EuropaBio Position on the Supplementary Protection Certificate Export Waiver

This paper outlines the position of EuropaBio (November 2018) and its members on the proposal of amendment of the Regulation (EC) No 469/2009 concerning the supplementary protection certificate (SPC) for medicinal products.

Introduction

Intellectual Property (IP) incentives are key enables of biomedical innovation – they provide the European biotech industry with the oxygen necessary for medical advancement, enable sustained investment, and fundamentally contribute to the economic growth in the sector. EuropaBio finds that the SPC Waiver, in its nature, provides uncertainty for existing and future IP rights held by developers of innovative therapies. Due to the delicate nature of the IP incentives system, rushed introduction of any changes that do not address it in a holistic and balanced manner, may result in a premature and incomplete answer to the perceived problem of low competitiveness of the EU biosimilar and generic manufacturers on the non-EU markets. The potential for weakening IP rights may result in harming innovation in Europe and put thousands of research-based jobs and investments at risk. It may provide only short-term economic growth and benefits while ultimately harming investment in research and development, diminishing Europe's position on the global arena[1]. It is also worth noting that in an EPO-EUIPO report from October 2016, the pharmaceutical sector was listed as the second-most IP-intensive industry[2].

Necessary Safeguards

1) Giving SMEs sufficient time to conduct necessary legal checks

EuropaBio's first and foremost concern is the well-being of the SMEs whose capacity of dealing with IP is significantly lower than that of their larger counterparts. As such, they need more time to ensure that, once the SPC Waiver application is made, their IP rights are not being infringed by the maker.

As the text stands now, the maker wishing to take advantage of the lapsing IP protection period is requested to notify the relevant authority of the wish to use the waiver 28 days before any action to that end is taken. The authority has then 15 days to publish such information, leaving the SPC holders less than 2 weeks to ensure none of their rights are infringed. We do not consider this short period to be enough to conduct all the necessary legal checks allowing the SPC holder to seek remedies in case the making of products under the waiver would infringe IP rights. This is particularly important for SMEs with limited resources. We therefore would like to bring the attention to a necessity of an **extension of the notification period envisioned by the Commission to 90 days.**

2) Shift of burden of proof from the SPC holder to the maker

Within the current legal framework, the SPC holder would need to prove that their IP rights have been, or will be, infringed through by using the waiver to export a product. We believe that this places an unnecessary and unfair stress on the innovative industry, and especially the SMEs, who may lack resources to conduct regular legal checks. We therefore instead propose for the burden of proof to be explicitly moved to the entity claiming that conditions of Article 4 (2) of the Regulation are complied with (the maker). The **makers should, together with the notification of their intention to use the Waiver, provide the authorities with a relevant document proving the IP rights of the SPC holder are not threatened.**

2 European Patent Office, European Intellectual Property Office, Intellectual property rights intensive industries and economic performance in the EU, industry-level analysis report, October 2016

3) Prevention of re-importation to the EU market

Special export packaging *(Article 1 amending Article 4 (2)(c))*

To decrease the main danger of infringement of IP rights, namely an illegal reintroduction to the EU market of the products intended for the third countries, we propose stronger safeguards on the packaging, aiming at clear distinction of internal and external--destined products. Among those**, products falling under the scope of the waiver, should not carry 2D barcode (or 2D data matrix) placement requirement**[3]. This measure would help to monitor possible infringements of the SPC regime, utilizing existing mechanisms normally serving for identification of falsified medicines within the EU market. Such exemptions would also benefit the makers by ensuring they do not have to invest in any additional technologies or means to safeguard the exported products from re-importation.

Additional legal safeguards measures (Article 1 amending Article 4 (new paragraph)

In order to further consolidate the existing measures against any illegal reintroduction of generic products on the EU market, additional legal safeguards should be established.

In situations in which it is suspected that generics or biosimilars developed for export purposes have actually been diverted for domestic use within the EU, there should be a strong presumption in favor of a rapid injunction against the generic company. This would help safeguard the implementation and the scope of the proposed Regulation

4) Preservation of legal certainty *(Preamble (22))*

Fostering investment in research and development requires a degree of legal certainty, which should be strengthened in the Commission's proposal. We argue that only the SPCs applied for after the date of the implementation of the regulation should fall under scope of the regulation. The current phrasing of the proposal suggests that the revision will apply to all SPCs "granted on or after specified date" meaning ones being in the process of review/granting. We see two major issues in maintaining the phrasing of the regulation.

Firstly, if the SPC waiver can be granted for the SPCs applied for prior to the entry into force the regulation, it could affect IP rights retroactively. Furthermore, IP holders should be entitled to the same rights of protection offered to them at the time of application for such protection. Such uncertainty will undoubtedly affect investments in research and development, which is the foundation of SMEs in this sector.

Secondly, some Member State authorities take more time than others to process requests for SPC protection. This may in turn lead to a situation where SPC application, even if filed on the same day in all Member States, could end up being affected by the Waiver only in some of them (where the process is slower and therefore where the authorities do not manage to conclude the procedure before the date of entry of the regulation). As a result, the SPC regime will become even more fragmented, creating an irregular situation even for generic companies, which will end up being able to benefit from the waiver in some countries and not in others.

By ensuring that the exemption covers only SPCs applied for after the date of entry, the proposal would strengthen uniform implementation of the waiver in all Member States.

Conclusions

Any reshaping of the current regime should be done with greatest care, taking into account the positions of the biotech industry, and especially its SMEs. EuropaBio and its members hope to be a reasonable and reliable partner in the effort to increase competitiveness of the European companies while preserving research and development-friendly environment.

The final text of the proposed regulation should stay true to the original intention of the European Commission (i.e. introduction of a waiver for export only) and should ensure the aforementioned safeguards are put in place and enforced. We therefore wish to express our support for a balanced support for the SPC manufacturing waiver, while preserving EU competitive advantage in the space of innovation. We, therefore, welcome the introduction of the legislation as long as the necessary safeguards for protecting innovation are in place.

[3] Introduced by Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use