BIA comments on the SPC manufacturing waiver proposal

June 2018

UK BioIndustry Association

Key points

- SPCs are a valuable and proven incentive for promoting investment and innovation in the life sciences. The introduction of a manufacturing waiver undermines this incentive and weakens the EU environment as a destination for biopharmaceutical investment and the provision of innovative medicines for patients
- We are concerned that the Commission's impact assessment considers only the interests of the generic and biosimilar sector when considering the alleged burdens on SMEs (which it significantly overstates). It fails properly to address the significant impact the waiver may have on the thriving innovative SME sector. Furthermore, as home to a greater number of innovator SMEs and new products in development, the UK will be disproportionately affected by the introduction of this waiver
- The BIA welcomes the fact that the proposed waiver does not extend to stockpiling nor granted SPCs, which would not be consistent with the general principles of legal certainty and life science businesses' legitimate expectations having already completed investment decisions based on the expectation of SPC protection. However, the scope of the Proposal is poorly defined in some areas, including:

– The definition of export markets to which the waiver applies is not consistent throughout the proposed Regulation and should be consistently identified (including in the exemption itself) only as "Third country markets outside the EU in which protection does not exist or has expired"

– The definition of "the maker" does not reflect the complexity of the medicines supply chain, which involves many stages of production and multiple parties, each a potential "maker"

- The safeguards in the Proposal do not confer sufficient protection to SPC holders, especially:

– The SPC holder may get no more than 13 days' notice of the maker's intention to take advantage of the exemption. This is far too short to allow the SPC holder to assess whether the conditions of the waiver are being breached and its rights are at risk of infringement, it should be extended to 90 days and the notification should be made to the SPC holder at the same time as the relevant authority

– The information provided in the notification is minimal, making it difficult for the SPC holder to assess risk of infringement. A comprehensive list of intended export countries should be provided and kept up to date

– The wording "intended start date" is imprecise, as it leaves open the possibility for the maker to bring the date forward. The "earliest possible start date" would be preferable.

– The export logo provides little safeguarding from illegal sale in protected EU markets. Not including a Unique Identifier for the generic or biosimilar product under the European Medicines Verification System would provide greater protection

- The BIA urges the UK government to adopt the following red lines as the Proposal is progressed through the EU legislative process:

– The scope of the proposal must not be expanded to include stockpiling; and

– The scope of the proposal must not be expanded to include existing granted SPCs

- Furthermore, the BIA urges the UK government to support the general principles of legal certainty and life science businesses' legitimate expectations (based on R&D investments already decided and made) by calling for:

– the Proposal to be amended to remove pending SPC applications from its scope; and

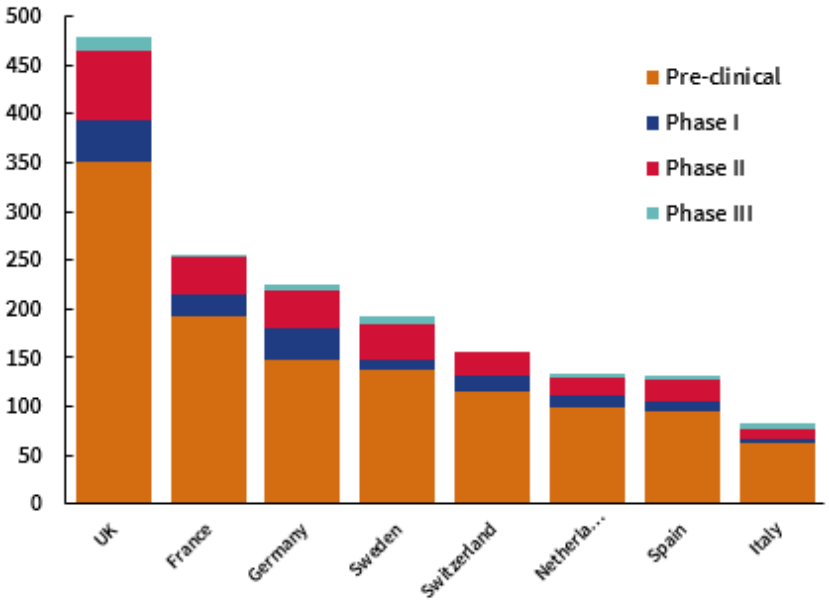
– the notification period to be extended to 90 days and to be made to the SPC holder as well as the relevant authority

Introduction

SPCs are a valuable and proven incentive for promoting investment and innovation in the life sciences. They promote the significant investment required to develop new medicines by providing an extended period of exclusivity to compensate for the patent life lost during the regulatory process that all medicines must go through. This extended period of exclusivity allows more time for the recouping of the R&D investment.

The introduction of a manufacturing waiver undermines this incentive and weakens the EU environment as a destination for biopharmaceutical investment and the provision of innovative medicines for patients. We are concerned that the Commission's impact assessment considers only the interests of the generic and biosimilar sector when considering the alleged burdens on SME's (which it significantly overstates). It fails to properly address the significant impact the waiver may have on the thriving innovative SME sector. The Proposal accepts that the waiver will lead to reduced revenues for originators, stating "The preferred option may cause a slight drop in the sales of products of SPC holders on export markets, due to the increased competition they would face from EU-based generics and biosimilars manufacturers during the SPC term in such 'non-SPC' non-EU countries." This impact will be felt most heavily by SME originators, which often have only one product in development or on the market, making global revenues all the more critical to the business. Furthermore, with more medicines in pre-clinical and clinical development than any other European country (Figure 1), this weakening of IP protection is likely to negatively impact the UK more than other Member States.

Figure 1. Products at each stage of development, 2017



Source: Informa Pharma Projects

www.bioindustry.org

The Proposal works on the assumption that the wider pharmaceutical industry will benefit from the waiver over time as more originators become involved in the generic and biosimilar markets. Whilst this may be true in some cases, SMEs are the least likely to work in both innovator and generic sectors and will thus see the least benefit as a subsector.

The waiver is a worrying erosion of IP protection in the EU that will impact the revenues of SMEs and other originators. As the Copenhagen Economics study identifies, the effective protection period provided by the range of incentives offered in the EU, including SPCs, has already declined from 15 years to 13 between 1996 and 2016. And, in fact, the period in which revenues can be generated is likely to be less than 13 years because of the way the effective protection period is defined.

Moreover, the introduction of a waiver undermines the facts on which original R&D investment decisions were made and, more crucially, reduces capital available for further R&D investments to develop new treatments for the benefit of patients.

As the UK trade association for innovative biosciences companies, the BIA welcomes the opportunity to provide input to the IPO on the EU's Proposal. Regulation (EC) No 469/2009 has been subject to extensive teleological interpretation and so it is important that the wording of this amending Regulation provides clarity for originators and generics/biosimilar manufacturers on the conditions of the exemption. It does not achieve this as currently drafted. The Commission is aware of the need for limitations to the scope of the waiver and has proposed safeguards to seek to ensure that those limits are not exceeded. However, clarification of the scope of the exemption and some strengthening of aspects of the safeguards are required to ensure adequate protection of innovator interests. This can easily be achieved without the objectives of the proposal being hindered. The comments and amendments raised in this submission seek merely to ensure that the limits of the proposal are not exceeded whilst allowing the exemption to operate as intended.

Comments on the scope of the Proposal

The BIA welcomes the fact that the proposed waiver does not extend to stockpiling nor granted SPCs. Stockpiling would increase the risk of illegal leakage of products onto the European market where the SPC is in force and would not support the stated objective of the Proposal to create "a level playing field between EU-based manufacturing and manufacturing in non-EU countries". The application of the waiver to granted SPCs would undermine the legitimate legal expectations of rights holders and send a chilling signal to the global industry that the EU is not a stable business environment in which to invest. As set out later in this document, these are two key features of the Proposal which must be maintained.

Definition of export markets

The wording of the Proposal is not clear or consistent on the definition of the intended export markets, which are described in three ways: "third countries" (Clause 2(a)(i)); "third country markets in which such protection does not exist or has expired" (Recital 7); and "outside the Union" (Recital 11). "Third country markets in which protection does not exist or has expired" is the preferred and most precise term that should be used throughout, including specifically in (Clause 2(a)(i)).

Definition of the maker

The Proposal also does not sufficiently define "the maker", which is described as "the person doing the making". This does not reflect the complexity of medicines production, which can involve multiple stages and intermediary products, all mediated by parties that could be considered "makers" Furthermore, these

activities can take place in multiple Member States. The BIA would recommend the Regulation is amended to state that the requirements apply to "each maker".

Comments on the safeguards

Notification period

The notification period of 28 days before the intended start date is too short to allow the SPC holder to assess whether its rights are at risk of infringement as a result of the notification to invoke Article 4, either in any Member State or third country export market. The notification is also made to the relevant authority, which then has a separate obligation to make that information publicly available within 15 days of receipt. This is a notice to the public which the SPC holder will need to monitor, thereby giving them effectively only 13 days' notice before manufacturing commences, which is extremely short notice. A notification period of 90 days would be more reasonable and the notification should be made directly to the SPC holder at the same time as the authority to ensure the full 90 days is utilisable to the affected rights holder.

Information within the notification

We recognise the need to find a balance in administration of the notification. However, the little information required to be provided to the relevant authority, and thus presumably posted on the public register, makes it difficult for the SPC holder to confirm in the short notification period provided that their IP rights are not being infringed. Information that could helpfully be disclosed could include a comprehensive list of the intended export markets, the quantity to be produced and exported, evidence that their production capacity and import of ingredients is not greater than that required to meet export market demand, and evidence that all requirements of the Regulation have been met. The wording "intended start date" is imprecise, as it leaves open the possibility for the maker to bring the date forward. The "earliest possible start date" would be preferable.

We do not accept concerns that have been expressed that the notification system is burdensome for SMEs. The SMEs concerned are, after all, companies engaged in manufacturing generics or biosimilars and wish to expand their capacity to engage in such activity. By the time they come to notify they will have completed supply contracts. In this context the provision of this information is not burdensome; it does not seem unreasonable to require a comprehensive list of intended third countries for export, rather than the "indicative list" currently in the Proposal. Furthermore, for the information to be valid, it cannot be a "one-off" notification as proposed; it should be kept up to date.

The export logo

The BIA does not believe that a logo on the packaging of the product is an effective safeguard against illegal leakage onto the European market or reimportation. Packaging can easily be removed and replaced.

The European Medicines Verification System (EMVS) provides a more effective mechanism. As manufactured for export, medicines produced under the exemption should not bear the Unique Identifier which will be required for dispensing in the EU as of February 2019.

However, this would not protect intermediary products involved in the supply chain, which may also have IP protection. It is much harder to determine safeguards for these but the identification of all parties involved in the maker's supply chain would make it easier to police.

Red lines

The BIA acknowledges that there is considerable political will to implement the Proposal and there will be a tension between amending the text and expediting the legislative procedure. Whilst there are many ways in which the Proposed Regulation could be improved, there are many conceivable ways it could be made worse. With this in mind, the BIA proposes the following red lines that the UK government should uphold to protect the interests of innovators in the UK and EU.

The scope of the proposal must not be expanded to include stockpiling

The Proposal states that it "does not go beyond what it is necessary to tackle the identified problem. It removes the barriers to the manufacture of generics and biosimilars in the Union for export." Furthermore, it acknowledges that exercise of the waiver will support the timely entry of generics and biosimilars into the EU market following SPC expiry, as they can build up production capacity. Stockpiling is therefore not necessary and permitting it increases the likelihood of illegal leakage into the EU market. The current safeguards in the Proposal give little confidence that such a thing would effectively be avoided. The exclusion of stockpiling is a necessary part of the "balanced" approach advocated by the Commission and the UK government should resist any efforts to expand the Proposal.

The scope of the Proposal must not be expanded to include existing granted SPCs

SPCs are applied for – and often litigated over – as part of a calculated business strategy intrinsically linked to wider investment decisions that benefit the EU. Including existing granted SPCs within the scope of the Proposal would go against the legitimate expectations of rights holders and undermine the EU as a pro-innovation, pro-business environment. Moreover, the exclusion of granted SPCs is a necessary part of the "balanced" approach advocated by the Commission and the UK government should resist any efforts to expand the Proposal.

Improving the Proposal

This document has identified a number of issues with the Proposal as it stands, which we hope can be remedied. However, for the purposes of prioritisation, the BIA proposes the following two amendments which would greatly improve the proportionality of the Proposal and support the general principles of legal certainty and life science businesses' legitimate expectations.

Exclude pending SPCs from the scope of the waiver

The Proposal acknowledges that companies make investment decisions based on the expectations of rights conferred by SPCs, and that these investments can be made in advance of applying for an SPC. Indeed, with medical R&D timelines regularly spanning 10 years or more, such decisions are made many years before the application. The inclusion of pending SPCs in the Proposal therefore appears an unnecessarily punitive approach, one that undermines the legitimate expectations of life science companies.

Furthermore, the time taken for granting of SPCs varies from Member State to Member State, and there are significant backlogs in national SPC-granting offices, including the UK. This means that companies that have already applied for an SPC, with an expectation at the time as to what rights that SPC would confer, are no longer guaranteed those rights subject to the efficiency of the national office. This will result in companies being subject to unequal treatment across the EU. The BIA therefore urges the UK government to call for pending SPC applications to be out of the scope of the Proposal, which would respect the general principles of legal certainty and life science businesses' legitimate expectations.

Extend the notification period to 90 days

As described above, the current 28-day notification period does not provide a reasonable period for the SPC holder to assess their legal position and take appropriate action where they believe their rights have or will be infringed. The SPC holder may get no more than 13 days' notice of the intention to take advantage of the exemption if the authority uses its full permitted time limit to publish the information. This is far too short to allow the SPC holder to assess whether the conditions of the waiver are being breached and its rights are at risk of infringement. The BIA therefore urges the UK government to seek to extend this period to 90 days, which we believe is reasonable and proportionate. Furthermore, the notification should be made to the SPC holder at the same time as the relevant authority.

About the BIA

The BIA is the trade association for innovative life sciences in the UK. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.

Our members include:

- Start-ups, biotechnology and innovative life science companies
- Pharmaceutical and technological companies
- Universities, research centres, tech transfer offices, incubators and accelerators
- A wide range of life science service providers: investors, lawyers, IP consultants, IR agencies

We promote an ecosystem that enables innovative life science companies to start and grow successfully and sustainably.

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