A Fair and Balanced System for Unitary Supplementary Protection Certificates (SPCs) and Centralised Procedure for Granting National SPCs in the European Union

November 2023

Explanatory Memorandum

The SPC system is currently fragmented. In particular, SPC litigation is dealt with nationally and in parallel proceedings in multiple jurisdictions that render invalidation challenges expensive and burdensome, delaying generic and biosimilar market entry in those cases where an SPC is invalid and it takes longer in certain Member States to declare that invalidity.

To tackle these fragmentation issues, the European Commission is proposing a Unitary SPC Regulation and a recast of the current SPC Regulation with the objective to provide a centralised procedure for granting unitary SPC and/or national SPCs. While for Unitary SPCs the competent court to decide on any dispute would be the Unified Patent Court (UPC), for those countries that are not signatories to the Unified Patent Court Agreement (UPCA) enforcement and litigation would still take place in parallel national litigation, which is the main and most problematic component of the existing fragmentation, to the detriment of legal certainty for the industry and of timely patient access to generic and biosimilar medicines in different Member States, and of sustainability of healthcare systems.

It is therefore essential to ensure the right safeguards in the SPC granting system in order to guarantee the highest quality of SPCs granted, avoid any litigation strategies to delay competition and allow equitable and timely access to generic and biosimilar medicines for patients on day 1 after protections expire.

Such safeguards are essential to achieve not only uniformity of decisions, but also a fair, efficient and balanced quality system that prevents weak SPCs to be granted, litigated in courts and then invalidated at a later stage, with huge negative effects on patient access to medicines and on competition more generally. Concrete examples of such issues are provided below.

The new system must therefore guarantee that no undue delay of competition takes place at intellectual property (IP) expiry, for the sake of timely patient access to medicines and sustainability of healthcare budgets, as well as the credibility of the whole SPC system.

In order to achieve the above objectives, the following safeguards should be maintained or integrated in the legislation:

- ✓ Ensure quality and independence of the central body, of examination and of examiners, to be selected on expertise, rather than political (or geographical) considerations
- ✓ Ensure accountability of the granting body to EU institutions with regular reviews and reports on the work of the EUIPO
- ✓ Foresee clear timelines for all procedures in order to ensure predictability and legal certainty. Time should not prevail over the quality of the SPCs granted
- ✓ Keep the pre-grant opposition mechanism to ensure a first scrutiny of SPCs in order to avoid enforcement of SPCs that are later invalidated and that unduly delay access to generic and biosimilar medicines
- ✓ Ensure full transparency, from SPC applications to publication of full decisions, without undue delay. Should SPC expiries be in Register, a clear ban of 'patent linkage' must be made in EU legislation to avoid unlawful abuses of the system and to ensure immediate patient access to generic and biosimilar medicines on day 1 after IP expiry
- ✓ Strengthen the system for third party observations, allowing them also in opposition and appeal procedures
- ✓ Guarantee a fair distribution of costs that will be set in implementing acts, which should not deter companies from engaging in oppositions and become an obstacle to the objective of ensuring the highest quality of granted SPCs
- ✓ Provide a maximum length of total market protection from marketing authorisation of 14ys (instead of 15), in line with US, China, to ensure level playing field and competitiveness of the European manufacturing industry
- ✓ Ensure that there is no double SPC protection (national & unitary) and that the obligation to use the unitary route if the conditions apply remains to ensure that there is no strategical (mis)use of the system to avoid central oppositions by filing separate, national SPC applications in the respective Member States

1. Background

The European Union first introduced Supplementary Protection Certificates (SPCs) in 1992.[1] An SPC is a *sui generis* intellectual property right that serves as an extension of the exclusivity attached to a patent right and applies to specific pharmaceutical and plant protection products authorised by regulatory authorities. Two hallmark characteristics of an SPC are: (1) they are always associated with an active, basic product patent that corresponds with a product's marketing authorisation,[2] (2) they are not unitary (European) titles even though EU law governs their existence.

'Non-unitary' means that pathways to attain or challenge the title are not governed at a European Union level, but at a Member State level. Throughout its existence, the legal status of an SPC as a non-unitary right has been subject to two major problems.

First, medicines manufacturers must apply for an SPC through individual, national filing routes in order to attain the right. These national filing routes have led to the occurrence of diverging practices and interpretation of SPC applications, often leading to substantive questions before the CJEU.[3] To illustrate, an SPC application was refused for the combination Zetia (ezetimibe) plus Lipitor (atorvastatin) in France, whereas an SPC was granted for the same combination in Belgium.[4] According to the European Commission, multiple Member State filings considerably increase the costs associated with an SPC, including: multiple filing fees, translation fees, duplicative work, missing out on generic medicines savings, etc.[5]

Second, SPC litigation is dealt with nationally and in parallel proceedings in multiple jurisdictions that render invalidation challenges expensive and burdensome, delaying generic and biosimilar market entry in those cases where an SPC is invalid and it takes longer in certain Member States to declare that invalidity. Some recent examples are shown below.

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[1] Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning SPCs for medicinal products entered into force on 2 January 1993. It was subsequently amended and later codified and repealed by Regulation (EC) No. 469/2009 (Medicinal SPC Regulation), which entered into force across the European Union on 6 July 2009.

[2] The *sui generis* nature of the SPC and the fact that it is limited to an extension of the market exclusivity rights attached to a patent is given by the fact that in the absence of a marketing authorization of the patented product an SPC could not be granted for that patent.

[3] https://www.pharmtech.com/view/harmonizing-rules-governing-spcs-for-medicinal-products
Fabre, Jules, and Sarah Taylor. "Supplementary Protection Certificates in Europe: Clarity at Last?." *Biotechnology Law Report* 40.5 (2021): 325-333.

[4] Labarre, I.; Touati, C. Supplementary Protection Certificates (SPC): A New IP Right to Come? *Plass.com*, 22 Feb. 2022

[5] European Commission. Com(2023)221 – Proposal for a Regulation of the European Parliament and Council on the unitary supplementary protection certificate for plant protection products (April 2023). Available from: https://single-market-economy.ec.europa.eu/publications/com2023221-proposal-regulation-unitary-supplementary-protection-certificate-plant-protection_en.

The EU Institutions' Position on enforcement fragmentation

This parallel litigation is a true issue for generic and biosimilar medicines manufacturers, which is reflected on timely access to generic and biosimilar medicines for patients in the different Member States. Indeed, diverging SPC regimes entail a very disruptive fragmentation in the enforcement and litigation phase.

The issue of "*[c]onflicting outcomes of court proceedings"* was clearly identified in the European Commission's SPC Evaluation[6], as well as in the 2020 IP action plan of the Commission that recognises "*parallel litigation in multiple EU countries*" and the need to "*avoid parallel [court] proceedings in multiple Member States, considerably reducing litigation costs*".[7] The European Parliament Resolution of November 2021 states that "*a level playing field for makers of generics and biosimilars in the Union is essential"* in the SPC reform.[8]

To solve these fragmentation issues, the European Commission is proposing **a Unitary SPC Regulation**,[9] *i.e.* a unitary title following one application procedure for all signatories to the Unified Patent Court Agreement (UPCA) and one court to deal with granting disputes such as the Unified Patent Court (UPC). However, not all European countries are signatories to the UPCA and the Commission is therefore also proposing **one single procedure for granting national SPCs through a Recast of the SPC Regulation**.[10] This procedure only relates to unifying the various national granting procedures for reasons of legal efficiency, but does *not* concern the enforcement/ litigation phase of SPCs, for which the existing fragmentation would remain the same. This would therefore permit multiple litigations in different Member States to remain, to the detriment of legal certainty for the industry and of timely patient access to generic and biosimilar medicines in different Member States.

To solve these problems, as stressed by several commentators, several aspects of SPC law could benefit from reform.[11] And indeed, certain aspects have been addressed by the European Commission in its newly proposed regulation.

[6] https://ec.europa.eu/docsroom/documents/43847, p. 35
[7] https://ec.europa.eu/docsroom/documents/43845
[8] European Parliament resolution of 11 November 2021 on the IP action plan, point 13, available here.
[9] https://single-market-economy.ec.europa.eu/publications/com2023222-proposal-regulation-unitary-supplementary-certificate-medicinal-products_en
[10] https://single-market-economy.ec.europa.eu/publications/com2023231-proposal-regulation-supplementary-protection-certificate-medicinal-products-recast_en
[11] Papadopoulou, Frantzeska. "*Supplementary protection certificates: still a grey area?*" Journal of Intellectual Property Law & Practice 11.5 (2016): 372-381.; Romandini, R., European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs. "*Study on the options for a unified supplementary protection certificates (SPCs) system in Europe.*" Max Planck Institute for Innovation & Competition Research Paper No. 23-09 (2022), 353 pages.

Medicines for Europe seeks to address some of the contents of the European Commission proposal in this paper to ensure the right safeguards in the SPC granting system in order to guarantee the highest quality of SPCs granted, avoid any litigation strategies to delay competition and allow equitable and timely access to generic and biosimilar medicines for patients. Such safeguards are essential to a fair and balanced quality system.

2. The granting process proposed by the Commission

The European Commission has proposed that a central granting body (EU Intellectual Property Office – EUIPO, with a new 'SPC division') would receive applications for Unitary SPCs and/or bundles of national SPCs, would examine these patents, with the support of SPC experts from national patent offices (NPOs) and would issue a binding opinion on the grant or refusal of the SPC. Only after this binding opinion is made, EUIPO (for Unitary SPCs) and/or NPOs would formally grant or refuse an SPC. The process would involve only one filing fee, one submission, one translation, and discard of many bureaucratic expenses associated with the current SPC regulations.

Such a system mirrors the international Patent Cooperation Treaty (PCT) system and stems from (i) the need to have uniformity and legal certainty in the SPC granting phase and (ii) the practical need for all Member States' NPOs to rely on the expertise of a smaller group of specialised SPC examiners.

Indeed, having a binding recommendation from an expert Central Body is beneficial for a variety of reasons:

1. it creates certainty for medicines manufacturers. National patent offices can no longer differ on the merits of an SPC application, giving manufacturers certainty as to where and for how long their SPC will apply. Generic or biosimilar medicines manufacturers also attain pre-launch certainty, securing a more reliable timeline for anticipated patient savings through more affordable medicines.
2. The binding recommendation centralises the procedure, creates greater European harmonization on IP, and discards much of the bureaucracy heckling the current system, which hits generic and biosimilar companies first of all, especially in relation to litigation.
3. More power is given to a Central Body that, with sufficient funding, will employ the most competent examiners to conduct examination proceedings of unitary and/or centralised SPC applications.

However, certain safeguards are essential for the system to work well and achieve not only uniformity of decisions, but also an efficient system that prevents weak SPCs to be granted, litigated in courts and

then invalidated at a later stage, with huge negative effects on patient access to medicines and on competition more generally.

3. Safeguards

Admittedly, the new SPC model requires corresponding safeguards to ensure that the system preserves the highest quality, transparency and efficiency. It must guarantee that no undue delay of competition takes place at intellectual property (IP) expiry, for the sake of timely patient access to medicines and sustainability of healthcare budgets, as well as the credibility of the whole SPC system.

In order to streamline the single procedure for granting bundles of national SPCs in the EU, the European Commission integrated in the SPC reform proposal some safeguards proposed by a study conducted by Professor Romandini at the Max Plank Institute for the European Commission.[12] We comment on the safeguards individually with the proposed regulation in mind and suggest additional essential safeguards where necessary.

3.1. Composition of the Central Body: Quality First

A safeguard concerns the composition of the Central Body. The proposed regulation proposes the Examining Panel to consist of: one EUIPO examiner, and two volunteering examiners from National Patent Offices (NPOs). Were the Central Body to receive the legal power to grant national or unitary SPCs through a binding recommendation and single granting procedure, the composition and qualifications of its examiner body must correspondingly excel.

Recommendation: In order to ensure the highest quality examination and, ultimately, SPCs, examiners on the Central Body should be experienced individuals with, ideally, a background in life sciences and patent law. Appointment procedures should be based on hiring meritorious, highly qualified examiners and should not discriminate against applicants from any particular Member State. In the interest of timely patient access to medicines, no political or geographical criteria should potentially frustrate the quality of granting procedures and, ultimately, of SPCs.

3.2. Independence

A third safeguard mentioned in the study is the need to preserve the independence of the Central Body, the single granting procedure, and the unitary SPC system as a whole. Medicines for Europe supports the reliance on applicants' fees as suggested in the proposed regulation but emphasises that

[12] Romandini, R., European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs. "*Study on the options for a unified supplementary protection certificates (SPCs) system in Europe.*" Max Planck Institute for Innovation & Competition Research Paper No. 23-09 (2022), 353 pages

the Central Body must be totally independent and should act in the interest of granting the highest quality of SPCs.

The new system needs to ensure that the dependence of the EUIPO SPC division on applicant fees does not affect, in any way, the impartiality of the decisions.

Recommendation: While relying on applicant fees for funding, the Central Body should remain impartial and prioritize the highest quality of SPCs. Financial dependence should not compromise decision-making impartiality.

3.3. Accountability and five-year revision

In the Explanatory Memorandum of the Commission's proposal, the Commission refers to the importance of accountability of the granting body, especially to the European Parliament.

The European patent system of today lacks of any real public oversight and accountability to any EU institutions, despite patents being private rights with huge impacts on the public, such as public healthcare budgets, European patient access to medicines and more generally competition in European markets. Considering the financial impact of granted SPCs on national healthcare budgets, on timely patient access, on competition and on litigation, as well as on businesses, appropriate mechanisms for regular review and reporting to EU institutions (European Parliament, Council of the EU, European Commission and European Economic and Social Committee) should be in place to swiftly assess and eventually correct any unforeseen deficiencies. Accountability ensures quality and transparency.

Recommendation: Accountability is essential to ensure an efficient, effective and unbiased granting body that grants high-quality national or unitary SPCs. Medicines for Europe believes that the new system should involve a requirement for the EUIPO to regularly report to and be held accountable by EU institutions, *ie*. the European Parliament, the Council of the EU, the European Commission and the European Economic and Social Committee. Medicines for Europe supports a legislative review of the functioning of the unitary SPC every five years. This five-year period ensures that possible dysfunctions or abuses of the system can be timely targeted and patients receive access to medicines without undue delay.

3.4. Examination Timelines

While Medicines for Europe acknowledges the great expertise and time needed to examine an SPC application, there should be overall timelines that render the examination process reliable and efficient. Speedy examination timelines are important because pre- or post-grant proceedings against

the grant of a national or Unitary SPC might further delay generic launch timelines to the detriment of patients and health insurers. The proposed regulation suggests the following timelines:

The process commences upon receipt of the SPC application, which must be made within 6 months of the grant of an MA. This application is published in a Public Register and gives third parties a period of three months to submit observations to the Patent Office. Upon completion of substantive examination, the examination opinion is published and third parties may oppose during a period of 2 months after publication. An opposition panel shall decide on the merits of the opposition within 6 months. Depending on the outcome of the opposition, the Office will amend the opinion or leave as is. Where the applicant or another party is adversely affected by a decision of the Office, the applicant or that party should have the right, subject to a fee, to file within 2 months an appeal against the decision before a Board of Appeal of the Office. A written statement setting out the grounds of appeal shall be submitted within 4 months of the opinion. Appeals of a decision by the Board of Appeal to the General Court of the EU shall be lodged within 2 months of the appeals decision.

The proposal does not include limits for the duration of the application examination, which will be addressed in implementing acts.

Recommendation: Medicines for Europe believes that clear timelines ensure predictability and legal certainty and stresses that the timeliness should ensure an effective and quality examination process, especially in relation to oppositions. Medicines for Europe is positive about the proposed timelines of the process. The process must be efficient, but, considering that SPC applications must be made within 6 months from the marketing authorisation, there is enough time to make a proper examination. Time should not prevail over quality.

3.5. Pre-Grant opposition mechanism

The proposed regulation sets out a carefully calibrated scheme of *pre*-grant and *post*-grant opportunities to provide a scrutiny of SPCs. Among these, the Commission has proposed a *pre*-grant opposition mechanism which would allow third parties to oppose a Body's examination opinion by providing reasons and evidence for such an opposition. The Commission's proposal to foresee a pre-grant opposition mechanism is essential to ensure the highest quality of the SPCs granted. In particular:

First, a pre-grant opposition mechanism offers third parties like generic or biosimilar medicines manufacturers a chance to challenge an SPC application before any protection is granted and enforced. It is counter-intuitive to first grant an SPC in order to retrospectively correct any examination errors made. This, unfortunately, often occurs with patents that were never supposed to be granted in the first place and that needed to be litigated in court to be invalidated, with huge litigation costs, delays

of generic/biosimilar launch and very hard possibilities to obtain any compensation for the loss occurred to the generic/biosimilar manufacturer. This is without prejudice, for reasons of legal symmetry, to the option of judicial review of erroneously granted SPCs, which remains available. This positively affects trust in and legal certainty of the SPC system.

The table below shows a recent concrete example of undue delay of generic launch in some countries due to 'patent linkage' (the unlawful link between IP and regulatory decisions on generics) significantly impacting patient access as well as healthcare budgets, due to an invalid SPC being enforced and blocking generic launch.

The existance of a pre-grant opposition mechanism would have avoided that the case described below had actually occurred, since the invalid SPC would have not been granted at all:

The HIV Case Study of Truvada (Emtricitabine/Tenofovir)

Critical medicine for HIV prevention & treatment (reduces HIV transmission by over 90%)

Patent expiry: July 2017 **SPC expiry: February 2020**

- The SPC challenged & invalidated in several EU national courts at different points in time & ultimately declared illegitimate by the CJEU
- Due to delayed national court decisions and 'patent linkage' in some countries, generics could NOT enter those markets despite invalidating decision all around Europe
  - The Netherlands: generic entry reduced price for 30-day supply from €344,28 to €47,95
  - Portugal: delayed court decision led to a loss of over €109 Million saving, equal to 1.1% of total 2018 health budget, impacting treatment for over 95.000 patients!

Second, while the Max Planck Institute study suggests that: *"[n]o evidence is available that parallel litigation specifically concerning the infringement of an SPC occurs so often and with diverging outcomes*", this is factually incorrect.

Just to provide a couple of examples, recently, for *darunavir* (Prezista) there was a reasonable doubt on the actual validity of the SPC since 'darunavir' was not mentioned in the related patent on which the SPC had been granted. Such SPC was challenged by multiple generic companies and it was indeed considered invalid by the Dutch, Spanish and Swedish Courts, while other courts (French and UK) seemed inclined to consider it valid. The dispute was then settled so there was no final decision on the actual validity of the SPC, but a pre-grant opposition on such SPC would have avoided that parallel litigation and diverging decisions. A similar issue took place recently for *dimethyl fumarate* (Tecfidera), where the Dutch patent office took a different stance on the SPC from other patent offices.

A pre-grant opposition proceeding would reduce the need for multi-Member State litigation and excessive costs for companies in individual countries altogether. These pre-grant opposition proceedings would offer an immediate scrutiny of SPCs and option to challenge SPC applications preventing diverging decisions and undue delays of generic and biosimilar medicines.

Third, the value of introducing a pre-grant opposition mechanism is stressed also by the World Intellectual Property Organisation (WIPO), that defines pre-grant oppositions as a "*simple, quick and inexpensive mechanism that ensures the quality and validity*", "*supports legal certainty*" and "*increases the validity of granted patents."*[13] Several countries have pre-grant mechanisms. In Australia, for example, several attempts have been made to move from a pre-grant to a post- grant opposition system, but these have failed due to the lack of evidence of beneficial effects from changing the system. According to the cited scholars, the average period of time from the end of the pre-grant opposition period to the time on which the opposed patent is finally sealed is 2.4 years.[14] A pre-grant opposition procedure before the Egyptian Patent Office is also provided in Egypt.[15] Or, the Indian Patent Act provides both pre-grant and post-grant opposition. Where an application for a patent has been published but a patent has not been granted, any person may, in writing, lodge an opposition with the Controller against the grant of a patent.[16] In addition to Australia, Egypt and India, other countries with pre-grant opposition mechanisms include: Israel, Portugal[17], New Zealand, Peru, Azerbaijan, Pakistan[18], Costa Rica, Colombia, Côte d'Ivoire, Ecuador, Honduras, Mongolia, Sri Lanka, Thailand, Zambia, Zimbabwe, and the Members of the African Intellectual Property Organization (OAPI).[19]

Fourth, a pre-grant opposition mechanism works perfectly in a granting system with a binding opinion to be formally adopted by the EUIPO or a NPO, because there is an adoption time period during which any third party (e.g. generic or biosimilar medicines manufacturers) may raise opposition arguments. Such a mechanism would not risk delaying the granting procedure beyond the expiry of the patent on which the SPC would apply. Indeed, SPC applications can be filed no later than 6 months from the granting of the marketing authorisation of the originator product, which means that the product will

[13] Available on the WIPO website: https://www.wipo.int/edocs/mdocs/scp/en/scp_18/scp_18_4.pdf
[14] Weatherall [et al.] Patent Opposition in Australia the Facts (2011), 93, 106, 119.
[15] Article 16 of the Law on the Protection of Intellectual Property Rights provides that any party may submit to the Patent Office a written notice opposing the grant of a patent and stating the reasons thereof within 60 days from the publication of the application acceptance in the Patent Gazette. Such an opposition is the subject to the payment of a fee which will be reimbursed in case the opposition is accepted.
[16] Section 25(1) of the Patent Act 1970.
[17] Industrial Property Code approved by Decree-Law 36/2003 of March 5, 2003 and last amended by Law 16/2008 of April 1, 2008.
[18] Patents Ordinance 2000, as amended by Patents Ordinance 2002.
[19] Available on the WIPO website.

enjoy at least 10 more years of monopoly on the market due to the regulatory market protection. On top of the regulatory protection, patents would normally last even longer, showing that there is no real risk of a pre-grant opposition mechanism to extend the SPC granting procedure beyond the supposed start of the SPC protection period.

Recommendation: A pre-grant opposition mechanism safeguards quality of the titles granted, legal certainty and the credibility of the system. It ensures a preliminary scrutiny on the validity of an SPC, without risks of delaying SPC granting procedures beyond the supposed start of the SPC protection period, and avoids that invalid SPCs be enforced and then invalidated in Court only at a later stage with undue and unlawful delays of access to generic and biosimilar medicines.

3.6. The Register's transparency: full disclosure of reasons for recommendations and decisions

The European Commission stresses in the proposal that the single granting procedure and subsequent actions taken to grant national or unitary SPCs should follow the greatest standards of transparency.

Medicines for Europe is in favour of the creation of an SPC Register where SPC applications, all legal documents during the granting process and SPC case reports be uploaded in a timely manner and can easily be downloaded by third parties.

Any opinion or decision taken by the Body at any point in time in the granting process (being it the first examination or the opposition or the appeal phase) needs to include detailed reasons for those opinion or decisions. Such detailed reasons should be fully disclosed together with the final determination as soon as practically possible in the interest of transparency and legal certainty for all players. The Register, which is meant to provide transparency in the process, should not include only a summary of or a mention to the opinion/decision taken but publication of the full decision, including its reasonings, should be foreseen.

Such transparency may also include a list of SPC expiries and transparency on the R&D funding of their corresponding products. However, if the Register will provide an online list of granted SPCs similar to Ireland[20], the European Commission should first formally abolish the practice of 'patent linkage' in the legislation and provide a clear disclaimer on the website that marketing authorisations, pricing and reimbursement (P&R) and participation to procurement should not be influenced by the data on the database. Otherwise, any such information might unlawfully be used to delay or block marketing authorisations, P&R and procurement procedures and subsequently delay generic or biosimilar market entry to the detriment of patients and payers, and competition more generally.

[20] https://eregister.ipoi.gov.ie/query/SPQuery.aspx.

'Patent linkage' occurs when generic & biosimilars' marketing authorisations/P&R decisions/tender bids are blocked due to existing patents covering the reference product. The Commission considers it "unlawful" and anti-competitive in its Sector Inquiry Report of 2009, as it delays generic/biosimilar medicines systematically.[21]

Such a formal ban is of utmost importance considering the delay in market launch experienced regularly by generic and biosimilars in several Member States. Indeed, only in some Member States (such as Denmark, Czeck Republic, Slovakia, Spain, Sweden, Belgium) there is no 'patent linkage' and all regulatory and administrative approvals for generics and biosimilars can be obtained before IP expiry, with the possibility for competitor products to be effectively launched on day 1 after IP expiry. In all the other several countries, the illegal practice of 'patent linkage' exists in different forms and leads to significant delays in access to generic and biosimilar medicines.

In the table below, there are some examples of delayed market entry due to 'patent linkage' as reported by Medicines for Europe member companies:

Molecule	Treatment	Country	Originator approval	SPC Expiry	Generic Entry	Delay	Cost of Delay Lost Savings
Oxycodone/ Naloxone	severe pain	Germany		29/3/2017	15/11/2017	231 days	**€ 51,6 Mln**
Ezetimibe/ simvastatin	high cholesterol	Italy	18/11/2004	16/10/2017	9/3/2018	144 days	**€ 15,4 Mln**
Ezetimibe/ simvastatin	high cholesterol	Germany	18/11/2004	17/4/2018	15/5/2018	28 days	**€ 11,3 Mln**
Lenalidomide	multiple myeloma, cancer	Hungary	14/06/2007	19/6/2022	1/6/2023	347 days	**€ 1.9 Mln**
Pirfenidone	idiopathic pulmonary fibrosis	Germany	27/02/2011	27/2/2021	15/11/2022	626 days	**€ 32,1 Mln**
Tapentadol	severe pain	Germany	19/08/2010	07/12/2020	15/1/2023	917 days	**€ 184,6 Mln**
Dasatinib	chronic myeloid leukemia	Poland	20/11/2006	22/5/2022	01/01/2023	224 days	**€ 4,5 Mln**
					Total:	**2,517**	**€ 301,4 Mln**

[21] For more information and additional examples of unlawful patent linkage, see the Medicines for Europe publication: "Why Clarification & Harmonisation of the Bolar Exemption and an Explicit Prohibition of Patent Linkage Is Needed in the European Union"

The case study on HIV treatment Truvada in the table at page 9 represents a concrete example of delayed generic entry due to an SPC that was even invalid, showing the exact reason why 'patent linkage' is unlawful in Europe.

A similar issue was experienced in Italy for sitagliptin/metformin (Janumet), a product used for treating type 2 diabetes, as shown in the table below:

The case study of Janumet (sitagliptin/metformin)

Medicine used for treating type 2 diabetes.

SPC for *Januvia* (sitagliptin) expired on 23 September 2022	SPC for *Janumet* (sitagliptin & metformin, older API with expired patent) expired on 7 April 2023

- In other Member States, **Janumet SPC had been already declared *invalid*** (German Federal Patent Court decision of 23 June 2021)
- **Patent linkage in Italy blocked reimbursement of generic** until 07 April 2023 (ca. 6.5 months) due to a delayed court decision
- Cost for Italian NHS for the originator: € 38 million
- Generic should have had a reduced price of at least 47,5% --> Minimum monthly saving of ca. € 1.5 million (further increased by the regional tendering mechanism)

→ For 6.5 months delay: **damage to the Italian NHS of at least € 9.8 million**

The EU has indeed taken several steps in the recent past to formally ban 'patent linkage':

- A 2012 *European Commission Proposal for a Revised Transparency Directive*[22], for example, included a prohibition of patent linkage, but the legislation was never adopted eventually.
- The *European Parliament Resolutions on Access to Medicines in 2017*[23] and the one *on the Pharmaceutical Strategy in 2021*[24] urged the Commission to end patent linkage to ensure immediate market entry for generic/biosimilar competitors.
- A *June 2021 study of the European Parliament*[25] confirmed the issue.
- A *2021 European Parliament Resolution on the IP Action Plan* urged the Commission to ban patent linkage.[26]

[22] Proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems

[23] European Parliament resolution of 2 March 2017 on EU options for improving access to medicines.

[24] European Parliament Resolutions on the Pharmaceutical Strategy in 2021

[25] European Parliament Study for the ENVI Committee "Access to medicinal products", June 2021

- Finally, a European Parliament Study on the unitary SPC refers to the "*prohibited practice of patent linkage*".[27]

Recommendation: Medicines for Europe would support timely transparency as to the whole granting procedures, from applications to the publications of full decisions, including full transparency on direct financial support received for research related to the development of the product for which the SPC is applied for. The Body should provide detailed reasons for all opinions or decisions taken in any phase of the granting process, in the interest of transparency and legal certainty. Full opinions/decisions should be fully published without undue delay. Moreover, it is essential to ensure that if the Register will include a database with SPC expiries the unlawful practice of 'patent linkage' is clearly banned in the legislation and on the Register to avoid that generic and biosimilar medicines are unduly delayed after protections expire.

3.7. Third Party Observations

The European Commission proposal includes the possibility for third parties to make observations within three months from the SPC application. These are also present in patent law. For instance, following publication of a European patent application under Art. 93, any person may present observations concerning the patentability of the invention.[28]

Recommendation: Medicines for Europe supports the right for third parties to make observations once an SPC application is made and urges lawmakers to introduce the possibility of also making third party observations in opposition and appeal proceedings. Third-party observations are essential to ensure that for any potentially invalid SPC application there is an accurate timely examination.

3.8. Fair distribution of costs

The proposal of the Commission foresees that the losing party in opposition and appeal proceedings shall bear the fees and costs paid by the other party, including travel and lawyers.

Recommendation: Medicines for Europe is of the opinion that the distribution of costs should not deter generic and biosimilar companies from engaging in opposition proceedings and become an obstacle to the objective of ensuring the highest quality of granted SPCs. It is therefore very important that the

[26] European Parliament resolution of 11 November 2021 on an intellectual property action plan to support the EU's recovery and resilience

[27] European Parliament Study for the JURI Committee "The potential impact of the unitary Supplementary Protection Certificate on access to health technologies"

[28] https://www.epo.org/law-practice/legal-texts/html/guidelines/e/e_vi_3.htm.

rules related to costs that will be set in a following implementing act be balanced in the interest of healthy competition.

3.9. Length of the total protection for approved innovative medicinal products

Europe provides the longest protection period in the world for innovative pharmaceutical products, *ie*. a maximum of 15 years of total protection from the marketing authorisation.[29] Such long protection periods represent an incentive to commercialise the product in the region's market but remain "*agnostic to the medicines' geographical origin*",[30] ie. the protection is applied to the product wherever the research and development (R&D) for that product takes place, since other factors affect companies' decisions to locate R&D facilities in one jurisdiction or another.[31] The downside of such longer protection periods is the impact on the local manufacturing industry, including the generic and biosimilar medicines industry.

Recommendation: Therefore, in order to ensure a level playing field and preserve the competitiveness of the EU manufacturing industry, similar to other jurisdictions like the United States or China[32], European SPC holders should be able to obtain a SPC protection so to enjoy an overall maximum of 14 years of exclusivity from the marketing authorisation, instead of the current 15 years.

3.10. No double SPC protection: Unitary SPC route and national procedures

The proposed regulations prohibit companies from filing both regional and national SPC applications for an identical invention. Moreover, for coherence and clarity, SPCs applied for centrally should only be available and maintained on the basis of a valid marketing authorisation. Similar to existing SPC law, the application should always cover a European marketing authorisation and its corresponding basic

[29] In addition to the 15 years of IP protection provided for in the SPC regulation, an additional paediatric extension of 6 months of protection can be obtained.

[30] European Commission's Impact Assessment of the Proposal for reform to the EU pharmaceutical system: https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en

[31] As stressed by the Commission Impact Assessment, factors stimulating localization of R&D investments are "*tax system and incentives; available grants, loans and other funding […]; pool of talents; proximity of top academia; clinical trials infrastructures; market size; security of supply chains; favourable reimbursement decisions*"

[32] Van de Wiele, V.L., Kesselheim, A.S., Nagar, S. et al. The prevalence of drug patent term extensions in the United States, 2000–2018. Nat Biotechnol 41, 903–906 (2023).; Eagle IP. A Detailed Dive into China's New Patent Term Extension Provisions (December 2020). Available from: https://www.eagle-ip.com/publications/a-detailed-dive-into-chinas-new-patent-term-extension-provisions/#:~:text=There%20is%20a%205%2Dyear,patent%20term%20post%20market%20approval.&text=PTE%20is%20at%20most%205,no%20more%20than%2014%20years..

patent. If it had to cover nationally granted marketing authorisations, then the purpose of a uniform European mechanism would fail.

Recommendation: Medicines for Europe strongly agrees with the proposal of the Commission to prevent such coexistence and also supports the obligation to file an SPC application centrally (to the EUIPO) every time there is a unitary or a European patent and the product is centrally approved. This is an important safeguard to ensure that the parallel SPC application routes are not (mis-)used strategically to avoid a central opposition mechanism altogether by filing separate, national SPC applications in the respective Member States.

4. Conclusion

The proposal for a centralized procedure to grant Unitary SPCs and bundles of national SPCs aim at tackling the existing fragmentation in the SPC system.

The **Unitary SPC**, while removing fragmentation both in the granting phase and in the enforcement/litigation phase (via the the Unified Patent Court), increases the geographical scope of protection of SPCs, since today SPCs are registered in 20 out of 28 Member States (as stressed by the Commission in the Explanatory Memorandum of the proposal). Therefore, the Unitary SPC system should not prevent equitable access where no product is launched (in the absence of an underlying MA).

A **centralised procedure for granting national SPCs** does not tackle the existing fragmentation in enforcement and litigation of SPCs, by only focusing on the granting procedures.

Therefore, in order to achieve a balanced system that ensures the highest quality and legal certainty, limiting the potential (mis-)use of the fragmented enforcement of SPCs, certain safeguards need to be kept or introduced in the legislation:

- ✓ Ensure quality and independence of the central body, of examination and of examiners, to be selected on expertise, rather than political (or geographical) considerations
- ✓ Ensure accountability of the granting body to EU institutions with regular reviews and reports on the work of the EUIPO
- ✓ Foresee clear timelines for all procedures in order to ensure predictability and legal certainty. Time should not prevail over the quality of the SPCs granted
- ✓ Keep the pre-grant opposition mechanism to ensure a first scrutiny of SPCs in order to avoid enforcement of SPCs that are later invalidated and that unduly delay access to generic and biosimilar medicines

- ✓ Ensure full transparency, from SPC applications to publication of full decisions, without undue delay. Should SPC expiries be in Register, a clear ban of 'patent linkage' must be made in EU legislation to avoid unlawful abuses of the system and to ensure immediate patient access to generic and biosimilar medicines on day 1 after IP expiry
- ✓ Strengthen the system for third party observations, allowing them also in opposition and appeal procedures
- ✓ Guarantee a fair distribution of costs that will be set in implementing acts, which should not deter companies from engaging in oppositions and become an obstacle to the objective of ensuring the highest quality of granted SPCs
- ✓ Provide a maximum length of total market protection from marketing authorisation of 14ys (instead of 15), in line with US, China, to ensure level playing field and competitiveness of the European manufacturing industry
- ✓ Ensure that there is no double SPC protection (national & unitary) and that the obligation to use the unitary route if the conditions apply remains to ensure that there is no strategical (mis)use of the system to avoid central oppositions by filing separate, national SPC applications in the respective Member States