Public consultation on Supplementary Protection Certificates (SPC) and patent research exemptions for sectors whose products are subject to regulated market authorisations.

Fields marked with * are mandatory.

PRELIMINARY FILTER

Given the technical, complex nature of the patent and supplementary protection certificate (SPC) framework, we recommend that respondents enlist the help of in-house or external experts.

*Which one of the following categories best describes you?

- I. You are a citizen and do not fall into any of the categories below
- II. You represent a research-based organisation/company ("innovator" or "originator"). For example: - Large pharmaceutical company focused mainly on original pharmaceutical or plant protection products - Start up or SME focused on innovative products; - An innovator in products not eligible for SPC protection (e.g. medical devices) - An association of the above type of companies - Research organisation other than a university - University or technology transfer office - Contracting research organisation conducting clinical trials.
- III. You represent a generics and/or biosimilars organisation/company. For example: - Large pharmaceutical company focused mainly on generic and/or biosimilar pharmaceutical or plant protection products - Start-up or SME focused on generics/biosimilars - Contracting research organisation conducting bioequivalence studies - An association of companies - Producers of active pharmaceutical ingredients (APIs) for third parties (whether the third party is an originator or generics/biosimilars company).
- IV. You are a large/specialised consumer of medicines or pesticides (individual consumer or a purchaser of large lots), a health professional, or you help set the regulated prices of medicines, negotiate reimbursement quotas of medicines, or distribute medicines or pesticides, etc. For example: - Patients' association, or individual patients with specialised knowledge of industrial property relating to pharmaceutical products - Farmers' association, or individual farmers with specialised knowledge of industrial property relating to plant protection products - Hospital or hospital association - Health Ministry - Doctor or doctors' association - Wholesaler or distributor of medicines or pesticides - Pharmacist or pharmacists associations - Health Technology Assessment Agency - Agency involved in setting the price of medicines - Health provider or health insurer - Agency involved in medicine tenders.
- V. You represent a patent office, judge or IP attorney or agent
- VI. You are a public authority not falling under categories IV or V. For example: a ministry or agency dealing with e.g. science, industry, trade or competition policies at international, national or local level.

* Please indicate how you prefer your response to be published on the Commission's website

Regardless of the option you choose, your contribution may be subject to a request for access to documents under Regulation 1049/2001 on public access to European Parliament, Council and Commission documents. In this case, the request will be assessed against the conditions set out in the Regulation and in accordance with applicable data protection rules.

- With your name: I consent to the publication of all information in my contribution and I declare that none of it is subject to copyright restrictions that prevent publication
- Anonymously: I consent to the publication of all information in my contribution and I declare that none of it is subject to copyright restrictions that prevent publication

* Is your organisation registered in the Transparency Register of the European Commission and the European Parliament?

If you are not answering this questionnaire as an individual, please sign up to the TransparencyRegister.

If your organisation/institution answers the questionnaire and is not registered, the Commission will process your contribution under a separate category 'non-registered organisations/businesses'.

- Yes
- No
- Not applicable

Please indicate your organisation's identification number in the Transparency Register.

20 character(s) maximum

I. GENERAL QUESTIONS, ESPECIALLY ADDRESSED TO THE GENERAL PUBLIC

Intellectual property (IP), such as patents or trademarks, plays a key role in encouraging investment in innovation. A 2013 study (IP Rights intensive industries: Contribution to economic performance and employment in Europe, EUIPO, 2013) revealed that 39% of economic activity in the EU is generated by IP-intensive industries, while 26% of all employment is provided directly by these industries.

Industry sectors whose products are subject to regulated market authorisations, such as the pharmaceutical, medical devices and agrochemical industries, rely heavily on industrial property protection through patents, Supplementary Patent Certificates (SPCs) and data /market exclusivity.

SPCs are a sui generis IP right that constitute an extension (of up to five years) to the term of a patent right (of twenty years). SPCs aim to offset the loss of effective patent protection that occurs due to the compulsory and lengthy testing and clinical trials that products require prior to obtaining regulatory marketing approval. The relevant EU legislation is Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96 on SPC covering pharmaceutical and plant protection products respectively.

The Bolar patent exemption aims at speeding up the entry of generic medicines into the market by allowing early preparatory development on generics to obtain pre-market regulatory approval even when the SPC of the reference medicine is still in force. It is regulated at EU level for the pharmaceutical industry only through Article 13(6) of Directive 2001/82/EC and Article 10(6) of Directive 2001/83/EC. The scope of the EU Bolar exemption has been updated in some EU MS, inter alia, to meet new pharmaceutical-related requirements.

The specific industrial property legal framework in the EU for industry sectors whose products are subject to regulated market authorisations might present several features not fit for purpose in today's global economy and in the light of new regulatory requirements.

Firstly, existing SPCs are granted and enforced at national level, which can result in Single Market fragmentation. There are cases where some Member States have granted SPC applications while the very same application has been either refused or granted with a different scope in other Member States.

Secondly, Member States implement the 'Bolar exemption' in different ways: on the one hand, some Member States do not allow the supply of active pharmaceutical ingredients to EU-based generic manufacturers for the purpose of seeking marketing authorisation, and on the other hand, in a number of Member States, it is not certain whether testing in the EU by originators and biosimilars can benefit from these exemptions for the purpose of seeking marketing authorisation in the EU and in non-EU countries, or for meeting emerging regulatory requirements such as those related to health technology assessment.

Thirdly, manufacturers of generic and biosimilar medicines based in non-EU countries where SPC protection does not exist (e.g. in Brazil, Russia, India and China) enter markets in which patent protection expired up to five years earlier than EU-based manufacturers. This is possible because EU-based manufacturers are not allowed to produce in EU Member States during the period of the SPC protection of the reference medicine. Such a situation could lead to a lack of playing field between EU and non EU manufacturers with an advantage for non EU manufacturers.

The Single Market Strategy, adopted in October 2015 (COM(2015)550), announced that the Commission will "consult, consider and propose further measures, as appropriate, to improve the patent system in Europe, notably for pharmaceutical and other industries whose products are subject to regulated market authorisations". In particular, the Strategy undertook to explore a recalibration of certain aspects of patent and SPC protection, and announced that this recalibration could mainly comprise the following three elements: the creation of a European SPC title; an update of the scope of the EU patent research exemptions; and the introduction of an SPC manufacturing waiver (the so-called 'SPC manufacturing waiver' for export purposes would allow EU based manufacturers of generics /biosimilars manufacturing their products during the EU SPC term of the reference medicine to export their products to countries with no SPC protection). The European Commission published an "inception impact assessment" on 15 February 2017.
The current public consultation seeks to gather feedback of all stakeholders on the way the SPC system currently functions in the EU and its effects on trade and competitiveness in particular.

The Commission will report on the results of its consultation which, together with ongoing evaluation studies, will help the Commission assess whether the EU SPC framework is still fit for purpose or needs to be recalibrated, notably as regards the aspects set out in Single Market Strategy.

Disclaimer

1. Did you know what a “supplementary protection certificate” (SPC) for pharmaceutical and/or plant protection products was before you read the introductory part of this survey?

- Yes
- No

*2. Are you aware of the existence of EU legislation on SPCs for pharmaceutical products such as medicines?

- Yes
- No

2.1. Do you agree that SPC legislation has encouraged investments for innovation in pharmaceuticals?

- Yes
- No

2.2. Do you feel that SPC legislation might not be efficient in encouraging the development of some types of pharmaceutical/health products for certain types of health-related treatments or conditions?

- Yes
- No
- Don't know/no opinion

Please specify in which treatments or health conditions (maximum 100 characters with spaces)

100 character(s) maximum

2.3. Should SPC legislation be extended to apply to additional types of pharmaceutical/health products not currently covered?

- Yes
- No

- Don't know/no opinion

Please specify which types of products (maximum 100 characters with spaces)

100 character(s) maximum

2.4. Do you think that SCP legislation has contributed, among other things, to the growth of the pharmaceutical industry in the EU?

- Yes
- No

*3. Are you aware of the existence of EU legislation on SPCs for plant protection products such as pesticides?

- Yes
- No

3.1. Do you agree that SPC legislation has encouraged investments for innovation in plant protection products such as pesticides?

- Yes
- No

3.2. Do you feel that SPC legislation might not be efficient in encouraging the development of some types of plant protection products for certain types of uses required by crop treatment?

- Yes
- No
- Don't know/no opinion

Please specify which crop treatments (maximum 100 characters with spaces)

100 character(s) maximum

3.3. Do you think that SPC legislation has contributed, among other things, to the growth of the plant protection products industry in the EU?

- Yes
- No

Sometimes the medicines we buy (or their 'active pharmaceutical ingredient(s)', i.e. the main component (s) of the medicine) are manufactured on another continent. Factories that manufacture pharmaceutical products outside the EU need to comply with the EU's strict criteria/rules to be able to sell their products in the EU. Many pharmaceutical companies are global players with a safe and global supply system that produce and distribute medicines all around the world. It's been argued that SPC protection in the EU might encourage certain pharmaceutical companies (producers of generic medicines) to produce their

medicines outside the EU and sell them in the EU.

4. Do you usually know where the medicines that you buy are made?

- Yes, and I do care where they're produced
- Yes, but I don't care where they're produced
- No, but I do care where they're produced even if I'm not aware most of the time
- No, and I don't care where they're produced

Please explain your answer, e.g. if you are worried about safety/quality issues (max. of 1.000 characters including spaces)

1000 character(s) maximum

II. INNOVATORS

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Disclaimer

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The following questions relates to the profile of the respondent:

*1. Mark the type of company/organisation that you represent:

- ○ Company (250+ employees annual turnover = €50 million+ annual balance sheet = €43 million+)
- ○ Small/medium company (except start-up) (fewer than 250 employees annual turnover – €50 million or less annual balance sheet = €43 million or less)
- ○ Start-up
- ○ Association - National
- ○ Association - European
- ○ University or university technology transfer office
- ○ Research organisation (other than university)
- ○ Contracting research organisation (other than a university), e.g. that conducts clinical trials
- ○ Other (please specify)

Free Text Question

50 character(s) maximum

* 1.1. If you represent a company, is it a:

- Parent company
- Subsidiary
- Independent company

* 1.2. Is the parent company (i.e. global headquarters) registered in the EU?

Yes
No

1.2.1. If “yes”, in which EU country?

20 character(s) maximum

1.3. Where is your company/organisation based?

- United States
- Switzerland
- India
- Canada
- China
- EU
- Japan
- Korea
- Singapore
- Other

Please specify

50 character(s) maximum

1.4. Your company (or a branch) is:

- research-based only ("originator")
- Mostly originator - but we also own a separate branch or business activity that develops or markets generics and/or biosimilars.

1.5. If you represent a company, please tell us about these products:

	Does your business work on these product types?	Which product(s) best represent(s) of your business?	% of your total turnover worldwide (approximately)
* Human medicinal			
* Veterinary medicinal			
* Plant protection			
* Medical devices			
* All your products			

2. What is the geographical scope of your commercial activity?

- ○ Mostly worldwide
- ○ EU-wide
- ○ One EU country only
- ○ Other: please specify

Please specify

50 character(s) maximum

3. Tell us more about your business activities in these geographical areas:

	% of your total employees	% of your turnover	% of your manufacturing output (whether outsourced or not)	% of your investment in clinical trials, or field trials for crop products	% of your inve (excluding
EU					
Switzerland					
Korea					
Japan					
United States					
China					
Singapore					
Canada					
India					

The next few questions are about how effective supplementary protection certificates (SPCs) and Bolar exemptions are in the EU.

We want to find out how much progress has been made in meeting the following objectives (from SPC legislation adopted in the 1990s):

- attracting research
- preventing delocalisation
- protection for long enough to recover investment
- promoting essential innovation for patients
- competition through innovation
- limiting the negative effects of fragmentation.

One indicator of trends in innovation in pharmaceutical/plant protection products is the number of marketing authorisations granted.

This information is publicly available. But we'd like to find out more about marketing authorisations from you.

4. How many marketing authorisations were granted to you in the periods below?

Please include (if possible) any authorisations granted to companies that have since changed structure due to mergers, acquisitions or other modifications.

	Number of marketing authorisations
1980 and 1990 (Introduction of SPC-type protection in the US)	
1991 and 2000 (Introduction of SPC protection in the EU)	
2001 and 2010	
After 2010	
Don't know/not applicable	

5. What percentage of your sales take place during the SPC protection period compared with the whole protection period (patent and SPC)?

Please select the 2 most representative ranges.

	Typically over 75% of the product sales occur during the SPC term	51% to 75%	26% to 50%	0% to 25%	Too much variation in our SPC portfolio to say	Don't know
Sales value	○	○	○	○	○	○
-	○	○	○	○	○	○

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?

between 5 and 5 answered rows

	YES, always	YES, to some extent	YES, but only if the investment will take place in the EU	NO	Don't know	Other: please specify
R&D (excluding clinical /field trials)	○	○	○	○	○	○
Clinical trials (medicinal products), or field trials (for plant protection products)	○	○	○	○	○	○
Manufacturing	○	○	○	○	○	○
Distribution	○	○	○	○	○	○
Marketing in EU Countries	○	○	○	○	○	○

If other, please specify:

Please give examples of the SPC protection importance to recoup your investment, if possible (max. 1 500 characters, incl. spaces):

1500 character(s) maximum

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
No
Don't know

If you answered ‘yes’ to Question 7, please give examples of such products and the SPC importance, if possible, in the box below.

1500 character(s) maximum

If you answered ‘yes’ to Question 7, was the prospective product being developed (or did most of its development take place) in the EU?

Yes
No
Don't know

Please give examples of such products and SPC importance, if possible, in the box below.

1500 character(s) maximum

8. Have the SPC regulations influenced the prioritisation of certain types of innovation in your organisation? (e.g. oncology or highly sought-after treatments)

Yes
No
Don't know

If you answered ‘yes’ to Question 8, please give examples, if possible, in the box below.

1500 character(s) maximum

The SPC is not the only factor that influences decision-making on investment in innovation, the location of innovation activities and manufacturing.

We’d like to find out how much you think the SPC affects your company’s/organisation’s decisions on where to locate innovation and manufacturing activities.

9. Select the 4 most relevant drivers that affect your decisions on the geographical location/allocation of

investments in innovation and manufacturing.

between 1 and 4 answered rows

	Investment in research (excluding clinical trials /field trials)	Investments in clinical trials (for medicines) or field trials (for plant protection products)	Investments in manufacturing
Availability of SPC-type protection	○	○	○
Availability of regulatory data protection	○	○	○
Availability of orphan incentives (e. g., market exclusivity)	○	○	○
Good health infrastructure (e.g. modern hospitals)	○	○	○
Proximity of research universities	○	○	○
An effective regulatory agency	○	○	○
Less strict regulatory legislation	○	○	○
Proximity to your manufacturing plants	○	○	○
Availability of public/private funding for our activities	○	○	○
Labour cost	○	○	○
Access to high-skilled labour	○	○	○
Easier to recruit patients or access to treatment groups	○	○	○
Large market (in terms of potential sales in the country where we decide to invest)	○	○	○
Taxation	○	○	○
Proximity to the place where the product research was carried out	○	○	○
Proximity to the place where the clinical trials (or filed trials) for the product were carried out	○	○	○
Possibility of getting “good manufacturing practices” (GMP) from the FDA and/or EMA for the factories based in that country	○	○	○

We outsource most of our manufacturing	○	○	○
Other, please specify	○	○	○

Please substantiate your answers (max. 2 500 characters, incl. spaces).

2500 character(s) maximum

SPC protection is designed to encourage innovation.

But since its introduction in the 1990s, major investments in innovation have taken place in countries with:

- no SPC protection
- no data or market exclusivity (e.g. some Asian countries).

In Question 10, we'd like to find out what other factors have encouraged you to invest in countries with no SPC protection

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?

between 1 and 4 answered rows

	In relation to investments in research (excluding clinical trials/field trials)	Investments in clinical (for medicines)/field trials (for plant protection products)	Investments in manufacturing
Good health infrastructure (e.g. modern hospitals)	○	○	○
Proximity of research universities	○	○	○
An effective regulatory agency	○	○	○
Less strict regulatory legislation	○	○	○
Proximity to your manufacturing plants	○	○	○
Availability of public/private funding	○	○	○
Labour cost	○	○	○
Access to high-skilled labour	○	○	○
Easier to recruit patients/easier access to treatment groups	○	○	○
Large market (in terms of potential sales in the country where we decide to invest)	○	○	○
Taxation	○	○	○
Proximity to the place where the product research was carried out	○	○	○
Proximity to the place where the clinical trials (or filed trials) for the product were carried out	○	○	○
Possibility of getting “good manufacturing practices” (GMP) from the FDA and/or EMA for the factories located in those countries	○	○	○
We outsource most of our manufacturing	○	○	○
Other, please specify	○	○	○

Please explain why those drivers are more important that SPC (max. 2 500 characters, incl. spaces)

2500 character(s) maximum

SPCs are regulated under EU law (Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96), but granted in each EU country by a national authority.

- They are enforced nationally in national courts.
- Registration procedures can vary between EU countries.
- Sometimes, authorities (grant authority or court) in different EU countries can reach different conclusions on the validity or scope of the SPC protection they grant (or refuse) in their country for the same product.
- National courts have referred several questions on the interpretation of SPC legislation to the Court of Justice of the EU.

In the next few questions, we'd like to hear about your experience of how harmonised SPC protection is across the EU.

11. Have authorities in different EU countries ever taken different decisions on SPC applications for one (or more) of your products?

Examples: some EU countries granted SPC national applications for one of your products but refused others; you were granted different durations of SPC protection for one of your products in different EU countries; national grant authorities interpreted EU Court of Justice rulings differently).

- Yes
- No
- Don't know

If you answered 'yes' to Question 11, please explain in the box below.

1500 character(s) maximum

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)?

- Yes
- No
- Don't know

If you answered 'yes' to Question 12, please explain in the box below.

1500 character(s) maximum

The efficiency of the current EU SPC system could be improved, for example by using a unitary (single) SPC.

In the next few questions, we'd like to find out how much complexity SPC applicants face when filing SPCs in the EU (of course, some degree of complexity is always expected in highly technical fields such as pharmaceutical or plant protection products innovation).

13. How would you rate the degree of complexity of registration procedures for SPCs in the EU?

- High
- Reasonable
- Low
- Don't know/No opinion

How could procedures be improved? (max. 1 500 characters, incl. spaces)

1500 character(s) maximum

14. How would you rate the degree of complexity of court litigation of SPCs in the EU?

- High
- Reasonable
- Low
- Don't know/No opinion

How could court litigation be improved?

1500 character(s) maximum

Next, we'd like to ask you some questions about the costs and benefits of SPCs.

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
- The cost of SPC protection barely exceeds the value of sales in some small markets. But we always register the SPC in all EU countries where the corresponding patents are in force.
- The cost of SPC protection barely exceeds the value of sales in some small markets. So we do not register the SPC in all EU countries where the corresponding patents are in force.
- NO, the administrative burden to register and maintain it in all EU countries is high
- Other: please specify

If "Other", please specify.

1500 character(s) maximum

16. Have you ever abandoned (or avoided) applying for SPC registration in an EU country owing to…

	Yes	No	Don't know/no opinion
…. the cost of registration/maintenance?			
…. burdensome administrative procedures?			

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).

	Euro
administrative fees	
Patent agent fees	
In house staff	
Others	

Sometimes SPC holders only file SPC protection in a few EU countries.

This may be because the basic patent is not in force in all EU countries.

But we'd like you to tell us about any other reasons you may have for not registering your SPC in all EU countries – e.g. the cost of SPC protection, or varying levels of coverage in each country.

18. Does the geographical scope of your requested SPC generally match the geographical scope of the territory in which you market the pharmaceutical products?

- Yes
- No, it is sometimes larger (i.e, we sometimes obtain SPC protection in countries where we do not market the protected product)
- No, it's usually narrower
- Don't know

19. In your experience, when enforcing an SPC in only one EU country, is the cost of enforcing SPCs proportionate?

- Yes, the potential cost is always covered by potential sales
- No, it's very high so sometimes we do not enforce it
- Don't know/no opinion

If you answered 'no' to Question 19, please give examples of the total cost of enforcement in the box below (in a max. of 2.000 characters).

2000 character(s) maximum

20. When enforcing an SPC in multiple EU countries, is the cost of enforcing SPCs proportionate?

- Yes - potential cost is always covered by potential sales
- No - it's very high. Sometimes we do not enforce in all EU countries.
- Don't know/no opinion

If you answered 'no' to Question 20, please give examples of the total cost of enforcement in multiple jurisdictions in the box below (in a max. of 3.000 characters).

3000 character(s) maximum

21. Is the length of proceedings relating to enforcing SPCs satisfactory?

- Yes
- No, it depends on the EU country
- Don't know/No opinion

EU-based generics and biosimilar manufacturers argue that EU SPC protection puts them at a disadvantage compared with foreign-based manufacturers.

They want to see the introduction of an ‘SPC manufacturing waiver’ (see introduction to this questionnaire for more details).

The next few questions are about this manufacturing waiver.

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

Please explain your answer (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

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

Please explain your answer (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

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

- Yes
- No
- Don’t know/no opinion

If you answered ‘yes’ to Question 24, please explain why (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

SPC legislation aims to ensure adequate protection for innovation and improving public health.

We want to evaluate whether the objectives of the SPC regulation match current needs and problems (e.g. only some types of innovations are eligible for SPC protection; new regulatory requirements did not exist when the SPC regulation came into force and some activities linked to new regulatory requirements are not covered by the Bolar exemption).

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

- Yes
- No
- Don’t know/no opinion

If you answered ‘no’ to Question 25, please give examples (max. 1 500 characters, incl. spaces).

1500 character(s) maximum

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
- No
- Don’t know/no opinion

If you answered ‘yes’ to Question 26, please give examples (max. 1 500 characters, incl. spaces).

1500 character(s) maximum

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.

2000 character(s) maximum

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 is not relevant (e.g. antibiotics, medicines for the treatment of orphan or neglected diseases)?

- Yes
- No
- Don't know/no opinion

If you answered 'yes' to Question 28, please give examples (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

We're interested in how the SPC and EU Bolar exemptions work in relation to national legislation.

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

Do you have suggestions on how to overcome these inconsistencies?

2000 character(s) maximum

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

- Yes
- No
- Don't know

Please explain your answers (max. 2 000 characters, incl. spaces)

2000 character(s) maximum

The following questions focus on the matters addressed by the European Commission 'inception impact assessment' (http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_grow_051_supplementary_protection_certificates_en.pdf) published on 15 February 2017: the 'SPC manufacturing waiver' (see explanation in the introduction to this questionnaire), the unitary SPC, and specific issues relating to Bolar and research patent exemptions.

Some originators produce, or plan to produce, biosimilars. We'd like to get feedback from you on where your biosimilars are manufactured.

31. On biosimilar products…

	Please, reply “Yes” or “
We have no plans to develop biosimilars	
We plan to start developing biosimilars	
We are developing biosimilar(s) but have not started marketing them	
We market biosimilars	
Don't know	

32. When you develop a biosimilar, do you always conduct the R&D and manufacturing in the same location?

- Yes – it's essential
- No – we often choose a different country for the manufacturing, then years later we move the manufacturing
- No – we often choose different country for the manufacturing, but we never consider moving the manufacturing later because it would highly complex, risky and costly
- Don't know/no opinion

There is no specific provision dedicated to SPCs in the package of legislative instruments related to the unitary patent. We'd like to get feedback from you on whether national authorities, when applying the SPC Regulations, could grant SPCs on the basis of unitary patents.

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
- No, EU legislation is needed to clarify the relationship between the unitary patent and the current SPC framework
- Don't know

In some EU countries, pharmaceutical originators, when conducting certain tests to meet new regulatory requirements to demonstrate efficiency for price purposes (health technology assessment / HTA), may infringe competitors' patents/SPCs.

Some EU countries have adapted their patent laws to exempt those testing requirements from patent/SPC infringement. However, some EU countries have not taken specific measures and the future Unified Patent Court may not exempt those testing requirements.

34. In all EU countries, do you have certainty on whether your activities relating to HTA are exempt from patent/SPC infringement?

- Yes
- No, we only have certainty in some EU countries, such as the UK and Ireland, which adopted specific national patent rules on this
- Don't know/no opinion

Please provide a brief explanation if you wish (max. of 2 000 characters, incl. spaces).

2000 character(s) maximum

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?

- Yes
- No
- Don't know

If you answered ‘yes’ to Question 35, please give examples (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

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?

- Yes - and that is undesirable
- Yes - but it would not be an issue for us
- No
- Don't know/no opinion

In the following questions, we’d like to find out your views on some options for improving the SPC and Bolar systems in the EU.

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

Please explain

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

Please explain your choice (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

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?	◯	◯	◯	◯	◯

Please state your alternative preference

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)?

- ◯ Yes, it would be the only way to maintain unitary protection
- ◯ No, some products are not eligible for centralised authorisation and therefore would not be eligible for protection under the unitary SPC
- ◯ Don't know/no opinion

Any other comments? (max. 3 000 characters, incl. spaces).

3000 character(s) maximum

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…

	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”	○	○	○

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

43. What would be the benefits of a unitary SPC?

	1 Strongly disagree	2 Disagree	3 Neither agree nor disagree	4 Agree	5 Strongly agree	Don't know /no opinion
Boost value of investments	○	○	○	○	○	○
Reduce red tape relating to litigation	○	○	○	○	○	○
Reduce red tape relating to registration	○	○	○	○	○	○
Same protection in all EU	○	○	○	○	○	○
Legal certainty	○	○	○	○	○	○
Reduce maintenance costs	○	○	○	○	○	○
Specialised court	○	○	○	○	○	○
Make licensing easier	○	○	○	○	○	○

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

* See explanation in the introduction to this questionnaire.

	1 Strongly disagree	2 Disagree	3 Neither agree nor disagree	4 Agree	5 Strongly agree	Don't know /no opinion
It would increase the risk of infringement of my SPCs in the EU	○	○	○	○	○	○
It would reduce protection to recoup our investments in R&D in the EU	○	○	○	○	○	○
In the short term, it would reduce our sales in countries outside the EU when protection abroad expires	○	○	○	○	○	○
In the long term, it would reduce our sales in countries outside the EU when protection abroad expires	○	○	○	○	○	○

III. GENERICS AND BIOSIMILARS

Intellectual property (IP), such as patents or trademarks, plays a key role in encouraging investment in innovation. A 2013 study (IP Rights intensive industries: Contribution to economic performance and employment in Europe, EUIPO, 2013) revealed that 39% of economic activity in the EU is generated by IP-intensive industries, while 26% of all employment is provided directly by these industries.

Industry sectors whose products are subject to regulated market authorisations, such as the pharmaceutical, medical devices and agrochemical industries, rely heavily on industrial property protection through patents, Supplementary Patent Certificates (SPCs) and data
/market exclusivity.

SPCs are a sui generis IP right that constitute an extension (of up to five years) to the term of a patent right (of twenty years). SPCs aim to offset the loss of effective patent protection that occurs due to the compulsory and lengthy testing and clinical trials that products require prior to obtaining regulatory marketing approval. The relevant EU legislation is Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96 on SPC covering pharmaceutical and plant protection products respectively.

The Bolar patent exemption aims at speeding up the entry of generic medicines into the market by allowing early preparatory development on generics to obtain pre-market regulatory approval even when the SPC of the reference medicine is still in force. It is regulated at EU level for the pharmaceutical industry only through Article 13(6) of Directive 2001/82/EC and Article 10(6) of Directive 2001/83/EC. The scope of the EU Bolar exemption has been updated in some EU MS, inter alia, to meet new pharmaceutical-related requirements.

The specific industrial property legal framework in the EU for industry sectors whose products are subject to regulated market authorisations might present several features not fit for purpose in today's global economy and in the light of new regulatory requirements.

Firstly, existing SPCs are granted and enforced at national level, which can result in Single Market fragmentation. There are cases where some Member States have granted SPC applications while the very same application has been either refused or granted with a different scope in other Member States.

Secondly, Member States implement the 'Bolar exemption' in different ways: on the one hand, some Member States do not allow the supply of active pharmaceutical ingredients to EU-based generic manufacturers for the purpose of seeking marketing authorisation, and on the other hand, in a number of Member States, it is not certain whether testing in the EU by originators and biosimilars can benefit from these exemptions for the purpose of seeking marketing authorisation in the EU and in non-EU countries, or for meeting emerging regulatory requirements such as those related to health technology assessment.

Thirdly, manufacturers of generic and biosimilar medicines based in non-EU countries where SPC protection does not exist (e.g. in Brazil, Russia, India and China) enter markets in which patent protection expired up to five years earlier than EU-based manufacturers. This is possible because EU-based manufacturers are not allowed to produce in EU Member States during the period of the SPC protection of the reference medicine. Such a situation could lead to a lack of playing field between EU and non EU manufacturers with an advantage for non EU manufacturers.

The Single Market Strategy, adopted in October 2015 (COM(2015)550), announced that the Commission will "consult, consider and propose further measures, as appropriate, to improve the patent system in Europe, notably for pharmaceutical and other industries whose products are subject to regulated market authorisations". In particular, the Strategy undertook to explore a recalibration of certain aspects of patent and SPC protection,
and announced that this recalibration could mainly comprise the following three elements: the creation of a European SPC title; an update of the scope of the EU patent research exemptions; and the introduction of an SPC manufacturing waiver (the so-called ‘SPC manufacturing waiver’ for export purposes would allow EU based manufacturers of generics
/biosimilars manufacturing their products during the EU SPC term of the reference medicine to export their products to countries with no SPC protection). The European Commission published an “inception impact assessment” on 15 February 2017.
The current public consultation seeks to gather feedback of all stakeholders on the way the SPC system currently functions in the EU and its effects on trade and competitiveness in particular.

The Commission will report on the results of its consultation which, together with ongoing evaluation studies, will help the Commission assess whether the EU SPC framework is still fit for purpose or needs to be recalibrated, notably as regards the aspects set out in Single Market Strategy.

Disclaimer

Please note that this document has been prepared by the Commission services for information and consultation purposes only. It has not been adopted or in any way approved by the Commission and should not be regarded as representative of its views. It does not in any way prejudge, or constitute the announcement of, any position on the part of the Commission on the issues covered. The Commission does not guarantee the accuracy of the information provided, nor does it accept responsibility for any use made thereof.

The following questions relate to the profile of your company/organisation:

*1. Which best describes you?

- Company (250+ employees annual turnover = €50 million+ annual balance sheet = €43 million+)
- Start-up
- Association - European
- Contracting research organisation, e.g. that conducts clinical trials only for biosimilars
- Small/medium company (except start-up) (fewer than 250 employees annual turnover – €50 million or less annual balance sheet = €43 million or less)
- Association - National
- Contracting research organisation, e.g. that conducts bioequivalence studies
- Other (please specify)

Free Text Question

50 character(s) maximum

* 1.1. If you represent a company, is it a:

- Parent company
- Subsidiary
- Independent company

* 1.2. Is the parent company (i.e. global headquarters) registered in the EU?

Yes
No

1.2.1. If “yes”, in which EU country?

20 character(s) maximum

* 1.3. Where is your company/organisation branch based?

- United States
- Switzerland
- India
- Canada
- China
- EU
- Japan
- Korea
- Singapore
- Other

Please specify

50 character(s) maximum

1.4. If you represent a company, please tell us about these products:

	Does your business work on these product types?	Whic
* Human medicinal		
* Veterinary medicinal		
* Plant protection		
* Medical devices		
* All your products		

2. What is the geographical scope of your commercial activity?

- ○ Mostly worldwide
- ○ EU-wide
- ○ One EU country only
- ○ Other: please specify

Please specify

50 character(s) maximum

3. Tell us more about your business activities in these geographical areas:

	% of your total employees	% of your turnover	% of you (wheth
EU			
Switzerland			
Korea			
Japan			
United States			
China			
Singapore			
Canada			
India			

The next few questions are about how effective supplementary protection certificates (SPCs) and Bolar exemptions are in the EU.

We want to find out how much progress has been made in meeting the following objectives (from SPC legislation adopted in the 1990s):

- attracting research
- preventing delocalisation
- protection for long enough to recover investment
- promoting essential innovation for patients
- competition through innovation
- limiting the negative effects of fragmentation.

SPCs are regulated under EU law (Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96), but granted in each EU country by a national authority.

- They are enforced nationally in national courts.
- Registration procedures can vary between EU countries.
- Sometimes, authorities (grant authority or court) in different EU countries can reach different conclusions on the validity or scope of the SPC protection they grant (or refuse) in their country for the same product.
- National courts have referred several questions on the interpretation of SPC legislation to the Court of Justice of the EU.

In the next few questions, we'd like to hear about your experience of how harmonised SPC protection is across the EU.

4. Have authorities in different EU countries ever taken different decisions on SPC applications for one (or more) of your products?
Examples: some EU countries granted SPC national applications for one of your products but refused others; you were granted different durations of SPC protection for one of your products in different EU countries; national grant authorities interpreted EU Court of Justice rulings differently).

- Yes
- No
- Don't know

If you answered 'yes' to Question 4, please explain in the box below.

1500 character(s) maximum

5. 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)?

- Yes
- No
- Don't know

If you answered 'yes' to Question 5, please explain in the box below.

1500 character(s) maximum

About your use of databases to monitor the status of your competitors' SPC protection across EU Member States…

6. About your use of databases to monitor the status of your competitors' SPC protection across EU Member States…

	Agree	Disagree	Don't know/no opinion
… to our knowledge, there are no databases available to conduct such monitoring			
… specialised databases are very costly			
Other reasons: …….			

In recent decades, there has been major investment in developing and manufacturing generics in countries outside the EU. The same thing may be happening now for biosimilars.

We'd like to find out about other factors that encourage you to invest in non-EU countries.

7. When you decide to invest outside the EU in development products (research, field trials, bioequivalence studies, etc.), what are the 4 main drivers?

Please mark maximum 4 choices

- [ ] Scope of SPC type protection for the reference medicine (i.e. there is no SPC type protection in the country or it has a manufacturing SPC waiver (see explanation in the introduction to this questionnaire)
- [ ] Regulatory data and market exclusivity
- [ ] Existence of a Bolar patent exemption
- [ ] Regulatory approval laws
- [ ] Price paid for the medicine
- [ ] Public funding
- [ ] Health infrastructure
- [ ] Labour costs
- [ ] Tax
- [ ] Less strict regulatory control
- [ ] Size of market (large)
- [ ] Proximity to manufacturing facilities
- [ ] Other: please specify

If you answered 'Other' to Question 7, please explain in the box below.

1500 character(s) maximum

The aim of the Bolar patent exemption is to speed up the development and market entry of generics /biosimilars.

In the next few questions, we'd like to find out:

(i) whether generics and biosimilars are making effective use of the Bolar exemption in the EU

(ii) whether sectors like the plant protection products use/rely on Bolar exemptions (there is no specific EU legislation on Bolar patent exemption for plant protection products).

8. Have you ever obtained marketing authorisations in the EU for generics and/or biosimilars before the expiry of the SPC protection of the reference product?

- ( ) Yes – because of the Bolar exemption
- ( ) Yes – even though I was not sure whether a Bolar patent/SPC exemption (e.g. in the case of plant protection products) was in place
- ( ) No
- ( ) Don't know

The efficiency of the current EU SPC system could be improved, for example by using a unitary (single) SPC.

In the next few questions, we'd like to find out how much complexity SPC applicants face when filing SPCs in the EU (of course, some degree of complexity is always expected in highly technical fields such as pharmaceutical or plant protection products innovation).

9. How would you rate the degree of complexity of registration procedures for SPCs in the EU?

- High
- Reasonable
- Low
- Don't know/No opinion

How could procedures be improved? (max. 1 500 characters, incl. spaces)

1500 character(s) maximum

SPC protection could have had unintended adverse effects in other sectors.

EU-based generics and biosimilar manufacturers argue that EU SPC protection puts them at a disadvantage compared with foreign-based manufacturers.

They want to see the introduction of an 'SPC manufacturing waiver' (see introduction to this questionnaire for more details).

In the next few questions, we'd like to find out about the challenges faced by this sector of the pharmaceuticals industry.

10. Do you agree or disagree with the following statements (if they apply to your business):

	Agree	Disagree	No opinion /not applicable
Longer SPC duration in the EU compared with other non-EU countries makes manufacturing in the EU less interesting for us	○	○	○
When it comes to exporting generics and biosimilars outside the EU, SPCs disadvantage EU-based generics and biosimilars manufacturing compared with generic companies based in countries with no SPC.	○	○	○
When placing generics and biosimilars on the EU market when the SPC expires, SPCs disadvantage EU-based generics and biosimilars manufacturing compared with generic companies based in countries with no SPC	○	○	○
The EU SPC, in its current form, increases our reliance on imports of medicines and active pharmaceutical ingredients from outside the EU	○	○	○

11. The entry into force of the EU SPC regulations in an EU country (note: in some countries, this was after 2004) mostly…

- ○ ... does not have an impact on our future decisions about manufacturing in that EU country
- ○ … triggers the delocalisation to another country or licensing of our manufacturing to a country with no or less stringent SPC type protection
- ○ … triggers the delocalisation or licensing of our manufacturing to a country with no or less stringent SPC type protection, but only for the initial launch in the EU
- ○ Don't know ○ No opinion

Some reports suggests that biosimilars tend to be developed and manufactured in the same location. We'd like to find out your experience of this.

12. When you develop a biosimilar, do you always conduct the R&D and manufacturing in the same location?

- ○ Yes – it's essential
- ○ No – we often choose a different country for the manufacturing, then years later we move the manufacturing
- ○ No – we often choose different country for the manufacturing, but we never consider moving the manufacturing later because it would highly complex, risky and costly
- ○ Don't know/no opinion

SPC legislation aims to ensure adequate protection for innovation and to improve public health.

We want to evaluate whether the objectives of the SPC regulation match current needs and problems (e.g. only some types of innovations are eligible for SPC protection; new regulatory requirements did not exist when the SPC regulation came into force and some activities linked to new regulatory requirements are not covered by the Bolar exemption).

13. In your experience, do some jurisdictions (e.g., the US or Japan) provide for SPC type protection for some types of innovation that you develop that are not eligible for an SPC in the EU?

- Yes
- No
- Don't know/no opinion

If you answered 'yes' to Question 13, please give examples (max. 1 500 characters, incl. spaces).

1500 character(s) maximum

The next few questions relate to the potential impact of applying the Bolar patent exemption and the SPC to the source of supply of active pharmaceutical ingredients for EU-based manufacturers (e.g. the Astellas case in Germany and Poland).

14. Has the implementation of the Bolar research exemption in EU countries affected your decisions regarding your sources of supply of active pharmaceutical ingredients (APIs)? (e.g. opting for in-house manufacturing or outsourcing, being forced to outsource outside the EU or from a particular EU country)

- Yes
- No
- Don't know

Please give an explanation/examples if possible (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

15. Has the implementation of SPCs in EU countries affected your decisions regarding your sources of supply of active pharmaceutical ingredients (APIs)? (e.g. opting for in-house manufacturing or outsourcing, being forced to outsource outside the EU or from a particular EU country)

- Yes
- No
- Don't know

Please give an explanation/examples if possible (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

16. How significant are the following drivers when you are deciding on your sources of supply of active pharmaceutical ingredients (APIs) (whether manufactured in-house or bought from a third-party manufacturer)? (score from 1 to 3)

	1 Minimum significance	2 Medium significance	3 Maximum significance
Compliance with regulatory standards	○	○	○
Scope of Bolar and indirect patent infringement rules in the country where the APIs are manufactured	○	○	○
Security of supply (e.g. having more than one supplier)	○	○	○
SPC protection (lack of)	○	○	○
Proximity to the manufacturing facilities of our final product	○	○	○

We're interested in how the SPC and EU Bolar exemptions work in relation to national legislation.

17. Please give examples of any inconsistencies between national legislation and EU legislation on SPCs and Bolar exemptions, if you know of any.
Do you have suggestions on how to overcome these inconsistencies?

2000 character(s) maximum

18. Have the EU SPC and Bolar exemptions brought added value compared with national initiatives?
- ○ Yes
- ○ No
- ○ Don't know

Please provide an explanation/examples if possible (max. 2 000 characters, incl. spaces)

2000 character(s) maximum

The following questions focus on the matters addressed by the European Commission 'inception impact assessment' (http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_grow_051_supplementary_protection_certificates_en.pdf) published on 15 February 2017: the 'SPC manufacturing waiver' (see explanation in the introduction to this questionnaire), the unitary (single) SPC, and specific issues related to Bolar and research patent exemptions.

19. Do you favour countries with no SPC protection when looking for a location to base or outsource your biosimilars manufacturing?

- Yes
- No
- Depends on the circumstances but it is a key factor.
- No opinion/Don’t know

There is no specific provision dedicated to SPCs in the package of legislative instruments related to the unitary patent. We’d like to get feedback from you on whether national authorities, when applying the SPC Regulations, could grant SPCs on the basis of unitary patents.

20. 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
- No, EU legislation is needed to clarify the relationship between the unitary patent and the current SPC framework
- Don't know

Some aspects of the EU Bolar patent exemption could be upgraded in line with best practice in some EU countries in view of changes in the way generics and biosimilars are developed in the EU, and in view of the future establishment of the Unified Patent Court which may not follow those best practices.

The Bolar patent exemption is not explicitly available for the plant protection products industry in the EU, but it might be available in the US.

21. Have you ever based your defence in a patent/SPC infringement case in multiple jurisdictions (taking place in several EU Member States) on the Bolar exemption?

- Yes, and the courts always interpreted the Bolar exemption in the same way
- Yes, and there were conflicting judgments
- No
- Don’t know/no opinion

If you answered ‘Yes, and there were conflicting judgments’, please provide examples (e.g. reference court cases, max. of 2 000 characters, inc. spaces).

2000 character(s) maximum

22. Are you always able to find a supplier of active pharmaceutical ingredients (APIs) manufactured in the EU?

- Yes
- No
- Don't know

23. If you are in the plant protection products sector, is there a Bolar-type or research exemption in EU countries in this sector?

- Yes, in some EU countries this is stipulated in their patent law or jurisprudence
- Only in a few of them it is stipulated in their patent law or jurisprudence
- It is not clear
- No opinion

24. If you are in the plant protection products sector, have you ever based your defence in a patent/SPC infringement case on the Bolar exemption?

- Yes, and the court recognised my allegedly infringing activities as Bolar-exempted
- Yes, but the court did not recognise my allegedly infringing activities as Bolar-exempted
- No
- Don't know/no opinion

25. Have you ever been sued for developing a product in the EU for its registration outside the EU?

- Yes, and the courts always ruled that this development was Bolar-exempted
- Yes, and on at least in one occasion a court ruled that this development was not Bolar-exempted
- No
- Don't know/no opinion

26. Do you think that there is a risk that the future Unified Patent Court could develop a practice regarding the Bolar patent exemption that conflicts with the one consolidated in the Irish, UK and German law /practice?

- Yes – and that is undesirable
- Yes – but it would not be an issue for us
- No
- Don't know/no opinion

In the following questions, we'd like to find out your views on some options for improving the SPC and Bolar systems in the EU.

27. Please indicate which of the following actions would be enough on its own to ensure consistent interpretation throughout the EU of the scope and eligibility of the SPC regulation?

	Yes	No	Don't know/no opinion
Amendment of the SPC Regulations to bring additional clarity			
Creation of a unitary SPC for the unitary patent			
Guidelines developed by the European Commission and EU countries			
Other actions – please explain:			

Other actions – please explain:

28. Based on your experience, do you think that all EU countries' national patent offices should conduct substantive examination (i.e. actual verification of the conditions stipulated in the SPC Regulation) of SPC applications?

- Yes
- No – some of them might not have the necessary administrative capacity/resources
- No – it's unnecessarily cumbersome, even for the offices with enough resources
- No opinion

29. Do you favour the creation of a unitary SPC title for the unitary patent?

- Yes
- No, there's no need
- No opinion

30. 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

Please explain your choice (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

31. 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?	◯	◯	◯	◯	◯

32. 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)?

◯ Yes ◯ No

◯ No opinion

33. 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

In the following questions, we'd like to find out your views on some options for improving the SPC and Bolar systems in the EU.

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

* See explanation in the introduction to this questionnaire.

	1 (min)	2	3	4	5 (max)
We would increase our manufacturing in the EU	○	○	○	○	○
We would not decrease our future manufacturing in the EU	○	○	○	○	○
It would increase the risk of infringement of SPCs in the EU	○	○	○	○	○
It would increase our sales in countries outside the EU when protection abroad expires	○	○	○	○	○
In the short term, it would reduce originators' sales in countries outside the EU when protection abroad expires	○	○	○	○	○
In the long term, it would reduce originators' sales in countries outside the EU when protection abroad expires	○	○	○	○	○

35. What would be the benefits of a unitary SPC?

	1 Strongly disagree	2 Disagree	3 Neither agree nor disagree	4 Agree	5 Strongly agree
Reduce cost and red tape relating to monitoring SPC-protected products (freedom to operate)	○	○	○	○	○
Reduce cost of SPC-related litigation	○	○	○	○	○
Legal certainty	○	○	○	○	○
Existence of a specialised court	○	○	○	○	○
Make licensing easier	○	○	○	○	○

36. Please indicate from 1 (disagreement) to 3 (agreement) to what extent you agree with the following statement:
If the supply of patented active pharmaceutical ingredients (APIs) were allowed under the Bolar patent exemption, we would increase our share of purchases from EU-based suppliers of APIs

- ○ 1
- ○ 2
- ○ 3
- ○ Don't know

IV. PATIENTS GROUPS, FARMERS, DOCTORS, HEALTH AUTHORITIES, AGRICULTURAL AUTHORITIES, INSURERS /TENDERERS

Intellectual property (IP), such as patents or trademarks, plays a key role in encouraging investment in innovation. A 2013 study (IP Rights intensive industries: Contribution to economic performance and employment in Europe, EUIPO, 2013) revealed that 39% of economic activity in the EU is generated by IP-intensive industries, while 26% of all employment is provided directly by these industries.

Industry sectors whose products are subject to regulated market authorisations, such as the pharmaceutical, medical devices and agrochemical industries, rely heavily on industrial property protection through patents, Supplementary Patent Certificates (SPCs) and data /market exclusivity.

SPCs are a sui generis IP right that constitute an extension (of up to five years) to the term of a patent right (of twenty years). SPCs aim to offset the loss of effective patent protection that occurs due to the compulsory and lengthy testing and clinical trials that products require prior to obtaining regulatory marketing approval. The relevant EU legislation is Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96 on SPC covering pharmaceutical and plant protection products respectively.

The Bolar patent exemption aims at speeding up the entry of generic medicines into the market by allowing early preparatory development on generics to obtain pre-market regulatory approval even when the SPC of the reference medicine is still in force. It is regulated at EU level for the pharmaceutical industry only through Article 13(6) of Directive 2001/82/EC and Article 10(6) of Directive 2001/83/EC. The scope of the EU Bolar exemption has been updated in some EU MS, inter alia, to meet new pharmaceutical-related requirements.

The specific industrial property legal framework in the EU for industry sectors whose products are subject to regulated market authorisations might present several features not fit for purpose in today's global economy and in the light of new regulatory requirements.

Firstly, existing SPCs are granted and enforced at national level, which can result in Single Market fragmentation. There are cases where some Member States have granted SPC applications while the very same application has been either refused or granted with a different scope in other Member States.

Secondly, Member States implement the 'Bolar exemption' in different ways: on the one hand, some Member States do not allow the supply of active pharmaceutical ingredients to EU-based generic manufacturers for the purpose of seeking marketing authorisation, and on the other hand, in a number of Member States, it is not certain whether testing in the EU by originators and biosimilars can benefit from these exemptions for the purpose of seeking marketing authorisation in the EU and in non-EU countries, or for meeting emerging regulatory requirements such as those related to health technology assessment.

Thirdly, manufacturers of generic and biosimilar medicines based in non-EU countries where SPC protection does not exist (e.g. in Brazil, Russia, India and China) enter markets in which patent protection expired up to five years earlier than EU-based manufacturers. This is possible because EU-based manufacturers are not allowed to produce in EU Member States during the period of the SPC protection of the reference medicine. Such a situation could lead to a lack of playing field between EU and non EU manufacturers with an advantage for non EU manufacturers.

The Single Market Strategy, adopted in October 2015 (COM(2015)550), announced that the Commission will "consult, consider and propose further measures, as appropriate, to improve the patent system in Europe, notably for pharmaceutical and other industries whose products are subject to regulated market authorisations". In particular, the Strategy undertook to explore a recalibration of certain aspects of patent and SPC protection, and announced that this recalibration could mainly comprise the following three elements: the creation of a European SPC title; an update of the scope of the EU patent research exemptions; and the introduction of an SPC manufacturing waiver (the so-called 'SPC manufacturing waiver' for export purposes would allow EU based manufacturers of generics /biosimilars manufacturing their products during the EU SPC term of the reference medicine to export their products to countries with no SPC protection). The European Commission published an "inception impact assessment" on 15 February 2017.
The current public consultation seeks to gather feedback of all stakeholders on the way the SPC system currently functions in the EU and its effects on trade and competitiveness in particular.

The Commission will report on the results of its consultation which, together with ongoing evaluation studies, will help the Commission assess whether the EU SPC framework is still fit for purpose or needs to be recalibrated, notably as regards the aspects set out in Single Market Strategy.

Disclaimer

Please note that this document has been prepared by the Commission services for information and consultation purposes only. It has not been adopted or in any way approved by the Commission and should not be regarded as representative of its views. It does not in any way prejudge, or constitute the announcement of, any position on the part of the Commission on the issues covered. The Commission does not guarantee the accuracy of the information provided, nor does it accept responsibility for any use made thereof.

The following questions relate to the profile of your company/organisation:

*1. Which best describes you?

- (●) Health, incl. medicines (human and/or veterinary medicines)
- ( ) Plant protection products (pesticides)
- ( ) Other: please specify

Please specify

* 1.1. If the health sector, are you a:

- ○ Individual
- ○ National patients' organisation
- ○ European patients' organisation
- ○ Public pricing authority
- ○ Consumers' association
- ○ Procurement authority
- ● Public health authority (e.g. Ministry of Health)
- ○ Private company organising/launching procurement
- ○ Health technology assessment authority
- ○ Veterinary association
- ○ Health care professionals (e.g. doctors, associations of health care professionals)
- ○ Hospital or hospital association/group
- ○ Insurance health provider
- ○ Other: please specify

Please specify

1.1. If the agrochemical sector, are you a:

- ○ Farmer
- ○ National farmers' organisation
- ○ European farmers' organisation
- ○ Legal counsellor representing farmers
- ○ Consumers' association
- ○ Public authority for agriculture
- ○ Other: please specify

Please specify

The next few questions are about how effective supplementary protection certificates (SPCs) and Bolar exemptions are in the EU.

We want to find out how much progress has been made in meeting the following objectives (from SPC legislation adopted in the 1990s):

- attracting research
- preventing delocalisation
- protection for long enough to recover investment
- promoting essential innovation for patients
- competition through innovation
- limiting the negative effects of fragmentation.

The SPC is an incentive for innovation investment in pharmaceutical and plant protection products. The SPC legislation was introduced in the EU in the 1990s.

In most of the following questions, we'd like to find out your views on how innovation and market competition are progressing for these products since SPC legislation was introduced in the EU.

2. In the last two decades in the EU, how do you perceive the progress made in……

	Down a lot	Down a bit	Stable	Up a bit	Up a lot	No opinion
…investments in pharmaceutical innovation in general	○	○	○	○	○	●
…investments in clinical trials	○	○	○	○	○	●
…investments in pharmaceutical manufacturing	○	○	○	○	○	●
…investments in innovation in plant protection products	○	○	○	○	○	●
...investments in the manufacturing of plant protection products	○	○	○	○	○	●
…competition in the pharmaceutical sector based on innovation	○	○	○	○	○	●
…competition in plant protection products based on innovation	○	○	○	○	○	●
… competition based on the quick market entry of generics/biosimilars following the expiry of SPC protection?	○	○	○	○	●	○
… dependency of supply of active pharmaceutical ingredients (APIs) manufactured outside the EU	○	○	○	○	●	○
… healthy supply of end products (e.g. vaccines, pesticides) manufactured in the EU	○	○	○	○	●	○
… dependency of supply of end products manufactured outside the EU	○	○	○	○	●	○

3. What do you think are the effects of SPC protection on investment in developing innovative medicines [/plant protection products] with added value for patients [/farmers and consumers]?

- ○ 1 (Negative)
- ○ 2
- ○ 3 (Positive)
- ○ Impossible to know
- ○ We don’t know
- ● No opinion
- ○ Answer 2

Please explain your answer (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

N/A

SPCs apply to patented pharmaceutical and plant protection products that have been authorised by regulatory authorities not earlier than 5 years after filing their 'basic patent' (i.e. the patent to be extended with the SPC). As explained in the introductory part of the questionnaire, the aim is to offset the loss of effective patent protection that occurs due to the compulsory and lengthy testing and clinical trials that products require prior to obtaining regulatory marketing approval.

4. Should the EU SPC system be available for other innovative products subject to lengthy regulatory approval?

- ○ Yes
- ○ No
- ● No opinion

If your answer is 'Yes', please provide examples (max. 1 500 characters, incl. spaces).

1500 character(s) maximum

Generics and biosimilars enter the market when the patent/SPC for that market expires (subject to other industrial property rights that could still be in force). A transparent SPC system can make it easier for generics/biosimilars to compete.

5. About your use of databases to monitor the status of SPC protection of your products across EU Member States…

	Agree	Disagree	Don't know/no opinion
… to our knowledge, there are no databases available to conduct such monitoring	○	●	○
… specialised databases are very costly	○	○	●

In the next few questions, we'd like to find out how much complexity SPC applicants face when filing SPCs in the EU (of course, some complexity is always expected in the highly technical fields such as pharmaceutical or plant protection products innovation).

6. How would you rate the degree of complexity of court litigation for SPCs in the EU?

- ○ High
- ○ Reasonable
- ○ Low
- ● Don't know/no opinion

How could litigation be improved? (max. 1 500 characters, incl. spaces)

1500 character(s) maximum

N/A

7. Have you ever decided not to enter into litigation relating to SPC infringement or SPC validity because of a lack of economic resources to litigate?

- ○ Yes
- ● No
- ○ Don't know

Please provide examples of the total cost of enforcement that you were faced with (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

N/A

SPC protection could have had unintended adverse effects in other sectors.

EU-based generics and biosimilar manufactures argue that the EU SPC protection puts them at a disadvantage compared with foreign-based manufacturers.

They want to see the introduction of an 'SPC manufacturing waiver' (see introduction to this questionnaire for more details).

In the next few questions, we'd like to find out about the challenges faced by this sector of the pharmaceuticals industry.

8. 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

Please explain your answer (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

No opinion

9. 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

Please explain your answer (max. 1 500 characters, incl. spaces).

1500 character(s) maximum

No opinion

10. If you answered 'yes' to Questions 8 or 9, does the issue matter more for biosimilars than for generics?

- ○ Yes
- ○ No
- ● Don't know/no opinion

If you answered 'yes' to Question 10, please explain why (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

SPC legislation aims to ensure adequate protection for innovation and improving public health.

We want to evaluate whether the objectives of the SPC regulation match current needs and problems (e.g. only some types of innovations are eligible for SPC protection; new regulatory requirements did not exist when the SPC regulation came into force and some activities linked to new regulatory requirements are not covered by the Bolar exemption).

11. In your experience, is SPC protection sufficient to encourage investment in certain types of innovations (e.g. antibiotics, medicines for the treatment of neglected diseases and orphan diseases)?

- ○ Yes
- ○ No
- ● Don't know/no opinion

Please explain your answer (max. 1 500 characters, incl. spaces).

1500 character(s) maximum

We're interested in how the SPC and EU Bolar exemptions work in relation to national legislation.

12. Please give examples of any inconsistencies between national legislation and EU legislation on SPCs and Bolar exemptions, if you know of any.
Do you have any suggestions on how to overcome those inconsistencies? Please explain your answer (max. 2 000 characters, incl. spaces.)

2000 character(s) maximum

No answer

13. Have the EU SPC and Bolar exemptions brought added value compared with national initiatives?

- ○ Yes
- ○ No
- ● Don't know

Please explain your answer (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

No answer

The following questions focus on the matters addressed by the European Commission's 'inception impact assessment' published on 15 February 2017: the 'SPC manufacturing waiver' (see explanation in the introduction to this questionnaire), the unitary SPC, and specific issues related to the Bolar and research patent exemptions.

In the following questions, we'd like to find out your views on some options for improving the SPC and Bolar systems in the EU:

14. Please indicate which of the following actions would be enough on its own to ensure consistent interpretation throughout the EU of the scope and eligibility of the SPC regulation?

	Yes	No	Don't know/no opinion
Amendment of the SPC Regulations to bring additional clarity	○	○	●
Creation of a unitary SPC for the unitary patent	○	○	●
Guidelines developed by the European Commission and EU countries	○	○	●
Other actions – please explain (max. 2 000 characters)	○	○	●

Other actions – please explain (max. 2 000 characters)

2000 character(s) maximum

No answer

15. Do you favour the creation of a unitary SPC title for the unitary patent?

- ○ Yes
- ○ No, there's no need
- ● No opinion

Please explain your answer (max. 1 500 characters, incl. spaces).

1500 character(s) maximum

No answer

16. Which language combination would you prefer for the publication of the unitary SPC?

- ○ The notice of granting a SPC should be published in all official languages of the EU
- ○ English, German and French would be sufficient (Commission working languages)
- ○ English only would be sufficient
- ● Other options, please explain:

Other actions – please explain (max. 2 000 characters)

2000 character(s) maximum

No opinion

In the following question, we'd like to find out your views on some options for improving the SPC and Bolar systems in the EU.

17. What would be the benefits of a unitary SPC?

	1 (min.)	2	3	4	5 (max.)
Reduce cost and red tape relating to monitoring SPC-protected products (freedom to operate)	○	○	○	○	○
Reduce cost of SPC-related litigation	○	○	○	○	○
Legal certainty	○	○	○	○	○
Existence of a specialised court	○	○	○	○	○
Make joint procurement by a group of EU countries easier	○	○	○	○	○

V. NATIONAL PATENT OFFICES, JUDGES AND IP PROFESSIONALS

Intellectual property (IP), such as patents or trademarks, plays a key role in encouraging investment in innovation. A 2013 study (IP Rights intensive industries: Contribution to economic performance and employment in Europe, EUIPO, 2013) revealed that 39% of economic activity in the EU is generated by IP-intensive industries, while 26% of all employment is provided directly by these industries.

Industry sectors whose products are subject to regulated market authorisations, such as the pharmaceutical, medical devices and agrochemical industries, rely heavily on industrial property protection through patents, Supplementary Patent Certificates (SPCs) and data /market exclusivity.

SPCs are a sui generis IP right that constitute an extension (of up to five years) to the term of a patent right (of twenty years). SPCs aim to offset the loss of effective patent protection that occurs due to the compulsory and lengthy testing and clinical trials that products require prior to obtaining regulatory marketing approval. The relevant EU legislation is Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96 on SPC covering pharmaceutical and plant protection products respectively.

The Bolar patent exemption aims at speeding up the entry of generic medicines into the market by allowing early preparatory development on generics to obtain pre-market regulatory approval even when the SPC of the reference medicine is still in force. It is regulated at EU level for the pharmaceutical industry only through Article 13(6) of Directive 2001/82/EC and Article 10(6) of Directive 2001/83/EC. The scope of the EU Bolar exemption has been updated in some EU MS, inter alia, to meet new pharmaceutical-related requirements.

The specific industrial property legal framework in the EU for industry sectors whose products are subject to regulated market authorisations might present several features not fit for purpose in today's global economy and in the light of new regulatory requirements.

Firstly, existing SPCs are granted and enforced at national level, which can result in Single Market fragmentation. There are cases where some Member States have granted SPC applications while the very same application has been either refused or granted with a different scope in other Member States.

Secondly, Member States implement the 'Bolar exemption' in different ways: on the one hand, some Member States do not allow the supply of active pharmaceutical ingredients to EU-based generic manufacturers for the purpose of seeking marketing authorisation, and on the other hand, in a number of Member States, it is not certain whether testing in the EU by originators and biosimilars can benefit from these exemptions for the purpose of seeking marketing authorisation in the EU and in non-EU countries, or for meeting emerging regulatory requirements such as those related to health technology assessment.

Thirdly, manufacturers of generic and biosimilar medicines based in non-EU countries where SPC protection does not exist (e.g. in Brazil, Russia, India and China) enter markets in which patent protection expired up to five years earlier than EU-based manufacturers. This is possible because EU-based manufacturers are not allowed to produce in EU Member States during the period of the SPC protection of the reference medicine. Such a situation could lead to a lack of playing field between EU and non EU manufacturers with an advantage for non EU manufacturers.

The Single Market Strategy, adopted in October 2015 (COM(2015)550), announced that the Commission will "consult, consider and propose further measures, as appropriate, to improve the patent system in Europe, notably for pharmaceutical and other industries whose products are subject to regulated market authorisations". In particular, the Strategy undertook to explore a recalibration of certain aspects of patent and SPC protection, and announced that this recalibration could mainly comprise the following three elements: the creation of a European SPC title; an update of the scope of the EU patent research exemptions; and the introduction of an SPC manufacturing waiver (the so-called 'SPC manufacturing waiver' for export purposes would allow EU based manufacturers of generics /biosimilars manufacturing their products during the EU SPC term of the reference medicine to export their products to countries with no SPC protection). The European Commission published an "inception impact assessment" on 15 February 2017.
The current public consultation seeks to gather feedback of all stakeholders on the way the SPC system currently functions in the EU and its effects on trade and competitiveness in particular.

The Commission will report on the results of its consultation which, together with ongoing evaluation studies, will help the Commission assess whether the EU SPC framework is still fit for purpose or needs to be recalibrated, notably as regards the aspects set out in Single Market Strategy.

Disclaimer

The following questions relate to the profile of your company/organisation:

*1. Which best describes you?

- (●) National patent office
- ( ) Professional having dealt with both registration and litigation of SPCs
- ( ) Professional having dealt with SPC litigation but not with registration
- ( ) Judge dealing with SPC enforcement
- ( ) Professional having dealt with registration of SPCs but not with litigation
- ( ) Other: please specify

Please specify

The next few questions are about how effective supplementary protection certificates (SPCs) and Bolar exemptions are in the EU.

We want to find out how much progress has been made in meeting the following objectives (from SPC legislation adopted in the 1990s):

- attracting research
- preventing delocalisation
- protection for long enough to recover investment
- promoting essential innovation for patients
- competition through innovation
- limiting the negative effects of fragmentation.

SPCs are regulated under EU law (Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96), but granted in each EU country by a national authority.

- They are enforced nationally in national courts.
- Registration procedures can vary between EU countries.
- Sometimes, authorities (grant authority or court) in different EU countries can reach different conclusions on the validity or scope of the SPC protection they grant (or refuse) in their country for the same product.
- National courts have referred several questions on the interpretation of SPC legislation to the Court of Justice of the EU.

In the next few questions, we'd like to hear about your experience of how harmonised SPC protection is across the EU.

2. Have authorities in different EU countries ever taken different decisions on SPC applications for one (or more) of products)?

Examples: some EU countries granted SPC national applications for one of your products but refused others; you were granted different durations of SPC protection for one of your products in different EU countries; national grant authorities interpreted EU Court of Justice rulings differently.

- (●) Yes
- ( ) No
- ( ) Don't know

If you answered 'yes' to Question 2, please explain in the box below.

1500 character(s) maximum

With respect to the duration of a certificate based on a national marketing authorization the DKPTO uses the decision date unless an official notification date exists whereas the Dutch Office uses the date where applicant received the marketing authorization for the calculation of the duration of the certificate.
An example is:
Product: Solifenacin
MA: RVG 29151, RVG 29152 (NL)
Date of MA in DK: 16/12/2003
Date of MA in NL: 22/12/2003

With respect to the EU Court of Justice rulings, the national offices interpret the Neurim (C-130/11) ruling differently. Some interpretations follow the ruling very strictly i.e. an MA for a product for veterinary use does not preclude a grant of an SPC on the basis for a later MA for the same product for human use.

3. Has an EU country's courts ever taken a different decision in relation to the SPC of a specific product (e.g. you observe the validity of an SPC upheld by some EU countries' courts but revoked by others; some EU countries' courts concluded that there was infringement of a specific SPC, while others did not)?

- (●) Yes
- ( ) No
- ( ) Don't know

If you answered 'yes' to Question 3, please explain in the box below.

1500 character(s) maximum

In case A-23-17, Gilead Sciences v Accord Healthcare Limited, the Danish Maritime and Commercial High Court issued a decision rejecting Gilead's motion for preliminary injunction against Accord Healthcare Limited based on Gilead's Danish SPC. Accord had defended the motion for preliminary injunction by arguing non-infringement and invalidity of the asserted SPC.

The Court supported Accord's argument that the SPC's combination was not protected by the basic patent, and, accordingly, the SPC had been granted in contrary to Article 3(a) of the SPC Regulation. The SPC is still in effect in the UK, but has since been challenged.

Generics and biosimilars enter the market when the patent/SPC for that market expires (subject to other industrial property rights that could still be in force). A transparent SPC system can make it easier for generics/biosimilars to compete.

4. About your use of databases to monitor the status of your competitors' SPC protection across EU Member States…

	Agree	Disagree	Don't know/no opinion
… to our knowledge, there are no databases available to conduct such monitoring	○	●	○
… specialised databases are very costly	○	○	●

We'd like to hear your views on how fragmented you think the EU SPC system is so that we can consider potential improvements (e.g. a unitary (single) SPC).

5. Has your country enacted legislation on SPCs to transpose the EU regulations on SPCs?

- ○ Yes
- ● No, the national authority that grants the SPC relies directly on the SPC regulations
- ○ Don't know/no opinion

5.1. If you answered 'yes' to Question 5, has your EU country ever updated that legislation following a judgment from the Court of Justice of the EU?

- ○ Yes
- ○ No
- ○ Don't know/no opinion

6. Has your country (e.g. your national patent office) adopted implementing guidelines for examining and registering SPCs?

- ● Yes
- ○ No, the national authority that grants the SPC relies directly on the SPC regulations
- ○ Don't know/no opinion

6.1. If you answered 'yes' to Question 6, do you usually update the guidelines following a judgment from the Court of Justice of the EU?

- ● Yes
- ○ No
- ○ Don't know/no opinion

The efficiency of the current EU SPC system could be improved, for example by using a unitary (single) SPC.

In the next few questions, we'd like to find out how much complexity SPC applicants face when filing SPCs in the EU (of course, some degree of complexity is always expected in highly technical fields such as pharmaceutical or plant protection products innovation).

7. How would you rate the degree of complexity of registration procedures for SPCs in the EU?

- ○ High
- ○ Reasonable
- ● Low
- ○ Don't know/ no opinion

How could procedures be improved? (max. 1 500 characters, incl. spaces)

1500 character(s) maximum

In Denmark the registration procedures are relatively easy.

SPC protection could have had unintended adverse effects in other sectors.

EU-based generics and biosimilar manufacturers argue that EU SPC protection puts them at a disadvantage compared with foreign-based manufacturers.

They want to see the introduction of an 'SPC manufacturing waiver' (see introduction to this questionnaire for more details).

In the following questions, we'd like to find out about the challenges faced by this sector of the pharmaceuticals industry.

8. Do you agree or disagree with the following statements?

	Agree	Disagree	No opinion
SPCs inadvertently disadvantage EU-based generics and biosimilars manufacturing compared with countries with no SPC (e.g. for exports outside the EU and for entry in the EU following the expiry of the SPC)	○	○	●
When placing generics and biosimilars on the EU market after the SPC expires, SPCs disadvantage EU-based generics and biosimilars manufacturing compared with generic companies based in countries with no SPC	○	○	●
The EU SPC, in its current form, increases reliance on imports of medicines and active pharmaceutical ingredients from outside the EU	○	○	●

The following questions relate to the cost of registration and enforcement of SPCs, and whether the current cost level impacts on SCP holders' behaviour (e.g. whether it limits the number of registrations).

9. Have you ever known an SPC applicant to abandon an SPC registration in an EU country owing to…

	Yes	No	Don't know/no opinion
… the cost of registration/maintenance?	○	●	○
… burdensome administrative procedures?	○	●	○

10. Does the geographical scope of SPCs generally match the geographical scope of the territory in which the protected pharmaceutical product is marketed?

- ○ Yes
- ○ No – sometimes it's larger (i.e. we sometimes obtain SPC protection in countries where the protected product will not be marketed)
- ○ No – it's usually narrower
- ● Don't know

If you are an IP professional/lawyer, please give examples of the total cost of registration and maintenance in multiple jurisdictions based on your experience (max. 5 000 characters, incl. spaces).

5000 character(s) maximum

N/A

11. If an SPC is enforced in only one EU country, is the cost of enforcement proportionate?

- Yes – the potential cost is always exceeded by potential sales
- No – it's very high and sometimes SPC holders give up enforcing it
- Don't know/no opinion

If you answered 'no' to Question 11 and if you are an IP professional/lawyer, please give examples of total cost of enforcement (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

N/A

12. If an SPC is enforced in multiple EU countries, is the cost of enforcement proportionate?

- Yes – the potential cost is always exceeded by potential sales
- No – it's very high and sometimes SPC holders give up enforcing it in some EU countries
- Don't know/no opinion

If you answered 'no' to Question 12 and if you are an IP professional/lawyer, please give examples of total cost of enforcement in multiple jurisdictions (max. 3 000 characters, incl. spaces).

3000 character(s) maximum

N/A

13. Is the length of proceedings relating to the enforcement of SPCs satisfactory?

- Yes
- No – it depends on the EU country
- Don't know/no opinion

In the next few questions, we'd like to find out how the competent EU country authorities manage SPC registrations.

Some authorities have greater administrative resources than others.

14. For national patent offices, do the administrative fees relating to SPCs cover the cost of handling SPC applications and their registration?

- Yes
- No
- No opinion

15. If the national patent office in your country has a backlog of SPC applications, what do you think are the 2 main reasons for this?

between 1 and 2 choices

- [ ] Insufficient administrative resources at the national patent office
- [ ] Insufficient technical abilities of the national patent office
- [ ] Increasing complexity of the subject matter of the application
- [ ] Delays caused by the applicant
- [x] There is no backlog
- [ ] Other, please specify:

Other, please specify:

16. Does the national patent office in your country sometimes need to rely on the work of another patent office in the EU to make a decision on granting an SPC?

- ( ) Yes
- (•) No
- ( ) Don't know/no opinion

SPC legislation aims to ensure adequate protection for innovation and to improve public health.

We want to evaluate whether the objectives of the SPC regulation match current needs and problems (e. g. only some types of innovations are eligible for SPC protection; new regulatory requirements did not exist when the SPC regulation came into force and some activities linked to new regulatory requirements are not covered by the Bolar exemption).

17. Is SPC protection not available for some types of innovations (e.g. certain categories of medical devices, veterinary medicines, or plant-related products)?

- (•) Yes
- ( ) No
- ( ) Don't know

Please give examples if possible (max. 1 500 characters, incl. spaces).

1500 character(s) maximum

In Denmark a SPC can't be granted for medical devices.

18. In your experience, is SPC protection sufficient to encourage investment in certain types of vital innovations (e.g. antibiotics, medicines for treating neglected or orphan diseases)?

- ( ) Yes
- ( ) No
- (•) Don't know

Please give examples if possible (max. 1 500 characters, incl. spaces).

1500 character(s) maximum

N/A

19. To your knowledge and in your experience, do other jurisdictions provide certain types of innovations that are not EU SPC-eligible with SPC type protection?

- ○ Yes
- ○ No
- ● Don't know

Please give examples if possible (max. 1 500 characters, incl. spaces).

1500 character(s) maximum

N/A

We want to find out how the SPC and Bolar EU frameworks work in relation to national legislation.

20. Please give examples of any inconsistencies between national legislation and EU legislation on SPCs and Bolar exemptions, if you are know of any. Do you have suggestions on how to overcome these inconsistencies? Examples & suggestions (max. 2 000 characters, incl. spaces)

2000 character(s) maximum

N/A

21. Have the EU SPC and Bolar exemptions brought added value compared with national initiatives?

- ○ Yes
- ○ No
- ● Don't know

Please provide an explanation/examples if possible (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

N/A

The following questions focus on the matters addressed by the European Commission 'inception impact assessment' published on 15 February 2017: the 'SPC manufacturing waiver' (see explanation in the introduction to this questionnaire), the unitary (single) SPC, and specific issues related to the Bolar and research patent exemptions .

There is no specific provision dedicated to SPCs in the package of legislative instruments related to the unitary patent. We would like to get feedback from you on whether national authorities, in applying the SPC Regulations, could grant SPCs on the basis of unitary patents.

22. 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
- ○ No, EU legislation is needed to clarify the relationship between the unitary patent and the current SPC framework
- ● Don't know

Some aspects of the EU Bolar patent exemption could be upgraded in line with best practice in some EU countries in view of changes in the way generics and biosimilars are developed in the EU, and in view of the future establishment of the Unified Patent Court which may not follow those best practices.

The Bolar patent exemption is not explicitly available for the plant protection products industry in the EU, but it might be available in the US.

23. In your experience, and in your country, is the Bolar exemption available for….

	Yes, stipulated in patent law or jurisprudence	No, neither stipulated in patent law nor in jurisprudence	It's uncertain	Don't know
…originators' activities related to 'health technology assessment'?	○	●	○	○
…development of a generic product (e.g. medicines or pesticides) for its registration outside the EU?	●	○	○	○
… development of generic plant protection products for its registration in your country?	○	●	○	○

24. Do you think that there is a risk that the future Unified Patent Court could develop a practice in terms of the Bolar patent exemption that conflicts with the one cemented in Irish, UK and German law/practice?

- ○ Yes, and it's undesirable
- ○ Yes, but it wouldn't be an issue for us
- ○ No
- ● Don't know

In the following questions, we'd like to find out your views on some options for improving the SPC and Bolar systems in the EU.

25. Please indicate which of the following actions would be enough on its own to ensure consistent interpretation throughout the EU of the scope and eligibility of the SPC regulation.

	Yes	No	Don't know
Amendment of the SPC Regulations to bring additional clarity	○	●	○
Creation of a unitary SPC for the unitary patent	○	●	○
Guidelines developed by the European Commission and EU countries	●	○	○
Other actions – please explain	○	●	○

Other actions – please explain

26. Based on your experience, do you think that all EU countries' national patent offices should conduct substantive examination (i.e. actual verification of the conditions stipulated in the SPC Regulation) of SPC applications?

- ○ Yes
- ○ No, some of them might not have the necessary resources
- ○ No, it's unnecessarily cumbersome even for the offices with enough resources
- ● No opinion

27. Do you favour the creation of a unitary SPC title for the unitary patent?

- ○ Yes
- ○ No, there's no need
- ● No opinion

Please provide an explanation (max. 2.000 characters, incl. spaces).

2000 character(s) maximum

We understand that the European Commission intends to issue a notice in this regard and we await to see the outcome.

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

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

Please indicate your alternative preference

29. 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 centralised marketing authorisations)	English only	None of these (please indicate your alternative preference)
… unitary SPC applications	○	○	○	●	○
… publishing unitary SPCs	○	○	○	●	○

30. 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)?

- ○ Yes
- ○ No
- ● No opinion

31. 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

In the following questions, we’d like to find out your views on some options for improving the SPC and Bolar systems in the EU.

32. If you are an EU country's patent office, would a unitary SPC have a significant impact on your organisation's budget (e.g. significant loss of income or staff redundancies)?

- ○ Yes
- ○ No
- ● Don’t know/no opinion

Please provide an explanation/examples (max. 2 000 characters, incl. spaces).

2000 character(s) maximum

The body entrusted with granting unitary SPCs should have the expertise to do so, which is both expertise with patents and regulatory and administrative procedures but also with the specific question of granting SPCs in the industrial sectors. The creation of a virtual office would of course also have to deal with the question of distribution of any received application fees.

33. If you are an EU country's patent office, would your organisation be able to participate in the implementation of a decentralised procedure to grant the unitary SPC?

- (●) Yes
- ( ) No
- ( ) Don't know/no opinion

34. What would be the benefits of a unitary SPC?

	1 Strongly disagree	2 Disagree	3 Neither agree nor disagree	4 Agree	5 Strongly agree	Don't know /no opinion
Improve value of investments	( )	( )	( )	( )	( )	(●)
Reduce red tape relating to litigation	( )	( )	( )	( )	( )	(●)
Reduce red tape relating to registration	( )	( )	( )	( )	( )	(●)
Same protection in all EU countries	( )	( )	( )	( )	( )	(●)
Legal certainty	( )	( )	( )	( )	( )	(●)
Reduce maintenance costs	( )	( )	( )	( )	( )	(●)
Specialised court	( )	( )	( )	( )	( )	(●)
Make licensing easier	( )	( )	( )	( )	( )	(●)

VI. PUBLIC AUTHORITIES RELATED TO SCIENCE, INDUSTRY, TRADE AND COMPETITION

Intellectual property (IP), such as patents or trademarks, plays a key role in encouraging investment in innovation. A 2013 study (IP Rights intensive industries: Contribution to economic performance and employment in Europe, EUIPO, 2013) revealed that 39% of economic activity in the EU is generated by IP-intensive industries, while 26% of all employment is provided directly by these industries.

Industry sectors whose products are subject to regulated market authorisations, such as the pharmaceutical, medical devices and agrochemical industries, rely heavily on industrial property protection through patents, Supplementary Patent Certificates (SPCs) and data /market exclusivity.

SPCs are a sui generis IP right that constitute an extension (of up to five years) to the term of a patent right (of twenty years). SPCs aim to offset the loss of effective patent protection that occurs due to the compulsory and lengthy testing and clinical trials that products require prior to obtaining regulatory marketing approval. The relevant EU legislation is Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96 on SPC covering pharmaceutical and plant protection products respectively.

The Bolar patent exemption aims at speeding up the entry of generic medicines into the market by allowing early preparatory development on generics to obtain pre-market regulatory approval even when the SPC of the reference medicine is still in force. It is regulated at EU level for the pharmaceutical industry only through Article 13(6) of Directive 2001/82/EC and Article 10(6) of Directive 2001/83/EC. The scope of the EU Bolar exemption has been updated in some EU MS, inter alia, to meet new pharmaceutical-related requirements.

The specific industrial property legal framework in the EU for industry sectors whose products are subject to regulated market authorisations might present several features not fit for purpose in today's global economy and in the light of new regulatory requirements.

Firstly, existing SPCs are granted and enforced at national level, which can result in Single Market fragmentation. There are cases where some Member States have granted SPC applications while the very same application has been either refused or granted with a different scope in other Member States.

Secondly, Member States implement the 'Bolar exemption' in different ways: on the one hand, some Member States do not allow the supply of active pharmaceutical ingredients to EU-based generic manufacturers for the purpose of seeking marketing authorisation, and on the other hand, in a number of Member States, it is not certain whether testing in the EU by originators and biosimilars can benefit from these exemptions for the purpose of seeking marketing authorisation in the EU and in non-EU countries, or for meeting emerging regulatory requirements such as those related to health technology assessment.

Thirdly, manufacturers of generic and biosimilar medicines based in non-EU countries where SPC protection does not exist (e.g. in Brazil, Russia, India and China) enter markets in which patent protection expired up to five years earlier than EU-based manufacturers. This is possible because EU-based manufacturers are not allowed to produce in EU Member States during the period of the SPC protection of the reference medicine. Such a situation could lead to a lack of playing field between EU and non EU manufacturers with an advantage for non EU manufacturers.

The Single Market Strategy, adopted in October 2015 (COM(2015)550), announced that the Commission will "consult, consider and propose further measures, as appropriate, to improve the patent system in Europe, notably for pharmaceutical and other industries whose products are subject to regulated market authorisations". In particular, the Strategy undertook to explore a recalibration of certain aspects of patent and SPC protection, and announced that this recalibration could mainly comprise the following three elements: the creation of a European SPC title; an update of the scope of the EU patent research exemptions; and the introduction of an SPC manufacturing waiver (the so-called 'SPC manufacturing waiver' for export purposes would allow EU based manufacturers of generics /biosimilars manufacturing their products during the EU SPC term of the reference medicine to export their products to countries with no SPC protection). The European Commission published an "inception impact assessment" on 15 February 2017.
The current public consultation seeks to gather feedback of all stakeholders on the way the SPC system currently functions in the EU and its effects on trade and competitiveness in particular.

The Commission will report on the results of its consultation which, together with ongoing evaluation studies, will help the Commission assess whether the EU SPC framework is still fit for purpose or needs to be recalibrated, notably as regards the aspects set out in Single Market Strategy.

Disclaimer

The following questions relate to the profile of your company/organisation:

*1. You are a ministry or public agency dealing with…

- Science and innovation policies
- Industrial policy
- Competition policy
- Trade policy
- Other: please specify

Please specify

The next few questions are about how effective supplementary protection certificates (SPCs) and Bolar exemptions are in the EU.

We want to find out how much progress has been made in meeting the following objectives (from SPC legislation adopted in the 1990s):

- attracting research
- preventing delocalisation
- protection for long enough to recover investment
- promoting essential innovation for patients
- competition through innovation
- limiting the negative effects of fragmentation.

The SPC is an incentive for innovation investment in pharmaceutical and plant protection products. The SPC legislation was introduced in the EU in the 1990s.

In most of the following questions, we'd like to find out your views on how innovation and market competition are progressing for these products since SPC legislation was introduced in the EU.

2. In the last two decades in the EU, how do you perceive the progress made in……

	Down a lot	Down a bit	Stable	Up a bit	Up a lot	No opinion
…investments in pharmaceutical innovation in general	○	○	○	○	○	○
…investments in pharmaceutical manufacturing	○	○	○	○	○	○
…investments in innovation in plant protection products	○	○	○	○	○	○
...investments in the manufacturing of plant protection products	○	○	○	○	○	○
…competition in the pharmaceutical sector based on innovation	○	○	○	○	○	○
…competition in the pharmaceutical sector based on generic market entry	○	○	○	○	○	○
…competition in plant protection products based on innovation	○	○	○	○	○	○
… dependency of supply of active pharmaceutical ingredients (APIs) manufactured outside the EU	○	○	○	○	○	○

The SPC is not the only factor that influences decision on investment on innovation, location of innovation activities and manufacturing. The European Commission would like to get feedback from stakeholders on the relative importance of the SPC in comparison with other factors in influencing the geographical location of their innovation and manufacturing- related decision.

3. Select the 4 most relevant drivers among the ones listed in the first column for each of the investment types indicated.

between 1 and 4 answered rows

	Investment in research (incl. clinical/field trials) for pharmaceutical products	Investment in research (incl. clinical/field trials) for plant protection products	Investment in manufacturing for pharmaceutical products	Investment in manufacturing for plant protection products

Availability of SPC type protection in the country where the investment is made				
Availability of regulatory exclusivities (market/data exclusivities) in the country where investment is made				
Health infrastructure				
Proximity of research universities				
An effective regulatory agency				
Less strict regulatory control				
Proximity to your manufacturing plants				
Availability of public /private funding				
Labour costs				
Access to high skilled labour				
Easier to recruit patients or access to treatment groups				
Large market (in terms of potential sales in the country where the investment is made)				
Taxation				
Proximity to the place where the product research was carried out				
Proximity to the place where the clinical trials (or field trials) for the product were carried out				

Possibility of getting 'good manufacturing practices' (GMP) from the FDA and/or EMA for the factories based in that country				

Next, we'd like to ask you some questions about the costs and benefits of SPCs.

SPC protection could have had unintended adverse effects in other sectors.

EU-based generics and biosimilar manufacturers argue that EU SPC protection puts them at a disadvantage compared with foreign-based manufacturers.

They want to see the introduction of an 'SPC manufacturing waiver' (see introduction to this questionnaire for more details).

In the next few questions, we'd like to find out about the challenges faced by this sector of the pharmaceuticals industry.

4. Based on your experience, do you agree with the claims below on how the SPC system is performing in the EU?

	Agree	Disagree	No opinion
In its current form, the SPC in the EU unintendedly discriminates against EU-based generics & biosimilars manufacturing compared with manufacturers located in non-EU countries with no SPC type protection (e.g. for exports outside the EU)			
In its current form, the SPC in the EU increases reliance on imports of medicines and active pharmaceutical ingredients from outside the EU			

SPC legislation aims to ensure adequate protection for innovation and improving public health.

We want to evaluate whether the objectives of the SPC regulation match current needs and problems (e.g. only some types of innovations are eligible for SPC protection; new regulatory requirements did not exist when the SPC regulation came into force and some activities linked to new regulatory requirements are not covered by the Bolar exemption).

5. In your experience, is SPC protection sufficient to encourage investment in certain types of innovations (e.g. antibiotics, medicines for the treatment of neglected diseases and orphan diseases)?

- Yes
- No
- Don't know/no opinion

Please explain your answer (max. 1 500 characters, incl. spaces.)

1500 character(s) maximum

6. In your experience, do some jurisdictions (e.g. the US or Japan) provide SPC type protection for some types of innovation that you develop that are not eligible for an SPC in the EU?

- Yes
- No
- Don't know/no opinion

Please give examples if possible (max. 2 000 characters, incl. spaces.)

2000 character(s) maximum

We're interested in how the SPC and Bolar EU exemptions work in relation to national legislation.

7. Please give examples of any inconsistencies between national legislation and EU legislation on SPCs and Bolar exemptions, if you know of any.
Do you have any suggestions on how to overcome these inconsistencies? Please, explain your answer (max. 2 000 characters incl. spaces).

2000 character(s) maximum

8. Have the EU SPC and Bolar exemptions brought added value compared with national initiatives?

- Yes
- No
- Don't know

Please explain your answer (max. 2 000 characters, incl. spaces.)

2000 character(s) maximum

The following questions focus on the matters addressed by the European Commission's 'inception impact assessment' published on 15 February 2017: the 'SPC manufacturing waiver' (see explanation in the introduction to this questionnaire), the unitary SPC, and specific issues related to the Bolar and research patent exemptions.

In the following questions, we'd like to find out your views on some options for improving the SPC and Bolar systems in the EU.

9. Do you favour the creation of a unitary SPC title for the unitary patent?

- Yes
- No, there's no need
- No opinion

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

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

preference Please indicate your alternative preference

11. 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 centralised marketing authorisations)	English only	None of these (please indicate your alternative preference
… registering unitary SPC applications					
… publishing unitary SPCs					

Please indicate your alternative preference

In the following questions, we'd like to find out your views on some options for improving the SPC and Bolar systems in the EU.

12. What would be the benefits of a unitary SPC?

	1 Strongly disagree	2 Disagree	3 Neither agree nor disagree	4 Agree	5 Strongly agree	Don't know
Boost value of investments	○	○	○	○	○	○
Reduce red tape relating to litigation	○	○	○	○	○	○
Reduce red tape relating to registration	○	○	○	○	○	○
Same protection across the EU	○	○	○	○	○	○
Legal certainty	○	○	○	○	○	○
Reduce maintenance costs	○	○	○	○	○	○
Specialised court	○	○	○	○	○	○
Make licensing easier	○	○	○	○	○	○

13. What impact would the introduction of an SPC manufacturing waiver* have in the EU?

* See explanation in the introduction to this questionnaire.

	1 Strongly disagree	2 Disagree	3 Neither agree nor disagree	4 Agree	5 Strongly agree	Don't know
It would reduce protection to recoup our investments in R&D in the EU	○	○	○	○	○	○
In the short term, it would reduce our sales in countries outside the EU when protection abroad expires	○	○	○	○	○	○
In the long term, it would reduce our sales in countries outside the EU when protection abroad expires	○	○	○	○	○	○