advantageousness in its advance, bearing a benefit to society in order to justify the grant of a monopoly.⁴⁸ An ‘inventive step’ can be said to have occurred if it would be not obvious to a skilled person, with regard to the state of the art. A ‘skilled person’ is an expert in the area of the art at the relevant date with average knowledge and ability, but lacking in inventive capability. ‘Obviousness’ is determined by assessing whether a skilled person would have logically arrived at it, given the prior art, without extraordinary skill. Such an assessment can take into consideration *mosaicing*: the combining of prior pieces of art to see if a skilled person would have put the combination together.⁴⁹

⁴³ MacQueen (n 13) 450.

⁴⁴ EPC (n 12), art 54(1).

⁴⁵ *ibid*, art 54(2).

⁴⁶ Seville (n 5) 106.

⁴⁷ MacQueen (n 13) 451.

⁴⁸ EPC (n 12), art 56.

⁴⁹ MacQueen (n 13) 462-465; Seville (n 5) 112.

Finally, only inventions which are capable of industrial application can be patented. This means that the invention must be able to be ‘made or used in any kind of industry, including agriculture’.⁵⁰ An ‘industry’ includes any technical activity, useful or practical arts, but excludes aesthetic arts. Moreover, mere potential use in an industry is sufficient; no actual evidence of use is required.⁵¹

Exclusionary provisions are also provided for in Articles 52(2), (4), and 53 of the EPC. Article 52(4) expressly excludes *methods* for the direct treatment of humans and animals by surgical, therapeutic or diagnostic methods from patentable subject matter. However, *products* are included within the scope of patentable subject matter. This distinction is based on ethical considerations in order not to prevent practitioners from performing their professional activities and duties when treating patients and animals. Nevertheless, this is not always determinative in itself and other factors must also be considered, such as whether the treatment is therapeutic, surgical or not.⁵²

2.5 Patent Infringement

Conferring rights for intellectual property would bear no significance without the possibility for the enforcement of such rights. However, as patents are subject to territorial effect, only infringement proceedings within a national state can be brought for an infringement within its borders. A proprietor of a patent, co-proprietors and those with an exclusive licence can undertake an infringement proceeding. Infringement proceedings are only concerned with acts which are committed while a patent is still in force and can be brought from the date a patent application is published until the end of the patent’s term; but the right cannot be enforced until the patent is actually granted.⁵³

⁵⁰ EPC (n 12), arts 52 and 57.

⁵¹ Saville (n 4) 117; MacQueen (n 13) 472.

⁵² Bengt Domeij, *Pharmaceutical Patents in Europe*, (Martinus Nijhoff Publishers, 2000) 14-16.

⁵³ MacQueen (n 13) 485.

Article 64(3) of the EPC states that ‘any infringement of a European patent shall be dealt with by national law’. Taking UK domestic law as an example, sections 60(1) and 60(2) of the Patents Act 1977 (“UKPA”) sets out when a patent infringement occurs. It makes it clear that an infringement only occurs, while when the patent is still in force, a person does any of the following acts within the UK in relation to the invention and without the consent of the patent holder:⁵⁴

- a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
- b) where the invention is a process, he uses the process or he offers it for use in the UK when he knows, or it is obvious to a reasonable person in the circumstances that its use there without consent of the proprietor would be an infringement of the patent;
- c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any products obtained directly by means of that process.

This indicates that the type of patent, product or process, dictates slightly different criteria for determining whether an infringement has occurred or not. In relation to products, there is no knowledge requirement. This means that someone who is unaware that they have committed an infringing act can nonetheless, still be found guilty if their act falls within section 60(1)(a).⁵⁵

Section 60(2) of the UKPA covers instances of *indirect* or *contributory infringement* which occurs when someone, while the patent is in force and without the consent of the proprietor, supplies or offers to supply any of the means, in relation to an essential element of the invention, for putting the invention into effect when it is obvious to a reasonable person in the circumstances that those means are suitable for putting, or intended for putting, the invention into effect in the UK.

⁵⁴ UKPA, sec 60(1).

⁵⁵ McQueen (n 13) 485.

3 Pharmaceutical patents and the SPC in the EU

3.1 Overview

This chapter aims to elucidate the primary interests of the different parties whom have a stake in the patent system and the pharmaceutical sector to illustrate the purpose of the SPC Regulation. This chapter begins by looking at the wider interests of the pharmaceutical sector in Europe in an attempt to illustrate the differing interests of the large pharmaceutical firms and generic manufacturers, and how they relate to the interests of consumers and the state. This chapter will then look at the solution posed by the Commission to deal with these competing interests in the pharmaceutical sector; that is, the SPC Regulation and its legal effects.

3.2 Primary interests at stake

The pharmaceutical sector is a knowledge based sector in which pharmaceutical research and the production of medicinal products perform a crucial role in our society, and is the result of long and costly research.⁵⁶ The majority of pharmaceutical activities occur in the US, Europe (particularly the UK, Germany, France, Switzerland, Italy, Belgium, Sweden and Denmark) and Japan; together, accounting for over 90 per cent of the world's expenditure in R&D and over two thirds of the world's production of pharmaceuticals.⁵⁷ The pharmaceutical sector in Europe alone spends €26 billion in excess annually on R&D, producing over 35 per cent of the pharmaceuticals in the world, second to the USA. The sector also plays a significant role in the European economy with regards to employment

⁵⁶ SPC Reg (n 6), recs 2-3.

⁵⁷ Pugatch (n 21) 94.

and manufacturing for highly trained people. In 2004, the EU reported more than 612,000 jobs in the industry.⁵⁸

Despite the significant impact the pharmaceutical industry has on many aspects of a nation's well-being, advancements in R&D to create new medicinal products to treat disease and illness are unlikely to persist without the possibility to recover the costs of investments. Much of the profitability of a pharmaceutical firm depends on its patented products. A pharmaceutical firm usually invests between 10 to 20 per cent of their annual sales in future R&D projects.⁵⁹ However, only one or two out of every 10,000 substances synthesised in a laboratory will successfully make it through all the stages to become a marketable medicine and those which do make it are thus, highly dependent upon patent protection.⁶⁰

Since the 1980s, the link between the actual patent term and profitability has increased due to the rise in competition of the generic pharmaceutical products, which are relatively cheap and easy to reproduce. Upon the expiration of a patent, the amount of sales of the formerly patented product drops significantly and opens up 'instant' competition to its generic version, generating a huge loss for the firm whom once had its patent.⁶¹ Thus, the longer a patent lifespan – the longer a firm can charge higher prices and postpone such competition. On the other hand, the generic manufacturers of pharmaceutical drugs also have an interest in patents being granted as without such, the 'know-how' behind the new products would not be disclosed and such generic reproductions could not be made.⁶²

⁵⁸ Pugatch (n 21) 94; Commission, 'A public-private research initiative to boost the competitiveness of Europe's pharmaceutical industry' IP/08/662 (Press Release 30 April 2008); Commission, 'Differences in Costs of and Access to Pharmaceutical Products in the EU' (Study 2010).

⁵⁹ Pugatch (n 21) 86-87.

⁶⁰ Commission Press Release (n 58); John Parker, "Pharmaceutical patent extensions in New Zealand, 1953 to 2000: an appraisal" (2002) EIPR 24(3) 99; Keeling (n 17) 259; Paul Grootendorst and Livio Di Matteo, 'The Effect of Pharmaceutical Patent Term Length on Research and Development and Drug Expenditures in Canada' (2007) Healthcare Policy 2(2) 63.

⁶¹ Pugatch (n 21) 86-87; *Medeva et al.* (n 8), para 77; Steven Ang, 'Patent term extensions in Singapore for "pharmaceutical products"' (2005) EIPR 27(10) 349.

⁶² Commission, 'Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products' COM (90) 101 final (April 1990) 14 (Explanatory Memorandum).

The interests of patients and society rest in between the competing interests of the large pharmaceutical firms and generic manufacturers. This is because it is both in their interest to ensure the on-going of R&D to develop new innovative drugs to treat and cure disease and illness, but it is also in their interest to ensure that such marketed products are priced as affordable as possible. The State also holds a similar interest in ensuring that expenditure in the public health sector is not artificially increased by protection sought for products which contain old active ingredients and are then modified without innovation and marketed as a new product.⁶³ Of course, patients and consumers also have an interest in being protected against the remarketing of old active ingredients in disguise. Perhaps, the overarching benefit of a longer patent can be said to be the value of the increase in health and quality of life that would otherwise be decreased or postponed, or not at all but for the introduction of a new medicinal product to society due to a sufficient patent term.⁶⁴

Another interest area that bears significant implications for both patients and SPC seekers is the area of combination medicinal products, and in particular, combination vaccinations. The importance of being able to offer protection against multiple diseases to the public cannot be underestimated. Its benefit to public health and the community is recognised by the Commission as one of the most cost-effective health measures available. It is highly encouraged that as many children as possible receive the main childhood vaccinations and, if possible, combination vaccinations which not only provide the same advantages of individual vaccines but can save families time and money whilst saving the child from further discomfort of more shots.⁶⁵ Thus, ensuring the on-going R&D for combination vaccinations is a highly important and legitimate area for the pharmaceutical and public health sector and any regulatory measures pertaining to the marketing and development of combination medicinal products should not unduly infringe upon these particular interests.

⁶³ *Medeva et al.* (n 8), para 77.

⁶⁴ Grootendorst (n 60) 64.

⁶⁵ *Medeva et al.* (n 8), para 82; WHO, 'Immunization Safety: six common misconceptions' <http://www.who.int/immunization_safety/aefi/immunization_misconceptions/en/index.html> (WHO 11 December 2010) accessed 7 October 2011. See also <http://ec.europa.eu/health/vaccination/policy/index_en.htm>.

Without adequate regulatory measures in place to balance all interests at stake in this complex environment, the State would be leaving society to its detriment. Though a patent is conferred for 20 years under legislation,⁶⁶ the actual effective patent life (“EPL”) for pharmaceutical drugs/medical products is considerably less in reality once formalities and regulatory requirements have been taken into account. This is because a patent alone does not confer the right to sell a medicinal product on the market; a marketing authorisation must first be obtained.⁶⁷ Due to the nature of pharmaceutical drugs, extensive testing and other formal requirements must be met before a product can be placed on the market, in order to ensure its safety for veterinary or human use.⁶⁸

The duration of a patent term is calculated from the date of the filing of the patent application from which point, in principle, the patent applicant can make use of their patent rights.⁶⁹ However, the actual grant of the patent can take up to several years. For example, in *Medeva et al.*, a patent application was submitted in 1990 and granted in 2009, almost a year before the patent was due to expire.⁷⁰ When this is coupled with the requirement to obtain a marketing authorisation, the EPL is significantly curtailed. The EPL effectively becomes the period from the medicinal product’s first marketing- to the expiration date of the patent. In some instances, patents can expire even before the product is placed on the market, in which case the generic rival-version of the product would most likely be all ready to be released out on the market.⁷¹ Thus, the length of the EPL is highly critical in ensuring that all the competing interests are adequately addressed. The Community recognises this in its Regulation concerning the SPC for medicinal products, which seeks to address these issues by ensuring the existence of an effective patent term for medicinal

⁶⁶ TRIPS (n 12), arts 28 and 33; EPC (n 12), art 63.

⁶⁷ EPC (n 12), art 63(1); Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67 (Medical Products Directive).

⁶⁸ Pugtach (n 21) 86-87; Medical Products Directive.

⁶⁹ Explanatory Memorandum (n 62) 3; Richard Miller, Guy Burkill, Colin Briss and Douglas Campbell, *Terrell on the Laws of Patents* (17th edn Sweet & Maxwell 2011) 140.

⁷⁰ *Medeva et al.* (n 8).

⁷¹ EPC (n 12), art 83; John N. Adams, ‘Supplementary Protection Certificates: The challenge to EC Regulation 1768/92’ (1994) EIPR 16(8) 323.

drugs. However, some SPC applications can present more difficulties than others when attempting to apply the substantive provisions of the Regulation. For instance, it is not uncommon that after a patent has been granted other active ingredients are added to the patented active ingredient/s in which a marketing authorisation is then sought for.⁷² This in turn means that the medicinal product seeking an SPC, the marketing authorisation and the patent are not made up of the same active ingredients. This often occurs in relation to combination vaccines which contain a number of active ingredients that together provide immunisation against multiple diseases.⁷³ Such a situation raises issues as to the interpretation and application of the relevant regulatory provision. The outcome of which, can have a significant impact in the field of combination medications.

3.3 Supplementary protection certificates: Regulation (EC) No 469/2009

In 1992, the EU introduced a Regulation concerning the creation of a SPC for medicinal products to address the disparities in the Community regarding patent term extension.⁷⁴ The aim of the SPC Regulation is to improve protection for innovation in the pharmaceutical sector by providing favourable rules to ensure effective protection and encourage research.⁷⁵ The 1980s saw the onset of a decrease in EPLs due to the increasing demands by the authorities who grant marketing permits for pharmaceutical drugs.⁷⁶ Europe was also in a weaker competitive position in comparison to the US and Japan who had already introduced patent term restoration for pharmaceuticals in the mid- to -late 1980s.⁷⁷ France and Italy were the first countries in Europe to introduce a patent extension. France introduced the Certificate of Complementary Protection (“CCP”) in 1991 as a new

⁷² Explanatory Memorandum (n 62) 21; *Medeva et al.* (n 8).

⁷³ *Medeva et al.* (n 8), para 2.

⁷⁴ Council Regulation 1768/92/EEC was first introduced and later became codified as Regulation 469/2009 (n 6). An EU Regulation is the most direct form of EU law, instantly binding upon its Member States and holds the same status as national law, see: European Commission, ‘Application of EU Law: What are EU Regulations?’ <http://ec.europa.eu/eu_law/introduction/what_regulation_en.htm>.

⁷⁵ SPC Reg (n 6), recs 3-6; Miller (n 1) 140.

⁷⁶ *Domeij* (n 52) 196.

⁷⁷ Nigel Jones and Robin Whaite, ‘Pharmaceutical patent term restoration - the European Commission's proposed Regulation’ (1990) *EIPR* 12(5) 179; Adams (n 71) 2; Seville (n 5) 158: the USA and Japan enacted their legislation in 1984 and 1987, respectively, restoring the patent term for pharmaceutical drugs.

intellectual property right; conferring a maximum CCP of 7 years which would come into effect after the patent expired, providing a maximum EPL of 17 years. Italy soon followed suit, providing a maximum CCP of 18 years and a maximum EPL of 20 years.⁷⁸

Consequently, the Commission proposed a solution in an attempt to unify the EPL in the Community; without unification, the free movement of pharmaceutical goods within the Community would be inhibited.⁷⁹ The solution was a proposal for a Commission regulation which would confer a SPC as a *sui generis* right, with the effect of extending the life of a patent.⁸⁰ The Explanatory Memorandum accompanying the proposal, though non-binding, sets out the justifications and motivations behind it, providing guidance on its provisions.⁸¹ However, the proposal did not please all its Member States.

In 1985, Spain challenged the validity of the SPC Regulation as an instrument of Community law in the CJEU under the Treaty Establishing the European Community 1957 (“EEC Treaty”; also known as the Treaty of Rome). Spain argued that the Regulation was *ultra vires* and requested that it be annulled. It was further argued that if the EU was found to have the competence to enact the Regulation, it acted under the wrong legal basis.⁸² The CJEU subsequently rejected these arguments in their decision of *The Kingdom of Spain v Council of Europe* case, concluding that the SPC Regulation was validly adopted under Article 100a of the Treaty. Moreover, the Court acknowledged that the Regulation struck a balance between the competing interests of patent holders and generic firms through its granting of a maximum term of five years; and that the interests of consumers and the generic pharmaceutical industry were not disregarded in the Regulation.⁸³ This is exemplified in recital 10 of the SPC Regulation which states that ‘all interests at stake’ should be taken into account, and that it is for this purpose that an SPC confers a five year extension of the EPL.

⁷⁸ Kolker (n 2) 249.

⁷⁹ SPC Reg (n 6), rec 7; Domeij (n 52) 196.

⁸⁰ Seville (n 5) 158; Explanatory Memorandum (n 62) 12.

⁸¹ Anne C. M. Meuwese, *Impact Assessment in EU Lawmaking*, (Kluwer Law International 2008), 81.

⁸² Adams (n 71) 4.

⁸³ Case C-350/92 *The Kingdom of Spain v Council of Europe* [1996] FSR, paras 37-40; Miller (n 1) 148.

An SPC grant holds important economic importance in the pharmaceutical sector despite its procurement of a mere additional five years to the end of a patent term. This is because patents for medical products are more valuable than patents in other fields. Moreover, an SPC is granted only for products which have already reached the market and only begins upon the expiration of the original patent. Thus, the product would already have established itself in the market prior to the extension procured by the SPC, and an SPC therefore bears with it significant commercial implications.⁸⁴

As the SPC Regulation is an instrument of EU law, the CJEU plays an important role in the interpretation of the Regulation, and any decisions of the Court have a paramount role as they are binding upon its Member States. This means that when the courts attempt to interpret the Regulation, significant weight will be duly given to the purposes and rationales set out in its recitals and the general principles of the Regulation.⁸⁵ Together, these underlying principles and the Explanatory Memorandum assist the court in determining the meaning behind the provisions of EU Regulations. In particular, the aim of preventing a heterogeneous development of national laws to ensure a uniform solution within the Community also carries significant weight when interpreting the Regulations.⁸⁶ However, the Advocate-General stated in the *Novartis* case that an analysis of the recitals in the SPC Regulation indicate that the main objective of the legislature was not to guarantee the free movement of medical products within the Community, but to ensure that conditions exist for profitable pharmaceutical research and to deter firms from relocating outside the Union.⁸⁷ The subsequent judgement of the CJEU in *Novartis*, however, did not wholly endorse this view but did nevertheless, agree with its conclusion.⁸⁸ Miller et al., argue that recitals 2-6 of the Regulation, together with other judgements of the CJEU,

⁸⁴ Miller (n 1) 144.

⁸⁵ *ibid* 145.

⁸⁶ *ibid* 148.

⁸⁷ Joined Cases C-207/03 and C-252/03 *Novartis AG, University College London and Institute of Microbiology and Epidemiology v Comptroller with Ministre de l'economie v Millenium Pharmaceuticals Inc.* AG Opinion Ruiz-Jarabo Colomer, para 42 (Novartis AG Opinion).

⁸⁸ *ibid*, paras 31-32.

support the approach taken by the Advocate-General as they also heavily emphasise upon the importance of ensuring pharmaceutical research.⁸⁹

To date, the CJEU has yet to make a ruling on the issues arising from the SPC Regulation. However, there have been numerous references for preliminary rulings, from which a number of Advocate-General opinions have been made.⁹⁰ Due to the current lack of a binding supreme decision, national courts are left to cite the relevant case law from other Member States. Though, they are non-binding, a national court can still place weight upon it in due course.⁹¹

3.4 Legal effect of an SPC

An SPC is a ‘national document harmonised at the Community level and is essentially different from the basic patent’.⁹² It provides for the same rights that are conferred by the basic patent, national or European, which the SPC is based on, and is subject to the same limitations and obligations.⁹³ Article 28 of TRIPS describes the rights a patent confers upon its owner: the exclusive rights to prevent third parties from making, using, offering for sale, selling, or importing.

Article 64 of the EPC provides that the rights of the basic patent are those prescribed by the national state and its domestic law, under which the patent was granted.⁹⁴ Article 69 states that the extent of protection conferred by a patent is to be determined by its claims. The Protocol on the Interpretation of Article 69 EPC of 1973 (“the EPC Protocol”)⁹⁵ states that a strict, literal meaning should not be given when interpreting the claims; nor should the claims serve as guidelines with the protection extending to what a person skilled in the art

⁸⁹ Miller (n 1) 149.

⁹⁰ *ibid* 145. Also, see Chapter 4.7 ‘The product and its corresponding “basic patent in force”’.

⁹¹ *ibid* 146.

⁹² Explanatory Memorandum (n 62) 12.

⁹³ SPC Reg (n 6), art 5. Note that an EPC patent also confers the same rights as a national patent: see EPC (n 12) art 64.

⁹⁴ EPC (n 12), art 64; Miller (n 1) 178.

⁹⁵ As revised by the Act revising the EPC of 29 November 2000.

has contemplated based on the drawings and descriptions. Instead, ‘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 parties’.⁹⁶

Article 30 of the UKPA provides that a patent be personal property and ‘shall vest by operation of law in the same way as any other personal property’.⁹⁷ Article 9 of the German Patent Act confers the exclusive use of the patent to its holder, preventing all others from ‘making, offering, putting on the market, or using...or importing or stocking’ the product. This wording is also identical to that in Article 3 of the Swedish Patents Act.

The subject matter of protection extends only to the product as covered by the marketing authorisation, within the limits of the protection conferred by the basic patent.⁹⁸ This means that an SPC based on a process patent will protect the product made as a result of that process, just as its patent would, and would be subject to the same limitations and obligations.⁹⁹

The duration of an SPC is governed by Article 13. The holder of a patent and an SPC can enjoy these rights for an, ‘overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community’; however, the SPC itself, cannot be granted for more than five years.¹⁰⁰ The first marketing authorisation to place the product on the market anywhere in the Community is the relevant authorisation used for calculating this duration. In some instances, this may not be the first authorisation in the Member State in which the SPC is being sought. This helps ensure homogeneity among the national laws of Member States by

⁹⁶ EPC Protocol (n 95), art 1.

⁹⁷ UKPA (n 54), art 30(3).

⁹⁸ SPC Reg (n 6), art 4.

⁹⁹ Miller (n 1) 178.

¹⁰⁰ SPC Reg (n 6), recs 9-10.

making sure that the SPC expires at the same point in time across the whole Community.¹⁰¹
The initial SPC proposal sought for a 16 year EPL with a 10 year SPC maximum.¹⁰²

An SPC can also be revoked if one of the grounds for invalidity under Article 15 can be satisfied. An SPC shall be held to be invalid if:

- a) it was granted contrary to Article 3;
- b) the basic patent has lapsed before its lawful term expires;
- c) the basic patent has been amended and no longer protects the product or, after the basic patent expires, it would be invalid.¹⁰³

An application to revoke an SPC can be brought before the relevant body responsible under the national law of the corresponding patent.

¹⁰¹ Miller (n 1) 179.

¹⁰² Kolker (n 2) 2.

¹⁰³ SPC Reg (n 6), art 15; Miller (n 1) 156.

4 Obtaining an SPC

4.1 Overview

This chapter builds on the previous one by expanding on the requirements for an SPC. In doing so, this chapter will examine the substantive provisions of the SPC Regulation and how they are to be applied. Recent European case law will also be discussed, where relevant, to illustrate how the courts interpret the Regulation, how the provisions operate and where potential issues may lie.

4.2 How to obtain an SPC

Any medicinal product, for human or veterinary use, protected by a patent in force in the territory of a Member State may be the subject of an SPC.¹⁰⁴ An SPC application must be lodged within six months of either an authorisation to market the product (the marketing authorisation), or, the granting of the basic patent; whichever is obtained first in the Member State it has been granted in.¹⁰⁵

Article 8 sets out the mandatory content that an SPC application must contain:

- a) a request for the grant of a certificate;
- b) a copy of the marketing authorisation to place the product on the market as referred to in article 3(b); and
- c) if the authorisation referred to in (b) is not the first authorisation, a copy of the appropriate notice of that first Community authorisation.

¹⁰⁴ SPC Reg (n 6), art 2. Note that the product must also be subject to an administrative authorisation before being placed on the market as a medicinal product.

¹⁰⁵ SPC Reg (n 6), art 7.

Article 3 sets out the conditions which must be fulfilled in order to successfully obtain an SPC. An applicant must be able to show in respect of the product that they have:

- a) a basic patent in force; and
- b) a valid marketing authorisation; and
- c) that authorisation is the first authorisation to place the product on the market; and
- d) the product must not already have had an SPC.¹⁰⁶

4.3 “Basic patent in force”

A basic patent provides the legal basis for an SPC. A ‘basic patent’ means ‘a patent which protects a product as such, a process to obtain a product or an application of a product...’¹⁰⁷

The definition is intended to have a wide interpretation and does not provide for any exclusions as ‘all pharmaceutical research...leads to a new invention that can be patented...must be encouraged, without discrimination and must be able to be given an [SPC] of protection provided that all the conditions...are fulfilled’.¹⁰⁸ If the product is protected by a number of patents, for example for both a process and a product, the patent holder must choose one as the ‘basic patent’ for the purposes of an SPC application.¹⁰⁹

A ‘product’ means ‘the active ingredient or combination of active ingredients of a medicinal product’.¹¹⁰ This definition is central to the operation of the provisions of the Regulation and its narrow interpretation reflects its use in patent law and the pharmaceutical field, as opposed to a proprietary medicinal product in the wider sense.¹¹¹ This concept is to be interpreted strictly to mean ‘active substance’ or ‘active ingredient’ and cannot include the therapeutic use of an active ingredient.¹¹²

¹⁰⁶ SPC Reg (n 6), art 3.

¹⁰⁷ *ibid*, art 1(c).

¹⁰⁸ Explanatory Memorandum (n 62) 17.

¹⁰⁹ SPC Reg (n 6), art 1; Explanatory Memorandum (n 62) 19.

¹¹⁰ SPC Reg (n 6), art 1(b).

¹¹¹ Explanatory Memorandum (n 62) 16.

¹¹² Case C-431/04 *Massachusetts Institute of Technology v Deutsches Patentamt* [2006] OJ C165/8; Case C-202/05 *Yissum Research & Development Company of the Hebrew University of Jerusalem v Comptroller-General of Patents* [2007] ECR I-02839; Miller (n 1) 156.

‘Medicinal product’ means ‘any substance or combination of substances presented for treating diseases or diagnosis...’ and hence, the ‘medicinal product’ must be able to be identified by the authorisation.¹¹³

4.4 “Valid authorisation to place the product on the market”

The product must also have a valid authorisation (the marketing authorisation) to place it on the market as a medicinal product, granted in accordance with the Medical Products Directive (Directive 2001/83/EC, or Directive 2001/82/EC depending on whether the product is for human or veterinary use).¹¹⁴ This authorisation required by Article 3(b) refers to the local marketing authorisation to place the product on the market in the state where the SPC application is being sought. An authorisation for another state in the Community is not relevant for the purposes of an SPC application under Article 3 and 7; although, it is relevant for calculating the duration of the SPC under Article 13.¹¹⁵ Furthermore, the CJEU decision in *Biogen* provides that an SPC can still be granted in cases where the basic patent and the marketing authorisation are held by different people and without the consent of the holder of the marketing authorisation.¹¹⁶

The subject matter of protection under an SPC is also linked to both the patent and marketing authorisation. In *Farmitalia*, the CJEU held that the terms of the marketing authorisation are not wholly determinative in itself and that even though the active ingredient in the authorisation was in the form of a salt, the SPC was capable of covering its derivatives to the extent in which they were also covered by the basic patent. That is, ‘where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, the certificate is capable of covering that product, as a medicinal product, in any of the forms enjoying the protection of the basic patent’.¹¹⁷

¹¹³ SPC Reg (n 6), art 1(a); Miller (n 1) 159-160.

¹¹⁴ SPC Reg (n 6), art 3(b).

¹¹⁵ Miller (n 1) 166.

¹¹⁶ Case C-181/95 *Biogen Inc v SmithKline Beecham Biologicals S.A.* [1997] R.P.C. 833; Miller (n 1) 155.

¹¹⁷ *Farmitalia* (n 122), paras 21-22.

4.5 “The product has not already been the subject of a certificate”

This provision relates to the product not already having had a certificate in the *same* Member State, as stated in the preamble of Article 3.¹¹⁸ The Explanatory Memorandum explains that the purpose of an SPC is to ‘encourage research into new medicinal products so that the duration of protection it affords, together with the effective duration of a patent, is to enable the investments made in the research to be recovered’.¹¹⁹ However, the Commission also acknowledge the balance which needs to be struck between competing interests, and in light of this, do not allow the total duration for ‘one and the same product’ to be exceeded, which may occur if a product could be granted several SPCs. The Memorandum also calls for a *strict* definition of the ‘product’ under Article 2. This means that despite the possibility for one product to have several patents and several authorisations in one Member State, it can only ever have one SPC based on *one* patent and *one* authorisation.¹²⁰

4.6 “The relevant authorisation is the first...to place the product on the market”

Some products may have several authorisations referring to it due to modifications made to the products pharmaceutical form, for example a change of form, dose or composition. The Explanatory Memorandum explains that when this is the case, only the *first* authorisation for the product to be placed on the market in the Member State is the relevant authorisation for an SPC application. This first authorisation is also relevant for calculating the six month period for making an application. Furthermore, if the relevant first authorisation is also the first to authorise the placement of the product within the Community, it is also the reference for all Member States when calculating the duration of each SPC granted in each Member State for the same product.¹²¹

¹¹⁸ Miller (n 1) 167.

¹¹⁹ Explanatory Memorandum (n 6) 20

¹²⁰ *ibid.*

¹²¹ Explanatory Memorandum (n 6) 19; Miller (n 1) 169.

4.7 The product and its corresponding “basic patent in force”

One of the most central substantive requirements for obtaining an SPC is the existence of a ‘basic patent in force’ protecting the product under which the SPC application is sought, as per Article 3(a). Much of the case law on Article 3(a) has involved combination drugs consisting of multiple active ingredients, with a corresponding basic patent that covers only one or some of the combination. The difficulty that arises in such cases relates to whether the protection conferred by an SPC can exceed the scope of protection conferred by the basic patent. A number of cases have recently been referred to the CJEU seeking clarification on this fundamental aspect for obtaining an SPC.¹²²

In the UK, case law has dealt with two competing approaches: the ‘infringement test’ and the ‘identification or disclosure test’. The former is a wider test and interprets Article 3(a) as extending to anything under which an action for infringement could be successfully brought under a national court. This requires looking at whether the product under the SPC would infringe upon the basic patent. The latter test applies a narrower interpretation of the provision in which a patent claim must sufficiently disclose the relevant product, including its combination, in order for the patent protection to cover it.¹²³

The infringement test was first dealt with in the *Takeda* case, which rejected the test; while the disclosure test first prevailed in the *Gilead* case.¹²⁴ In *Takeda*, the applicant sought for a number of SPCs, three of which were for combinations of the anti-ulcer agent lansoprazole with two antibiotics. The designated patent covered lansoprazole and the authorisation also related to lansoprazole as an active ingredient. Both the Hearing Officer and the Patent Court (England and Wales) held that the basic patent did not protect the product seeking an

¹²² SPC Reg (n 6) art 4; Case C-392/97 *Farmitalia Carlo Erba Srl* [1999] ECR I-5553 as cited in *Astellas Pharm Inc Patents Court* [2009] EWHC 1916 (Pat) (Astellas). Cases currently awaiting a preliminary ruling by the CJEU include: *Medeva et al.* (n 8); *Yeda Research and Development Company Ltd v Comptroller-General of Patents* [2010] EWHC 1733 (Pat); *Daiichi Sankyo Company Limited* [2010] EWHC 2897 (Pat); Case C-630/10 *University of Queensland and CSL Ltd v Comptroller-General of Patents* (referral to CJEU 2011/C 89/19).

¹²³ Miller (n 1) 165-166.

¹²⁴ *Takeda Chemical Industries Ltd’s SPC Application (No. 3)* [2003] EWHC 649 (Pat) (Takeda); *Gilead’s SPC Application* [2008] EWHC 1902 (Pat) (Gilead); *Astellas* (n 122).

SPC that is, the combination. The latter judgement reiterated that a combination as such, must be protected by the basic patent. Jacob J held:

The [SPC] system is to provide supplementary protection to that provided by the patent – to extend the relevant part of the patent monopoly. It is not a system for providing protection for different monopolies. Here, Takeda's monopoly is in lansoprazole. The monopoly which they seek is a combination of lansoprazole and an antibiotic. The fact that combination might infringe the monopoly given by the patent simply because one component infringes is irrelevant.¹²⁵

The *Takeda* case followed and cited a Swedish case whereupon an SPC was sought for a combination of two active ingredients but the basic patent only covered one active ingredient. Both the Swedish Patent Office and Patent Appeals Court held that the SPC application did not comply with Article 3(a), and subsequently, the SPC application was rejected.¹²⁶

In the *Gilead* and *Astellas* cases, both claimants argued that *Takeda* was wrongly decided and that the ‘infringement test’ was the correct test to apply. In *Gilead*, the court distinguished *Takeda* based on its material facts. The applicants’ patent in *Gilead* disclosed and claimed a combination of active ingredients. Gilead’s patent claim 27 was for the ingredient ‘tenofovir and optionally other therapeutic ingredients’.¹²⁷ The wording thus, covered a combination of tenofovir together with other ingredients. In this case, the subject of the SPC application was a combination of tenofovir and emtricitabine. Subsequently, Kitchin J held that the combination was protected by the patent claim under Article 1(b) and 3(a) despite whether or not the ‘infringement test’ ought to be adopted. Kitchin J’s approach was to identify the relevant active ingredients and examine whether they were covered by the protection conferred under the relevant patent claim; thus, the ‘identification

¹²⁵ *Takeda* (n 124), para 12.

¹²⁶ Case 3248–1996 *Hässle AB’s SDP Application* Supreme Administrative Court of Sweden (2 February 2000).

¹²⁷ *Gilead* (n 124) as cited in paras 17-18 of *Astellas* (n 122).

or disclosure test'. This means that a patent claim for active ingredient (A) would not protect a combination of active ingredients (A+B) because *only* (A) would come under the patent protection, as (B) was not disclosed in the patent claim. Kitchin J also noted that the outcome in *Takeda* could produce harsh results.¹²⁸ However, as the case was distinguished from *Takeda*, the court's comments regarding the infringement test are merely obiter.¹²⁹ Interestingly but perhaps un-surprisingly, Miller et al. state that 'anecdotal evidence suggests that patents are now being drafted and even amended...to include generalised claims similar to this claim 27 in order to mitigate the perceive[d] effect of the *Takeda* case.'¹³⁰

Astellas is another case which dealt with these two competing approaches. Arnold J in *Astellas* distinguished the *Gilead* case, as the claimants in *Astellas* did not disclose the combination in the basic patent, although the patent claim did cover it. Thus, it was held that the disclosure test was not satisfied. Arnold J also contended that Jacob J's reasoning in *Takeda* remained persuasive and further agreed that there exists a distinction between 'the scope of protection and the question of infringement'.¹³¹ Nevertheless, Arnold J went further and agreed with the comments of Kitchin J in *Gilead* regarding the existence of favourable arguments for the infringement test which were not considered in *Takeda* and deserve consideration by a higher court, notably the CJEU. However, he did not think it necessary to make such a reference himself.¹³²

France and Spain are among the jurisdictions which follow the same lines as the UK in applying the 'identification or disclosure test'; whereas other jurisdictions, including Germany and Switzerland, apply the 'infringement test'.¹³³ The Belgium courts have recently had to consider which road to follow. The Antwerp Commercial Court chose to

¹²⁸ *ibid*, paras 20 and 35-37.

¹²⁹ Miller (n 1) 172.

¹³⁰ *ibid*.

¹³¹ *Astellas* (n 122), para 34.

¹³² *ibid*, para 35.

¹³³ Kristof Roox, 'First Belgian decision on SPC's coverage of combination products' (*Kluwer Patent Blog* 17 June 2011) <<http://kluwerpatentblog.com/2011/06/17/first-belgian-decision-on-spc%E2%80%99s-coverage-of-combination-products/>> accessed 10 November 2011.

apply the ‘infringement test’. The case involved the pharmaceutical company, *Novartis*, who owned two SPCs, one for the combination of ‘valsartan/HCTZ’ and one for valsartan alone. Both SPCs were based on the basic patent for the single active ingredient valsartan. *Novartis* were also proprietors of a ‘blockbuster’ drug called Co-Diovan, which was comprised of the valsartan/HCTZ combination. *Teva*, another pharmaceutical company, had manufactured a generic version of this drug and sought to declare its SPC for the combination invalid. *Teva* argued that their drug did not infringe on the SPC for valsartan alone. Not surprisingly, *Novartis* argued for the ‘infringement test’ while *Teva* argued for the ‘identification or disclosure test’.¹³⁴

The Antwerp Court held that ‘protected by’ in Article 3(a) of the SPC Regulation could only be interpreted as meaning ‘covered by’ or ‘what would be infringing on’; and thus, applied an ‘infringement’ approach in assessing the validity of the SPC for the combination in question.¹³⁵ The Court held that it was irrelevant whether a combination was disclosed or not in the basic patent so long as it was protected by it.¹³⁶ The Court also referred to the *Farmitalia* case where the CJEU stated that the court must have regard to the national laws governing the patent when determining whether a combination drug is protected by a patent in force, which in this case did not allow for the Belgium Court to apply a narrower interpretation to the relevant provisions.¹³⁷ However, in regards to whether *Teva*’s product infringed upon the SPC for valsartan alone, the Court held that it did not and in examining the scope of protection of the SPC, applied the ‘identification test’. Therefore, *Teva*’s product did not infringe upon the SPC for the mono-ingredient.¹³⁸

¹³⁴ *Novartis AG v Teva Pharma Belgium NV* Court of Appeal (8th Chamber of the Court of Appeal of Antwerp) (9 February 2011) 2011/1396; Roox (n 133).

¹³⁵ *ibid.*

¹³⁶ *ibid.*

¹³⁷ *ibid.* Pieter Van Den Broecke and Tom De Coster, ‘Belgium - Healthcare: “Infringement test” applied to SPC validity’ (*Linklaters* 19 July 2011)

<http://www.linklaters.se/Publications/Publication1392Newsletter/July_2011/Pages/Belgium-Healthcare_Infringement_Test_Applied_SPC_Validity.aspx> accessed 10 November 2011.

¹³⁸ Roox (n 133).

4.8 The Medeva case

The most recent case to deal with combination drugs, and in particular, combination vaccines, is the case of *Medeva*. This case was recently given a joint CJEU Opinion and is currently awaiting a preliminary ruling by the CJEU.¹³⁹ However, the joined cases in the CJEU Opinion have now been disjoined for their preliminary rulings, both due late November this year.¹⁴⁰

4.8.1 The facts

The facts of *Medeva* concern a patent for the active ingredients of pertactin and filamentous haemagglutinin antigen (“FHA”), which are antigens usable in vaccines against whooping cough. The patent was filed in 1990, granted in 2009 and expired in 2010. The first commercial vaccine was made in 1996 using their invention and provided vaccination against whooping cough, diphtheria and tetanus. From 2000, larger multi-disease vaccines were launched in the UK providing vaccination against whooping cough, diphtheria, tetanus, meningitis and polio. Since 2004, the combined vaccination against all of these has been recommended as the primary immunisation for babies in the UK.¹⁴¹

In 2009, a number of SPC applications were made for several different combinations of active ingredients concerning pertactin and FHA together with other non-patented active ingredients, and one SPC application referring to just pertactin and FHA. The UKIPO and the Patents Court refused the latter application as it contained fewer active ingredients than its marketing authorisation and therefore, was not a valid authorisation under Article 3(b). All other applications were rejected for failing to fall under the protection of the basic patent according to Article 3(a), as they covered more active ingredients than were referred to in the subject matter of the basic patent.¹⁴² An appeal was then brought to the Court of

¹³⁹ *Medeva et al.* (n 8).

¹⁴⁰ *ibid*, Order of disjoinder by CJEU dated 11 October 2011; Jeremy Phillips, ‘Medeva and Georgetown rulings: save the date!’ (*The SPC Blog* 30 October 2011) <<http://thespcb.blogspot.com/2011/10/medeva-and-georgetown-rulings-save-date.html>> accessed 2 November 2011.

¹⁴¹ *Medeva et al.* (n 8), paras 10-14; Miller (n 1) 174.

¹⁴² *Medeva BV v The Comptroller-General of Patents* [2010] EWHC 68 (Pat) (*Medeva* EWHC); *Medeva et*

Appeal. However, having doubts as to the interpretation of Articles 3(a) and (b) the Court referred a number of questions to the CJEU for a preliminary ruling.¹⁴³

4.8.2 The questions referred to the CJEU

The questions referred to the CJEU involve the clarification of whether, in relation to Article 3(a), a combination of active ingredients can be regarded as ‘protected by a basic patent in force’ when a patent exists only in respect of one or some of the active ingredients used in the combination; and whether different criteria are to apply for multi-disease vaccines under Article 3(a). The Commission, and the Portuguese and Lithuanian Governments argued that a combination of both patented and non-patented active ingredients *cannot* in their entirety be classified as a ‘product...protected by a basic patent in force’ within the meaning of Article 3(a). However, the UK Government and Medeva argued in the affirmative. They argued that where at least one of the active ingredients in a combination of active ingredients falls within the extent of the protection conferred by the basic patent, the entire combination is also protected by that basic patent. They further contended that this applies without restriction to multi-disease vaccines. Lastly, all parties argued that Article 3(a) does not apply differently to medicinal products with just one active ingredient on the one hand and multiple active ingredients on the other.¹⁴⁴

4.8.3 The CJEU Opinion

In the Advocate-General’s Opinion of *Medeva et al.*, a literal approach was first applied to the interpretation of Articles 1-3 in pursuit of answering the questions referred to the court.¹⁴⁵ This led her to conclude that the definition of ‘product’ in Article 1(b), ‘the active ingredients or combination of active ingredients of a medicinal product’,¹⁴⁶ must be interpreted to mean the *entire* combination of active ingredients as such, not just the

al. (n 8), paras 15-17.

¹⁴³ *Medeva BV v The Comptroller-General of Patents* [2010] EWCA Civ 700, R.P.C 27 (Medeva EWCA).

¹⁴⁴ *Medeva et al.* (n 8), paras 42-47.

¹⁴⁵ See above Chapter 4.8.3 ‘The CJEU Opinion’.

¹⁴⁶ SPC Reg (n 60), art 1(b).

patented parts.¹⁴⁷ Her reasoning was based on the fact that on a literal interpretation of the wording ‘only the combination of active ingredients of that medicinal product in its entirety, and not the patented part of that combination, can be described as a product within the meaning of Article 1(b)’.¹⁴⁸ Therefore, ‘[a] literal interpretation of Regulation No 469/2009...leads to the conclusion that, in the case of medicinal products with multiple active ingredients, [an SPC] may be granted only in relation to the entire combination of active ingredients’.¹⁴⁹ This is because in the case of medicinal products with only partially patented active ingredients, ‘...it would actually, as a rule, be de facto impossible for the basic patent within the meaning of Article 1(c)...to exist’.¹⁵⁰

The question of whether the basic patent is comprised of the product under Article 1(b) is to be determined by the national laws governing the patent. Furthermore, the Advocate - General found it incompatible for a national court to ‘invoke the protective effect of the patent granted for a specific active ingredient in order to declare that patent to be the basic patent for all combinations of active ingredients in which the patented active ingredient was to be used’.¹⁵¹

The Advocate-General then went on to consider whether this result was compatible with the aim of the SPC Regulation, which is worth restating here: ‘it is essentially to extend the term of patent protection for active ingredients used in medicinal products’.¹⁵² She concluded that a literal interpretation of Article 1 and 3 was not compatible with its aim.¹⁵³ In particular, she highlighted that this would essentially create a situation where it would never be possible to extend a term of patent protection when a manufacturer is, for either legal or practical reasons, obliged to combine their patented active ingredient with others to market it as a medicinal product. Such a result would not only be incompatible with the

¹⁴⁷ *Medeva et al.* (n 8), para 63.

¹⁴⁸ *ibid.*, para 67.

¹⁴⁹ *ibid.*

¹⁵⁰ *ibid.*, para 64.

¹⁵¹ *ibid.*, paras 65-72.

¹⁵² *ibid.*, para 75.

¹⁵³ *ibid.*, para 79.

purposes of the Regulation, but also create unreasonable barriers for patent holders.¹⁵⁴ Thus, the Advocate-General held that a teleological approach must be used to complement a literal approach to the Regulation which ‘ensures that the rules on [SPCs] contained in those provisions can also be fully effective in respect of medicinal products in which the combination of active ingredients is only partly the subject matter of a patent’.¹⁵⁵

In applying a teleological approach to the Article 1(b), she interpreted the definition of ‘product’ widely so as to include ‘an’ active ingredient or ‘a’ combination of active ingredients, widening the scope of the provision. In contrast, a narrower, literal interpretation would limit it to ‘the’ active ingredient or ‘the’ combination of active ingredients. Therefore, a wider interpretation allows a combination of patented and non-patented active ingredients to fall within the scope of the SPC Regulation.¹⁵⁶ However, the Advocate-General also acknowledged that if a teleological approach to Article 1(b) is accepted, there may be a risk that a manufacturer could ‘develop a number of medicinal products with different combinations of active ingredients on the basis of one patented active ingredient or combination of active ingredients and place those products on the market with a time lag in some cases, for the purpose of optimising the protection under the certificate’.¹⁵⁷ Therefore, in order to mitigate this potential risk and ensure the proper functioning of the Regulation and balance of the competing interests at stake; she concluded that Article 3(a) must be interpreted to mean the product within the subject matter of the basic patent under Article 1(c).¹⁵⁸ This means that whichever combination of active ingredients is chosen to be used for an SPC application, the product relied upon will be the same and thus, only one SPC will be granted on the basis of that product which is the subject matter of the basic patent under Article 1(c).¹⁵⁹ Furthermore, any subsequent combinations will be refused as the product would have already been the subject of an SPC

¹⁵⁴ *ibid*, para 80.

¹⁵⁵ *ibid*, para 88.

¹⁵⁶ *ibid*, paras 89-90.

¹⁵⁷ *ibid*, para 96.

¹⁵⁸ *ibid*, para 98.

¹⁵⁹ *ibid*, paras 99-101.

(therefore, not satisfying the requirement under Article 3(c)).¹⁶⁰ Whether the product forms the subject matter of the basic patent, is a question to be determined by the rules governing the basic patent. If this is answered in the affirmative, the product is thereby, protected by the basic patent.¹⁶¹

Under this interpretation, the Advocate-General rejects the ‘infringement test’ by distinguishing between the subject matter of the basic patent and its protective effect; the definition of a basic patent under Article 1(c) is based on the subject matter, and not the protective effect, of the patent. The subject matter of which, must be comprised of the product under Article 1(b). The protective effect is, thereby, not relevant for determining whether an active ingredient or a combination of active ingredients forms the subject matter of a basic patent.¹⁶²

It is worth noting that the Advocate-General fails to mention the ‘identification or disclosure test’ as such. However, it can be argued that the ‘identification or disclosure test’ bears similarity to a ‘literal approach’, as they both rely on the subject matter of the patent claim and determining whether it corresponds with the subject matter under the SPC application.¹⁶³ See Chapter 5 for more analysis on the similarities and differences of these approaches.

¹⁶⁰ *ibid*, para 103.

¹⁶¹ *ibid*, para 116.

¹⁶² *ibid*, paras 68-113; Tim Powell and Rebecca Lawrence, ‘Supplementary Protection Certificates for Combination Products’ (*JIPLP* 4 November 2011) <<http://jiplp.blogspot.com/2011/11/supplementary-protection-certificates.html>> accessed 8 November 2011.

¹⁶³ See above Chapter 4.7 ‘The product and its corresponding “basic patent in force”’ for more information on the ‘identification or disclosure test’.

5 Does the current approach to the regulatory regime provide adequate protection for combination drugs?

5.1 Overview

This chapter aims to provide an analysis of how the provisions of the SPC Regulation affect SPC applications for combination drugs by exploring a range of different application scenarios. These scenarios will be considered in light of different approaches, (as discussed above in Chapters 4.7-4.8), to the Regulation which the courts may apply. The aim of this exploration is to examine the effects of the different approaches on combination drugs, and how the results correlate with the objectives of the Regulation and the competing interests at stake, in pursuit of determining whether or not the Regulation provides adequate protection for combination drugs.

5.2 The current approach to the regulatory regime: a recap

To determine the adequacy of the current SPC regulatory regime we must first re-cap the objectives behind the SPC. The first paragraph of the Explanatory Memorandum states that ‘the Regulation is to improve the protection of innovation in the pharmaceutical sector’.¹⁶⁴

The aims are further elucidated in the recitals of the SPC Regulation, which include:

- To provide favourable rules providing for sufficient protection encouraging research for medicinal products (recital 3)
- A uniform solution at the Community level to prevent disparities likely to create obstacles to the free movement of medicinal products (recital 7)
- To “provide *adequate* effective protection” (recital 9)

¹⁶⁴ Explanatory Memorandum (n 62) 3.

- To take into account all the interests at stake, including the public health sector and the pharmaceutical sector (recital 10).¹⁶⁵

The crux of whether an SPC application can be obtained rests on the conditions laid out in Article 3. For combination drugs, the issue often raised in case-law has centred on Article 3(a), which requires that the product must be protected by a ‘basic patent in force’.¹⁶⁶ As we have seen in the discussions above, different approaches to the current regime have been employed by national courts which have led to a divergence at the national level; namely, the ‘infringement test’ versus the ‘identification or disclosure test’.¹⁶⁷ Such a divergence among the Community states seems to fall short of the aim in recital 7, and only serves to foster heterogeneity within the Community and to the granting of SPCs for medicinal products. National courts have a hard time knowing how to apply the Regulation and the continuance of such divergence should be put to an end by the CJEU at the next opportune time, such as in their pending preliminary ruling on *Medeva*. Furthermore, the UK courts have acknowledged in recent cases that the approach adopted by their courts under the ‘identification or disclosure test’ may produce harsh results.¹⁶⁸

5.3 Scenarios for analysis

The following hypothetical scenarios seek to provide a basis from which an analysis of the different approaches may be applied, to examine when a combination drug can and cannot be granted an SPC. The approaches which will be considered in turn are as follows: the ‘infringement test’ approach, the ‘identification or disclosure test’ approach and the ‘teleological approach’.

Scenario 1:

Basic patent = A.

¹⁶⁵ Note: these are taken from the consolidated SPC Regulation.

¹⁶⁶ See *Takeda* (n 124), *Gilead* (n 124), *Astellas* (n 122) and *Medeva et al.* (n 8).

¹⁶⁷ See above Chapter 4.7 ‘The product and its corresponding “basic patent in force”’.

¹⁶⁸ *Astellas* (n 122) paras 17-18; *Medeva* EWHC (n 142) para 30.

Marketing authorisation = A.

SPC is sought for = A.

Scenario 2:

Basic patent = A.

Marketing authorisation = A+B.

SPC is sought for = A+B.

Scenario 3:

Basic patent = A.

Marketing authorisation = A+B+C.

SPC is sought for = A+B+C.

Scenario 4:

Basic patent = A+B.

Marketing authorisation = A+B.

SPC is sought for = A+B.

Scenario 5:

Basic patent = A+B.

Marketing authorisation = A+B+C.

SPC is sought for = A+B+C.

Scenario 6:

Basic patent = A+B.

Marketing authorisation = A+B+C+D.

SPC is sought for = A+B+C+D.

Evidently, in a situation where an SPC application is sought for an active ingredient or combination of active ingredients in which a corresponding basic patent exists for the same

active ingredient or combination of active ingredients, an SPC can be unequivocally obtained, assuming that the other prerequisites of Article 3 have been satisfied.¹⁶⁹ This is illustrated in scenarios 1 and 4 above, as the subject of the SPC application in these scenarios is identical to the corresponding basic patent. No matter which approach a court may apply, these scenarios will yield a grant of an SPC. Not surprisingly however, difficulties arise when the substantive elements of an application are not as straightforward.

5.4 The ‘infringement test’ approach

As we have seen from the above discussions in Chapter 4.7 on this test, the European jurisdictions are somewhat split and non-uniform in their application of this approach. For example, the German, Swiss and Belgium courts are among the states that currently apply this test.¹⁷⁰ The recent referral of the *Medeva* case for a preliminary CJEU ruling provides a chance for the CJEU to create some uniformity among Community law on the application of the SPC Regulation in relation to combination drugs. As discussed above, the Advocate-General’s Opinion on *Medeva* rejected the ‘infringement test’.¹⁷¹ However, at the time in which this thesis is being written, there is still no telling which way the pending CJEU ruling will fall.

The infringement test applies a wider approach to the interpretation of Article 3(a) and is therefore, more favourable towards a party seeking to obtain an SPC for a combination drug. If applied, this approach allows a combination of active ingredients to rely on just the patented part of its combination, under its corresponding basic patent in force.¹⁷² The SPC holder, if granted an SPC, is then able to prevent the marketing of a product (comprised of the same combination) even though the product is not wholly patented.¹⁷³

¹⁶⁹ See Chapter 4 ‘Obtaining an SPC’ for a discussion of the different approaches and the requirements for obtaining an SPC under Article 3 of the SPC Regulation.

¹⁷⁰ Roox (n 133). This is not an exhaustive list on the matter but merely a sample for illustrative purposes.

¹⁷¹ See above Chapter 4.8.3 ‘The CJEU Opinion’.

¹⁷² SPC Reg (n 6), art 3(a). See above Chapter 4.7 ‘The product and its corresponding “basic patent in force”’.

¹⁷³ Sangeeta Puran and Sarah Byrt, ‘European Union: Advocate General’s Opinion Concerning the EU Harmonised Test For Granting An Extension Of The Term Of A Patent For Medicinal Products’ (*Mondaq* 29 July 2011)

Applying this approach to the scenarios above, it can be argued that *all* of the SPC applications would be granted. This is because all of the products which seek an SPC in the scenarios above are either made up of a combination which is wholly, or partially, patented. The products seeking an SPC under scenario 1 and 4 are entirely patented, and the products seeking an SPC under scenarios 2, 3, 5 and 6 are partially patented. This means that the sale of any of these products and/or combination drugs would result in an infringement on scenarios 1 and 4, and therefore, they would be able to obtain an SPC under an application of the ‘infringement test’.

5.5 The ‘identification or disclosure test’ approach

This approach is currently the prevailing approach in the UK, France and Spain.¹⁷⁴ This is a narrower test compared to the ‘infringement test’ and requires looking at the patent claim to see whether the combination seeking an SPC is expressly disclosed or identified in the corresponding basic patent.¹⁷⁵

Applying this approach to the scenarios above, only scenarios 1 and 4 would successfully obtain an SPC. This is because in those two scenarios the basic patent has *disclosed* the same combination, or single active ingredient, that makes up the product under the SPC application. Scenarios 2, 3, 5 and 6 would not, on the facts at hand, successfully obtain an SPC unless the patent claim in those scenarios include, as in *Gilead*, the words ‘and optionally other...ingredients’,¹⁷⁶ in which case an SPC application is likely to succeed before the courts.¹⁷⁷ However, in the absence of such, only where the basic patent has

<<http://www.mondaq.com/x/140116/Biotech+Life+Sciences+Healthcare/Advocate+Generals+opinion+conce+the+EU+harmonised+test+for+granting+an+extension+of+the+term+of+a+patent+for+medicinal+pro+produ>> accessed 9 November 2011.

¹⁷⁴ *Roox* (n 133). This is also not an exhaustive list on the matter but merely a sample for illustrative purposes.

¹⁷⁵ See above Chapter 4.7 ‘The product and its corresponding “basic patent in force”’.

¹⁷⁶ *Gilead* (n 124) as cited in *Astellas* (n 122) paras 17-18.

¹⁷⁷ See above Chapter 4.7 ‘The product and its corresponding “basic patent in force”’.

disclosed or identified all the active ingredients in an SPC application, so that: the basic patent = the SPC, an SPC will be granted. And thus, only scenarios 1 and 4 would succeed.

This test was not expressly mentioned in the Advocate-General's Opinion of *Medeva et al.*¹⁷⁸ However, this approach is very similar to the literal approach applied by the Advocate-General. Both approaches require that the basic patent relied upon match the combination seeking an SPC in its entirety, or disclose the combination in its entirety. Thus, it can be argued that they essentially apply the same approach to Article 3(a) and Article 1(b) and (c) of the SPC Regulation.

On this analysis, it would follow that the Advocate-General subsequently rejects the 'identification or disclosure test' (as well as the 'infringement test') by finding that a literal approach alone, is incompatible with the purposes of the Regulation. However, it is arguable that the 'identification or disclosure test' holds a slightly wider approach, as in *Gilead* it was held sufficient if the basic patent merely mentions the *option* of the active ingredients in combination with others.¹⁷⁹

5.6 The teleological approach

A teleological approach to law requires looking at the "spirit" of the text by examining its purpose or object.¹⁸⁰ When a literal interpretation of the text runs counter to the purposes sought to be achieved by legislation, a teleological approach can be applied or used to complement the literal interpretation of the words to ensure that the legislative intent be fully effective.¹⁸¹

¹⁷⁸ See above Chapter 4.8.3 'The CJEU Opinion'.

¹⁷⁹ *Medeva et al.* (n 8), paras 51-72.

¹⁸⁰ L. Neville Brown, and Tom Kennedy, *The Court of Justice of the European Communities* (4 edn Sweet & Maxwell 1994) 317.

¹⁸¹ *Medeva et al.* (n 8), para 88. Furthermore, the CJEU has already accepted the relevance of a broad, teleological approach to the SPC Regulation in case-law. Also see *Farmitalia* (n 122).

When applying this approach to the SPC Regulation, the competing interests of the pharmaceutical sector must be taken into account; such interests are namely those of the pharmaceutical companies, the generic manufacturers, the consumer and the state. These competing interests must be borne in mind, together with the aims of the Regulation. In attempting to balance these factors in the CJEU Opinion in *Medeva et al.*, the Advocate-General found it necessary to interpret the definition of “product” under Article 1(b) widely so as to include ‘an’ active ingredient or ‘a’ combination of active ingredients. This interpretation allows combinations of active ingredients which are only partly the subject matter under a patent to fall within the scope of the Regulation.¹⁸² However, the Advocate-General also found that such a wide interpretation would also encompass a risk of exploitation by manufacturers who might seek to produce slightly different combinations of active ingredients based on the same patent in an attempt to extend their exclusive rights numerous times.¹⁸³ In recognition of this, the Advocate-General contended that a teleological approach must limit the interpretation of Article 3(a) and Article 1(c) so that the product must form the basis of the subject matter of the basic patent, which when read together with Article 3(c), would preclude a manufacturer from obtaining more than one SPC on the basis of one patent, resulting in ‘one SPC for one patent’.¹⁸⁴

Applying this approach to the scenarios above, it would seem that anyone could be granted an SPC, but the applicant must choose *one* combination to seek an SPC out of those which share the same basic patent. All of the scenarios above are qualified to receive an SPC as they are all either: a product consisting of ‘an’ active ingredient (scenario 1); or ‘a’ combination of active ingredients, (scenarios 2, 3, 4, 5 and 6). However, an applicant must *choose* one of the scenarios out of scenarios 1-3 (as the designated patent in these scenarios are the same, a basic patent for (A)) and one scenario out of 4-6 (as these scenarios are also both based on the same designated patent, a basic patent for (A+B)).

¹⁸² *Medeva et al.* (n 8), para 90.

¹⁸³ *ibid*, paras 92, 96 and 97.

¹⁸⁴ *ibid*, paras 98-101.

Though the ‘one SPC for one patent’ restriction arguably has its merits in attempting to prevent the exploitation of a widened interpretation of Article 1(b), it can also be argued that it unreasonably restricts and impedes upon the pharmaceutical industry’s ability to adequately protect the development of innovative drugs, particularly combination drugs and combination vaccines that target multiple diseases; gives rise to an erroneous interpretation of the wording of Article 3(c). Therefore, it is arguable that reading in such a limitation does not align with the purposes behind the SPC Regulation, and accordingly, it should not be a part of any teleological approach to the Regulation.

This limitation imposed by the Advocate-General was based on the CJEU ruling in *Biogen* where the Court stated ‘only one certificate may be granted for each basic patent’; however, this statement has been the topic of much contention among commentators across Europe for being inconsistent with the European practice and several examples have since been brought forward in which multiple SPCs have been granted on the basis on one patent.¹⁸⁵ Though, the CJEU’s ruling in *Biogen* seems to follow the CJEU Opinion on *Biogen*, the Advocate-General’s Opinion on that case made a very different statement in regards to the ‘one SPC for one patent’ line of thinking. He stated that, ‘it is nowhere stated that a patent can be the subject of only one certificate, or of a certificate only in respect of one medicinal product, as the same patent may be used for widely differing medicinal products’.¹⁸⁶ Moreover, the facts in *Biogen* gave rise to the issue of whether a product protected by multiple patents could result in multiple SPCs for *each* patent owner, and did not specifically look at whether one patent could be the basis for multiple SPCs for different products. Thus, it is arguable that *Biogen* can be distinguished from *Medeva* and other cases with similar material facts.

¹⁸⁵ *Biogen* (n 116), para 28. This contention is described by Jeremy Phillips in his blogpost, ‘Medeva and the role of the Advocate General: a call for more communication’ (*The SPC Blog* 30 October 2011) <<http://thespcblogger.blogspot.com/2011/10/medeva-and-role-of-advocate-general.html>> accessed 12 November 2011.

¹⁸⁶ Case C-181/95 *Biogen Inc v SmithKline Beecham Biologicals S.A.* [1996] Opinion of AG Nial Fennelly, para 53 (Biogen AG Opinion).

Despite the Advocate-General acknowledging that ‘manufacturers of medicinal products may have a legitimate interest in marketing multi-disease vaccines’,¹⁸⁷ and referring to the referring courts views that:

Vaccine manufacturers are forced by countries’ purchasing policies to produce large combinations of vaccines wherever possible...the market is thus dictated by the State which insists that vaccines be combined where possible. In such circumstances, there may not be a market for patented vaccines which are provided on their own;¹⁸⁸

she fails to acknowledge and deliberate the effect a ‘one SPC for one patent’ approach might have on combination vaccines, which one would think the CJEU would consider when applying a teleological approach.

The principles of demand and supply for pharmaceuticals differ from that of other markets; they are principally oligopsonistic in the sense that those who purchase pharmaceuticals are predominantly hospitals and governments, and the demand by their customers differ from customers of other markets as they do not often have a choice in the drugs they want to purchase.¹⁸⁹ This structure generally guarantees a large profit for pharmaceutical companies who have a substantial market. However, the market for vaccines is less profitable than other medicinal drugs and represents around 2 per cent of the revenues generated from pharmaceuticals.¹⁹⁰ Pharmaceutical companies are thus, less willing to invest in costly R&D for vaccines compared to R&D investment in other drugs. Furthermore, the main customer base for vaccines are governments whom are unlikely to pay enough for them to provide companies with a profit, especially governments of less

¹⁸⁷ *Medeva et al.* (n 8), para 87.

¹⁸⁸ *ibid*, para 86.

¹⁸⁹ Valbona Muzaka, *The Politics of Intellectual Property Rights and Access to Medicines* (Palgrave MacMillian 2011) 31.

¹⁹⁰ WHO Factsheet Sheet No. 288, ‘Immunization against diseases of public importance’ (2005) <http://whqlibdoc.who.int/fact_sheet/2005/FS_288.pdf>; PATH, “Immunization Financing: Vaccine market” (April 2009).

developed countries and the non-profit organisations that help them purchase them, such as UNICEF.¹⁹¹ In light of these factors, the Advocate-General's approach in *Medeva et al.* should be examined with a critical eye.

Now, let us revert back to scenarios 4 and 6 outlined above and re-examine the consequences of a 'one SPC for one patent'. Let us say that scenario 4 seeks an SPC for the vaccine (A+B) directed at immunising against polio and tetanus ("product X"), and is protected by a basic patent also for (A+B). Then suppose that the producers of this vaccine subsequently developed a new way to combine this vaccine with other active ingredients which together, are directed at immunisation against polio, tetanus, hepatitis B and meningitis ("product Y") with the combination of active ingredients (A+B+C+D), and the corresponding basic patent (A+B), as in scenario 6 above. This can be summed up by saying that the two products, X and Y, are directed at immunising against a different mix of diseases, though they do not comprise of mutually exclusive active ingredients. This latter multi-purpose, combination vaccine (product Y), is clearly more beneficial and would be highly likely to be sought after for public health reasons by the state. Nonetheless, the basic patent has already been designated in scenario 4, and as a result, the new and improved combination in scenario 6 would fall short of obtaining an SPC. However, if we reconsider the wording of Article 3(c) it reads, 'the product has not already been the subject of a certificate'. Here, it can be argued that though product Y includes two of the same active ingredients in product X, (A+B), it is arguably a different product altogether and should therefore, be able to obtain an SPC as it has not previously been the subject of a certificate.

The Commission specifically state in their Explanatory Memorandum that:

The Regulation...concerns only new products...*only one certificate may be granted for any one product*, a product being understood to mean an active substance in the strict sense. *Minor changes* to the medicinal product such as a new dose, the use of

¹⁹¹ *ibid.*

a different salt or ester or a different pharmaceutical form will not lead to the issue of a new certificate.¹⁹²

The Commission do not draw the line at ‘one SPC for one patent’ but instead, and consistently with the literal wording of Article 3(c), they draw the line at ‘one SPC for one product’. Applying this approach to the scenarios 4 and 6, both applications would be able to obtain an SPC, given they can both be regarded as ‘products’.

In light of the comments by the Commission in their Explanatory Memorandum and the Advocate-General’s Opinion on *Medeva et al.*, the issue for combination drugs seems to rest on what constitutes a new ‘product’. More specifically, when is the modification of an existing medicinal product sufficient enough to constitute the creation of a new medicinal product, not merely the ‘modification’ of the existing one? This may partly, or substantially, depend on the criteria for determining a ‘minor change’ as posed by the Commission. When a pharmaceutical company develops a multiple-disease vaccine and another exists based on the same patent, merely providing protection against two diseases, should such a change be sufficiently ‘major’ so as to constitute a ‘new product’? In light of the “spirit” of the Regulation, and in encouraging pharmaceutical R&D, yes it should constitute a new product, having undergone a major change. Product X and Y bear significant differences in the diseases they target and should be thought of as independent products and not merely differing combinations, or modifications of each other. Thus, if product Y constitutes a new product and not merely a different combination of product X, the conditions under Article 3(a) and (c) will be satisfied, assuming that it has not already been the subject of an SPC.

The mere fact that two products do not have mutually exclusive ingredients should not, by virtue of this cross-over of ingredients, deprive them of adequate patent protection. If such a cross-over of ingredients were to always restrict a product and subsequent developments of it, there would be enormous setbacks in the development of pharmaceutical drugs as

¹⁹² Explanatory Memorandum (n 62) 8 (emphasis added).

once a patent were obtained, its proprietors would know from the outset that it bears such a restriction – possibility of only *one SPC* – even for substantial ‘modifications’ to its original form. Furthermore, the ‘risk’ of prolonging patent protection, which the Advocate-General seeks to avert through this limitation, is not a perpetual risk as an SPC can only be sought upon an existing patent.¹⁹³ Therefore, once a patent has exhausted its lifespan and no longer exists, the opportunity for any SPC grants is also exhausted and thus, there exists a time-frame in which SPCs will cease to be obtainable. Moreover, the ‘risk’ can be averted through other avenues, such as setting a standard by which any products seeking an SPC on the same patent must first show their own ‘uniqueness’ and/or ‘independent functionality’ to determine whether or not they can be held as independent enough products for two SPC grants.

5.7 Conclusion

The anomalies highlighted above by the national courts, the CJEU Opinion in *Medeva et al.* and the Regulation itself, need to be addressed in order to ensure adequate protection for combination drugs and the fulfilment of the Regulation’s objectives. If the Advocate-General’s approach is followed by the CJEU in their upcoming preliminary ruling, its effect will resonate throughout national jurisdictions within the Community and have a positive effect in 1) providing a consistent application of the Regulation across the Community; and 2) making it easier for combination drugs to obtain an SPC by virtue of a teleological approach. However, the ‘one SPC for one patent’ restriction imposed by the Advocate-General’s teleological approach to Articles 1 and 3 potentially procures a detrimental effect on the development of combination drugs, and in particular multi-purpose vaccines. Creating a rule in which only medicinal products with mutually exclusive active ingredients are able to obtain patent protection seems to frustrate the very purposes in which the SPC Regulation was enacted, and in particular, seems to defy recitals 3, 9, and 10 of its preamble.

¹⁹³ SPC Reg (n 6), art 3(a).

Extending a patent's EPL by granting an SPC should be based on the basic patent it corresponds with, its marketing authorisation, and the innovation added to the pharmaceutical industry and its benefits to consumers, and not how different the combination of active ingredients in one product is from the next. Furthermore, the Regulation itself does not, in any of its provisions, prevent a patent from being the basic patent for more than one SPC. A single patent can be the basis for many new innovative products, as described in the CJEU Opinion on *Biogen*.¹⁹⁴ Limiting an SPC to one product per patent would provide insufficient protection for the encouragement of research and innovation in pharmaceutical drugs, which would impede upon of the main objectives of the SPC Regulation. Furthermore, the continuity of an adequate protective regulatory regime for the development of medicinal products cannot be overestimated and should never be undermined.

The CJEU needs to make an unequivocal ruling on how the provisions of the Regulation are to be applied to combination drugs; and in particular, whether or not the basic patent and the subject of the SPC application must match in their entirety. If they find for the affirmative, the legislature of the EU may need to consider whether they ought to amend the wording of the Regulation to provide a clear platform from which the courts can interpret their text and adequately give effect to the purpose of the regime.

If the CJEU find for the negative, and follow the Advocate-General's Opinion, this would create an easier regime for combination drugs to obtain an SPC; however, should they also follow the limitation imposed in the Opinion, the EU legislature may also need to consider intervening as this limitation clearly goes beyond the scope of their Explanatory Memorandum. Whichever approach the CJEU do choose to apply in their ruling on *Medeva*, they should tread carefully as the precedent which needs to be set and guide the Community must also ensure adequate and effective protection for pharmaceutical research, innovation and investment for now and the future.

¹⁹⁴ *Biogen AG* Opinion (n 186), para 53.

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