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The SPC waiver under Regulation (EU) 2019/933 — Part II: Analysis of manufacturers' obligations and discussion of the case law of the Member State courts regarding the scope of the notification obligation

The manufacturing privilege ("SPC Waiver") pursuant to Regulation (EU) 2019/933 provides for exceptions to the supplementary protection certificate, allowing EU manufacturers to start production before the certificate protection expires, provided they comply with strict requirements. The discussion on the legal framework for the manufacturing privilege received new impetus from the judgments of the Regional Court of Munich I of October 20, 2023 (GRUR-RS 2023, 39994 — Biosimilar), the District Court in The Hague on January 23, 2024 (Ref. C/09/ 657817 / KGZA23—1039) and, most recently, the Flemish-language Commercial Court in Brussels on December 23, 2024 (Ref. A/24/02113 — Kluwer Patent Blog 31 December 2024, available at <https://beck-link.de/ex8ct>) with regard to the disclosure obligation pursuant to Art. 5 V lit. e Regulation (EU) 2019/933, among other things. While the first part of the article (published in GRUR-Prax 2024, 795) dealt in depth with the meaning and purpose and the territorial, material, and personal scope of application of the Regulation, the second part explains the obligations under Regulation (EU) 2019/933. The focus is on presenting and discussing the hitherto inconsistent and, in some cases, contradictory national case law regarding the notification obligation.

I. Manufacturer's obligations

[1] In order to invoke the manufacturing privilege, the manufacturer must fulfill notification, due diligence, and labeling obligations, on which the material scope of the manufacturing privilege depends. A breach of these obligations leads to a negation of the privilege and thus almost inevitably to an infringement of the supplementary protection certificate in question in the Member State in which the acts took place. This legal consequence is based on the wording of Article 5(2) of Regulation (EU) 2019/933, which lists these obligations as conditions for the manufacturing privilege. According to recital 13, the European legislator considers these measures to be "effective and proportionate safeguards [...] to improve transparency, to assist the holder of a certificate in enforcing its protection in the Union, to verify compliance with the conditions laid down in this Regulation, and to reduce the risk of unlawful diversion to the

Union market during the period of validity of the certificate." The exact scope of these obligations is at the center of numerous pre-court and court disputes between originators and generic or biosimilar manufacturers, as mentioned above. These obligations are explained in more detail below, with a focus on the notification obligation, which, as the first contact between the manufacturer and the certificate holder, often forms the prelude to the legal dispute, as is also the case in the aforementioned legal disputes.

1. Duties of care

[2] According to the structure of Regulation (EU) 2019/933, the manufacturer is the main privileged party that benefits (most) economically from the manufacturing privilege and therefore also has to fulfill due diligence obligations towards third parties along the value chain. Pursuant to Art. 5 II lit. e in conjunction with Art. 5 IX of Regulation (EU) 2019/933, the manufacturer must ensure by appropriate and documented means that any person who is in a contractual relationship with him and who carries out activities covered by the manufacturing privilege within the meaning of Art. 5 II lit. a of Regulation (EU) 2019/933, is fully informed of the following: First, that these privileged activities are subject to the limits and obligations of Art. 5 II of Regulation (EU) 2019/933 (Article 5 IX lit. a Regulation (EU) 2019/933), and secondly, that activities outside the privileged area, such as the re-importation into the EU of a medicinal product manufactured under the export privilege, could violate the certificate referred to in Article 5 II Regulation (EU) 2019/933 (Article 5 IX lit. b Regulation (EU) 2019/933). This is a tautology, meaning that Article 5 IX lit. b Regulation (EU) 2019/933 is superfluous. The manufacturer can ensure compliance with this duty of care by including this information in contracts with third parties along the supply chain in the EEA who perform privileged activities under the manufacturing privilege, for example the exporter and the person carrying out storage (see Recital 20). As Recital 9 clearly states

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, the manufacturing privilege "shall also apply to related acts of third parties who are in a contractual relationship with the manufacturer."

[3] Recital 20 clarifies that a manufacturer who fails to comply with these obligations of care shall not benefit from the exemption, nor shall third parties who perform a related act in the Member State of manufacture or in another Member State where a protection certificate is in force. It is questionable whether a contracting party is liable for an intentional or negligent breach of the relevant certificate if this breach lies exclusively within the sphere of responsibility of the other contracting party and it had no reason to question the other party's compliance with its obligations. For this reason, both privileged third parties and manufacturers are well advised to conclude indemnification agreements for breaches of contract. This clearly defines and delimits the respective party's area of responsibility with regard to the obligations under Regulation (EU) 2019/933.

2. Labeling requirements

[4] The labeling requirements serve to prevent the re-importation or diversion of products manufactured in third countries into the European internal market under the export privilege (see recitals 13 and 21).

"in order to facilitate the identification of such products or medicinal products as being intended exclusively for export to third countries by means of a logo"). According to Art. 5 II lit. d of Regulation (EU) 2019/933, the manufacturer must ensure that products or medicinal products containing these products that are manufactured for export to third countries ensure that a logo in the form specified in Annex I is affixed to the outer packaging of the product or medicinal product containing that product and, where feasible, to its primary packaging. The logo must be black and of a size that makes it sufficiently visible. With regard to EEA countries that are not EU Member States, the logo must read "EEA export" instead of "EU export" (OJ 2022 L 267, 50, Art. 1 IV). In addition, pursuant to Art. 5 VIII of Regulation (EU) 2019/933, the manufacturer must ensure that medicinal products manufactured for export to third countries do not bear any so-called active individual identification feature within the meaning of Commission Delegated Regulation (EU) 2016/161. Recital 21 of Regulation (EU) 2019/933 emphasizes once again that compliance with the labeling requirements is a prerequisite for the application of the SPC exemption. This refers to labeling requirements under both Article 5(II)(d) of Regulation (EU) 2019/933 and Article 5(VIII) of Regulation (EU) 2019/933 with regard to the active individual identifier, as recital 21 requires that the product "be labeled in the manner provided for in this Regulation." The exact interpretation of the term "affix" remains unclear, in particular with regard to whether it requires permanent affixing or whether, for example, the use of a removable sticker is sufficient. This question is of considerable practical relevance, as changes to the labeling are not possible or only possible to a limited extent in the exporting country for regulatory reasons.

[5] Furthermore, according to Art. 5 II lit. d Regulation (EU) 2019/933, the labeling of food packaging is mandatory. In contrast, the labeling of primary packaging is only mandatory if it is

"feasible." It stands to reason that the

terms **"primary packaging"** and **"secondary packaging"** in Art. 5 II lit. d of Regulation (EU) 2019/933 in accordance with Art. 1 No. 23-24 of Directive 2001/83/EC, so that these terms cover both the primary packaging of the product and the subsequent packaging layer. However, the wording in Regulation (EU) 2019/933 leads to ambiguities. The "primary packaging" of the finished product may, for example, include a pierceable bottle containing the medicinal product or a blister pack, while the "secondary packaging" of the finished product belongs to the secondary packaging and probably includes all subsequent packaging, such as shipping cartons. The latter may also include further layers of outer packaging.

[6] It remains unclear how the term "feasible" should be interpreted. The term could imply practical infeasibility, e.g., in the case of very small bottles or blister packs, or financial infeasibility associated with unacceptably high labeling costs for a product. If the term is interpreted from the point of view of technical practicability, it may make sense in the case of combination packaging to label only the "primary packaging" of the otherwise patent-infringing product. In addition, the term could mean legal impracticability, such as non-compliance with the legal provisions of the country of destination (outside the EU/EEA) that prohibit such labeling. In this context, recital 21 clarifies that the labeling requirements under Regulation (EU) 2019/933 should not affect those in third countries.

3. Notification obligation

[7] The obligation, which is highly controversial between originators and generic or biosimilar manufacturers both in and out of court, relates to the manufacturer's notification to the certificate holder. Art. 5 II lit. b. Regulation (EU) 2019/933 requires the manufacturer to provide the competent authority of the Member State of manufacture and the certificate holder with the information listed exhaustively in Art. 5 V of Regulation (EU) 2019/933 in an appropriate and documented manner no later than three months before the start of manufacture (or the first related activity in that Member State). According to Art. 5 II lit. c of Regulation (EU) 2019/933, the manufacturer must update this information as necessary and notify both the competent authority and the certificate holder before any changes to the content of the notification take effect. The manufacturer must use the standard form in Annex Ia for the notification to the authority, which is also recommended in relation to the certificate holder (cf. Art. 5 VI of Regulation (EU) 2019/933 in conjunction with Recital 15).

[8] The competent authority pursuant to Art. 9 I SPC Regulation is the competent authority for industrial property rights in the Member State that issued the applicable protection certificate. Pursuant to Art. 11 IV SPC Regulation, this authority shall publish the information listed in Art. 5 V Regulation (EU) 2019/933 as soon as possible.

with the date of transmission of this information and any changes. Recital 14 clarifies that the manufacturer must comply with the notification obligation in each Member State if manufacturing takes place in more than one Member State.

II. Discussion of the notification obligation regarding exporting countries pursuant to Art. 5(e) of Regulation (EU) 2019/933, taking into account the case law of the Regional Court of Munich I, the District Court of The Hague, and the Flemish-speaking Commercial Court of Brussels.

[9] The information to be provided by the manufacturer, as enumerated in Article 5(5) of Regulation (EU) 2019/933, includes its contact details, the Member States where privileged acts will take place, the number of the relevant conflicting certificates and, in accordance with Article 5(5)(e) of Regulation (EU) 2019/933, "for medicinal products intended for export to third countries, the number of the marketing authorization or equivalent in each third country of export, as soon as it is publicly available." The latter piece of information is also at the heart of the legal dispute between originators and generic or biosimilar manufacturers. The interpretation of this provision was the subject of both the aforementioned proceedings between Janssen and Formycon/Fresenius Kabi before the Regional Court of Munich I on October 20, 2023 (GRUR-RS 2023, 39994 — Biosimilar), as well as the proceedings between Janssen and Samsung Bioepis before the District Court of The Hague at the beginning of last year (decision of January 23, 2024 — C/09/657817 / KGZA23—1039), and

recently in the proceedings between Amgen and Samsung Bioepis before the Flemish-speaking Commercial Court in Brussels in December last year (decision of 23.12.2024 — A/24/02113 — Kluwer Patent Blog, 31.12.2024, available at <https://beck-link.de/ex8ct>).

[10] In view of the importance and practical relevance of this provision, the history of the standard and the relevant recitals will be briefly discussed below. The Commission's first draft proposal (COM (2018) 317 final) initially provided that the manufacturer would have to submit an indicative list of the intended third country or countries to which the product would be exported. However, the European Parliament objected to such a provision, which would have required generic and biosimilar companies to disclose strictly confidential information to direct competitors (see COM (2018) 317 final — Analysis of the final compromise text with a view to reaching an agreement). As a rule, this information is known to the health authorities but is treated as confidential vis-à-vis third parties due to its economic sensitivity and for health and safety reasons (see Vidal-Qua-dras, IIC 2019, 971, 996). The Parliament's version corresponds in this respect to the current version of Article 5(e) of Regulation (EU) 2019/933, which now only requires "the number of the marketing authorization or something equivalent to this authorization in each exporting third country, as soon as it is publicly available" for medicinal products. Similarly, Recital 15 emphasizes: "This information

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. Accordingly, Recital 17 also refers to cases where an application has been submitted but the marketing authorization has not been published until after the notification. It follows that the manufacturer is only required to provide such information once it is publicly available, without this affecting the legal requirement for early notification.

[11] In the first court ruling to address the notification requirement under Regulation (EU) 2019/933, the Regional Court of Munich I (GRUR-RS 2023, 39994 — Biosimilar) ruled that the exemption provision in Article 5 of Regulation (EU) 2019/933 must be interpreted restrictively in accordance with its meaning and purpose, such that the manufacturer cannot invoke it if it has not notified the approval number for at least one country and has also not declared to which third country an export is to take place (GRUR-RS 2023, 39994 para. 17 — Biosimilar). According to the court, the amendments made during the legislative process in accordance with the parliament's version were aimed at

"to simplify the obligation to notify the national patent authority, but not to impair the examination rights of the intellectual property right holder" (LG Munich I GRUR-RS 2023, 39994 marginal no. 29 — Biosimilar). The court argued that this information was necessary for the certificate holder to check whether intellectual property rights had expired or still existed in the exporting countries, because the manufacturer's privilege only applied in the case of exports to countries where there were no intellectual property rights. The three-month period specified in Article 5 II(b) of Regulation (EU) 2019/933 is intended not only to enable the intellectual property rights holder to check whether the requirements of Regulation (EU) 2019/933 are met and, in particular, whether there is a risk of the products being diverted to the Union market, but also whether market authorization already exists in the intended country of export (LG Munich I GRUR-RS 2023, 39994 para. 22 - Biosimilar). If the manufacturer were to merely notify the intention to manufacture without providing details of the export country, it could begin after the deadline had expired and subsequently submit the approval number (LG Munich I GRUR-RS 2023, 39994 marginal no. 27 — Biosimilar). The owner of the property right would only find out about this shortly before market entry, which could prevent effective legal protection, as the facts would already have been established at that point (LG Munich I GRUR-RS 2023, 39994 para. 27 — Biosimilar). The court rejected the defendant's objection that this argument implies extraterritorial effect of foreign property rights as follows: In the case of manufacture in a member state of the Union, the infringement takes place there, so that there is no case of extraterritorial protection (LG Munich I GRUR-RS 2023, 39994 para. 24 — Biosimilar).

[12] In a similar case, the District Court in The Hague (judgment of January 23, 2024 — C/09/65 7817 / KG ZA 23-1039) expressly rejected the German court's reasoning and ruled in favor of the biosimilar manufacturer. In the opinion of the Dutch court, manufacturers must first indicate the reference number of the marketing authorization,

if it is publicly available. If it is not available, they can submit the notification and add the reference number later. The Dutch court confirmed that the regulation allows notifications even without marketing authorization, with the possibility of adding the reference number later. It referred to recital 17 and the legislative history and emphasized that the notification requirement was deliberately designed to enable EU-based manufacturers to compete fairly with non-EU manufacturers. In the court's view, it follows explicitly from the history of the legislative process that the notification obligation regulated in Art. 5 of Regulation (EU) 2019/933 is to be understood as prohibitive, which prevents certificate holders from requesting further confidential or sensitive business information.

[13] In December of last year, the Commercial Court in Brussels agreed with the opinion of the District Court in The Hague in a decision on interim relief (known as "Dorf geding") dated December 23, 2024 (Ref. A/24/02113 — Kluwer Patent Blog 31 December 2024, available at <https://beck-link.de/ex8ct>) and also distanced itself from the interpretation of the Regional Court of Munich I. In her decision, the judge of the Brussels Commercial Court referred in particular to what she considered to be the clear wording of Regulation (EU) 2019/933, according to which a notification pursuant to Art. 5 V Regulation (EU) 2019/933 is also lawful if the authorization number for export countries is missing, provided that the latter is not yet publicly available. In such a case, the notification does not have to name the export countries as a substitute, as required by the Munich I Regional Court. The result of the primary grammatical interpretation is consistent with the historical and teleological interpretation of Regulation (EU) 2019/933, especially since the European legislator consciously and explicitly decided against a more comprehensive notification content by giving priority to the protection of trade secrets of privileged manufacturers over the interests of certificate holders. **This** is also supported by the external form of the standard form in Annex Ia to Regulation (EU) 2019/933 itself, which explicitly includes the option in the form of a checkbox to update an existing notification. Similarly, neither the wording nor the purpose of the standard justifies the interpretation that the manufacturing privilege or export privilege only privileges manufacturing activities for the purpose of export to non-protected third countries.

III. Fazit

[14] The interpretation of the Dutch and Belgian courts is preferable, as it is consistent with the wording and legislative history of the Regulation (see von Czettritz/Thewes PharmR 2024, 253 [257]). In contrast, the interpretation of the Regional Court of Munich I is not compatible with the wording of Article 5 V lit. e of Regulation (EU) 2019/933 and the legislative history of the Regulation, according to which disclosure of the authorization number is only required once it is publicly available. The Regional Court's reference to recitals

— Nilsson et al. and ECJ BeckRS 2006, 70031 para. 76 — IATA, ELFAA/Ministry of Transport). — Nilsson et al. and ECJ BeckRS 2006, 70031 para. 76 — IATA, ELFAA/Ministry of Transport).

[15] According to the wording of Art. 5 V lit. e Regulation (EU) 2019/933 ("as soon as it is publicly available") and, according to the preparatory work, deliberately decided against the interpretation advocated by the Regional Court of Munich I and in favor of only requiring the manufacturer to provide the authorization number for placing the product on the market if and as soon as this information is publicly available. The obligation originally provided for in the Commission proposal (COM(2018) 317 final) was rejected in the current version due to objections from the European Parliament and in view of the manufacturer's confidentiality interests, which are recognized as worthy of protection (see above, para. 10).

[16] Furthermore, linking the application of certificate rights to the scope of protection of foreign property rights would imply an inadmissible extraterritorial effect of foreign property rights in the EU (see Stiel Journal of Intellectual Property Law & Practice 2024, 695 ff. and Stief Journal of Intellectual Property Law & Practice 2024, 754 ff.). The courts in The Hague and Brussels clearly rejected this argument. Based on recital 18, according to which it is the manufacturer's responsibility to verify that protection does not exist in an exporting country, certificate holders have argued that privileged manufacturing in the EU can only commence after the relevant intellectual property protection in the third country to which exports are to be made has expired. However, this approach implies an impermissible extraterritorial effect of IP protection, which is contrary to the internationally applicable principle of territoriality (see Romandini/Klicznik IIC 524, 530; Kühnen, Handbuch

of patent infringement, 16th ed. 2024, Chapter 8, margin note 592) of IP rights. Export to third countries as such, i.e., import into third countries, does not require the consent of the certificate holder, even if the same person is the holder of the intellectual property right in the third country. The manufacturing privilege applies exclusively to activities within the EU (see Recital 13). The requirement that manufacturing in the EU may only commence after the relevant intellectual property protection in third countries has expired would deprive the exemption of *its raison d'être* and thus perpetuate the disadvantages experienced by manufacturers based in the EU compared to their competitors in third countries where such restrictions do not apply (see recital 8). This interpretation is consistent with the legislative history of Regulation (EU) 2019/933 (see the Council's third revised proposal, Brussels, November 22, 2018, 14647/18, 3: "While noting that it is obviously not the intention of the proposal to encourage the infringement of IP rights in third countries, the Presidency has not included this suggestion as, inter alia, it is not the role of a court in the Union to investigate the legal situation of the product to be exported in third countries.").