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European Federation of Pharmaceutical Industries and Associations

Future-proofing EU competitiveness by limiting the negative impact of the SPC manufacturing waiver






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A REFRESHER ON HOW SPCs WORK AND WHAT IS BEING PROPOSED

The SPC (Supplementary Protection Certificate) is a *sui generis* right which intends to partially compensate innovators for the substantial patent time lost during lengthy clinical tests, trials, and other regulatory requirements needed to secure approval of a medicine. This unique right was created to provide the pharmaceutical industry with appropriate incentives to innovate. An SPC comes into effect after the corresponding basic patent expires. The compensation provided by the SPC cannot go beyond 5 years and the total combined duration of exclusivity of a basic patent and SPC cannot exceed 15 years (see figure 1).

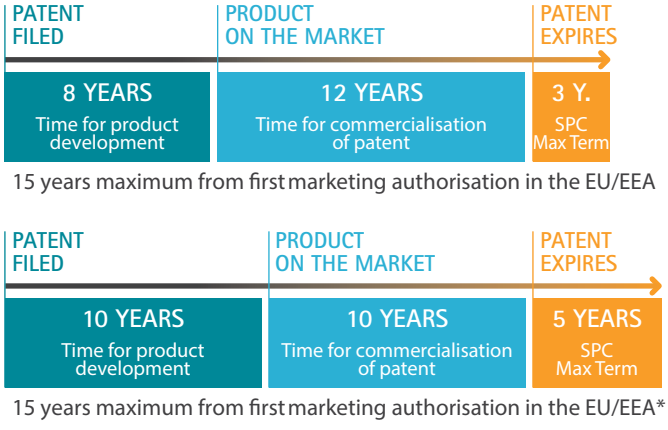
As part of the Single Market Strategy review, the European Commission proposed the introduction of a manufacturing waiver for export in the SPC Regulation[1]. The proposal would allow generic manufacturers to produce a medicinal product still under SPC protection for export to third countries. The proposed manufacturing waiver therefore introduces an exemption to a critical Intellectual Property (IP) right.

The proposed SPC manufacturing waiver's impact on innovative companies and R&D investment has not been properly assessed by the legislator.[2,3] Moreover, there is data suggesting that it is doubtful the waiver will manage to achieve its intended purpose: support European generic and biosimilar manufacturers to compete on a level playing-field outside of the EU.

For this to work, patent or other IP protection in export countries must expire before the EU SPC expiry date. This is frequently not the case: an IMS Quintiles study has shown that there are only a handful of cases in which the SPC expiry date is earlier in export jurisdictions than in the EU.[4] The European Commission also underestimated the barriers faced by EU companies (both innovators and generics) wanting to export to third country markets, where authorities often require some level of local manufacturing and tend to give preference to locally produced products in their pricing and reimbursement process.

PATENTS AND SPCs ENSURE THAT MEDICINES ARE PROTECTED FROM UNFAIR COMPETITION FOR A LIMITED PERIOD OF TIME

Figure 1: HOW DOES IT WORK? TWO CASES TO ILLUSTRATE



** ECIPE Policy Brief #4/2017 based on Pharmaceutical Compliance Monitor (2013).*

THE VALUE OF A ROBUST IP FRAMEWORK FOR PATIENTS AND INNOVATION

The EU's robust IP framework is the foundation of its globally competitive innovative pharmaceutical industry.

1 IP encourages R&D investments that give patients access to new medicines

IP makes it possible for companies to sustain investments in risky, costly, and lengthy R&D. Europe has benefited enormously from the introduction of robust IP incentives, that have allowed the pharmaceutical industry to transform the lives of patients, improve health outcomes and contribute to a thriving economy. Since the 1990s, the innovative pharmaceutical industry has brought over 1,100 new medicines to European patients, radically improving their lives. For example:

- Medicines have transformed HIV/AIDS from a death sentence to a manageable disease.
- Approximately 83% of survival gains in cancer are attributed to new treatments.[5]
- A series of pharmaceutical innovations has transformed the lives of patients living with Multiple Sclerosis.
- Patients with Hepatitis C can be cured through an 8-12 week course of treatment.

A few examples of how patients have benefited from the innovations fostered by SPCs:

- **Multiple Sclerosis:** Fingolimod is a drug that failed in its initial indication for renal failure after a kidney transplant. It was eventually brought to market for the treatment of Multiple Sclerosis, thanks to the SPC which enabled continuous investment in new extensive research and clinical trials. In fact, this treatment is today considered a milestone in the treatment of this disease.
- **Psoriasis:** Secukinumab is a medicine that set new standards for the treatment of psoriasis. It provided a new treatment option for ankylosing spondylitis (a type of arthritis that affects the spine) as well as psoriatic arthritis. Secukinumap had to undergo complex trials with prolonged timelines due to the enrolment of adult and paediatric patients. The prospect of offsetting some of this time spent on research, thanks to an SPC, made the investment, and therefore trials, possible.
- **Chronic Obstructive Pulmonary Disease (COPD):** Terol/Fluticasone Furoate is a combination drug for the treatment of COPD. It is the result of 10 years of research efforts that aimed to develop a once- daily dual combination, instead of twice-daily, to improve patient adherence. The development of this drug would not have been possible without the potential to secure a reasonable period of exclusivity provided by the patent and the SPC.

"SPCs also seem to increase innovation and thereby foster the supply of innovative products. It seems likely that SPCs increase expected profits for R&D projects in such a way that more projects reach the development stage."

Source: Copenhagen Economics Study on pharmaceutical incentives and rewards, p. 237

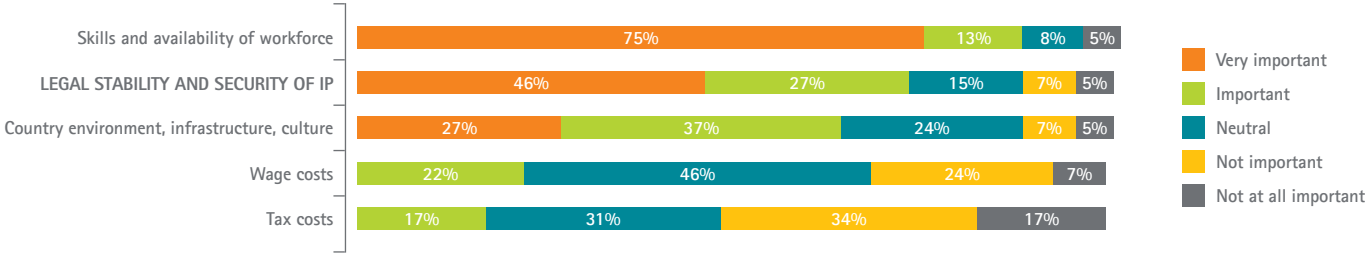
2 Strong, predictable, and enforceable IP incentives allow the innovative pharmaceutical industry to create highly-skilled jobs and to invest across Europe

This is all the more important given that, in a globalised economy, a strong IP system is crucial for companies deciding where to make their R&D investments. Currently, the EU faces competition in particular from the United States and Japan, both of which have their own versions of SPC regulations in place. China is considering the introduction of an SPC-type regulation to increase its global attractiveness for pharmaceutical R&D investments.[6]

INNOVATORS CONSIDER MANY FACTORS, INCLUDING THE ROBUSTNESS OF IP PROTECTION, WHEN DECIDING WHERE TO INVEST

Figure 2: IMPORTANCE OF GENERAL FACTORS FOR R&D LOCATION DECISIONS (2015 SURVEY)

The survey contains 30 companies that are among the top 2,000 Scoreboard Firms (EU Industrial R&D Investment Scorboard published by the European Commission covering 90% of worldwide R&D expenditure spent by private businesses).[7]



3 SPCs are a key part of this IP framework

Because the objective of the SPC is to offset some of the effective patent term lost during the development of a medicine,[8] the SPC Regulation provides innovative pharmaceutical companies with much-needed certainty: if a medicine makes it to the market,[9] it will be protected from unfair competition for a limited period of time, allowing companies to sustain investments in R&D. Nonetheless, the study on the 'Economic Impact of SPCs, pharmaceutical incentives and rewards in Europe', highlights that "*the effective protection period for the medicinal products in our dataset has declined from an average of 15 years to 13 years during the period 1996 to 2016.*"[10]

SMEs AND IP[11]

"Strong patents are the lifeblood of the innovative biopharmaceutical industry. They are critical in ensuring a steady stream of capital to biopharmaceutical companies developing innovative medicines. And they are essential to the technology transfer process from inventions in the lab to products for patients. The majority of biopharmaceutical companies are SMEs that are at pre-profit stage (no marketed product), and thus their research and development activities rely on very large amounts of private sector investment over many years. Without an economic and institutional environment that is conducive to entrepreneurship and innovation including a strong, predictable and enforceable protection for patented inventions, investors will shy away from investing in biopharmaceutical innovation, reducing the ability of SMEs to provide solutions for the most pressing medical challenges facing Europe and the world."

VALUING INNOVATION IN THE CONTEXT OF THE SPC MANUFACTURING WAIVER PROPOSAL

The SPC manufacturing waiver proposal removes certain exclusive rights currently protected by SPCs and sends a negative signal about Europe's commitment to innovative bio-pharmaceutical development in Europe.

In this context, it is absolutely vital that the final legislative text does not further erode IP incentives, provides clarity and certainty on what the waiver entails, and under which conditions it applies. This will help ensure that there is no further reduction of essential IP rights for innovators, which would adversely impact investment in the medicines of the future.

As per the Commission's proposal,[12] the waiver should only apply for exports and if the maker (1) has notified its intention to take advantage of the exception, (2) has taken appropriate labelling measures and (3) has informed any of its contractors of the conditions of the exception. EFPIA believes that these safeguards can only be effective if they are clarified and strengthened.

To protect Europe's innovation environment, the proposal must address three issues:

1 / TRANSPARENCY AND LEGAL CERTAINTY

The Commission proposal rightly suggests that there should be transparency of the generic or biosimilar manufacturer's intention to rely on the waiver from the start. To provide legal certainty to both parties and to prevent infringement, the legislation should require that:

- The 'making' is for the exclusive purpose of export to third countries where protection for the product or medicinal product does not exist or has expired;

- A proper notification system is put in place:
  - the generic or biosimilar manufacturer ('maker') must inform the relevant authority of their intention to seek the benefit of the waiver;
  - the right holder should also be notified, in addition to the relevant authority;
  - an appropriate notification period i.e., 3 months before the earliest start of the 'making';
  - the notification should include:
    - exhaustive and updated list of export countries
    - name, address, country of manufacturing
    - number of SPC
    - number of manufacturing authorisation/GMP certificate.

- No other IP Rights in the EU are impacted by the waiver.

2 / ENSURING THE WAIVER REALLY IS FOR EXPORT

To protect IP rights, it is important that the products, made under the SPC waiver, are not re-imported into the EU or put on the EU market before SPC expiry. To that end, the Commission proposal suggests that a logo is affixed to the outer packaging of the product. This measure can be easily circumvented due to, among other things, various labelling restrictions in different markets. At a minimum, the logo should be affixed on the inner packaging, as close to the product as possible. To ensure an easy, workable and effective solution, EFPIA proposes to rely on the European Medicines Verification System (EMVS),[13] mandated by the Falsified Medicines Directive (FMD).[14] This would be achieved by requiring that the unique identifier (which will be mandatory for any medicine to be dispensed in the EU) is not placed on the product intended for export under the manufacturing waiver.

3 / NO CHANGING OF THE RULES ALONG THE WAY

To ensure legal certainty and harmonised implementation across the EU, the waiver should only apply to SPCs applied for on, or after the entry into force of the Regulation. This would also preserve the legitimate expectations that any innovator considers when deciding to invest in researching and developing a medicine in a country or region.

Certain stakeholders want the proposed waiver to apply to all SPCs - already granted or even in effect as early as possible. Such a retroactive application would mean expropriating existing IP rights and appear difficult to reconcile with Article 17 of the EU Charter of Fundamental Rights, which specifically applies to intellectual property rights. It would also undermine legal certainty and legitimate expectations of innovators.

The same stakeholders argue that without such expropriation of existing SPCs, the commercial opportunity created by an upcoming so-called 'patent cliff'. This claim is unfounded. A study by IQVIA shows that out of the 10 global products by value, 8 have already lost patent protection in Europe[15]. Therefore, European biosimilar producers can already produce for the EU market in Europe and start preparing for launch in the US and 'rest of the world' markets[15].

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[1] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products

[2] OHE: https://www.ohe.org/publications/review-cra%E2%80%99s-report-%E2%80%9Cassessing-economic-impacts-changing-exemption-provisions-during

[3] https://www.europabio.org/sites/default/files/Europe%20Economics%20report%20-%20Review%20CRA%20study%20SPC%20waiver.pdf

[4] Ramya Logendra, Per Troein (2017), "Assessing the impact of proposals for a Supplementary Protection Certificate (SPC) Manufacturing Exemption in the EU"

[5] Sun et al. 'The determinants of recent gains cancer survival: an analysis of the surveillance, epidemiology, and end results (SEER) database'

[6] State Council of China of 12 April 2018 presided by Premier Mr. Li Keqiang ("Breaking News on New Policies of Innovative Drugs in China", Lexology https://tinyurl.com/y7282oae

[7] https://www.pwc.de/de/steuerberatung/assets/pwc-a-survey-of-taxation-and-corporate-innovation-2015.pdf

[8] On average, it takes 12-13 years to develop a medicine and to get a Marketing Approval. Effectively, this means that 12-13 out of 20 years of effective patent term, is lost. Source – The Pharmaceutical Industry in Figures 2018

[9] Only 1-2 out of 10 000 molecules make it to the market. Source – The Pharmaceutical Industry in Figures 2018

[10] https://www.copenhageneconomics.com/dyn/resources/Publication/publicationPDF/5/445/1527517171/copenhagen-economics-2018-study-on-the-economic-impact-of-spcs-pharmaceutical-incentives-and-rewards-in-europe.pdf

[11] EBE's position paper on the SPC MW

[12] https://ec.europa.eu/docsroom/documents/29462

[13] https://emvo-medicines.eu/mission/emvs/

[14] https://ec.europa.eu/health/human-use/falsified_medicines_en

[15] The Impact of Biosimilar Competition in Europe 2018, IQVIA. Fourth stakeholder conference on biosimilar medicines, DG GROW, 14 September 2018. https://ec.europa.eu/growth/content/fourth-stakeholder-conference-biosimilar-medicines_et

WHO WE ARE AND WHY OUR VOICE MATTERS FOR THE HEALTH OF EUROPE'S CITIZENS AND ITS ECONOMIC WELLBEING

The research-based bio-pharmaceutical industry is one of Europe's top performing high-technology sectors. Industry investment in Europe continues to grow over the years (including R&D expenditure increase), despite economic turmoil. This is also the result of a strong IP framework.

Thanks to major steps in pharmaceutical research and advances in prevention, screening, diagnosis and treatment, EU citizens can expect to live up to **30 years longer** than they did a century ago.

We invested more than **€35 billion** in R&D across Europe in 2017 and we plan to sustain these R&D investment levels in Europe over the next 5 years.

With over **7000 medicines** in development, new treatments will continue to change patients' lives; slowing disease progression, avoiding illness and reducing overall costs for healthcare systems.

Europe is the second largest pharmaceutical market in the world and accounts for **22%** of world pharmaceutical sales.

We employ **115,000** people in R&D alone and **750,000 in total**.

The EU research-based pharmaceutical sector is considered to be the high-tech sector contributing the most to the EU trade balance with a trade surplus of **€79.7 billion** in 2017.

SUMMARY

Intellectual property (IP) incentives, such as Supplementary Protection Certificates (SPCs), have been created and finetuned over the years to encourage innovation that brings new therapies to patients.
The extensive range of new medicines that are available today and that are in the pipeline for tomorrow would not exist without the EU's robust standards of IP protection. This IP framework makes it possible for industry to take risks on innovation, and to continue to invest in the long, complex and costly process of R&D that brings improved and new medicines to patients.

The SPC manufacturing waiver proposed by the Commission removes the exclusive right of "making" currently protected by SPCs.
It sends a signal to the world that Europe is weakening its commitment to IP incentives and innovation, which adversely impacts companies' decisions to invest in Europe.

In addition, the proposed SPC export waiver's impact on innovative companies and R&D investments has not been properly assessed by legislators, nor is the European Commission's Impact Assessment conclusive on its benefits. As a result, the proposed waiver is of great concern, as it could upset a carefully balanced framework.

As it covers the very end of the exclusivity period, the SPC is a critical guarantee for pharmaceutical innovators and their ability to sustain the significant investments in R&D required to develop future treatments.
Any dilution of IP protection in Europe would be detrimental to its ability to compete effectively for global R&D investment, affecting jobs, the EU's trade balance, market competition and availability of innovative medicines to patients.

It is therefore crucial that the final legislative text does not further erode IP incentives, provides clarity and certainty on what the waiver entails, under which conditions it applies, and that effective safeguards are ensured.
In the absence of an appropriate impact assessment on innovation or convincing evidence of the net benefits to health and the EU economy, the proposal should not be changed to allow stockpiling or to make the waiver applicable to exisiting SPCs. Such an extension of the waiver's scope would further diminish the incentive to innovate.

Our key requirements for the proposal are:

- **Do not allow stockpiling and maintain to the limited and targeted proposal made by the Commission (ie., waiver for export).**
- **Ensure predictability: respect existing SPCs and pending applications.**
- **Implement a transparent, timely and fair notification system in order to check that the boundaries of the waiver are respected: innovators have the right to know that generic companies intend to manufacture during their exclusivity period.**
- **Secure EU markets from re-importation of products manufactured under the waiver: adopt robust labeling measures.**

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 36 national associations and 40 leading pharmaceutical companies, EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. Our vision is for a healthier future for Europe. A future based on prevention, innovation, access to new treatments and better outcomes for patients.

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