Public consultation on supplementary protection certificates (SPCs) and patent research exemptions

Submission from IPHA, January 2018

Question 22

Does the EU SPC framework put EU based generics / biosimilars manufacturing at a disadvantage compared with foreign-based manufacturers when exporting generics and biosimilars outside the EU?

	☑ / ☒
Yes	
No	☑
Don't know / no opinion	

We believe that there is no evidence supporting any assertion that the EU SPC framework puts EU-based generics / biosimilars manufacturing at a disadvantage when compared with foreign-based manufacturers when exporting generics and biosimilars outside the EU.

QuintilesIMS, in its 2017 white paper *Assessing the impact of proposals for a Supplementary Protection Certificate (SPC) Manufacturing Exemption in the EU* (the "**QuintilesIMS Report**"), finds that SPC / patent expiry dates in the EU are often earlier (or at least not significantly later) than similar rights in non-EU markets. It is therefore not possible to commercialise generic products in target export markets earlier than would be feasible to do so legally in the EU other than through the promotion of infringing products. We consider that such promotion has the effect of directly harming innovators.

The question of whether or not to adopt an SPC manufacturing waiver is not the only factor impacting upon a potential export strategy to target non-EU markets. There are also a number of environmental factors that must be considered, such as barriers to trade, price levels and the ability to manage commercial relations locally. Sussell et al, in their recent paper *Reconsidering the Economic Impact of*

the EU Manufacturing and Export Provisions ("**Sussell's Paper**") consider that estimates of job growth resulting from the adoption of an SPC are significantly overstated.

There is also evidence to suggest that the environmental factors outlined above (i.e., barriers to trade, price levels, localisation measures) could put European generics at a disadvantage in foreign markets.

Question 23

Does the EU SPC framework put EU based generics / biosimilar manufacturing at a disadvantage compared with foreign-based manufacturers when it comes to placing generics and biosimilars on the EU market when SPC protection in the EU expires?

	☑ / ☒
Yes	
No	☑
Don't know / no opinion	

SPCs directly incentivise R&D investment in Europe. There is no evidence to support the generics industry's claims that SPC-induced delays affect competition. The generic industry's proposal may impact European originators' exports; substituting the export value of originator products for lower value generics thereby reducing employment in innovative pharmaceuticals. It will impact originators' abilities to monitor or enforce their IP rights and it would be too onerous to ensure the limitations of the intended scope of the proposals. .

The Quintiles IMS Report states European SPC expiry dates are not always later than in the target markets and states despite Regulation (EC) No 469/2009 (the "**Regulation**"); generic manufacturers are often "*first to the market*". There is no evidence of advantages to non-EU businesses over EU counterparts. There is a limited opportunity to capitalise on a SPC waiver because expiry dates often occur before target export markets.

Introducing a SPC manufacturing waiver is not likely to change generic medicines manufacturing or affect that sector's EU employment rates. Several economists agree that previous estimates of associated employment growth were overestimated. Potential employment must be weighed against risk to the EU innovation economy. Our view is damage to innovation outweighs the negligible employment growth.

Global and EU generics/biosimilar manufacturers have equal access to the EU market and can launch on the same date. Determinants of generic entry cause delays and are not attributable to the Regulation. Evidence that the Regulation does not cause delays is the CRA study's findings of

correlations between speed of generic products' entries to the EU market and size and value of the generic organisation.

Uncertainties about SPCs' effectiveness could undermine Europe's R&D reputation. Changing the SPC regime could also put Europe's patent restoration system at a disadvantage internationally.

Question 24

If you answered 'yes' to Questions 22 or 23, does the issue matter more for biosimilars than for generics?

N / A.

Question 29

Please give examples of any inconsistencies between national legislation and EU legislation on SPCs and Bolar exemptions, if you know of any.

Each Member States' patent authority has a different procedure in place for granting an SPC. Such administrative differences are likely to result in non-harmonised interpretations of the Regulation.

Directive 2011/83/EC and Directive 2004/28/EC (the "Directives") govern the Bolar exemption which allows early preparatory development of new products to obtain pre-market regulatory approval even when the SPC of the reference medicine is still in force.

Harmonising the application of the exemption will not be achieved because of Member States' discretion in transposing the Directives. Some Member States have transposed the Bolar Directives in a broad manner whereas other Members States have limited a Bolar exemption which is only one use of a patented medicine for the purposes of the abridged authorisation procedure for generics, hybrids and biosimilars in an EEA country.

Non-harmonisation in applying exemptions across the EU is not ideal but is not problematic in the macro sense.

Do you have any suggestions on how to overcome these inconsistencies?

SPC Grant Procedures

If the SPC Regulations are revised it will be opportune to eliminate or minimise administrative differences in Member States

Bolar Exemption

Any harmonisation of the Bolar exemption would necessitate engagement with Member State at a national legislation level because the exemption has been implemented differently across Member States.

Question 30

Have the EU SPCs and Bolar exemptions brought added value compared with national initiatives?

	☑ / ☒
Yes	☑
No	
Don't know	

We agree that the EU SPC rights (created by the Council Regulation (EEC) No. 1768/92, codified as Regulation (EC) No. 469/2009 concerning the SPC for medicinal products, and Regulation (EC) No.1610/96 concerning the creation of an SPC for plant protection products) and Bolar exemptions have brought added value to entities operating in this sector when compared with exclusively national initiatives, as they each have provided much needed clarity on how SPC rights can be enforced during clinical trials (notwithstanding some divergence in implementation across Member States in terms of the Bolar exemptions). Further, as an SPC is effective throughout the EU, this harmonised approach incentivises the biopharmaceutical industry to invest in research and development, innovation and manufacturing in the EU.

On the Bolar exemption we would support proposals to recalibrate the scope of the 'Bolar exemption', however the SPC Regulation does not need to be re-opened to implement these changes; we believe that guidelines from the Commission could achieve this.

Question 37

What would be your preferred option to improve consistent interpretation throughout the EU of the 'substantive' provisions of the SPC regulation (e.g., the scope of protection, eligibility of SPC protection)?

	☑ / ☒
Amend the SPC Regulations to provide extra clarity	
Create a unitary SPC for the unitary patent	
Guidelines developed jointly by the European Commission and EU countries	☑
Don't change the current SPC system – rely on referrals	

to the Court of Justice of the EU	
None of the above, please explain	
Do not know / no opinion	

We consider that the current SPC Regulation should remain in place. As a result of the constantly evolving landscape that the SPC Regulation caters for, it has taken some time for the necessary case law to develop to assist with its interpretation, particularly with regard to technologies / medical advances not anticipated by legislators as it did not exist at the time. We consider that new / amended legislation in this area would not provide further clarity but would instead increase the number of referrals to the Court of Justice of the EU (the "**CJEU**") for interpretation of the new provisions.

Notwithstanding that they do not have binding legal effect, we consider that guidelines developed jointly by the European Commission and Member States would be very useful to summarise / clarify developments in case law that assist with interpretation of the SPC Regulation.

Question 38

Which granting authority would you favour to grant and register a unitary SPC?

	☑ / ☒
EU Intellectual Property Office	
European Patent Office	
A new EU agency	
European Medicines Agency	
EU countries' patent offices (e.g., virtual office approach or mutual recognition with reference offices, under EU rules)	☑
None of the above, please indicate your alternative preference	

While we do not seek a unitary SPC right (except in the case of Unitary Patents (discussed below) but if one is adopted we are of the view that there should be a single granting procedure for obtaining unitary SPCs as this will reduce the administrative burden associated with applying for and registering SPCs and the inconsistencies at national levels.

We recommend that (i) Member States use the existing SPC Regulation to designate a single authority with the ability to grant unitary SPCs; and (ii) a virtual authority comprised of experts from individual Member States' patent offices be set up to grant unitary SPCs. In this regard, we believe that while the grant of the unitary SPC should be made by a virtual authority, and that a right of appeal in respect of that authority's decisions made should be before the Unitary Patent Court (the "**UPC**"). By virtual agency, we mean one similar to that proposed by EFPIA (the European Federation of Pharmaceutical Industries and Associations), ECPA (the European Crop Protection Association) and IFAH (Representing the European Animal Health Industry) comprising of a virtual agency made up from existing staff of national patent offices, who will collectively receive and examine applications for unitary SPCs and take decisions on grant.

We consider that this approach to a unitary SPC would reduce the time and resources required for SPC filings in each Member State, and increase consistency in SPC practice. A key factor contributing to this increased consistency is making the most of expertise already in use in Member State patent offices. Article 3(b) of the UPC Agreement states that it shall apply to any SPC issued for a product protected by a European Patent or a Unified Patent, and so the UPC Agreement had anticipated that it be the court of jurisdiction should one emerge.

Question 39

Which language combination would you prefer for:

	English, French, German, Italian and Spanish (as for the EU Intellectual Property Office)	**English, French and German (as for the European Patent Office)**	**All EU official languages (as for the centralised marketing authorisations)**	**English only**	**None of these (please state your alternative preference)**
…registering unitary SPC applications?		☑			
…publishing unitary SPCs?		☑			