The SPC Manufacturing Waiver in 2025

Fitness for Purpose and Commentary on Recent Trends

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The SPC Manufacturing Waiver – Background and Purpose

Bringing new therapies to patients is a risky, uncertain, long-term endeavor that relies on intellectual property (IP) – particularly patents – to secure both the initial and long-term, sustainable investments for the necessary complex research and development. It typically takes 12-15 years before a given therapeutic can be made available to patients, from the beginning of product development through the lengthy, rigorous regulatory approval process. This represents more than half of the 20-year patent term. In recognition of this, the EU introduced supplementary protection certificate (SPC) to offset part of a given patent's lost term. As a result, the SPC is the key – *i.e.* last to expire – IP protection driving pharmaceutical investment in Europe for over half of innovative products.

The SPC Manufacturing Waiver (Amending Regulation (EU) 2019/933) was introduced as an exception to this critical EU IP right. As such, it should be delineated and interpreted narrowly. To that purpose and to partly limit the anticipated negative impact on EU competitiveness, the Waiver was expressly intended only to benefit the generic and biosimilar industry that manufactures within the EU, either by making active pharmaceutical ingredient (API) or formulating API into a finished product. Under the SPC Manufacturing Waiver, manufacturing (and acts strictly necessary thereto) are exempted during the SPC term for two purposes **only**: (1) exporting to countries where IP protection does not exist or has expired; and (2) stockpiling in the country of manufacture during the *last six months* of a given SPC term, in order to place the product on the EU market on the first day after SPC expiry.

The provisions of the Waiver were drafted with the overall aim of striking a balance between: (1) creating a level playing field for European generic and biosimilar manufacturers in non-EU export markets having less or no IP protection compared with the EU; and (2) ensuring the protection of exclusive rights for rights holders within the EU (Recitals 3 and 4).

Criticality of Safeguards

In order to balance the rights and interests of stakeholders, the legislation acknowledged the need to impose effective and proportionate safeguards to preserve the legitimate interests of the SPC holder. The legislators therefore included, as safeguards, a number of mandatory conditions to be met by generic and biosimilar manufacturers to benefit from these exceptions, covering acts which would otherwise be considered as infringement of the SPC. Notably, a

notification system was made a requirement for a generic entrant to benefit from the Waiver, specifically: notifications must be sent to SPC holders three months in advance of the first act that would otherwise infringe the SPC.

The notification's main purpose is to ensure that a generic's or biosimilar's intended activities are within the scope of the Waiver, and that the SPC holder is informed that an exception to a valid IP right is being claimed. Notably, it is critical to recall that the mere act of notification does not allow manufacture; it only allows manufacture if the provisions of the Regulation are complied with. The three-month period in the legislation was set to provide sufficient time for both parties to raise and resolve any potential disputes between them, prior to that first act taking place. Further, clear communication of the intent to make use of the Waiver serves to increase transparency for all parties involved.

The notification to the SPC holder must include the marketing authorisation ("MA") number(s) in the export market(s), once available, as per Article 5.5(e). Further, Article 5.4 and Recital 18 clarify that rights holders can prevent exports to a country where IP protection exists, allowing legal action in appropriate circumstances. These sections of legislative text make clear that the purpose of the notification is the verification and, if needed, enforcement of the SPC if the acts do not fall within the scope of the Waiver. As explained throughout multiple Recitals, the Waiver regulation is intended to support export to third-country markets "in which protection does not exist or has expired," (Recital 8), and that effective safeguards must "increase transparency," "check compliance" with the conditions of this exception, and "reduce the risk of illicit diversion" (Recital 13).

It is critical to remember that the SPC Manufacturing Waiver is an exception to the protection provided by the SPC. As a basic legal principle, exceptions are to be defined and construed narrowly, lest the overall right is inadvertently eroded, thereby prejudicing the legitimate interests of the SPC holder.

Recent challenges to and non-compliance with these clearly intended safeguards pose a threat to the stability and enforceability of the European intellectual property system and the competitiveness of the EU as a whole. It should also be noted that any further derogation of IP rights in the EU would put at serious risk the goals described and recommended in the Draghi report[1] and the EU Competitiveness Compass[2]. Further, EFPIA has consistently raised concerns

[1] https://commission.europa.eu/topics/strengthening-european-competitiveness/eu-competitiveness-looking-ahead_en
[2] https://commission.europa.eu/document/download/10017eb1-4722-4333-add2-e0ed18105a34_en

that the Waiver would undermine EU competitiveness and would provide little, if any, benefit to European generic and biosimilar manufacturers.[3]

Recent Challenges

Recently, there have been multiple instances of generic entrants submitting incomplete, or even blank, notifications and subsequently arguing that they were complying with the provisions of the Regulation. These notifications under the Regulation have notably been the subject of three recent legal proceedings: in Germany (Munich), in the Netherlands (The Hague) and in Belgium (Brussels Dutch-speaking Court). These legal proceedings appear to have been decided with differing results:

- The German case resulted in a granted Preliminary Injunction ("PI") and ultimate settlement, with the Court reinforcing the need to provide the MA number for at least one export target and the identification of the proposed export countries. Importantly, it reemphasized the need for safeguards to verify that export is realistic and legitimate.
- The Dutch court refused the PI request and indicated that identification of a granted MA number in an export market is not required, contrary to the intent and text of the legislation.

It is important to note, however, that these first two decisions were in the context of preliminary proceedings; as to the Dutch case, EFPIA looks forward to the notification requirements of the Regulation being clarified as this case progresses on appeal.

- The Belgian decision concerningly rejected the need to provide a foreign MA number or identify export countries. It is a judgment on the merits, even though an appeal remains possible at this time.

If, as it appears in some of these cases, one export market was the United Kingdom where an equivalent SPC existed, this would fall outside the limits intended in the legislation, highlighting the necessity of maintaining rigorous safeguards to prevent misuse of the Waiver.

Given the contrasting conclusions by various European courts on the critical issue of the implementation of the notification provisions, EFPIA strongly believes that a resolution of the matter by the CJEU is clearly warranted. Without clarity and enforceability for rights-holders – and subsequent respect and accountability by users – on the critical notification safeguards, the underlying SPC rights themselves lose their weight, undermining trust in the EU IP framework as a whole.

[3] *See, e.g.*, 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

This worrying jurisprudential trend, demonstrated by the Belgian and Dutch decisions, is compounded by suggestions put forth by the generic industry that the notification safeguards enshrined in the Regulation should be further eroded. In June 2024, Medicines for Europe (MfE) published a Review of the SPC Manufacturing Waiver: a 2024 Industry Report,[4] which bases its conclusions on a survey of experiences with the Regulation but falls short of providing robust data. This contrasts with data previously provided by MfE in support of a comprehensive and usable SPC Manufacturing Waiver. Instead, this new report largely just presents anecdotal evidence from a limited number of companies, which calls into question the thoroughness of its findings and recommendations. It therefore does not provide a solid foundation for analysis or for drawing reasoned conclusions.

MfE worryingly describes the required notifications as "unnecessary conditionalities," and subsequently calls to remove them, despite the critical role of notifications in preserving European competitiveness in the innovative pharmaceutical sector and the jobs it represents. Further, despite the fact that the legislation clearly intends that litigation is a valid option to remedy non-compliance with the Regulation in the three months after notification and before manufacture, the MfE report seeks to characterize such litigation as abusive or frivolous. The extremely limited number of cases regarding Waiver notifications, however, are a clear indication that the option for legal action is being used judiciously; a single-digit number of cases over the span of six years can hardly be characterized as abusive. The report further argues that the notification requirements create a disadvantage for EU-based manufacturers and distort competition without providing any benefits; importantly, no explanation is provided on how the relevant articles and recitals can function without this minimal information relating to the export market(s) being provided.

Disclosure of Commercially Sensitive Information

The generic industry also raises concerns about the disclosure of commercially sensitive information through the notification process. However, the legislation explicitly limits the use of such information to assessing compliance with the Waiver and related legal proceedings. The concern that competitors might misuse this information is speculative and lacks any substantive basis. Alternatively, perhaps a limit on or delay of the publication of notifications by the intellectual property office that receives them could provide a viable option to allay these concerns.

[4] https://www.medicinesforeurope.com/wp-content/uploads/2024/06/Updated-2024-Industry-Report-on-SPC-Manufacturing-Waiver-Medicines-for-Europe-REV-CLEAN.docx.pdf

Current Use and Unfulfilled Promises

Reports regarding the use of the Waiver, including reports directly from the generic industry via MfE which were published in June 2023[5] and June 2024[6], state that the companies participating in the underlying survey reported production in Europe for more than 67% of products and that the numbers have been increasing. Thus, even if the data is in large part anecdotal, it appears that the notification requirements have little to no negative impact on European generic and biosimilar manufacturers' ability to rely on the SPC Manufacturing Waiver. The overwhelming majority of notifications appear to have indeed functioned effectively, even when they have resulted in some further correspondence with the SPC holder or even legal proceedings in a few exceptional cases to ensure that the notification has taken place correctly and that the proposed activities fall within the scope of the Waiver. This confirms anecdotal evidence from generic parties at public meetings who have stated that they benefit from the Waiver by utilizing the exception. As a result, there is no valid basis to undermine these safeguards, especially considering their importance in preserving SPC holders' legitimate interests and thereby a competitive and balanced European IP and innovation ecosystem.

At the same time, a significant discrepancy between the projected and actual job creation resulting from the implementation of the SPC Manufacturing Waiver should be noted. MfE claimed during the negotiations on the Waiver that its adoption would lead to the creation of at least 20,000 to 25,000 direct new jobs by 2025. In fact, less than 1,400 direct new jobs (less or equal than just 7 % of what has been predicted) were reported as of 2024, according to the MfE report. This stark contrast underscores that the anticipated benefits of the SPC Waiver in terms of job creation were greatly overstated and have not materialized. This is consistent with the concerns that EFPIA has consistently raised about the lack of significant benefit for European generics despite the risk to the European innovative sector, which continues to lose ground to global competitors such as those in the United States and China. Given this remarkable shortfall, any expansion or alteration of the Waiver, or a judicial "reading-out" of the notification requirements, should be approached with a high degree of caution as to its overall economic benefit to high-value European industry. Given the criticality of the SPC to innovative industry, any negative impact would likely outweigh any perceived positives. This only further highlights the need for a thorough and evidence-based evaluation of the Waiver's impacts and any projected benefits.

Conclusion

In view of the above, EFPIA does not consider that any expansion or alteration of the SPC Manufacturing Waiver, especially with respect to its critical notifications safeguards, is justified.

[5] https://www.medicinesforeurope.com/wp-content/uploads/2023/06/SPC-Waiver-REPORT-Medicines-for-Europe-12-June-2023.pdf
[6] *See* FN 4.

The exception should remain no wider than needed to fulfill the policy objectives underlying it, and the evidence indicates that the objectives of the Waiver, particularly its use by generics and the effectiveness of the majority of filed notifications in policing the exception, are being achieved. The handful of Court decisions and outside recommendations to further limit or remove the already limited safeguards that ensure the Waiver is applied as intended would improperly disregard the critical boundaries that mitigate the impact of this reduction of SPC protection on rights holders. These boundaries were extensively debated and balanced during the legislative process and should not be altered lightly to even further disproportionally benefit the generic and biosimilar industry.

Importantly, the status of the Waiver must be looked at in the context of the ongoing discussions regarding the General Pharmaceutical Legislation (GPL), particularly in the context of the Bolar exemption. Through proposed changes to this exemption – via its proposed expansion to additional protected actions including filing and obtaining pricing and reimbursement and health technology assessments, currently without critical complementary safeguards – a significant weakening of IP rights is again being proposed, affecting stability, predictability, and enforceability within the EU IP framework. The European Union must avoid a trend whereby intellectual property rights are incrementally eroded based on promises of benefits that ultimately fail to materialize, undermining the EU's long-term competitiveness and attractiveness for innovation and investment.