

SPC Manufacturing and Stockpiling Waiver—part 2

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Abstract

- This two-part article analyses and discusses the legal requirements of, as well as the opportunities and risks associated with the SPC Manufacturing and Stockpiling Waiver as introduced by EU Regulation 2019/933. The introduction of the SPC Manufacturing/Stockpiling Waiver on 1 July 2019 opened up opportunities for generics and biosimilars companies established in the EU to manufacture and stockpile medicinal products before expiry of the respective SPC, either for export to third countries or for timely Day-1 market entry in the EU. But unlike, for example, the bolar exemption, application of the SPC Waiver is dependent upon compliance with specific notification, due diligence and labelling obligations. Although introduced more than 4 years ago, there is still considerable legal uncertainty surrounding the application of the SPC Waiver, something recent court decisions in Germany and The Netherlands have exacerbated rather than clarified.
- The first part of the present article, published in the *Journal of Intellectual Property Law and Practice*, 2024, Vol.(...), issue (...) analysed and discussed the policy background of the Regulation and examined the SPC Waiver with particular focus on the territorial and temporal scope. This second part scrutinizes the material scope and core components of the waiver, with a particular focus on privileged acts and the conditions under which the waiver is applicable. It distinguishes between primary and closely related privileged acts, and dissects various elements, such as the timing, location, and purpose of these privileged acts.

A. Introduction

The SPC waiver introduced by Regulation 2019/933 aims to level the playing field for EU-based generics and biosimilars, but its implementation has been controversial, marked by litigation and differing interpretations amongst Member States courts. While the waiver allows EU manufacturers to enter the market before SPC expiry, it also imposes restrictions and obligations akin to a compulsory license. Legal uncertainty persists due to ambiguous clauses and a complex legislative process, hindering its practical application. Despite its legitimate aim, the waiver in its current form fails to address challenges for EU-based generics and biosimilars. Without revision, it risks hindering timely market entry and exacerbating costs for EU generics and biosimilars.

This article serves as a continuation of part one, which was published in *Journal of Intellectual Property Law and Practice*, Vol.(...) Issue (...) Link...]. In the first part (Sections B.I–III), the policy background of the Regulation was introduced and the SPC waiver was examined with a focus on its territorial and temporal scopes, as well as its personal scope of application. The second part of the article commences with a thorough examination of the

material scope (Section B.IV), delving into the core components of the waiver, particularly focusing on defining privileged acts and the conditions under which the waiver is applicable. It will scrutinize the privileged acts, distinguishing between primary and closely related acts, and dissecting various elements such as the timing, location, and purpose of these privileged actions (Section B.IV.1). Furthermore, within this material scope, the article analyses the obligations imposed on the maker, contingent upon the specific provisions of the waiver. These obligations include notification, due diligence, and labelling responsibilities (Section B.IV.2). This section will also provide new insights into recent litigation surrounding the SPC waiver. This includes the outcome of the notable case of Janssen against Formycon before the District Court of Munich from October 2023, concerning the biosimilar ‘Stelara’, pertaining to the information duty of generics and biosimilars manufacturers towards the certificate holder, as outlined in Article 5(5) lit. e). [Section C](#) will delve into the integration of SPC waiver provisions into the new EU Pharmaceutical Package. Finally, the article will conclude with a critical evaluation of the SPC Waiver’s current regulatory framework and practical implications ([Section D](#)).

B. The SPC Waiver under Regulation (EU) 2019/933

I. Material scope

Article 5(2) lit. a) Regulation EU 2019/933 allows for basically two different types of waivers. The so-called 'manufacturing waiver' under Article 5(2) lit. a) (i) allows for the 'making' of a medicinal product for the purpose of export to third countries, where no protection exists during the entire protection period of the SPC. The so-called 'stockpiling waiver', on the other hand, privileges under Article 5(2) lit. a) (iii) the making of a product, or a medicinal product containing that product, 6 months before the expiry of the certificate, for the purpose of storing it in the Member State of making for Day-1 EU-market entry after expiry of the corresponding SPC.

Both waiver categories also privilege the so-called 'related acts' under Article 5(2) lit. a) (ii) and (iv), respectively. These are acts other than the main acts *per se*, which are strictly necessary for the latter, respectively, namely either the making and the actual export in case of the manufacturing waiver of Article 5(2) lit. a) (i) or the making and actual storage in the case of the 'stockpiling waiver' of Article 5(2) lit. a) (iii). Typical examples would be the possession, import, use, or synthesizing of an active ingredient.¹ That exemption should also apply to the related acts performed by third parties who are in a contractual relationship with the maker (see Part 1, Section B.III.3).² While the manufacturing waiver privileges by definition manufacturing activities for export to third countries during the whole duration of the SPC, the stockpiling waiver only privileges manufacturing activities for stockpiling no earlier than 6 months before the expiry of the SPC for Day-1 market entry in the EU. Hence, while both provisions privilege main and related acts, they also contain different temporal, geographical, and causal elements. The related acts, of course, have to comply with the same temporal, geographic, and causal elements as the main acts depending on the waiver in question. For example, an act related to the 'stockpiling waiver' can take place no earlier than 6 months before the expiry of the SPC for Day-1 market entry in the EU, cf. Article 5(2) lit. a) (iv) of the Regulation EU 2019/933.

No cherry-picking is allowed between the different waiver types, meaning that when the applicable waiver type is ascertained, the privileged acts have to comply with the requirements of the applicable waiver type, a kind of a 'lock-in-effect'.³ It is worth stressing that, central to distinguishing the waiver types is the causal element: when export to third countries is intended, Article 5(2) lit. a) (i), (ii) apply. On the other hand, when stockpiling for subsequent export in the EU is intended, then Article 5(2) lit. a) (iii), (iv) apply. Determining the category of the applicable waiver category is insofar important, as, depending on the category, the 'maker' has to fulfil specific obligations.

For the sake of correct dogmatic application, it is noteworthy that the interpretation of the SPC Waiver Regulation could allow for a third waiver category that entails a combined application of the aforementioned waiver types, when manufacturing is aimed at both export to third countries and stockpiling in the EU for subsequent EU market entry. This can be derived by Article 5(5) lit. b) of the SPC Waiver Regulation regarding the content of the information obligations that requires that the maker has to

disclose towards the certificate holder and the competent authority *inter alia* 'whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing' (emphasis added). This option is also included verbatim in the standard form for notification contained in Annex-Ia that the maker shall use for the purposes of notification to the authority under Article 5(2) lit. b) and c), cf. Article 5(6) of the SPC Waiver Regulation.

Under this section, the material scope of application of the waiver(s) will be analysed by addressing practical problems that arise in the course of interpretation and application of the various elements of the provisions.

1. Privileged acts

1.1 'Making of a product, or a medicinal product containing that product'

Both waiver types privilege the making of a product, or a medicinal product containing that product categorizing it as the main privileged act. The 'manufacturing waiver' of Article 5(2) lit. a) (i) considers as main act 'the actual export', whereas the 'stockpiling waiver' of Article 5(2) lit. a) (iii) includes the 'actual storage', respectively. It is unclear, what this distinction serves, since in both waiver types both export (eg to EU countries) or storage (eg before exporting in third countries) can take place, rendering this categorization superfluous.⁴ It is also questionable on the basis of the territoriality principle, whether the act of export as such requires the consent of the SPC holder which is applicable regarding the 'making', since it only affects the SPC application in the country of import in question. Regarding the definitions of 'product' and 'medicinal product', respectively, reference shall be made to Article 1 of the amended Regulation (EC) No 469/2009. According to Article 1 lit. a) of the above, 'a "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals'. According to Article 1 lit. b) of the above, 'a "product" means the active ingredient or combination of active ingredients of a medicinal product'.⁵

It is noticeable that Regulation 2019/933 uses the rather unclear term 'making' instead of 'manufacturing', which is more broadly used in EU pharmaceutical legislation. Article 2(1) of the Commission Delegated Regulation (EU) No 1252/2014, which supplements Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use, defines manufacturing as 'any total or partial operation of receipt of materials, production, packaging, repackaging, labelling, relabelling, quality control or release of active substances, and the related controls'. It can be assumed that the SPC waiver categorizes manufacturing into 'making' and

⁴cf Medicines for Europe, 'Review of the SPC Manufacturing Waiver: a First Industry Report', (Medicines for Europe, June 2023) 8. Available at <https://www.medicinesforeurope.com/2023/06/13/review-of-the-spc-manufacturing-waiver-a-first-industry-report/> (accessed 8 February 2024), 7: 'Removing the distinction between "export" and "stockpiling" waiver, and instead providing a single SPC Manufacturing Waiver, would solve the problem'.

⁵cf Commission, 'Proposal for a Regulation of the European Parliament and the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006' COM(2023) 193 final, Definitions art 4(1) No 1–4.

¹cf reg (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending reg (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products [2019] OJ L135/1, Recital 9.

²cf reg (EU) 2019/933 (n 1) Recital 9.

³ibid Recital 12.

related acts. Thus, the SPC Waiver Regulation refers with the term ‘making’ to core production activities, thereby excluding packaging, labelling, and storage. The use of the term ‘making’ is in line with what is found in TRIPS Article 28.1, the Unified Patent Court Agreement Article 25, and the European Patent Convention Article 29.⁶

1.2 Strictly necessary related acts

Both waiver categories also privilege so-called ‘related acts’ under Article 5(2) lit. a) (ii) and (iv), respectively. These are acts other than the main acts *per se*, which are strictly necessary for the latter, respectively, namely either the making and the actual export in case of the manufacturing waiver of Article 5(2) lit. a) (i) or the making and actual storage in the case of the ‘stockpiling waiver’ of Article 5(2) lit. a) (iii). Related acts can only be privileged in accessory with the main acts, meaning that one cannot perform related acts in the EU, whereas the main acts of ‘making’ take place in third countries. Therefore, a company cannot use the waiver only to import and repackage or relabel products for example with a view to EU Day-1 market entry. This corresponds with the purpose of the waiver to facilitate pharmaceutical production in the EU by privileging companies established in the EU. Recital 9 of Regulation 2019/933 provides a non-exhaustive catalogue of privileged related acts.⁷ Accordingly, typical examples of related acts would be the possession, import, use, or synthesizing of an active ingredient.⁸ That exemption should also apply to related acts performed by third parties who are in a contractual relationship with the maker (see Part 1, Section B.III.3).⁹ While the manufacturing waiver privileges by definition manufacturing activities for export to third countries during the whole duration of the SPC, the stockpiling waiver only privileges manufacturing activities for stockpiling no earlier than 6 months before the expiry of the SPC for Day-1-market entry in the EU. Hence, while both provisions privilege main and related acts, they also contain different temporal, geographical, and causal elements. The related acts, of course, have to comply with the same temporal, geographic, and causal elements as the main acts depending on the waiver in question. For example, an act related to the ‘stockpiling waiver’ can take place no earlier than 6 months before the expiry of the SPC for Day-1-market entry in the EU, cf Article 5(2) lit. a) (iv) of the Regulation EU 2019/933.

The necessity element can be based on a logical causality nexus with the main act. To prove that a related act is strictly necessary, it suffices to refer to rules and principles of Good Manufacturing Practice that require such a related act.¹⁰ A related act is not strictly necessary when it exceeds its scope of application: when, for example, a maker applying the manufacturing waiver for export to third countries, also produces for EU market entry, thereby infringing on the temporal element of 6 months prior to the expiry of the applicable SPC regarding the ‘making’.

The ‘necessity’ element seeks as a control mechanism to carve out potential abusive practices under the pretext of an applicable waiver that unreasonably prejudice the legitimate interests of the certificate holder.¹¹

1.3 Explicitly not privileged acts

Recital 11 of the SPC Waiver Regulation identifies certain acts that are excluded from the privileged material scope of application. These exemptions mainly reflect the approach of the EU to integrate measures against illicit diversion to the EU market, cf also Recital 13.¹² Additionally, they confirm the aforementioned lock-in effect: depending on the purpose of the manufacturing, different provisions apply. Accordingly, the exemption should exclude the placement of a product, or a medicinal product containing that product, specifically manufactured for export to third countries or for storage with the intention of entering the EU market on the first day, within a Member State where a certificate is currently in force. This exclusion applies both directly and indirectly after export, and it also prohibits the re-importation of such a product or medicinal product into a Member State with a valid certificate. Additionally, it should not include any acts conducted solely for the purpose of importing products, or medicinal products containing those products, into the European Union for repackaging and subsequent re-export without undertaking any manufacturing activities, cf Article 5(3) of the SPC Waiver Regulation. This aligns with the purpose of the Regulation to privilege EU-based manufacturers, instead of those who would wish to take advantage of the waiver provisions just to import and store their products with a view to an undelayed EU market entry. Lastly, Recital 11 clarifies in a rather declaratory nature the obvious that the exemption should not encompass the storage of products, or medicinal products containing those products, for any purposes other than those explicitly outlined in this Regulation.

1.4 The purpose of ‘making’: export to third countries or EEA?

The ‘manufacturing waiver’ under Article 5(2) lit. a) (i) allows for the ‘making’ for the purpose of export to third countries where no protection exists. The ‘stockpiling waiver’, on the other hand, privileges under Article 5(2) lit. a) (iii) the making for the purpose of storing it in the Member State of making for subsequent Day-1 EU-market entry after expiry of the corresponding SPC. As stressed above, the causal element is central to differentiating between the applicable waiver type and thus determining which legal elements apply and what kind of obligations must be fulfilled. Following the publication of the Draft Proposal that initially limited the scope of application to ‘making’ solely for export to third countries, it has been debated whether EU countries with no SPC protection could be considered as such.¹³ However, the clear dichotomy between the waiver types based on the enacted Regulation regarding third countries and Member States defines

⁶Xavier Seuba, ‘The Export and Stockpiling Waivers: New Exceptions for Supplementary Protection Certificates’ [16 November 2019] CEIPI 2019–13, 8. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3500774 (accessed 12 February 2024).

⁷*Ibid.*

⁸cf reg (EU) 2019/933 (n 1) Recital 9.

⁹*Ibid.*

¹⁰Three legal instruments lay down the principles and guidelines of GMP in the EU: reg No 1252/2014 and Directive 2003/94/EC, applying to active substances and medicines for human use; Directive 91/412/EEC applying to medicines for veterinary use. In addition, Directive 2001/83/EC and Directive 2001/82/EC lay down related provisions. The EU GMP guidelines provide interpretation of these principles and guidelines, supplemented by a series of annexes that modify or augment the detailed guidelines for certain types of product, or provide more specific guidance on a particular topic. The GMP/Good Distribution Practice (GDP) Inspectors Working Group provides additional interpretation of the EU GMP guidelines in the form of Q&As.

¹¹cf reg (EU) 2019/933 (n 1) Recital 12.

¹²cf Commission, ‘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’ COM(2018) 317 final, Available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A317%3AFIN> (accessed 12 February 2024) 8: ‘The proposal is accompanied by non-cumbersome and inexpensive measures in relation to transparency and anti-diversion requirements, with a view to discouraging acts that would interfere with the exclusivity that the SPC holder would continue to enjoy in the Union. These measures would also facilitate enforcement against such acts’.

¹³cf Miguel Vidal-Quadrás, ‘Analysis of EU Regulation 2019/933 on the SPC Manufacturing Waiver Exception’ [2019] IIC 971, 986; Marco Stief and Robert Wenzel, *Supplementary Protection Certificates (SPC)* (2nd edn, C.H.Beck München 2021) para 225.

third countries as non-EU countries.¹⁴ Recital 2 provides for a legal definition: ‘countries outside the Union (“third countries”)’. This distinction is also evident in the legislative history.¹⁵ Accordingly, only with regard to export to EU countries, anti-diversion measures were considered.¹⁶ However, as already established (Part 1, Section B.I.1), third countries are non-EU and non EFTA-EEA (Norway, Iceland) states, whereby Liechtenstein must be considered a third country, as the SPC Waiver Regulation does not apply. Therefore, depending on whether export outside or inside the EEA is intended, the manufacturing waiver provisions apply in the former case and the provisions of the stockpiling waiver apply in the latter.

1.5 Where can main and related acts take place?

Manufacturers choose the sites of manufacturing based on various political, economic, social, and technological reasons including R&D, labour costs, taxation purposes, facilities costs, proximity to raw materials and resilience of supply chains which are in turn influenced by unexpected geopolitical events.¹⁷ The complexity of real-life supply chains, manufacturing and distribution networks are hardly reflected in the Regulation’s rather narrow wording. In principle, privileged main and related acts can take place in multiple Member States incl. EFTA EEA states, provided that the making takes place in the EEA due to the accessory of privileged related acts. This can be derived by Recital 14 of the Regulation 2019/933 that presupposes that related acts can take place in Member States other than the Member State of ‘making’ and that the ‘making’ as such can take place in more than one Member State.

However, storage within the application of stockpiling waiver, thus for EU Day-1 market entry, according to Article 5(2) (a) (iii) (iv) is only possible ‘in the Member State of making’. As established above, making refers to core production activities, thereby excluding packaging and labelling (refer to making) or other merely related acts. The EU legislator implemented this additional territorial restriction as an anti-diversion measure.¹⁸ Thus, one cannot just store products made under the SPC Waiver in the Member States where market entry is planned, unless core manufacturing activities take place there, cf ‘in the Member State of making’. Where makers divide manufacturing activities into different jurisdictions, storage before export in the EU market is only privileged in the Member State of the chronologically last ‘making’ acts.

1.6 When can main and related acts take place?

1.6.1 Time of ‘making’ and related acts

While the manufacturing waiver privileges by definition ‘making’ and related acts hereto for export to third countries during

the whole duration of the SPC, the stockpiling waiver only privileges such acts for stockpiling no earlier than 6 months before the expiry of the SPC for subsequent Day-1-market entry in the EU. This can be based on the systematic comparison of the wording of Article 5(2) lit. a) (i), (ii) with Article 5(2) lit. a) (iii), (iv): the legislator omitted any temporal restriction with regard to the manufacturing waiver in the wording of Article 5(2) lit. a) (i), (ii), whereas he explicitly required that privileged acts under the stockpiling waiver of Article 5(2) lit. a) (iii), (iv) can only commence within 6 months before the expiry of the corresponding SPC. Therefore, such a temporal restriction was clearly not intended by the legislator (*argumentum e contrario*) regarding the manufacturing waiver, nor it can be applied by way of analogy.

Recital 9 of the amending regulation merely includes the term ‘temporary storing’ as an example of privileged acts. However, this example alone in a recital cannot lead to the conclusion that storage under Regulation 2019/933 should only be permissible within narrow temporal limits. It must once again be emphasized that operational provisions cannot be solely derived from recitals and examples mentioned therein without a basis on the operative terms. Moreover, Recital 9 only contains the self-evident note that storage is only temporary, which follows from the fact that the products are intended for export. If anything, it can only be inferred that the product must not be stored permanently in the EU, since that would obviously contradict the purpose of the manufacturing waiver.

The legislative history of Article 5(2)(a)(i) and (ii) of Regulation 2019/933 also supports the conclusion that a time limit to restrict the manufacturing waiver was never envisaged. Such considerations existed exclusively for the strictly separate stockpiling waiver under Article 5(2)(a)(iii) and (iv), which were added to the Regulation in a much later stage during the legislative process. This can be explained by the completely different interests at stake regarding the stockpiling waiver, namely, to justify the greater intervention in the rights of certificate holders in the EU and to address the risks of distribution in the EU before the certificate expires. Finally, rigid storage deadlines within the framework of the export privilege would also undermine the purpose of the regulation, since short storage deadlines would disadvantage EU-based manufacturers compared to their counterparts from third countries.

In conclusion, main and related acts of the stockpiling waiver can take place no earlier than 6 months before the expiry of the corresponding SPC where the main or related act takes place for Day-1 market entry in the EU, whereas main or related acts of the manufacturing waiver are subject to no temporal restrictions during the duration of the corresponding SPC. For the sake of clarity, it is important to note that the ‘maker’ must also comply with the 3-month period of the notification obligation of Article 5(2)(b) of Regulation 2019/933. For example, in the case of the stockpiling waiver, the maker can only commence main or related privileged acts the earliest 6 months before the expiry of the corresponding SPC, if the maker has previously notified the certificate holder and the competent authority thereof 3 months in advance.

The 6-month period still disadvantages EU-established manufacturers compared to those in third countries, where relevant protection does not exist or has expired. The time of the expiry of the SPC protection inevitably leads to discrepancies in a transnational manufacturing and distribution network, since the ‘maker’ would have to take into account different dates of expiry of each applicable SPC depending on the jurisdiction of the manufacturing sites and on where related acts take place. This cannot be the intention of the EU legislator and it shows that the stockpiling

¹⁴Cf Kühnen, *Handbuch der Patentverletzung* (15th edn Carl Heymanns 2023), ch E.III.20 para 1126.

¹⁵Cf Commission, ‘Proposal COM(2018) 317 final’ (n 12) 5: ‘Finally, any export of SPC-protected products outside the Union will be subject to compliance with specific labelling requirements, though any burden stemming from this will be outweighed by the benefits arising from the exception’.

¹⁶Council of the European Union, Brussels, 18 February 2019, Proposal for a regulation amending reg (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products—analysis of the final compromise text with a view to agreement: ‘In order to ensure that “stockpiling” does not lead to illicit diversion to the EU market, additional safeguards were introduced into the text of the Regulation (storing and related acts are covered, as for the export waiver; making for the purpose of storing in view of Day-one entry only for a maximum period of 6 months before the expiry of the certificate’.

¹⁷See J McGee et al, *Strategy: Analysis and Practice* (McGraw-Hill New York, NY 2005).

¹⁸Council of the European Union, ‘Proposal for a Regulation amending Regulation (EC) No 469/2009’ (n 16).

waiver was not carefully calibrated measured against its real-life implementation.

The 6-month period is as such inadequate, particularly when it comes to manufacturing finished dosage forms, especially for more intricate products. The required duration depends on various factors, including the complexity of the molecule, the production process, and manufacturing capabilities. While a 6-month period might suffice for straightforward molecules or later stages of production, it is consistently reported to be inadequate for complex generics or biosimilars. Notably, if both the active pharmaceutical ingredient (API) and the final dosage forms are manufactured under the SPC waiver within the EU, the 6-month period is undoubtedly insufficient. This is due to the fact that API manufacturing can entail up to 10–12 synthetic steps, intricate processes, and extensive testing across various facilities (including tests for DRX, heavy metals, microbiology, and more). Consequently, adhering to this timeline becomes impractical for the production, testing, and release of the final dosage form. Furthermore, reserving manufacturing capacity at contract manufacturing organizations (CMOs) for biologics often requires booking years in advance, and the mere production of the drug substance alone takes more than 6 months. This situation is particularly detrimental to EU-based API producers, as, given the exceedingly brief timeframe, producers of finished dosage forms tend to favour sourcing API from non-EU countries.

Regarding biologic products specifically, it was noted that these products are frequently sensitive and necessitate sterile manufacturing and filling, as well as specialized transportation, careful handling, and intricate packaging. They often require filling into specialized vials and assembly into delivery devices. The entire process of creating a biosimilar molecule, from its primary structure (typically proteins expressed by genetically engineered cells) to bulk (typically the protein in a specific formulation for intravenous or subcutaneous injection), may already require 9 months. Following drug substance manufacturing, an additional minimum of 3 months is needed for the production of the medicinal product, including activities like sterile vial filling, labelling, secondary and tertiary packaging, quality testing, assays, and batch release. In light of these challenges, the generics and biosimilars industry has suggested to eliminate the 6-month limitation, as it is deemed completely unjustified and contrary to the fundamental purpose of the legislation, which aims to facilitate Day-1 product launches.¹⁹

1.6.2 Time of export: the effect of infringement in countries of export on the waiver

Regarding the act of export to the EEA market, the relevant point in time is the expiry of the applicable SPC in the country of export. It is unclear, whether infringement of the SPC in the country of export also constitutes infringement in the country where privileged acts take place. Regarding the EU market, it can be argued that the waiver is granted on the condition of preventing illicit diversion in the EU market, where an SPC is in force.²⁰ This nexus is evident in the wording of Article 5(2)(a)(iii) that explicitly privileges the 'making' for the purpose 'to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate'. In contrast hereto, such an explicit link is missing from the operative

term of Article 5(2)(a)(i) regarding exports to third countries. Based on the territoriality principle, an infringement of IP protection in third countries cannot constitute an infringement of the scope of application of the SPC waiver in the EU Member States of 'making', since Regulation 2019/933 does not provide for any extraterritorial effect of foreign IP rights (see Part 1, Section B.I.2).²¹

Regarding exports within the EU or EEA, where the Regulation 2019/933 is directly or indirectly with some modifications applicable, it has to be first examined whether the alleged infringing act falls within the scope of protection of the SPC, meaning that it would otherwise require the consent of the SPC holder where privileged acts under the waiver take place. This in turn will depend on the basic patent falling under this jurisdiction.²² A further question would be whether 'no SPC protection' means that the relevant API is not the subject matter of a certificate in force, according to Article 4, or is not covered by the scope of protection of a certificate in force according to Article 5.²³ Still, this question might be referred to the CJEU.²⁴

2. Obligations of the maker

The other side of the 'bargain' for the 'maker' who applies the SPC waiver, entails notification, due diligence, labelling, and fee obligations, on which the application of the waiver depends, meaning that infringement of these obligations would exceed the scope of the waiver, resulting in infringement of the applicable SPC in the countries where otherwise privileged acts would have taken place. This is based on the wording of Article 5(2) that enlists these obligations in subparagraphs as conditions for the waiver: 'if the following conditions are met'.

Undeniably, these obligations lie at the centre of dispute between 'certificate holders' and 'makers'. The EU legislator considers these measures 'as a series of safeguards to ensure transparency and avoid the possible diversion onto the Union market of generics and biosimilars in respect of which the original product is protected by an SPC'.²⁵ Originators claim that the content of the notification is insufficient to determine whether the privileged acts that would take place, fall within the scope of application of the waiver or if related acts are indeed 'strictly necessary' to the 'making'.²⁶ Still, the notification on behalf of the maker sets the stage for litigation measures on behalf of the originator.²⁷ As one senior patent counsel at an originator company figuratively stated: 'You could put out the flame while it's starting, before it goes into full blast'.²⁸ Precisely for this reason, generics and biosimilars claim that the notification serves as a pretext to force disclosure of highly commercially sensitive information throughout the whole supply chain and could lead to abusive litigation.²⁹ In general, they argue that these obligations perpetuate their disadvantages compared to non-EU manufacturers and effectively

²¹cf Marco Stief/Robert Wenzel (n 13) para 226.

²²ibid.

²³reg (EU) 2019/933 (n 1).

²⁴ibid.

²⁵Commission, 'Proposal COM(2018) 317 final' (n 12) Explanatory Memorandum; cf reg 2019/933 (n 1) Recital 13.

²⁶Rory O'Neill, 'Risk of SPC waiver counterattack makes generics extra cautious' [21 July 2022] Managing IP; cf EFPIA, 'Future-Proofing EU Competitiveness by Limiting the Negative Impact of the SPC Manufacturing Waiver' Available at <https://www.efpia.eu/media/412469/future-proofing-eu-competitiveness-by-limiting-the-negative-impact-of-the-spc-manufacturing-waiver.pdf> (accessed 12 February 2024).

²⁷cf Jan Krauß, 'Aktuelles aus dem Bereich Biotechnologie—Einschränkungen des Schutzes eines ergänzenden Schutzzertifikats durch die neue VO (EU) 2019/933' Mitt. Heft 4/2020, 157, 160.

²⁸O'Neill (n 26).

²⁹Medicines for Europe (n 4) 7ff, with reference to Janssen Biotech Inc -V- Amgen Technology [Ireland] Unlimited Company 2023/1328 P.

¹⁹cf Medicines for Europe, 'Review' (n 4) 6 sq.

²⁰cf Regulation (EU) 2019/933 (n 1) Recital 11: 'The exception should not cover placing a product, or a medicinal product containing that product, which is made for the purpose of export to third countries or of storing with a view to EU day-one entry, on the market of a Member State where a certificate is in force [...]'.
Downloaded from <https://academic.oup.com/jip/advance-article/doi/10.1093/jip/jpae051/7697060> by Sandra Wilhelm on 30 July 2024

prevent them from applying the waiver.³⁰ The following section will analyse and comment the content of each obligation while seeking to provide guidance on their compliance that ensures legal certainty.

2.1 Notification obligations

According to Article 5(2)(b) of Regulation 2019/933, the maker, through appropriate and documented means, must notify the competent authority in the Member State in which that making is to take place, and the certificate holder, of the information exhaustively enlisted in Article 5(5) of Regulation 2019/933 no later than 3 months³¹ before the start date of the making in that Member State, or no later than 3 months before the first related act, prior to that making, that would otherwise be prohibited by the protection conferred by a certificate, whichever is the earlier. According to Article 5(2)(c) of Regulation 2019/933, the 'maker' must update this information as and when appropriate and notify both the competent authority and the certificate holder, before any changes take effect. According to Article 5(6), the maker shall use the standard form for any kind of notification contained in Annex-Ia, also regarding the certificate holder.³² Additionally, Article 5(2)(e) requires the fee payment if applicable according to Article 12(2) of the amended Regulation (EC) No 469/2009.

According to Article 5(5) of Regulation 2019/933, the information to be provided by the maker for the purposes of Article 5(2)(b) shall be as follows:

- (a) 'the name and address of the maker;
- (b) an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;
- (c) the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place;
- (d) the number of the certificate granted in the Member State of making, and the number of the certificate granted in the Member State of the first related act, if any, prior to that making; and
- (e) for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available'.

The competent authority according to Article 9(1) of the amended Regulation (EC) No 469/2009 is the competent industrial property office of the Member State that granted the applicable SPC.³³ According to Article 11(4) of the amended Regulation (EC) No 469/2009, this authority shall publish as soon as possible, the information listed in Article 5(5), together with the date of notification of that information, along with any changes to the information notified in accordance with Article 5(2)(c).

A central question regarding the notification obligation is which authority and which certificate holder in which Member

State the 'maker' has to notify. According to Recital 14, if the 'making' takes place in more than one Member State, then the 'maker' has to comply with notification obligations in each Member State. However, if related acts take place in Member States other than those of the Member State where the 'making' takes place, it suffices to comply with notification obligations in the Member State of 'making', provided that the 'maker' informs according to Article 5(5) of Regulation 2019/933 about 'the Member State in which the first related act, if any, prior to that making is to take place' and provides 'the number of the certificate granted in the Member State of the first related act, if any, prior to that making'.³⁴ Yet, this presupposes that there is a clear distinction between 'making' and related acts, which cannot be found in Regulation 2019/933. Therefore, 'makers' are well advised to comply with notification obligations in all Member States, where privileged acts take place, thereby avoiding an unnecessary legal dispute about whether an act is considered 'making' or a merely related one. This can guarantee some legal certainty, keeping in mind that the application of the waiver is dependent on compliance with these obligations.

Given the legislative history of this provision, one provision that deserves special attention is the information that the 'maker' must provide regarding a third country of export. In the first Draft Proposal,³⁵ the 'maker' had to provide 'an indicative list of the intended third country or third countries to which the product is to be exported'. The European Parliament objected to such a provision that would have obliged generics and biosimilars companies to communicate highly confidential information to their direct competitors.³⁶ Indeed, the identity of the manufacturer and the manufacturing sites are explicitly considered as confidential by the EU health authorities.³⁷ Disclosing the names of manufacturers or suppliers of the active substance or the excipients is necessary for public health reasons, as well as those of other manufacturers involved in the procedures.³⁸ Generally, this information is known to the health authorities, but it is kept confidential to third parties due to its commercially sensitive and valuable nature.³⁹

Article 5(5)(e) of the amended SPC Regulation now merely requires only regarding medicinal products 'the reference number

³⁴See *ibid.*

³⁵Commission, 'Proposal COM(2018) 317 final' (n 12).

³⁶cf Council of the European Union, 'Proposal for a Regulation amending Regulation (EC) No 469/2009' (n 16): 'At the end, the EP was willing to accept the Council's approach. However, as part of the overall compromise, one adaptation in the information to be made in the notification as regards export countries needed to be made, as a concession to the EP (see point (f) of Article 5(3)). The reference to the third country of export was dropped, as the EP insisted that this would be commercially sensitive information and the EP, although it had moved a long way from its initial mandate, would not accept to include it'.

³⁷cf HMA/EMA Transparency Recommendations: Recommendations on release of information with regard to new applications for medicinal products before and after opinion or decision on granting of a marketing authorisation (published in November 2010, EMA/484 118/2010) establish that: 'In view of the lack of a legal definition and for the purpose of harmonisation "commercial confidential information" shall mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information'; cf HMA/EMA Guidance Document on the identification of commercially confidential information and personal data within the structure of the marketing authorisation (MA) application—release of information after the granting of a marketing authorisation (HMA/EMA Working Group on Transparency, formally adopted by written procedure on 9 March 2012, and edited on 14 March 2012) explicitly considers the manufacturers of (a) the medicinal products, and (b) the active substances and the sites of manufacture commercially confidential information.

³⁸HMA/EMA Working Group on Transparency, ss 1, 3.1.1, 3.4, and HMA/EMA Guidance Document on the identification of commercially confidential information and personal data within the structure of the marketing authorization (MA) application, ss 1.2.5.2, 1.2.5.3, 1.5.6, 1.5.8, 1.5.10, 1.5.22, 1.9, 3.2.5.2, and 3.2.P.3.

³⁹Vidal-Quadras (n 13) 996.

³⁰*ibid.*

³¹See reg (EU) 2019/933 (n 1) Recital 19 for the notification within the transitional period.

³²reg (EU) 2019/933 (n 1) Recital 15: 'The standard form for notification could also be used to inform the certificate holder, and the information provided should be updated as and when appropriate'.

³³cf reg (EU) 2019/933 (n 1) Recital 14.

of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available'.⁴⁰ Accordingly, Recital 17 of Regulation 2019/933 refers to the case where a notification has been filed, but the marketing authorization has been published after notification. It follows that the 'maker' must provide such an information only if and as soon as it is publicly available without any effect on a compliant notification. For example, the originator cannot block any privileged acts based on the argumentation that the 3-month period prior to the making has not commenced, allegedly in the absence of a complete notification.

However, this view was rejected in October 2023 by the District Court of Munich (Landgericht München I).⁴¹ The court issued a preliminary injunction against Formycon after the pharmaceutical company announced its intention to launch a biosimilar of the drug Stelara after the associated patent and SPC had expired. Janssen Biotech argued that the defendant needed a relevant marketing authorization before it could start marketing the drug after the SPC expired. Formycon argued that Article 5(5)(e) of the amended SPC Regulation requires the notification of the marketing authorization number for a third country as soon as it becomes publicly available. The defendant claimed that authorizations, especially for biosimilars, and thus the allocation of a number, are lengthy. It is noteworthy that Formycon also rejected the request to instead name the third country for which it is planning production. It claimed this would mean the disclosure of distribution channels, which are confidential. This one of the first cases in which a court rendered a decision on the basis of the SPC Waiver Regulation, and which has not been settled under the condition of confidentiality instead. According to the court, such a notification is incomplete if it does not specify the reference number of the marketing authorization or the destination country of the export itself, when the former is not publicly available. The court held that this information would have been necessary for the certificate holder to examine, whether IP rights in the countries of export have elapsed or still exist.

Here, the court *contra legem* applied the recitals to overturn a provision that is unambiguous *per se*, namely Article 5(5) lit. e) of the Regulation, 'as soon as it is publicly available', to require the disclosure of information that is not yet publicly available. As outlined earlier (see Part 1, Section B.I.2), according to standing case law of the CJEU, the recitals cannot be referenced to derogate the operative terms.⁴² The legislative history of this provision proves that the legislator explicitly decided against requiring the 'maker' to provide the marketing authorization number when such information is not publicly available. Furthermore, the legislator in particular decided against disclosure of the third country of the intended export even *in lieu* of a marketing authorization. The 7th Revised Proposal shows that the European Parliament had objected to a provision that would have obliged generics and biosimilars companies to communicate highly confidential information to their direct competitors.⁴³ As a result, any reference related to the obligation to disclose third countries of intended export was intentionally and explicitly omitted:

'At the end, the EP was willing to accept the Council's approach. However, as part of the overall compromise, one adaptation in the information to be made in the notification as regards export countries needed to be made, as a concession to the EP (see point (f) of Article 5(3)). The reference to the third country of export was dropped, as the EP insisted that this would be commercially sensitive information and the EP, although it had moved a long way from its initial mandate, would not accept to include it.'⁴⁴

The European legislator may exercise their assessment prerogative in characterizing information related to third countries of export as confidential and deciding against their disclosure on behalf of the generics and biosimilars companies. The District Court thus acted *contra legem* when it disregarded the legislator's decision. Furthermore, linking the application of SPC rights with the scope of protection of foreign IP-rights would imply an impermissible extraterritorial effect of foreign IP-rights in the EU (see Part 1, Section B.I.2).

In early 2024, the District Court of the Hague⁴⁵ explicitly disapproved of the German court's argumentation and decided in favour of the biosimilar manufacturer in a similar process. According to the Dutch Court, manufacturers must provide the marketing authorization reference number, when it is publicly available. If not available, they can submit the notification and later add the reference number. The Dutch Court reiterated that the Regulation allows notifications even without a marketing authorization, with the option to include the reference number later, while referring to in Recital 17. The Dutch Court further cited the legislative history to highlight that the design of the information requirement was deliberately chosen in order to allow EU-based manufacturers to compete fairly with non-EU counterparts. This allows both to begin biosimilar manufacturing before obtaining marketing authorization. According to the court, the legislative process also emphasizes a thoroughly specific information requirement, preventing manufacturers from disclosing any further confidential or sensitive business information to certificate holders. The Dutch Court criticized in the proceedings the German court's decision for lacking any basis in the legislative history of Article 5(5) lit. e).

Litigation in the cases described above is inextricably linked with a structural flaw of the Regulation. Article 5(4) of the amended SPC Regulation clarifies that the information provided to the certificate holder for the purposes of points (b) and (c) of paragraph 2 shall be used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance. Firstly, it is hard to prove that this information is used on behalf of the 'certificate holder' solely for verifying compliance with the SPC waiver, as it can inevitably impact other strategic decisions regarding the competition. Secondly, it regrettably served as an invitation to litigation for originators who have been placed on the position to verify the compliance of an *ipso iure* applicable exemption to their SPCs.⁴⁶

Admittedly, the problem in the practical application of the waiver is not the lack of litigation, but that legal uncertainty and abusive litigation practices render the waiver unattractive for generics and biosimilars companies. In this regard, Regulation

⁴⁰cf Reg (EU) 2019/933 (n 1) Recital 15: 'That information should be limited to what is necessary and appropriate for the certificate holder to assess whether the rights conferred by the certificate are being respected, and should not include confidential or commercially sensitive information'.

⁴¹Konstanze Richter, 'Formycon and Janssen Biotech put EU SPC waiver to the test in Munich'.

⁴²Case C-162/97, Nilsson et al, para 54, 1998, ECR I-07477; and Case C-344/04, IATA, ELFAA v Department for Transport, s 76.

⁴³cf 7th Revised Proposal, Council of the European Union, Brussels, 18 February 2019, 6383/19, p 4sq.

⁴⁴*ibid*.

⁴⁵District Court of the Hague, Judgment of 23 January 2024, C/09/657817 / KG ZA 23-1039.

⁴⁶cf Jan Krauß, 'Aktuelles aus dem Bereich Biotechnologie – Einschränkungen des Schutzes eines ergänzenden Schutzzertifikats durch die neue VO (EU) 2019/933' 160.

2019/933 solely refers under Recital 20 to the general obligation for Member States according to Article 3(2) of the Enforcement Directive,⁴⁷ to provide safeguards against abusive enforcement of intellectual property rights, which does not oblige 'certificate holders' per se. Certainly, a more precise legal mechanism to prevent abusive litigation would have been more effective rather than an invitation hereto under Article 5(4) of the amended SPC Regulation.

For example, such a legal mechanism could be found in Recital 22 and Article 7(2) of Directive (EU) 2016/943 regarding the protection of trade secrets.⁴⁸

'The smooth functioning of the internal market would be undermined if the measures, procedures and remedies provided for were used to pursue illegitimate intents incompatible with the objectives of this Directive. Therefore, it is important to empower judicial authorities to adopt appropriate measures with regard to applicants who act abusively or in bad faith and submit manifestly unfounded applications with, for example, the aim of unfairly delaying or restricting the respondent's access to the market or otherwise intimidating or harassing the respondent.'

According to Article 7(2), such measures may include 'awarding damages to the respondent, imposing sanctions on the applicant or ordering the dissemination of information concerning a decision'. The German Trade Secrets Protection Act implemented this provision in section 14 GeschGehG: accordingly, the assertion of claims under this Act is inadmissible if it is abusive in view of all the circumstances. Furthermore, in the event of abusive litigation, the opposing party may demand compensation for the expenses necessary for its legal defence, while further claims for compensation remain unaffected. A similar provision in Regulation 2019/933 that would have rendered claims on behalf of the certificate holders inadmissible, if they were manifestly abusive, could have provided for effective safeguards against such litigation practices.

2.2 Due diligence

According to Article 5(2)(e) that refers to Article 5(9) of the amended SPC Regulation, the maker must ensure, through appropriate and documented means, that any person in a contractual relationship with the maker who performs acts falling under Article 5(2)(a) is fully informed and aware of the following: (i) that those acts are subject to Article 5(2); (ii) that the placing on the market, import or re-import of the product, or the medicinal product containing that product, referred to in Article 5(2)(a)(i) or the placing on the market of the product, or the medicinal product containing that product, referred to in Article 5(2)(a)(iii) could infringe the certificate referred to in Article 5(2) where, and for as long as, that certificate applies. The 'maker' can ensure compliance with the so-called due diligence obligation by including this information verbatim in the contracts with third parties across the supplychain in the EEA, who carry out privileged acts by the waiver that would otherwise require the consent of the certificate holder, for example the exporter and the person conducting the storage.⁴⁹

Compliance with the due diligence requirements is condition for the application of the waiver. In this regard, Recital 20 of Regulation 2019/933 clarifies that 'a maker who fails to comply with those due diligence requirements should not benefit from the exemption, nor should any third party performing a related act in the Member State of making or in a different Member State in which a certificate conferring protection for the product is in force'. It is questionable whether the third party can be liable for intentionally or negligently infringement of the corresponding SPC for circumstances that exclusively lie in the sphere of responsibility of the 'maker', provided it has no grounds to question the compliance of the waiver obligations on part of the waiver. This also concerns the opposite case. Therefore, both third parties and the 'maker' that act within the scope of the SPC waiver are well advised to conclude indemnification agreements for breaches of contract, thus for not complying with the obligations under the SPC waiver that exclusively lie in the sphere of responsibility of the other party. These indemnification agreements would shield them, depending on the applicable law, from liability towards the 'certificate holder' or at least from the incurred damages for which the other party is responsible, in case the 'certificate holder' files a lawsuit against them.⁵⁰ This is also relevant when the third party is commissioned to adhere to the labelling obligations on behalf of the maker (see below).

2.3 Labelling obligations

According to Article 5(2)(d) of the amended SPC Regulation, the maker must ensure in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, that a logo, in the form set out in Annex-I, is affixed to the outer packaging of the product, or the medicinal product containing that product and where feasible to its immediate packaging. The logo shall appear in black and in such a size as to be sufficiently visible. As regards the EFTA EEA states, the logo that must be affixed as part of the labelling obligations of the 'maker' must read 'EEA export' instead of 'EU export'.⁵¹ Furthermore, according to Article 5(8) of the amended SPC Regulation, the maker shall ensure that medicinal products made for export to third countries do not bear an active unique identifier within the meaning of Commission Delegated Regulation (EU) 2016/161. Recital 21 of Regulation 2019/933 reiterates that compliance with the labelling obligations is condition for the application of the SPC waiver. This refers to labelling obligations both according to Article 5(2)(d) and Article 5(8) regarding the active unique identifier, as Recital 21 requires that the product 'is labelled in the manner provided for in this Regulation'. The precise interpretation of the term 'affix' remains ambiguous, particularly regarding whether it necessitates a permanent attachment or if the use of a removable sticker, for instance, would suffice. While this may appear to be a theoretical concern, its relevance could emerge in light of the prohibition on altering labelling for regulatory reasons.

Furthermore, in accordance with Article 5(2)(d) of the amended SPC Regulation, the labelling of outer packaging is obligatory, while the labelling of immediate packaging is only mandated where 'feasible'. 'Immediate packaging' and 'outer packaging' in Article 5(2)(d) of the Regulation could be construed in alignment with Article 1 Nr 23–24 of Directive 2001/83 EC, thereby encompassing both the immediate packaging of the product and the subsequent layer of packaging. However, the phrasing within the

⁴⁷ Commission, 'Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights' OJ L 157/45.

⁴⁸ Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.

⁴⁹ cf reg (EU) 2019/933 (n 1) Recital 20.

⁵⁰ cf Kühnen, Handbuch der Patentverletzung (n 14) ch A.V.8 para 651 sq.

⁵¹ Decision of the EEA Joint Committee No 197/2022 of 10 June 2022 amending Annex XVII (Intellectual property) to the EEA Agreement [2022/1897], art 1 (4).

SPC Regulation introduces ambiguity. The ‘immediate packaging’ of the finished product, for example, may comprise a vial containing the medicinal product or blister packaging, whereas the ‘outer packaging’ of the finished product pertains to secondary packaging and likely includes any subsequent packaging, such as shipper boxes. The latter could also encompass any further layers of external packaging. In cases involving combination packaging, it may be reasonable to label only the ‘immediate packaging’ of the otherwise patent-infringing product, but clarity in this regard is lacking. Similarly, in the instance of solvents or items like syringes, labelling could be only mandatory if they could potentially be deemed contributory or indirect infringements. It is also questionable whether labelling obligations also extend to upstream products (related acts) that are not inherently prepared for export outside the EU and encompass interim packaging. The labelling obligations refer to a ‘made’ product, so that the obligations should apply before the immediate act of export to third countries.

It is further unclear what ‘feasible’ means. The term ‘feasible’ could imply impracticability, such as in the case of very small vials or blisters or financial infeasibility, involving unacceptably high labelling costs for a product, or it could signify legal impracticability, such as non-compliance with regulatory provisions in the destination country (outside the EU or EEA) that prohibit such labelling. In this regard, Recital 21 further clarifies that the ‘labelling obligations should be without prejudice to labelling requirements of third countries’. This can be interpreted so that labelling obligations apply only insofar as they do not infringe on labelling requirements in a third country of export, for example regarding Northern Ireland: on 13 January 2021, Commission Delegated Regulation (EU) 2016/161 was amended by Commission Delegated Regulation (EU) 2021/457 to allow a temporary exemption from the requirement to deactivate unique product identifiers for goods exported to the UK, extending this exemption until 31 December 2021. The purpose of this derogation was to ensure the continued supply of medicinal products to smaller markets traditionally reliant on the UK, including Northern Ireland, Cyprus, Ireland, and Malta. In these small markets, many medicinal products were historically sourced from the UK by wholesalers lacking the necessary manufacturing and importation authorizations to meet the importation requirements outlined in Directive 2001/83/EC and Delegated Regulation (EU) 2016/161. To ensure that medicinal products in Northern Ireland, Cyprus, Ireland, and Malta continue to be available with unique identifiers, the Commission Delegated Regulation (EU) 2022/315⁵² extended the temporary derogation for an additional 3 years, until 31 December 2024. This extension shall provide the industry with the necessary time to adapt their supply chains for medicines destined for these regions.⁵³ However, it is important to note that this derogation is limited to medicinal products exclusively intended for the UK market or for the UK market in conjunction with Cyprus, Ireland, or Malta.⁵⁴ It does not apply to medicinal products intended for markets other than the UK or those with EU-wide or global labelling.⁵⁵

All these inquiries regarding the labelling obligations ultimately rest with the ‘maker’, who bears the risk that the waiver

may not apply should a court subsequently determine, for example, that the labelling of outer packaging is inadequate. Until legal precedents offer resolutions to these questions, providing at least partially reliable guidelines, uncertainty will persist.

C. SPC Waiver under the new EU pharmaceutical package

Under the new EU Pharmaceutical Package, the EU Commission has published two Regulation Proposals: the Unitary SPC Regulation Proposal,⁵⁶ on the one hand, introduces a unitary SPC waiver and, on the other hand, the revised SPC Regulation Proposal,⁵⁷ maintains the SPC waiver for national SPCs. In this regard, both proposals include under Article 5, respectively, exactly the same provisions and obligations of Regulation 2019/933, albeit in different subparagraphs, in order to avoid discrimination between unitary and national SPCs and ensure a uniform application.⁵⁸ It is noteworthy that according to Article 5(3) lit. b) of the Unitary SPC Regulation Proposal, regarding a waiver for a Unitary SPC, both the EUIPO and the competent authority of the country where privileged acts take place, along with the unitary SPC holder, must be notified.

In Recital 22 of the Unitary SPC Regulation Proposal and Recital 42 of the revised SPC Regulation, the EU Commission reiterates that the reasons for the introduction of the waiver and the conditions of its application remain applicable. This can be interpreted as a subtle reference to the recitals of Regulation 2019/933 that can be still considered for the interpretation of the SPC waiver provisions. Against this background, it is noteworthy that the revised SPC Regulation Proposal adopts, adapts, and strikes out many Recitals of Regulation 2019/933 under its own Recitals 42–59, 67–68. In most of the cases, these adaptations have little material substance, as they mostly concern grammatical corrections, language style adaptations, cross-references to Regulations, and other text adaptations that seem to adhere to the EU Joint Practical Guide for drafting EU legislation, such as deletion of text that entails non-mandatory language or reproduces or paraphrases the operative terms of the Regulation.⁵⁹ One substantial change arises out of the corrections, namely under Recital 50 of the SPC Regulation Proposal, which adapts Recital 14 of Regulation 2019/933: regarding the notification obligations, the Proposal deletes the rather confusing provision not to comply with the notification obligations in the country where solely related acts take place, if the ‘maker’ complies with these obligations in the country of ‘making’ and refers in their notification to the countries where related acts take place. Therefore, notification obligations arise in every country that privileged acts take place, regardless thereof, if it is ‘making’ or a merely related act hereto. It is questionable

⁵⁶Commission, ‘Proposal for a Regulation of the European Parliament and of the Council on the Unitary Supplementary Certificate for Medicinal Products, and Amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013’ COM(2023) 222 final [2023/0127 (COD)]. Available at https://single-market-economy.ec.europa.eu/publications/com2023222-proposal-regulation-unitary-supplementary-certificate-medicinal-products_en (accessed 12 February 2024).

⁵⁷Commission, ‘Proposal for a Regulation of the European Parliament and of the Council on the Supplementary Protection Certificate for Medicinal Products (recast)’ COM(2023) 231 final [2023/0130 (COD)]. Available at https://single-market-economy.ec.europa.eu/publications/com2023231-proposal-regulation-supplementary-protection-certificate-medicinal-products-recast_en (accessed 12 February 2024).

⁵⁸reg (EU) 2019/933 (n 1) Recital 22.

⁵⁹Cf European Union, ‘Joint Practical Guide of the European Parliament, the Council and the Commission for persons involved in the Drafting of European Union Legislation’ (2015) 31. Available at <https://eur-lex.europa.eu/content/techleg/KB0213228ENN.pdf> (accessed 1 September 2023).

⁵²Commission Delegated reg (EU) 2022/315 of 17 December 2021 amending Delegated Regulation (EU) 2016/161 as regards the derogation from the obligation of wholesalers to deactivate the unique identifier of medicinal products exported to the UK.

⁵³ibid.

⁵⁴ibid.

⁵⁵ibid.

whether these corrections, although accurate, were indeed necessary. It can be expected that they will lead to more confusion rather than legal certainty.

One may wonder why the Commission did not make any substantial changes to the waiver. In the Explanatory Memorandum of both Proposals, the EU Commission notes that 'an evaluation of the SPC manufacturing waiver, which is an exemption introduced by Regulation (EU) 2019/933, [...] will be undertaken in the near future (as foreseen in Article 21a of Regulation (EC) No 469/2009)'. One can assume that the EU Commission preferred not include the SPC waiver in the overall negotiations regarding the revised EU Pharmaceutical Package.

D. Conclusion

In principle, the waiver pursues a legitimate aim, in its current form and practical application though, it perpetuates the same disadvantages and chilling effects for generics and biosimilars it sought to resolve in the first place. Implementing additional obligations for the EU-based manufacturers is not justified.⁶⁰ When a medicinal product is manufactured within the EU, it must abide by an authorization process, thus providing information about the applicant and, if located within the European Union, the manufacturer of the medicinal product. If such a medicinal product, were to be (re-)imported into a Member State, the SPC holder would have been informed thereof via the marketing authorization.⁶¹ Therefore, the notification obligations are excessive in their scope and unnecessary, as this information is inevitably made public and accessible to the SPC holder in advance. By contrast, if the medicament is the API manufactured for export, this information will remain confidential in third countries, where similar disclosure obligations do not apply, thus the SPC waiver's 'level-playing field' is not so attractive for the EU-based manufacturers.

Additionally, none of the exemptions that have been recognized for third parties in the patent laws requires any communication to the patent office or the patent holder from the person who carries out acts falling within the scope of the patent protection.⁶² The obligation to disclose information which will be communicated to the patentee about the acts that the competitor intends to carry out implies an otherwise impermissible exercise of a control on the independent activity of a competitor in the context of a self-executing exemption. The reasons pointed out in the text, such as transparency or reduction of illicit diversion of medicaments onto the EU market, are not empirically supported.⁶³ Conversely, it negatively impacts the competitiveness and potential business prospects for European manufacturers of generic and biosimilar products.⁶⁴ Court decisions, such as the problematic decision of the District Court of Munich,⁶⁵ could create further chilling effects for the generics and biosimilars

industry. However, the latest decision by the District Court of the Hague⁶⁶ gives hope that the German decision will not go 'viral' in the EU jurisprudence.

Abusive litigation, which stems from the unnecessary obligation duties, on part of the SPC holder is not a mere risk but a direct by-product of the Regulation. Article 5(4) of Regulation 2019/933 is an open invitation to frivolous litigation: 'The information provided to the certificate holder for the purposes of points (b) and (c) of paragraph 2 shall be used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance.' The Regulation should have provided additional effective safeguards against abusive litigation. Additionally, the principle of proportionality anchored in Article 5(7) should have been more broadly construed in order to address for example mere negligence regarding the maker's obligations. Instead, the Regulation currently prescribes an SPC infringement for any violation of the obligation on part of the maker and the related third parties, for which they ultimately bear the burden of proof.

The flawed design of the SPC Waiver is plainly exposed in its unitary application, according to Article 5 of the Unitary SPC Regulation Proposal.⁶⁷ There, the unitary scope of protection of unitary SPCs must be logically divided into various territorial segments for which the maker has to separately notify the same SPC holder, if 'making' or other related acts take place there. To translate this concept into the classic SPC waiver, for example, in Germany, one would have to require the maker filing separate notifications for each German state (Bundesland) within Germany. In both cases, the result is absurd.

The SPC waiver was not created as part of a general review of the SPC Regulation but rather as a targeted amendment to tackle specific problems.⁶⁸ Thus, it is questionable why the SPC Waiver has been left out by the current revision of the EU pharmaceutical legislation. It is even more questionable why problematic provisions of the SPC Waiver have been blindly transferred into its unitary application. The EU pharmaceutical legislation cannot really be revised without addressing the flaws of the SPC waiver. Until then, a timely market entry for EU-based generics and biosimilars cannot be guaranteed, resulting into loss of competitiveness for the EU generics industry, higher medicines costs for the healthcare systems, medicines shortages, unreasonable bureaucracy, let alone the already high litigation costs that the waiver's application is inextricably linked with.

Acknowledgements

The author would like to thank Konstantinos Tsakiliotis for his valuable assistance in preparing this article.

⁶⁰Vidal-Quadras (n 13) 996 sq.

⁶¹ibid.

⁶²ibid 997.

⁶³ibid 1004.

⁶⁴Medicines for Europe (n 4) 2 sq.

⁶⁵Landgericht München I, Case reference: 21 O 12030/23.

⁶⁶District Court of the Hague (n 45).

⁶⁷Commission, 'Proposal COM(2023) 222 final' (n 56).

⁶⁸Commission (n 12) Explanatory Memorandum 2.