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?

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

Please specify

Ministry of Health

*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

Ministry of Health

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

It is impossible to say what products would not have been developed in the absence of SPC protection.

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

It is clear that the complexity of the litigation is mainly due to the high volume of jurisprudence that exists for certain parts of the regulation. The complexity will remain high as long as the uncertainties around several articles keep existing. This requires not just guidelines, but preferably a clarification in the legislative text.

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

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

EU based manufacturers are unable to produce for export during the SPC period. This gives non-EU based manufacturers the advantage during the SPC period, but also for entering the EU market directly after expiry of the SPC term.

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

EU based manufacturers are unable to produce for export during the SPC period. This gives non-EU based manufacturers the advantage during the SPC period, but also for entering the EU market directly after expiry c the SPC term.

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

1) In our opinion, SPC protection is not the right trigger for certain types of innovatior especially antibiotics and neglected diseases. If a low return-on-investment is already anticipated because of e.g. very low or unpredictable sales of certain antibiotics, extr SPC protection will not really change the path for innovation. Therefore also other incentives have been put in place with the intention to incentivize these types of innovations, such as market exclusivity for orphan drugs.

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

1500 character(s) maximum

2) However, whether or not such incentives have positive or negative effects on innovation and access to patien is subject of investigation, based on the Council Conclusions during the Dutch Presidency. We therefore support the Commission's work to study the effects of these incentives in a coherent manner instead of individually.

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

N/A

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

N/A, similar provisions did not exist.

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

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

The advantages of a unitary patent are also applicable to SPCs. A unitary system could lessen the complexity of the process, both in administrative terms as in the difficulties that arise from difference in interpretation.

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

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

National Patent Office of the Netherlands

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.

- [x] Yes
- [ ] No
- [ ] Don't know

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

1500 character(s) maximum

Every expert in this field will acknowledge that the interpretation of the Regulation is not uniform throughout Europe. Numerous examples could be given. In our practice, when we reject an SPC application the applicant wil often point to the fact that it was granted in other member states. Referrals to the CJEU also often highlight the fact that the SPC was granted in some member states, but refused in others.

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)?

- [x] Yes
- [ ] No
- [ ] Don't know

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

1500 character(s) maximum

Every expert in this field will acknowledge that the interpretation of the Regulation is not uniform throughout Europe. Numerous examples could be given. In our practice, when we reject an SPC application the applicant wil often point to the fact that it was granted in other member states. Referrals to the CJEU also often highlight the fact that the SPC was granted in some member states, but refused in others.

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

The registration procedures could be improved by removing uncertainties stemming from the extensive jurisprudence surrounding the regulation.

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

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

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

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
- [x] Increasing complexity of the subject matter of the application
- [ ] Delays caused by the applicant
- [ ] There is no backlog
- [x] Other, please specify:

Other, please specify:

Opposition procedures against the basic patent.

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
- (x) 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)?

- (x) Yes
- ( ) No
- ( ) Don't know

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

1500 character(s) maximum

1/2 Only two SPC regulations, 469/2009 and 1610/96, exist and it is self-evident that no SPC protection is available to products which fall outside the scope of these regulations.

2/2 Whether certain medical devices fall under the scope of Regulation 469/2009 is the subject of referral C-527/17, now pending before the CJEU. Many innovations in completely different areas of technology (e.g. consumer products, vehicles, electronics, materials) may require some kind of regulatory approval and testing fo safety or efficacy before they can be sold onto the market.

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
- (x) No
- ( ) Don't know

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

1500 character(s) maximum

In our opinion, SPC protection does not encourage investment in certain types of innovations, especially antibiotics and neglected diseases. If a low return-on-investment is already anticipated because of e.g. very lo or unpredictable sales of certain antibiotics, extra SPC protection will not change the return-on-investment fron negative to very positive

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?

- [x] Yes
- [ ] No
- [ ] Don't know

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

1500 character(s) maximum

In the US the Drug Price Competition and Patent Restoration Act also known as the Hatch-Waxman Act permits patent term extensions not only to human drug products but also medical devices, food additives, and colour additives.

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
- [x] Don't know

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

2000 character(s) maximum

N/A, similar provisions did not exist.

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?

- [x] 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
- [x] 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

The advantages of a unitary patent are also applicable to SPC's. A unitary system could lessen the complexity o the process, both in administrative terms as in the difficulties that arise from difference in interpretation.

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

Total amount of work spent on SPCs at the Netherlands Patent Office is about 1500 hours, which is divided over 4 patent examiners, 1 legal advisor, and two administrators.

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?

- [x] 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
- [x] 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

In our opinion, SPC protection does not encourage investment in certain types of innovations, especially antibioti and neglected diseases. If a low return-on-investment is already anticipated because of e.g. very low or unpredictable sales of certain antibiotics, extra SPC protection will not change the return-on-investment from negative to very positive.

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?

- [x] Yes
- [ ] No
- [ ] Don't know/no opinion

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

2000 character(s) maximum

In the US the Drug Price Competition and Patent Restoration Act also known as the Hatch-Waxman Act permits patent term extensions not only to human drug products but also medical devices, food additives, and colour additives.

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

N/A

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

- [ ] Yes
- [ ] No
- [x] Don't know

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

2000 character(s) maximum

N/A, similar provisions did not exist.

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?

- [x] 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
- [x] 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	○	○	○	○	○	✓