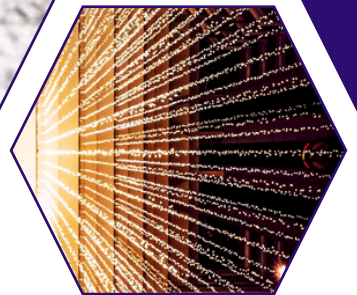


Supplementary Protection Certificates in the European Union: *Briefing Document*



Medicines Law & Policy
June 2019

Acknowledgements:

This series of briefing papers have been prepared by Pascale Boulet, Christopher Garrison and Ellen 't Hoen of Medicines Law & Policy, with editing by Jacquelyn Veraldi and Kaitlin Mara of Medicines Law & Policy. The authors would like to thank the following reviewers, whose helpful comments have improved the papers: David Banta, Sven Bostyn (Centre for Advanced studies in Biomedical Innovation Law (CeBIL)), Pierre Chirac (La Revue Prescrire), Thyra de Jong (Technopolis Group), Sergio Napolitano (Medicines for Europe), Yannis Natsis (European Public Health Alliance), Judit Rius (UNDP), Ancel.la Santos (Health Action International). The opinions expressed are, however, those of Medicines Law & Policy.

Medicines Law & Policy wishes to thank the Open Society Foundations for providing the financial support that made these papers possible. More information at: www.opensocietyfoundations.org.

This series of briefing documents is licensed under Creative Commons, Attribution-NonCommercial-NoDerivatives 4.0 International. The documents may be shared freely so long as Medicines Law & Policy is credited, redistribution is not being done for commercial purposes, and the text is not modified.

Two images on the cover are used under Creative Commons: Blood samples by the Pan American Health Organization (2007); flags of the European Union by the European Parliament (2017).

Table of Contents

Supplementary Protection Certificates (SPCs) in the EU: <i>Briefing Document</i>	1
<i>SPCs: Sui generis rights at the interface of patent and regulatory systems</i>	1
<i>SPCs Uniform Legal Framework</i>	2
<i>Diverse interpretations of conditions for SPC grant by national patent offices</i>	5
<i>Effect of SPCs on prices and affordability of medicines</i>	7
<i>SPCs not required by the TRIPS Agreement</i>	8
<i>Have SPCs generated the expected outcome?</i>	9
<i>SPC waiver reform: A missed opportunity to address excessive pricing</i>	11
<i>Conclusions and recommendations</i>	12
Further Reading	14

Supplementary Protection Certificates (SPCs) in the EU: *Briefing Document*

SPCs: *Sui generis* rights at the interface of patent and regulatory systems

Supplementary protection certificates (SPCs) are certificates providing a supplementary market protection for pharmaceutical products in the European Union. Patents in the EU last 20 years from the filing date. SPCs can add up to five years of supplementary protection to certain patents covering pharmaceutical products at the expiration of the patent term, to make up for periods when the patent could not be exploited because the medicine had not yet been granted regulatory approval for commercial use.

Pharmaceutical product development requires the generation of pre-clinical and clinical studies to evaluate the safety and efficacy of a medicine before it can be approved for commercial use in humans or animals. Given drug development timelines are estimated to be an average of around 10 years,¹ patents generally are filed several years before the application for marketing authorisation is made. Patent holders cannot get returns on their investments until the product is authorised (or registered) with the relevant medicines regulatory agency. As a result, economic exploitation during the early years of patent protection is not possible because the medicine cannot be sold.

Therefore, mechanisms of patent term *restoration*, *extension*, and in Europe, SPCs were created to compensate for the lack of commercial exploitation possibilities during the years of medicines development and regulatory approval processes of a pharmaceutical product.

¹ Copenhagen Economics, 'Study on the Economic Impact of Supplementary Protection Certificates, Pharmaceutical Incentives and Rewards in Europe' (*European Commission*, May 2018), p.182. <<https://ec.europa.eu/docsroom/documents/29521>>. Some have argued that given that SPC periods are on average 3.5 years long (as recognised by several studies of the Commission) and are designed to give 15 years total enjoyment of exclusivity, the effective patent protection, from the date of the marketing authorisation to the expiration of the patent, must be 11.5 years (i.e. 11.5 years + 3.5 years of SPC = 15 years) on average. Therefore, it can be concluded that the development time, before the product is approved, is on average 8.5 years, after deduction of 11.5 years from the 20-year patent protection.

SPCs Uniform Legal Framework

At the EU level, SPCs were triggered by the publication in 1988 of a “Memorandum on the necessity to restore the effective duration of patents for pharmaceutical products” by the European Federation of Pharmaceutical Industry Associations.² One of the objectives was to ensure a level of protection to medical research equal to that enjoyed in other sectors, but mostly to create a normative framework for European industries comparable to that of industries in the United States (US) and Japan, to support competitiveness in Europe. The US had introduced patent term restoration in 1984 via the *Drug Price Competition and Patent Term Restoration Act* (also known as the Hatch-Waxman Amendments),³ and in Japan, a system for Patent Term Extension was introduced by the 1987 revision of Patent Act.⁴

This prompted France and Italy to adopt distinct SPC regulations. To avoid a proliferation of various national SPCs regulations in Europe, Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, was adopted to ensure a “uniform solution at Community level.”⁵

The effect of an SPC granted for a pharmaceutical product is exactly like the effect of the basic patent claiming the product: SPCs extend the duration of the exclusive right benefiting the patent holder, delaying generic competition and resulting price decreases.

At the time, the Regulation applied only to nine countries. Today the agreement is in force in all EU member states and the European Economic Area (EEA) countries Norway and Iceland. A recent study reports over 20,000 SPCs have been granted since the adoption of the Regulation in 1993.⁶

The stated objective of the regulation is “to provide adequate effective protection” so that manufacturers of new pharmaceutical products “enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community.” However, to take account of “public health”⁷ interests, “the certificate cannot be granted for a period exceeding five years” ... like the US patent term restoration system

² European Commission, ‘Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products’ COM(90) 101 final – SYN255, available at <<http://aei.pitt.edu/12237/1/12237.pdf>>.

³ Under the Drug Price Competition and Patent Term Restoration Act, a maximum of 5 years can be restored to the patent, but not exceeding 14 years from the product’s approval date.

⁴ In Japan, the duration of a patent may be extended for a maximum of 5 years.

⁵ Now superseded by Regulation 469/2009 Concerning the Supplementary Protection Certificate for Medicinal Products [2009] OJ L152/1.

⁶ Copenhagen Economics (n 1).

⁷ Recital 10 Regulation 1768/92 Concerning the Creation of a Supplementary Protection Certificate For Medicinal Products [1992] OJ L182/1.

of maximum 5 years extension / 14 years of effective protection,⁸ plus one year to add value to the European market possibly?

To take an example, the basic patent of human immunodeficiency viruses (HIV) medicine dolutegravir,⁹ one of the recommended first line treatments for HIV, was filed on 28/04/2006. But the medicine was only authorised by the European Medicine Agency (EMA) 8 years later in January 2014. This means that the patent owner and manufacturing company ViiV Healthcare could benefit from more than 12 years of market exclusivity, based on the granted patent, between 2014 and the date of expiration of the patent on 28/04/2026. ViiV Healthcare requested and obtained SPCs in several European countries to prolong its exclusive rights on dolutegravir for 3 additional years until 21/01/2029, 15 years after the date of approval of the product, as allowed by the EU Regulation.¹⁰

To summarise, if the period between the patent filing date and the medicine authorisation date is less than five years, no SPC can be obtained because the patent holder will enjoy at least 15 years of effective patent protection. If this period is between five and ten years, an SPC up to 5 years may be granted to restore the effective patent protection term lost before the medicine was authorised for marketing. If the period between the patent filing date and the authorisation date is more than ten years, any SPC granted will have a maximum five-year term. A one-off paediatric extension of six months on top of the maximum five years SPC is also possible, provided the applicant has complied with what is called an agreed Paediatric Investigation Plan (PIP).

SPCs are not granted automatically. Article 3 of the Regulation establishes conditions under which a patent office can grant an SPC:

- (a) the medicine should be protected by a “basic patent in force” – which can be a national or European patent
- (b) a marketing authorisation should have been granted for the medicine in question – either by the national regulatory authority or by the European Medicines Agency
- (c) the authorised medicine should not have already been the subject of an SPC; and
- (d) the marketing authorisation should be the first to place the medicine on the market.

Even though SPCs are based on a European regulation, they must be applied to the patent office of each country where supplementary protection is sought. The patent owner may apply for an SPC within 6 months from the grant of the marketing authorisation, or from the grant of the “basic patent,” whichever is later.

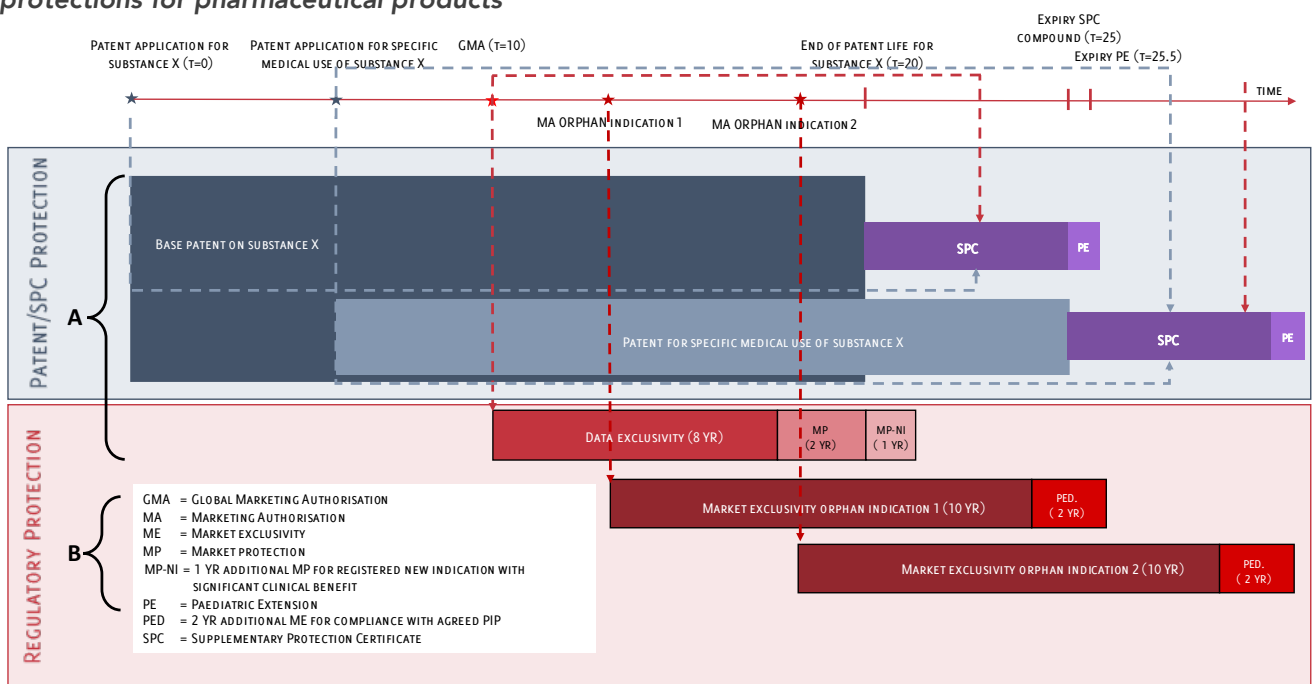
⁸ Drug Price Competition and Patent Term Restoration Act (Public Law 98-417).

⁹ European Patent Office Application Number 06758843.

¹⁰ According to Article 13 Regulation 469/2009 (n 5), the SPC term is calculated by taking the difference between the filing date of the patent and the marketing authorisation date of the medicinal product protected by the patent, minus 5.

Given that the SPC is linked to a patent and a marketing authorisation, if the patent or the marketing authorisation are invalidated, the SPC is cancelled.¹¹ A patent, in the absence of a marketing authorisation, does not provide a right to obtain an SPC. Additionally, the scope of the certificate may be more limited than the basic patent, as it is only intended to cover the product (intended as active pharmaceutical ingredient, as specified in the Explanatory Memorandum of the SPC Regulation)¹² as approved for use, whereas the scope of a pharmaceutical patent can be broader. The link with the existence of a market authorisation and the narrower scope of the SPC compared to a patent confirms the *sui generis* nature of the SPC.

Figure 1: Relation between the different patent/SPC and regulatory protections for pharmaceutical products



Blue represents patent protection; Red represents regulatory protection. The purple colour for the SPCs indicates the combination of features of patent and regulatory systems. Dotted lines show the relationships between patent application and marketing authorisation dates and how they relate to certain protection mechanisms. The width of the boxes (and the positioning of the two boxes exemplifying the patents) represents the scope of protection provided by the respective instruments. Note that the above depiction is a simplification: the situation could become more complex when considering, for example, the possibility to apply for different SPCs invoking the same basic patent. **Figure extracted from Technopolis Group report “Effects of supplementary protection mechanisms for pharmaceutical products,” May 2018.**

¹¹ Article 15 of the SPC Regulation (n 5) provides that “The certificate shall be invalid if: (a) it was granted contrary to the provisions of Article 3; (b) the basic patent has lapsed before its lawful term expires; (c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.”

¹² See the Commission Explanatory Memorandum (n 2) 8: “a product being understood to mean an active substance in the strict sense.”

Preparatory work leading to the adoption of the SPC regulation indicates that the original intention of Article 3 was to grant one SPC per any one medicinal product, only for substances that were authorised for the first time as active ingredients of a medicine.¹³ If the product had already been authorised in the past, and the applicant identified new uses or a new formulation of the product and obtained a more recent marketing authorisation, an SPC was meant to be excluded. This is coherent with the fact that research and development of new chemical entities is longer and riskier than it is for new indications or new uses of known molecules. In practice, however, the SPC regulation gave rise to a handful of jurisprudence from national courts and the Court of Justice of the European Union (CJEU) far away from the original principle of only one SPC for one new medicine. One of the most discussed rulings of the CJEU, in the *Neurim* case, has established the possibility to obtain an SPC for a second medical use indication based on a second medical use patent.^{14,15}

Diverse interpretations of conditions for SPC grant by national patent offices

Unlike patents, which can be granted by the European Patent Office, SPCs are granted only by national patent offices, in accordance with Regulation (EEC) No 469/2009.¹⁶ As a result, despite this common European legal framework intended to prevent a heterogeneous development of national laws, national patent offices and courts have interpreted the Regulation in different ways, generating disparities of protection among EU countries. The hybrid nature of SPCs, which are granted based on the existence of both a basic patent and a marketing authorisation covering the product, contributed to a plethora of judicial decisions based on the SPC Regulation. The Max Planck Institute Study on the legal aspects of Supplementary Protection Certificates¹⁷ in the EU provides a thorough analysis of the SPC case law developed in the past 25 years.

¹³ Ibid.

¹⁴ Case C-130/11 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents* [2012] EU:C:2012:489.

¹⁵ See in Figure 8 of the Technopolis Group report: "Possibilities to obtain SPCs on different types of patents for the same compound": Thyra de Jongh and others, 'Effects of Supplementary Protection Mechanisms for Pharmaceutical Products' Final Report (*Technopolis Group*, May 2018) 54 <<http://www.technopolis-group.com/wp-content/uploads/2018/06/2718-Technopolis-report-on-supplementary-protection-mechanisms.pdf>>.

¹⁶ Although this could change when the unitary patent comes into effect: 'Unitary Patent' (*European Commission*) <https://ec.europa.eu/growth/industry/intellectual-property/patents/unitary-patent_en>.

¹⁷ Max Planck Institute for Innovation and Competition, 'Study on the Legal Aspects of Supplementary Protection Certificates in the EU' (*European Commission*, 2018) <<https://ec.europa.eu/docsroom/documents/29524>>.

The case of the medicine Truvada,¹⁸ a fixed-dose combination of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) used for the treatment and prevention of HIV, illustrates well the differences of interpretation in the SPC Regulation among national patent offices.

The basic patent covering tenofovir expired in July 2017. However, an SPC had been granted to extend the protection of Truvada by several patent offices, including France, the United Kingdom (UK), Spain and Switzerland. By contrast, the Netherlands, Italy and Greece refused to grant the same SPC. The main reason for the rejection of the SPC was that the patent in question claimed tenofovir but not emtricitabine specifically, so these patent offices decided that the patent did not protect the product tenofovir/emtricitabine, as required by the Regulation, but only part of it. In France, the generic drug maker Mylan challenged the granted French SPC and the courts confirmed that the SPC was invalid.¹⁹ The same happened in Spain.²⁰ In the UK, where several generic companies challenged the granted SPC, the judge of the High Court asked clarification to the European Court of Justice on how to interpret the EU Regulation.

The CJEU ruling in July 2018 clarified the definition of 'basic patent', especially with regards to combination products, such as Truvada.²¹ Importantly, the Court recalled that "In the light of the need, referred ... in ... the preamble to Regulation No 469/2009, to take into account all the interests at stake, including those of public health, to accept that an SPC that could grant ... protection which goes beyond ... the invention it covers, would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European Union by the use of SPCs."²² In other words, the Court pointed to the risks of SPCs being used to 'evergreen' patent protection, in contradiction with the text and spirit of the Regulation to take "all the interests at stake," and in particular public health interests.

The question of the beneficiary of the SPC, not specified in the Regulation, also gave rise to case-law when the owner of the basic patent differs from the holder of the marketing authorisation.²³

¹⁸ Pascale Boulet, 'Will the European Court of Justice Put a Stop to the Evergreening of Truvada Patents?' (*Medicines Law & Policy*, 8 May 2018) <<https://medicineslawandpolicy.org/2018/05/will-the-european-court-of-justice-put-a-stop-to-the-evergreening-of-truvada-patents/>>.

¹⁹ Tribunal de grande instance de Paris, 'Ordonnance de référé rendue le 5 septembre 2017' No. RG 17/57112.

²⁰ Núria Ribera, 'Preliminary injunctions revoked due to prima facie invalidity of Truvada SPC' (*International Law Office*, 8 January 2018) <<https://www.internationallawoffice.com/Newsletters/Intellectual-Property/Spain/Grau-Angulo/Preliminary-injunctions-revoked-due-to-prima-facie-invalidity-of-Truvada-SPC#>>.

²¹ Pascale Boulet, 'CJEU Ruling on Truvada recalls "evergreening" goes against public health interests' (*Medicines Law & Policy*, 10 September 2018) <<https://medicineslawandpolicy.org/2018/09/cjeu-ruling-on-truvada-recalls-evergreening-goes-against-public-health-interests/>>.

²² Case C-121/17 *Teva UK and Others v Gilead* [2018] EU:C:2018:585.

²³ See Max Planck Institute for Innovation and Competition (n 17) Chapter 13 of MPI Study on the legal aspects of Supplementary Protection Certificates.

According to the SPC Regulation, the holder of a basic patent claiming an authorised medicine is entitled to an SPC without having to ask permission from the marketing authorisation holder. This situation does not raise issues in most cases; generally, the marketing authorisation holder is the patent owner, or a licensee. However, this is not always the case. The following question was only recently referred by a UK court to the CJEU for clarification: “Does the SPC Regulation preclude the grant of an SPC to the proprietor of a basic patent in respect of a product which is the subject of a marketing authorisation held by a third party without that party’s consent?”²⁴

Effect of SPCs on prices and affordability of medicines

The effect of an SPC granted for a pharmaceutical product is exactly like the effect of the basic patent claiming the product. SPCs extend the duration of the exclusive right benefiting the patent holder. The grant of an SPC therefore further delays generic competition and resulting price decreases. The extended monopoly position is usually used by the patent/SPC holder to impose the highest possible price that the market can bear for the product. Conversely, the refusal or lack of SPC can result in significant improvements in a medicine’s affordability. The disparities of SPC protection within EU countries illustrate the price difference for the same medicine in a country which granted an SPC as compared to a country that did not.

While the benefits of expanded patent protection for commercial companies are clear, the key question is what are the costs/benefits of patent term extensions such as SPCs from a public interest perspective.

The Truvada example described above is useful to understand the consequences of SPCs on pricing and affordability of medicines. Truvada is a critical medicine for HIV treatment and prevention. The use of Truvada as pre-exposure prophylaxis or PrEP can reduce HIV transmission by over 90%. Affordable pricing of the product is therefore important for public health. Since July 2017, Truvada has been progressively available in generic forms in European countries without SPCs (e.g. the Netherlands and Greece) but not in others with SPCs in force (e.g. Switzerland).

A report from the Technopolis Group for the government of the Netherlands titled the *Effects of supplementary protection mechanisms for pharmaceutical products*, published in April 2018,²⁵ evaluated the cumulative costs of the supplementary protections to the Dutch healthcare system for three drugs. For Lipitor (atorvastatin, used to prevent cardiovascular disease) and Losec (omeprazole, used to treat gastrointestinal illnesses), the total costs of the supplementary protections that delayed competition are estimated to have been over €600m for each medicine.

²⁴ *Eli Lilly & Co v Genentech, Inc* [2019] EWHC 388 (Pat)
<<https://www.bailii.org/ew/cases/EWHC/Patents/2019/388.html>>.

²⁵ Technopolis Group (n 15).

For Cozaar (losartan, which treats high blood pressure), the estimate is lower, at around €118 to €130m, mostly as a result of a significantly lower number of users. The authors conclude that “for high-grossing drugs, the supplementary protections can represent a substantial amount of additional revenue for companies, which is borne as a cost by the healthcare system.”²⁶

Table 1: SPC status and corresponding prices of TDF/FTC in Europe

Country	SPC status	Price TDF/FTC box (30 tablets) in €
The Netherlands	never granted	30.65 ²⁷
France	revoked	170 ²⁸
Switzerland	in force	800 ²⁹

SPCs not required by the TRIPS Agreement

Article 33 of the World Trade Organisation Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) provides that “The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date” of the patent application, therefore patents should have a minimum 20-year patent term from the filing date.

In addition, TRIPS Article 1 states that “Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement.”

Read together, both articles clearly indicate that WTO member states have an obligation to make available patents for a minimum of 20 years from the filing date, but are not obliged to extend protection beyond that duration. Therefore, SPCs are clearly not mandated by the WTO.

While the benefits of expanded patent protection for commercial companies are clear, the key question is what are the costs/benefits of patent term extensions such as SPCs from a public interest perspective.

²⁶ Technopolis Group (n 15) 151.

²⁷ Zorginstituut Nederland, ‘Medicijnkosten.nl’ <<https://www.medicijnkosten.nl/>>.

²⁸ EurekaSanté, ‘Truvada’ <<https://eukasante.vidal.fr/recherche/index/q:truvada/>>.

²⁹ Stephen Mossaz, ‘La Prep, cette pilule "anti-VIH" efficace, mais peu utilisée en Suisse’ (RTS info, 1 décembre 2017) <<https://www.rts.ch/info/sciences-tech/medecine/9133952-la-prep-cette-pilule-anti-vih-efficace-mais-peu-utilisee-en-suisse.html>>.

Have SPCs generated the expected outcome?

Council Regulation (EEC) No 1768/92 (as now superseded by Regulation 469/2009) was based on two premises, as quoted:

1. "Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research;"³⁰
2. "The period that elapses between the filing of an application for a patent for a new medicinal product and the authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research."³¹

Twenty-five years after the adoption of the SPC Regulation, it is necessary to assess whether it generated the expected outcome; that is, if the period of effective protection under patents *needs* to be supplemented "to cover the investment put into the research" and whether such supplementary protection has incentivised research and development (R&D) in Europe.

The report of the Technopolis Group concludes that "The SPC Regulation offers innovator companies an adequate compensation for their effective loss of patent term." However, as an incentivising measure, the report says, "the effect is much less clear. First, the SPC Regulation has failed to incentivise pharmaceutical R&D in Europe sufficiently to narrow the gap with the US. Furthermore, the relation between investment incentives and a 'reward' that is not received until many years, or even decades, after the decision to invest in development of a product is made – particularly when the outcomes of that investment decision are highly uncertain – remains unclear."³²

Given that investments put into research on medicines are not available in a clear and transparent format, it is difficult to conclude if the period of effective protection needs to be supplemented "to cover the investment put into the research" or if there is clear evidence that such supplementary protection has encouraged research.

³⁰ Recital 3 Regulation 1768/92 Concerning the Creation of a Supplementary Protection Certificate For Medicinal Products [1992] OJ L182/1.

³¹ Recital 4 Regulation 1768/92 Concerning the Creation of a Supplementary Protection Certificate For Medicinal Products [1992] OJ L182/1.

³² Technopolis Group (n 15) 9.

In May 2018, Copenhagen Economics published its *Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe*, commissioned by the European Commission.³³ The report found that 45% of medicinal products approved in 1996-2016 have obtained an SPC in at least one of the European countries, and that SPCs delay an average price drop of approximately 50% following the entry of generics. The Copenhagen Economics report also concluded the longer protection stimulates R&D; other studies do not support this conclusion, however, including the Technopolis Group study noted in the previous paragraph.

Given that investments put into research on medicines are not available in a clear and transparent format, it is difficult to conclude whether the period of effective protection *needs* to be supplemented “to cover the investment put into the research” and whether there is clear evidence that such supplementary protection has *encouraged* research. However, annual revenues of pharmaceutical companies provide an indication that, with very high prices, a pharmaceutical firm might still make the necessary return on investment in the remaining (five +) years of the patent term, without the need for supplementary protection.

Further, as noted by the Technopolis Group, “whilst the SPC regulation clearly embodies an intent to promote pharmaceutical innovation in Europe, it does not contain any provisions to favour innovation originating from Europe over that from elsewhere. Rather, all pharmaceutical innovation is treated equally, regardless of the country where the applicant is based or where the R&D has been performed. Consequently, the greatest economic returns from the SPC regulation appear destined to flow towards where the greatest research and innovation intensity is, which makes it even more difficult to draw evidence-based conclusions.”³⁴

Indeed, a study published by the European Commission on the Economic Analysis of Supplementary Protection Certificates in Europe shows that the majority of the SPCs in Europe derive from the US: “[t]here is no clear geographic bias in the use of SPCs by the location of patent holders. Almost 44% of SPC applicants are US-based, while the EU has close to 30%, followed by Japan and Switzerland at roughly 7% and 6%, respectively. These figures track those of the geography of R&D activity overall.”³⁵

³³ Copenhagen Economics (n 1).

³⁴ Technopolis Group (n 15) 86.

³⁵ Margaret Kyle, 'Economic Analysis of Supplementary Protection Certificates in Europe' (2017) 4 <<https://ec.europa.eu/docsroom/documents/25621/attachments/1/translations/en/renditions/native>>.

Similarly, a study on SPCs conducted by the Max Planck Institute for the European Commission concludes that “the expectation expressed by the historical lawmakers about the impact on (re)location of research centres [to Europe] was somewhat unrealistic from the beginning.”³⁶

The SPC Regulation, among its aims, also included the possible reduction of prices of medicines due to the extended exclusivity period, as stated in the Explanatory Memorandum of the regulation: “the present proposal, moreover, favours a possible fall in prices of the medicinal products covered by this proposal in light of the extension of the period for recuperation of investments.”³⁷

However, the Technopolis Group report confirms that “[f]rom an economic perspective, the [...] case studies give no indications for any difference in pricing between the time that a drug is under ‘ordinary’ patent protection and when it is under protection by an SPC. Price changes typically do not occur before generics enter the market.”³⁸ As a consequence, the Technopolis Group concludes that “[t]he implicit objective of encouraging lower prices for still-protected products, by offering pharmaceutical innovators increased time to recoup their investments, appears not to have been realised at all.”³⁹

SPC waiver reform: A missed opportunity to address excessive pricing

SPCs are often discussed in the context of a manufacturing waiver for export or stockpiling purposes. The waiver will enable EU-based (generic and biosimilar) companies to manufacture medicines protected by SPCs exclusively for export to non-EU markets, or to stockpile medicines until the expiration of the SPC for launch in the EU markets. Currently, EU-based manufacturers of generics and/or biosimilars can manufacture samples for submitting a regulatory dossier under the Bolar patent exception,⁴⁰ but export outside the EU to

Given skyrocketing prices of some patented new medicines introduced onto the market and the consequences of those prices on public health expenses in all EU countries, it might be opportune for EU policy makers, to consider measures to better balance dual objectives to “cover investments put into research” and “to take public health interests into account,” as outlined in the SPC Regulation.

³⁶ Max Planck Institute for Innovation and Competition (n 17) 22.

³⁷ Commission Explanatory Memorandum (n 2) 22.

³⁸ Technopolis Group (n 15) 157.

³⁹ *ibid* 163.

⁴⁰ The Bolar exemption is governed by European Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as amended by European Directive 2004/27/EC, particularly Article 10 thereof. Article 10 (6)

countries where SPC protection has expired or does not exist is not possible in the absence of a voluntary licence or a compulsory licence for export.⁴¹ The main objective of this waiver is to remove the competitive disadvantages of EU-based manufacturers of generics and biosimilars in non-EU markets where protection does not exist or has expired.

While this measure will certainly have a positive effect on the growth of the EU generic industry, it fails to address the question of whether an SPC is justified for any newly approved medicine protected by a basic patent. The amendment of the SPC Regulation to enable the grant of SPCs based on the Unitary patent may offer such an opportunity.

Conclusions and recommendations

SPCs are not dependent on the revenue or profit a pharmaceutical company obtains from a given product. The calculation of the SPC extension is exclusively awarded based on the time elapsed between the patent filing date and the market authorisation date to ensure that medicinal products have 15 years of exclusive market protection. But is that justifiable in the case of blockbuster products such as Humira, an arthritis treatment that generated sales of more than USD 16bn in 2016 alone⁴²?

Recent analysis and reports indicate that the Regulation has been used opportunistically as a tool to maximise exclusivity rents whenever the effective market protection is less than 15 years exclusivity, without clear evidence that such exclusivity is systematically necessary “to cover the investment put into the research.”

Given skyrocketing prices of some patented new medicines introduced onto the market and the consequences of those prices on public health expenses in all EU countries, it might be opportune for EU policy makers to consider measures to better balance *dual* objectives to “cover investments put into research” and “to take public health interests into account,” as outlined in the SPC Regulation. The initial objectives of the Commission were to create a “system effective and appropriate for the Industry’s requirements without neglecting other substantial aspects of national and Community health policy.”⁴³

excludes from infringement of patent rights or supplementary protection certificates (SPCs): “Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4.” Paragraphs 1-4, i.e. Articles 10 (1)-(4) of the Directive, concern the provision of data during the marketing approval process.

⁴¹ 'Special Uses of Compulsory Licences for Export of Medicines, or “Article 31 bis”' (*Medicines Law & Policy*) <<https://medicineslawandpolicy.org/tools/special-compulsory-licences-for-export-of-medicines/>>.

⁴² Alex Philippidis, 'The Top 15 Best-Selling Drugs of 2016' (*Genetic Engineering & Biotechnology News*, 6 March 2017) <<http://www.genengnews.com/the-lists/the-top-15-best-selling-drugs-of-2016/77900868>>.

⁴³ Commission Explanatory Memorandum (n 2).

Medicines Law & Policy therefore makes the following recommendations:

- 1. Make granting of SPCs conditional on applicants providing evidence that “the period of effective protection under the patent [is] insufficient to cover the investment put into the research.”** Upon application for an SPC, applicants would be required to provide patent offices with data on all past and future development costs, excluding public funding, and expected revenues.⁴⁴ Such data could be made public to increase transparency and trust in the system. If an SPC is granted, patent owners would be required to submit return on investment data either on a yearly basis, or at the latest, six months before the entry into force of the SPC, so that the need of the SPC could be confirmed based on actual reported profits. If the period of effective patent protection was sufficient to cover the investments put into the research programme that launched the medicine, the SPC would be cancelled.
- 2. Alternatively, make the entry into force of an SPC subject to review six months before the expiration of the basic patent.** Patent owners would be required to provide patent offices with full data of development costs of the related programme, excluding public funding, and of reported profits during the effective period of patent protection.¹ Review of such data six months before the expiration of the patent would confirm whether the period of effective protection under the patent needs to be supplemented by the SPC or not.
- 3. Give third parties an opportunity to submit “observations” to the patent office to pre-empt the entry into force of an SPC** based on evidence, from actual reported profits, that the period of effective protection under the patent was sufficient to cover the investment put into research.
- 4. Make procedures to revoke a granted SPC, modelled on opposition procedures against patents, available in all EU countries.** Such procedures, which are currently lacking in many countries, could include an extra ground of sufficient return on investments to challenge the SPC.
- 5. Tie the entry into force of an SPC to a requirement on pricing.** For example, a company could benefit from extra years of protection if it both demonstrated that extra protection is necessary to cover R&D investment and that the product is affordable during the protection period.

⁴⁴ In the context of orphan medicinal product protection, a European Commission notice indicates that ‘sufficient return’ will be assessed “...on the basis of all past and future development costs and expected revenues”: Commission Notice on the Application of Articles 3, 5 and 7 of Regulation (EC) No 141/2000 on Orphan Medicinal Products [2016] C424/03.

Further Reading

This document is part of a series of briefing papers; the rest of the series is available at <https://medicineslawandpolicy.org/useful-resources/briefs/#EUReview>.

- Max Planck Institute for Innovation and Competition, 'Study on the Legal Aspects of Supplementary Protection Certificates in the EU' (European Commission, 2018) <<https://ec.europa.eu/docsroom/documents/29524>>.
- Medicines Law & Policy, 'The TRIPS Flexibilities Database', <<http://tripsflexibilities.medicineslawandpolicy.org>>
- Thyra de Jongh and others, 'Effects of Supplementary Protection Mechanisms for Pharmaceutical Products' Final Report (Technopolis Group, May 2018) <<http://www.technopolis-group.com/wp-content/uploads/2018/06/2718-Technopolis-report-on-supplementary-protection-mechanisms.pdf>>.