AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Consultation response

Public consultation on Supplementary Protection Certificates (SPCs) and patent research exemptions

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2016, directly supports more than 4.5 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium • **T** +32 2 513 68 92
info@amchameu.eu • amchameu.eu • European Transparency Register: 5265780509-97

Question 4: How many marketing authorisations were granted to you in the periods below? 4 periods are mentioned.
No response
Question 5: What percentage of your sales take place during the SPC protection period compared with the whole protection period (patent and SPC)?
No response
Question 6: "For innovative products or potential innovative products, does the possibility of getting EU SPC protection play a role when your company/organisation is deciding on the following investments?
No response
Question 7: Has a prospective product's eligibility for SPC protection ever been a decisive factor in its development (i.e., without an SPC you would have discarded it despite having already invested in part of its development)?
Yes SPCs and other forms of IP protection are essential to the innovative R&D based pharmaceutical industry, and decisive in developing prospective products. SPCs and other incentives are key to driving investment and innovation to bring benefits to patients and address public health needs. They provide transparency and certainty that facilitate investment decisions, which carry outsized risk in the healthcare innovation space. Without SPCs and other IP incentives, innovators do not have the predictability and certainty they need to collaborate with partners, compete successfully and accelerate the launch of new products. Weakening SPC protection would lead to a considerable amount of uncertainty and could harm R&D prospects. Moreover, it would send a negative signal about the EU's attractiveness for investment. Any step towards weakening these incentives, whether this is intended by the Commission or not, not only threatens the development and diffusion of medical advancements, but could undermine the European economy.
Question 8: Have the SPC regulations influenced the prioritisation of certain types of innovation in your organisation?
No response
Question 9: Select the 4 most relevant drivers that affect your decisions on the geographical location/allocation of investments in innovation and manufacturing
For the comment box: As a trade association we cannot give top 4 list of criteria: this is likely to differ from company to company. However all the listed elements play a role in investment decisions, and IP is usually a key criteria when making investment decisions. We would also note the inconsistency in identifying individual components of the IP system when the system needs to be considered as a whole.
Question 10: When you invest on innovation or manufacturing in countries that do not grant SPC protection, what are the 4 main drivers that influence your decision?".

For the comment box. As a trade association we cannot give top 4 list of criteria: this is likely to differ from company to company. However all the listed elements play a role in investment decisions, and IP is usually a key criteria when making investment decisions. In relation to the total investment across our industries, only a minority of investments take place in countries without SPC- or RDP-like protection. As such, we would challenge the assumption that **major** investment took place in these countries. We would also note the inconsistency in not including any points on IP when the question refers to a lack of SPCs.
Question 11: Have authorities in different EU countries ever taken different decisions on SPC applications for one (or more) of your products?
No response
Question 12: Have courts in different EU countries ever taken different decisions on the SPC of one of your products (e.g the validity of your SPC was upheld by courts in some EU countries but revoked by others; some EU country courts concluded that your SPC had been infringed while others did not)?
No response
Question 13: How would you rate the degree of complexity of registration procedures for SPCs in the EU?
Low The registration procedures for SPCs in the EU are generally straightforward, albeit duplicated across all Member States. The introduction of a unitary SPC - which would allow companies to apply with a single granting office - would simplify the procedure and administrative burden to apply for SPCs across separate Member States. It would also simplify accessibility to information about the SPC.
Question 14: How would you rate the degree of complexity of court litigation of SPCs in the EU?
reasonable
Question 15: Is the cost of registering and maintaining an SPC in all 28 EU countries proportionate?
YES, the cost is always relatively low compared with product sales
Question 16: Have you ever abandoned (or avoided) applying for SPC registration in an EU country owing to…?
No response
Question 17: Please give if possible a breakdown of all costs in euros of registering/maintaining your SPCs (e.g. patent agents' fees for each country, in-house staff costs, administrative fees).
No response

Question 18: Does the geographical scope of your requested SPC generally match the geographical scope of the territory in which you market the pharmaceutical products?
No response
Question 19: In your experience, when enforcing an SPC in only one EU country, is the cost of enforcing SPCs proportionate?
Yes
Question 20: When enforcing an SPC in multiple EU countries, is the cost of enforcing SPCs proportionate?
Yes
Question 21: Is the length of proceedings relating to enforcing SPCs satisfactory?
yes
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?
No. Several studies (See Q. 23 references) show that claims regarding the benefits of an SPC waiver are at best exaggerated. Firstly, SPCs/ patents in the EU often expire earlier or not significantly later than IPR in foreign markets. In such cases, it is not possible to commercialise generic products in target export markets except by promoting infringing products, harming innovators. Many other factors affect potential export strategies to a target country which may disadvantage European generics in foreign markets. E.g. trade barriers, price levels, competitiveness of local generics, ability to manage commercial relations locally and incentives favouring domestic producers. SPCs are unlikely to be the key factor determining generic manufacturing location. Studies also challenge the claim that an SPC waiver would create jobs in Europe. When considering parameters of economic uncertainty, the estimated number of jobs created is not statistically distinguishable from zero. The proposal may though harm exports of European originators by lessening their export value, and result in significant job losses to the EU's innovative pharma sector (see Q. 23), a major contributor to the EU's trade balance. A waiver risks undermining this in a race to the bottom. These 3 elements strongly call into question the benefits of an SPC waiver. What is certain is that it would de facto weaken the IP system. This would disadvantage Europe vs. e.g. USA/ Japan, and emerging markets e.g. China that are considering improvements to their IP. A waiver would encourage similar exemptions in other countries with more competitive manufacturing bases. This will send a negative signal to US / global investors - who may see this as a first step in undermining IP - as to the prospects of the European R&D sector. The EU should respect IP and encouraging other countries e.g. China, Russia and India to raise their levels of IP protection – not take measures to exploit their lack of IP.

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?

No.

IP incentives not only support innovation but also competition, and pave the way for generic medicines when exclusivity rights expire. Innovative medicines of today are the generics and biosimilars of tomorrow: by weakening the current EU IP framework, and potentially the long-term flow of pharmaceutical innovation in the EU, it is the future of the generic and biosimilar offer overall that is at stake.

European generic companies are often first to market in the EU under the current system, and are therefore not at a disadvantage compared with foreign-based manufacturers. An SPC waiver allowing stockpiling of generics and biosimilars in the EU would therefore not level the playing field with foreign sourced generics or biosimilars. Instead, it stands to negatively impact and risk thousands of jobs in the innovative pharmaceutical sector. Indeed, the study found that adoption of such a waiver would lead to the loss of between 4,500-7,700 direct jobs in the industry with an additional loss of between 19,000 and 32,000 indirect job losses in the innovation economy. It would also result into a decrease of between EUR 215 million to EUR 364 million in R&D investment.

With the potential adoption of an SPC waiver, SPCs would no longer confer the same exclusivity rights as patents. This contradicts the fundamental purpose of the SPC – that is, to compensate innovators for the substantial patent term lost due to lengthy development timelines Any weakening of the EU's IP incentives framework would undercut pharmaceutical R&D investment by large and small innovators alike, and put European innovators at a disadvantage with competitors based in countries with more competitive IP systems.

Please see:

Quintiles IMS, *Assessing the impact of proposals for an SPC Manufacturing Exemption in the EU*, 2017

Sussell et al., *Reconsidering the economic impact of the EU manufacturing and export provisions*, 2017

Pugatch Consilium, *Unintended Consequences*, 2017

Question 24. If you answered 'yes' to Questions 22 or 23, does the issue matter more for biosimilars than for generics?

N/A

Question 25: Is SPC protection available for all your innovative types? (e.g certain categories of medical devices, veterinary medicines, or plant – related products)

No.

AmCham EU members represent over 155 companies that invest in a range of innovative products both in the healthcare sector (including medical devices, diagnostics, formulations), plant protection sector and more broadly in other sectors (e.g. energy and digital technology) for which SPC protection is not available. The type and degree of IP protection available for different innovative product types is largely a product of varying development and regulatory timelines and processes across different sectors.

Question 26: In your experience, do other jurisdictions (e.g. the US or Japan) provide for SPC – type protection to certain types of innovations you develop that are not eligible for an SPC in the EU?
Yes
Question 27: Please give examples of SPC – protected products of yours that have significantly improved public health and where the SPC played a key role in their development.
Unmet medical needs of critical importance to Europe's ageing population - including potential treatments for Alzheimer's and other neurological conditions - include areas of complex R&D that require the reaffirming, not the weakening, of incentives for long-term research. The European incentives framework for the biopharmaceutical sector comprises several components, including SPCs that stimulate innovation to address a complex range of medical needs. These work together to provide a coherent and complementary set of incentives, recognising the inherent risk and amount of capital investment required for innovation in all R&D intensive sectors of the European economy. When prospects of return are uncertain or non-existent for a given sector, investment risks being diverted towards other sectors of the economy or towards other geographical areas that are perceived as less risky and provide more certainty on financial returns. As a key element in the EU's framework of incentives, SPCs play a important role in this decision. The current IP incentives framework has worked for Europe, generating a healthy market for both innovation and generic competition. As challenges to healthcare— from Alzheimer's to Zika —grow ever more complex, an environment of certainty in Europe promotes, not hinders, investment and research into unmet healthcare needs
Question 28: Are there some types of products that you do not invest in despite the possibility of getting a SPC, or that you invest in but for which an SPC in not relevant (e.g. antibiotics, medicines for the treatment of orphan or neglected diseases)?
Do not know/No opinion. Antibiotics and orphan medicines are eligible for SPCs so are therefore wholly relevant in this case. In the case of orphan medicines, additional incentives (i.e. the Orphan Regulation) exist to drive the development of treatment for rare diseases and address a very specific unmet need. Since the introduction of the Orphan Regulation in 2000, the number of EU approved orphan drugs has gone up from eight to about 133 treatments today. In the case of developing new antibiotics, there is a global consensus that a complementary mix of different and complementary incentives is needed, while acknowledging that there is no 'one-size-fits-all' solution and that policies should be tailored to each specific national context.
Question 29. Please give examples of any inconsistencies between national legislation and EU legislation on SPCs and Bolar exemptions, if you know of any.
No response
Question 30. Have the EU SPCs and Bolar exemptions brought added value compared with national initiatives?

Yes. Uniform EU SPC legislation has brought significant value to the biopharmaceutical industry, providing innovative R&D companies with more incentives to invest and manufacture throughout Europe.
Question 31: On biosimilars products…
No response
Question 32: When you develop a biosimilar, do you always conduct the R&D and manufacturing in the same location?
No response
Question 33: Would it be possible to grant national SPCs for a product covered by the future European patent with unitary effect (unitary patent) without legislative changes?
Yes
Question 34: In all EU countries, do you have certainty on whether your activities relating to HTA are exempt from patent/SPC infringement?
No response
Question 35: Have you ever moved to another country clinical trials or testing relating to HTA because of uncertainty about the scope of the Bolar/research patent exemption in the country requiring the HTA?
No response
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?
No response
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 (select)** • **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 AmCham EU supports the creation of a Unitary SPC which can be obtained with a single granting procedure. This will reduce administrative hurdles faced when applying for and registering SPCs.

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

No response

Question 39: Which language combination would you prefer for…

No response

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 response

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). Would you use the unitary patent system if…

Would you use the unitary patent system if…

	Yes	No	Don't know /no opinion
… there is EU legislation on a "unitary-SPC"	○	○	○
… there 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"	○	○	○
…. if the Commission issues a communication stating that the current SPC framework is compatible with the "unitary patent"	○	○	○

1. Yes

2 and 3 No opinion

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**
- No - legislative action would still be needed
- No - and no legislative action is needed
- Don't know/no opinion

Question 43: What would be the benefits of a unitary SPC?

	Strongly disagree	Disagree	Neither	Agree	Strongly agree	No opinion
Boost value of investments				X		
Reduce red tape relating to litigation				X		
Reduce red tape relating to registration					X	
Same protection in all EU					X	
Legal certainty				X		
Reduce maintenance costs					X	
Specialised court				X		
Make licensing easier				X		

44. What would be the impact of the introduction of an SPC manufacturing waiver* in the EU?

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: Strongly Agree

In the short term, it would reduce our sales in countries outside 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

https://ec.europa.eu/eusurvey/runner/c48fab55-7cbf-4e0a-9891-1f07d54a4838?draftid=894dc748-d9c6-407c-bf7c-a39181d6eea6