Review of the SPC Manufacturing Waiver: a 2024 Industry Report

Updated in June 2024

Executive Summary

The Supplementary Protection Certificate (SPC) Manufacturing Waiver Regulation is **applicable since 2 July 2022**. The SPC Waiver has been introduced with the objective **to remove the competitive disadvantage that European manufacturers** of generic and biosimilar medicines are facing vis-à-vis third countries' manufacturers, which can start manufacturing generics and biosimilars earlier due to shorter IP protection periods.

This Report, based on the feedback of EU generic and biosimilar companies that have had experience in the use of the SPC Waiver so far, provides an **industry, first hand perspective of the practical implications** of the main requirements of the SPC Waiver. It shows, in particular, that while the SPC Waiver has been increasingly used by generic and biosimilar medicines manufacturers over the past two years, a **full exploitation of the potential of this measure has been severely limited** by the several unnecessary limitations and conditionalities introduced in the Regulation. The SPC Waiver, in its current form, is not considered to be completely suitable for removing the obstacles it is meant to remove.

As a consequence, the **following recommendations** are put forward in order to improve the SPC Manufacturing Waiver. These recommendations should be implemented **in the Regulation** as a result of the 5-year review required by Regulation and that is supposed to take place in 2024. In addition, the Report stresses the need to **rapidly issue guideline/Notice** to remove the existing uncertainties and limit the misuses of the – unnecessary – safeguards by SPC holders:

1. **Enable effective day 1 competition in the EU & Remove barriers to free movement of goods in the EU single market and ensure equitable access in the EU**

- The EU needs **a single SPC manufacturing waiver** without differentiation between "export" and "stockpiling" waiver. The **6-month time limitation** for making products destined for EU Member States (currently in Art. 5.2 (a) (iii)) **must be deleted**. It does not provide any safeguard against phantom illicit diversions and prevents day 1 competition in the EU, especially for complex products, such as biosimilars, for which it takes over 12 months to manufacture. It also creates uncertainty in case an SPC paediatric extension is granted while a SPC Waiver is already in use.
- **Explicitly allow intra-EU transport & export to EU countries with no SPC in force**. The SPC Waiver should not include **any limitations regarding storage and intra-EU transportation**, **which today prevents day 1 launch** and timely access in some Member States. This will help remove a

fundamental gap that frustrates the EU single market and the purposes of the SPC Waiver, defeating EU producers' competitiveness vis-à-vis non-EU producers that can actually enter those markets on day 1. Under the current SPC Waiver legislation, production for those Member States is not addressed.

2. <u>Remove existing discriminations against EU based pharmaceutical manufacturers</u>

- The **aspects of the current SPC Waiver that disadvantage EU based manufactures and distort competition without providing any benefits <u>need to be removed</u>**. These include:
  - The **notification of marketing authorisation numbers in third countries** (today Art. 5.5(e)). Today this is used as a trigger for unnecessary litigation or threat of litigation, raising questions about what should be considered 'abusive litigation'.
  - The **publication of SPC Waiver notification details** (today Art. 5.5). Non-EU manufacturers are advantaged since their manufacturing and business plans are not published anywhere. Therefore, to tackle anticompetitive disclosure of commercially confidential information, the notification should be sent only to the relevant National Patent Offices and SPC holder, and only a receipt of notification should be published.
  - The **unnecessary "Due Diligence requirements"** (today Art. 5.9), to avoid that SPC holders force disclosure and obtain access to highly commercially sensitive information throughout the whole supply chain and open the doors to potential abuses. Today, this potentially makes the makers and their contractual partners, which are often SMEs, a target for unnecessary litigation. In addition, this unnecessary safeguard discourages manufacturers intending to produce in the EU, due to the risks of unnecessary litigation that outside of Europe would not exist.
  - The **unnecessary "labelling requirements"** (today Art. 5.2 (d)).
- Additionally, **due to the legal uncertainty as to the interpretation, application of and obligations under the SPC Manufacturing Waiver, which has been compounded by conflicting national decisions in Janssen v Formycon ("*Formycon*") and Janssen v Samsung Bioepis ("*Samsung Bioepis*"),** the **European Commission should <u>clarify</u>**:
  - That **third country IP right status is of no relevance for the EU SPC Waiver**. Otherwise, this would break the territoriality doctrine of IP rights and extend to the EU the effects of foreign IP rights, opening the doors for abusive litigation in the EU based on those foreign rights, which is especially deterrent for SMEs.
  - The safeguards against **abusive litigation**, with **concrete examples of abusive litigation**, a **mechanism for competition authorities to monitor litigation or threatened litigation** in relation to the SPC Waiver.
  - Exemptions to **re-importing due to technical reasons** (i.e. certain related act being possible in third countries for example when certain steps in the manufacturing including packaging must be carried out in a third country by a contract manufacturing organisation (CMO) and the product must then be re-imported into the EU for final manufacturing and release)**.**
  - That there should be **no unnecessary restrictions on storage in the use of the export waiver**.

- That **day 1 launch is an explicit objective of the SPC Waiver** both **for launch in EU** countries as well as **for export and launch in third countries**, since the objective of the waiver is to create a level playing field between EU and non-EU manufacturers.

3. <u>Rapidly implement these policies following the 2024 review required by the Regulation</u>

- **<u>Urgently carry out the review required by the Regulation in 2024 (or as soon as possible afterwards – no later than 2025)</u>**: the legislators should seize the earliest opportunity to fix the apparent flaws in the current SPC Manufacturing Waiver legislation, *i.e.* immediately after the first review period in 2024. Waiting further would mean losing further business investments in Europe.
- **<u>One legislation design instead of a patchwork</u>**: this timing provides the unique opportunity to craft a "one-design", coherent EU legislation on pharmaceuticals. It coincides with the EU Pharma legislation reform, which contains many other policies with the same objective, *i.e.* day 1 competition (*e.g.*, the clarification of the EU Bolar exemption in the revised directive on human use medicines). It also coincides with the recasting of the relevant EU SPC law with proposals for Regulations on supplementary protection certificates as part of the IP Action Plan.
- **<u>Regulations</u>**: **the relevant Articles on the SPC Waiver in the relevant Regulations should be amended** as soon as possible after the **2024 review required by the Regulation**, to facilitate application of the SPC Waiver in practice, and to reduce the likelihood of unnecessary abusive litigation in the Member States.
- **<u>Guideline/Notice: as an additional and rapid short-term measure:</u>** the European Commission should issue guidelines or a Notice to remove the existing uncertainties and limit the misuses of the – unnecessary – safeguards by SPC holders.

Introduction

The Supplementary Protection Certificate (SPC) is a *sui generis* protection that extends the market protection of patented medicines by up to five and half years (including a paediatric extension) to compensate the time lost in obtaining regulatory approval of medicines. As such, the European Union protection is the longest in the world.

As a policy measure, the SPC proved to produce unintended results: the generic and biosimilar medicines industry was forced to produce medicines outside of Europe, to be able to launch their product in export markets and in the EU immediately at intellectual property (IP) protections expiry. This disadvantaged EU-based manufacturers. To fix this issue, the SPC manufacturing waiver ('SPC Waiver') has been introduced in the EU with Regulation (EU) 2019/933 ("SPC Waiver Regulation").

Due to its transitional provisions, the SPC Waiver Regulation is applicable since 2 July 2022. In February/March 2023, Medicines for Europe conducted a survey with its Member Companies, to gather feedback on the first experiences in the use of the SPC manufacturing waiver. The results of the Medicines for Europe survey were described in the First Report published in June 2023 as a preliminary stock-taking exercise reflecting eight months of practical experience. Already during that period, significant flaws of the SPC Waiver Regulation were manifest. A subsequent survey conducted in April 2024 has gathered additional feedback on the use of the SPC Waiver. This 2024 Updated Report confirms the issues described in the 2023 First Report and describes additional issues that emerged over the past year, including in the first case law.

In a first section ("*Findings*"), we are summarising the main feedback received from the responding Medicines for Europe member companies, leading to clear requests for revision of the SPC Waiver Regulation in a second section ("*Policy Recommendations*"). The recommendations aim to remove the unnecessary obstacles that are today built into the SPC Waiver Regulation, and optimise the practical use of the SPC Waiver, so that it can effectively achieve its stated objectives.

Overall, the SPC Waiver continues to be seen as a step in the right direction, but there is ample consensus that it needs significant improvement in several aspects in order to be able to produce the results it is intended for.

Findings

Findings on the Business Impact of the SPC Manufacturing Waiver

- **Usage**:

  In the first 8 months since the Regulation was enacted, more than half of the 13 responding companies had submitted at least one SPC manufacturing waiver notification in one or more Member States. In the past 12 months, replying companies have reported to have filed SPC Waiver notifications for over 30 additional products. The use of the SPC Waiver continues to be gradually growing, showing European companies' interest in manufacturing in Europe for **maintaining and re-establishing competitiveness vis-à-vis non-EU industry in European as well as in export markets**.

- **Business impact**:

  The majority of respondents found the SPC Waiver to have a significant impact on their business, with ratings ranging from 4 to 9 in 2024 on a scale of 1-10. However, almost all respondents are of the opinion **that SPC Waiver in its current version does not achieve the expected results**.

- **Reasons for not using the Waiver:**

  Since the adoption of the SPC Waiver, responding companies reported that they decided to manufacture in Europe over 60 products (25 according to the 2023 Survey, and 36 additional products according to the 2024 Survey), whereas they have **decided NOT to manufacture in Europe 34 products (24** according to the 2023 Survey, and **10 additional products** according to 2024 Survey)**. The main reason for opting for a non-EU supply were the complexities embedded in the legislation which cause legal uncertainty, unnecessary disclosure of confidential information, unnecessary limitations and the risk of frivolous/abusive litigation** (these obstacles are described in detail in the sections below).

  Regarding biosimilars, a respondent reported that **for the production of three biosimilars they opted for a 100% non-EU supply chain due to the too short timelines (6 months) and the storage requirements for production for EU countries, and the disclosure of commercially sensitive information.** It stressed that it takes over 12 months to manufacture a biosimilar including drug substance and drug product and thus the 6 month limitation renders the current SPC waiver as inoperable for biosimilars. The same respondent reported to be **"largely dissatisfied" with the SPC Waiver due to the above mentioned obstacles and stressed that for the same reasons it is not planning future biosimilar production in Europe, but rather in non-EU countries**. In a non-EU country without an SPC, the manufacturing for the EU can start at any time and with no legal uncertainty, nor disclosure of commercially sensitive information, nor costly frivolous litigation.

- **Effect of not using the SPC Waiver:**

  The loss of business activity for the EU derived from not using the waiver and investing abroad was estimated by two respondents, with one stating a "low amount of millions" lost, and the other

estimating a transfer of 30% to 80% of production capacities to Europe if certain amendments were made to the current system.

- **Positive effects when the SPC Waiver is used:**

  Several respondents reported having increased operations (including for small molecule APIs) and investing in new equipment and facilities in Europe. One respondent to the 2023 survey had reported increased business in Europe with higher revenues for one specific product only, and another mentioned the decision to expand or build three EU manufacturing sites, resulting in investments of EUR 600 million, and 300 new manufacturing jobs. Additionally, in the 2024 survey, one respondent stated that they were able to successfully launch 2 products from the EU on day 1 thanks to the SPC waiver provision; otherwise, the launch would not have been as successful, or the volumes would have been much lower. One respondent also reported to have manufactured 6 APIs and 5 finished dosage forms in Europe thanks to the SPC Waiver. Furthermore, the SPC Waiver provision was reported to be a stimulating factor for establishing partnerships using EU-based manufacturing site as the main supply chain. It also stimulated the establishment of a new manufacturing site in the EU for highly potent products. Additional new manufacturing activities were reported in Germany, Austria, the Netherlands and Ireland.

  However, some respondents reported they did not increase operations in Europe due to the SPC Waiver, with one stating that the Waiver, in its current form, is not attractive for investments in the EU. These companies expressed dissatisfaction with the legal uncertainties and the unnecessary conditionalities and limitations in the legislation. Some respondents stated they have not elaborated data on the increase of operation in Europe yet. Some preferred not to disclose this information.

  Savings for companies triggered by the SPC Waiver in 2023 were reported to be up to €10mn. Most companies, however, found it too early to assess the amount of savings, or do not expect savings at all with the current version of the SPC Waiver.

  In terms of **jobs**, one company reported the creation of 100-500 new jobs in the EU. Seven companies reported the SPC Waiver allowed them to create up to 100 new jobs within the EU according to the 2023 Survey, and two additional companies reported the same numbers in the 2024 Survey. For the other respondents, this information is still unknown.

- **How to increase use and business impact of the SPC Waiver:**

  44% of the respondents stated that they would have decided to use the SPC Waiver in the absence of the existing complex conditionalities and limitations for its use. **These limitations discouraged them from investing in Europe and led them to choose a non-EU country for manufacturing investments**. One respondent reported to be **"largely dissatisfied"** with the SPC Waiver due to the existing unnecessary obstacles and stressed that for the same reasons **it is not planning future biosimilar production in Europe, but rather in non-EU countries**. In detail, uncertainties in the application of the SPC Waiver, the 6- month limitation being too short period for EU day 1 launch, and concerns with disclosing sensitive information were named.

- **How users increase the impact of the SPC Waiver:**

Respondents have made a variety of changes to their manufacturing strategies to improve the impact of the Waiver, such as **moving some manufacturing back to the EU** (44%), **increasing existing manufacturing activity in the EU** (44% according to the 2023 Survey, and 60% according to the 2024 Survey), **starting manufacturing in the EU** (33% according to 2023 Survey, and 20% according to 2024 Survey), **moving manufacturing back to countries that frequently have SPCs** (11% according to 2023 Survey, and 20% according to 2024 Survey), setting up a monitoring system for SPCs (33% according to 2023 Survey, and 80% according to 2024 Survey), and adopting *ad-hoc* business development procedures (11%).

- **Time to fix the issues**

Respondents highlighted the huge importance to carry out the foreseen review and revision of the Regulation to assess if it has achieved its purpose as a policy measure (foreseen for 2024 according to the Regulation). Waiting for another 5-year-period (until 2029) would be too late. I It was confirmed that **uncertainties and shortcomings are already evident and should be fixed now to stop further transfer of manufacturing capacities outside of the EU**. Some respondents also stressed that the **review should be conducted objectively, limiting external influences, which have already affected a Regulation that started with the best intentions but ended being hardly usable**.

Respondents requested the EU to reduce uncertainties and provide clarifications in the SPC Waiver framework by **amending the Regulation and in parallel by introducing a broad Bolar exemption, since both measures aim at the same objective: day 1 competition**. As an additional and possibly more rapid short-term measure, companies requested the issuing of a guideline/Notice to remove the existing uncertainties and limit the misuses of the – unnecessary – safeguards by SPC holders.

Findings on the Notification System

- **SPC holders' responses to SPC Waiver notifications - (1) Lawsuits & the first (conflicting) case law:**

Since the publication of the 2023 First Report, **two national Court decisions concerning the SPC Waiver have been published**, showing not only a **conflicting understanding of the language of the SPC Waiver Regulation**, but also the **attempt of a SPC holders to create artificial obstacles to the use of the waiver via frivolous litigation**, raising questions about **what could be considered 'abusive litigation'**.

All respondents showed **very strongly concern about the first judgement on the SPC Waiver issued by the Munich District Court, Germany in October 2023, in the case *Janssen v Formycon*[1]** ("*Formycon*").[2] In this judgement, the Munich District Court adopted an inordinately restrictive interpretation of the SPC manufacturing waiver, which cannot be derived from the letter of the law, and which contradicts the purpose and spirit behind the amendments that were introduced during its inception until its final approval. This utterly frustrates the aims of the Regulation.

The Munich Court judgement purports that SPC Waivers for export would require notification of a marketing authorisation (MA) number - even if no MA number is publicly available yet - or the

[1] Janssen Biotech, Inc v Formycon, Regional Court of Munich, October 2023

[2] https://www.medicinesforeurope.com/wp-content/uploads/2024/01/Press-release-SPC-waiver-18-Jan-2024.pdf

disclosure of confidential information about future countries of submission, deducing those requirements from an alleged need to ensure that no conflicting IP rights should exist in the foreign country of export. Respondents stressed that both purported requirements are not supported by the letter of the law and are in conflict with the objectives of the SPC manufacturing waiver, as evidenced by the legislative history and its explanatory memorandum.

The judgment further suggests that for manufacturing in the EU and export to a third country to be permissible, a granted MA in such third country is required, a position which is fundamentally wrong and is a complete misunderstanding of which activities require a marketing authorisation under pharmaceutical regulatory laws. Whilst this is a matter of the national law of each country, generally only placing a medicinal product on the market requires a MA, not the manufacture, making or import.

Moreover, **despite there being no limitation on the duration of storage for export in the Regulation**, the Court even suggested that long-term storage would not be permissible.

Although it is a first-instance judgment in an expedited procedure, issued in a single – but, for the pharmaceutical industry, significant - EU country, **it is already being used by SPC holders to further threaten existing and future users of the SPC Manufacturing Waiver with lawsuits, or to sue them, a practice that distorts the use of the waiver, frustrating its goals.** The judgement even maintains that "*the Regulation is not intended to put manufacturers within the Union on a completely equal footing with manufacturers in third countries*"[3] , which clearly reflects a **fundamental misunderstanding by the Court of the aims of the Regulation**.

This judgement shows that the **current SPC Waiver legislation is drafted in a way that allows SPC holders to misinterpret the language before Courts to the detriment of EU-based manufacturers**, and to the benefit of producers established out of Europe. Respondents to this survey report that this threatens planned and committed investments in manufacturing in Europe to the detriment of the fundamental goals of the legislation.

Following the Munich District Court decision, **several lawsuits have already been reported with the same unfounded argument that at least one MA in export markets should be included in any initial notification for the SPC Waiver to be valid**. A respondent reported having received even **4 lawsuits for 1 product in 1 Member State** Another respondent reported having been sued even without any warning letter. Another one reported being sued for an allegedly ineffective notice as the country of export was not named.

A respondent stressed that if, in an absurd hypothesis, a final MA in a non-EU country were required for validly using the SPC Waiver in the EU, the SPC Waiver would be unusable for biosimilars, for which approval timelines are about 12 months in major third countries, and waiting until a MA publication for starting manufacturing in Europe would be such a disadvantage that no company would ever use the waiver.

In the second case, ***Janssen v Samsung Bioepis***[4] ("*Samsung BioEpis*"), in direct contrast to the Munich District Court in *Formycon*, the **District Court of the Hague held that it is clear from the wording of**

[3] Unofficial translation

[4] Janssen Biotech, Inc., v Samsung Bioepis NL B.V, District Court of the Hague, 23 January 2024

Article 5(5)(e) of the Regulation that the maker is required to provide the MA for each exporting third country *"only as soon as it is available to the public*." Moreover, it stated that **there is no requirement under the Regulation for intended export countries to be free of patent rights nor that the manufacturer must demonstrate this in advance**, citing that it would **otherwise be contrary to the objective of the Regulation** to ensure a level playing field with global competition.

The Dutch Court considered the opposing ruling in *Formycon* but disagreed with the Munich Court's reasoning, noting that **the requirement to name the exporting countries in the notification had been removed during the legislative procedure due to concerns about the disclosure of trade secret information by manufacturers**.

As to limitations to storage in case of export, whilst the Munich Court suggested that "long-term storage" was not allowed, the **Dutch Court was of the view that there is no requirement in the Regulation that products manufactured for export must be exported "almost immediately" nor is there a requirement in terms of the maximum duration of the storage**.

According to respondents, the excessively strict and ***contra-legem* interpretation of the Regulation in *Formycon*** and the uncertainty due to the **conflicting interpretation in *Samsung Bioepis*** will likely lead to further unwillingness by generic and biosimilar manufacturers to utilise the SPC Waiver, potentially resulting in more divestment outside of the EU and/or delays to access of affordable medicines in the EU, frustrating the primary goals of the Regulation.

Finally, it was stressed that the **costs associated with attempting to avoid litigation** — both financially and in terms of time — are exorbitant, often involving exhaustive interactions with the SPC holder over notification details that should not be contentious.

- **<u>SPC holders' responses to SPC Waiver notifications - (2) Threats of litigation</u>**

  In response to notifications, almost all respondents were **threatened with legal action**, *e.g.* to clarify whether the exported goods were considered infringing in the country of destination, or requesting to disclose confidential information not foreseen in the notification requirements. One respondent reported being **threatened to be sued in all the Member States of manufacturing as well as in all the export markets**.

  This, in addition to the case-law described below, shows a **regular attempt by SPC holders to use Recitals 8 and 18 (reference to third-country markets where "the protection does not exist or has expired") to achieve extra-territorial protection of patents by limiting manufacturing in EU Member States based on non-EU patents or other non-EU IP rights**.

  More than one third of respondents experienced pressure from SPC holders, **despite stipulations not to launch** in the target country before the SPC expiry. In multiple cases, respondents received a **warning letter and were sued in the country of export named in the notification, but not in the country of manufacturing**, reporting that the notification appeared to be the triggering act for that litigation.

  Another response to a SPC Waiver notification from a SPC holder was **threatened judicial action, claiming production under the export waiver was not allowed while IP protection in the export countries is in place**. This interpretation is at odd with the goal of restoring a global level playing field for makers of generics and biosimilars in and outside the Union.

In some cases, since the expected costs of an expected lawsuit in the export country were higher than the benefit of producing in Europe under the SPC Waiver, the SPC export waiver was then abandoned, leading to a general disincentive to use the waiver.

These actions are not conform with the SPC Waiver Regulation: information in the notification is allowed to be used exclusively to verify the applicability of the waiver (Art. 5.4), and not to inform a lawsuit in a third country.

Two respondents reported receiving **requests for confidential information about their manufacturing processes**. An increasing trend was reported of increasingly more details being requested by the SPC holders, including planned activities, production timelines, involved parties, jurisdictions, and planned export markets when no foreign marketing authorisation is public.

Very often, **these requests are an attempt to extort confidential information from the SPC Waiver users. They are often presented in warning letters as a series of assumptions and requests for confirmation**.

One respondent even reported that **by obtaining information on a supply chain actor, an SPC holder harassed this supply chain partner** (a contract manufacturing organisation - CMO) to stop or delay its operations. This, according to the respondent, also puts **strains on relationships with such CMOs, which are unwilling and/or unprepared to face threats of patent litigation**. Paradoxically, this makes them think they are taking on a risk when the waiver should actually be removing such risks and making the process easier.

The requirements of disclosure of confidential launch planning in the SPC Waiver Regulation, in combination with additional information requests by the SPC holders, constitute a significant competitive disadvantage for users of the EU SPC Waiver compared to Third country manufacturing companies. This could lead companies to forego the SPC Waiver and to rather establish manufacturing outside the EU.

In one case related to an API production, **a SPC holder raised unjustified doubts about the effectiveness of a notification submitted by a company, creating uncertainty as to the starting time limits to act under the SPC Waiver**. No further communication confirming/denying that alleged ineffectiveness was received.

- **<u>Safeguards against 'abusive litigation' (art. 5.4 & recital 20):</u>**

  The **arguments used by SPC holders in the case law described above triggered questions for respondents around what should be considered 'abusive litigation'**, as referred to in Recital 20. According to respondents, "**ambiguity incentivizes gamesmanship from deep-pocketed SPC holders**". The safeguard provided for in **Art. 5(4) is considered ineffective or even detrimental** for the generic industry, since **its presence suggests there is some form of anti-abuse provision, some sort of fair or level playing field, but in reality it has no effect**.

  Respondents emphasized the **need for stronger safeguards against abusive litigation**, including a possible clear **definition of what would actually constitute abusive litigation** within the Regulation.

A respondent **proposed the creation of a bond deposit or a higher court fee required for SPC holders** when filing claims under the SPC Waiver Regulation, as well as including **provisions regarding cost liability for the damages** suffered by the users of the Waiver.

Additional safeguards could be provided in guidelines, which could clarify certain meanings of the terms of the SPC Waiver, to avoid that every single word's interpretation need to be clarified in courts in frivolous litigation, potentially even in several EU Member States and judicial instances.

- **Publication of SPC Waiver notifications:**

The majority of respondents felt **very uncomfortable about the national patent office (NPO) publishing the notification that contains commercially confidential information**. **Some companies stressed that they prefer not to use the SPC Waiver due to the disclosure of the information**. This publication is today foreseen by recital 14 of the SPC Waiver Regulation.

Particularly commercially sensitive aspects for respondents are: **(i) the country of manufacturing**, **(ii) the third country information**, and **(iii) the supply chain information (e.g., in relation to country of related acts)**.

Respondents suggested that **the notification information should only be disclosed to national patent offices (NPOs) and SPC holders, and NPOs should only publish the receipt of a SPC Waiver notification for a given SPC, and not its contents, which otherwise, once in the public domain, could be used without control by any possible actors.**

A respondent also suggested that in cases there are third party SPCs on the same product, the notification should only need to be addressed to the originator's SPC, in order to avoid uncertainty.

- **Terms triggering uncertainty:**

The concern about the **interpretation of 'maker'** already expressed in the 2023 First Report was confirmed. Two responses highlighted the complexities in determining the "maker" when production is commissioned by one entity but marketed by another. A potential literal interpretation of "on behalf" as meaning "the making must be done purely in the interest of the maker" is seen as insufficient to reflect the complexity of the pharmaceutical manufacturing process.

A respondent highlighted the **difficulties with tracking marketing authorisations** and updating the waiver notification accordingly in different countries for successful products.

The **notification submission process seems to work well for most users, except in cases where full address details of the SPC holder are not available on NPO's registers or in multinational companies' registers.** Additionally, in some countries, like Romania, filing without the involvement of a local patent attorney is challenging. There have also been some administrative issues, including incorrect publication dates and errors in updating earlier notifications by patent office officers. One company mentioned potential issues with data protection laws in its country. Moreover, it was reported that **foreign SPC holders prefer that generic manufacturers contact their subsidiaries in the EU instead of following the requirement of the waiver to notify the SPC holder, creating legal uncertainty**.

It was suggested that **all national patent offices should provide confirmation of receipt and an indication about the waiver request status, to provide legal certainty** for the user.

The language "**strictly necessary**" ("Making a product or medicinal product containing that product and *any related act strictly necessary…*") in the Art.5.2 (a) (ii) and (iv) has received mixed opinions from respondents. Some believe that it is too restrictive and unclear, while others believe that "necessary" alone would be sufficient. There is **concern that this may lead to uncertainty in the supply chain, leading to litigation**.

One reported situation related to API includes the case in which as a result of an analysis made by a customer in a third country, it turned out that the exported API did not meet specification requirements. Since innovators may consider this as "related act", the API could not be re-imported to the EU for re-processing by the maker, with a significant loss for the maker.

It is suggested that the design of a supply chain should be dictated primarily by supply chain considerations, and any necessary steps should be considered "related acts", and that "strictly" be deleted from the provisions on related acts.

Findings specifically on EU day 1 Launch

- **Hurdles to EU day 1 Launch and the single market:**

  Multiple respondents confirmed that they **do not find it feasible to launch generic or biosimilar products in the EU on day 1 after SPC expiry**. This is due to flaws in the SPC waiver (6-months' time limitation, storage requirement, EU countries without SPCs not being addressed)**, combined with the lack of a broad Bolar exemption covering also pricing and reimbursement procedures**. This stresses that the revision of the SPC Waiver Regulation and the revision of the general pharma legislation need to be concerted and work synergistically to enable EU day 1 competition.

  All respondents agreed that **intra-EU transportation of the products/medicinal products should be allowed under the SPC waiver to make day 1 market entries possible**: Preparations such as storing the product and transportation take time. **Delaying distribution until day 1 at the earliest delays market entry in many Member States, which defeats the purpose of the waiver and frustrates the single market**. Some respondents stated that transit of IP protected goods should be allowed anyway, and in case the SPC Waiver did not allow it, the legislation should be amended accordingly.

  In response to the argument that the storage limitation was necessary to prevent illicit diversion, some responses argue that not at least, **packaging and labelling (i.e., compliant with the falsified medicines directive rules) would prevent illicit diversion anyway**. Indeed, some **respondents showed surprise about the stated risk of illicit diversion in a highly regulated market like the EU**. According to some respondents, there would be no need for any additional unnecessary internal market restriction: **limiting storage to certain countries for not fully justified reasons undermines the EU single market and free movement of goods**. It is stressed that pharmaceutical markets are constantly monitored and subject to numerous Regulations: **the idea that illicit diversions somehow remain undetected is therefore farfetched and there is no persuasive evidence to the contrary**.

  It was stressed that the **assumption that enabling generic and biosimilar manufacturers to start production for day 1 EU entry (or for export) would increase the risks** of generic or biosimilar products being placed on the EU market prior to SPC expiry has **never been supported by any evidence**.

Whether the manufacture of a generic or biosimilar product takes place within or outside of the EU bears no relevance to the level of risk of an illicit diversion onto the EU market during the term of the SPC. Since **the Bolar exemption was introduced in EU law, without any of the safeguards implemented for the SPC Manufacturing Waiver, there has not been any evidence that the exemption has led to an increased risk of illicit diversion**.

It was stressed in the survey's answers that the legislator's reasoning is premised on the **two further mistaken assumptions** that: **(i)** the first time an SPC holder will become aware of a generic or biosimilar launch is after the generic or biosimilar product is placed on the EU market; and **(ii)** if that were the case, it would be too late for the SPC holder to effectively enforce its rights.

From both a regulatory and practical perspective, this is not the case. Medicinal products are heavily regulated. In all Member States the grant of a marketing authorisation, the grant of price and reimbursement status, and the placing on the market of generic or biosimilar products are already subject to **official publications allowing SPC holders to monitor these activities and enforce their rights** if they believe they are infringed by an illegitimate launch, including by seeking a preliminary injunction, in accordance with Directive 2004/48/EC on the enforcement of IP rights. Clinical trials (for hybrid and biosimilar products) are also already subject to official publications.

The alternative scenario, where an SPC holder failed to monitor generic and biosimilar activities and does not have sufficient advance notice of a generic or biosimilar launch, is highly unlikely but even in such circumstances, **SPC holders are entitled to enforce their rights and can (and have been able to) obtain urgent interim relief to protect their monopoly**.

In view of the above, **the majority of the safeguards under the Regulation are unnecessary and detrimental to generic and biosimilar manufacturers, undermining the Legislator's fundamental objective** of putting generic and biosimilar manufacturers in the EU on a level playing field with manufacturers based in third countries.

Another respondent underlined that **if the product can be stored anywhere within the Member State of making (as the legislation suggests), there is no reason why the product should not be transported for storage in another Member State, for the sake of the single market**.

Moreover, a respondent submitted there could be several interpretations of "Member State of making", which renders the storage requirement unclear.

Therefore, **the storage limitation of the current SPC Waiver Regulation is unnecessary and should be deleted**.

- **<u>Advantages of non-EU manufacturers</u>:**

Some respondents reported that **manufacturers located in non-EU countries** have an advantage over those in the EU for selling products covered under a SPC, as they do not need to use the Waiver, and don't need to comply with the 6-month time limitation prior to SPC expiry, and can start ramping up production earlier.

It has been stressed that **these limitations have made the SPC Waiver completely unattractive in comparison with using a non-EU manufacturer**. In this context, it was again stressed that production for EU countries without SPC is not addressed under the current SPC waiver scheme. Certain

respondents stressed that **for this exact reason they had to outsource production to non-EU third-party manufacturers**. They believe that this goes **blatantly against the purposes of the legislation** and a legislative fix is absolutely necessary to explicitly permit this type of launch. The current SPC Waiver is seen as favoring third-party manufacturers outside the EU for what concerns launch in these EU unprotected Member States, which clearly goes against the original intention of the legislation.
Multiple respondents stressed that the **6-month period for making and storing is insufficient to produce a finished dosage form especially for more complex products**. The length of time required depends on the complexity of the molecule, production process, and manufacturing capacities. For simple molecules or later production steps, 6 months may be enough, but **for complex generics or biosimilars, it is reported not to be sufficient**. It was reported that **if both API and final dosage forms are manufactured under SPC waiver in the EU, the 6-month period is clearly insufficient**, since API manufacture may involve for many molecules up to 10-12 synthetic steps or complex processes and long testing in different sites (for DRX, heavy metals, microbiology, etc.). Therefore, this prevents being on time to produce, test and release the final dosage form. Manufacturing capacity at contract manufacturing organisations (CMOs) for biologics must be booked years in advance, and the mere drug substance manufacture takes alone more than 6 months. This is **particularly detrimental for EU API producers, since, considering the very short timeframe, finished dosage form producers tend to prefer sourcing API from producers in non-EU countries**.

Specifically for biologic products, it was reported that those products are most often sensitive and require sterile manufacture and filling, frozen or cooled transportation, and delicate handling and packaging. Often, they require filling into special vials and assembly into delivery devices. **The pure making of a biosimilar molecule from primary structure** (most often proteins expressed by genetically engineered cells) **to bulk** (most often the protein in a specific formulation for intravenous or subcutaneous injection) **might require already 9 months**. After that drug substance manufacture, it takes approximately **at least another 3 months to produce the medicinal product** (fill and finish activities, such as sterile filling into vials, labelling and secondary and tertiary packaging, quality testing and assays and release of the batch).

It was stressed that the 6-month limitation would also put limits to the quantities potentially produced, since **6 months would be a too short timeframe for producing bigger quantities of products**, creating an unnecessary obstacles to the competitiveness of EU producers.

It was **suggested that the 6-months limitation should be deleted, since such limitation is completely unjustified and is contrary to the core purpose of the legislation (i.e. day 1 launch)**.

- **<u>Problems related to paediatric extensions</u>:**

  It is possible that **paediatric extensions (PEs) are granted less than 6 months before SPC expiry**. Some respondents gave specific examples of late-granted paediatric extensions, such as 11 out of 65 PEs in the UK being granted less than 6 months prior to the original SPC expiry date, and two examples in Portugal.

  The majority of respondents (83%) believed that if an **SPC paediatric extension** is granted during the 6-month SPC waiver period, generic manufacturers should not be liable for SPC infringement for any acts undertaken under the waiver.

Findings specifically on Export

- **EU countries without SPC not addressed in SPC Waiver Regulation:**

  Some respondents underlined the fact that **limiting "Export" to third countries** (i.e. non-EU countries), could **exclude from its scope those EU Member States without SPC protection**, **undermining the purposes of the SPC Waiver when a medicinal product is produced and stored in a Member State with SPC for a EU country without SPC.**

  It was reported that an SPC may well be revoked or invalidated in one EU Member State (non-SPC protected EU country) but remains in force in the EU country of making under SPC Waiver. Even in this case, the SPC Waiver arguably does not allow the manufacturer to supply the product to the non-SPC protected EU country.

  This puts the EU manufacturer at a competitive disadvantage vis-à-vis non-EU producers (which is the primary issue that the SPC Waiver was intended to tackle) and **affects timely access to medicines in the Member State without SPC, undermining at the same time the concept of single market**.

  Removing the distinction between "export" and "stockpiling" waiver, and instead providing a single SPC Manufacturing Waiver, would solve the problem.

  One situation related to API production was strongly stressed: if an API manufactured under the waiver in an EU SPC protected country needs to be sent to another EU country with no SPC to manufacture the finished dosage form (FDF), innovators have argued that it would not be possible to apply the export waiver because the API will be sent to an EU country (i.e., not exported to a third country as defined in the Regulation). At the same time, it would not be formally possible to request the waiver in that EU country where the FDF is produced, because there is no SPC. **This kafkaesque situation could be solved by including those EU countries with no patent or SPC within the notion of third countries**.

- **Storage limitation**

  As highlighted above, the existing case law shows that an **SPC holder has argued in multiple EU litigations that the export waiver implicitly includes a limited storage time period** following production. They contend that products manufactured under the SPC Waiver for export should not be stored within the EU at all. **This interpretation, followed by the Munich Court and dismissed by the Dutch Court, complicates the use of the export waiver and makes it less attractive**.. This stance undermines the practicality and intent of the waiver, which is designed to facilitate competitive manufacturing and export activities within the EU.

- **Overstepping territoriality of IP rights:**

  Some respondents stated that **they were sued and/or threatened to be sued because of the existence in the export country of an SPC-like protection at the moment of start of manufacturing**. In a 2023 recent case, litigation was started in Ireland on the basis that the user of the waiver could not actually

rely on the waiver because there were patents in force in the US. This case was then settled, but it already immediately showed that litigation is not just threatened and for frivolous reasons.[5]

It was noted that, as shown also in the *Formycon* and *Samsung Bioepis* case law described above, SPC holders assert the necessity of knowing the export country to verify if they hold relevant protections, such as patents, in those countries. This is because, if such protections exist, they argue that the notification would be invalid. They base this argument on the last sentence of Recital 18. The presence of any protection — whether a patent, SPC, or Patent Term Extension (PTE) — in a third country should not affect the applicability of the waiver in the EU. If a relevant patent, SPC, or PTE exists in a third country, then the rights holder is entitled to enforce it within that country as it see fit if attempts are made to import into that country.

Respondents stressed that using the SPC manufacturing waiver to prevent production in Europe in light of a protection in a third country is inconsistent with the purposes of the legislation and highlighted that **using the SPC Waiver to enforce in Europe a patent/SPC in force in a non-EU country is abusive/frivolous litigation**. No EU Court should assess the validity of IP rights in third countries. Respondents propose that the wording of Recital 18 be clarified to avoid ambiguity and ensure that the SPC Waiver can be applied fairly without **illegitimately extending in Europe protections that exist in third countries**.

- **Unnecessary labelling requirements:**

  While most respondents were able to comply with **labelling requirements for export** to third countries, they stressed the requirement was unnecessary. Another respondent mentioned that labelling requirements may contradict national regulatory requirements in some export countries, *e.g.* Brazil or others.

  One respondent emphasized that the Regulation l**acks clarity regarding the labelling of intermediate products**. It specifies labelling requirements for the active ingredient (no labelling is required) and the final medicinal product. However, it fails to address cases where an intermediate product, whether in bulk or not fully packaged, is exported. This ambiguity creates a significant compliance gap for products in stages between these two extremes.

  The **immediate packaging of biologics** presents another challenge due to its very limited space, making it impossible to add export labels.

  Additionally, the need to **remove labels after the expiry of the SPC can cause confusion and inconvenience for customs officials, pharmacists, and patients**. This process incurs substantial costs and demands significant resources, both internally and from regulatory authorities in third countries.

Findings on Other Aspects

- **Re-packaging and initial packaging**

[5] Janssen Biotech Inc -V- Amgen Technology [Ireland] Unlimited Company 2023/1328 P

The current language in the SPC Manufacturing Waiver (SPC MW) concerning packaging operations is ambiguous, particularly when distinguishing between re-packaging and initial packaging. It is crucial to explicitly clarify that all packaging operations are considered steps of "making," and thus are integral parts of the manufacturing operations covered under the waiver. This clarification is essential to ensure that these activities are not categorized under the exclusions typically associated with re-packaging, as outlined in the recitals. Emphasizing that packaging is a core manufacturing operation highlights its importance and supports the rationale for onshoring such activities within the EU.

- **Unnecessary Due Diligence requirements:**

  Most companies have not yet faced big obstacles in complying with **due diligence requirements to inform supply chain** actors about potential SPC infringement. However, some companies find the requirement superfluous (since the notification is made public) and impractical, **creating legal uncertainty. The due diligence requirements may be used by SPC holders to force disclosure of commercially confidential information, potentially offering to SPC holders a way to block logistics**. They argue that SPC holders can simply enforce their SPC in case of any infringing act not falling under the SPC Waiver Regulation, anyway, without the need for any due diligence. There are also concerns that smaller players such as SMEs in the value chain may be unfamiliar with SPC law and disadvantaged by these measures.

  Moreover, there is uncertainty as to the actual “persons in contractual relationship with the maker” that need to be informed in accordance with the due diligence requirement and on how the SPC holder might try to control compliance with the formal requirements set out in the due diligence requirement. Generic/biosimilar companies’ confidential or commercially sensitive information on supply chain or employees needs to be kept confidential at all times.

- **Inflexibility and uncertainty:**

  Most respondents have faced or expect to face other issues with the use of the Waiver. These issues include the **lack of flexibility in the use of the Waiver to adapt to companies specificities**, **other forms of threat of litigation, especially for smaller companies and SMEs and uncertainty regarding API manufacturing.**

  A reported situation is the case in which one small step of production must be carried out in a non-EU CMO due for example to missing technical abilities, which may require some flexibility to export and re-import.

Policy Recommendations

1. **Enable effective day 1 competition in the EU & Remove barriers to free movement of goods in the EU single market and ensure equitable access in the EU**

- The EU needs **a single SPC manufacturing waiver** without differentiation between "export" and "stockpiling" waiver. The **6-month time limitation** for making products destined for EU Member States (currently in Art. 5.2 (a) (iii)) **must be deleted**. It does not provide any safeguard against phantom illicit diversions and prevents day-1 competition in the EU, especially for complex products, such as biosimilars, for which it takes over 12 months to manufacture. It also creates uncertainty in case an SPC paediatric extension is granted while a SPC Waiver is already in use.

- **Explicitly allow intra-EU transport & export to EU countries with no SPC in force**. The SPC Waiver should not include **any limitations regarding storage and intra-EU transportation**, **which today prevents day 1 launch** and timely access in some Member States. This will help remove a fundamental gap that frustrates the EU single market and the purposes of the SPC Waiver, defeating EU producers' competitiveness vis-à-vis non-EU producers that can actually enter those markets on day 1. Under the current SPC Waiver legislation, production for those Member States is not addressed.

2. **Remove existing discriminations against EU based pharmaceutical manufacturers**

- The **aspects of the current SPC Waiver that disadvantage EU based manufactures and distort competition without providing any benefits need to be removed**. These include:
  - The **notification of marketing authorisation numbers in third countries** (today Art. 5.5(e)). Today this is used as a trigger for unnecessary litigation or threat of litigation, raising questions about what should be considered 'abusive litigation'.
  - The **publication of SPC Waiver notification details** (today Art. 5.5). Non-EU manufacturers are advantaged since their manufacturing and business plans are not published anywhere. Therefore, to tackle anticompetitive disclosure of commercially confidential information, the notification should be sent only to the relevant National Patent Offices and SPC holder, and only a receipt of notification should be published.
  - The **unnecessary "Due Diligence requirements"** (today Art. 5.9), to avoid that SPC holders force disclosure and obtain access to highly commercially sensitive information throughout the whole supply chain and open the doors to potential abuses. Today, this potentially makes the makers and their contractual partners, which are often SMEs, a target for unnecessary litigation. In addition, this unnecessary safeguard discourages manufacturers intending to produce in the EU, due to the risks of unnecessary litigation that outside of Europe would not exist.
  - The **unnecessary "labelling requirements"** (today Art. 5.2 (d)).
- Additionally, **due to the legal uncertainty as to the interpretation, application of and obligations under the SPC Manufacturing Waiver, which has been compounded by conflicting national decisions**

in Janssen v Formycon ("Formycon") and Janssen v Samsung Bioepis ("Samsung Bioepis"), the **European Commission should clarify**:

- That **third country IP right status is of no relevance for the EU SPC Waiver**. Otherwise, this would break the territoriality doctrine of IP rights and extend to the EU the effects of foreign IP rights, opening the doors for abusive litigation in the EU based on those foreign rights, which is especially deterrent for SMEs.
- The safeguards against **abusive litigation**, with **concrete examples of abusive litigation**, a **mechanism for competition authorities to monitor litigation or threatened litigation** in relation to the SPC Waiver.
- Exemptions to **re-importing due to technical reasons** (i.e. certain related act being possible in third countries for example when certain steps in the manufacturing including packaging must be carried out in a third country by a contract manufacturing organisation (CMO) and the product must then be re-imported into the EU for final manufacturing and release)**.**
- That there should be **no unnecessary restrictions on storage** in the use of the export waiver.
- That, **day 1 launch** is an **explicit objective of the SPC Waiver** both **for launch in EU countries** as well as **for export and launch in third countries**, since the objective of the waiver is to create a level playing field between EU and non-EU manufacturers.

3. Rapidly implement these policies following the 2024 review required by the Regulation

- **Urgently carry out the review required by the Regulation in 2024 (or as soon as possible afterwards – no later than 2025)**: the legislators should seize the earliest opportunity to fix the apparent flaws in the current SPC Manufacturing Waiver legislation, *i.e.* immediately after the first review period in 2024. Waiting further would mean losing further business investments in Europe.
- **One legislation design instead of a patchwork**: this timing provides the unique opportunity to craft a "one-design", coherent EU legislation on pharmaceuticals. It coincides with the EU Pharma legislation reform, which contains many other policies with the same objective, *i.e.* day 1 competition (*e.g.*, the clarification of the EU Bolar exemption in the revised directive on human use medicines). It also coincides with the recasting of the relevant EU SPC law with proposals for Regulations on supplementary protection certificates as part of the IP Action Plan.
- **Regulations**: **the relevant Articles on the SPC Waiver in the relevant Regulations should be amended** as soon as possible after the **2024 review required by the Regulation**, to facilitate application of the SPC Waiver in practice, and to reduce the likelihood of unnecessary abusive litigation in the Member States.
- **Guideline/Notice: as an additional and rapid short-term measure**: the European Commission should issue guidelines or a Notice to remove the existing uncertainties and limit the misuses of the – unnecessary – safeguards by SPC holders.