Specialeafhandling: An Analysis of Central Conditions for Obtaining a Supplementary Protection Certificate and Identification of Critical Issues

Fagområde: Immaterialret

Problemformulering: This thesis examines the SPC regime and elucidates the legal landscape on two issues in particular. The two issues pertain to Art. 3(a) and Art. 3(d) of the SPC Regulation and are of particular interest due to the issues being a constant source of legal uncertainty despite the issues having undergone a continuous evolution in case law. The thesis will therefore seek to answer the following two research questions:

Research question 1: When is a product protected by basic patent in force?
Research question 2: When is it possible to obtain an SPC for second and further medical uses of an active ingredient already authorised as a medicinal product?

Based on an analysis of the above the thesis seeks to identify critical issues and discuss possible remedies.

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Afleveringsdato: 2. april 2020 | Karakter:
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*Danish Abstract*  

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1. Introduction

The pharmaceutical sector is essential for the health of citizens who need access to innovative, safe and affordable medicines. At the same time it is an important driver of economic growth and employment. This intricate position between imperative societal interests has induced a willingness from the EU legislator to enact policies and legislation that create an environment aimed at ensuring the viability of the sector.¹

Companies engaging in research and development in this sector will generally incur large fixed and sunk costs.² In this regard the patent system is of importance; patents are legal mechanisms of protection that allows an inventor to recoup such investment. However, in the pharmaceutical industry the patent protection period of 20 years has proven insufficient to allow for the recoupment of the large investments. This is due to the time needed to comply with market authorisation (MA) requirements which results in the average drug having been more than 10 years in development before reaching the market.³ As a result of this, the effective patent protection is the period between a product reaching the market and the expiration date of the patent.

Since the effective patent protection was assessed to be suboptimal to recover research and development costs in the industry, the Supplementary Protection Certificate (SPC) was created with Regulation No. 1768/92, which has since been repealed and replaced by Regulation No. 469/2009 (the SPC Regulation). An SPC is a sui generis intellectual property right whose existence presuppose the presence of a patent and an MA whereupon it can extend the exclusivity period of up to five years.⁴ Patents and MAs are governed by provisions that are external to the SPC Regulation which makes the regime unique and highly intricate. Moreover, it is a highly technical field wherein any measure requires the balancing of several interests and involves delicate choices in both economic and social policy. Through these optics, the SPC regime is one of the most sophisticated and multifaceted issues in the field of intellectual property with one of the highest financial values.

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A vague wording in the SPC Regulation coupled with teleological interpretation from the CJEU has resulted in a long list of case law and considerable legal uncertainties in relation to SPCs. This thesis documents the legal position in relation to two of the main issues regarding the conditions for obtaining SPCs pertaining to the SPC Regulation Art. 3(a) and Art. 3(d) in particular. As will be evident, the case law gives rise to many questions with several cases seemingly raising as many questions as they answer. Both main issues of the thesis have seen recent development but unresolved issues and unanswered questions remain. This is rather perplexing in light of the long list of case law coupled with the recent completion of two formal reviews of the European SPC system which evaluated both the legal aspects and the economic impact of SPCs. Nonetheless, these reviews did not cause the EU legislator to settle many of the outstanding issues as only one of the recommendations in these studies was implemented. Add to this the fact that the Agreement on a Unified Patent Court (the UPC Agreement) is now looking increasingly unlikely to enter into force and it becomes evident that the discussion on unresolved issues in the SPC regime is still highly relevant.

1.1. Research Questions and Purpose

The purpose of this thesis is to examine the SPC regime and to elucidate the legal landscape on two issues in particular. The two issues pertain to Art. 3(a) and Art. 3(d) of the SPC Regulation and are of particular interest due to the issues being a constant source of legal uncertainty despite the issues having undergone a continuous evolution in case law. The thesis will therefore seek to answer the following two research questions:

- **Question 1:** When is a product protected by basic patent in force?
- **Question 2:** When is it possible to obtain an SPC for second and further medical uses of an active ingredient already authorised as a medicinal product?

Based on an analysis of these questions the thesis seeks to identify critical issues and discuss possible remedies.

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6 It was decided to create an SPC manufacturing waiver which has now been implemented in Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

1.2. Delimitation

There are several issues relating to the conditions for obtaining an SPC and Art. 3 of the SPC Regulation is one of the most referred-to provisions of the EU legislation on intellectual property. However, due to constraints in scope and time this thesis will not seek to analyse all of these issues. Rather the focus will be to elucidate the issues of the research questions above in an attempt to contribute to the discussion pertaining to these. From academic literature, case law and statements from National Patent Offices (NPOs) it is evident that the issues within research question 1 and 2 are of particular interest in the SPC regime as they form a significant source of legal uncertainty.

Since the thesis is limited to the issues above, Regulation 1610/96 (on SPCs for plant products) and Regulation 1901/2006 (on paediatric use) - although mentioned - will not be the subject of analysis. Furthermore, exclusivity in the pharmaceutical sector is generally comprised of two forms of protection; one is protection through patents which - under some circumstances - can be extended by SPCs. This is the focus of this thesis. Another form of protection can be obtained through marketing and data exclusivity. These are outside the scope of this thesis and will only be briefly included in sections where it adds to the discussion. Since such regulatory aspects are outside the scope it follows that any issues pertaining to different types of Marketing Authorisations (MAs) according to Directive 2001/83 (on medicinal products for human use) are also not the subject of a thorough analysis.

Lastly, even though the outcome of the United Kingdom’s withdrawal from the European Union (popularly referred to as ‘Brexit’) and the destiny of the UPC Agreement can have a significant impact on the SPC regime, a thorough analysis of these elements will not be within the scope of this thesis.

1.3. Methodology

This thesis adopts a legal-dogmatic research method in order to access, identify and analyse the substance of current law. Proper and faithful use of the legal method require accurate use

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8 Max Planck Institute for Innovation and Competition 2018, page 173.
9 Ibid., page 128.
of legal sources. In attempting to answer the research questions of issue the relevant sources of law will be identified and their intricate meaning established. From this it is the ambition that *de lege lata* can be comprehensively described.

European and international legal sources will be drawn upon alongside case law from the Court of Justice of the European Union (CJEU) as the principal sources. With regard to the case law from the CJEU the analysis will primarily focus upon the reasoning and guidance from this Court in its rulings on preliminary references and in an auxiliary capacity on the national approach following such guidance. Thus, even though the regulation regarding European patent law acts in both a European- and national dimension this thesis will primarily focus on the European aspects. National aspects will only be included in an attempt to add to specific discussions.

When deemed expedient the thesis will include ancillary legal sources such as academic literature in the form of books, articles and reports written by prominent legal scholars and practitioners in the field of European intellectual property law and the life sciences. Furthermore, the Opinions of Advocate Generals (AG) in preliminary references will be drawn upon. In this context it is necessary to keep in mind that different legal sources should be ascribed different levels of precedential value. Note in this regard that AG Opinions have no binding effect on neither the CJEU nor national courts. However, they can add value to discussions of recent developments where the CJEU have yet to issue their rulings.

Some sections of the thesis will include a discussion in which the judicial policy method will be involved to a lesser extent in consideration of *de lege ferenda*. For this purpose, the thesis will consider the legal (un)certainty of the current regulation based on the problems, uncertainties and questions identified in the analysis.

### 1.4. Outline of the Thesis

The thesis will initially provide an overview of the legal context in which the SPC regime operates. In section 2 the focus will be on European patent law including some remarks on regulatory aspects in relation to MAs and in section 3 on the SPC regime itself.

Subsequently in section 4, the thesis will embark on the analysis of research question 1, while section 5 will focus on research question 2. In both sections relevant case law is analysed in chronological order. Cases will not be analysed to an equal extent since some can be considered incremental steps in the development while others represent bigger leaps requiring more in-depth analysis. On the basis of such analyses, section 4 and 5 will attempt to answer
the research questions. In closing of each of these sections a discussion on the status of the issue is presented.

Finally, section 6 will include an overall discussion of the current shape of the SPC regime and some final remarks.

2. Legal Context

SPCs can be classified as *sui generis* intellectual property rights whose existence presuppose the presence of a patent and an MA. These legal instruments are governed by provisions that are external to the SPC regime which makes the regime unique and highly intricate. The following sections will briefly give an account of European patent law and the MA procedure.

2.1. Preliminary Remarks on European Patent Law

Patent law has historically been highly influenced by globalisation and several international conventions have been enacted in an effort to ensure more uniform application of the law. This has had the effect that one needs to inspect a multitude of legal sources when trying to layout the patent law in its entirety. The purpose of this section is to provide only a brief overview of the legal landscape of importance in this thesis.

The period after the Second World War saw the emergence and development of the European patent regime with the draft of various conventions aimed at regulating intellectual property. Some of these conventions ensure a minimum level of protection, such as TRIPS\(^1\), while others streamline and centralise case administration, such as the European Patent Convention (EPC). The EPC entered into force in 1978 and with it the ‘bundle patent system’.\(^2\) The EPC almost exclusively govern the procedure relating to the granting of a patent and by and large not the substantive law related to the legal effects of patents.\(^3\) The exception to this is Art. 69 EPC, which establishes that the extent of protection is to be determined from the patent claims with descriptions and drawings assisting in interpretation of these claims.

\(^1\) Agreement on trade-related aspects of intellectual property (TRIPS)
\(^3\) Lindgreen, Nicolai; Schovsbo, Jens; Thorsen, Jesper, ‘Patentloven med kommentarer’, 2018, 2. udgave, Jurist- og Økonomforbundets Forlag, page 232. (Lindgreen et al. 2018)
2.2. What is a patent?

A patent is a right of limited-term monopoly (usually 20 years)\(^\text{16}\) which enables the proprietor to prevent all others from carrying out certain acts in relation to the invention protected within the territorial scope of the patent. Under the EPC it is possible to obtain a patent for inventions of any method or product that has a technical character. It is a requirement of patentable inventions that they must, by reason of this technical feature specifically, constitute a sufficient advance over the state of the art. The provisions governing the grant of patents are found in Articles 52-57 EPC and concern patentability, novelty, inventive step, industrial application and sufficient disclosure. It is worth noting that the EPC uses a first to file system in which it is the entity who applies for a patent first that inherits priority for a patent which naturally creates an incentive to file as soon as possible.

All EU member states have implemented the EPC into their national legal systems. An actor based in Europe wanting to apply for a patent currently has three different methods of doing so, but the result of all three current methods will invariably be one or more national patents. This in turn means that the rights conferred will be territorially delimited by the granting state and that so called European patents take effects as bundles of national patents regulated by national law.\(^\text{17}\) In spite of patent law historically being highly influenced by internationalisation the current European patent law regime is nevertheless left without the possibility of obtaining a single grant that confers equal and uniform protection throughout the EU member states. A system offering such a single grant is in the works with the UPC Agreement. However, when, and indeed if, the UPC Agreement will enter into force is uncertain at the time of writing due to a decision by the Constitutional Court in Germany rendering the conferment of sovereign powers on the UPC void and a recent rejection of participation by the United Kingdom.\(^\text{18}\) However, it is worth mentioning that if the UPC Agreement is ratified the UPC will eventually have exclusive jurisdiction in respect of all European patents as well as SPCs.\(^\text{19}\)

2.3. What is the Purpose of Patent Law?

The patent system can be described as a facilitator of a ‘social contract’ between society and inventors. As a ‘party’ to this contract inventors are provided with a limited-term exclusionary

\(^{16}\) E.g. TRIPS Article 33 and Article 63 EPC

\(^{17}\) Pila and Torremans 2016, page 116


\(^{19}\) Pila and Torremans 2016, page 236.
right in respect of new, inventive, and industrially applicable inventions. In exchange for this
grant of exclusionary right society gains disclosure of the working principle behind the invention
in patent specifications. 20

The primary problem that the patent system seeks to solve is the so called appropriability
problem which rests on a fundamental characteristic of innovation; the fact that initial discovery
may require substantial investment while capitalizing on the discovered knowledge afterwards
often times require considerably less effort. The entity capitalizing in such a way will not have
endured the high research and development (R&D) costs of discovery and hence would place
the researching entity at a competitive disadvantage. The rationale of the patent protection is
that such occurrences will discourage innovation, as without any legal mechanisms of
protection the inventor frequently cannot recover the R&D spending which increases the risk
associated with the investment thus having a negative effect on the net present value. 21

2.3.1. Patent Law in the Pharmaceutical Sector

The pharmaceutical industry is characterised by the balancing of some very important societal
interests with several critical stakeholders trying to achieve different objectives. The objectives
range from underpinning innovation to ensuring access to innovative and safe medicines as
soon as possible while keeping public expenditure under control by making sure those
medicines are affordable.

The supply side of the sector can be split into two types of companies. First, we have the R&D-
based companies (originator companies), who conduct research into new discoveries and
have a product portfolio that is largely patent-protected. Second, we have the so-called generic
companies who by and large produce and sell pharmaceutical products that have lost their
exclusivity. These products are generally sold at a much lower price than the original product,
since generic companies have not incurred the same heavy costs as the originator companies,
which helps contain public health budgets and ultimately benefits consumers. 22

The pharmaceutical industry is one of the most intensive users of the patent system and a
general tendency of a yearly increase in the amount of applications 23 and grants 24 can be
observed. Pharmaceutical development requires extensive R&D and furthermore time-

Law and Economics (Second Series), page 1-2. (Dam 1994).
22 The European Commission 2009, page 22-36. This division is becoming increasingly blurred in
practice and should not be interpreted rigidly. However, for the present purposes the division is useful.
23 Pila and Torremans 2016, page 123.
consuming and expensive clinical trials and pharmacovigilance. On top of the heavy costs associated with R&D in this sector only a fraction of potential pharmaceutical products make it successfully through the last stage of clinical trial and onto the market. In order to sustain incurring the losses associated with the failed results the products that make it to market must generate enough profit to cover the companies in relation to the failed investments.

Patent proprietors in this sector are facing a challenge given that several of their best selling products have come to or approached the end of their patent terms at a time when innovators are finding it increasingly difficult to develop new drugs to replace these ‘blockbuster’ drugs. Perhaps due to these challenges many companies have the last decade entered into a transitional phase observing, amongst other things, that a new point of attention could be patient-focused personalised medicines. Such transition is likely to make pharmaceutical companies more aggressive in their deployment of various patenting strategies by engaging in ‘evergreening’. ‘Evergreening’ is a term encompassing the myriad of ways in which patent proprietors use the patent law and related regulatory processes to extend their exclusionary rights. An example of such strategy would be applying for several patents in respect of the product (meaning the active ingredient or combination of active ingredients) which highlights another noteworthy aspect of the pharmaceutical industry; the concept of secondary patents. During the R&D process, innovating companies will typically file an initial patent application that is concerned with the active ingredient(s) itself. However, during later stages of the lifecycle, secondary patent applications will be made for other aspects of the active ingredient(s). This could be in the form of different dosage forms, particular formulations or for use in the treatment of a different indication.

Such secondary (or further) patents are often referred to as medical indication patents or second medical use patents as they cover a new use of existing active ingredients which can reside in the treatment of a new medical condition, a new mode of administration, a new patient group, a new dosage regime etc. Combine this with the increasing prevalence of

27 The European Commission 2009, page 33-34.
29 This term is widely used by stakeholders in the industry to delineate patents that from a time perspective follow the primary patent. No difference in quality or value is to be attributed to this term, cf. The European Commission 2009, page 14.
30 Ibid., page 51.
personalised medicine (medicine applicable to individuals of certain specific subgroups)\textsuperscript{32} and
the increasing relevance and importance of second medical use patents becomes evident.\textsuperscript{33}

Hence, the influx of personalised medicine has made second medical use patents one of the
most attractive forms of patent protection, which in turns means that SPCs on the basis of such
patents are highly valuable. This is the subject of analysis in section 5.

2.4. Market Authorisation

Since no positive rights of use are conferred by a patent, a person wanting to bring an invention
to the market will need a separate right to commercialize. Such a right is in the pharmaceutical
sector granted through a separate regulatory approval procedure laid out in the ‘Medicinal
Products Directive’\textsuperscript{34}, the ‘Clinical Trial Directive’\textsuperscript{35}, and ‘Veterinary Products Directive’\textsuperscript{36}. This
market authorisation (MA) regime allows patent proprietors to obtain an MA which is necessary
for them to sell their medicinal products on the market in EU member states.\textsuperscript{37} The MA process
seeks to ensure that only medicines that have a positive benefit-risk ratio as regards safety and
efficacy are placed on the market.

Detailed results of pharmaceutical tests, pre-clinical tests, and clinical trials must be submitted
for a new medicine amongst other information, cf. Medicinal Products Directive Art. 8. This
procedure can be very costly, and the MA regime is thus yet another important driver of costs
in the pharmaceutical industry. In this regard it should be mentioned that generic medicines
also require MAs, but applicants need not re-submit detailed test and trial results. The generic
companies simply need to show that the generic product is equivalent to a medicine previously
authorised as this will allow use of a so-called abridged application, cf. Medicinal Products
Directive Art. 10.\textsuperscript{38}

The combination of a first to file system, that incentivises entities to file a patent application as
soon as possible, with the lengthy and costly MA procedure as described above will create an

\textsuperscript{32} See more details in ‘1.5 Definitions’ above.
\textsuperscript{33} Bostyn 2016, page 35.
\textsuperscript{34} Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the
Community code relating to medicinal products for human use. (Medicinal Products Directive)
approximation of the laws, regulations and administrative provisions of the Member States relating to
the implementation of good clinical practice in the conduct of clinical trials on medicinal products for
human use.
Community code relating to veterinary medicinal products.
\textsuperscript{37} Medicinal Products Directive Article 6.
\textsuperscript{38} However, use of this procedure is only permitted once the originator company's data relating to the
pharmaceutical tests, pre-clinical tests, and clinical trials is no longer protected. Data and Market
Exclusivity is not within the scope of this thesis, cf. the delimitation section.
often lengthy gap in time between the grant of a patent and the right to commercialize products pertaining hereto. This creates a risk of negatively affecting innovation as originator companies are discouraged from investing in R&D with a more limited exclusionary time frame to try and recoup their investment. The SPC regime seeks to remedy this undesirable situation while balancing the interests of the stakeholders within the pharmaceutical sector.

3. The SPC Regime

This section seeks to give a brief overview of the SPC regime primarily focusing on matters of relevance to the scope of this thesis. The legal analysis in section 4 and 5 of this thesis depends, among other thing, on the background, raison d’être and legal objectives underpinning the SPC system.

3.1. Preliminary Remarks on SPCs

In Europe, the exclusivity stemming from a patent can last up to 20 years from the date of a patent application. As briefly alluded to above, the regulation of the pharmaceutical industry creates an environment in which the time between filing a patent application and access to the market can be significantly longer than in other sectors and has been identified to account for an average delay of more than 10 years.\(^{39}\) SPCs have been designed as a legal mechanism aiming to counter this tendency. Under the SPC system a medicinal product can be granted supplementary protection of up to five years after patent expiry.\(^{40}\) A more detailed account of how this duration is calculated will be given in section 3.4.

The legal basis of extension of the term of a patent can be found in Art. 63(2)(b) EPC which explicitly permits extension for products that require market approval.\(^{41}\) The latest regulation governing the actual SPC system is Regulation EC 469/2009 (the SPC Regulation). This regulation is a revised version of the first SPC regulation EC 1768/92\(^{42}\) (the First SPC Regulation) which entered into force in 1992 due to i.a. a concern that the situation of limited

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40 the SPC Regulation No 469/2009, art. 13.
41 One of the reasons for the creation of SPCs as a sui generis right was to avoid triggering a violation of the old art. 63(1) and (2) EPC since the legal basis referred to was not present when SPCs were initially introduced in Regulation No 1768/92. However, many saw this as a circumvention of the EPC which was then subsequently amended. For more on this see Max Planck Institute for Innovation and Competition 2018, section 3.3.2.2.
exclusivity could result in research centres and companies situated in the EU relocating to countries that already offered some mechanism of extension and thus greater protection.\footnote{Recitals of The First SPC Regulation. Same consideration is found in EC 469/2009 recital 6.}

3.2. Conditions for obtaining an SPC

In order to be eligible for an SPC, the SPC Regulation states in Art. 3 that the following conditions must be met:

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

This can be summarized as follows: The product must (a) be protected by a basic patent that is in force; (b) have been granted an MA somewhere in the EU; (c) not have been protected by an SPC before, and; (d) the MA must be the first authorisation in the EU to place the product on the market as a medicinal product. The four conditions have been the subject of a long series of cases considered by the CJEU. While few have questioned the appropriateness of SPCs in the effort of trying to compensate patent proprietors for the curtailing of their exclusivity period by the regulatory approval scheme, the case law of the CJEU has been the subject of considerable controversy. This might be a symptom of the complex nature of the SPC regime but also of the conciseness of the reasoning given in the decisions and the fact that the CJEU is not a specialised court.\footnote{Max Planck Institute for Innovation and Competition 2018, page 240.}

As mentioned, the research questions of this thesis pertain to two of these conditions: Art. 3(a) and Art. 3(d):

Article 3(a) is the subject of a long list of case law and has historically been one of the most contended provisions of the EU intellectual property regime.\footnote{Ibid., page 173.} However, as the analysis will
show this is not tantamount to a high degree of legal clarity. A need for more clear guidance is evident from the fact that industry actors perceive the provision as unclear.\(^{46}\)

Article 3(d) has led the CJEU to seemingly waver, not being able to conclusively decide on the issue in relation to SPCs for second and further medical uses. However, the influx of personalised medicines and second medical use patents makes it vital for industry actors to have a higher degree of legal certainty with regard to the possibilities of obtaining an SPC for new medical uses of active ingredient(s) authorised as a medicinal product.

3.3. Subject Matter and the Definition of ‘Product’

The SPC regime operates by requiring member states to establish a system for handling and deciding applications from a patent proprietor for the grant of an SPC as a follow on protection on the same terms as the original patent, but the protection conferred by an SPC only extends to the product covered by the MA.\(^{47}\) From this, two things should be noted: Firstly, this entails that SPCs are national IP rights issued by individual member states. Secondly, SPCs provide the same level of protection as the patent on which it is based but the scope is limited as an SPC only encompass the specific medicinal product and its use which is the subject of an MA. From this perspective it can be said that SPCs are not actually patent extensions as such but suffice to say that an SPC grants an exclusivity right that is narrower in scope but identical in nature to the patent right.

It follows from the SPC Regulation Art. 4 that the subject matter relates to the: ‘...product covered by the authorisation to place the corresponding medicinal product on the market...’. The question then becomes: What is the definition of ‘product’ in relation to medicinal products? Art. 1(b) establishes that ‘product’ means the active ingredient or combination of active ingredients of a medicinal product.’. This provision has, like Art. 3(a) and (d), been the subject of a string of CJEU case law. However, the question of what the meaning of ‘product’ is has now been settled to a great extent following C-431/04 (MIT), C-210/13 (GSK), and C-631/13 (Forsgren). In the latter it was held that: ‘...the term ‘active ingredient’... concerns substances producing a pharmacological, immunological or metabolic action of their own.’.\(^{48}\) From these cases it is evident that ‘product’ should be interpreted narrowly and that a excipient substance which is in itself not an active ingredient cannot be the basis of an SPC, even if this excipient has a beneficial therapeutic effect on the active ingredient, since this will not be

\(^{46}\) Max Planck Institute for Innovation and Competition 2018, page 35, 119 and 198.

\(^{47}\) the SPC Regulation, Art. 4.

\(^{48}\) C-631/13, pr. 25.
interpreted as being a ‘combination of active ingredients’. As it stands it is thus unlikely that most excipients, adjuvants, carrier proteins etc. will satisfy the holding from the Forsgren case by producing a pharmacological, immunological or metabolic effect of their own.

3.4. Duration

The EU legislator intended to build a system that would provide ‘adequate effective protection’. To achieve this purpose, the duration of an SPC was limited to a maximum term of five years after expiration of the patent. In addition, an upper limit of 15 years was set on the overall maximum protection to be enjoyed, determined from the time the medicinal product in question first obtained an MA to be placed on the market. The SPC period can thus be calculated as:

\[ SPC = (date \ of \ first \ MA - date \ of \ filing \ of \ the \ basic \ patent) - five \ years \]

With the constraint that an SPC can last for a maximum of five years.

To exemplify:

Having a patent with a filing date of 1 July 1995 and a date of first MA of 1 July 2003, subtracting the former from the latter would equal eight years. Subtracting five from this outcome results in three. Consequently, the SPC in this example would have a duration of three years. Using the formula above it looks like this:

\[ SPC = (1 \ July \ 2003 - 1 \ July \ 1995 = 8 \ years) - five \ years = three \ years \]

Another example can illustrate what happens when the time between filing of the patent and grant of MA is longer and the upper limit kicks in. This would e.g. happen if you have a patent with a filing date of 1 July 1995, as above, but then a later first MA of 1 July 2010:

\[ SPC = (1 \ July \ 2010 - 1 \ July \ 1995 = 15 \ years) - five \ years \]
\[ = 10 \ years \ (constraint \ kicks \ in) \]

In this example the SPC would have a duration of five years even though the output shows the result to be 10 years. This is due to the constraint that an SPC has a maximum duration of five years. The purpose of this is to give medicinal products an effective period of exclusivity comparable to other industries with less strict pre-marketing regulation while still balancing the

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49 However, the definition of ‘product’ in Art. 1(b) is of relevance in relation to Art. 3(d) which will be examined in section 5.

50 Technopolis Group 2018, page 38-39. This question becomes relevant to the analysis of the Apax case in section 5.

51 Recital 9 of the SPC Regulation No 469/2009 (also referenced in the First SPC Regulation No 1768/92)
interests of other stakeholders. The duration of effective legal protection can then be illustrated as follows in illustration 1:

*Illustration 1*

Patent protection (blue line) is declining with time since each year before launch implies one year less of protection on the market. SPCs (red line) provide no additional protection for products that take less than five years before marketing due to the mechanism described above. Furthermore, if the first MA is granted at least ten years after the first patent application, SPC is automatically obtained for five years, creating a kink in the curve.

Additionally, EU lawmakers recognised an unmet need for effective and safe paediatric drugs. This resulted in the possibility of obtaining a paediatric extension of six months to the SPC, cf. the SPC Regulation Art. 13(3) and the Paediatric Regulation. A paediatric extension can only be granted to an existing SPC. This can result in an incentive for seeking an SPC even if the calculated duration will be negative. The CJEU applied a teleological interpretation in MSD C-125/10 in holding that SPCs with a negative duration may be granted.

It follows from this that a paediatric extension is of use if the negative duration of an SPC is not more than six months. As stated in the delimitation, this thesis will not go more in depth with the issues revolving around paediatric extensions. However, the result of the MSD case is

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52 Max Planck Institute for Innovation and Competition 2018, page 22.
53 And also for drugs to treat rare and orphan diseases which falls outside the scope of the thesis entirely.
55 MSD, C-125/10, pr. 37-38.
interesting and interlinked with the scope of this thesis since it highlights a teleological interpretation by the CJEU, a common theme which we will revisit in the next sections.

4. When is a Product Protected by the Basic Patent in Force?

The requirement under the SPC Regulation Art. 3(a) states that ‘the product is protected by a basic patent in force’. This deceptively simple statement has been the subject of several requests for preliminary rulings by the CJEU and continues to be so despite guidance having been sought repeatedly since the SPC Regulation entered into force. Couple this with the fact that many stakeholders in the pharmaceutical industry perceive the case law on Art. 3(a) as unclear and it suggests that the CJEU has failed to provide sufficiently clear guidelines on the applicable criteria under Art. 3(a). However, such failings cannot be ascribed to the CJEU taking a static approach to the problem since the jurisprudence of the CJEU has undergone a continuous transformation through the years. The purpose of this section is to analyse the cases of significance in the case law revolving around Art. 3(a) and using this as a basis for answering the question: When is a product protected by the basic patent in force?

4.1. The Cornerstone Cases Pertinent to Article 3(a)

4.1.1. Farmitalia Stage

The Farmitalia (C-392/97 of 16 September 1999) case can be seen as the foundation for the rest of the CJEU jurisprudence relating to Art. 3(a) and the concept of the product being ‘protected by the basic patent’. In the following the thesis will examine this case along with the developments following in its wake.

4.1.1.1. Facts & Analysis

The request for preliminary ruling came from the Federal Supreme Court in Germany. Farmitalia had obtained a patent for the active ingredient idarubicin, in which the claims specifically covered idarubicin hydrochloride, as well as an MA for medicinal product ‘Zavedos’ with idarubicin hydrochloride as the active ingredient. When applying for SPCs at the German Patent and Trade Mark Office on this basis Farmitalia were granted their ancillary request of an SPC 'for the medicament Zavedos containing as its active ingredient idarubicin

56 Max Planck Institute for Innovation and Competition 2018, page 118-119.
57 Farmitalia, C-392/97, pr. 6-8.
hydrochloride' while the SPC primarily sought ‘for idarubicin and salt thereof including idarubicin hydrochloride’ was denied. On appeal to the German Federal Patent Court this SPC request was again denied, the reason being that the SPC was not directed to the specific form of the substance for which the MA was granted, but to any forms of that substance (cf. ‘salt thereof’). The Federal Patent Court further found that salts of idarubicin could not be granted an SPC under the circumstances, since it was not within the subject matter of the protection conferred by the patent concerned.

The SPC Regulation Art. 3(a) was hereby brought in issue. The CJEU made rather quick headway in holding that in order to determine whether a product is protected by a basic patent, reference must be made to the rules which govern that patent. The Court reached this result by reasoning that the absence of central EU provisions regarding the determination of the scope of protection made interpretation with reference to the national rules which govern the patent necessary. It was thus established that the non-EU rules of patents were decisive when determining the criteria for the concept of the product being protected by the basic patent. However, this was merely a minor clarification for industry actors since the case did not clarify which rules one would then need to apply. The CJEU refrained from giving clarification on this, despite the referring court asking explicitly: ‘Is the wording of the claim for the basic patent or the latter’s scope of protection the determining criterion?’ This question highlights two schools of interpretation which is the subject of the following section.

4.1.1.2. Infringement Test or Disclosure Test?

There are fundamentally two tests that have been debated in relation to the question of what is protected by a patent: the ‘Infringement Test’ and the ‘Disclosure Test’.

A) The Infringement Test

Under the approach of the Infringement Test, the product is protected by the basic patent if it falls under the subject matter of protection of the patent in question pursuant to Art. 69 EPC and corresponding domestic provisions. Such interpretation is determined from the familiar concept of ‘protection’ from patent law. This approach is the broadest of the two and therefore the most generous in terms of allowing the grant of SPCs. A patent claim of a composition comprising A would render any combination with A (i.a., A+B or A+B+C etc.) an infringement

58 Farmitalia, C-392/97, pr. 9.
60 The case also referred questions relating to the SPC Regulation Art. 3(b).
61 Farmitalia, C-392/97, pr. 27 and 29.
62 Ibid., pr. 26-27.
63 Ibid., pr. 16(2).
of the basic patent in force protecting A, simply from the fact that all combinations contain A. This approach will thus entail that an SPC applicant would be granted an SPC for any combination of A with X, Y, Z since all of these combinations would constitute an infringement. See illustration 2 further below.

B) The Disclosure Test

This approach entails that only what is disclosed in the patent is protected by the basic patent within the meaning of Art. 3(a). The Disclosure Test is best viewed as an additional requirement to the Infringement Test. This follows from the fact that under the Disclosure Test a product must first fall under the scope of protection of the patent in order for it to be eligible for an SPC. Hereinafter, the requirement of disclosure sets in. From this it can be construed that the Disclosure Test must be more restrictive. The basic idea is that the right of exclusivity should not be wider in scope than the original innovation in the basic patent. Under this approach, if the basic patent claims the active ingredient A, and an MA is obtained for A+B, only A will be protected by the patent and an SPC cannot be granted for A+B since that would exceed the scope of the protection. It follows that this approach is favourable to generic companies since an originator company may find itself in a situation in which a patent has been granted for active ingredient A, after which the company conducts further research resulting in the development of an MA for a medicinal product based on combination product A+B. The fact that B may not be disclosed in the basic patent could very well preclude the originator from obtaining an SPC for the combination product which arguably does not seem to be in line with the purpose of the SPC Regulation. However, the Disclosure Test can also lead to less restrictive conclusions as will be evident in further case law analysis.

Illustration 2:

<table>
<thead>
<tr>
<th></th>
<th>Basic Patent</th>
<th>SPC</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infringement Test</td>
<td>A</td>
<td>- A</td>
<td>- SPC granted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- A+B+ [...] X+Y+Z</td>
<td>- SPC granted</td>
</tr>
<tr>
<td>Disclosure Test</td>
<td>A</td>
<td>- A</td>
<td>- SPC refused</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- A+B+ [...] X+Y+Z</td>
<td></td>
</tr>
</tbody>
</table>

The CJEUs rather ambiguous holding of ‘reference must be made to the rules which govern that patent’ in the Farmitalia case has prompted debate over which of the two tests the CJEU

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65 Max Planck Institute for Innovation and Competition 2018, page 211.
66 Ibid., page 411.
follows. Some hold that since the wording refers to the rules that govern ‘the patent’ this clearly suggests that the Infringement Test is followed. This conclusion is reached based on the notion that the Infringement Test relates to patent law while the Disclosure Test relates more strongly to regulatory law. However, there are strong counterarguments to this position i.a. the fact that an infringement is not carried out by a product but rather by an act performed by a person in relation to a product. It can therefore be argued that it would be erroneous to apply the national rules that define what amounts to an infringement when trying to determine whether a product is protected by the basic patent in force, as these rules generally confer on its proprietor the right to prevent third parties from committing certain acts. It stands to reason that such acts cannot be performed by a product alone.

However, both tests are defensible and have each their pros and cons. A conclusion of which test the CJEU had in mind in Farmitalia based on this ruling alone seems premature, especially since the CJEU had the opportunity to select one of the two tests (remember that it was a part of the referred question) and it could be that they deliberately chose not to do so. The thesis will return to consider the two tests again when relevant in the analysis of further case law.

4.1.2. Medeva Stage

The next stage of the CJEU’s attempt to clarify what is protected by a basic patent is marked by the Medeva case C-322/10 of 24 November 2011. The case was joined with another, Georgetown University C-422/10, for the purposes of the oral procedure, but subsequently disjoined for the purposes of the judgement. There were two separate questions in the case; one relating to the SPC Regulation Art. 3(a) and another relating to Art. 3(b). The issue of relevance in the present section relates to a discrepancy between the products claimed in the patent (in this instance a method claim) and the products claimed in the SPC application.

4.1.2.1. Facts & Analysis - Medeva C-322/10

The facts of the case concerned Medeva’s SPC applications directed to vaccines. Vaccines are highly technical and they make up a special case since they mostly contain a mixture of a variety of active ingredients. They are thus almost always combination products containing

68 See Justice Arnold in Teva UK Ltd & Ors v Gilead Sciences Inc [2017] EWHC 13 (Pat) (13 January 2017), pr. 37. This case has since been the subject of a preliminary ruling by the CJEU in Case C-121/17 which will be discussed in section 4.1.4.
69 Medeva, C-322/10, pr. 18.
70 The issue in Georgetown University C-422/10 related only to the SPC Regulation Art. 3(b) which is why Medeva is the focus in the present section.
several active ingredients. Furthermore, it is frequently necessary to adapt vaccines to either
1) the evolution of an infection or 2) recommendations and requirements from competent
authorities. Consequently, situations will often occur where the basic patent does not, indeed
cannot, claim all the variations in the composition of vaccines necessary to permit the grant of
an SPC given the above-mentioned externalities.\textsuperscript{71}

Medeva applied for five SPC applications on the basis of their patent claiming a method for the
preparation of a vaccine against Bordetella pertussis (whooping cough agent). The end
product consisted of the active ingredients pertactin (A) and filamentous haemagglutinin (B) in
a ratio such as to provide a synergistic effect in vaccine potency.\textsuperscript{72} In support of the
applications, Medeva submitted MAs for a range of medicinal products each of which
contained, in addition to the combination of A and B, between eight and eleven other active
ingredients. Four of Medeva’s five SPC applications pertained to the question of Art. 3(a) since
they were rejected by the UK-IPO\textsuperscript{73} on the basis that they included more products than the
basic patent.

On appeal, six questions were referred to the CJEU, five of which related to Art. 3(a). Once
again, the question of what is meant in Art. 3(a) by ‘the product is protected by a basic patent
in force’ and ‘what are the criteria for deciding this’ came before the Court. Reference was
made to the Farmitalia rule stating that in the absence of a harmonized EU rule set, the extent
of protection can only be determined from national rules. In relation to this the Court remarked
that the SPC Regulation creates a uniform EU approach which should serve to prevent the
heterogeneous development of national laws.\textsuperscript{74} After this, the CJEU stated what has come to
be known as the Medeva rule:

\begin{quote}
‘It follows that Article 3(a) of the regulation precludes the grant of an SPC relating
to active ingredients which are not specified in the wording of the claims of the
basic patent.’\textsuperscript{75} [emphasis supplied]
\end{quote}

It was stated that these conclusions are supported by the second subparagraph of pr. 20 of
the Explanatory Memorandum to the SPC Regulation\textsuperscript{76} (the Explanatory Memorandum), which
in the context of what is protected by the patent refers exclusively to the claims of the patent.

\textsuperscript{71} Brückner 2015, page 247-251, notes 89-97.
\textsuperscript{72} Medeva, C-322/10, pr. 13.
\textsuperscript{73} The Intellectual Property Office of the United Kingdom.
\textsuperscript{74} Medeva, C-322/10, pr. 22-23.
\textsuperscript{75} Ibid, pr. 25.
\textsuperscript{76} The explanatory memorandum to the proposal for Council Regulation (EEC) of 11 April 1990
concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101
final) (the Explanatory Memorandum)
As mentioned, the Medeva case concerned a vaccine composed of a combination product which might have some characteristics that could make an assessment of such different to that of a single compound. The Court did not give an explicit answer on whether or not further or different criteria for determining what is protected by the patent is needed when dealing with combination products and vaccines. However, the CJEU chose to answer all the questions related to Art. 3(a) in conjunction which speaks to the reasoning and operative part of the judgement being of general application, i.e. the criteria are no different; one must always take reference to what is specified in the wording of the claims. This is also the holding in the AG Opinion to the case.\(^77\)

With the holding of the CJEU, the rejection decided by the UK-IPO was confirmed since Medeva had more active ingredients specified in their applications for SPCs than were identified in the wording of the claims of the basic patent and they were therefore not protected by the basic patent under Art. 3(a) of the SPC Regulation. The situation can be illustrated as follows:

<table>
<thead>
<tr>
<th>Basic patent claims</th>
<th>MA claims</th>
<th>SPC claims</th>
<th>Allowed under Art. 3(a)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A+B</td>
<td>A+B+C</td>
<td>A+B+C</td>
<td>Not allowed</td>
</tr>
</tbody>
</table>

This interpretation from the CJEU adopts the Disclosure Test. The reason being that had the Court opted for the Infringement Test a patent claiming A could serve as a basic patent for an SPC comprising A+B. However, the ruling does not settle all difficulty of interpretation. It can be argued that the statement of ‘specified in the wording of the claims’ both clarifies and obscures the SPC landscape. It gives guidance towards reference to the wording of the patent claims being necessary but at the same time the guidance becomes an issue of its own; how should ‘specified’ be interpreted? Case law following the Medeva case sets the stage for attempting to answer this question.

4.1.2.2. In the wake of Medeva

A collection of orders delivered by the CJEU in close connection with Medeva answers further Art. 3(a) questions. The decisions were given by reasoned order because the CJEU determined that the referred questions were, for all essential purposes, answered by the

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\(^77\) Opinion of Advocate General Trstenjak, Cases C-322/10 and C-422/10, pr. 125(2).
judgment in Medeva. The following will provide some concise case briefs with a focus on the CJEU’s conclusions and their implications.

**Yeda case - C-518/10**

The Yeda case of 25 November 2011 ruled on the situation where an SPC application covers one active ingredient (e.g. A), while the patent claims only specify A in combination with another active ingredient (A+B). The CJEU ruled by reasoned order that:

“Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting an SPC where the active ingredient specified in the application, even though identified in the wording of the claims of the basic patent as an active ingredient forming part of a combination in conjunction with another active ingredient, is not the subject of any claim relating to that active ingredient alone.”[emphasis supplied].

As emphasised above the CJEU did not use the wording ‘specified’ in the claim as in the Medeva case. Instead, they referred to ‘identified in the wording of the claims’ and ‘the subject of any claim’. Going forward it should be noted that the CJEU in the Yeda case used the word ‘identified’ to say that product A might be ‘identified’ as a part of the combination product but this is not sufficient to make A satisfy the requirements in Art 3(a) since it does not make A ‘the subject of any claim’. It could be claimed that this wording was chosen to underline a distinction between the words ‘specified’ and ‘identified’ or that the introduction of ‘subject of any claim’ meant a deviation from the wording of ‘specified in the wording of the claims’ as used in Medeva. However, the Court did not elaborate on why such specific wording was used nor on whether or not a departure from Medeva was intended. Still, given the continuous reference to the Medeva case and the decision by reasoned order it must be assumed that, for all intents and purposes, the answer should be interpreted as in alignment with that of Medeva. The answer with regard to Art. 3(a) can be illustrated as follows:

**Illustration 4:**

<table>
<thead>
<tr>
<th>Basic patent claims</th>
<th>MA claims</th>
<th>SPC claims</th>
<th>Allowed under Art. 3(a)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A+B</td>
<td>A</td>
<td>A</td>
<td>Not allowed</td>
</tr>
</tbody>
</table>

78 The answer was already ascertained in Medeva C-322/10, pr. 26.
79 Yeda C-518/10, pr. 39.
80 Ibid., pr. 24, 31, 34-38.
University of Queensland case - C-630/10
This C-630/10 case of 25 November 2011 concerned vaccines just as Medeva did. The MAs concerned were obtained for a variety of different HPV type active substances. Just as in Medeva, the MAs and the SPC application contained combinations that were not in the same constellation as claimed in the patent, e.g. A+B+C with the patent claiming A+B.81 Once again by reasoned order, the CJEU ruled:

“Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting an SPC relating to active ingredients which are not identified in the wording of the claims of the basic patent relied on in support of the SPC application.” [emphasis supplied].

The answer was thus the same as the one given in Medeva, but this time the Court used the wording ‘identified’ instead of ‘specified’ without going into detail as to whether or not such difference in the wording was intended to constitute a legal significance or not.

Daiichi case - C-6/11
Another case decided on 25 November 2011 by reasoned order one day following the Medeva decision. Daiichi Sankyo had their SPC applications refused on the ground that the product concerned - the active ingredients olmesartan medoxomil and hydrochlorothiazide - was not protected by the basic patent held by Daiichi Sankyo, because that patent disclosed only the ingredient olmesartan medoxomil, not that active ingredient in conjunction with one or more active ingredients.82 The CJEU ruled in exactly the same manner and wording as in the University of Queensland case above. That is to say they once again used ‘identified’ instead of ‘specified’.

In sum, the CJEU did not explain whether any meaning should be ascribed to the different uses of ‘specified in the wording of the claims’ or ‘identified in the wording of the claims’. Before moving on to the next stage of case law regarding the SPC Regulation Art. 3(a) an analysis of whether any legal significance is vested in the differing use of ‘specified’ and ‘identified’ will follow.

4.1.2.3. Legal significance of ‘identified’ vs. ‘specified’

The rather peculiar situation in which the CJEU determined that the referred questions were answered by the judgment in Medeva, and therefore chose to deliver a verdict by reasoned order, but then used a slightly different wording in its conclusions, is the subject of this section.

81 University of Queensland - Case C-630/10, pr. 15-19.
82 Daiichi Sankyo - Case C-6/11, pr. 18.
This interim discussion is carried out before moving on to more recent case law since it is appropriate to know the point of departure of the CJEU during subsequent reasonings.

On the one hand, one would think that the CJEU is highly meticulous in its choice of words and conscious about being consistent in this regard in order to avoid unintended consequences. At *prima facie* a natural interpretation of ‘identified’ versus ‘specified’ seems to suggest some degree of difference; the former meaning ‘*to recognize something and say or prove what that thing is*’ with the latter meaning ‘*to explain or describe something clearly and exactly*’. This would indicate that the use of ‘identified’ entails a more lenient approach. Furthermore, the Yeda, University of Queensland and Daiichi cases were all decided only one day after Medeva. This could suggest that a simple lapse or inaccuracy should be less likely, especially with regard to the University of Queensland and Daiichi cases where the conclusions were identical except for ‘specified’ being replaced with ‘identified’. Such inaccuracy seems more peculiar considering that the Court was composed of the same judges in all instances.

However, the above is open to counter arguments as there are also sound objections against the CJEU wanting to depart from the Medeva ruling. It could be argued that if indeed the Court, composed of the same judges, in the subsequent cases had realized some sort of deficiency in the use of the word ‘specified’ and wanted to rectify this by using the word ‘identified’ then they would have done so explicitly as to alleviate any confusion and ensuing legal uncertainty. It would also seem to run counter to the very idea of a decision by reasoned order, which is used to confirm previous case law under circumstances that are for all intents and purposes the same. To change a test set out by the Court merely one day after its introduction by reasoned order does not harmonize very well with this idea.

When assessing the meaning of words in an EU legal context due regard can be had to other language versions. In the table below the wording of Medeva, Daiichi and Queensland are compared while Yeda is omitted due to the conclusion not being (almost) identical to the one from Medeva:

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84 Recall that in the Yeda case it was used slightly different with the “...not the subject of any claim relating to that active ingredient alone” added in closing.

85 All composed of: J.-C. Bonichot, President of the Chamber, A. Prechal, L. Bay Larsen, C. Toader (Rapporteur), and E. Jarašiūnas.

Table 1:

<table>
<thead>
<tr>
<th>Case</th>
<th>English</th>
<th>Danish</th>
<th>German</th>
<th>French</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medeva</td>
<td>Specified</td>
<td>Fremgår</td>
<td>Genannt</td>
<td>Mentionnés</td>
</tr>
<tr>
<td>Queensland</td>
<td>Identified</td>
<td>Fremgår</td>
<td>Genannt</td>
<td>Mentionnés</td>
</tr>
<tr>
<td>Daiichi</td>
<td>Identified</td>
<td>Fremgår</td>
<td>Genannt</td>
<td>Mentionnés</td>
</tr>
</tbody>
</table>

The table above clearly shows that the translations of the cases does not ascribe any material difference to the meaning of ‘specified’ compared to ‘identified’.

In light of the above, it must be concluded that the case law following Medeva developed and confirmed that the test for Art. 3(a) is that the active ingredient must be ‘identified’ or ‘specified’ in the wording of the claims with no substantial difference between these two words being intended. However, the cases did not provide much in terms of general indication of how this test could be applied. Further developments followed in the Eli Lilly and Actavis cases.

4.1.3. Eli Lilly & Actavis Stage

The Eli Lilly case C-493/12 concerned a single product and not a combination as Medeva and its progeny.

4.1.3.1. Facts & Analysis - Eli Lilly C-493/12

Human Genome Sciences (HGS) owned a patent which related to the discovery of a new protein, Neutrokine alpha (A). The patent both disclosed and claimed that protein, and also related to antibodies that bind specifically to A. Because of the way A acts, antibodies that bind specifically to it may inhibit its activity and be useful in the treatment of autoimmune diseases. The patent included claims related to antibodies that specifically binds to A; these did not disclose the structure of any of the antibodies, but they described procedures for the development of the antibodies.

Eli Lilly wished to market a medicinal product containing an antibody (A+) that bound to A. It was undisputed that if Eli Lilly marketed this medicinal product before the expiry of HGS’s patent the antibody contained in the medicinal product would infringe the patent. Faced with this realization, Eli Lilly brought an action for a declaration that any SPC relying on HGS’ patent

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87 Eli Lilly - Case C-493/12, pr. 12.
89 Eli Lilly - Case C-493/12, pr. 14-15.
and based on an MA for a medicinal product containing the antibody A+ would be invalid. Hence, their argument was that A+ was not covered by the basic patent within the meaning of the SPC Regulation Art. 3(a) by reason of HGS’s patent being too broadly formulated for it to be possible for that antibody to be considered as being ‘specified’ or ‘identified’, for the purpose of the Medeva test. It was raised that in order for A+ to be regarded as covered by the basic patent the patent would have to claim a structural definition rather than claiming A+ by its function of binding to A. This is particularly important for antibodies. Antibodies are rarely, if ever, claimed in terms of the structural characteristics. HGS counter argued that its form of claim was standard and that it was routinely granted by the European Patent Office (EPO) while it also had been held valid in proceedings both before the EPO and in the UK.

On the question of whether an active ingredient must be identified in the claims of the patent by a structural formula, or whether the active ingredient may also be claimed by a functional formula for the purpose of being protected by the basic patent as defined in Art. 3(a), the Court ruled that a functional definition may be sufficient. To this it added the requirement that the claims under such circumstances must: ‘relate, implicitly but necessarily and specifically, to the active ingredient in question.’ In this regard, the Court held that it must be possible to do so on the basis of the claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the EPC and the Protocol on the interpretation of that provision.

In reaching its decision, the CJEU had some interesting reasonings. For one, it referenced the Medeva case and the requirement of ‘specified’ in the claims of a basic patent in paragraph 34, but then subsequently cited this paragraph in stating that an active ingredient which is not ‘identified’ in the claims of a basic patent cannot be considered protected by a basic patent. This seems to confirm the conclusion above that no material difference should be ascribed to the usage of ‘specified’ compared to ‘identified’. Furthermore, the Court once again stressed the importance of the patent claims with reference to the Explanatory Memorandum and Art. 69 EPC. The Court also seemed to abandon the Infringement Test, at least in its pure form, and instead align itself with the Disclosure Test. This is evident from paragraph 33:

90 Eli Lilly - Case C-493/12, pr. 16-17.
91 Technopolis Group 2018, page 42.
92 Eli Lilly - Case C-493/12, pr. 20.
93 Ibid., pr. 44.
94 Ibid., pr. 44.
95 Ibid., pr. 34 cf. pr. 38.
96 Ibid., pr. 35.
‘for the purpose of determining whether a product is ‘protected by a basic patent in force’ within the meaning of Article 3(a) of Regulation No 469/2009, recourse may not be had to the rules governing infringement proceedings’.

The CJEU further remarked that whether an action may be considered an infringement ‘is not a crucial factor’ in determining whether an active ingredient is protected by a basic patent. This is an emphasis of the disassociation from the Infringement Test.

With its holding in this case it is apparent that the CJEU added another layer to the intricate interpretational guidelines relating to the SPC Regulation Art. 3(a). It is evident that an unclear definition such as ‘relate, implicitly but necessarily and specifically’ is prone to bring along some degree of legal uncertainty. However, one can appreciate what the Court is struggling with since it does not have jurisdiction to interpret the provisions of the EPC. This makes it a difficult task to provide detailed guidance to the referring court. Thus, as the SPC regime is currently configured the final interpretation will be left to the individual member states. This is another possible source of disharmonization which in turn can result in legal uncertainty for cross-border industry actors. Nevertheless, when outlining a general purpose guidance, the CJEU does have more room for manoeuvring than what they tend to make use of in this legal area. The conciseness of the CJEU judgements can in this regard be criticised as they are relative short which is generally in stark contrast to the related AG Opinions.

Another source of ambiguity was added by the CJEU in considering that refusal of an SPC could be justified from a more teleological and purpose-oriented approach. It was argued that the holder of a patent - following the grant of the patent - can make it possible to clearly and specifically ascertain the active ingredient that may be brought to market by carrying out more in-depth research, if it is not already possible to ascertain this from the patent as granted. It was thus suggested that evidence of such research could qualify the patent to serve as a basis for an SPC. Evidence could take the form of a subsequent divisional patent specifically identifying the product, as argued by The French and Latvian Governments. Moreover, it could be the grant of an MA to the patent holder for the specific product. The CJEU reasoned that failure to provide evidence of research efforts that make it possible to ascertain clearly the active ingredient would mean that the holder in question had not made

97 Eli Lilly - Case C-493/12, pr. 37.
98 Ibid., pr. 40.
99 Ibid., pr. 43.
100 Ibid., pr. 27-28.
101 Ibid., pr. 43, according to which the absence of an MA for a specific product is taken as an indication of failure to take any steps to carry out more in-depth research in pursuit of identification of this product.
any investment in research relating to the clear identification of a product that makes it to market, which in turn would undermine the objective of the SPC Regulation as referred to in recital 4 in the preamble thereto.\textsuperscript{102} In this regard it should be kept in mind that the SPC Regulation does not discriminate between different stages or forms of research according to the Explanatory Memorandum paragraph 29:

\textit{‘The proposal does not provide for any exclusions. In other words, all pharmaceutical research, provided that it leads to a new invention that can be patented…must be encouraged, without any discrimination…’}\textsuperscript{103}

Besides the fact that it is essential for society and for the relevance of the SPC Regulation that research and innovation reach the end consumer in the form of a medicinal product, nothing seems to suggest that the SPC Regulation is designed primarily to reward the resources devoted to developing such medicinal products for the market.\textsuperscript{104} Such holding would also place an undue burden on NPOs in trying to determine to what extent work done at one phase has any value in developments at a later stage. In consideration of the fact that NPOs are already strained with the work in relation to the SPC regime this cannot have been the intention of the CJEU.\textsuperscript{105}

This teleological approach is interesting as it seems to alter the Medeva test; it could entail that an SPC can be granted, even when the basic patent does not meet the requirement of ‘specified’ in the claims, as long as the holder has taken subsequent further steps to carry out more in-depth research to ascertain the product concerned on the basis of which the SPC is applied for. However, it can be questioned with some merit whether such considerations have any bearing with regard to Art. 3(a) and what is considered to be ‘protected by the basic patent in force’. This provision concerns the circumstances in which the basic patent can serve as the basis for an SPC. The assessment in this regard is whether a product is or is not protected by the patent. To involve an element of later research, whether manifested by subsequent patents or the obtainment of an MA, seems erroneous. It can be argued that the Court has answered a question more pertinent to the question of who can obtain and SPC, rather than the circumstances in which an SPC can be granted. However, such issue of ownership of an MA is more suitable for consideration under the SPC Regulation Art. 3(b).\textsuperscript{106}

\textsuperscript{102} Eli Lilly - Case C-493/12, pr. 43.  
\textsuperscript{103} The Explanatory Memorandum pr. 29.  
\textsuperscript{104} This issue of what kind of research the SPC Regulation is intended to incentivise is analysed more in-depth in section 5.2.3.2.  
\textsuperscript{105} Max Planck Institute for Innovation and Competition 2018, page 127.  
\textsuperscript{106} This issue is outside the scope of this thesis. For more on this see Jens Schovsbo et al., ‘Reap what you sow! – But what about SPC squatting?’, 2018, Journal of Intellectual Property Law & Practice, Vol. 13, No. 7.
The Eli Lilly case seems to open as many questions as it closes. What it does answer is the issue of substances that are only claimed in functional terms instead of structural terms. It was held that active ingredients covered by such claims are not precluded from being granted an SPC, as long as it is possible to reach the conclusion that these claims ‘relate, implicitly but necessarily and specifically, to the active ingredient in question’. Moreover, the Court finally identifies the specific rules it has in mind when referencing the non-EU rules governing patents as being the rules relating to the extent of the invention covered by the patent i.e. Art. 69 of the EPC and the Protocol.

However, these conclusions open new alleys of interpretation. The wording of the judgement along with the reference to the EPC seems to suggest that an SPC may be based on an active ingredient claimed by its function on the condition that the person skilled in the art necessarily understands such claim to relate specifically to this active ingredient. It could thus be asked: ‘does the skilled person read this specific active ingredient automatically into the claim?’

However, the legal uncertainty in this regard is underscored by the fact that the referring court, with Mr. Justice Warren presiding, interpreted the ‘relate, implicitly but necessarily and specifically to the actual active ingredient’ only to relate to combinations claimed by general wording serving to extend a claim, e.g. ‘comprising of’, but also that those words reflect, in the context of a functional definition, no more and no less than the words ‘specified’ or ‘identified’ in the case of a structural definition where the claims have a focused scope and the question according to Mr. Justice Warren is simply whether the product falls within the scope of the claims. However, this test is arguably an Infringement Test with an added proviso which the CJEU rejects.

4.1.3.2. Facts & Analysis - Actavis I & II C-443/12 & C-577/13

Further developments came with the Actavis I & II cases. The factual scenarios of relevance for this thesis were similar and the cases will thus be examined together. The questions referred revolve around both Art. 3(a) and Art. 3(c); the section at hand will focus on the arguments and issues relevant to the SPC Regulation Art. 3(a) which in this case will also entail some issues pertaining to Art. 3(c).

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107 Eli Lilly - Case C-493/12, pr. 44.
108 Ibid., pr. 32.
111 Kalden 2015, page 127.
112 Actavis v Sanofi C-443/12 and Actavis v Boehringer Ingelheim C-557/13
Actavis I

In this case, Sanofi had a patent claiming the active ingredient irbesartan (I), but also claimed that active ingredient in association with an undisclosed diuretic. MAs had been obtained for both the single active ingredient I as medicinal product ‘Aprovel’ and the combination of I with hydrochlorothiazide (H), which is a well-known and off-patent diuretic, as medicinal product ‘CoAprovel’. Sanofi further obtained two SPCs; the first one issued for I and the second one issued for the combination I+H, expiring about one year later. Actavis intended to market generic versions of both ‘Aprovel’ and ‘CoAprovel’ and accordingly challenged the validity of the second SPC. It was mutually understood that Actavis would infringe the second SPC in the event that it was valid.

Actavis II

In this case the situation was much the same in the way that an applicant, this time Boehringer Ingelheim, first filed an SPC for an active ingredient Telmisartan (T) that was protected by a basic patent. T was contained and marketed in the medicinal product ‘Micardis’ and an SPC was consequently granted. Afterwards an MA was obtained for a combination of T with hydrochlorothiazide (H) in medicinal product ‘MicardisPlus’. On the basis of this second MA for T+H, Boehringer requested an SPC for this combination. The facts of the two cases can be summed as follows:

Illustration 5:

<table>
<thead>
<tr>
<th>Basic patent</th>
<th>MA</th>
<th>SPC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Actavis I</strong></td>
<td>I and I+H</td>
<td>1. Aprovel (I)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. CoAprovel (I+H)</td>
</tr>
<tr>
<td><strong>Actavis II</strong></td>
<td>T and T+H</td>
<td>1. Micardis (T)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. MicardisPlus (T+H)</td>
</tr>
</tbody>
</table>

A difference in the factual scenarios can be identified in the wording of the claims. In Actavis I the claim that encompassed H was worded as: ‘a pharmaceutical composition containing irbesartan in association with a diuretic’. Meanwhile, Boehringer’s basic patent in Actavis II

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113 Actavis I C-443/12, pr. 11.
114 Ibid., pr. 13-14.
115 Ibid., pr. 16.
116 Actavis II C-557/13, pr. 10-11.
117 Ibid., pr. 12.
118 Actavis I C-443/12, pr. 11.
related to $T$ alone and to one of the salts thereof.\textsuperscript{119} On this latter account the UK-IPO indicated via letter that an SPC could not be granted for a combination not clearly claimed in the patent and thus suggested that Boehringer amended their patent to insert a claim to $T+H$ which was subsequently done.\textsuperscript{120}

**Analysis**

With regard to Actavis I, the CJEU did not provide much guidance with respect to the SPC Regulation Art. 3(a), since the question of whether $H$ was specified/identified by the claim to a diuretic was not answered; it was deemed unnecessary in light of the Court’s answer to question 2, which the CJEU dealt with on the basis of Art. 3(c).\textsuperscript{121} It was found that even if the condition laid down in Art. 3(a) was satisfied under the circumstances, it could not be accepted under Art. 3(c) that the holder of a basic patent could obtain a new SPC each time an MA was granted containing the active ingredient constituting the ‘core inventive advance’ of that patent (in this case $I$) and another active ingredient which was not protected ‘as such’ by that patent (in this case $H$).\textsuperscript{122}

The dispute between Actavis and Sanofi does however have some relevance to Art. 3(a) despite the lack of considerations relating to this provision by the CJEU. Looking at the proceedings before the referring court, Mr. Justice Arnold provided some interesting considerations in offering his own solution to the interpretation of Art. 3(a). In his reasoning, he suggested that whether a combination product is protected by the basic patent should be determined by reference to the ‘inventive advance’ or ‘technical contribution’ of the patent. If the ‘technical contribution’ lies in ingredient $A$ only, whichever combination with that active ingredient would not be protected by the patent relied on.\textsuperscript{123} In Actavis I this would mean that, if we assume $I$ is the ‘inventive advance’ of the patent, a medical product whose active ingredient is $I$ would be protected within the meaning of Art. 3(a). Meanwhile, a medicinal product whose active ingredients are $I+H$ in combination is not protected because the combination of $I+H$ does not embody the inventive advance of the basic patent. Note that this is for all intents and purposes effectively the same test as the ‘core inventive advance’ applied by the CJEU in paragraph 30 of Actavis I, albeit Mr. Justice Arnold applies it to Art. 3(a) while the CJEU applies it to Art. 3(c).

\begin{enumerate}
\item \textsuperscript{119} Actavis II C-557/13, pr. 10.
\item \textsuperscript{120} Ibid., pr. 14-20.
\item \textsuperscript{121} Actavis I C-443/12, pr. 44.
\item \textsuperscript{122} Ibid., pr. 30.
\item \textsuperscript{123} Actavis Group PTC EHF v Sanofi [2012] EWHC 2545 (Ch), [2013] R.P.C. 24, pr. 76.
\end{enumerate}
It can be argued that if one were to apply the Medeva test to the Actavis I case, \( H \) would indeed be specified in the claims on the basis of it being within the scope of the patent as interpreted via Art. 69 EPC, which was the finding in parallel cases before the German and Dutch national courts.\(^{124}\) One could in this respect ask the question put forth above: ‘\textit{does the skilled person read this specific active ingredient automatically into the claim?}’. If yes, the ruling should be to consider \( H \) protected by the basic patent. If we assume \( H \) is considered protected by the basic patent according to the Medeva test and we then apply the ‘\textit{core inventive advance}’ test to Art. 3(c), it follows that an SPC cannot be granted anyway unless \( I+H \) embodies the ‘\textit{core inventive advance}’. This is basically the exact process of the CJEU as evident from paragraph 30 of Actavis I. One might then question whether there is any practical difference in applying the ‘\textit{core inventive advance}’ test to Art. 3(a), as Mr. Justice Arnold, compared to Art. 3(c), as the CJEU. At a closer inspection differences emerge:

Firstly, Art. 3(c) can easily be circumvented as the case law stands. The provision was intended to allow only one certificate per product. Now its application is limited to prohibiting only the grant of a second SPC in case of identity of the applicants. Thus, if it is accepted that Art. 3(c) does not apply when applications originate from two legally different applicants it follows that circumvention is a risk to consider.\(^{125}\)

Furthermore, reliance on Art. 3(c) will not be possible in all situations, since it requires that an earlier SPC has been obtained for a single active ingredient within the combination. This is not always the case as will be seen in the Teva case examined below.\(^{126}\)

Accordingly, whether you apply the ‘\textit{core inventive advance}’ test to Art. 3(a) or Art. 3(c) is not irrelevant. As goes for the concept of the ‘\textit{core inventive advance}’ test in general it has the advantage over the Medeva test of not being a question of the wording of the claims, which can be manipulated by the drafter, but of the substance of the innovation, as highlighted by Mr. Justice Arnold.\(^{127}\) The CJEU in Actavis I have adopted some of the same considerations as Mr. Justice Arnold albeit by applying these in the context of Art. 3(c). It is unclear whether the Court has been aware of the difference described above yet still chosen to go with this route over the one suggested by Mr. Justice Arnold. However, if the previous case law can be taken as an indication, it is not inconceivable that the CJEU could have overlooked such details. On the same note, it is worth observing that the Court in Actavis I remarked that an SPC for the combination of \( I+H \) could prolong the de facto monopoly for \( I \) by means of protection from contributory infringement.\(^{128}\) However, this argument is not legally sound; an

\(^{125}\) Max Planck Institute for Innovation and Competition 2018, page 252-255.
\(^{126}\) Section 4.1.4.
\(^{128}\) Actavis I C-443/12, pr. 37.
SPC for I+H does not prevent any competitor from marketing I, and the marketing of I as such can only amount to a contributory infringement if it is evident that I will be brought to market for the purpose of realising I+H which is all but impossible under the circumstances.\textsuperscript{129}

In contrast to Actavis I, Actavis II refers to both Art. 3(a) and 3(c) in its conclusion. In doing so the CJEU arrived at the same result as in Actavis I, but this time it added that in order for a basic patent to protect a product ‘as such’, within the meaning of Art. 1(c) and 3(a), that product must constitute the ‘sole subject-matter of the invention’ covered by that patent.\textsuperscript{130}

Hence, instead of using the wording of the ‘core inventive advance’ as suggested by Mr. Justice Arnold in the Actavis I referral and referenced in Actavis I pr. 30 and 41, the CJEU introduced the concept of the ‘sole subject matter of the invention’. However, the continuous cross referencing in Actavis II to the Actavis I ruling could suggest that no different standard is meant by this difference in expression.\textsuperscript{131} Following the Actavis I and Actavis II cases it is unclear whether the ‘core inventive advance’ or ‘sole subject matter of the invention’ test supplements or replaces the requirement of ‘specified’ or ‘identified’ from Medeva and subsequent case law. It is moreover uncertain whether the ‘core inventive advance’ test should apply only when Art. 3(c) is relevant.

4.1.4. Teva Stage

The uncertainties remaining after the Eli Lilly and Actavis stage resulted in further reference to the CJEU with the Teva case in the UK.\textsuperscript{132} Once again Mr. Justice Arnold referred the question: ‘\textit{What are the criteria for deciding whether ‘the product is protected by a basic patent in force’ in article 3(a) of [the SPC Regulation]?}’.\textsuperscript{133}

4.1.4.1. Facts & Analysis - Teva C-121/17

The facts of the case were broadly similar to those in Actavis I and II. Gilead marketed a medicinal product under the name ‘Truvada’ containing two active ingredients, tenofovir disoproxil (TD) and emtricitabine (E). Gilead had a patent protecting i.a. TD while other claims in the patent mentioned that compound might, if necessary, be associated with ‘other therapeutic ingredients’ which was neither defined nor explained further.\textsuperscript{134} Gilead subsequently obtained an SPC for a ‘composition containing [TD], optionally in the form of a

\textsuperscript{129} Brückner 2015, page 381, note 439.  
\textsuperscript{130} Actavis II C-557/13, pr. 38-39.  
\textsuperscript{131} Cross referencing in Actavis II C-557/13, pr. 33-37.  
\textsuperscript{132} Teva UK Limited v Gilead Sciences Inc. [2017] EWHC 13 (Pat) referred to the CJEU in Teva Case C-121/17.  
\textsuperscript{133} Teva UK Limited v Gilead Sciences Inc. [2017] EWHC 13 (Pat), pr. 95.  
\textsuperscript{134} Teva C-121/17, pr. 16-17.
pharmaceutically acceptable salt, hydrate, tautomer or solvate, together with Emtricitabine’. Against this background Teva along with other generic companies filed an invalidity claim submitting that E was not specified in the basic patent at issue and that the expression ‘other therapeutic ingredients’ used in that claim does not specify any active ingredient, whether structurally or functionally. Consequently, the combination of TD+E should not be considered to be protected within the meaning of the SPC Regulation Art. 3(a). What separates this situation from the factual scenario in Actavis I and II is that Gilead had not obtained an SPC for a monovalent product prior to applying for an SPC for TD+E. They had obtained an MA for a medicinal product called ‘Viread’ containing a fumerate of TD but had not applied for an SPC hereto presumably because the time between the patent application and the MA did not allow for a positive extension so that the term of any SPC would have been negative. Thus, the factual scenario can be summarized as follows:

Illustration 6:

<table>
<thead>
<tr>
<th>Basic patent</th>
<th>MA</th>
<th>SPC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gilead</td>
<td>TD and TD+E</td>
<td>1. Viread (TD)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Truvada (TD+E)</td>
</tr>
</tbody>
</table>

In the case in question, since no certificate was previously granted for TD alone, compliance with Art. 3(c) of the SPC Regulation was not in dispute.

In referring the question to the CJEU Mr. Justice Arnold stated that he hoped the Court would ‘provide a clear answer this time’ and that he was encouraged to believe that they would do so given their introduction of the ‘core inventive advance’ or ‘sole subject matter of the invention’ in Actavis I and II. He then concluded by specifying that it was clear that ‘something more’ was required for protection than for one claim to fall within the Disclosure Test, but what that ‘something more’ might be was not clear. During the oral hearing the partaking Member States all endorsed the ‘core inventive advance’ test, although subject to some qualifications. In the Opinion AG Wathelet, he found that the ‘core inventive advance’ test was only relevant for the purposes of Art. 3(c) which was not at issue in the Teva case.

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135 Teva C-121/17, pr. 19.
136 Ibid., pr. 22.
138 Ibid., pr. 91 and 96.
139 Teva C-121/17, Opinion of Advocate General Wathelet, pr. 38-43.
since there was no prior SPC for TD.\textsuperscript{140} Hence the issue was quite contested even before the ruling of the CJEU.

It was therefore disappointing for actors in the industry that the CJEU once again omitted to address certain outstanding questions.

For one, Gilead had contended that in order to check whether Art. 3(a) is satisfied, it is necessary and sufficient that the product in question falls under the scope of protection of at least one claim of the basic patent applying the Disclosure Test. This was answered by the AG in specifying that, according to him, it was necessary but not sufficient.\textsuperscript{141} It should be noted that the CJEU does not reject this holding, but neither does it adopt it nor express itself explicitly in this regard.

The same goes for the second omission, where, as briefly alluded to above, the AG refuses the ‘\textit{core inventive advance}’ test as generally applicable in holding that the means of determining what falls within the scope of Art. 3(a) is to be found only in the wording, or interpretation of the wording, of the claims, and nowhere else, i.e. the ‘\textit{core inventive advance}’ test does not belong in the framework of Art. 3(a) but rather Art. 3(c).\textsuperscript{142} Again, the Court neither contradict nor confirm such holding explicitly. Instead the CJEU held that Art. 3(a) must be interpreted as meaning that a combination of products is ‘\textit{protected by a basic patent in force}’ when the claims relate necessarily and specifically to that combination. For the purpose of determining this a two-part test was introduced where, from the viewpoint of the person skilled in the arts and on the basis of the prior art at the filing date:

- ‘the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and
- each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.’\textsuperscript{143}

By this answer a new formula was introduced and the CJEU found its way to this by way of a teleological reasoning. It refers to the purpose of the SPC regime and to the balancing of the interests of the pharmaceutical industry and those of public health and concludes that it would conflict with these to extend the protection conferred by a patent beyond the invention which is covered by the patent in question.\textsuperscript{144} The rule introduced in Teva is also notable for the fact that the CJEU directs that implementation should be administered from the perspective of a

\textsuperscript{140} Teva C-121/17, Opinion of Advocate General Wathelet, pr. 67-68.
\textsuperscript{141} Ibid., pr. 75.
\textsuperscript{142} Ibid., pr. 72.
\textsuperscript{143} Teva C-121/17, pr. 57.
\textsuperscript{144} Ibid., pr. 39-42.
person skilled in the arts.\textsuperscript{145} The test consists of two parts which will be analysed separately in the following:

\textbf{A) The First Part}

The CJEU did not explicitly define what the criterion ‘fall under the invention’ means. It could seem that there is some resemblance to the ‘core inventive advance’ test as suggested by Mr. Justice Arnold. This would mean that if the focus of the patent was $TD$, but it was also claimed optionally in combination with ‘other therapeutic ingredients’ such as $E$, then only $TD$ and not $TD+E$ would arguably ‘fall under the invention’.

Support for this can be drawn from paragraph 48, which states that it is necessary for the skilled person to understand, without a doubt, whether ‘the product to which the claims of the basic patent relate is a specification required for the solution of the technical problem disclosed by that patent’.\textsuperscript{146} Taking the example from the case, if the presence of $E$ is optional in the claims alongside $TD$ (as it was explicitly worded as in the claims)\textsuperscript{147} then the specification $TD+E$ is arguably not required for the solution of the technical problem. The CJEU did not hold that the use of the word ‘optionally’ was fatal to Gilead’s case but it highlighted the word.\textsuperscript{148} Note that it is not the CJEU’s job to venture further on the use of this specific word; the Court did what it is supposed to do in answering preliminary rulings by exercising appropriate restraint and leaving it for the national court to decide. Nonetheless it seems to be a strong indication that the CJEU does not believe that $TD+E$ ‘falls under the invention’.

Additional support for the Teva case adopting a test consonant with the ‘core inventive advance’ test can be found in the reference to Actavis II.\textsuperscript{149} Further bolstering this position is the similarity in the wording and the fact that the CJEU chose not to confirm the AGs rejection of the ‘core inventive advance’ test, albeit admittingly this argument cuts both ways; it could equally be raised that the fact the CJEU chose not to contradict the AG indicates that the Court wanted to depart from the ‘core inventive advance’ test.

If this were to be the case, another interpretation of Teva could be that the first part only requires that the product falls under the scope of the basic patent pursuant to Art. 69 EPC with a modification; since the CJEU ruled in Teva that the product must necessarily fall under the invention, and since it must represent a feature required for solving the technical problem

\begin{itemize}
\item\textsuperscript{145} Teva C-121/17, pr. 47.
\item\textsuperscript{146} Ibid., pr. 48.
\item\textsuperscript{147} Claim 27: ‘A pharmaceutical composition comprising a compound according to any one of claims 1-25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients’ and the SPC then relating to a ‘composition containing [TD], optionally in the form of a pharmaceutically acceptable salt, hydrate, tautomer or solvate, together with Emtricitabine.’
\item\textsuperscript{148} Teva C-121/17, pr. 54.
\item\textsuperscript{149} Ibid., pr. 41-42.
\end{itemize}
disclosed in the patent, the active ingredient cannot be covered exclusively by an optional claim if the first part is to be satisfied. Thus, the product’s presence must be required, not merely permitted, by the wording. Such holding seems to be what the national courts in Germany have adopted.\textsuperscript{150}

\textbf{B) The Second Part}

By the second part, holding that each of those active ingredients must be ‘\textit{specifically identifiable}', the CJEU seems to concur with the reasoning of the AG in relation to his criteria of ‘\textit{specifically and precisely identifiable in the wording of the claims of the basic patent}'.\textsuperscript{151} This draws a dividing line between what is protected by the patent in terms of EPC Art. 69 and what is protected by the patent within the meaning of the SPC Regulation Art. 3(a), thus indicating that the latter represents a subdivision of the former.\textsuperscript{152}

However, the AG Opinion and the CJEU judgement are not concurrent throughout. The AG finds that the person skilled in the arts must be able to specifically and precisely identify active ingredient(s) from ‘\textit{the wording of the claims}', cf. ‘\textit{all the information disclosed by the patent}' as held by the CJEU.\textsuperscript{153} In this regard, to include all information disclosed by the patent is arguably more expedient as to allowing specific and precise identification of active ingredients, since the description is needed for detailed information on the invention which will be absent if only relying on the claims.\textsuperscript{154}

Another question that is raised by the second part of the Teva ruling is whether the second part is intended to merely stop the clock regarding the prior art material that can be used to satisfy the test, as argued by Gilead in the case, or whether it extends further by imposing a restriction on the type of knowledge which can be relied on, such as that it must form part of the common general knowledge. The prior art is any evidence that is made available to the public while common general knowledge is what constitutes information that can be found in basic handbooks, encyclopaedias, textbooks etc. according to established case law.\textsuperscript{155} Although there is nothing in the wording to suggest so, Mr. Justice Arnold found, in the ruling on the merits, that it imposed a restriction such that it must form part of the common general knowledge.\textsuperscript{156} This holding by Mr. Justice Arnold is controversial and for a reference to the


\textsuperscript{151} Teva C-121/17, Opinion of Advocate General Wathelet, pr. 81.

\textsuperscript{152} Ibid., pr. 83.

\textsuperscript{153} Teva C-121/17, Opinion of Advocate General Wathelet, pr. 81, cf. Teva C-121/17, pr. 49.

\textsuperscript{154} This is evident when comparing the EPC Rule 42 on content of the description with EPC Rule 43 on form and content of the claims.

\textsuperscript{155} See for example: T 768/91, T 671/94, T 438/97, T 1253/04, T 1641/11.

\textsuperscript{156} Teva UK Limited v Gilead Sciences Inc., [2018] EWHC 2416 (Pat), pr. 39.
prior art to be substituted with a reference to the common general knowledge it will arguably need to be founded in a more solid legal basis that is not in direct conflict with the wording of the CJEU. In Teva, the Court referred to the ‘prior art’ on numerous occasions in its reasoning and in its verdict while ‘general knowledge’ - and thus not the well-known EPO concept of ‘common general knowledge’ - is only referred to once in paragraph 48. It can also be argued that it seems like too high a standard to require that a party, having otherwise fully identified the active ingredients, must further prove that it was common general knowledge at that point in time.

The decision of the CJEU provided yet another test to mosaic into the already extensive catalogue of Art. 3(a) case law. This time the Court comprised their test in two parts, both of which give rise to several issues as examined above. Sure enough, national courts who subsequently applied the test took different directions. This is understandable since all of the diverging arguments above are viable and none are irrefutable. The complicated nature of the test is underscored by the conclusive remarks of Lord Justice Floyd in The Court of Appeals decision from 10. December 2019. In this decision Lord Justice Floyd remarked that he would prefer to hold on answering the difficult questions related to the second part of the test to a case where their resolution would affect the result. However, he highlighted the complications and uncertainties and hinted at the suggested implementation of the second part by Mr. Justice Arnold being too restrictive.

As a consequence, further reference to the CJEU was to be expected, for instance under circumstances where a national court considers the question of whether the ‘core inventive advance’ test applies under the SPC Regulation Art. 3(a) a pertinent issue it must refer this question once more. Some recent referrals are pending before the CJEU but have been the subject of an AG Opinion.

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157 This is also the holding of Advocate General Hogan in joined cases Royalty Pharma C-650/17 and Sandoz v Searle C-114/18, pr. 71.
160 Teva UK Limited v Gilead Sciences Inc., [2019] EWHC Civ 2272, pr. 6., the judgement under appeal being the decision from The High Court of Justice before Mr. Justice Arnold.
161 Teva UK Limited v Gilead Sciences Inc., [2019] EWHC Civ 2272, pr. 84.
The most recent development within Art. 3(a) of the SPC Regulation has been the opinion of AG Hogan in joined cases Royalty Pharma C-650/17 and Sandoz v Searle C-114/18.\textsuperscript{162} The referrals occurred before the CJEU decision in Teva. However, all parties maintained their referrals after the decision in Teva, the former because the Teva judgement did not explicitly adopt or reject the concept of the ‘core inventive advance’, the latter because it did not expressly decide on whether the two-step test applies also for combination products.\textsuperscript{163} Thus, further clarification of Art. 3(a) was needed, though the AG stated that to his mind the questions originally raised by the referring courts had in large part been superseded by the Teva case. Nevertheless he proposed to provide some insight into the application of the judgement and the answers to some specific questions, while being attentive to the: ‘delicate exercise as any minor or even inadvertent departure from the wording used in that judgment could be perceived as a new or different test, thereby reopening a debate which I believe was finally settled by [the Teva case].’\textsuperscript{164}

It must be kept in mind that the Opinion of an AG is not binding upon the CJEU nor the member states. It is the role of the AG to propose to the Court a legal solution to the cases for which they are responsible.\textsuperscript{165} However, the Opinion is illustrative in light of the preceding Teva analysis precisely because of this, as the Opinion of an AG will generally elucidate the subject of the analysis in a more detailed manner than the usually concise reasonings from the CJEU. The AG Opinion in this case is especially useful in this exercise as AG Hogan explicitly states that the object of his Opinion is to provide some insight into the application of Teva without departing from the operative part of the ruling.\textsuperscript{166}

The Sandoz v Searle case C-114/18 related to patent claims in the form of what is often called Markush formulae\textsuperscript{167}, where it was based on a structural formula having a fixed element with

\textsuperscript{162} Sandoz v Searle C-114/18 case has been withdrawn following the Opinion of Advocate General Hogan. See Order of the President of the Fourth Chamber of the Court of 17 January 2020 on removal from the register.

\textsuperscript{163} Joined cases Royalty Pharma C-650/17 and Sandoz v Searle C-114/18, Opinion of Advocate General Hogan, pr. 34-35.

\textsuperscript{164} Ibid., pr. 44.

\textsuperscript{165} Article 252 of the Consolidated version of the Treaty on the Functioning of the European Union, C-326/47.

\textsuperscript{166} Joined cases Royalty Pharma C-650/17 and Sandoz v Searle C-114/18, Opinion of Advocate General Hogan, pr. 44.

\textsuperscript{167} As described by the referring court: ‘the Markush formula enables a large class of compounds to be claimed without the necessity of writing out every single chemical entity. The use of a Markush formula in a claim is an appropriate means of claiming an invention where the patentee’s invention has involved the discovery of a new technical effect which he predicts will be common to all members of the claimed class provided they share a common structural element’, see Joined cases Royalty Pharma C-650/17 and Sandoz v Searle C-114/18, Opinion of Advocate General Hogan, pr. 23.
variable substituents to be chosen from amongst a defined class.\textsuperscript{168} Here, the AG made swift progress in resolving the issues referred in the Sandoz v Searle case of the application of the Teva ruling to products consisting of a single active ingredient and to claims using Markush formulae.\textsuperscript{169} AG Hogan resolved this by reference to Teva C-121/17 pr. 53 in which it was held that when a product is ‘protected by the basic patent in force’: ‘such an interpretation of Article 3(a) of [the SPC Regulation] must also be upheld in a situation, such as that at issue in the case in the main proceedings, where the products which are the subject of an SPC are composed of several active ingredients which have a combined effect’. The emphasis is provided by the AG and from this he considered it clear from the very language used by the CJEU that the Teva ruling is generally applicable and not limited to the case of a combination product.\textsuperscript{170} He then explicitly stated that the grant of an SPC for an active ingredient which is covered by a Markush formula is not precluded provided that the two-part test is satisfied.\textsuperscript{171} This followed from reasoning that the two-part test is technology neutral in line with the CJEU’s case law in Eli Lilly and Teva and that there is no reason to depart from this position.\textsuperscript{172} It follows from this that AG Hogan considers that the two-part test does not care how a product is claimed so long as both parts of the test are satisfied. This may be why it appears that the Sandoz v Searle C-114/18 case has been withdrawn following the rather swift and clear-cut reasoning by AG Hogan and consequently will not be the subject of a CJEU ruling.\textsuperscript{173}

The national court in the Royalty Pharma case maintained its request for a preliminary ruling since it held that it was not clear whether the concept of the ‘core inventive advance’ was still relevant.\textsuperscript{174} Here AG Hogan drew from the reasoning of paragraph 64 to 75 in the Opinion of AG Wathelet in the Teva case, where it was considered that the concept of the ‘core inventive advance’ should only apply when Art. 3(c) is at issue. Based on this, and a phraseological and text-oriented interpretation, AG Hogan concluded that the concept of the ‘core inventive advance’ could have no application in the context of Art. 3(a) since the CJEU at no point in its consideration of the operative part of Teva referred to such concept but rather chose to create its own formula.\textsuperscript{175}

\textsuperscript{168} Joined cases Royalty Pharma C-650/17 and Sandoz v Searle C-114/18, Opinion of Advocate General Hogan, pr. 22.
\textsuperscript{169} Ibid., pr. 35.
\textsuperscript{170} Ibid., pr. 48.
\textsuperscript{171} Ibid., pr. 66.
\textsuperscript{172} Ibid., pr. 62 and 65.
\textsuperscript{173} Order of the President of the Fourth Chamber of the Court of 17 January 2020 on removal from the register.
\textsuperscript{174} Joined cases Royalty Pharma C-650/17 and Sandoz v Searle C-114/18, Opinion of Advocate General Hogan, pr. 34.
\textsuperscript{175} Ibid., pr. 53-54.
Next, the AG turned to consider the specifics of the first part of the two-part test. It was found that the first prong requires that the claims in a patent in relation to a product are required for the solution of the technical problem disclosed by the patent in question. This is thus an endorsement of the alternative to the concept of ‘core inventive advance’ described above in the analysis of Teva where it is sufficient that a product fall under the scope of the basic patent pursuant to Art. 69 EPC with a modification; this modification being that the product must be required in the solution of the technical problem.

The AG then further considered the second part of the test. As opposed to Mr. Justice Arnold in the Teva case decision on the merits, the AG found that reference should be made to the prior art, which includes any evidence that is made available to the public, rather than the more restrictive reference to the common general knowledge. He added that the second prong requires that it be established that a person skilled in the art (with all the conditions pertaining hereto) would have been able to ‘derive the product in question’.

Thus, it is clear that AG Hogan supports the two-part test as set out by the CJEU fully and in the Opinion he manoeuvres within the scope of interpretation illustrated in the Teva analysis above while being careful not to graft further conditions onto the test. However, as mentioned above the AG Opinion is a proposition of a possible verdict to the service of the CJEU and while the AG clearly provides guidance as to how he suggests the two-part test should be implemented, it does little to alleviate the questions and legal uncertainties standing after the Teva analysis.

4.2. Summary of Case Law on Art. 3(a)

The case law on Art. 3(a) is still in development. Starting in Farmitalia, C-392/97, it was established that in order to determine whether a product is protected by a basic patent, reference must be made to the rules which govern that patent. Which rules the Court was referring to in this instance was unknown, since there are two sets of rules which might be relevant; this led to the two schools of interpretation, the Infringement Test and the Disclosure Test, but the CJEU did not explicitly adopt one.

In Medeva, C-322/10, the CJEU repeated what it had said in Farmitalia and added that no SPC could be granted relating to active ingredients which are not ‘specified’ in the wording of the

176 Joined cases Royalty Pharma C-650/17 and Sandoz v Searle C-114/18, Opinion of Advocate General Hogan, pr. 72.
177 Ibid., pr. 70-71.
178 Ibid., pr. 77.
claims of the basic patent. In Medeva’s progeny of Queensland and Daiichi, which were
decided by reasoned order, the CJEU stated that the questions referred in this case were, for
all essential purposes, similar to those referred in Medeva. It then repeated both its reasoning
and answer from Medeva, except that its answer rather peculiarly used the word ‘identified’
rather than the word ‘specified’. Based on the analysis above, no legal significance should be
ascribed to the difference in wording. The cases adopt the Disclosure Test in that it is
necessary that the product should fall within the claims of the basic patent, albeit suggesting
that this is not sufficient and that something more is required.

Eli Lilly, C-493/12, answered whether a product can be defined by functional claims for the
purposes of Art. 3(a). The CJEU clearly stated that Art. 3(a) does not preclude a product being
protected by a basic patent by virtue of a functional definition. It added that this is only permitted
where the claims ‘relate, implicitly but necessarily and specifically’ to the product in question.
The Court did not explain what this precisely means but it seems to suggest once again that
something more is required on top of the product falling within the scope of the basic patent
applying the Disclosure Test.

In Actavis I, C-443/12, and Actavis II, C-577/13, the CJEU introduced the test of what
constitutes the ‘sole subject-matter of the invention’. It is uncertain to what extent, if any, this
concept mirrors the concept of ‘core inventive advance’ as suggested by Mr. Justice Arnold.
The purpose of the test introduced by the CJEU is to identify the subject-matter of the basic
patent in contrast to other active ingredients not protected as such by the basic patent but
simply referred to in the wording of the claims of the patent in general terms. However, the
cases left uncertainty as to whether this concept applied only in the context of the SPC
Regulation Art. 3(c) or that of Art. 3(a) too, not least because of the inconsistency of the CJEU
in Actavis I cf. Actavis II.

The Teva case forms the latest Art. 3(a) development from the CJEU. The decision introduced
a two-part test from which several Understandings are possible as highlighted in the analysis.
In this context AG Hogan has issued an opinion in joined cases Royalty Pharma C-650/17 and
Sandoz v Searle C-114/18 (the latter of these has now been withdrawn) in which he states
how, to his mind, the two-part test is to be applied. Interestingly, he holds that the concept of
the ‘core inventive advance’ test does not apply and is of no relevance in the context of Art. 3
(a). However, as of writing of this thesis the CJEU have yet to rule on the issue in Royalty
Pharma C-650/17.
The development of Art. 3(a) is illustrated below:

**Illustration 7:**

<table>
<thead>
<tr>
<th>1st Stage of CJEU Art. 3(a) Case Law:</th>
<th>2nd Stage of CJEU Art. 3(a) Case Law:</th>
<th>3rd Stage of CJEU Art. 3(a) case law:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Farmitalia &amp; Medeva</strong></td>
<td><strong>Eli Lilly &amp; Actavis</strong></td>
<td><strong>Teva &amp; Royalty Pharma</strong></td>
</tr>
<tr>
<td>The product is protected by the basic patent when - it falls under the scope of protection of the basic patent - it is specified in the wording of the claims of the basic patent</td>
<td>The product is protected by the basic patent when - it falls under the scope of protection of the basic patent - it is specified in the wording of the claims of the basic patent, and - (it embodies the core inventive advance of the basic patent)</td>
<td>The product is protected by the basic patent when - those claims relate necessarily and specifically to that combination. For this purpose, from the perspective of a person skilled in the art based on the prior art at the filing date - the active ingredient(s) must fall under the invention covered - each active ingredient must be specifically identifiable</td>
</tr>
<tr>
<td>The CJEU seemingly endorses the Disclosure Test albeit with 'something more' required.</td>
<td>The 'something more' could be the inventive advance.</td>
<td>A new take on the 'something more' which leaves room for several understandings.</td>
</tr>
</tbody>
</table>

4.3. Discussion & Status of the Issue

The rulings of the CJEU have established that it is not the Infringement Test that should be applied when assessing the scope of a basic patent invoked for an SPC. Consequently, it has been held that the Disclosure Test applies. However, detailed guidance on how this test should be applied have been lacking which is apparent from the extensive list of case law on this subject. With the most recent development in Teva, the CJEU seems to yet again guide the issue one step further while again leaving room for several understandings and further questions. This will eventually result in further referrals as to how Art. 3(a) is best applied until the legal position does finally become clear.

Based on the analyses above it must be concluded that legal uncertainty still remains. What is clear is that the CJEU seems inclined to take a rather narrow approach towards what is protected by the basic patent most obvious by their adoption of some variation of the Disclosure Test rather than the Infringement Test. In moving away from the Infringement Test
the Court embarked on a journey of case law where they have sought to provide guidance to an elusive concept which is not easily done. We see this in the struggling of the CJEU in the case law starting from Medeva until most recently Teva. It seems that what the Court is trying to define as the crucial factor in deciding when a product is protected by a basic patent is what the patent is actually about which could constitute the ‘something more’ required for protection of a product in addition to it being within the scope of the claims. In this regard it might be helpful to recall the general remarks on patent law in section 2 of this thesis; a patent holder is provided with a limited-term exclusionary right to an invention in return for the disclosure of this invention. Where a patent precisely identifies an active ingredient this will most often be the working principle behind the invention of the patent, the disclosure of which society stands to benefit from. This working principle that is beneficial to society can in turn arguably constitute what the patent is actually about and thus the ‘something more’. Conversely, the fact that the patent would be infringed because that active ingredient is used in a combination of active ingredients does not in and of itself mean anything in relation to the invention disclosed in the patent.

The Disclosure Test is rather difficult to articulate definitely but it essentially involves such fundamental considerations which has then in turn been shaped in the form of different tests set out by the CJEU. In an attempt to put it briefly, the CJEU is with the Disclosure Test trying to create a legal landscape in which Art. 3(a) should only enable the holder of a basic patent to obtain an SPC for what that patent holder actually invented and not for what the patent holder did not invent.

In comparison, the Infringement Test is straightforward and simply involves determining what is protected by the basic patent by reference to the national law of patent infringement. Since the analyses of the case law illustrates that the issue of determining when a product is protected by a basic patent in relation to Art. 3(a) remains unresolved one might consider whether an adoption of the Infringement Test could prove beneficial. This test may have proved a more manageable test with an accompanying higher degree of legal certainty. However, it would undoubtedly also lead to more SPCs as all eventualities where a third-party would infringe the patent would be ‘protected by the basic patent’. Due to the repeated rejection of the Infringement Test by the CJEU it must be assumed that the Court considers that the test would alter the balance of the SPC regime in favour of originator companies, bringing a disequilibrium that would be detrimental to the interests at stake.

The issue of legal certainty with regard to the SPC Regulation Art. 3(a) is particularly difficult compared to other areas of the legal landscape. Whilst it can be argued that the CJEU case law is getting clearer one can also with some merit claim that the issues should already have
been resolved given the large number of referrals. It seems that the CJEU struggles with the very concept of disclosure and scope of protection in patent law while also being inaccurate with their choice of wording. The reason for this could be the intricacy of the concepts coupled with the fact that the CJEU is not a specialised court. Given the conclusions of this section above it is interesting that the CJEU itself thinks that the situation is perfectly clear following the Teva decision. This is indicated by the fact that the CJEU recently asked the national courts in Germany and the Netherlands to withdraw their pending referrals albeit they both refused to do so, highlighting the tension in this area.\textsuperscript{179}

Given this position by the CJEU it is unlikely that significant change is coming up via case law leaving one to consider whether legislative changes in relation to Art. 3(a) are appropriate. In this regard it is helpful to consider the possible systemic inadequacies and whether an amendment of the provision would have a positive impact on the legal certainty with these in mind.

At prima facie it is clear that Art. 3(a) is a very concise and precise provision. Much of the legal uncertainty revolving around the provision presumably stems from the fact that the SPC regime operates in a highly complex legal landscape which is characterised by both technical patent law and regulatory law - at both the EU and national level. The concise reasonings and regularly misapplied patent terminology from the CJEU does not help in this regard.\textsuperscript{180} Add to this the fact that the frequency of litigation is high due to the heavy investments and potential profits involved in SPCs for pharmaceutical products, meaning that companies will often decide on litigating a matter even when the chances of having claims sustained are slim.\textsuperscript{181} This factor also means that the issues that come before the CJEU are often marginal cases that have limited practical relevance.\textsuperscript{182} Thus, all other things equal an amendment of Art. 3(a) would arguably not correct matters much. On the contrary it could be argued that it would impair the situation as the development on Art. 3(a) since the introduction of the SPC Regulation No 1768/92 that has been achieved through analysis would be abandoned. Instead, an amendment would create new issues of interpretation of any new wording and also of transitioning between the current provision and a new provision.

\textsuperscript{180} Teva UK Limited v Gilead Sciences Inc., [2018] EWHC 2416 (Pat), pr. 13 and 15.
\textsuperscript{181} Max Planck Institute for Innovation and Competition 2018, page 128.
\textsuperscript{182} Ibid., page 208.
Thus, despite Art. 3(a) being a clear and concise provision the CJEU has failed to provide clear guidance for its application. It is still difficult to determine when a product is protected by basic patent in force and the present uncertainty is unsatisfying for industry actors.

This thesis presents the argument above that the fact that CJEU case law on Art. 3(a) is not clear in every detail does not unequivocally call for an amendment of the provision. This is so because many of the presumed causes for the lack of clarity come from other sources than the provision itself and that an amendment might not alleviate the systemic shortcomings. It is thus clear that the position is that there is a need for more clarity in relation to Art. 3(a) but that such should be achieved without an express amendment of Art. 3(a).

In this scenario, if it is accepted that a root cause of the uncertainty stems from the fact that the CJEU is not a specialised court, it is tempting to dismiss the issue by reference to the fact that the UPC may then mitigate uncertainty. Unfortunately, it is becoming increasingly unlikely that the UPC will enter into force following the recent ruling by The Federal Constitutional Court of Germany and the rejection by the United Kingdom.183 In the wake of a collapse of the UPC that has been years in the making, a launch of a project with the intention of creating a pan-EU specialised patent court must be considered highly improbable.

Considering the difficult operating environment, a supplementary instrument may be preferable which could consist of the implementation of soft-law provisions. Such measures could mitigate uncertainty via guidelines for interpretation of Art. 3(a) which could coexist with and rely on existing case law by being updated at regular intervals to take account of new developments. An example of such guidelines having a significant impact is the EPO’s ‘Guidelines for Examination in the European Patent Office’.184 This approach could arguably be criticised as being a half measure since a failure to follow a procedure set out in such soft-law provisions will not in itself constitute a substantial violation. However, if we assume the adoption of soft-law provisions relating to the interpretation of Art. 3(a) industry actors may reasonably expect, in accordance with the established ‘principle of good faith’, that NPOs and the CJEU will strive to interpret in agreement with such guidelines.

The issues revolving around Art. 3(a) are particularly difficult due to the complexity of the legal matter and they are a source of permanent divergence across EU Member States, which counteract the objectives of the SPC Regulation of creating a uniform solution to the benefit of the functioning of the internal market.185 There is no approach that will manifestly ensure a

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185 The SPC Regulation No 469/2009, recital 7.
more clear and expedient interpretation of Art. 3(a) and there are arguments for and against all. The above should not be construed as suggesting that an adoption of soft-law regulation is the quintessential approach and the pursuit of such a finding is well outside the scope of this thesis. Rather, it is meant to contribute to the important discussion of what possible measures could mitigate some of the uncertainty pertaining to Art. 3(a).

5. SPCs for Second and Further Medical Uses

Second and further medical use patents allow industry actors to recoup research investments that brings therapeutic advances based on known active ingredients. The term covers the situation where a substance or composition is patented for a use after the first medical use is already patented. An incentive to conduct research into a substance for which the first medical use is already patented is thus generated since any second or further use that is novel and inventive may still be patented.

Art. 3(b) and Art. 3(d) of the SPC Regulation are interrelated in that they both concern the MA granted for the medicinal product. Art. 3(b) provides the condition that a valid MA must have been granted, while Art. 3(d) provides that this MA must be the first authorisation in the EU to place the product on the market as a medicinal product. The issue of SPCs second and further medical uses primarily concern the requirement under the SPC Regulation Art. 3(d).

The SPC Regulation Art. 1(c) provides a definition for the term ‘basic patent’ and in doing so it does not discriminate between different types of patents which in turn means that all patents can serve as a basic patent upon which an SPC can be granted. This in principle also means that second and further medical use patents can serve as a basic patent for an SPC. However, this is where Art. 3(d) poses a possible hindrance since a literal interpretation of this provision provides that any product that has already been the subject of an MA cannot serve as a basis for an SPC, seemingly blocking SPCs for second and further uses of a product that has already been the subject of an MA.

Also, with regard to Art. 3(d) the CJEU case law has undergone a continuous transformation through the years. The purpose of this section is to analyse the cases of significance in the case law revolving around Art. 3(d) and to discuss the findings in relation to SPCs for new uses of active ingredients already authorised as medicinal products. Given the increasing use of second and further medical use patents such discussion is of growing practical relevance and achieving clarity in this regard is more important than ever.
5.1. Preliminary Remarks on the Patentability of Medical Uses

The provision governing patentability is found in Art. 52 EPC and concerns novelty, inventive step and industrial application. In order to protect the freedom of doctors to choose the therapy or surgery most expedient to the needs of the patient an exclusion is found in Art. 53(c) EPC which excludes medical methods from patent protection, albeit allows products that are used in such medical methods to be the subject of a patent.

In the Enlarged Board of Appeal (EBA) decision G5/83 it was confirmed that claims directed to therapeutic uses were in direct conflict with the old Art. 52(4) in EPC(1973), which is materially similar to Art. 53(c) EPC(2000). Despite such direct conflict, the EBA applied a teleological interpretation in finding that: ‘No intention to exclude second (and further) medical indications generally from patent protection can be deduced from the terms of the European Patent Convention; nor can it be deduced from the legislative history of the articles in question’.186 Consequently it was held that second and further medical uses could be patented via so-called Swiss-type claims whereby claims are directed to the use of a substance or composition ‘for the manufacture of a medicament’ for a specified new and inventive therapeutic application.187

With the introduction of EPC(2000) the new Art. 54(4) and (5) EPC addressed the issue by providing that a substance and a composition, even if part of the state of the art, are considered patentable as product claims (albeit limited to the specific use of the substance), if a patent application discloses a use of such substance for one of the methods referred to in Art. 53(c) EPC and such use is not comprised in the state of the art.188 Hence, the so called ‘purpose limited product claims’ has been introduced for known substances which are intended to be used in the treatment of the human or animal body. With such claims the scope of protection is limited to the medical uses. Notable in this regard is the fact that the EPO does not require that a new medical indication exists, meaning that it is not required that the active ingredient is used to treat a new disease. The EPO also allows the grant of patents where the only new feature of the use claimed is a new dosage, a new regimen for administration or a new subgroup of patients that can be treated with the compound.189 Art. 54(4) and (5) EPC thus

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186 Enlarged Board of Appeal decision G5/83, pr. 22.
187 Ibid., pr. 23.
188 Following the introduction of Art. 54(5) EPC(2000) Swiss-type claims are no longer accepted if the application has a filing or earliest priority date of 29 January 2011 or later (see the Notice from the EPO dated 20 September 2010, OJ EPO 2010, 514).
189 Enlarged Board of Appeal decision G2/08, section 6.1.
provide for an exception from the general principle that product claims can only be obtained for novel products.

5.2. The Cornerstone Cases Pertinent to SPCs for Second and Further Medical Uses

In light of the above, the question in relation to SPCs become whether Art. 3(d) is to be interpreted such that once a product has been the subject of an earlier MA, irrespective of use, no SPC can be granted, as the product within the meaning of Art. 1(b) has already been the subject of an earlier MA or alternatively whether it allows grant of an SPC despite an earlier MA for the product when reference is made to a different use of the active substance.

5.2.1. Earliest Case Law

Some CJEU case law from the 2000s is relevant to the question of SPCs for second and further medical uses even though the cases do not concern Art. 3(d) in a strict sense.

Pharmacia

Pharmacia Case C-31/03 concerned the transitional provision contained in Art. 19(1) of the First SPC Regulation 1768/92/EEC according to which an SPC could only be granted for a product if, on the date the Regulation entered into force, it was protected by a basic patent and ‘the first authorisation to place it on the market as a medicinal product in the Community was obtained after’ 1 January 1988. An MA for the veterinary product ‘Galastop’ had been granted in 1987 but Pharmacia applied for an SPC on the basis of a later MA for the human medicinal product ‘Dostinex’, granted for the first time in the Netherlands in 1992. Both were granted for the same indication. This scenario can be illustrated as:

Illustration 8:

Pharmacia argued from on a teleological interpretation by submitting that it follows from an examination of the SPC Regulation, including its broad logic and purpose, that a distinction is drawn in principle between medicinal products for human use and veterinary use, and thus

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190 Inhibition of prolactin secretion thereby suppressing lactation, see Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents [2010] EWHC 976 (Pat), pr. 36.
that it is the date of the first MA to place the product on the market for human use which is relevant.\textsuperscript{191} In his opinion AG Jacobs advised that the relevant date was that of the first MA to place the product on the market for either human or veterinary use which to his mind appeared consistent with Art. 3(c) and (d) since those provision highlight the significance for the system put in place by the SPC Regulation of the notion of one certificate per product\textsuperscript{192} without distinction depending on the number of MAs.\textsuperscript{193}

In its judgment, the CJEU followed the advice of the AG, holding:

‘It follows, first, that the decisive factor for the grant of the certificate is not the intended use of the medicinal product and, second, that the purpose of the protection conferred by the certificate relates to any use of the product as a medicinal product without any distinction between use of the product as a medicinal product for human use and as a veterinary medicinal product.’\textsuperscript{194} [emphasis supplied].

Thus, the Court said that the intended use of the product was immaterial. It further re-iterated its holding from Case C-127/00 Hässlé, pr. 72, that the words ‘first marketing authorisation’ must be interpreted in the same way throughout the SPC Regulation, i.e. the reasoning is also relevant for Art. 3(d).\textsuperscript{195} In sum, it was found that an earlier MA for a veterinary use could be used against a later MA for human use.

\textbf{MIT}

MIT Case C-431/04 concerned the definition of ‘product’ in the SPC Regulation Art. 1(b). It was held that combinations that consists of two substances of which only one has a medicinal effect for an indication and the other permits a new form of administration cannot be considered a combination of active ingredients within the SPC Regulation.\textsuperscript{196}

\textit{Illustration 9:}

<table>
<thead>
<tr>
<th>First MA</th>
<th>Second MA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human use Indication A</td>
<td>Human use Indication A</td>
</tr>
</tbody>
</table>

\textsuperscript{191} Pharmacia C-31/03, pr. 17.
\textsuperscript{192} This might be read as saying that there can be only one SPC per product, but it is clear from the decisions in Biogen C-181/95 and AHP C-482/07 that one SPC may be granted per patent per product.
\textsuperscript{193} Pharmacia C-31/03, Opinion of Advocate General Jacobs, pr. 50.
\textsuperscript{194} Pharmacia C-31/03, pr. 20.
\textsuperscript{195} Ibid., pr. 21.
\textsuperscript{196} MIT C-431/04, pr. 18 and 31.
The case is interesting with regard to new medical uses for two reasons.

Firstly, in his opinion, AG Léger advised that Art. 1(b) should be interpreted as including such combinations. He applied a teleological approach and found that costly innovation was involved in producing combinations such as the one at issue, and that the SPC Regulation was designed to protect exactly such innovation.¹⁹⁷ Nonetheless, as stated above the CJEU did not follow the AGs advise, and this can be taken to convey that a teleological approach cannot be pressed too far.

Secondly, the case is relevant due to the CJEU’s reference to paragraph 11 of the Explanatory Memorandum in which it i.a. is stated that ‘Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new [SPC].’¹⁹⁸ It further references paragraph 68 which states that ‘in conclusion, it should be noted that, although one and the same substance may be the subject of several patents and several marketing authorisations in one and the same Member State, the SPC will be granted for that substance only on the basis of a single patent and a single authorisation, namely the first granted in the Member State concerned.’¹⁹⁹

### Yissum

In Yissum Case C-202/05 the scenario can be illustrated as follows:

*Illustration 10:*

<table>
<thead>
<tr>
<th>First MA</th>
<th>Second MA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human use</td>
<td>Human use</td>
</tr>
<tr>
<td>Indication A</td>
<td>Indication B</td>
</tr>
</tbody>
</table>

It was held that if a basic patent protects a second medical use, this use is not an integral part of the definition of ‘product’.²⁰⁰ The CJEU found that this result followed clearly from the case law, e.g. Pharmacia C-31/03 and MIT C-431/04 and gave its decision by reasoned order.²⁰¹ Since a therapeutic use according to this ruling cannot be relevant for determining whether something is a ‘product’ within the meaning of Art. 1(b), it would seem to follow that it cannot

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¹⁹⁸ MIT C-431/04, pr. 19.
¹⁹⁹ Ibid., pr. 23. Once again this might be read as saying that there can be only one SPC per product, but it is clear from the decisions in Biogen C-181/95 and AHP C-482/07 that one SPC may be granted per patent per product.
²⁰⁰ Yissum C-202/05, pr. 20.
²⁰¹ Ibid., pr. 15, 17 and 19.
be relevant for determining whether an MA invoked is the first MA for that ‘product’ as a medicinal product in relation to Art. 3(d).

5.2.2. Neurim C-130/11

5.2.2.1. Facts and National Proceedings

The Neurim C-130/11 case involved Art. 3(d) and has in this context been considered one of the most influential and controversial SPC rulings. The factual scenario concerns the active ingredient Melatonin (M) which at the time was off patent. Neurim was the holder of a basic patent which concerned a process for preparing a formulation of M and included a second medical use claim for the use of the formulation manufactured by the claimed process for the treatment of insomnia. Neurim then obtained an MA for the product ‘Circadin’ on 29 June 2007 and subsequently filed an application for an SPC on 26 September 2007 basing its application on aforementioned MA and designating that as the first MA to place the product on the market within the meaning of Art. 3(d). The UK-IPO refused to grant the SPC with reference to an earlier MA for the product ‘Regulin’ granted in 2001, which was for M for use in sheep. Accordingly, Neurim’s MA could not be considered the first authorisation to place the product on the market as a medicinal product and could thus not satisfy the SPC Regulation Art. 3(d). The factual scenario in Neurim involved both different species and a difference in indication and can be illustrated as follows:

Illustration 11:

<table>
<thead>
<tr>
<th>First MA</th>
<th>Second MA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Veterinary use</td>
<td>Human use</td>
</tr>
<tr>
<td>Indication A</td>
<td>Indication B</td>
</tr>
</tbody>
</table>

The case then moved through the legal system on appeal. The SPC was once again rejected by Justice Arnold of the High Court of England. The fact that Neurim concerned both different species and different uses could, according to Justice Arnold, not entail that the case should be distinguished from Yissum (same species, different indication) and Pharmacia (different species, same indication). He thus argued that since case law has established that a difference in the species or a difference in the indication is immaterial in this context it follows from logic

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202 Neurim C-130/11, Opinion of Advocate General Trstenjak, pr. 7.
203 Ibid., pr. 10.
204 Ibid., pr. 11.
that a difference in both (species and indication) is also immaterial.205 This ruling was then further considered by The Court of Appeal who referred questions to the CJEU. In its reasoning for referral the court showed sympathy for Neurim’s situation by holding:

‘We consider that Neurim’s arguments are not only tenable: in our view they are right. Many kinds of valuable pharmaceutical research will not get the encouragement or reward they deserve if they are not. Pharmaceutical research is not confined to looking for new active compounds. New formulations of old active substances are often sought. Most are unpatentable but from time to time a real invention is made and patented.’206

The Court of Appeal concluded that if the research conducted by Neurim could not be the subject of an SPC, then the SPC Regulation would not be fit for purpose.207 After such monumental language and possible far-reaching consequences of the decision it was found that this should clearly be a matter for the CJEU.208

5.2.2.2. Analysis

In its referred questions, the Court of Appeal was seeking to ascertain in particular whether Art. 3(d) precludes the grant of an SPC based on a second MA, where this second medicinal product is protected by a basic patent for a common active ingredient also present in the first MA, but where the protective scope of the patent does not extend to the first medicinal product.209

In the opinion of AG Trstenjak, she broke up the consideration of this question in a literal interpretation and a teleological interpretation.

In her interpretation on the basis of the wording, the AG found that this would entail that no SPC could be granted for the medicinal product for human use ‘Circadin’, since the earlier ‘Regulin’ medicinal product contains the same product in the meaning of Art. 1(b) which then conflicts with the wording of Art. 3(d).210

She then turned to a schematic and teleological approach, which she held has great importance in interpreting EU legislation.211 AG Trstenjak found that it is a common feature of

207 Ibid., pr. 30.
208 Ibid.
209 Neurim C-130/11, pr. 16.
210 Neurim C-130/11, Opinion of Advocate General Trstenjak, pr. 24-25 & 27.
211 Ibid., pr. 28.
the conditions under Art. 3(a), (b) and (c) of the SPC Regulation that, in principle, more than one SPC for a product may be granted. The argument then is that a schematic reading of Art. 3(d) suggests an interpretation which essentially also permits the grant of more than one SPC for a product.\textsuperscript{212} This is followed up by the holding that the grant of an SPC in the circumstances of the case is also most consistent with the objectives of the SPC Regulation. Support for this position is found by referencing the undisputed fact that the research conducted by Neurim led to the development of a new and beneficial medicinal product for human use, for which a patent was granted, and that such pharmaceutical research into possible new uses is an (increasingly) important part of research in the pharmaceutical sector.\textsuperscript{213} To AG Trstenjak’s mind, this is supported by the introduction of Art. 54(4) and (5) in EPC(2000) which renders possible the patenting of second and further medical uses by creating an exception to Art. 53(c) EPC, as described in 5.1. above.\textsuperscript{214}

In conclusion the AG was of the opinion that manufacturers of medicinal products who discover new therapeutic applications of active ingredients, that are already the subject of an MA, may have a legitimate interest in the extension of that exclusive protection in order to recoup their investment.\textsuperscript{215} However, in holding this she recognized the need for caution in not allowing a schematic and teleological interpretation to go beyond the aim of achieving a balance of interest within the industry. She found that such balance could best be ensured by adopting as the crucial factor whether or not the first use of an active ingredient, which is the subject of the first MA, is within the scope of protection conferred by the designated basic patent for a further use of that active ingredient in another medicinal product. If not, an applicant should be granted an SPC.\textsuperscript{216} This ‘scope of protection of the basic patent test’ can be illustrated using the Neurim case as an example:

\textsuperscript{212} Neurim C-130/11, Opinion of Advocate General Trstenjak, pr. 30-37.
\textsuperscript{213} Ibid., pr. 47-48.
\textsuperscript{214} Ibid., pr. 49.
\textsuperscript{215} Ibid., pr. 51-52.
\textsuperscript{216} Ibid., pr. 54.
The CJEU presented its ruling in a more concise fashion. The Court made reference to the purpose of the SPC Regulation and paragraph 29 of the explanatory memorandum which specifies that all types of inventions may serve as a basis for an SPC and that all pharmaceutical research, provided that it leads to a new invention that can be patented, including a new application of a known product, must be encouraged without any discrimination. The ruling is in agreement with the Opinion of AG Trstenjak by holding that if a patent protects a new use of a known active ingredient, which has already been the subject of an MA for another use, the MA obtained on the basis this basic patent may enable its proprietor to obtain an SPC. In its final conclusion the CJEU thus held:

‘...in a case such as that in the main proceedings, the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the [SPC].’

The CJEU reaches the same result as AG Trstenjak. However, the ruling of the CJEU was significantly less detailed and provided hardly no test or guidance as to the scope of the Neurim holding.

The AG specifies her suggested test of interpreting Art. 3(d) in several relatively comprehensive paragraphs which according to her will ensure the optimal balance of interests. Compare this to the CJEU who leaves ample scope for interpretation with regard

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217 The Explanatory Memorandum, pr. 29.
218 Neurim C-130/11, pr. 24.
219 Ibid., pr. 25.
220 Ibid., pr. 36(1).
221 Neurim C-130/11, Opinion of Advocate General Trstenjak, pr. 53-57.
to several issues. It is for instance unclear whether the CJEU accepts that reference to the scope of the basic patent should be the decisive factor in interpreting Art. 3(d). In this direction, the CJEU states that a first MA for a specific indication will be the first MA for a medicinal product when that indication corresponds to that protected by the basic patent invoked.\(^{222}\) This could suggest that the CJEU wanted to take the same direction as the AG albeit the decision is much less precise and detailed which fosters legal uncertainty. In this regard it deserves notice that the referred question 1 referenced the limits of the protection conferred by the basic patent in relation to the first MA expressly.\(^{223}\) Despite the holding by the AG and the referred question 1, the CJEU only expressly stated that the ‘new application’ must be within the scope of protection of the basic patent; the CJEU did not mention if it is decisive whether or not the first MA for the active ingredient is within the scope of protection or what is precisely meant by ‘new application’.

The Court may have been reluctant to explicitly adopt AG Trstenjak’s test given that precise assessments of whether a first MA of a given product falls within the scope of protection of a basic patent could overburden national patent offices (NPOs). Bear in mind that one of the intentions behind the SPC Regulation was to establish a system as transparent and simple as possible.\(^{224}\) It can be inferred from the Explanatory Memorandum that one of the reasons for this was an ambition of avoiding the overburdening of NPOs, some of which are ill-equipped to perform complex technical value judgments such as those of assessing the scope of a patent. This can be derived from formulations such as:

“\textit{There is no need for any new administrative body and the patents offices should be able to implement the procedure for granting the certificate without an excessive burden being placed on their administrations… Examination of the conditions to be fulfilled for the certificate to be granted involves the use of objective data that are easy to verify.}\(^{225}\)

However, in this regard it is undeniable that the Neurim holding is at variance with this objective nonetheless by introducing vague concepts without further guidance, i.e. ‘\textit{new therapeutic application}’ and ‘\textit{different application}’, which opens a myriad of interpretations that can involve complex and subjective assessments by NPOs.

The CJEU may have also been concerned about a clash with its own earlier decisions, namely Pharmacia, MIT and Yissum, which Justice Arnold in the decision of the High Court of England

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\(^{222}\) Neurim C-130/11, pr. 26.

\(^{223}\) Ibid., pr. 16.

\(^{224}\) The Explanatory Memorandum, pr. 16-17.

\(^{225}\) Ibid., pr. 16.
had already assessed and considered to preclude Neurim from obtaining an SPC. It is indeed difficult to see how Neurim does not conflict with the previous cases especially considering that the CJEU decided Yissum by reasoned order through reference to Pharmacia and MIT despite the factual differences described above. This suggests that the CJEU in Yissum found the reasoning from the cases generally applicable and not confined to the specific factual scenarios concerned. It is certainly a striking feature of Neurim that neither the AG Opinion nor the CJEU decision contains any mentioning of Pharmacia, MIT or Yissum. Since the Court did not refer to those decisions it is in turn difficult to know if it intended to depart from the holdings in those cases and it is difficult to know if those decisions are to be regarded as having been overruled, or as limited in some unspecified manner.

Nevertheless, the CJEU did not expressly rescind any previous cases and it is generally assumed that the CJEU accepted that a precondition for a grant of an SPC under the circumstances is that the ‘new application’ is covered by the basic patent while the earlier MA for the same compound is not, thus adopting the test conceived by AG Trstenjak. This means that the CJEU in Neurim accepted a different definition of ‘product’ in relation to Art. 3(d) compared to the definition of ‘product’ in Art. 1(b) of established case law. Under Art. 3(d) uses are relevant, e.g. a product for use A is different to a product for use B. Leaving aside the fact that this alone is a contradiction of previous case law, according to which the words used in the SPC Regulation must in principle be given a uniform interpretation, this raises the question of whether Neurim applies to Art. 3(c). Answered in the negative, this provision could serve to limit the practical implications of Neurim. Some remarks on Art. 3(c) in this context are beneficial.

The scope of Art. 3(c) was originally intended to allow only one certificate per product. However, after undergoing a transformation in case law the provision now prohibits the grant of a second SPC only when two applications are filed by the same applicant, as discussed in the analysis of Actavis I and II in section 4.1.3.2. Multiple certificates for the same product became possible. In the AHP decision it was clear that the CJEU was aware that Art. 3(c) had the function of avoiding the same product being the subject of a number of successive SPCs, so that the overall duration of protection for one and the same medicinal product could be exceeded. Furthermore, it is apparent that the combination of Art. 3(c) and Art. 3(d) was

227 Yissum C-202/05, pr. 17 and 19.
229 Hässle, C-127/00, pr. 57 and 72.
230 AHP Manufacturing, C-482/07, pr. 43.
231 Ibid., pr. 42.
meant to function as instruments for ensuring the correct balance of interests as decided by the EU legislator. However, in AHP the CJEU found that it was not necessary to apply a wide scope of Art. 3(c) in order to protect these interests since any maximum protection period could not be exceeded given the maximum patent term of 20 years and the maximum SPC duration mechanism ensured by the SPC Regulation Art. 13, as described in section 3.4. of this thesis. However, with Neurim the CJEU seem to have created a legal landscape in which this reasoning can no longer hold true; since Neurim changes which MA is identified as the ‘first authorisation’ this will mean that SPCs granted for the same product may indeed have an overall protection period exceeding 15 years because the MA identified as the first to put a product on the market is a part of the formula for calculating the SPC duration. See illustration 13 below as illustrative of this.

The above example demonstrates the delicate interaction of the provisions in the SPC Regulation and the fact that changing the definition in relation to one provision in a specific case may have knock-on effects in other cases. Following Neurim it is uncertain whether the holding is to apply in relation to Art. 3(c). The answer to this question can have important practical consequences since a negative answer would limit the possibilities of evergreening to scenarios where on the basis of the first MA for a product either 1) no SPC has been granted or 2) an SPC has been granted to an another entity.

Its application to Art. 3(c) notwithstanding it is clear that the Neurim judgement has a huge economic potential for industry actors who on the basis of this could be able to obtain extended effective protection. Such a proliferation of several SPCs for the same product(s) would increase the possibilities of evergreening. These possibilities can be illustrated as:

Illustration 13:

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232 AHP Manufacturing, C-482/07, pr. 40-41.
233 This issue has been referred to the CJEU for preliminary ruling in case Novartis C-354/19.
Admittedly, the legal situation following Neurim is not as clear as indicated in illustration 13 above; it is apparent that Neurim leaves some uncertainty as to whether the ruling applies only to the specific factual scenario of Neurim. The Neurim decision gives little guidance about whether an SPC is also permissible when the first MA was granted for a use of the active ingredient for the same species as the first MA. That Neurim is applicable under such situations (same species) seems suggested by pr. 25 of the CJEU ruling where the Court states:

‘Therefore, if a patent protects a therapeutic application of a known active ingredient which has already been marketed as a medicinal product, for veterinary or human use, for other therapeutic indications…’

In this paragraph the CJEU thus indicates that the holding is applicable irrespective of whether the first MA is for a veterinary or human use. A counterargument to this - i.e. that Neurim is only applicable in the specific scenario - is that the CJEU does not explicitly state that Yissum, which concerned same species but different indications, is overruled even though an SPC was refused in that case. Furthermore, the CJEU in its concluding paragraph includes the phrase: ‘…in a case such as that in the main proceeding’. To add to this uncertainty there is a further possibility - an intermediate approach - whereby an SPC can be obtained for the same species but subject to the requirement that a new medical indication is present, while new formulations of old active ingredients is not sufficient for Neurim to apply.

It is apparent that the courts involved in the proceedings (both the national courts and the CJEU) agree that a literal interpretation could not result in an SPC for Neurim under the circumstances. However, upon taking a schematic and teleological approach divergences appeared. With regard to a teleological interpretation and the uncertainties mentioned directly above, it becomes important to consider whether the purpose of the SPC Regulation is to reward any patented pharmaceutical inventions with SPCs or only research that leads to ‘new active ingredients’. The question of the scope of Neurim has thus unsurprisingly been the subject of recent case law where these teleological considerations are central.

5.2.3. Abraxis C-443/17

The scope and application of Neurim is unclear and it is not difficult to see that the ruling has opened the door for a lot of scenarios where similar arguments can be invoked to obtain SPC protection. In the Opinion of AG Trstenjak in Neurim, it is strongly emphasised that the crucial factor is whether or not the first MA falls within the scope of the patent designated in an application for an SPC for a second or further use. This seems to suggest that an SPC can

234 Neurim C-130/11, pr. 25.
235 Ibid., pr. 27.
236 Meaning, in this regard, the treatment of a new disease.
also be granted for a new formulation as long as this requirement is met. The CJEU was not as categorical in its phrasing but the operative part of the decision refers in general terms to the possibility of obtaining an SPC on the basis of the first MA relating to a ‘new application’ of a previously authorised product.\textsuperscript{237} The uncertainty regarding Neurim’s applicability in relation to a new formulation resulted in the Abraxis case being referred to the CJEU.

5.2.3.1. Facts and National Proceedings

Abraxis marketed paclitaxel formulated as albumin bound nanoparticles (‘nab-paclitaxel’ or NP), sold as the medicinal product ‘Abraxane’ pursuant to an MA. Paclitaxel (\(P\)) has been the subject of two prior MAs used in the treatment of certain cancers, the details of which are immaterial for present purposes.\textsuperscript{238} NP is a new formulation of \(P\) and is protected by a basic patent for the same use. It allows the active ingredient to exercise its therapeutic effects with an increased efficacy.\textsuperscript{239} The factual scenario can be illustrated as follows:

\textit{Illustration 14:}

\begin{center}
\begin{tabular}{|c|c|}
\hline
\textbf{First MA} & \textbf{Second MA} \\
\hline
Human use & Human use \\
Indication A & Indication A \\
Formulation A & Formulation B \\
\hline
\end{tabular}
\end{center}

Despite having been granted SPCs in nine EU member states, the application was refused by the UK-IPO on the basis that \(P\) is the subject of an earlier MA for the same use, thus conflicting with the SPC Regulation Art. 3(d).\textsuperscript{240} The intrinsic characteristics and effects of NP was not seen as sufficient to consider it a new ‘product’ in the meaning of the SPC Regulation. It was found to be merely a new formulation of an existing product with the same therapeutic effect, since the substance combined with \(P\) to make it NP does not produce a therapeutic effect of its own.\textsuperscript{241} The UK-IPO consequently did not view ‘Abraxane’ as a new product under Art. 1(b) and rejected the application on the grounds of Art. 3(d), since \(P\) was already the subject of a prior MA.\textsuperscript{242}

\textsuperscript{237} Neurim C-130/11, pr. 27.
\textsuperscript{238} Abraxis C-443/17, pr. 10.
\textsuperscript{239} Ibid., pr. 9.
\textsuperscript{240} Ibid., pr. 11.
\textsuperscript{241} UK Intellectual Property Office, decision by the Comptroller-General of Patents, BL O/410/16, pr. 184.
\textsuperscript{242} Ibid., pr. 194.
Abraxis subsequently appealed the decision under the argument that the condition laid down in Art. 3(d) of the SPC Regulation was met considering the decision in Neurim. Since the scope of Neurim was unclear, as established above, the interpretation of Art. 3(d) of the SPC Regulation was not obvious in the case of a new formulation of an old active ingredient and for that reason the UK High Court of Justice referred a question as to the interpretation of Art. 3(d) to the CJEU.²⁴³

5.2.3.2. Analysis

In the Opinion of AG Saugmandsgaard Øe, he addressed case law subsequent to Neurim, where the Court has confirmed the interpretation of the concept of ‘product’ within the meaning of Art. 1(b) adopted in MIT.²⁴⁴ The AG made further reference to another case, Forsgren C-631/13, in which the Court again recalled that interpretation. Interestingly, in Forsgren the CJEU emphasised that the SPC regime is intended to cover the cost of research leading to the discovery of new ‘products’.²⁴⁵ Accordingly, the AG agreed that the intention of the legislator was to protect only research leading to the placing on the market for the first time of an active ingredient or a combination of active ingredients as a medicinal product in contrast to all pharmaceutical research.²⁴⁶ With this in mind, AG Saugmandsgaard Øe found that there was insufficient basis for an interpretation that departed from the wording of the SPC Regulation.²⁴⁷ He subsequently proposed the abandonment of the ‘scope of protection of the basic patent test’ and a return to a literal interpretation of Art. 3(d) in alignment with Art. 1(b) of the SPC Regulation.²⁴⁸ In the Abraxis case, this would mean that, although the MA for ‘Abraxane’ is the first to fall within the scope of the basic patent protecting the new formulation (NP) of a known active ingredient (P), it is not the first MA for that active ingredient (P). The AG goes further in suggesting an alternative if the CJEU does not wish to take this approach. To this effect he suggests limiting the scope of Neurim to the specific scenario of an earlier MA for veterinary use and a subsequent MA for human use.²⁴⁹

In its decision, the CJEU also found that a new formulation of an older active ingredient, where the substance added has no therapeutic effect of its own, cannot constitute a new product distinct from the product consisting solely of the older active ingredient within the meaning of

²⁴⁴ Glaxosmithline, C-210/13, pr. 44, as addressed in Abraxis C-443/17, Opinion of Advocate General Saugmandsgaard Øe, pr. 40.
²⁴⁵ Forsgren, C-631/13, pr. 52.
²⁴⁶ Abraxis C-443/17, Opinion of Advocate General Saugmandsgaard Øe, pr. 69.
²⁴⁷ Ibid., pr. 85.
²⁴⁸ Ibid., pr. 86.
²⁴⁹ Ibid., pr. 105.
Art. 1(b). Accordingly, only the first MA for a medicinal product, consisting of the product concerned as defined by Art. 1(b), may be regarded as the first MA within the meaning of Art. 3(d). The Court then addressed Neurim and suggested a limiting scope to which it only applies ‘in a situation such as that in the case which gave rise to that judgement’. Moreover, the CJEU held that Neurim does not, in any event, refer to cases of a new formulation of the product at issue and it therefore cannot be relied on under the circumstances of Abraxis.

The CJEU thus returns to a literal interpretation of Art. 3(d) in alignment with Art. 1(b) of the SPC Regulation. While doing so, the Court also makes some comments indicating a narrow application of the Neurim ruling, i.e. to the specific circumstances and not in cases of a new formulation. This is in accordance with that suggested by the AG in the alternative.

Interestingly, the CJEU agrees with the AG Opinion in acknowledging that the SPC regime has the purpose of compensating for the lack of protection conferred by a patent with respect to covering the investment put into research leading to ‘…the first marketing of an active ingredient’. This question of whether the purpose of the SPC regime is to allow for the recoup of investments relating to all pharmaceutical research or more narrowly only the research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product is at the crux of many SPC issues and deserves closer attention.

Pharmaceutical research can have many purposes and it is not unequivocal what types of research the SPC Regulation intends to promote. In particular two lines of the Explanatory Memorandum can be referenced to counter-argue the holding of AG Saugmandsgaard Øe and the CJEU in Abraxis. First, paragraph 12 holds that: ‘all research, whatever the strategy or final result, must be given sufficient protection’ and second, paragraph 29 provides: ‘all pharmaceutical research provided it leads to a new invention which can be patented…must be encouraged without any discrimination’. Furthermore, it is well established that all types of patents may be designated as a basic patent and it can be argued that the fact that EPC(2000) included new exemptions for the patenting of second and further medical uses may be taken as an indication of a development in the legal landscape justifying a contra legem interpretation. From these arguments it can reasonably be held that the purpose of the SPC

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250 Abraxis C-443/17, pr. 31.
251 Ibid., pr. 40.
252 Ibid., pr. 41.
253 Ibid., pr. 43.
254 Ibid., pr. 37.
255 The Explanatory Memorandum, pr. 12.
256 Ibid., pr. 29.
257 EPC(2000) Art. 54(4) and Art. 54(5). The introduction of these provisions is described above in section 5.1.
regime is to foster pharmaceutical research ‘without any discrimination’ and consequently an SPC should be available whenever a pharmaceutical patent and subsequent MA has been granted.

Still, the conclusions from the AG and the CJEU seem to have a more solid legal foundation. The SPC Regulation intended to counter an assumed decline in the invention of new molecules for medicinal use. When new molecules are developed, they must undergo extensive and rigorous tests and trials required for a full stand-alone MA according to Art. 8 of the Medicinal Products Directive. This reduces the period of exclusivity, especially when considering the incentive to file a patent application as soon as possible due to the first-to-file principle. Such reduction in patent life is the exact effect that led to the assumed lack of protection that was a primary motivating factor behind the SPC Regulation. Paragraph 11 of the Explanatory Memorandum in particular supports this argument:

‘The proposal for a Regulation therefore concerns only new medicinal products. It does not involve granting a certificate for all medicinal products that are authorised to be placed on the market. 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 a different salt or ester or a different pharmaceutical form will not lead to the issue of a new certificate.’

Peculiarly, when reference is made to ‘new medicinal products’ throughout the Explanatory Memorandum it is rather unclear what is meant by this terminology. It can be argued that it refers to the active ingredients and that when the Explanatory Memorandum refers to the marketed medicine it uses ‘proprietary medicinal product’. However, it can arguably also be understood as a generic reference to innovative medicines. Paragraph 11 and 12, in which the expressions ‘new medicinal products’ and ‘new products’ is seemingly used in accordance with the meaning of the SPC Regulation supports this conclusion.

It is clear from the Explanatory Memorandum that the legislator was fully aware that one and the same product could be successively granted several MAs when a modification was made affecting the pharmaceutical form, dose, composition, indications, etc. Nevertheless, it was still held that only the first MA should be taken into account for the purposes of the regulation.

258 Max Planck Institute for Innovation and Competition 2018, page 15.
259 The Explanatory Memorandum, pr. 11.
260 This is the argument in Max Planck Institute for Innovation and Competition 2018, page 16-17, with reference to the Explanatory Memorandum pr. 28-29.
261 The Explanatory Memorandum, pr. 35.
262 Ibid., pr. 36.
Irrespective of what is meant by reference to ‘new medicinal products’ in the Explanatory Memorandum, much seem to counter the argument that it is all pharmaceutical research that is intended for protection. This is further supported by the fact that the risk of market failure, where the ordinary patent protection period cannot bring profitable results, was perceived and to some degree documented for new active ingredients where a significant amount of pre-clinical and clinical work prevails.\(^{263}\) No such perception and/or documentation of market failure relating to second and further medical uses seem to have been considered at the time.

What is then meant in paragraphs 12 and 29 invoked to argue that the intention was to protect all pharmaceutical research must be that the concept of ‘basic patent’ includes patents relating to a process for the manufacture of a known product or to an application of it. That is to say that those types of patents are not excluded from being relied upon as the basis for an SPC per se. They can serve as such ‘provided that all of the conditions governing the application of the proposal for a Regulation are fulfilled’\(^{264}\), meaning that Art. 3(a)-(d) must still be satisfied.

Furthermore, the argument that the EPC(2000) and its introduction of Art. 54(4) and (5) EPC can be taken to suggest that the same inventions should be allowed to obtain an SPC is flawed. As discussed in section 5.1. above, the EBA confirmed in decision G5/83 that second and further medical uses could be patented via so-called Swiss-type claims. The practice of allowing the patenting of those inventions was therefore well established when the drafting of the First SPC Regulation No 1768/92 occurred. Of even more convincing force; the EPC had already been revised upon the initial work of the SPC Regulation (No 469/2009). From this perspective it cannot be accepted that the revision of the EPC constitutes a legal and societal development which the legislature failed to anticipate.

In its Abraxis decision, the CJEU also rejects the ‘scope of protection of the basic patent test’ since the Court found it would risk leading to legal uncertainty and inconsistencies as to the circumstances in which an SPC may be obtained. This is so since it would be difficult to determine in which specific circumstances an MA granted in respect of a new formulation of an old active ingredient may be covered by that provision.\(^{265}\) This echoes the argument from the Neurim analysis above where it is submitted that it was the intention to create a transparent and simple system to mitigate the burden placed upon the NPOs.

The Abraxis decision bases its reasonings and operative part on sound legal considerations; it limits the scope of Neurim by reversing some of the teleological interpretations relied on in the case by raising its own that are grounded in a more solid legal basis. However, in

\(^{263}\) Max Planck Institute for Innovation and Competition 2018, pages 237-238 and pages 630-631.

\(^{264}\) The Explanatory Memorandum, pr. 29.

\(^{265}\) Abraxis C-443/17, pr. 39.
interpreting Neurim as an exception the CJEU ignores that the reasoning of Neurim, more specifically paragraphs 22-26, seems to suggest a more general scope of applicability. In these paragraphs the CJEU refers to i.a. the fostering of pharmaceutical research in general conflicting with the holding of fostering only new active ingredients never authorised before in the Abraxis decision. Furthermore, while the Abraxis decision is based on sound legal arguments it does not answer to what extent the earlier case law of Pharmacia, MIT and Yissum can be reconciled with Neurim and it avoids giving full and definitive guidance on the scope of the Neurim exception.

The CJEU spends a considerable share of the reasoning on the specifics relating to ‘Abraxane’ and the fact that \( P \) is not a new ‘product’ under Art. 1(b) and then it re-establishes the link between this provision and Art. 3(d).\(^{266}\) With this in mind it is difficult to see how the Neurim judgement can be reconciled with the Abraxis holding, more precisely pr. 24-25 of the former with pr. 37 of the latter. It is therefore submitted that it is improper of the CJEU to simply ‘relegate’ Neurim to a narrow exception.\(^{267}\)

At the moment the case Santen C-673/18 is pending before the CJEU. The Cour d’appel de Paris has referred questions pertaining directly to the concept of ‘different application’ within the meaning of the Neurim judgment and how this is to be precisely interpreted. Furthermore, it is asked whether the Neurim case entails that the scope of the basic patent must be the same as that of the MA relied upon and, therefore, be limited to the new medical use corresponding to the therapeutic indication of that MA.\(^{268}\) At the time of writing the AG Opinion has been handed down\(^{269}\) but is unavailable in a language familiar to this author. It will consequently not be the subject of analysis but early indications suggest that AG Giovanni Pitruzzella in the Santen case takes a strict literal interpretation and goes against Neurim, quite like the approach of the AG in Abraxis.\(^{270}\) The AG Opinion in Santen also, as was the case with the AG Opinion in Abraxis, suggests an answer to the question in the situation where the CJEU does not want to overrule Neurim. In this instance it is suggested that Neurim is interpreted as to allow SPCs for new therapeutic indications or for uses of the same active which have a pharmaceutical, immunological or metabolic action of their own.\(^{271}\)

\(^{266}\) Abraxis C-443/17, pr. 31 and 44.
\(^{267}\) Ibid., pr. 43.
\(^{268}\) Request for a preliminary ruling from the Cour d’appel de Paris (France) in case Santen C-673/18 lodged on 30 October 2018.
\(^{271}\) See ‘To Neurim or not to Neurim, that is the question’: \url{https://united-kingdom.taylorwessing.com/synapse/ti-neurim-or-not.html} (last visited March 10, 2020).
5.3. Summary of Case Law

The interpretation of Art. 3(d) of the SPC Regulation has caused considerable difficulty with ensuing legal uncertainty as illustrated by the analyses of the case law above. Some of these cases concerned problems that are in principle separate but are still relevant as they consider issues that interact with Art. 3(d). The issue of SPCs for second and further medical uses is situated at a crossroad between an established narrow interpretation of what constitutes a ‘product’ within the meaning of Art. 1(b) and a consideration of the need to promote (some) pharmaceutical research, which the SPC regime is founded upon. In the early case law, the CJEU took a strict approach:

- **Pharmacia C-31/03** concerned different species but the same indication and held that no SPC could be permitted. In doing so, the CJEU found that the decisive factor for the grant of the certificate is not the intended use of the medicinal product and that this is the case without any distinction between use of the product as a medicinal product for human use and as a veterinary medicinal product.

- **MIT C-431/04** concerned same species and the same indication but dealt with the question of whether the inclusion of an adjuvant in a compound could render it a new product according to Art. 1(b). It was held that Art. 1(b) must be strictly interpreted so as to not entail a new product under the circumstances.

- **Yissum C-202/05** concerned the same species but different indications and was decided by reasoned order with reference to the two above mentioned cases. This decision is naturally read as a confirming that the concept of ‘product’ in Art. 1(b) needs to be interpreted strictly and therefore cannot include the therapeutic use of the active ingredient.

However, through the application of a teleological approach the CJEU came to a conclusion in Neurim C-130/11 which can be difficult to reconcile with the above. Here, the CJEU relied on the argument that research required to obtain a patent and an MA for a second and further medical use justifies the grant of an SPC in spite of the fact that the same ‘product’ has already been the subject of an MA. Neurim thus suggests that Art. 1(b) must be strictly interpreted, while Art. 3(d) may be more broadly interpreted.

The decision has since been applied in different ways. Some have understood Neurim as being applicable only to the factual scenario referred to in the case (different species and different indication). Others have applied Neurim when the patent covered a second and further medical use and the MA granted was the first covered by the basic patent. As the analysis shows, such holding can be supported with reference to several passages of the judgment. Nevertheless, it seems to go beyond what was intended by the legislator as a
thorough reading of the Explanatory Memorandum suggests that it was the time and the investments related to the development of new active ingredients that the SPC regime intended to foster.

The CJEU in its Abraxis decision attempted to align the case law once again following Neurim’s de facto circumvention of settled case law. The Court did so by confirming the well-established strict interpretation of Art. 1(b) and re-establishing a connection between this provision and Art. 3(d). However, in doing so the CJEU once again avoided explicitly rescinding Neurim and instead classified it as an exception to the strict interpretation of Art. 1(b).

5.4. Discussion & Status of the Issue

It is not difficult to reconcile the Neurim judgement with logic and a sense of fairness. No matter the line drawn between which pharmaceutical research is intended to benefit from the SPC Regulation and which is not, it is prima facie easy to accept an argumentation such as the following: i) the patent system has economic underpinnings in seeking to establish a system that lets actors recoup R&D investments that are beneficial to society, ii) the SPC regime is founded on much the same considerations, thus iii) when an actor undertakes prolonged and expensive research in order to identify second and further medical uses, with the consequence of enduring a long wait before market entry, such investment should also - in line with other investments of such character - be able to secure fair compensation through the grant of an SPC. This is true if one accepts the premise that such incentive mechanisms provide an increase in innovation that is beneficial to society. This applies all the more considering the decrease in the identification of ‘new products’ and increase in second and further medical uses.

It is however difficult to reconcile the Neurim holding with the SPC Regulation and thus with a sense of legal legitimacy. The CJEU has gone against the express wording of both the SPC Regulation and the intention of the legislator, as recorded in the Explanatory Memorandum. Even though it can be argued that the Explanatory Memorandum does not excel in clarity, and that the words may not have been chosen with a sufficient degree of meticulousness to warrant a decisive literal interpretation, it must be found that in combination with the specific wording of the SPC Regulation, the Neurim decision manifestly takes the principle of teleological interpretation too far by altering the balance explicitly drawn by the legislator through case law.

Thus, no matter how one may consider the overall result of Neurim fair or not, the reasoning and the result must be considered flawed. It is inappropriate for the CJEU to take such an activist position and a departure of such significance from established EU law cannot be
accepted. Indeed, if such arbitrary practice from the judiciary was the norm it would in and of itself create legal uncertainty making it difficult for industry actors to arrange matters in accordance with the law and consequently result in a loss of efficiency across industries.

While it from a legal perspective is welcome that the Abraxis ruling in some way mitigates the impact of Neurim, and alleviates some of the uncertainty linked to this, it arguably takes the easy way out by relegating Neurim to an exception to the strict interpretation of Art. 3(d). The analysis of the Neurim decision reveals systemic inconsistencies and a bending of the established interpretation of some of the provisions in the SPC Regulation. Indeed, if one accepts the broad interpretation of Art. 3(d), delinking it from Art. 1(b), it must also be considered how this carries over to the interpretation of other provisions such as Art. 4, 5 and 13. Since these points of criticism have been formed in case law it is incumbent upon the CJEU to resolve this by means of judicial decision that expressly rescinds the Neurim ruling.

If a legal landscape where the Neurim holding is no longer law is deemed inexpedient, it falls within the EU legislator’s sphere of responsibility to execute corrections. The current situation could therefore call for a legislative change if the legislator and stakeholders find that a literal interpretation renders the SPC Regulations not fit for purpose. In this assessment it would be highly relevant to see some data documenting that investments in second and further medical uses do indeed have difficulties with recoupment. It may also be worthwhile to consider if soft law measures could be useful but given the constraints of the wording in the SPC Regulation it may not be appropriate if a fundamental change is deemed necessary.

A legislative change could adopt an express accept of second and further medical use SPCs under a specified set of requirements and circumstances. By this approach a new definition of ‘product’, that includes the therapeutic use, should apply to Art. 3(d).

Another approach could inspect the specific regulatory burdens associated with the different types of MAs with a legal basis in the Medicinal Products Directive and then make the grant of SPCs dependant on whether a given MA surpasses a certain threshold of regulatory scrutiny.

Furthermore, data and economic research may be able to clarify the underlying economic differences between patents; this could be used to show that a specific type of patent (e.g. a second medical use patent) generally does not provide industry actors with sufficient opportunity to recoup their investment. Under such circumstances it could be a viable option to distinguish between patents by creating a shorter-term *sui generis* right specifically tailored to the scenario of such patents. This could potentially make the system more adaptable and fit for the purpose of compensating for the loss of exclusivity time during the period of bringing a product to market while avoiding disincentivizing developers of new medicines.
It stands to reason that definitive conclusions cannot be drawn from the speculative final remarks above. However, a more detailed assessment of options for the EU legislator is ultimately of political nature and is outside the scope of this legal thesis. With regard to Art. 3(d) and the situation of SPCs for second and further medical uses it has been ascertained that legal uncertainty prevails. As a feature of the rule of law, legal certainty constitutes a precondition for the operational necessities of market interactions.\textsuperscript{272} Industry actors extract value from being able to arrange and organize their companies and other interests according to their legitimate expectations of the legal landscape. Legal uncertainty in this sector is thus detrimental to actors on the market, and as consequence also to the open market in the EU and the many interests involved in the pharmaceutical industry. As mentioned above, the CJEU has a chance to mitigate uncertainty related to Art. 3(d) in Santen C-673/18. However, one is tempted to say that the CJEU may just once again raise as many questions as it answers.

6. Final Remarks

This thesis finds that the legislator’s original intention for the SPC regime to provide for ‘a simple, transparent system which can easily be applied by the parties concerned’\textsuperscript{273} is generally not reflected in practice regarding the SPC Regulation Art. 3(a) and (d). The analyses have revealed the immense practical complexity of the SPC regime despite the simple wording of the SPC Regulation. In this regard, the CJEU has taken simply worded concepts and turned them more complex. This is not solely caused by erring from the CJEU; it will always be difficult to reconcile the simple wording with the highly complex landscape in which the SPC regime operates, wherein regulatory matters need to be conjoined with intellectual property law. Add to this the fact that the pharmaceutical industry, at the time of the drafting of the Explanatory Memorandum and the SPC Regulation No 1768/92, was very different. the SPC Regulation was originally created with single-compound products in mind, but there has since been an increase in more complex combination products.\textsuperscript{274}

It might be worthwhile to consider whether it is expedient to attempt to regulate such a complex system via simply worded regulation. If not, it is arguably regrettable that the EU legislator went with the \textit{sui generis} right-model over a patent extension-model. The motivation for this was purportedly that a patent extension-model would have required a revision of the EPC which

\textsuperscript{273} The Explanatory Memorandum, pr. 16.
\textsuperscript{274} Max Planck Institute for Innovation and Competition 2018, page 110 and 126.
would have delayed the legislation considerably. In hindsight, the adoption of the patent extension-model might have been worth a simple delay in the regulation. As already discussed, the simple drafting and wording of the regime was also a consequence of the characteristics of the NPOs, some of which may lack the resources necessary to conduct a sophisticated technical examination. However, setting some mandatory minimum requirements for administrative bodies which could allow for the drafting of a system with resourceful recipients in mind might allow for a more manageable system.

As it stands, the regime has been shaped by the CJEU trying to define simple key terms in the SPC Regulation more thoroughly in an attempt to accommodate complex situations. In doing so the CJEU has arguably overreached its jurisdiction and taken an activist position. It has adopted an argumentation that recognises minimal methodological constraint thus leaving ample room for judicial discretion, effectively allowing the CJEU to rely on the interpretative approach that may support its own preferred conclusions. The absence of a high level of methodological rigour will plainly foster legal uncertainty. This is closely associated with the systemic inadequacies of the CJEU decisions in this area with regard to predictability, consistency, preciseness and comprehensiveness. This is obviously problematic but the more so when considering that the CJEU operates in an unusually permissive political environment since its interpretation of the law cannot be challenged and its position leaves the Member States with little influence and control.

It is clear from the analyses and the above discussions that the SPC regime is open to criticism on several accounts ranging from its conception to its implementation via the interpretation of the provisions by the CJEU. The elucidation of the issues of the research questions in relation to Art. 3(a) and (d) call for a critical review and possibly some update of the SPC regime as it currently creates unpredictable and arbitrary legal situations and consequently does not provide a satisfying degree of legal certainty. In a sector as complex and sensitive as the pharmaceutical sector the consistency of case law and the highest possible level of legal certainty for the various economic and societal stakeholders is especially vital. How such update should be implemented goes beyond the scope of this thesis, but it has been argued that soft law measures might be most expedient in relation to Art. 3(a) while a substantive change of 3(d) is most likely needed if it is deemed necessary to incentivise second and further medical uses via the SPC Regulation.

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275 An amendment of the EPC would have been necessary to avoid triggering a violation of Art. 63 EPC 1973, which gave very little room for maneuver in terms of patent extensions beyond 20 years. See Max Planck Institute for Innovation and Competition 2018, page 40-41.

In consideration of the call for change above it is regrettable that the EU Commission, in the wake of the completion of two formal reviews of the SPC regime\textsuperscript{277}, decided to ignore all but one of the recommendations in these studies.\textsuperscript{278} The call for some degree of revision is amplified by the situation regarding the UPC which is now looking increasingly unlikely to enter into force.\textsuperscript{279} This means that it is not probable that the UPC will alleviate some of the systemic inadequacies of the system. Thus, at the moment it looks like the industry and its stakeholders must entrust the CJEU to clear matters up. One can hope that future judgements from the Court will be clearer and more comprehensive.

\textsuperscript{277} Copenhagen Economics 2018 and Max Planck Institute for Innovation and Competition 2018.

\textsuperscript{278} It was decided to create an SPC manufacturing waiver which has now been implemented in Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

7. Conclusion

An SPC is designed to re-establish a sufficient period of effective protection of a patent by granting the patent proprietor an additional period of exclusivity of up to five years following the expiry of the patent. The need for such instrument has among other things been generated due to a delay in commercial exploitation of a patent by reason of the time a medicinal product spends under regulatory scrutiny when applying for an MA. There is general agreement that this instrument fundamentally fulfils its purposes.

However, this thesis highlights some legal uncertainties regarding the details of the conditions for obtaining an SPC. With regard to both issues in this thesis’ research questions, the CJEU’s decisions and the subsequent national application of these have left a rather obscure legal landscape that is difficult to oversee. This obstructs the smooth functioning of the system and makes it difficult for the NPOs to manage in any harmonious manner.

Research question 1 concerned the question of when a product is considered protected by basic patent in force. The rulings of the CJEU have established that to answer this question reference to the non-EU rules that govern patent must be made. The relevant rules for this purpose are the extent of protection rules that highlights the importance of the wording of the claims. In this regard it is the Disclosure Test that should be applied; there must be some disclosure in the patent that allows the product to be ‘specified’ or ‘identified’ from the wording of the claims. However, case law has suggested that this is not sufficient and that ‘something more’ is needed to consider a product ‘protected by the basic patent in force’. What precisely this ‘something more’ constitutes has since undergone a continuous evolution in the case law. The most recent development is found in the Teva case C-121/17 in which it is held that a product is protected by the basic patent when the claims relate necessarily and specifically to that product. For the purpose of determining this, the CJEU proposed a two-part test from which several understandings are possible. AG Hogan highlighted one of the possible ways to apply this two-part test in his Opinion. He found that the first part requires that the claims in a patent in relation to a product are required for the solution of the technical problem disclosed by the patent in question. The second part then requires that it be established that a person skilled in the art, on the basis of the prior art and all the other conditions pertaining hereto, would have been able to ‘derive the product in question’. However, the CJEU have yet to develop the two-part test further.

Research question 2 concerned the issue of when it is possible to obtain an SPC for second and further medical uses. Patents for such uses allow industry actors to recoup research investments that brings therapeutic advances based on known active ingredients and they are
of increasing importance in the pharmaceutical industry. Previous case law had established a narrow interpretation of what constitutes a ‘product’ within the meaning of Art. 1(b) which in the situation of second and further medical use SPCs conflicts with a literal interpretation of Art. 3(d), as the wording of the latter precludes the grant of an SPC when a ‘product’ has already been the subject of an MA. However, the Neurim C-130/11 judgment applied a teleological interpretation to reach a conclusion in conflict with both a literal interpretation and previous case law. Neurim suggested two different interpretations of ‘product’; in relation to Art. 1(b) this should be strictly interpreted while in relation to Art. 3(d) it should be more broadly interpreted.

The application of Neurim has since been highly debated and the analysis finds that the decision goes against the wording of the SPC Regulation and the established case law while also going beyond what was intended by the legislator. In Abraxis C-443/17 the CJEU attempted to align the case law once again by confirming the well-established strict interpretation of Art. 1(b) and re-establishing a connection between this provision and Art. 3(d). However, in doing so the CJEU avoided explicitly rescinding Neurim despite some apparent conflicts and instead classified it as an exception to the strict interpretation of Art. 1(b). This is open to criticism and it remains to be seen whether the CJEU will set the record straight and choose to either rescind or follow Neurim expressly in the pending case Santen C-673/18.

Much of the legal uncertainty identified in the analyses of this thesis is the result of the CJEU trying to fill the legal vacuum left by the simple wording in the SPC Regulation. The thesis takes the position that Art. 3(a) and (d) call for a critical review and possibly an update as it currently does not provide a satisfying degree of legal certainty to actors in the pharmaceutical sector. The precise details of how such updates might be enacted and implemented goes beyond the scope of this thesis, but it is suggested that soft law measures might be most appropriate in relation to Art. 3(a) while a substantive change of 3(d) is most likely needed if the legislator recognises the need to incentivise research into second and further medical uses via the SPC regime.
Danish Abstract

Opgaven analyserer og vurderer SPC ordningen med særligt fokus på to af betingelserne for udstedelse af et SPC for lægemidler, der har givet særlig anledning til overvejelser. Reglerne om SPC’er har til formål at kompensere patentvævere for den tid, der forløber i forbindelse med opnåelse af en såkaldt markedsføringstilladelse (MA), således at der skabes en tilstrækkelig eksklusivitets-periode til at genvinne investeringsomkostningerne.

Første forskningsspørgsmål omhandler fortolkningen af kravet i SPC forordningens art. 3(a), nærmere bestemt hvad der ligger i kravet om, at ‘produktet er beskyttet ved et grundpatent, der er i kraft’. Til belysning heraf foretages en analyse af en række af afgørelser fra EU Domstolen. Analysedelen viser, at fortolkningen af art. 3(a) har undergået en konstant udvikling, og at der stadig er en del uklarheder og ubesvarede spørgsmål. Praksis viser, at der skal noget ‘mere’ til, end at et ‘produkt’ falder under patentets beskyttelsesområde. Hvad dette ‘mere’ nærmere præcist er har givet anledning til usikkerhed. Den seneste udvikling findes i Teva C-121/17, hvor en to-trins test er fremført. Testen giver en vis vejledning og klarhed over, hvordan man skal gribe fortolkningen an, men efterlader samtidig en del usikkerhed i forhold til den nærmere effektuering af de to trin. Der argumenteres i opgaven for, at der kan opstå større retssikkerhed med implementering af anbefalinger og retningslinjer.

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