BUSINESSEUROPE

15 January 2018

BusinessEurope Feedback to the Commission Public Consultation on supplementary Protection Certificates (SPCs) and Patent Research Exemptions

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?[1]

As explained in its response on 23 June 2017 in the Allensbach «Survey on the legal aspects of the SPCs in the EU» conducted for the Max Planck Institute for Innovation and Competition and the European Commission, BUSINESSEUROPE is sceptical regarding proposals to introduce a Supplementary Protection Certificate (SPC) manufacturing waiver in the EU for export purposes for the following reasons:

• We are concerned that weakening the SPC framework by a waiver would send a negative signal about EU's respect for intellectual property and commitment to building a knowledge-based economy. Additionally, it could be perceived to be inconsistent with EU's trade policy to consistently argue against localisation policies and more particularly using IP tools to favour domestic production. Finally, such a policy could encourage the introduction of similar exemptions by other countries, which are mostly more competitive than Europe from a manufacturing perspective.

• Introducing a SPC manufacturing waiver would have an effect on European originators' exports to third markets and cause job losses in the EU's innovative pharmaceutical sector. It would further deprive originators of potential licence revenues.

• The potential of such a measure to bring more highly-skilled jobs back to Europe, is questioned because reducing demands of originator products would at the same time risk highly-skilled job losses for the innovative pharmaceutical sector."

BUSINESSEUROPE is ready to discuss the potential job creation in the generic and biosimilar industry in Europe. However, the European Commission should not rush on the introduction of a manufacturing waiver in the SPC regulation. Furthermore, we believe it is essential to maintain the current (up to 5 years) level of SPC protection on the EU market.

[1] Lewiatan - the Polish Confederation, MGYOSZ – Business Hungary, CEA – the Croatian Employers' Association, OEB – the Cyprus Employers & Industrialists Federation, clearly concur with the European Commission and the Charles River Associate study "Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe" that currently the SPC regulation puts the European pharmaceutical industry at strong disadvantage vis-à-vis foreign based manufacturers. As the CRA study demonstrates, the SPC manufacturing waiver would give a boost to the EU based pharmaceutical industry in terms of sales (up to €9.5 billion by 2025) and direct jobs (25,000). It would also benefit the API industry in Europe and SMEs and internal market of the EU. The European Commission should therefore rapidly implement this proposal.

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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?

As regards to access to the EU market, the same playing field should apply to all generics/biosimilar manufacturers. To allow for necessary acts and preparations for EU based manufacturers, Bolar exemptions have been introduced into EU law. A harmonized application of the Bolar provisions throughout the EU should allow for a timely introduction into the EU market after SPC expiry.

Question 29. Please give examples of any inconsistencies between national legislation and EU legislation on SPCs and Bolar exemptions, if you know of any.

There are no variations with regard to the EU Member States implementation of the SPC regulations. There are however significant variations between the various national patent offices with regard to obtaining SPCs, where national procedural provisions vary and different (national) case law has to be taken into account.

The implementation of the Bolar provisions as introduced in Art. 13(6) of Directive 2001/82/EC / Art. 10(6) of Directive 2001/83/EC has not been uniform resulting in differences between the Member States. Some EU Member States, such Germany, Denmark, Italy, Spain and the UK, introduced a Bolar exemption which covers the use of a patented medicine for the purposes of obtaining regulatory approval for any medicinal product in any country (wide scope). Other Member States, such as Belgium, Sweden and the Netherlands, introduced a Bolar exemption which covers one use of a patented medicine for the purposes of the abridged authorisation procedure for generics, hybrids and biosimilars in an EEA country only (narrow scope). A harmonized application of the Bolar provisions throughout the EU should include necessary acts and preparations for any medicinal product to allow for a timely introduction into the EU market after SPC expiry.

Question 30. Have the EU SPCs and Bolar exemptions brought added value compared with national initiatives?

SPCs have brought enormous value for innovations in the EU. A unitary SPC[2] would bring additional benefits by providing a harmonized system and unified scope of protection in the EU and at the same time increase transparency for all involved parties.

With regard to the EU Bolar exemption, it has provided a much-needed clarity on how patent rights can be enforced during clinical trials. This applies even though it has been implemented in the 'wide' scope in some countries and a 'narrow' scope in others. As

[2] CEOE - the Confederation of Employers and Industries of Spain, does not support the response to questions 30, 36, 37, 38 and 39 on the unitary SPC.

such, harmonized application of the Bolar exemption in the EU would bring further clarity and added value.

Question 36. Is there a risk that the future Unified Patent Court could develop a practice regarding the Bolar patent exemption that conflicts with the one consolidated in Irish, UK and German law/practice?

BUSINESSEUROPE stresses the importance of developing harmonised jurisprudence by the Unified Patent Court on these topics.

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

Harmonization of SPCs can be achieved through the introduction of a unitary SPC having the same territorial scope as the unitary patent, with one granting procedure and one granting authority. By harmonizing the European system for obtaining both patents and SPCs, this unifies the variations between national systems and prevents fragmentation. Further, a unitary SPC is also considered to be mandatory for the successful introduction of a unitary patent system as such. The creation of a unitary SPC based on unitary patents could be done in a stand-alone regulation.

In addition, there is a strong need for the current system of national SPCs based on national patents or European patents validated in member states. Consequently, the current SPC regulation should remain in place. Clarifications of the regulation have been obtained by the decisions of the CJEU. These decisions can just be applied together with the existing regulation or further laid down in examination guidelines.

Question 38. Which granting authority would you favour to grant and register a unitary SPC?

Tick Box 5.

For the granting authority, elements such as the establishment of a harmonized and uniform granting procedure, a transparent and efficient register for unitary SPCs and the possibility for appeals of decisions in court are important. A granting authority should consequently be chosen along these principles.

BusinessEurope is aware of and ready to discuss the proposal that unitary SPCs could be granted by a virtual office being composed of experienced patent examiners out of national patent offices, provided it meets the above requirements or an alternative proposal that they should be granted by a single authority namely the EPO on the basis of Articles 63 and 149a of the European Patent Convention.

The appeal process should be before the UPC.

Question 39. Which language combination would you prefer?

English, French and German as in the EPO.

Question 40. Should the unitary SPC be available only for products authorised by way of a centralised marketing authorisation (e.g. assessed by the European Medicines Agency)?

No, as this would not take differences in marketing authorizations for different sectors into account. Any marketing authorisation, granted in accordance with EU law, should be eligible as a basis for the grant of a unitary SPC, for unitary SPCs being equally applicable in the sectors of human and animal medicines, as well as for agrochemicals.

Question 41. Some experts believe that no legislation is needed for the future unitary patent system to work with the current SPC framework (i.e. the unitary patent would be extended in each participating EU country by applying for the national SPC).

… there is EU legislation on a “unitary-SPC” – **Yes**

… here is EU legislation, or a judgement from the Court of Justice of the EU, stating that the current SPC framework is compatible with the “unitary patent” - **Don't know /no opinion**

… if the Commission issues a communication stating that the current SPC framework is compatible with the “unitary patent” – **No**

Question 42. Would it be useful for a more consistent/integrated EU approach on the patent Bolar and research exemptions if a group of Commission and EU country experts is set up to monitor developments relating to these exemptions?

Yes.

Question 43. What would be the benefits of a unitary SPC? (From 1 – Strongly disagree to 5– Strongly Agree)

Boost value of investments – **Agree**

Reduce red tape relating to litigation – **Strongly agree**

Reduce red tape relating to registration – **Strongly agree**

Same protection in all EU – **Strongly agree**

Legal certainty – **Strongly agree**

Reduce maintenance costs – **Strongly agree**

Specialised court – **Strongly agree**

Make licensing easier – **Agree**

Question 44. What would be the impact of the introduction of an SPC manufacturing waiver in the EU?[3]

It would increase the risk of infringement of my SPCs in the EU – **Strongly agree**

It would reduce protection to recoup our investments in R&D in the EU – **Agree**

In the short term, it would reduce our sales in countries outsides the EU when protection abroad expires – **Strongly agree**

In the long term, it would reduce our sales in countries outside the EU when protection abroad expires – **Strongly agree**

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[3] Lewiatan - the Polish Confederation, MGYOSZ – Business Hungary, CEA – the Croatian Employers' Association, OEB – the Cyprus Employers & Industrialists Federation, strongly believe that there would be no risk of infringement with a manufacturing waiver, as demonstrated by the CRA study, and it would not reduce the SPC protection in Europe. As to the impact on the export of originator drugs from Europe, Lewiatan - the Polish Confederation, MGYOSZ – Business Hungary, CEA – the Croatian Employers' Association, OEB – the Cyprus Employers & Industrialists Federation, believe that generic and biosimilar competition outside the EU comes anyway from non-EU countries where generics and biosimilars are produced, since the absence of the waiver today does not mean that generics and biosimilars are not produced and exported. It means that generics and biosimilars are produced in non-EU countries and exported from non-EU countries.